Evidence Report/Technology Assessment
Number 208

6. Prevention of Healthcare-Associated Infections

Closing the Quality Gap: Revisiting the State of the Science

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Evidence-Based Practice

Evidence Report/Technology Assessment
Number 208

6. Prevention of Healthcare-Associated Infections

Closing the Quality Gap: Revisiting the State of the Science

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This report is based on research conducted by the Blue Cross and Blue Shield Association Technology Evaluation Center Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2007-10058-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

In 2004, AHRQ launched a collection of evidence reports, Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies, to bring data to bear on quality improvement opportunities. These reports summarized the evidence on quality improvement strategies related to chronic conditions, practice areas, and cross-cutting priorities.

This evidence report is part of a new series, Closing the Quality Gap: Revisiting the State of the Science. This series broadens the scope of settings, interventions, and clinical conditions, while continuing the focus on improving the quality of health care through critical assessment of relevant evidence. Targeting multiple audiences and uses, this series assembles evidence about strategies aimed at closing the "quality gap," the difference between what is expected to work well for patients based on known evidence and what actually happens in day-to-day clinical practice across populations of patients. All readers of these reports may expect a deeper understanding of the nature and extent of selected high-priority quality gaps, as well as the systemic changes and scientific advances necessary to close them.

AHRQ expects that the EPC evidence reports will inform consumers, health plans, other purchasers, providers, and policymakers, as well as the health care system as a whole, by providing important information to help improve health care quality.

We welcome comments on this evidence report or the series as a whole. Comments may be sent by mail to the Task Order Officer named in this report to: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Preventing Healthcare-Associated Infections

Closing the Quality Gap: Revisiting the State of the Science

Structured Abstract

Objectives. To update the Agency for Healthcare Research and Quality (AHRQ) Evidence Report Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies: Volume 6–Prevention of Healthcare-Associated Infections on quality improvement (QI) strategies to increase adherence to preventive interventions and/or reduce infection rates for central line–associated bloodstream infections (CLABSI), ventilator-associated pneumonia (VAP), surgical site infections (SSI), and catheter-associated urinary tract infections (CAUTI).

Data Sources. MEDLINE®, CINAHL®, and Embase® were searched from January 2006 to January 2012 for English-language studies with sample size ≥100 patients, a defined baseline period, and reported statistical analysis for adherence and/or infection rates. Articles from the previous report were screened and those meeting selection criteria were included.

Review Methods. We sought studies that evaluated the following QI strategies to improve adherence to evidence-based preventive interventions and/or reduce healthcare-associated infection (HAI) rates: audit and feedback; financial incentives, regulation, and policy; organizational change; patient education; provider education; and provider reminder systems. Data were abstracted by a single reviewer and fact-checked by a second. Outcomes were adherence to preventive interventions, infection rates, adverse outcomes, and cost savings. Study quality was assessed using relative rankings based on study design, adequacy of statistical analysis, length of followup, reporting and analysis of baseline and postintervention adherence and infection rates, and implementation of the intervention independent of other QI efforts. Combinations of QI strategies were assessed, not individual strategies. Strength of evidence was judged according to the AHRQ Methods Guide.

Results. Sixty-one articles yielded 71 analyses at the infection level, including 9 articles (10 analyses) from the 2007 report, which evaluated the use of one or more QI strategies to improve adherence or infection rates and also controlled for confounding or secular trend. Twenty-six analyses were performed on CLABSI, 19 on VAP, 15 on SSI, and 11 on CAUTI. There were 34 analyses on adherence, of which 31 (91%) showed significant improvement. There were 63 analyses of infection rates, of which 42 (67%) showed significant improvement.

Conclusions. There is moderate strength of evidence across all four infections that both adherence and infection rates improve when either audit and feedback plus provider reminder systems or audit and feedback alone is added to the base strategies of organizational change and provider education. There is low strength of evidence that adherence and infection rates improve when provider reminder systems alone are added to the base strategies. There was insufficient evidence for reduction of HAI in nonhospital settings, cost savings for QI strategies, and the nature and impact of the clinical contextual factors.

Contents

Tables

Figures

Appendixes

Executive Summary

Background

The Centers for Disease Control and Prevention (CDC) define a healthcare-associated infection (HAI) as:

> [A] localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s). There must be no evidence that the infection was present or incubating at the time of admission to the acute care setting.[1]

The CDC estimates that in 2002 there were 1.7 million HAI and 99,000 HAI-associated deaths in hospitals. The four largest categories of HAI, responsible for more than 80 percent of all reported HAI, are central line–associated bloodstream infections (CLABSI, 14%), ventilator-associated pneumonia (VAP, 15%), surgical site infections (SSI, 22%), and catheter-associated urinary tract infections (CAUTI, 32%).[2]

In a CDC report, national costs of HAI were estimated, based on 2002 infection rates and adjusted to 2007 dollars using the Consumer Price Index for inpatient hospital services. Estimates of the total annual direct medical costs of HAI for U.S. hospitals ranged from $35.7 billion to $45 billion. Using the same adjustment, the estimates of patient hospital costs for the four most common HAI ranged from $3.45 billion to $10.07 billion for SSI, $0.67 billion to $2.68 billion for CLABSI, $1.03 billion to $1.50 billion for VAP, and $0.39 billion to $0.45 billion for CAUTI.[3] It is estimated that the cost savings of preventing 70 percent of HAI would be $25.0 billion to $31.5 billion, using the same adjustments.[3]

The prevention and reduction of HAI is a top priority for the U.S. Department of Health and Human Services (www.cdc.gov/HAI/prevent/prevention.html). A call to action for the elimination of HAI has been issued jointly by the Association for Professionals in Infection Control and Epidemiology, Inc., the Society for Healthcare Epidemiology of America, the Infectious Diseases Society of America, the Association of State and Territorial Health Officials, the Council of State and Territorial Epidemiologists, the Pediatric Infectious Diseases Society, and the CDC.[4] In a consensus statement issued by these groups, a plan for the elimination of HAI includes the promotion of adherence to evidence-based practices through partnering, educating, implementing, and investing.

In 2003, the Institute of Medicine (IOM) published a report, Priority Areas for National Action: Transforming Health Care Quality.[5] The report identified 20 clinical topics for which there are quality concerns because of the gap between knowledge of the topic and integration of that knowledge into the clinical setting. In response to the IOM report, the Agency for Healthcare Research and Quality (AHRQ) initiated a series of technical reviews on quality improvement (QI) strategies focused on improving the quality of care for the IOM's 20 priority areas.[6]

Objectives

This systematic review updates the AHRQ Evidence Report Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies: Volume 6—Prevention of Healthcare-

Associated Infections.[7] From here on, this report is referred to as the 2007 report. The objective of that evidence review was to identify QI strategies that successfully increase adherence to effective preventive interventions and reduce infection rates for CLABSI, VAP, SSI, and CAUTI.

The current review expands the settings to be considered from primarily hospitals to include ambulatory surgery centers, freestanding dialysis centers, and long-term care facilities, where the prevention of HAI needs to be addressed as well.

Where applicable, the current report also applies the recommendation of a report prepared for AHRQ by RAND Health[8] in which the impact of context on the effectiveness of patient safety practices is assessed. The context of an intervention—for example, the type of health care setting, the leadership structure, the safety culture, the openness to innovation—can have an important impact on whether preventive interventions are adopted.

Key Questions for this report follow.

Key Question 1. Which quality improvement strategies are effective in reducing the following healthcare-associated infections?

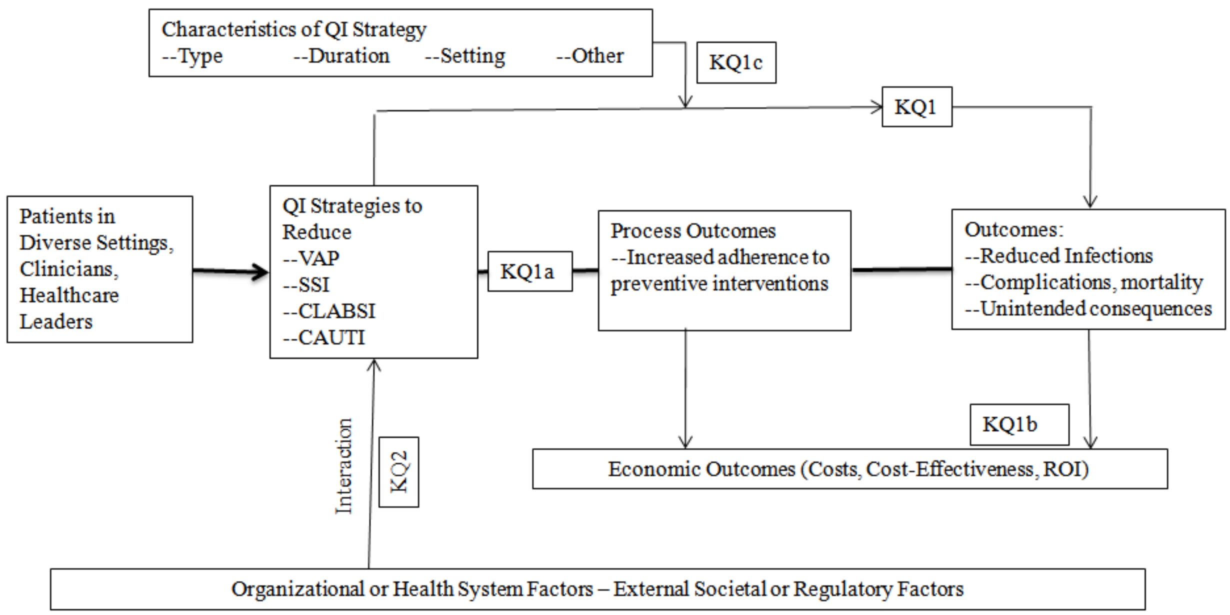
- Central line–associated bloodstream infections (CLABSI)
- Ventilator-associated pneumonia (VAP)
- Surgical site infections (SSI)
- Catheter-associated urinary tract infections (CAUTI)
    a. Which quality improvement strategies are effective in increasing adherence to evidence-based preventive interventions for the four healthcare-associated infections listed above?
    b. What is the cost, return on investment, or cost-effectiveness for health care providers, patients, and society as a whole of quality improvement strategies to reduce these healthcare-associated infections?
    c. Which factors are associated with the effectiveness of quality improvement strategies, including, for example,
        1. Type of quality improvement strategy
            a. Clinician education
            b. Patient education
            c. Audit and feedback
            d. Clinician reminder systems
            e. Organizational change
            f. Financial or regulatory incentives for patients or clinicians
            g. A combination of the above
        2. Duration of intervention
        3. Setting, for example, hospitals (intensive care unit, surgical or ventilator-dependent patients), outpatient surgical centers, long-term care facilities, and freestanding dialysis centers, and which kinds of clinicians implement the quality improvement strategies?

Key Question 2. What is the impact of the health care context on the effectiveness of quality improvement strategies, including reducing infections and increasing adherence to preventive interventions?

Analytic Framework

The analytic framework depicts the potential impact of the implementation of QI strategies on reducing the following HAI: CLABSI, VAP, SSI, and CAUTI (Figure A). Key Question 1 shows the link between QI strategies and health outcomes: decreased infection rates, decreased complications and mortality, as well as unintended consequences. Key Question 1a shows the link between QI strategies and process outcomes; that is, adherence to preventive interventions. There are economic implications from both the process outcomes and the health outcomes, as depicted by Key Question 1b. Characteristics of the QI strategies, such as type of strategy, duration of the implementation, and setting, determine the effect of the QI strategies on the outcomes (Key Question 1c). Link Key Question 2 marks the interaction between the implementation of QI strategies and contextual factors of the organization. For example, institutions with an existing patient safety infrastructure may have fewer barriers to implementing QI strategies than other institutions.

Figure A. Analytical framework for systematic review on quality improvement strategies to reduce healthcare-associated infections



Abbreviations: CAUTI = catheter-associated urinary tract infection; CLABSI = central line–associated bloodstream infection; KQ = Key Question; QI = quality improvement; ROE = return on investment; SSI = surgical site infection; VAP = ventilator-associated pneumonia.

Methods

Input From Stakeholders

This systematic review was developed and written by the Blue Cross and Blue Shield Association Technology Evaluation Center Evidence-based Practice Center (EPC). Individuals from various stakeholder groups were invited as Technical Experts and/or Peer Reviewers to guide this systematic review. The Technical Expert Panel (TEP) reviewed the research protocol

in two phases: (1) initial draft protocol, (2) revised protocol that incorporated the TEP's comments on the draft and findings of a preliminary literature search. The final research protocol was posted on the AHRQ Web site. Peer reviewers were invited to provide written comments on the draft report based on their clinical, content, or methodological expertise. The draft report was also posted for public comment.

All potential Technical Experts and Peer Reviewers were required to disclose any potential conflicts of interest in accordance with AHRQ policy. The AHRQ Task Order Officer and the EPC worked to balance, manage, or mitigate any potential conflicts of interest identified. Writing and editing the report was solely the responsibility of the EPC.

Data Sources and Selection

Articles from the 2007 report[7] that met our inclusion criteria were included in this report. Then the same search strategy used in the prior report[7] was rerun on MEDLINE®, CINAHL®, and Embase®. Duplicate records were deleted. The search covered the time period from January 2006, when the search in the last report ended, to April 2011. The search was updated in January 2012 while the draft report was available for public comment, and relevant articles were added. Additional efforts were made to identify articles on interventions in nonhospital settings, which are likely to be reported less frequently, by querying the TEP and conducting a specific search on relevant studies in nursing homes. (See Appendix A for search strategy details.) We also screened the bibliographies of included articles to identify additional references. Web sites of entities involved in efforts to reduce HAI, such as the Institute for Healthcare Improvement, were scanned to ensure that no relevant peer-reviewed publications were missed and to identify descriptions of implementation strategies for which outcomes have been published in the peer-reviewed literature.

Titles and abstracts from the literature search citations were placed in a Microsoft Access® database for the first round of screening. Three trained reviewers conducted the screening. Each title and abstract was screened and marked as either: (1) retrieve for full-text review, (2) do not retrieve for full-text review, or (3) uncertain. Studies were marked for retrieval for full-text review if the citation reported the outcomes of an intervention for any one of the four specified HAI or a combination of HAI that included at least one of the four. The reasons for excluding an article were noted. Articles deemed uncertain for full-text review were screened by a second reviewer. If both reviewers were uncertain, the article was retrieved for full-text review. Articles were included if the study described an implementation strategy to increase adherence with one or more preventive interventions with the intent of reducing one or more of the four types of infections covered in this report. The following implementation strategies were included: clinician education, patient education, audit and feedback, clinician reminder systems, organizational change, financial or regulatory incentives for patients or clinicians, or a combination of these strategies. Articles also had to include statistical analysis comparing baseline and postintervention infection or adherence rates.

Data Abstraction and Quality Assessment

Following an extensive training process, reviewers abstracted articles selected for inclusion in the review; a second reviewer conducted a fact check on the abstracted items, using a clean copy of the article. The abstracter and the fact checker discussed discrepancies; any unresolved issues were decided through consultation with a third reviewer. Two reviewers independently

conducted quality appraisals for each article; discrepancies were resolved by discussion or by the inclusion of a third reviewer, when necessary.

Abstracted data included the following: QI strategies, evidence-based preventive interventions, adherence and infection rates, unintended consequences, costs, savings, and contextual factors. Completeness of reporting was not assessed independently. The criteria to evaluate study quality are as follows:

1. Study design
2. Whether baseline and postintervention adherence rates were reported and analyzed statistically
3. Whether baseline and postintervention infection rates were reported and analyzed statistically
4. Whether the statistical analysis was adequate
    - Were potential confounders (e.g., baseline patient characteristics) assessed?
    - If potential confounders existed, were they controlled for in the analysis?
    - For interrupted time-series designs, was an interrupted time-series analysis used?
5. Whether the intervention was independent of other QI improvement efforts implemented at the same time
6. Whether the followup period was 1 year or longer

Study design was used for the initial study quality classification so that all controlled trials were assigned higher quality, interrupted time-series analyses were assigned a quality of medium, and all simple before-after studies were assigned a quality of lower. Then, for each study, criteria 2 through 6, listed above, were assigned a plus, minus, or uncertain. Any study with two or more minuses was moved to the next lower quality ranking. The terms “higher” and “lower” are used to indicate the relative ranking of quality in this report.

Data Synthesis and Analysis

As in the previous review,[7] the articles in this review differed greatly in QI targets, QI strategies, preventive interventions and methods of measuring adherence to them, contexts, and study design. Quantitative analyses are not feasible, and the studies are synthesized in a qualitative manner.

The articles included in this review are divided into two categories, those with infection rates or adherence rates that were adjusted for confounding or secular trends and those that adjusted for neither. Because of the extensive challenges to the validity of the latter, they are not included in the detailed description of the body of evidence or assessment of the strength of evidence. They are described briefly under each type of infection in the Results chapter of the full report and enumerated in an appendix.

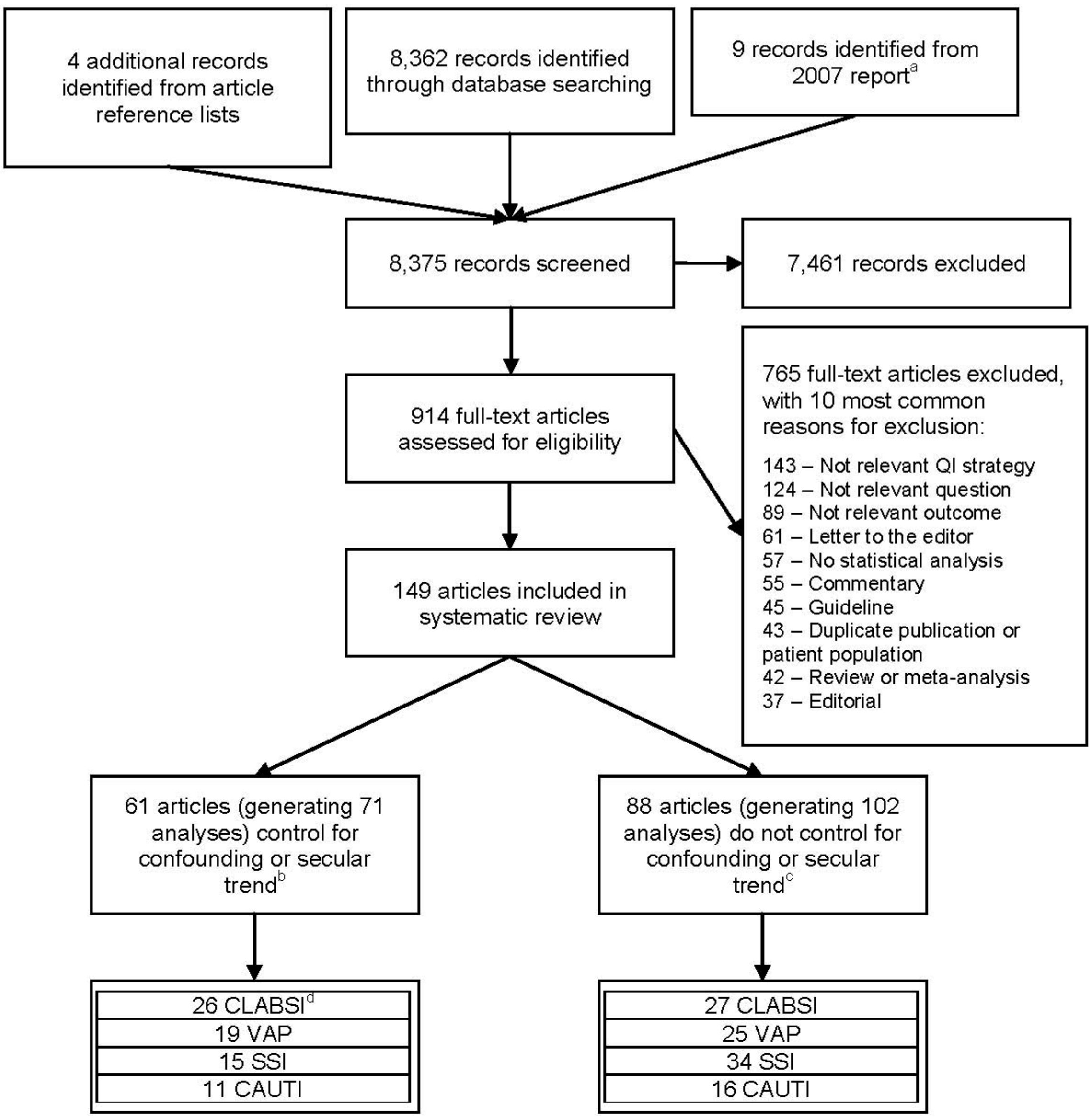
The overall strength-of-evidence grade was determined in compliance with AHRQ’s Methods Guide for Effectiveness and Comparative Effectiveness Reviews [9] and is based on a system developed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group.[10]

Results

Overview

The literature review yielded 8,362 abstracts. One hundred and thirty-six articles from the literature search met all selection criteria for inclusion in the current report. An additional four articles were identified from a review of article reference lists. Articles from the 2007 report were screened: 9 articles (generating 10 analyses at the infection level) met selection criteria for this report and controlled for confounding or secular trend. See the Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) diagram in Figure B for additional details.

Figure B. Search results and article triage



[a]Ranji SR, Shetty K, Posley KA, Lewis R, Sundaram V, Galvin CM, Winston LG. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies (Vol. 6: Prevention of Healthcare-Associated Infections). AHRQ Publication No. 04(07)-0051-6. Rockville, MD: Agency for Healthcare Research and Quality; 2007. www.ncbi.nlm.nih.gov/pubmed/20734530.
[b]Eight of these studies reported on two infections and one, on three infections.
[c]Five of these articles reported on two infections; three, on three infections; and one, on four infections.
[d]One of these articles has an updated publication 1 year later. In the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram these studies were cited as a single study.

The 149 articles (generating 173 analyses at the infection level) were divided into two groups. The first group consisted of 61 articles, most of which were quasi-experimental studies that controlled for confounding or secular trend. Eight of these articles reported on two types of infection, and one article report ed on three infections; each infection reported is treated as a separate study from this point forward. Sixty-one articles yielded 71 analyses, including 9 articles (10 analyses) from the 2007 report; these studies evaluated the use of one or more QI strategies to improve adherence or infection rates and also controlled for confounding or secular trend. There were 26 analyses performed on CLABSI, 19 on VAP, 15 on SSI, and 11 on CAUTI. The words "analysis" and "study" are used interchangeably and refer to the infection-level results.

The other 88 articles (102 analyses) did not account for the many potential sources of confounding and for secular trend. Therefore, their results are at high risk of bias. These were simple before-after studies or controlled before-after studies (2 of 88) with two group tests, for example, t-tests and chi-square tests. The two controlled before-after articles were demoted due to lack of between-group comparisons. Of these 88 articles, 5 articles reported on 2 types of infection, 3 articles reported on 3 infections, and 1 article reported on 4 infections, for a total of 102 analyses; each infection is treated as a separate study from this point forward. The characteristics of this second group of studies are summarized in tables for each infection in Appendix F, but they were excluded from the analysis in this report. Table A provides study characteristics of the 71 included studies, as well as the study quality characteristics for all 173 studies (149 articles).

Table A. Number of studies in each category by infection type and overall

Study Characteristic	Category	CLABSI	VAP	SSI	CAUTI	*All*
Design	Cluster RCT	2	2	1	0	***5***
	Individual RCT	0	0	1	1	***2***
	Stepped wedge	1	1	1	1	***4***
	Controlled study	4	2	1	1	***8***
	Interrupted time series	3	5	1	2	***11***
	Simple before-after	16	9	10	6	***41***
	Total	**26**	**19**	**15**	**11**	***71***
Number of QI Strategies	5 QI strategies	2	0	0	0	***2***
	4 QI strategies	8	7	2	2	***19***
	3 QI strategies	7	5	5	2	***19***
	2 QI strategies	5	7	4	4	***20***
	1 QI strategy	4	0	4	3	***11***
Outcomes Reported	Adherence only	1	1	2	3	***7***
	Infection rates only	16	9	5	2	***32***
	Both adherence and infection rates	9	9[a]	8	6[a]	***32***

Table A. Number of studies in each category by infection type and overall (continued)

Study Characteristic	Category	CLABSI	VAP	SSI	CAUTI	*All*
Sample Size (Range Across Studies When Reported)[b]	Patients postintervention	50 to 4,671	81 to 4,761	115 to 10,617	93 to 1,794	***NA***
	Postintervention infection rate	0 to 7.7 per 1,000 catheter-days	0.7 to 22.5 per 1,000 ventilator-days	0% to 7.7%	1.8 to 12.9 per 1,000 catheter-days	***NA***
	Baseline infection rate	1.84 to 17 per 1,000 catheter-days	1.9 to 39.7 infections per 1,000 ventilator-days	1.1% to 15%	1.7 to 21.5 per 1,000 catheter-days	***NA***
Length of Followup (Months)	Mean	20	22	14.4	23	***20***
	Median	23	17	12	17	***18***
	Range	3.5 to 46[c]	4 to 54	1 to 30[d]	3 to 61	***1 to 61***
Location	United States	18	9	11	2	***40***
	Other	8	10	4	9	***31***
Multisite or Single Site	Multisite	12	4	7	3	26
	Single site	14	15	8	8	45
Study Quality	Higher	1	3	2	1	***7***
	Medium	9	4	3	3	***19***
	Lower	16	12	10	7	***45***
	Did not control for confounding or secular trend	27	25	34	16	***102***

Abbreviations: CAUTI = catheter-associated urinary tract infection; CLABSI = central line–associated bloodstream infection; NA = not applicable; QI = quality improvement; RCT = randomized controlled trial; VAP = ventilator-associated pneumonia; SSI = surgical site infection.

[a]One study compared two sets of QI strategies, and another compared early and later infection rates.

[b]Patients may be defined differently across studies within a given infection category—for example, patients on ventilator or patients on ventilator for at least 48 hours.

[c]Four studies did not report length of followup.

[d]One study did not report length of followup.

Analyzing the impact of QI strategies, the objective of this report, is complicated by the fact that more than one QI strategy was used in most studies (60 of 71). Disentangling the effect of a single QI strategy is not possible with the available body of evidence. With 71 studies, 16 different combinations of QI strategies were used. The following approaches were considered for evaluating the effectiveness of the QI strategies, but all had limitations and were rejected.

- Considering each QI strategy individually within each study. The effect of a strategy cannot be disentangled from the impact of other strategies.
- Using the number of QI strategies. This option was not viable as the types of QI strategies included may have confounded the effect.
- Identifying the incremental impact of a single QI strategy. This approach could be measured only by comparing two combinations of QI strategies in the same clinical context, in which one combination contained the QI strategy of interest and the other did not. None of the studies identified for this report had such a design.

Therefore in this report, QI strategies are grouped together based on the combinations of strategies used in our included studies (Table B). This approach mirrors common practice, which relies on combinations of QI strategies, and can therefore potentially yield practical insights.

To develop a workable classification of QI strategy combinations for the purposes of this report, we hypothesized that organizational change and provider education constitute base strategies. Face validity is the initial rationale for the hypothesis, as 90 percent of the included studies used at least one of these two strategies. While this hypothesis is open to debate, the use of these strategies was ubiquitous, so in practical terms, little distinction could be made between those studies that used these two strategies and those that did not. In addition, it is difficult to imagine how any preventive intervention or QI effort could be implemented without at least some level of organizational change and/or provider education. Further, it is plausible that those studies that did not report using organizational change or provider education may simply have taken these elements for granted. Analyzing the effectiveness of specific components of organizational change would be useful, but the heterogeneity of organizational change across studies and variations in thoroughness of reporting preclude such an analysis based on current evidence. Scant information is available in this literature comparing different educational strategies.

So, for simplicity, from here on we refer to organizational change, provider education, or the combination of both as base strategies. This concept allowed us to organize our data into categories of strategies used in combination with the base strategies. These additional strategies are: (1) audit and feedback plus provider reminder systems; (2) audit and feedback only; (3) provider reminder systems only. Only two[11,12] studies reported the use of financial incentives, regulation, or policy, and two[13,14] reported on patient education, so these QI strategies are not treated separately despite their potential importance. The main variation across QI strategy combinations, therefore, is in the use of audit and feedback and/or provider reminder systems. For each infection, the QI strategy combinations were grouped into two or three categories in developing the strength-of-evidence tables. The composition of these groups varies to some degree from infection to infection, based on which combinations were reported in the included studies.

Within each study, the intervention period was compared with a period of no intervention (usual care), which refers to the absence of additional QI efforts other than the standard of care already in place. Thirteen studies implemented QI strategies in a stepwise fashion and did not report rates before any intervention in the study was implemented.[11,15-26] The comparator for these studies was defined as a low-intensity intervention. Also, a separate strength-of-evidence evaluation was conducted for studies reporting both adherence and infection rates because studies that report both outcomes have more reliable results than those that do not. This evaluation reported results for each QI combination across all four types of infections.

The strength-of-evidence conclusions rely both on the underlying effect of different QI combinations on outcomes and on the availability of studies to assess the relationship. A low strength of evidence, therefore, does not necessarily mean that there is no relationship between the QI strategy and improved outcomes. It is therefore possible that the strength of evidence will change as additional evidence accumulates.

Table B. QI strategy combinations across infections

Combination of QI Strategies	Organizational Change	Provider Education	Audit and Feedback	Provider Reminder Systems	Patient Education	Financial Incentives	CLABSI[a]	VAP[a]	SSI[a]	CAUTI[a]	All[a]
Variants of Base Strategies (Organizational Change and Provider Education)	•	•					3[b]	3[b]	1	0	***7***
	•						0	0	2[b]	0	***2***
		•					3	1	0	0	***4***
Variants of Base Strategies With Audit and Feedback	•	•	•		([c])		4	4[d]	3[b]	1	***12***
	•		•				0	1	1	0	***2***
		•	•				0	0	1	1	***2***
			•		•		1	1	0	1	***3***
Variants of Base Strategies With Provider Reminder System	•	•		•			2	1	2	1	***6***
	•			•			0	0	1	2	***3***
				•			1	0	2	3	***6***
Variants of Base Strategies With Audit and Feedback + Provider Reminder System	•	•	•	•		([c])	10[b,e]	6[b]	2	2[b]	***20***
	•		•	•			1	1	0	0	***2***
		•	•	•			1	1	0	0	***2***
Total	55	51	43	39	4	2	26	19	15	11	***71***

Abbreviations: CAUTI = catheter-associated urinary tract infection; CLABSI = central line–associated bloodstream infection; HAI = healthcare-associated infection; QI = quality improvement; VAP = ventilator-associated pneumonia; SSI = surgical site infection.

[a]These columns indicate the number of studies for each HAI or for all HAI that use the variant of QI strategies indicated in each row.

[b]Comparator for one article is low-intensity intervention.

[c]These two strategies did not define the combinations; therefore, a dot is not included in the definition of the combinations.

[d]One study also includes patient education.

[e]Two studies also include financial incentives.

Key Questions 1 and 1a. QI Strategies Used To Improve Adherence and Infection Rates

Central Line–Associated Bloodstream Infection

Twenty-six studies that addressed the prevention of CLABSI and controlled for confounding factors or secular trend met the inclusion criteria.[11,12,14,16,17,19,20,24,27-44] One study was rated

higher quality,[19] 9 studies[11,17,20,24,28-32] were rated medium quality, and 16 studies[12,14,16,27,33-44] were rated lower quality. The strength of evidence for the combinations used to target CLABSI is summarized in Table C.

Table C. Strength of evidence for combinations targeting CLABSI

SOE	Combination	Outcome	Number/Type of Studies
Moderate	Base strategies + audit and feedback + provider reminder system	Infection rate	1 controlled study[17] 2 interrupted time series[11,32] 8 simple before-after[12,33,38-41,43,44]
	Base strategies + audit and feedback or provider reminder system	Infection rate	1 interrupted time series[31] 6 simple before-after[14,16,27,35-37]
	Base strategies	Infection rate	3 controlled studies[28-30] 1 simple before-after[42]
Low	Base strategies + audit and feedback + provider reminder system	Adherence: insertion bundle	1 controlled study[24] 1 interrupted time series[11] 1 simple before-after[43]
		Adherence and infection rates	2 interrupted time series[11,32] 1 simple before-after[43]
	Base strategies + audit and feedback or provider reminder system	Adherence and infection rates	1 interrupted time series[31] 4 simple before-after[14,16,35,36]
Insufficient	Base strategies + audit and feedback + provider reminder system	Adherence: maintenance bundle	1 interrupted time series[11]
		Adherence: hand hygiene	1 interrupted time series[11]
	Base strategies + audit and feedback or provider reminder system	Adherence: multiple measures	1 interrupted time series[31]
		Adherence: hand hygiene	1 simple before-after[14]
	Base strategies	Adherence: multiple measures	1 simple before-after[34]
		Risk of infection	1 simple before-after[34]
		Adherence rate and risk of infection	1 simple before-after[34]

Abbreviations: CLABSI = central line–associated bloodstream infection; SOE = strength of evidence.
Note: The base strategies are organizational change and provider education.

Moderate Strength of Evidence

All combinations used in studies targeting CLABSI had a moderate strength of evidence for improving infection rates:

- Audit and feedback and provider reminder systems with the base strategies compared with usual care
- Audit and feedback or provider reminder systems with the base strategies compared with usual care
- Base strategies compared with usual care

Ratings of low or insufficient strength of evidence, summarized below for adherence outcomes, reflect the limited number of studies for each of the results.

Low Strength of Evidence

Low strength of evidence was found for audit and feedback and provider reminder systems combined with the base strategies, compared with usual care, for improving adherence to an insertion bundle as well as improving adherence and infection rates. The strength of evidence for the use of audit and feedback or provider reminder systems with the base strategies, compared with usual care, for improving both adherence and infection rates was found to be low.

Insufficient Evidence

The use of audit and feedback and provider reminder systems with the base strategies for improving adherence to a maintenance bundle or hand hygiene was judged to have insufficient strength of evidence. The strength of evidence for the use of audit and feedback or provider reminder systems with the base strategies for improving multiple preventive interventions or hand hygiene was found to be insufficient. Also, the strength of evidence for the use of the base strategies alone for improving adherence to multiple preventive interventions, risk of infection, or both adherence and risk of infection was judged to be insufficient.

Ventilator-Associated Pneumonia

Nineteen studies of implementation of QI strategies to reduce rates of VAP met the inclusion criteria and also controlled for confounding or secular trend.[13-15,19-22,24-27,44-51] Three studies[19,45,46] were ranked of higher quality, 4[20,24,25,47] of medium quality, and 12 of lower quality.[13-15,21,22,26,27,44,48-51] The strength of evidence for the combinations used to target VAP is summarized in Table D.

Table D. Strength of evidence for combinations targeting VAP

SOE	Combination	Outcome	Number/Type of Studies
Moderate	Base strategies + audit and feedback + provider reminder system	Adherence: overall/summary	1 controlled study[45] 2 interrupted time series[15,47]
		Adherence: HOB elevation	2 controlled studies[24,45] 2 interrupted time series[15,47]
		Adherence: oral care	1 controlled study[45] 2 interrupted time series[15,47]
		Infection rate	1 controlled study[45] 3 interrupted time series[15,20,47] 3 simple before-after[22,44,50]
		Adherence and infection rates	1 controlled study[45] 2 interrupted time series[15,47]
	Base strategies + audit and feedback	Adherence: overall/summary	2 simple before-after[13,27]
		Infection rate	2 interrupted time series[25,26] 3 simple before-after[13,14,27]
		Adherence and infection rates	3 simple before-after[13,14,27]
Insufficient	Base strategies + audit and feedback + provider reminder system	Adherence: readiness to wean	2 controlled studies[24,45] 1 interrupted time series[15]
	Base strategies + audit and feedback	Adherence: hand hygiene	1 simple before-after[14]
	Base strategies + provider reminder system	Infection rate	1 simple before-after[49]
	Base strategies	Adherence: HOB elevation	1 controlled study[46]
		Infection rate	1 controlled study[46] 2 simple before-after[48,51]
		Adherence and infection rates	1 controlled study[46]

Abbreviations: HOB = head of bed; VAP = ventilator-associated pneumonia; SOE = strength of evidence.
Note: The base strategies are organizational change and provider education.

Moderate Strength of Evidence

Moderate strength of evidence was found for the use of audit and feedback and provider reminder systems with the base strategies on improving adherence to an overall bundle, head-of-bed elevation, and oral care. The use of this combination compared with usual care for improving infection rates alone and with adherence rates was also judged to have moderate strength of evidence. Furthermore, the evidence for the use of audit and feedback with the base strategies, compared with usual care, for improving an overall bundle, infection rates, and both infection and adherence rates was determined to be moderate.

Insufficient Evidence

Insufficient evidence was available to make any conclusions about the use of audit and feedback and provider reminder systems with the base strategies for improving readiness to wean. The strength of evidence for the use of provider reminder systems with the base strategies for improving infection rates was also judged to be insufficient. Use of base strategies to improve head-of-bed elevation, infection rates, or adherence and infection rates was found to have insufficient evidence.

Surgical Site Infection

A total of 15 studies were identified from the literature search that used QI strategies to implement preventive interventions aimed at reducing SSI, controlled for confounding or secular trends, and met all other criteria for inclusion in this systematic review.[18,52-65] Two studies were rated higher quality,[18,58] 3 studies were rated medium quality,[52,53,59] and 10 studies[54-57,60-65] were rated lower quality. The strength of evidence for the combinations used to target SSI is summarized in Table E.

Table E. Strength of evidence for combinations targeting SSI

SOE	Combination	Outcome	Number/Type of Studies
Moderate	Base strategies + audit and feedback +/- provider reminder system	Adherence: antibiotic timing	1 interrupted time series[53] 1 stepped wedge[52] 2 simple before-after[55,60]
Low	Base strategies + audit and feedback +/- provider reminder system	Adherence: antibiotic selection	1 stepped wedge[52] 2 simple before-after[55,60]
		Adherence: shaving	2 simple before-after[60,61]
	Base strategies + provider reminder system	Adherence: antibiotic timing	1 controlled study[58] 2 simple before-after[57,62]
		Infection rate	1 controlled study[58] 3 simple before-after[57,62,63]
Insufficient	Base strategies + audit and feedback +/- provider reminder system	Adherence: antibiotic duration	1 stepped wedge[52] 3 simple before-after[55,60,61]
		Adherence: normothermia	2 simple before-after[55,60]
		Adherence: glucose control	2 simple before-after[55,60]
		Infection rate	1 interrupted time series[53] 4 simple before-after[55,60,61,64]
		Adherence and infection rates	1 interrupted time series[53] 1 stepped wedge[52] 3 simple before-after[55,60,61]
	Base strategies + provider reminder system	Adherence: antibiotic selection	1 simple before-after[54]
		Adherence: antibiotic duration	1 simple before-after[54]
		Adherence: hair removal	1 simple before-after[57]
		Adherence and infection rates	1 controlled study[58] 2 simple before-after[57,62]
	Base strategies	Infection rate	1 controlled study[59] 2 simple before-after[56,65]

Abbreviations: SOE = strength of evidence; SSI = surgical site infection.
Note: The base strategies are organizational change and provider education.

Moderate Strength of Evidence

The use of audit and feedback with or without provider reminder systems with the base strategies, compared with usual care, for improving adherence to appropriate antibiotic timing was judged to have moderate strength of evidence.

Low Strength of Evidence

The use of audit and feedback with or without provider reminder systems with the base strategies, compared with usual care, for improving adherence to appropriate antibiotic selection or shaving was judged to have low strength of evidence. The evidence for the use of provider reminder systems with the base strategies to improve antibiotic timing or infection rates was deemed low.

Insufficient Evidence

Insufficient evidence was found to make any conclusions on the use of audit and feedback with or without provider reminder systems with the base strategies to improve antibiotic duration, normothermia, glucose control, infection rates, or both adherence and infection rates. In addition, insufficient evidence was found for the use of provider reminder systems with the base strategies for improving antibiotic selection, antibiotic duration, appropriate hair removal, or both adherence and infection rates. Insufficient evidence was also found for the use of the base strategies alone to improve infection rates.

Catheter-Associated Urinary Tract Infections

The literature search identified 11 studies that addressed the prevention of CAUTI and controlled for confounding factors or secular trend.[14,23,35,61,64,66-71] One study[66] was ranked of higher quality, three[67,69,70] of medium quality, and seven[14,23,35,61,64,68,71] of lower quality. The strength of evidence for the combinations used to target CAUTI is summarized in Table F.

Table F. Strength of evidence for combinations targeting CAUTI

SOE	Combination	Outcome	Number/Type of Studies
Moderate	Base strategies + provider reminder system	Adherence: overall urinary catheterization	3 controlled studies[66,69,70] 1 interrupted time series[67] 2 simple before-after[35,68]
Insufficient	Base strategies + audit and feedback + provider reminder system	Adherence: appropriate urinary catheterization	1 simple before-after[71]
		Infection rate	1 interrupted time series[23]
	Base strategies + audit and feedback	Adherence: overall urinary catheterization	1 simple before-after[61]
		Adherence: hand hygiene	1 simple before-after[14]
		Infection rate	3 simple before-after[14,61,64]
		Adherence and infection rates	2 simple before-after[14,61]
	Base strategies + provider reminder system	Adherence: inappropriate urinary catheterization	1 controlled study[66] 1 interrupted time series[67]
		Adherence: correctly inserted urinary catheters	1 controlled study[70]
		Infection rate	1 controlled study[66] 1 interrupted time series[67] 1 simple before-after[35]
		Adherence and infection rates	1 controlled study[66] 1 interrupted time series[67] 1 simple before-after[35]

Abbreviations: CAUTI = catheter-associated urinary tract infection; SOE = strength of evidence.
Note: The base strategies are organizational change and provider education.

Moderate Strength of Evidence

The use of provider reminder systems alone or with the base strategies, compared with usual care, for improving adherence to duration of overall urinary catheterization was found to have moderate strength of evidence.

Insufficient Evidence

The following strategies were used to improve infection rates, but insufficient evidence was found:

- Audit and feedback and provider reminder systems with the base strategies
- Audit and feedback with the base strategies
- Provider reminder systems with the base strategies

Insufficient evidence was also found for the use of both audit and feedback and provider reminder systems with the base strategies to improve appropriate urinary catheterization. Use of audit and feedback with the base strategies to improve overall urinary catheterization, hand hygiene, or simultaneous improvement of adherence and infection rates was also found to have insufficient evidence.

Provider reminder systems with or without the base strategies to improve inappropriate urinary catheterization, correctly inserted urinary catheters, infection rates, and both adherence and infection rates were found to have insufficient evidence.

Key Question 1b. Cost of QI Strategies

Fourteen studies[11,17,36,37,41,44,46,69,70,72-76] were identified that provided information related to the implementation costs and/or savings of QI initiatives to reduce HAI. Ten studies[11,17,36,37,41,44,46,69,70,75] that adjusted for confounding or secular trend reported information on savings. Four studies that did not adjust for confounding or secular trend provided information on the costs of the QI initiative. The literature reviewed for this report identified only one study[69] that provided a detailed analysis for net savings, and no studies provided a comprehensive analysis of return on investment.

Given the limited number of studies that evaluated costs and/or savings and the lack of data on net cost savings, as well as the variation in QI initiatives used in those studies and the varied metrics studied related to costs, the strength of evidence related to the overall cost and savings associated with use of various QI strategies to reduce HAI is insufficient.

Furthermore, no studies were identified that addressed the important questions of the total cost of the QI program or the return on investment of the various QI initiatives.

Key Question 1c. Factors Associated With Effectiveness of QI Strategies

We limit this analysis to studies that reported and analyzed changes in both adherence rates and infection rates because these studies provide the strongest possible causal evidence. To provide a more generalizable and robust synthesis of QI strategies, the analysis in this section combines studies across the four HAI. Because all of the included studies were in hospital settings and there were no direct comparisons between multiple units in a single hospital or across hospitals, we were unable to conduct any setting comparisons. Since length of followup

was an aspect of the quality rating, it was not analyzed separately. The focus of this section is on the type or combination of QI strategies, for which there is the most evidence. Twenty-six studies analyzed both adherence and infection rates.[11,13-16,20,27,31,32,34-36,43,45-47,52,53,55,57,58,60-62,66,67] Four of these studies did not separately analyze adherence rates, but adherence was included in the regression analysis for infections.[16,32,36,52] Three studies analyzed adherence and infection rates for multiple individual infections.[14,35,61] These studies are treated as separate studies, one for each infection, as was done for Key Questions 1 and 1a. This brings the total number of analyses included in this Key Question to 30. One study[68] was excluded from this analysis because it differentiated between early versus late infection rates and thus was not comparable with the other studies.

The strength of evidence for the combinations reported to improve both adherence and infection rates across all four infections is summarized in Table G.

Table G. Strength of evidence for combinations of QI strategies

SOE	Combination	Outcome	Number/Type of Studies
Moderate	Base strategies + audit and feedback + provider reminder system	Adherence and infection rates	1 controlled study[45] 1 stepped wedge design[52] 4 interrupted time series[11,15,32,47] 2 simple before-after[43,55]
Moderate	Base strategies + audit and feedback	Adherence and infection rates	1 controlled study[20,a] 2 interrupted time series[31,53] 8 simple before-after[13,14,27,60,61,a,b,c]
Low	Base strategies + provider reminder system	Adherence and infection rates	2 controlled studies[58,66] 1 interrupted time series[67] 6 simple before-after[16,35,36,57,62,d]
Insufficient	Base strategies	Adherence and infection rates	1 controlled study[46] 1 simple before-after[34]

Abbreviations: QI = quality improvement; SOE = strength of evidence.
Note: The base strategies are organizational change and provider education.
[a]One study also includes financial incentives.
[b]One study also includes patient education.
[c]Two of these studies report on more than one infection.
[d]One of these studies reports on more than one infection.

Moderate Strength of Evidence

Audit and feedback plus provider reminder systems with the base strategies and audit and feedback with the base strategies were found to have moderate strength of evidence for improving both adherence and infection rates across HAI.

Eight studies reported both adherence and infection rates, and used audit and feedback plus provider reminder systems with the base strategies, compared with usual care.[11,15,32,43,45,47,52,55] Three reported on CLABSI,[11,32,43] three reported on VAP,[15,45,47] and two reported on SSI.[52,55] One[45] was of higher quality, four[11,32,47,52] were of medium quality, and three[25,43,55] were of lower quality.

Eleven studies reported both adherence and infection rates, and used audit and feedback with the base strategies, compared with usual care.[13,14,20,27,31,53,60,61] Two[14,31] reported on CLABSI, four[13,14,20,27] reported on VAP, three reported on SSI,[53,60,61] and two reported on CAUTI.[14,61]

Three[20,31,53] were of medium quality and eight (from five articles)[13,14,27,60,61] were of lower quality.

Low Strength of Evidence

Provider reminder systems alone or with the base strategies were found to have low strength of evidence for improving adherence and infection rates.

Nine studies reported both adherence and infection rates, and used provider reminder systems alone or with the base strategies, compared with usual care.[13,35,36,57,58,62,66,67] Three studies[16,35,36] reported on CLABSI, three reported on SSI,[57,58,62] and three reported on CAUTI.[35,66,67] Two[58,66] were of higher quality, one[67] was of medium quality, and six (in five articles)[16,35,36,57,62] were of lower quality. Even though this combination of QI strategies was found to have moderate strength of evidence when used to improve CAUTI rates, there were limited data for this combination for the other three infections. Therefore, this conclusion was not generalizable across all four infections.

Insufficient Evidence

There is insufficient strength of evidence that the use of base strategies improves adherence and infection rates compared with usual care.

Two studies reported both adherence and infection rates and used base strategies, compared with usual care.[34,46] One reported on CLABSI[34] and one reported on VAP.[46] One[46] was of higher quality and the other[34] was of lower quality.

Key Question 2. Effect of Context on Effectiveness of QI Strategies

The 71 studies that controlled for confounding or secular trend were also evaluated to address the impact of context on the effectiveness of the QI strategies. Context, generally, can be thought of as the "characteristics of the organization and its environment that influence the implementation and effectiveness of the patient safety practice."[77] Seven contextual factors, in addition to organizational characteristics such as institution size, financial status, and location, were captured in this report, as the authors of the RAND report recommend for use when evaluating the effectiveness of patient safety practices:[8]

- Theory behind patient safety practice
- Existing patient safety infrastructure
- External factors
- Patient safety culture and teamwork at unit level
- Leadership at unit level
- Change in responsibilities at unit level
- Availability of implementation and management tools

While contextual factors impact the effectiveness of QI strategy implementation and the sustainability of the outcomes, reporting these factors is neither standardized nor required. Another barrier to reporting such information is the required brevity of journal articles. Investigators of some studies in this review attempted to control for contextual factors in the analyses, others provided discussions of contextual differences, and still others did not address contextual issues at all. Our synthesis of context is limited to mapping the frequency with which contextual factors were reported and providing examples of how contextual factors were

addressed in some of the studies. Table H provides the frequency of reporting of the seven additional contextual factors across the four infections.

Roughly two-thirds of the studies took place in single sites,[11,13-15,17,21-23,25,26,28-31,33-39,41,42,44-49,51,54-58,62,64,65,67-69] and about half were from the United States.[11-13,18-21,25,27,28,30,32,33,36,40-42,44,45,50,52,54-57,62,63,65,71] The most commonly reported contextual factor was availability of implementation materials, followed by changes in responsibilities at the unit level and leadership at the unit level. The contextual factors that were discussed the least were theory behind patient safety practice and patient safety culture and teamwork at the unit level. Two studies reported no additional contextual factors other than organizational characteristics.[29,53] Twenty-nine studies (four[20,24,27,44] of which reported on two infections each) reported at least half of the additional contextual factors of interest.[11,12,16-18,20-24,27,36-38,40-44,52,55,56,60,70,71] However, no study reported all seven additional contextual factors. Because all of the included studies were in hospital settings and there were no direct comparisons between multiple units in a single hospital or across hospitals, we were unable to conduct any setting comparisons.

Table H. Frequency of contextual factors used in included studies

Contextual Factor	CLABSI	VAP	SSI	CAUTI	Total
Theory Behind Patient Safety Practice	9	3	4	0	16
Existing Patient Safety Infrastructure	8	6	2	4	20
External Factors	9	7	5	2	23
Patient Safety Culture and Teamwork at Unit Level	14	10	3	4	31
Leadership at Unit Level	17	12	5	3	37
Change in Responsibilities at Unit Level	14	11	12	7	44
Availability of Implementation and Management Tools	19	13	11	6	49

Abbreviations: CAUTI = catheter-associated urinary tract infection; CLABSI = central line–associated bloodstream infection; VAP = ventilator-associated pneumonia; SSI = surgical site infection.

Discussion

Key Findings and Strength of Evidence

This report reviews 71 studies (61 articles) of QI strategies targeting healthcare-associated infections, 10 included in the 2007 review and 61 published subsequently. Four HAI were reviewed: CLABSI, VAP, SSI, and CAUTI. We limited our synthesis to studies that had statistical analyses that adjusted for confounding or secular trend, without which no causal inference can be made about the reported results.

Most studies used multiple QI strategies; only 12 studies used a single QI strategy. Outcomes of interest to the review were adherence to various preventive interventions, change in infection rates, and costs and return on investment. Information was also sought on unintended consequences of QI strategies and contextual factors that might influence the success of a strategy, but data were sparse. Only one study, which did not control for confounding or secular trend, was identified that addressed QI strategies to improve adherence to preventive interventions or reduce HAI rates outside the hospital setting. Most comparisons were with usual care; for 13 studies, the comparison was with a period of a low-intensity QI intervention.[11,15-26]

Evidence synthesis of QI strategies presented considerable challenges. It was not possible to disaggregate the data into individual strategies or to systematically assess the incremental effects of adding a particular strategy to a combination of strategies. Moreover, a wide variety of

combinations of specific QI strategies were used in the studies, making it challenging to categorize consistent combinations of QI strategies or to compare such combinations with each other.

As discussed in the Results section, to develop a workable classification of QI strategy combinations, we hypothesized that organizational change and provider education constitute base strategies. This simplifying concept allowed us to organize our data into categories of strategies used in combination with the base case. These additional strategies are: (1) audit and feedback plus provider reminder systems, (2) audit and feedback only, (3) provider reminder systems only.

Key Findings and Strength of Evidence Across Infections

Our key findings, shown in Table G, assess the evidence across all four infections, applying the framework for grading strength of evidence described in Methods Guide for Effectiveness and Comparative Effectiveness Reviews, which is based on GRADE.[9,10] Only studies that reported on both adherence and infection rates are included in our key findings across infections: 30 of the 71 studies (42%). All comparisons are with usual care.

- There is moderate strength of evidence that adherence and infection rates improve when these strategies are used with the base strategies:
  - Audit and feedback plus provider reminder systems
  - Audit and feedback alone
- There is low strength of evidence that adherence and infection rates improve when this strategy is used with the base strategies:
- Provider reminder systems alone
- There is insufficient evidence that the base strategies alone (listed below) improve adherence and infection rates:
  - Organizational change plus provider education
  - Provider education only

We consider these to be our most robust and generalizable findings. Note that the strength-of-evidence analysis describes the evidence for only the specified combination of QI strategies compared with usual care. The conclusions do not imply that one combination is superior to another. We can only describe the strength of evidence that is available for each combination of QI strategies. Furthermore, the finding of moderate strength of evidence, given a heterogeneous incomplete literature, is noteworthy and suggests that these implementation strategies can be effective in reducing HAI, which is the ultimate objective of the QI efforts.

Findings and Strength of Evidence for Each Infection

Table I displays moderate-strength findings for each infection. There were no QI strategy combinations for which the strength of evidence was rated high. For each infection, studies varied in the adherence rates reported and whether significant improvements were found. Thus, Table I shows the specific adherence rates that were improved with each combination of QI strategies.

In general, within-infection results concur with the key results across infections displayed in Table G. There is moderate strength of evidence to support audit and feedback plus provider reminder systems with the base strategies, as well as audit and feedback alone with the base strategies. Two differences are worth noting.

- Studies of CLABSI demonstrate the impact of differing approaches to the QI strategy on the outcome. Two studies compared simulation-based provider education with traditional provider education (lecture and/or video-based education).[28,30] Both studies found the simulation-based approach to provider education to be superior to the traditional method. This finding may warrant further confirmatory research.
- Studies of CAUTI focused on provider reminder systems as the main strategy for reducing duration of urinary catheterization. There was moderate strength of evidence that provider reminder systems alone or used in combination with the base strategies improve adherence related to duration of overall urinary catheterization, compared with usual care. This finding was not generalizable to other infections given the current body of evidence.

Table I. Combinations of QI strategies with moderate strength of evidence for each infection

Infection	Combination	Outcome
CLABSI	Base strategies + audit and feedback + provider reminder system	Infection rate
	Base strategies + audit and feedback or provider reminder system	Infection rate
	Base strategies	Infection rate
VAP	Base strategies + audit and feedback + provider reminder system	Adherence: overall/summary
		Adherence: HOB elevation
		Adherence: oral care
		Infection rate
		Adherence and infection rates
	Base strategies + audit and feedback	Adherence: overall/summary
		Infection rate
		Adherence and infection rates
SSI	Base strategies + audit and feedback ± provider reminder systems	Adherence: antibiotic timing
CAUTI	Provider reminder systems ± base strategies	Adherence: overall urinary catheterization

Abbreviations: CAUTI = catheter-associated urinary tract infection; CLABSI = central line–associated bloodstream infection; HOB = head of bed; QI = quality improvement; VAP = ventilator-associated pneumonia; SSI = surgical site infection.
Note: The base strategies are organizational change and provider education.

Alternative interpretations may account for these CLABSI and CAUTI results, which cannot be empirically verified from the evidence available from this review. Simulation-based provider education may have a greater impact than traditional, more passive teaching techniques. Alternatively, however, simulation may have attributes that are similar to audit and feedback, and may even, under some circumstances, constitute a form of audit and feedback. With respect to CAUTI, might audit and feedback enhance the results of provider reminder systems? Moreover, in the setting of initiating urinary catheterization, which is addressed by only 3[14,23,70] of 11 studies, audit and feedback might be more relevant than provider reminder systems. These alternative interpretations remind us that it is important to understand the potential synergies among QI strategies and that certain QI strategies may be more effective for some preventive interventions than others.

Findings in Relationship to What Is Already Known

2007 Evidence Report

Authors of the 2007 Evidence Report identified several strategies with potential benefit, but for which further research is needed:

1. Printed or computer-based reminders with use of automatic stop orders may reduce unnecessary urethral catheterization.
2. Printed or computer-based reminders may improve adherence to recommendations for timing and duration of surgical antibiotic prophylaxis.
3. Staff education using interactive tutorials (including video and Web-based tutorials) and checklists may improve adherence to insertion practices for placement of central venous catheters.
4. Staff education, including use of interactive tutorials, may improve adherence to interventions to prevent VAP.

The report concluded that the evidence for QI strategies to improve preventive interventions for HAI was generally of suboptimal quality, and therefore they were unable to reach firm conclusions.[7]

Evidence on the results of QI strategies to reduce HAI has shown improvement since the 2007 report. There was improved methodological quality in the included studies of the current report compared with the previous report. Of the 42 studies included in the 2007 report, only 14 (33%) had a control group or more sophisticated statistical analysis than a two-group test. Of the 173 studies included in the current systematic review, 71 (42%) had a control group or more sophisticated statistical analysis. Both the absolute number of studies and the proportion of studies with statistical analysis to control for confounding and secular trend increased. We were therefore able to reach firmer conclusions. We found moderate strength of evidence to support several combinations of strategies across all four infections and for specific infections.

In addition, the number of relevant publications per year has increased. This trend continued while the systematic review was being prepared. An update of the literature search from April 2011 to January 2012 yielded 40 included articles, compared with 103 articles between January 2006 and April 2011.

The 2007 report concluded that:

> Investigators should attempt to perform controlled trials of QI strategies when possible, and should report both adherence rates and infection rates. If performing a controlled trial is impractical, investigators should perform interrupted time series studies, involving reporting data for at least 3 time points before and after the intervention and formal time series statistical analysis.[7]

We are in complete agreement with the authors' conclusions. Relatively small changes in research design and statistical analysis—such as collecting data for three time points before the intervention and using interrupted time series statistical analysis—could substantially strengthen the body of evidence.

Other Studies and Systematic Reviews

Comparing the results of this systematic review with the published literature is challenging. First, the effectiveness of quality improvement strategies may vary with the context and with the clinical issue being addressed. A number of other studies, including several Cochrane reviews, address efforts to change clinical practice regarding use of preventive services, implementation of guidelines, and prescribing patterns (e.g., Shojania and colleagues,[78] Jamal and colleagues,[79] Grimshaw and colleagues[80]). The impact may also vary with the context, and as this report concludes, the usable information available on context remains sparse. Another recent systematic review of the influence of context on the success of QI in health care concludes that the current body of work is in an early stage of development (Kaplan and colleagues, 2010[81]). The present report relies on the concepts developed by a blue-ribbon panel of experts and reported in the RAND report.[8] The definition and scope of QI strategies also varies (e.g., Scott, 2009;[82] Grimshaw and colleagues, 2004[80]). For example, in this report, provider education is treated as a single entity, in accordance with the categorization used in the 2007 report.[7] A report focusing on education might break it down into distribution of educational materials, educational meetings, and educational outreach visits.[80] As noted, examining the difference between simulation-based provider education and traditional provider education might also be worthwhile.

Finally, the approaches to analyzing individual QI strategies, such as audit and feedback, vary because they often form part of a bundle of QI strategies. Should the focus be on individual strategies, even if they form part of a bundle of interventions that may vary from study to study? The advantage is the ability to focus on specific components that may be critical to the success of an intervention. The disadvantage is the inability to disentangle the effects of different strategies grouped together. The focus on individual strategies was used in the 2007 report and a number of other studies.[7,83] The current report groups combinations of similar strategies, which will help to account for interactions among individual QI strategies. However, because of the large number of different QI strategy combinations, the groupings are not entirely homogeneous and there are fewer studies per combination. The results are also more challenging to present (e.g., base strategies and audit and feedback or provider reminder systems). Nevertheless, we think this approach produces more valid and generalizable conclusions because it allows for interaction effects to a greater degree. Furthermore, in actual practice, bundles of QI strategies are frequently used.

De Vos and colleagues[84] conducted a systematic review of controlled studies on the impact of implementing quality indicators in hospitals. The article included 21 studies from 1994 to 2008, none of which focused on efforts to reduce HAI. Most studies used multiple implementation strategies, and the most commonly used strategy for incorporating information on quality indicators was audit and feedback. Fourteen of the studies adjusted for potential confounders, and the results of these studies appeared to be less effective than those for unadjusted studies. Effective or partly effective studies (defined by the proportion of improved measures) appeared to use audit and feedback together with other implementation strategies. Despite the differences between this article and the current systematic review, the findings appear to be congruent.

The systematic reviews on provider reminder systems tended to focus on specific types of reminder systems, e.g., onscreen point-of-care computer reminders.[78] Given the diversity of provider reminder systems used in the studies included in the current report, the findings for these disparate types of reviews were not compared. One meta-analysis focused on reminder systems to reduce urinary tract infections and urinary catheter use in hospital patients.[85] Based on

a review of 14 articles published before September 2008, the authors found that the rate of CAUTI fell by 52 percent ($p < .001$) when reminders or stop orders were used. There was overlap between the studies included in this article and in the current report, but Meddings and colleagues[85] appear to have included simple before-after studies. Their overall conclusion is therefore similar to that in the current report, but the size of the effect is likely to be overestimated.

Comparing the results of the current systematic review with other findings echoes the challenges encountered in conducting this review. Specifically, the heterogeneity encountered in articles on implementation of preventive interventions to reduce HAI is magnified in the literature on QI strategies in general. Overall, however, the results of the current review appear to be congruent with those of other studies and systematic reviews. They suggest that improvements in adherence and infection rates may result from use of audit and feedback as well as provider reminder systems.

Limitations of the Current Review

The limitations of this review are those that are generally encountered in assessments of complex interventions that are used in complex settings. Such studies are typically heterogeneous in design, setting, measurement, outcomes, and reporting. The resulting data are not amenable to quantitative analysis, thus requiring a qualitative approach. As noted above, evidence synthesis of QI strategies presented considerable challenges. To develop a workable classification of QI strategy combinations, we hypothesized that organizational change and provider education constitute base strategies and categorized other QI strategies that were combined with organizational change and provider education. As is often the case in qualitative research, the validity of the classification must be demonstrated by its application. Is it a useful way to organize the evidence? Most importantly, and as yet unknown, is the issue of whether the classification can be used prospectively to predict success of QI strategies.

Moreover, this review adopted the existing classification system of QI strategies, with whatever limitations may be inherent in this system. One limitation that is apparent to us is that the same strategy may in fact incorporate very different interventions. For example, as noted above, the different provider education methods may vary in intensity, and thus their potential effect on the outcomes of interest may vary. To this end, the recommendations of Shekelle and colleagues to advance the science of patient safety include “more detailed descriptions of interventions and their implementation.”[77]

Future Research Needs

We found both critical methodologic weaknesses in the literature and gaps in evidence to address the Key Questions of our review.

Improving Methodologic Quality

Studies selected for this systematic review used either an experimental design with a control group or a quasi-experimental design. Most studies of QI strategies are effectiveness studies rather than efficacy studies. The interventions are implemented in a “real-world” setting rather than using the highly controlled designs that are the standard for efficacy studies. The factors that can confound the results of such quasi-experimental studies are well known. Although 173 studies met initial selection criteria for this review, 102 were excluded from our synthesis because they used statistical analyses that did not control for confounding or secular trend. While

these studies reported an association between QI strategy and outcome, they do not support causal inference. To advance the science of using QI strategies to reduce HAI, studies need to demonstrate a causal linkage between improved adherence and reduced infection rates as well. To evaluate this, studies should report both adherence with the preventive interventions and infection rates.

The circumstances under which studies of QI strategies are conducted merit a thoughtful approach to improving the development of evidence. Conducting a rigorous evaluation of a complex intervention is a challenging undertaking. The usual call to improve the quality of evidence by producing randomized controlled trials may not pertain to this issue. A more productive approach would be to improve the quality of quasi-experimental studies through (1) conducting more rigorous study designs, (2) taking into account secular trends and potential confounders, and (3) reporting and analyzing both adherence and infection rates. The enthusiasm of institutions and institutional collaborations might be harnessed by creating toolkits and accessible consultation so that organizations that are engaged in QI initiatives can make a meaningful contribution to the accumulation of knowledge about successful QI strategies.

Methodologic quality would also be improved by systematic collection and reporting of factors that may contribute to the generalizability of QI strategies. Although we abstracted contextual factors from the studies included in this review, the available data were too disparate to be synthesized in a meaningful fashion. This is not surprising, as available studies largely predate the dissemination of recommendations to advance the science of patient safety through emphasis on the effect of context. Presently, the approach to collecting and reporting on factors that may influence generalizability is not sufficiently standardized to produce a robust evidence base. We suggest that availability of toolkits and consultation to organizations undertaking QI evaluation studies could assist this effort.

Adopting more standardized approaches to measuring adherence would strengthen the body of evidence. While preventive interventions are well known, the way in which adherence is measured varied from study to study, thus reducing the comparability of adherence outcomes across studies. Another potential confounder is that studies varied in how preventive interventions were implemented—for example, in the frequency of oral care for ventilated patients or the use of antibiotic-impregnated catheters.

Evidence Gaps

Only one study, which did not control for confounding or secular trend, was found on the use of QI strategies to reduce HAI in nonhospital settings such as ambulatory surgical centers, freestanding dialysis centers, and long-term care facilities. Yet a substantial proportion of health care is delivered outside hospitals.

The studies on using QI strategies to reduce HAI were very limited in providing data about the implementation costs, cost savings from the implementation, and return on investment from implementing the QI strategies. The data related to savings are weakened by the number of simple before-after studies that present information on cost savings when the impact on infection rates is uncertain. One reason for not adopting successful QI strategies is that they are "too expensive," so the lack of data related to this measure is a major deficiency.

Finally, there are limited data related to the long-term durability and sustainability of the impact of the QI strategies over time. Many studies lasted only 1 year postintervention or less. To eliminate, or at least reduce, HAI, the QI strategies must show sustained effectiveness over several years.

Conclusions

The magnitude of the potential harm caused by HAI and their ubiquity, as well as the recent reduction in infection rates, highlight the importance and feasibility of identifying the most effective ways for health care institutions to address their prevention. Although the practical challenges in measuring the effectiveness of different strategies in a real-world environment are many, the results of this systematic review demonstrate that it can be done and that practical lessons can be gleaned even from a less than ideal evidence base. In this update of the 2007 AHRQ report (Ranji and colleagues, 2007),[7] there is moderate strength of evidence across all four infections examined that both adherence and infection rates improve when either audit and feedback plus provider reminder systems or audit and feedback alone are added to the base strategies of organizational change and provider education. There is low strength of evidence that adherence and infection rates improve when provider reminder systems alone are added to the base strategies. There is insufficient evidence for reduction of HAI in nonhospital settings, cost savings for QI strategies, and the nature and impact of the clinical context. Relatively modest improvements in research approaches have the potential to substantially strengthen the evidence and provide further insight into how to protect patients from healthcare-associated infections.

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Introduction

Background

In 2003, the Institute of Medicine (IOM) published a report, Priority Areas for National Action: Transforming Health Care Quality.[1] The report identified 20 clinical topics for which there are quality concerns because of the gap between knowledge of the topic and integration of that knowledge into the clinical setting. In response to the IOM report, the Agency for Healthcare Research and Quality (AHRQ) initiated a series of technical reviews on quality improvement (QI) strategies focused on improving the quality of care for the IOM's 20 priority areas.[2] The current systematic review serves to update and expand the 2007 Evidence Report, Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies. Volume 6: Prevention of Healthcare-Associated Infections.[3]

Healthcare-Associated Infections

The Centers for Disease Control and Prevention (CDC) define a healthcare-associated infection (HAI) as "[A] localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s). There must be no evidence that the infection was present or incubating at the time of admission to the acute care setting."[4] The CDC estimates that in 2002, there were 1.7 million HAI and 99,000 HAI-associated deaths in hospitals. The four largest categories of HAI, responsible for over 80 percent of all reported HAI, are central line-associated bloodstream infections (CLABSI; 14%), ventilator-associated pneumonia (VAP; 15%), surgical site infections (SSI; 22%), and catheter-associated urinary tract infections (CAUTI; 32%).[5]

The most recent national HAI data available are on CLABSI and SSI, reported by the National Healthcare Safety Network (NHSN), a public health surveillance system established in 2005 by the CDC's Division of Healthcare Quality Promotion (DHQP). Twenty-two states and the District of Columbia have required or have plans to require their health care facilities to report HAI to the NHSN; CLABSI and SSI are the infections most frequently mandated by these states for reporting. In a current report, the NHSN provides Standardized Infection Ratios (SIR) for CLABSI and SSI nationally and by state, for January 2009 to December 2009. The SIR measures the relative difference in HAI occurrence during a reporting period compared with a referent period. The referent period for this report is January 2006 through December 2008. For 2009, the CLABSI SIR is 0.83, which translates to a 17 percent national reduction compared with the referent period, and the SSI SIR is 0.92, for a national reduction in incidence of 8 percent. However, facility-specific SIRs for both infections showed great variability, with some facilities showing progress in their preventive efforts, while other facilities demonstrated increasing rates.[6]

Burden of Healthcare-Associated Infections

According to the CDC, about one in four patients acquiring a bloodstream infection from the insertion of a central line dies (www.cdc.gov/VitalSigns/HAI/index.html). Identifying more effective ways to treat these patients is essential, but far better to prevent the infections in the first place. The prevention and reduction of HAI is a top priority for the United States Department of Health and Human Services (www.cdc.gov/HAI/prevent/prevention.html). A call

to action for the elimination of HAI has been issued jointly by the Association for Professionals in Infection Control and Epidemiology, Inc., the Society for Healthcare Epidemiology of America, the Infectious Diseases Society of America, the Association of State and Territorial Health Officials, the Council of State and Territorial Epidemiologists, the Pediatric Infectious Diseases Society, and the CDC.[7] In a consensus statement issued by these groups, a plan for the elimination of HAI includes the promotion of adherence to evidence-based practices through partnering, educating, implementing, and investing.

In a CDC report, national costs of HAI were estimated, based on 2002 infection rates and adjusted to 2007 dollars using the Consumer Price Index (CPI) for inpatient hospital services. Estimates of the annual direct medical costs of HAI for U.S. hospitals ranged from $35.7 billion to $45 billion. Using the same adjustment, the estimates of patient hospital costs for the four most common HAI ranged from $3.45 billion to $10.07 billion for SSI, $0.67 billion to $2.68 billion for CLABSI, $1.03 billion to $1.50 billion for VAP, and $0.39 billion to $0.45 billion for CAUTI.[8] It is estimated that the cost savings of preventing 70 percent of HAI would be $25.0 billion to $31.5 billion, using the same adjustment.[8]

2007 Technical Assessment of Prevention of Healthcare-Associated Infections

The objective of the 2007 report was to identify quality improvement (QI) strategies that successfully increased adherence to effective preventive interventions and reduce infection rates for the following healthcare-associated infections:

- Central line-associated bloodstream infection (CLABSI)
- Ventilator-associated pneumonia (VAP)
- Surgical site infection (SSI)
- Catheter-associated urinary tract infection (CAUTI)

The QI strategies included in this review were those identified in the first volume of the Closing the Quality Gap series (Table 1).[3] Authors of this report concluded that there were no QI strategies that effectively decreased the rate of SSI, although some did increase adherence to preventive interventions. Two studies reported lower CLABSI rates when an explicit checklist was implemented, empowering nurses to stop procedures until preventive interventions were used. The assessment concluded that several QI strategies, provider education and printed or computer-based reminder systems, were worthy of further study and possibly wider implementation, and that higher quality studies on implementation strategies were needed In many instances, the authors were unable to reach firm conclusions, because of the uncertainty associated with single-center and simple before-after studies.[3]

Table 1. Quality improvement strategies from 2007 report[3]

QI Strategy	Examples
Provider reminder systems	Reminders in charts for providers Computer based reminders for providers Computer based decision support
Facilitated relay of clinical data to providers	Transmission of clinical data from outpatient specialty clinic to primary care provider by means other than medical record, e.g., phone call or fax
Audit and feedback	Feedback of performance to individual providers Quality indicators and reports National/state quality report cards Publicly released performance data Benchmarking – provision of outcomes data from top performers for comparison with provider's own data
Provider education	Workshops and conferences Education outreach visits (e.g., academic detailing) Distribution of education materials
Patient education	Classes Parent and family education Patient pamphlets Intensive education strategies promoting self-management of chronic conditions
Promotion of self-management	Materials and devices to promote self-management
Patient reminder systems	Postcards or calls to patients
Organizational change	Case management, disease management Total quality management, cycles of quality improvement Multidisciplinary teams Change from paper to computer based records Increased staffing Skill mix changes
Financial incentives, regulation, and policy	***Provider Directed:*** Financial incentives based on achievement of performance goals Alternative reimbursement systems (e.g., fee for service, capitated payments) Licensure requirements ***Patient Directed:*** Copayments for certain visit types Health insurance premiums, user fees ***Health System Directed:*** Initiatives by accreditation bodies (e.g., residency work hour limits) Changes in reimbursement schemes (e.g., capitation, prospective payment, salaried providers)

Current Review Modifications

In planning the current evidence review, the continued relevance of the topic was assessed, as well as whether changes in scope were warranted. Given the continued prevalence of these infections, despite efforts to reduce them, the topic remains relevant. Many studies have been published since 2007. Whether the list of infections should be expanded was also considered. Three possible additions were considered: Methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile (C. difficile),* and norovirus. MRSA and *C. difficile* are already the subjects of comparative effectiveness reviews under AHRQ's Effective Health Care Program.[9,10] The study on MRSA focuses specifically on the effectiveness of universal screening, while the report on *C. difficile* is broader in scope. Serious consideration was given to the inclusion of norovirus, because the need to include cleaning staff, clinical staff, and others in efforts to reduce infections

might shed more light on the importance of context in influencing the effectiveness of various QI strategies to implement preventive interventions. However, the Healthcare Infection Control Practices Advisory Committee (HICPAC) guidelines for norovirus were in draft form when this project was started. Furthermore, there was concern that the epidemic nature of norovirus outbreaks would make it more difficult to link specific QI strategies to changes in infection rates. Based on these factors, this report will focus on the same four infections that the 2007 report did.[3].

The scope of this report was expanded by broadening the list of health care settings included. Much of the initial work on HAI focused on hospital settings, as is evident in the 2007 report. Less information is available on HAI in nonhospital health care settings, such as ambulatory surgery centers, freestanding dialysis centers, and long-term care facilities, but it is clear that HAI are found in these settings as well and deserve attention.[11-14] CDC has issued guidelines specifically for other health care settings.[15] Although comparable estimates of the costs of HAI for nonhospital settings were not found, it is clear that the total direct medical costs of HAI are higher when other settings are included. This report, therefore, sought to include studies on the effectiveness of QI strategies in these nonhospital health care settings as well.

The 2007 report focused on "the implementation of preventive interventions that are recommended for universal use in target patient populations by professional societies and governmental organizations." For the current report, we rely on guidelines from CDC, the SHEA, and IDSA. The CDC Guidelines are developed by HICPAC, which was formed to provide guidance to the CDC and the Secretary of Health and Human Services regarding strategies for prevention and surveillance of HAI and includes broad stakeholder input. We also reviewed SHEA/IDSA Compendium of Strategies to Prevent Healthcare-Associated Infections. The Compendium highlights evidence-based HAI prevention strategies to be implemented in acute care hospitals.[16-19]

In reviewing efforts to improve health care quality and specifically to prevent HAI, it is important to use consistent terminology to differentiate among several concepts.

- The first step in designing a quality improvement project is to identify a **quality gap**: According to Ranji and colleagues, a quality gap refers to the difference between health care processes or outcomes observed in practice and those potentially achievable on the basis of current professional knowledge.[3] In this proposal, the quality gaps are the levels of HAI found in various health care settings.
  - **Quality improvement target** is the outcome process or structure that the QI strategy is aimed at changing.[3]
  - **Preventive intervention** is a specific infection control practice that has been demonstrated to reduce the incidence of an HAI.[3] An example would be using maximal sterile barrier precautions when inserting a central line.
  - A **quality improvement strategy** aims to narrow the quality gap for a group of patients who are representative of those seen in routine practice by increasing the use of preventive interventions.[3] An example would be staff training about the use of maximal sterile barrier precautions and authorizing any member of the team to stop the procedure if any part(s) of the preventive intervention is not being used.
  - The effectiveness of a QI strategy is dependent not only on the strategy chosen but also on the **context** in which it is implemented. According to a recent report prepared by RAND for AHRQ,[20] there is no standard definition of context but it may include

barriers and facilitators related to the organizational and policy environment, as well as information about the processes of implementation.

- The above terminology is based on the terminology used in the original report on Closing the Quality Gap: Reducing Healthcare Associated Infections.[3] Different terminology is used in other studies, such as patient safety practices in the RAND report cited above, which also is used to establish the framework for parts of this report.[20] For consistency across this series, the term "quality improvement strategy" or "QI strategy" will be used.

Quality Improvement Strategies

How to spur the adoption of preventive interventions has been the subject of considerable research in recent years. These efforts are taking place in single hospitals or units within a hospital, as well as across entire states and even multistate collaboration. For example, AHRQ has funded CUSP (Comprehensive Unit based Safety Program) to bring toolkits from Michigan's Keystone project to every other state in the United States and to Puerto Rico (www.hret.org). The focus will first be on bloodstream infections and then on catheter-associated urinary tract infections. An interim report released in April 2011 reported a 35 percent reduction in CLABSI rates from 1.8 to 1.17 infections per 1,000 central line-days among over 350 adult intensive care units (www.ahrq.gov/qual/onthecusprpt/). While not focused on prevention efforts, a recent report on infection control lapses in ambulatory surgical centers (ASCs) found that 46 of 68 ASCs audited had at least one lapse in infection control.[21] Some efforts have been initiated internally by dedicated staff. Others have been spurred in part by external forces, such as Medicare's policy not to pay for "never events," which include "patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by the healthcare facility" (www.qualityforum.org/Publications/2008/10/Serious_Reportable_Events.aspx; www.cms.gov/MedicareAdvtgSpecRateStats/downloads/oon-payments.pdf). A great deal of activity in this field since 2007 warrants an update and reexamination of what has been learned.

A corollary of the increase in quality improvement research has been the development of guidelines for reporting as well as of research frameworks to guide QI efforts. Pronovost and colleagues developed one research framework,[22] whose structure parallels that of pharmaceutical research with phases from T0 through T4. Phase T3 focuses on moving evidence-based guidelines into practice, through delivery, dissemination, and diffusion research. The focus of this report falls within this phase.

Consistency in reporting of QI research was addressed in 2008 with the development of the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines, which provide researchers and journals a checklist of how to report on QI research.[23] However, the SQUIRE guidelines do not provide much detail on how the setting or context in which research takes place should be described. Additions from the RAND report and other discussions of the impact of context on research may increase the uniformity of reporting in the body of evidence.[20,24-26]

The challenges of implementing prevention and surveillance programs for HAI are many. These efforts are labor intensive and require an infrastructure that coordinates the education and supervision of staff, and in larger health care facilities, computerized support.[27] There are a number of steps in creating the evidence base that supports efforts to reduce HAI. Once the targets of the efforts are identified, for example, the types of infections and most common locations or patient populations, the next step is to identify preventive interventions that, if

undertaken, are likely to prevent these HAI. Extensive research in this area has resulted in the development of evidence-based guidelines, such as those produced by HICPAC and SHEA/IDSA. But knowledge of effective interventions to reduce HAI can be difficult to convert into practice. As extensive efforts to improve adherence with hand washing have shown, it can be difficult to translate the knowledge that hand washing can reduce infections into consistent, appropriate practice. This report will focus on the implementation of QI strategies to prevent HAI, for example, how to get health care workers to wash their hands and to do so correctly for each clinical situation.

The field of implementation of QI strategies is evolving, with reviews covering broad topics such as how to change provider behavior[28] or how to incorporate guidelines into clinical practice.[29] The reviews have found that studies often combine strategies into multifaceted approaches, rather than implement a single strategy. While the reviews report that these multifaceted approaches are more likely to be successful, there are challenges in determining which components are potentially effective alone, or if all components or a subset of the components are necessary for efficacy.[28-31] In a health technology assessment on the effectiveness of guideline dissemination and implementation strategies, Grimshaw et al. report that the most common intervention strategy implemented was the use of provider reminders.[29] Moderate improvements in the utilization of guidelines were reported when provider reminders were used. The next most common intervention was educational outreach, which was defined as the use of a trained person who met with providers in their practice settings to provide information with the intent of changing the provider’s practice. Educational outreach, which was often one component of a multifaceted approach, demonstrated modest effects. The assessment found less evidence on the distribution of printed educational materials, audit and feedback, and patient directed interventions. The authors conclude that there is not a robust generalizable evidence base on effective strategies to promote guideline utilization.[29]

Reviews that focused on a single QI strategy included studies implementing the QI strategy alone, as well as studies in which the QI strategy was part of a multifaceted intervention system. A Cochrane review on the effects of audit and feedback on health care outcomes reported variable effects.[31] For studies with dichotomous outcomes, the adjusted risk difference of adherence varied from a 16 percent decrease in adherence to a 70 percent increase in adherence. For studies with continuous outcomes, the adjusted percent change varied from a 10 percent decrease in adherence to a 68 percent increase in adherence.[31] Another Cochrane review focused on a specific type of provider education strategy, educational outreach visits.[30] This review reports that educational outreach visits, whether alone or in combination with other strategies, show consistent and small improvements in prescribing patterns, and small to moderate improvements in other professional performance measures. A review that focused solely on the effect of health information technology or health information systems on clinicians’ adherence to evidence-based guidelines has found a positive effect on adherence, but inconsistent effects on patient outcomes.[32] Many reviews cite a difficulty in forming conclusions on the effectiveness of a particular QI strategy due to the variability among studies, whether the strategy was implemented singly or as part of a multifaceted intervention.[28-31]

Shekelle et al. note that context may be the distinguishing factor between evaluating the impact of a QI strategy versus a clinical intervention.[20] The RAND report identified important evaluation questions for QI strategies, reporting requirements, and the elements of context that may have an impact on the effectiveness of implementing QI strategies, all of which are incorporated into the present evidence review.

Objectives

This systematic review updates the AHRQ Evidence Report on Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies. Volume 6: Prevention of Healthcare-Associated Infections.[3] The objective is to identify QI strategies that successfully increase adherence to effective preventive interventions and reduce infection rates for CLABSI, VAP, SSI, and CAUTI. Successful strategies help to close the quality gap regarding HAI. The purpose of this review is to inform and assist health care decisionmakers, patients, clinicians, health systems leaders, and policy makers.

This review will evaluate the large number of implementation studies that have been published since 2006, when the literature search for the 2007 report ended. It will not expand infections included, for reasons previously explained. It will expand the settings to be considered from primarily hospitals to include ambulatory surgery centers, freestanding dialysis centers, and long-term care facilities, where the prevention of HAI needs to be addressed as well.

The current report also will apply the recommendations, where applicable, of a patient safety methodology report prepared for AHRQ by RAND Health.[20] The objective of this report was to identify criteria for assessing the impact of context on the effectiveness of patient safety practices, which are a type of QI strategy. The context of an intervention, for example, the type of health care setting, the leadership structure, the safety culture, the openness to innovation, can have an important impact on whether preventive interventions are adopted. Furthermore, the ability to transfer a successful QI strategy from one setting to another may depend in part on whether the contexts differ. For example, cultures in which nurses are able to question a physician's adherence to recommended practices may be able to implement an intervention more successfully than those where they are not.

Key Questions

Key Question 1. Which quality improvement strategies are effective in reducing the following healthcare-associated infections?

- Central line–associated bloodstream infections (CLABSI)
- Ventilator-associated pneumonia (VAP)
- Surgical site infections (SSI)
- Catheter-associated urinary tract infections (CAUTI)
    a. Which quality improvement strategies are effective in increasing adherence to evidence-based *preventive interventions* for the four healthcare-associated infections listed above?
    b. What is the cost, return on investment, or cost-effectiveness for health care providers, patients, and society as a whole of quality improvement strategies to reduce these healthcare-associated infections?
    c. Which factors are associated with the effectiveness of quality improvement strategies, including, for example,
        1. Type of quality improvement strategy
            a. Clinician education
            b. Patient education
            c. Audit and feedback
            d. Clinician reminder systems
            e. Organizational change

    f. Financial or regulatory incentives for patients or clinicians
    g. A combination of the above
2. Duration of intervention
3. Setting, for example, hospitals (intensive care unit, surgical or ventilator-dependent patients), outpatient surgical centers, long-term care facilities, and freestanding dialysis centers, and which kinds of clinicians implement the quality improvement strategies?

Key Question 2. What is the impact of the health care context on the effectiveness of quality improvement strategies, including reducing infections and increasing adherence to preventive interventions?

Methods

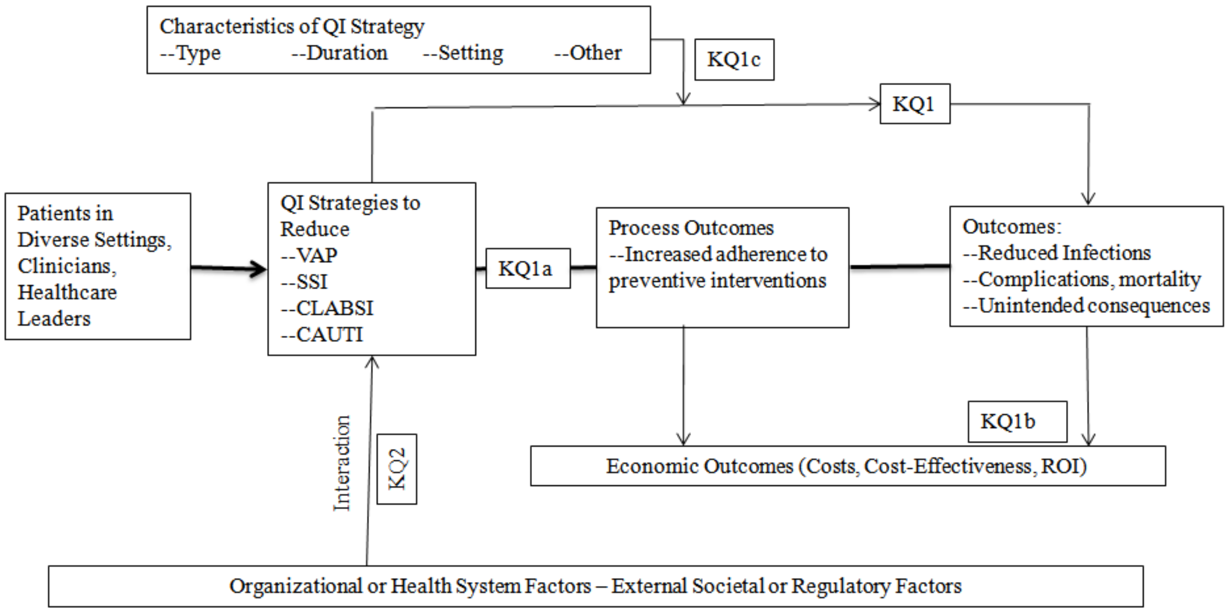
Scope

As in the 2007 Evidence Report, Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies. Volume 6: Prevention of Healthcare-Associated Infections,[3] the current report focuses on QI strategies for implementing preventive interventions for the following healthcare-associated infections (HAI): CLABSI, VAP, SSI, and CAUTI. The scope of the current report has been expanded from the previous report. Both hospital and nonhospital health care settings, such as ambulatory surgery centers, freestanding dialysis centers, and long-term care facilities are included. Also, information recommended for consideration in the recent RAND report for AHRQ on Assessing the Evidence for Context-Sensitive Effectiveness and Safety of Patient Safety Practices[20] is included in the evaluation.

Analytic Framework

The analytic framework depicts the potential impact of the implementation of QI strategies on reducing the following HAI: CLABSI, VAP, SSI, and CAUTI (Figure 1). Key Question 1 shows the link between QI strategies and health outcomes: such as decreased infection rates, decreased complications and mortality, as well as unintended consequences. Key Question 1a shows the link between QI strategies and process outcomes; that is, adherence to preventive interventions. There are economic implications from both the process outcomes and the health outcomes, as depicted by Key Question 1b. Characteristics of the QI strategies, such as type of strategy, duration of the implementation, and setting, determine the effect of the QI strategies on the outcomes (Key Question 1c). Link Key Question 2 marks the interaction between the implementation of QI strategies and contextual factors of the organization. For example, institutions with an existing patient safety infrastructure may have fewer barriers to implementing QI strategies than other institutions.

Figure 1. Analytical framework for systematic review on quality improvement strategies to reduce healthcare-associated infections



Abbreviations: CAUTI = catheter-associated urinary tract infection; CLABSI = central line–associated bloodstream infection; KQ = Key Question; QI = quality improvement; ROE = return on investment; SSI = surgical site infection; VAP = ventilator-associated pneumonia.
Note: Adapted from Shekelle et al.[20]

Literature Search Strategy

The same search strategy used in the prior report[3] (Appendix A) was rerun on MEDLINE®, CINAHL®, and Embase®. Duplicate records were deleted. The search covered the time period from January 2006, when the search in the last report ended, to April 2011. The search was updated in January 2012 while the draft report was available for public comment, and relevant articles were added. Additional efforts were made to identify articles on interventions in nonhospital settings, which are likely to be reported less frequently. The members of the Technical Expert Panel (TEP) were queried, and they provided recommendations of experts on these additional settings. Articles authored by these recommended experts were retrieved. A search on relevant studies in nursing homes was conducted in July 2011. We also screened the bibliographies of included articles to identify additional references. Web sites of entities involved in efforts to reduce HAI, such as the Institute for Healthcare Improvement, were scanned to ensure that no relevant peer-reviewed publications were missed and to identify descriptions of implementation strategies for which outcomes have been published in the peer-reviewed literature.

Article Selection

Titles and abstracts from the literature search citations were placed in a Microsoft Access® database for the first round of screening. Three trained reviewers conducted the screening. Each title and abstract was screened and marked as either: (1) retrieve for full-text review, (2) do not retrieve for full-text review, or (3) uncertain. Studies were marked for retrieval for full-text

review if the citation reported the outcomes of an intervention for (a) any one of the four specified HAI, or (b) a combination of HAI that included at least one of the four. The reasons for excluding an article were noted. Articles deemed uncertain for full-text review were screened by a second reviewer. If both reviewers were uncertain, the article was retrieved for full-text review. To ensure the quality of this first round of screening, an investigator not involved with the screening reviewed a random sample of 114 titles and abstracts that were marked “do not retrieve.” The investigator agreed with all the exclusions. The project lead reviewed another 101 abstracts marked “do not retrieve,” one-third from each of the three reviewers, and agreed with all of the exclusions.

The full-text articles were retrieved and a similar process was followed to select the final group of articles for inclusion and abstraction in the report. Articles were included if the study described an implementation strategy to increase adherence with one or more of the preventive interventions listed above, with the intent of reducing one or more of the four types of infections covered in this report. A listing of studies excluded at the full-text level and reasons for exclusion can be found in Appendix B. Evidence tables of abstracted data can be found in Appendix C.

Inclusion and Exclusion Criteria

The same selection criteria were used for this report as for the 2007 report,[3] with the addition of a criterion related to the setting. Specifically, included studies were required to:

- Report the effect of a QI strategy on the incidence of HAI (CLABSI, VAP, SSI, or CAUTI), *or* report the effect of a QI strategy on adherence to evidence-based prevention interventions.
    - The specific prevention interventions used to reduce infections were selected from recommendations with a grade of 1A or 1B in the HICPAC guidelines (see www.cdc.gov/hicpac/pubs.html), analogous to the approach used in the 2007 report, or with a grade of A-I or A-II in the SHEA/IDSA Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals.[16-19] The list of preventive interventions was reviewed and amended by the TEP. The compiled list of infection-specific preventive interventions can be found in Table 2 as well as Appendix D.
    - If the study did not describe a QI strategy and focused on the effect of prevention interventions only, such as comparing antibiotic choice to prevent SSI or comparing antiseptic cleansers for skin preparation prior to surgery, the study was excluded.
- Use either an experimental design with a control group *or* a quasi-experimental design.
    - Quasi-experimental studies must have a clearly defined baseline and post-intervention time period.
    - Interrupted time series designs, by definition, must report more than one time point of data before and after the intervention.
    - Studies that reported only postintervention data were excluded.
- Report on one of the following settings: hospitals, outpatient surgical centers, freestanding dialysis centers, and long-term care facilities.
- To be included, studies that report related outcomes, such as costs, health services utilization, patient or provider satisfaction with care, or unanticipated consequences of an intervention, must also report infection rates or adherence with preventive interventions.

- Conduct a statistical analysis comparing baseline and postintervention infection rates or adherence rates.
  - If a study reported baseline and postintervention infection rates or adherence rates, but did not perform a statistical analysis to compare the rates, the study was excluded.
- Have a combined baseline and postintervention patient sample size ≥100.

Table 2. Included preventive interventions for healthcare-associated infections

Infection	Prevention Intervention
All HAI	hand hygiene
SSI	appropriate perioperative antibiotic prophylaxis (including appropriate antibiotic selection, timing, and duration) (2007 report) perioperative glucose control (2007 report) decreasing shaving [or hair removal] of the operative site (2007 report) specific technique for clinicians when washing hands prior to surgery (CDC/HICPAC IB) treat infections prior to surgery (CDC/HICPAC IA) encourage tobacco cessation (CDC/HICPAC IB) bathe and prepare skin with antiseptic agent (CDC/HICPAC IB) develop policies to manage infected surgical team (CDC/HICPAC IB) maintain positive pressure ventilation and minimal 15 air changes per hr during surgery (CDC/HICPAC IB) disinfect environmental surfaces (CDC/HICPAC IB) sterile instruments and surgical wear (CDC/HICPAC IB) after surgery, protect incision with sterile dressing (CDC/HICPAC IB) normothermia [recommended by Technical Expert Panel] intraoperative administration of oxygen (FIO2), for abdominal or colorectal cases [recommended by Technical Expert Panel]
CLABSI	adherence to maximal sterile barrier precautions (2007 report) use of chlorhexidine for skin antisepsis (2007 report); If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives. (CDC/HICPAC IA) avoidance of femoral catheterization (2007 report) decontaminate hands before donning sterile gloves when inserting a central intravascular catheter (CDC/HICPAC IB) do not use arterial or venous cutdown procedures during insertion (CDC/HICPAC IA) do not use organic solvents on skin (CDC/HICPAC IA) clean injection ports with 70% alcohol before accessing (CDC/HICPAC IA) prepare admixtures using sterile technique (CDC/HICPAC IB) do not use in-line filters for infection-control purposes (CDC/HICPAC IA) do not administer systemic antimicrobial prophylaxis routinely prior to catheter insertion (CDC/HICPAC IA) after insertion, remove nonessential catheters (SHEA/IDSA A-II); Promptly remove any intravascular catheter that is no longer essential (CDC/HICPAC IA) After insertion, change dressings and perform site care every 5-7 days and change gauze every 2 days (SHEA/IDSA A-I); Replace dressings used on short-term CVC sites at least every 7 days for transparent dressings, except in those pediatric patients in which the risk for dislodging the catheter may outweigh the benefit of changing the dressing. (CDC/HICPAC IB) After insertion, use antimicrobial ointments (SHEA/IDSA A-I); Do not use topical antibiotic ointment or creams on insertion sites, except for dialysis catheters, because of their potential to promote fungal infections and antimicrobial resistance. (CDC/HICPAC IB) (Need to resolve inconsistency based on TEP advice.) Weigh the risks and benefits of placing a central venous device at a recommended site to reduce infectious complications against the risk for mechanical complications (e.g., pneumothorax, subclavian artery puncture, subclavian vein laceration, subclavian vein stenosis, hemothorax, thrombosis, air embolism, and catheter misplacement) (CDC/HICPAC IA) Avoid the subclavian site in hemodialysis patients and patients with advanced kidney disease, to avoid subclavian vein stenosis (CDC/HICPAC IA)

Table 2. Included preventive interventions for healthcare-associated infections (continued)

Infection	Prevention intervention
CLABSI (continued)	Use a fistula or graft in patients with chronic renal failure instead of a CVC for permanent access for dialysis (CDC/HICPAC IA) Use ultrasound guidance to place central venous catheters (if this technology is available) to reduce the number of cannulation attempts and mechanical complications. Ultrasound guidance should only be used by those fully trained in its technique. (CDC/HICPAC IB) Use a CVC with the minimum number of ports or lumens essential for the management of the patient. (CDC/HICPAC IB) When adherence to aseptic technique cannot be ensured (i.e. catheters inserted during a medical emergency), replace the catheter as soon as possible, that is, within 48 hours. (CDC/HICPAC IB) Maintain aseptic technique for the insertion and care of intravascular catheters. (CDC/HICPAC IB) Antiseptics should be allowed to dry according to the manufacturer's recommendation prior to placing the catheter. (CDC/HICPAC IB) Use either sterile gauze or sterile, transparent, semipermeable dressing to cover the catheter site. (CDC/HICPAC IA) Replace catheter site dressing if the dressing becomes damp, loosened, or visibly soiled. (CDC/HICPAC IB) Do not submerge the catheter or catheter site in water. Showering should be permitted if precautions can be taken to reduce the likelihood of introducing organisms into the catheter (e.g., if the catheter and connecting device are protected with an impermeable cover during the shower). (CDC/HICPAC IB) Ensure that catheter site care is compatible with the catheter material. (CDC/HICPAC IB) Monitor the catheter sites visually when changing the dressing or by palpation through an intact dressing on a regular basis, depending on the clinical situation of the individual patient. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or bloodstream infection, the dressing should be removed to allow thorough examination of the site. (CDC/HICPAC IB) Do not routinely replace CVCs, PICCs, hemodialysis catheters, or pulmonary artery catheters to prevent catheter-related infections. (CDC/HICPAC IB) Do not use guidewire exchanges routinely for non-tunneled catheters to prevent infection. (CDC/HICPAC IB) Do not use guidewire exchanges to replace a non-tunneled catheter suspected of infection. (CDC/HICPAC IB) Use a guidewire exchange to replace a malfunctioning non-tunneled catheter if no evidence of infection is present. (CDC/HICPAC IB)
VAP	semirecumbent patient positioning (2007 report) daily assessment of readiness for ventilator weaning (2007 report) perform antiseptic oral care (CDC/HICPAC A-I)
CAUTI	reduction in unnecessary catheter use (2007 report) adherence to aseptic catheter insertion and catheter care (2007 report) maintain a closed drainage system and maintain unobstructed urine flow (CDC/HICPAC IB); do not disconnect unless irrigation needed (SHEA/IDSA A-I)

Inclusion of Articles From the 2007 Report

Articles included in the 2007 report were screened by a single reviewer using the inclusion criteria of the current report. Articles with only two-group tests, whether controlled or uncontrolled, were excluded. Those selected for inclusion were reviewed by a second reviewer. Both the first and second reviewers assessed study quality; any discrepancies were resolved through consensus or use of a third reviewer. Selected elements relating to study design, implementation, and results were abstracted from each article.

Data Abstraction and Data Management

Many of the data elements to be abstracted were qualitative, so an extensive training process was conducted to increase consistency among abstractors. A list of the data abstraction elements can be found in Appendix E. Five sample articles from the included articles list were

independently abstracted by each abstractor. A meeting was held to discuss any differences and to agree on common strategies. A second meeting was held several weeks after abstraction began to agree on what to include in fields where there was ambiguity and to add or delete fields as needed. Abstractors then corrected the previously completed abstractions. When new abstractors were added, they abstracted the same five articles and were informed about the common strategies.

Following the training process, reviewers abstracted articles selected for inclusion in the review; a second reviewer conducted a fact check on the abstracted items, using a clean copy of the article. Discrepancies were discussed by the abstractor and the fact checker; any unresolved issues were decided through consultation with a third reviewer. Quality appraisals for each article were conducted independently by two reviewers; discrepancies were resolved by discussion, or by the inclusion of a third reviewer, when necessary.

The authors of the RAND report suggested elements should be considered. These elements were adapted for this review and can be found in the following data elements list.[20]

The following data elements were abstracted from the included articles:

- Study description
  - Study design
  - Health care setting and clinical setting
  - Population size
  - Population demographic and clinical characteristics
  - Statistical analyses performed
- Context, adapted from RAND report[20]
  - Theory or logic model behind the patient safety practice
  - Structural organizational characteristics (such as size, location, financial status, existing quality and safety infrastructure)
  - External factors (such as regulatory requirements or incentive systems)
  - Patient safety culture, teamwork, and leadership at the level of the unit
  - Availability of implementation and management tools (such as staff education and training, use of internal audit and feedback, presence of internal or external individuals responsible for implementation)
  - Description of interveners, intervenees, and their roles in the implementation process
- QI Strategy
  - Type of QI strategy
    - Clinician education
    - Patient education
    - Audit and feedback
    - Clinician reminder systems
    - Organizational change
    - Financial or regulatory incentives for patients or clinicians
    - A combination of the above
  - Preventive intervention
    - See Table 2 in Inclusion and Exclusion Criteria section
  - Length of intervention, length of followup
  - Target of QI strategy (all clinical staff, physicians, nurses, respiratory therapists, other ancillary staff, patients, other)
  - Method of allocation into intervention and control groups

- Outcome measures
  - Baseline and postintervention infection rates
  - Baseline and postintervention adherence to preventive interventions
  - Infection related complications, mortality
  - Costs, cost-effectiveness, return on investment
  - Unanticipated complications

However, for the update search, only data abstraction fields that were involved in the synthesis of the report were abstracted.[a] This was done for efficiency purposes as the addition of the update was larger than expected.

Individual Study Quality Assessment

Challenges in Evaluating Quality Improvement Efforts

Evaluating the impact of QI efforts is challenging. Most clinical QI interventions occur at the group level (e.g., hospital, intensive care unit). Therefore, an individual level randomized controlled trial, the generally preferred research design for other clinical trials, is not recommended.[33] For example, if the intervention aims to increase adherence to recommended strategies to reduce HAI, the clinical staff who adopt the recommended practices may apply them to most patients, not simply to those randomized to the intervention. Cluster randomized trials, which randomize the site or group rather than the individual, are the strongest design for evaluations of QI efforts,[34] if they are designed and implemented well.

Most studies of QI strategies are effectiveness studies, rather than efficacy studies. The interventions are implemented in a "real world" clinical setting, rather than the highly controlled designs typical of efficacy studies. The setting for the QI study may have already implemented other QI strategies. The specific interventions often vary from study to study, and the way in which they are interpreted may differ by setting and, in some cases, by health care provider. Although the definitions of the outcomes—for example, infections—are largely standardized, the actual measurement may vary from one setting to another. Adherence to preventive interventions may provide supportive evidence, but may be measured differently or focus on distinct preventive interventions. These differences do not negate the value of evaluating the impact of QI interventions. Rather, they highlight the need to interpret the results with careful consideration of all these issues. Furthermore, a group of studies with similar results provides stronger evidence than a single study.

There are a number of factors that may confound the results of quasi-experimental studies, examples of which are listed below. More extensive discussions can be found in a series of articles addressing efforts to reduce HAI[35,36] or in the revision[37] of the classic text on quasi-experimental design by Cook and Campbell.[38]

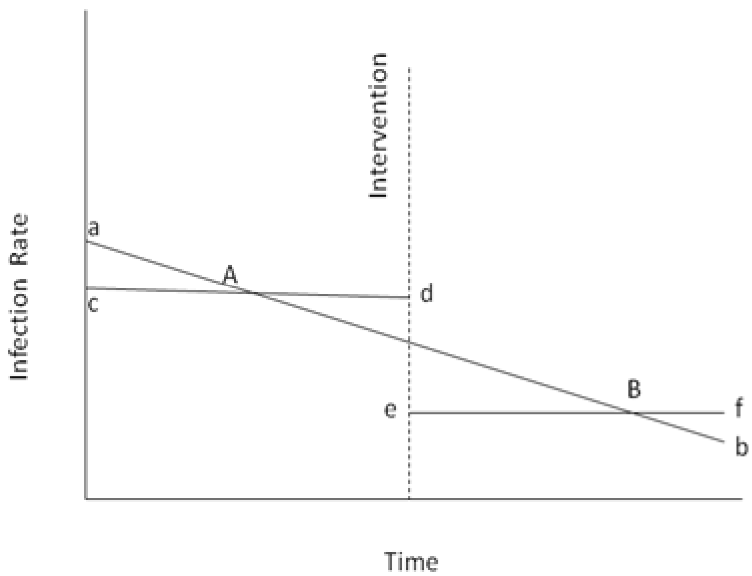
- Unlike most clinical trials, QI studies often do not follow the same patients over time. The patients included in the baseline group may be different from those in the

[a]The following fields were NOT abstracted for the studies that controlled for confounding and/or secular trend: (1) clinical characteristics, (2) number of health care staff, (3) interventionists, (4) intervention expected influence on behavior, (5) financial status, (6) description of incentives, and (7) description of feedback and consequences.
For the studies that did not control for confounding, less was abstracted. Only the following fields were abstracted for this set of articles: (1) study design, (2) infections reported, (3) QI strategies, (4) intervention and comparator used, and (5) cost data, if available

postintervention group a year or two later. Therefore, any differences between the groups of patients that may increase or decrease the risk of infection should be taken into account. In a simple before-after study, this can be done using regression analysis. In a cluster randomized controlled trial, the expectation is that randomization will allocate these factors evenly between groups. But with smaller sample sizes, this may not always occur.

- Infection (or adherence) rates may have been changing before the intervention was undertaken. For example, given the increased attention to HAI in the aftermath of publications of seminal reports by the Institute of Medicine, such as To Err is Human[39] and Closing the Quality Chasm,[40] infection rates may have been falling over time in the institution(s) where the study is conducted. A simple before-after study, even if differences in patient characteristics are accounted for using regression, may mistake the effect of the intervention with the underlying trend in infection rates that preceded the intervention (Figure 2).

Figure 2. Illustration of potential confounding by secular trend



- For example, if the baseline point A is simply compared with postintervention point B, it appears that the intervention has been effective in reducing the infection rate. However, if several data points are measured before the intervention and several after, the secular trend before the intervention can be determined. In the example in Figure 2, if the before and after data points are on line ab, then the intervention does not appear to have had an impact on infection rates. Rather, infection rates were declining before the intervention and continued to fall at the same rate (i.e., slope of the line) afterward. On the other hand, if the data points before the intervention are on line cd, then the infection rate was not declining before the intervention. After the intervention, the whole line falls down to line ef, so infection rates did decline after the intervention, with a onetime drop equivalent to d – e. Many other combinations are possible. The point is that without having multiple data points to discern the trend and position of the line before or after the intervention, one cannot tell whether the rate of infection declined solely as a result of the intervention. A simple before-after study design compares point A with point B and cannot control for any secular trend that may confound the interpretation of the decline. Interrupted time

series, with at least three data points before and three data points after the intervention, permit differentiation between these two scenarios: line ab versus lines cd and ef.

- Another potential factor is regression to the mean. For example, if an intervention is undertaken because infection rates have spiked, a decrease in infections after the intervention may be due to regression to the mean. The baseline outcomes may represent an unusually high infection rate that would have declined to a more typical level even without the intervention.
- The assumption of independence of observations underlying many statistical approaches is violated in most of these study designs. First, outcomes for patients within a given site are unlikely to be independent, because of the common context within a site and the fact that the patients may be cared for by the same providers, among other possible factors. This issue may be addressed by using a site level research design, such as the cluster randomized, controlled trial, or using statistical techniques that account for the interdependence of observations from the same site. Second, when rates from the same site are measured over time, as in interrupted time series, the data points for each site are also related and may be more similar the shorter the time that has elapsed between measurements. This phenomenon is called autocorrelation and may be tested for (e.g., using the Durbin-Watson test) and appropriately addressed once detected or may simply be taken into account in the original choice of statistical approach (e.g., autoregressive integrated moving average [ARIMA] model).
- Another possibility is that some external factor caused infection rates (or adherence rates) to change around the same time as the intervention was implemented. To detect this situation, the changes before and after the intervention need to be compared with changes over the same time period in a comparable setting that did not have the intervention. In other words, adding a contemporaneous control group can be helpful in identifying this situation.

The strongest evidence of causality possible with these types of studies is when both adherence and infection rates are reported. One may then observe a potentially causal link between implementing an intervention using specific QI strategies, an increase in adherence rates to the preventive interventions, and a decline in infection rates. When only adherence is measured, one can infer that the infection rate should decline if the adherence rate rises. This is especially true when there is strong evidence linking the use of the preventive intervention and infection rates, but one cannot rule out the potential effect of intervening factors. Similarly, if infection rates decline after an intervention one might assume that the intervention was effective, but there are other possible factors that cannot be ruled out.

One potentially complicating factor is that measures of adherence may be far more common than infections. What if the adherence rate shows statistically significant improvement, while the change in infection rates is nonsignificant? This result could be due to the weakness of the link between the preventive intervention underlying the adherence rate and the infection rate; to insufficient power to detect a statistically significant change in infections (infections occurring relatively rarely); or to other confounding factors (e.g., a rise in infection rates due to increased prevalence of infectious agents or to other changes in the system of care).

Evaluation of Study Designs

The evidence on the effectiveness of different QI strategies to encourage the use of preventive interventions, which in turn may reduce the rates of HAI, is contained in a set of studies that is heterogeneous in terms of research design, statistical methods, interventions, settings, and outcomes. The approaches used in these studies differ substantially from those used in more traditional clinical trials.

These study design categories form the basis for quality evaluation of individual articles. Several other characteristics are also taken into account, as noted below. Table 3 summarizes some of the key characteristics of these study types. The table is based on discussions by Shadish, Cook, and Campbell,[37] Wagner and colleagues,[41] Harris and colleagues,[35] and Shardell and colleagues ,[36] which provide additional details on these issues.

Evaluation of Study Quality

To assess the quality of the studies included in our review, we initially planned to use the quality assessment criteria developed by the authors of the 2007 AHRQ Evidence Report on HAI.[3] This original plan was altered after an examination of the studies highlighted the heterogeneity of the research designs, statistical methods, and outcomes. In addition to the study design, which was emphasized in the 2007 report, the statistical approaches used to analyze the data are a key determinant of the validity of these studies. Therefore, both study design and adequacy of statistical analysis are now included as quality criteria. Two items from the 2007 report are included as well: whether both adherence rates and infection rates were reported, and whether the intervention was independent of other QI efforts. The following item from the RTI Item Bank[42] for assessing risk of bias and precision for observational studies was also included: Is the length of followup sufficient to support evaluation of primary outcomes and harms? One-year followup was considered necessary to demonstrate durability of results. Some of the validity criteria used in the last report, for example, whether CLABSI, VAP, and CAUTI rates were adjusted for device days, were almost universally present and provided no discriminatory power. Therefore, this criterion was not used to assess quality, but its widespread use is noted. Completeness of reporting, as described in the SQUIRE guidelines,[23] for example, was not assessed independently. To summarize, the criteria to evaluate study quality are as follows:

1. Study design
2. Whether baseline and postintervention adherence rates were reported and analyzed statistically
3. Whether baseline and postintervention infection rates were reported and analyzed statistically
4. Whether the statistical analysis was adequate
    a. Were potential confounders (e.g., baseline patient characteristics) assessed?
    b. If potential confounders existed, were they controlled for in the analysis?
    c. For interrupted time series designs, was an interrupted time series analysis used?
5. Whether the intervention was independent of other QI improvement efforts implemented at the same time
6. Whether the followup period was 1 year or longer

Study design was used for the initial study quality classification so that all controlled trials were assigned higher quality; interrupted time-series analyses were assigned a quality of

medium; and all simple before-after studies were assigned a quality of lower. Then, for each study, criteria 2 through 6 listed above, were assigned a plus, minus, or uncertain. Any study with two or more minuses was moved to the next lower quality ranking.

The terms "higher" and "lower" are used to indicate the relative ranking of quality in this report. All of these studies were conducted in "real world" situations where the many controls against bias available in clinical randomized, controlled trials, for example, are not feasible. Such trials are often precluded for ethical reasons. Furthermore, the focus on the group as the unit of analysis weakens the study design because the sample size is usually much smaller, taking into account the number of groups and the intraclass correlation coefficient. All of the quality assessments and conclusions about evidence were made with this limitation in mind.

Data Synthesis and Grading the Body of Evidence

As in the previous review,[3] the articles in this review differed greatly in QI targets, QI strategies, methods of measuring adherence to preventive interventions, preventive interventions, contexts, and study design. Quantitative analyses are not feasible and the studies are synthesized in a qualitative manner.

The articles included in this review are divided into two categories, those with infection rates or adherence rates that were adjusted for confounding or secular trends and those that adjusted for neither. Because of the extensive challenges to the validity of the latter, they are not included in the detailed description of the body of evidence or assessment of the strength of evidence. They are described briefly under each type of infection in the Results chapter of the full report, included in Appendix C, and enumerated in Appendix F.

Table 3. Characteristics of different study designs

Quality Hierarchy	Study Design	Strengths	Limitations
Higher	Cluster RCT[a]	Most highly recommended research design when interventions occur at the group level.	The number of groups may be limited. The sample size is a function of both the number of groups and the intraclass correlation coefficient (a measure of the degree of homogeneity within groups). Despite randomization, the baseline outcomes may vary substantially between intervention and control groups, especially when the number of groups is relatively small.
	Individual RCT	Potential advantages are large sample sizes (relative to cluster randomized trials) and value of randomization.	Generally not an appropriate design to address the questions considered in this report because the intervention occurs at the group level. Design is limited by unit of analysis problem. Issue may be dealt with using statistical methods, in some cases. The effects of the intervention may contaminate the control group if clinicians alter their practice for all patients in the unit.
	Controlled Interrupted Time Series	Interrupted time series are the most useful quasi-experimental design for the questions addressed in this report. Looking at trends over time can determine whether apparent changes in adherence or infection rates are simply a continuation of a previous trend. Statistical methods are available to deal with autocorrelation, which is often an issue with this design. Adding a control group increases the validity of the study. For example, if the change seen in the intervention group is mirrored in the control group, then the change is not linked to the intervention.	Although some say 3 data points before and 3 data points after the intervention are sufficient, based in part by guidance from Cochrane EPOC, others recommend having outcomes data on far more data points before and after the intervention. Collecting such data may be difficult and costly.
	Controlled Before-After	By adding a control group to a simple before-after study, an attempt is made to control for external factors that many influence both increased adherence and infection rates. If the expected changes are seen in the intervention group and are not seen in the control group, the validity of the study increases. This study design is easier to implement than any of those above it in this table.	This study design does not directly address secular trends in the intervention unit, for example, the experience of the control group may have differed from that of the intervention group before the study started.

[a]Stepped wedge designs are a variant of cluster RCTs in which the interventions are randomly assigned to the groups and then a crossover of interventions occurs at varying time points.

Table 3. Characteristics of different study designs (continued)

Quality Hierarchy	Study Design	Strengths	Limitations
Medium	Interrupted Time Series (at least 3 data points before and 3 after the intervention)	Interrupted time series is the most useful quasi-experimental design for the questions addressed in this report. Looking at trends over time can determine whether apparent changes in adherence or infection rates are simply a continuation of a previous trend. Statistical methods are available to deal with autocorrelation, which is often an issue with this design.	Although some say 3 data points before and 3 data points after the intervention are sufficient, based in part by guidance from Cochrane EPOC, others recommend having outcomes data on far more data points before and after the intervention. Collecting such data may be difficult and costly. Without using a control group, the possibility increases that the change seen in outcomes may be due to factors other than the intervention.
Lower	Before-after with adjustment for individual characteristics	This study design is easier to implement and requires less extensive data collection.	Few inferences about causality can be drawn from studies with this design, because of the inability to differentiate between a continuation of the baseline trend and a change in trend due to the intervention. This design may be strengthened if outcomes at additional data points are collected, while not yet meeting the requirements of an interrupted time series.

Note: The features of the study design depend in part on the type of statistical analysis undertaken. If simpler analyses are used, the quality of the study may be weakened. Individual-level characteristics would confound the analysis only if they predicted the outcome and if they "changed in relationship to the time of the intervention."[41]

The overall strength-of-evidence grade was determined in compliance with AHRQ's Methods Guide for Effectiveness and Comparative Effectiveness Reviews[43] and is based on a system developed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group.[44] This system explicitly addressed the following domains: risk of bias, consistency, directness, and precision. The grade of evidence strength was classified into the following four categories:

- **High.** High confidence that the evidence reflected the true effect. Further research was very unlikely to change our confidence in the estimate of effect.
- **Moderate.** Moderate confidence that the evidence reflected the true effect. Further research may have changed our confidence in the estimate of effect and may have changed the estimate.
- **Low.** Low confidence that the evidence reflected the true effect. Further research was likely to change our confidence in the estimate of effect and was likely to change the estimate.
- **Insufficient.** Evidence was either unavailable or did not permit estimation of an effect.

Additional domains including strength of association, publication bias, coherence, dose response relationship, and residual confounding were addressed if appropriate. Specific outcomes and comparisons were rated depending on the evidence found in the literature review. The grade rating was made by independent reviewers, and disagreements were resolved by consensus adjudication.

Originally, we planned to use the modification of the GRADE approach for patient safety practices proposed in the RAND report,[20] but then decided to use the qualitative approach outlined above, given the heterogeneity of the included studies.

Peer Review, Public Commentary, and Technical Expert Panel

A Technical Expert Panel (TEP) was formed to provide consultation on the development of the protocol and evidence tables for the review. Ad hoc clinical questions were also addressed to the TEP. The TEP consisted of experts in healthcare–associated infectious diseases, epidemiology, hospital medicine, surgery, critical care, and perioperative nursing.

Experts in hospital–acquired infections and QI implementation fields and individuals representing stakeholder and user communities were invited to provide external peer review of this CER; AHRQ and an associate editor also provided comments. The draft report was posted on the AHRQ website for 4 weeks to elicit public comment. We addressed all reviewer comments, revising the text as appropriate, and documented everything in a disposition of comments report that will be made available 3 months after the Agency posts the final CER on the AHRQ website.

Results

The literature review yielded 8,362 abstracts. One-hundred and thirty-six articles from the literature search met all selection criteria for inclusion in this review. An additional four articles were identified from a review of article reference lists. Articles from the 2007 report were screened: nine met selection criteria and controlled for confounding or secular trend. See the Preferred Reporting Items of Systematic reviews and Meta-Analyses (PRISMA) diagram in Figure 3 for additional details.

The 149 articles (generating 173 analyses at the infection level) were divided into two groups. The first group consisted of 61 articles, most of which were quasi-experimental studies that controlled for confounding or secular trend. Eight of these articles reported on two types of infection and one article reported on three infections; each infection reported is treated as a separate study from this point forward. These 71 analyses—26 on CLABSI, 19 on VAP, 15 on SSI, and 11 on CAUTI—form the basis of this report. The words ‘analysis’ and ‘study’ are used interchangeably and refer to the infection-level results.

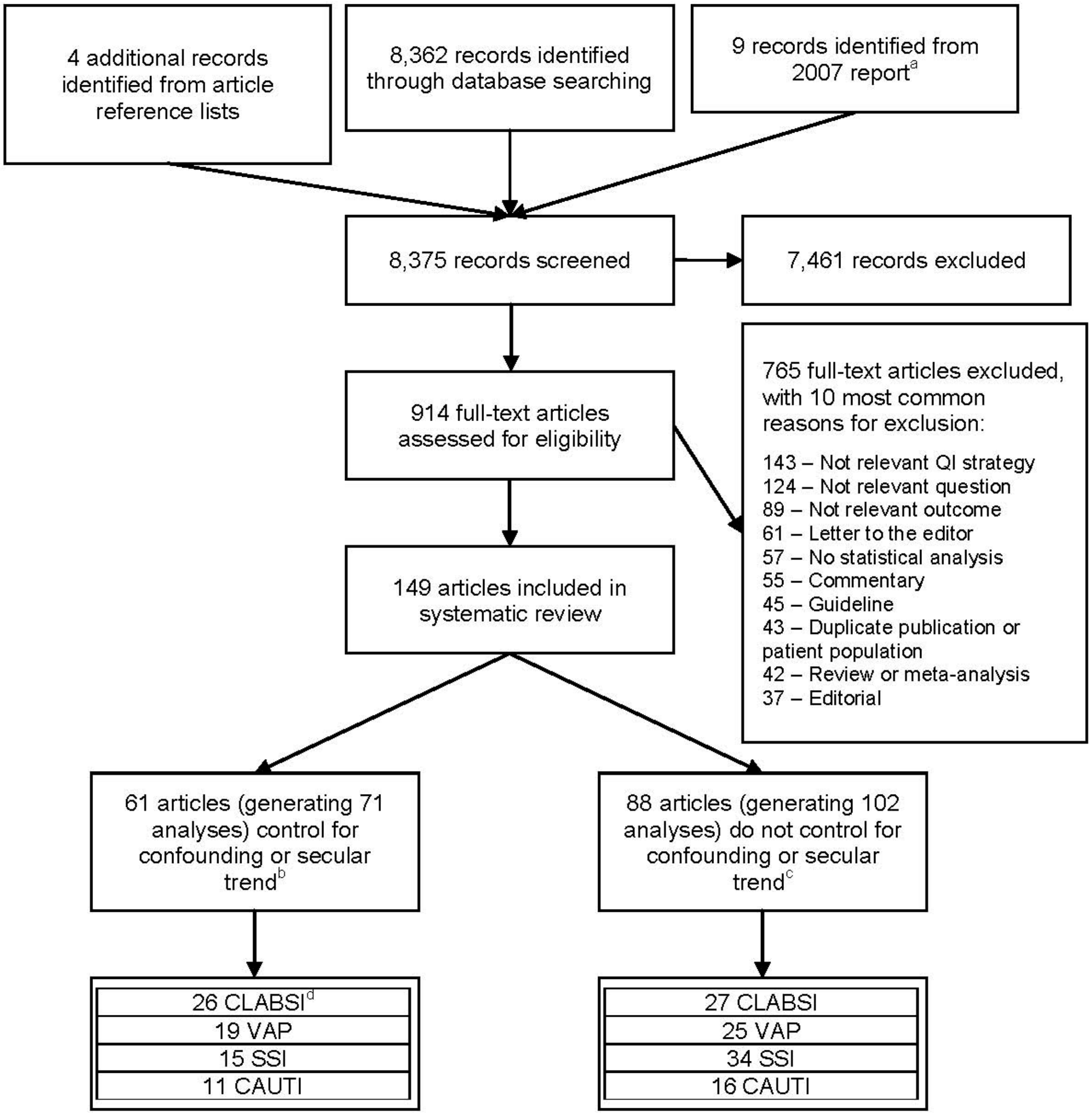
The other 88 articles (generating 102 analyses) did not account for the many potential sources of confounding and for secular trend. Therefore, as discussed in the Methods chapter, their results are at high risk of bias. These were simple before-after studies or controlled before-after studies (2 of 88) with two group tests, for example, t-tests and chi-square tests. The two controlled before-after studies were demoted due to lack of between group comparisons. Of these 88 articles, five reported on two types of infection and three articles reported on three infections, and one article reported on four infections; each infection is treated as a separate study from this point forward. The characteristics of this second group of 102 studies are summarized in tables for each infection in Appendix F, but they were excluded from the analysis in this report. Despite concerted efforts to identify studies from nursing homes, dialysis centers, and outpatient surgical centers, only one study, which did not control for confounding or secular trend, met inclusion criteria and took place in a nonhospital setting (See Appendix A for search strategy details).

The distribution of the 71 studies (61 articles) analyzed in this report across other dimensions is also presented in Table 4 with the exception of the study quality category, which includes all 173 studies (149 articles). These articles are also cited and discussed in further detail in their respective infection sections below.

Adherence rates measured adherence with evidence-based preventive interventions identified by Healthcare Infection Control Practices Advisory Committee (HICPAC), Infectious Diseases Society of America (IDSA), Society for Healthcare Epidemiology of America (SHEA), or members of the Technical Expert Panel. These interventions were supported by studies that linked their increased use to lower infection rates. Therefore, they are considered direct outcomes in the strength of evidence tables. Lowering infection rates is the primary objective of the patient safety initiatives, but many factors may affect these rates besides the interventions themselves, especially in an environment of heightened attention to the risks posed by HAI. Therefore, the strongest evidence of the effect of a QI intervention is to see changes in adherence to the targeted preventive interventions and a change in the infection rate. Because infections are, fortunately, relatively rare, in some cases changes in adherence rates may not be associated with a change in infection rates because of a lack of power to detect a significant change in the latter, rather than due to a lack of impact on infection rates. The majority of studies relied on CDC NHSN/NNIS criteria for identifying infections. These are generally accepted in the United States as the standard definition, although they have some limitations, including possible differences in how they are applied from one setting to another. However, this report focuses on changes in

infection rates over time, so as long as the method of identifying infections is stable over time, the results should be fairly reliable.

Figure 3. Search results and article triage



[a]Ranji SR, Shetty K, Posley KA, Lewis R, Sundaram V, Galvin CM, Winston LG. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies (Vol. 6: Prevention of Healthcare-Associated Infections). AHRQ Publication No. 04(07)-0051-6. Rockville, MD: Agency for Healthcare Research and Quality; 2007. www.ncbi.nlm.nih.gov/pubmed/20734530.
[b]Eight of these studies reported on two infections and one, on three infections.
[c]Five of these articles reported on two infections; three, on three infections; and one, on four infections.
[d]One of these articles has an updated publication one year later. In the PRISMA diagram these studies were cited as a single study

Table 4. Number of studies in each category by infection type and overall

Study Characteristic	Category	CLABSI	VAP	SSI	CAUTI	All
Design	Cluster RCT	2	2	1	0	***5***
	Individual RCT	0	0	1	1	***2***
	Stepped wedge	1	1	1	1	***4***
	Controlled studies	4	2	1	1	***8***
	Interrupted time series	3	5	1	2	***11***
	Simple before-after	16	9	10	6	***41***
	TOTAL	***26***	***19***	***15***	***11***	***71***
Number of QI Strategies	5 QI strategies	2	0	0	0	***2***
	4 QI strategies	8	7	2	2	***19***
	3 QI strategies	7	5	5	2	***19***
	2 QI strategies	5	7	4	4	***20***
	1 QI strategies	4	0	4	3	***11***
Outcomes Reported	Adherence only	1	1	2	3	***7***
	Infection rates only	16	9	5	2	***32***
	Both adherence and infection rates	9	9[a]	8	6[a]	***32***
Sample Size (Range Across Studies When Reported)[b]	Patients postintervention	50 to 4,671	81 to 4,761	115 to 10,617	93 to 1,794	***NA***
	Postintervention infection rate	0 to 7.7 per 1,000 catheter days	0.7 to 22.5 per 1,000 ventilator-days	0% to 7.7%	1.8 to 12.9 per 1,000 catheter days	***NA***
	Baseline infection rate	1.84 to 17 per 1,000 catheter days	1.9 to 39.7 infections per 1,000 ventilator-days	1.1% to 15%	1.7 to 21.5 per 1,000 catheter days	***NA***
Length of Followup (Months)	Mean	20	22	14.4	23	***20***
	Median	23	17	12	17	***18***
	Range	3.5 to 46[c]	4 to 54	1 to 30[d]	3 to 61	***1 to 61***
Location	United States	18	9	11	2	***40***
	Other	8	10	4	9	***31***
Multisite or Single Site	Multisite	12	4	7	3	***26***
	Single site	14	15	8	8	***45***
Study Quality	Higher	1	3	2	1	***7***
	Medium	9	4	3	3	***19***
	Lower	16	12	10	7	***45***
	Did not control for confounding or secular trend	27	25	34	16	***102***

Abbreviations: CAUTI = catheter-associated urinary tract infection; CLABSI = central line–associated bloodstream infection; NA = not applicable; QI = quality improvement; RCT = randomized controlled trial; VAP = ventilator-associated pneumonia; SSI = surgical site infection.

[a]One study compared two sets of QI strategies, and another compared early and later infection rates.

[b]Patients may be defined differently across studies within a given infection category—for example, patients on ventilator or patients on ventilator for at least 48 hours.

[c]Four studies did not report length of followup.

[d]One study did not report length of followup.

Analyzing the impact of QI strategies, the objective of this report, is complicated by the fact that more than one QI strategy was used in most studies (60 of 71). Disentangling the effect of a single QI strategy is not possible with the available body of evidence. With 71 studies, 16 different combinations of QI strategies were used. The following approaches were considered for evaluating the effectiveness of the QI strategies, but all had limitations and were rejected.

- Considering each QI strategy individually within each study. The effect of a strategy cannot be disentangled from the impact of other strategies.
- Using the number of QI strategies. This option was not viable as the types of strategies included may have confounded the effect.
- Identifying the incremental impact of a single QI strategy. This approach could be measured only by comparing two combinations of QI strategies in the same clinical context, in which one combination contained the QI strategy of interest and the other did not. None of the studies identified for this report had such a design.

Therefore, in this report, QI strategies are grouped together based on the combinations of strategies used in our included studies (Table 5). This approach mirrors common practice, which relies on combinations of QI strategies, and can therefore potentially yield practical insights.

To develop a workable classification of QI strategy combinations for the purposes of this report, we hypothesized that organizational change and provider education constitute base strategies. Face validity is the initial rationale for the hypothesis as 90 percent of the included studies used at least one of these two strategies. While this hypothesis is open to debate, the use of these strategies was ubiquitous, so in practical terms, little distinction could be made between those studies that used these two strategies and those that did not. In addition, it is difficult to imagine how any preventive intervention or QI effort could be implemented without at least some level of organizational change and/or provider education. Further, it is plausible that those studies that did not report using organizational change or provider education may simply have taken these elements for granted. Analyzing the effectiveness of specific components of organizational change would be useful, but the heterogeneity of organizational change across studies and variations in thoroughness of reporting preclude such an analysis based on current evidence. Scant information is available in this literature comparing different educational strategies.

So, for simplicity, from here we refer to organizational change, provider education, or both as base strategies. This concept allowed us to organize our data into categories of strategies used in combination with the base strategies. These additional strategies are: (1) audit and feedback plus provider reminder systems; (2) audit and feedback only; (3) provider reminder systems only. Only two[45,46] studies reported the use of financial incentives, regulation, or policy, and two[47,48] reported on patient education, so these QI strategies were not treated separately despite their potential importance. The main variation across QI strategy combinations, therefore, is in the use of audit and feedback and/or provider reminder systems. For each infection, the QI strategy combinations were grouped into two or three categories in developing the strength-of-evidence tables. The composition of these groups varies to some degree from infection to infection, based on which combinations were reported in the included studies.

Table 5. QI strategy combinations across infections

Combination of QI Strategies	Organizational Change	Provider Education	Audit and Feedback	Provider Reminder Systems	Patient Education	Financial Incentives	CLABSI[a]	VAP[a]	SSI[a]	CAUTI[a]	All[a]
Variants of Base Strategies (Organizational Change and Provider Education)	•	•					3[b]	3[b]	1	0	***7***
	•						0	0	2[b]	0	***2***
		•					3	1	0	0	***4***
Variants of Base Strategies With Audit and Feedback	•	•	•		([c])		4	4[c]	3[d]	1	***12***
	•		•				0	1	1	0	***2***
		•	•				0	0	1	1	***2***
			•		•		1	1	0	1	***3***
Variants of Base Strategies With Provider Reminder System	•	•		•			2	1	2	1	***6***
	•			•			0	0	1	2	***3***
				•			1	0	2	3	***6***
Variants of Base Strategies With Audit and Feedback and Provider Reminder System	•	•	•	•		([c])	10[b,e]	6[b]	2	2[b]	***20***
	•		•	•			1	1	0	0	***2***
		•	•	•			1	1	0	0	***2***

Abbreviations: CAUTI = catheter-associated urinary tract infection; CLABSI = central line–associated bloodstream infection; HAI = healthcare-associated infection; QI = quality improvement; VAP = ventilator-associated pneumonia; SSI = surgical site infection.

[a]These columns indicate the number of studies for each HAI or for all HAI that use the variant of QI strategies indicated in each row.

[b]Comparator for one article is low-intensity intervention.

[c]These two strategies did not define the combinations; therefore, a dot is not included in the definition of the combinations.

[d]One study also includes patient education.

[e]Two studies also include financial incentives.

The quality of the studies and the strength of evidence for the QI strategy combinations should be viewed in the context of the clinical issue being addressed. Because these studies measure effectiveness, not efficacy, and are implemented in actual health care settings, many factors cannot be controlled for as they would be in a traditional, individual–level randomized, controlled trial. Some health care facilities would not participate in these studies if they could not undertake a QI intervention while the study was underway. This position was the reason that a number of the comparative studies launched multiple interventions simultaneously, even though the presence of any active QI activity in a control group may increase adherence rates even for other types of infections. Because of the challenges inherent in studying this field, the highest rating for strength of evidence was limited to moderate, reflected in the available study designs.

Due to the heterogeneity of studies and the qualitative nature of the evidence synthesis, magnitude of effect was not considered quantitatively in evaluating the strength of evidence. We did not attempt to compare the magnitude across studies, taking into account confidence intervals, because of the differences in baseline rates, statistical analysis, et cetera. However, magnitude is sometimes considered qualitatively in judging whether the changes overall appear large enough to have clinical benefit. Furthermore, some studies appeared to manifest a "ceiling" or "floor" effect. For example, some sites began the studies with low infection rates and brought them down to zero for months at a time. The change might not be statistically significant, yet there was not room for further improvement. In other cases, there were large differences in the baseline adherence rates. These issues were considered qualitatively in assigning strength of evidence.

Within each study, the intervention period was compared with a period of no intervention (usual care), which refers to the absence of additional QI efforts other than the standard of care already in place. Thirteen studies implemented QI strategies in a stepwise fashion and did not report rates before any intervention was implemented.[45,49-60]The comparator for these studies was defined as a low-intensity intervention. Also, a separate strength-of-evidence evaluation was conducted for studies reporting both adherence and infection rates, because studies that report both outcomes have more reliable results than those that do not. This evaluation reported results for each QI combination across all four types of infections.

The strength-of-evidence conclusion relies both on the underlying effect of different QI combinations on outcomes and on the availability of studies to assess the relationship. A low strength of evidence, therefore, means that the current body of evidence does not support a stronger conclusion. Whether or not the strength of evidence will change as additional evidence accumulates cannot be determined at this time.

In the study summaries that follow, standard deviations, 95% confidence intervals, and p values are included when they are reported in the article.

Key Questions 1 and 1a. Which QI strategies are effective in improving HAI and adherence to evidence-based preventive interventions?

Central Line-Associated Bloodstream Infection (CLABSI)

Overview

The literature search identified 26 studies,[45,46,48,53,58-75] and there were four from the 2007 report,[49,76-78] that addressed the prevention of central line-associated bloodstream infections (CLABSI) and controlled for confounding factors or secular trend (Table 6).

There was 2 cluster randomized, controlled trials,[58,60] 1 nonrandomized stepped-wedge study,[53] 3 controlled before-after studies,[61-63] 1 controlled interrupted time series,[49] 3 interrupted time series,[45,64,65] and 16 simple before-after studies.[46,48,59,66-78] One study implemented five quality improvement (QI) strategies,[45] 10 studies implemented four QI strategies,[46,49,65,66,71,72,74,75,77,78] 6 studies implemented three QI strategies,[58,59,64,67,70,76,] 5 studies implemented two QI strategies,[48,53,60,68,73] and 4 studies implemented one QI strategy.[61-63,69] Twenty two of 26 studies implemented provider education.[45,46,49,58-68,70-74,76-78] Organizational change was implemented in 20 studies.[45,46,49,53,59,60,64-68,70-78] Table 7 shows the specific attributes

of organizational change that were implemented for each study. Fifteen studies implemented a provider reminder system.[45,46,49,58,59,65,66,69-72,74,75,77,78] Audit and feedback was implemented in 17 studies.[45,46,48,49,53,58,64-67,71,72,74-78] Two studies[45,46] were subject to financial incentives, regulation, and policy and another study implemented patient education.[48]

One study[58] analyzed adherence rates only, 16 studies[46,49,53,60-63,66,67,71-74,76-78] analyzed infection rates only, and 9 studies analyzed both adherence and infection rates.[45,48,59,64,65,68-70,75]

Eight studies[46,58-60,65,67,71,75] were conducted in multiple sites while the other 18[45,48,49,53,61-64,66,68-70,72-74,76-78] took place in a single tertiary and/or university affiliated hospital. Number of ICUs involved in each study ranged from one to 103. Three studies were statewide initiatives.[46,65,67] Eighteen studies[45,46,49,53,59-61,63,65-67,70-74,76,77] were conducted in the United States, 3[62,68,69] in Europe, 1[58] in Canada, 1[78] in Korea, 1[64] in Thailand, 1 in Colombia,[48] and 1[75] in Australia.

The sample size for the postintervention period ranged from 50 patients to 4,671 patients, with many studies not reporting sample size. Infection rates during the postintervention period ranged from 0 to 7.7 infections per 1,000 catheter-days. Baseline infection rates ranged from 1.84 to 17 infections per 1,000 catheter-days.

The search also identified 27 studies that addressed prevention of CLABSI, but did not control for confounding or secular trend (Appendix Table F2).[54,79-104] These studies are not included in the analysis due to their weak designs and potential for biased results.

Methodological Quality of Included Studies

As displayed in Table 8, 1 study[60] was rated of higher quality, 9 studies[45,49,53,58,61-65] were rated medium quality, and 16[46,48,59,66-78] lower quality. Seventeen studies had data for longer than 1 year after the intervention.[45,46,48,49,60,63-67,71-77] Twenty studies were considered to have adequate control for confounding or secular trend.[45,46,48,53,58-60,63-74,78] Six studies[45,48,53,64,68,69] analyzed both adherence rates and infection rates. Only 2 studies[46,62] explicitly report being independent of other QI efforts; this dimension was not applicable for the randomized, controlled trials.[58,60]

Table 6. Overview of CLABSI articles that control for confounding or secular trend

Author, location-year	Study type	Analysis for infection rates	Sample size (infections)	Organizational change	Provider education	Audit and feedback	Provider reminder systems	Patient education	Financial incentives
Scales, Canada - 2011[58]	Cluster RCT	Generalized linear mixed model			•	•	•		
Speroff, United States - 2011[60]	Cluster RCT	Hierarchical negative binomial regression		•	•				
Lilly, United States - 2011[53]	Nonrandomized stepped wedge	Logistic regression	pre: 1529 (19) post: 4761 (29)	•		•			
Berenholtz, United States - 2004[49]	Controlled interrupted time series	Poisson regression		•	•	•	•		
Khouli, United States - 2011[61]	Controlled before-after	Generalized linear model with Poisson distribution	control pre: (12) control post: (8) study pre: (20) study post: (5)		•				
Perez Parra, Spain - 2010[62]	Controlled before-after	Poisson regression	control pre: (118) control post: (91) study pre: (45) study post: (34)		•				
Barsuk, United States - 2009[63]	Controlled before-after	Poisson regression	control pre: (22) control post: (17) study pre: (25) study post: (4)		•				
Apisarnthanarak, Thailand - 2010[64]	Interrupted time series	Segmented regression	pre: 1115 (88) post: 1204 (7)	•	•	•			
Costello, United States - 2008[45]	Interrupted time series	Segmented regression	pre: 911 (26) post: 936 (11)	•	•	•	•		•
Miller, United States - 2010[65]/[105]	Interrupted time series	Generalized linear model		•	•	•	•		
McKee, United States - 2008[66]	Simple before-after	Statistical process control chart		•	•	•	•		
Frankel, United States - 2005[76]	Simple before-after	Statistical process control chart		•	•	•			
Wall, United States - 2005[77]	Simple before-after	Statistical process control chart		•	•	•	•		
DePalo, United States - 2010[67]	Simple before-after	Mixed model with Poisson distribution		•	•	•			
Pronovost, United States - 2010[46]	Simple before-after	Generalized linear latent and mixed model with Poisson distribution		•	•	•	•		•

Table 6. Overview of CLABSI articles that control for confounding or secular trend (continued)

Author, location-year	Study type	Analysis for infection rates	Sample size (infections)	Organizational change	Provider education	Audit and feedback	Provider reminder systems	Patient education	Financial incentives
Render, United States - 2011[71]	Simple before-after	Poisson GEE regression	2006: (681) 2007: (683) 2008: (543) 2009: (404)	•	•	•	•		
Zingg, Switzerland - 2009[68]	Simple before-after	Cox proportional hazards model	pre: 499 (24) post: 500 (7)	•	•				
Barrera, Colombia - 2011[48]	Simple before-after	Poisson regression	total: 14,516 (total # HAI: 2,398)			•		•	
Kim, United States - 2011[72]	Simple before-after	Poisson regression	pre: (275) post: (50)	•	•	•	•		
Harris, United States - 2011[74]	Simple before-after	Logistic regression	pre: 817 (31) intervention: 601 (19) post: 961 (15)	•	•	•	•		
Seguin, France - 2010[69]	Simple before-after	Poisson regression	pre: 676 (12) post: 595 (2)				•		
Duane, United States - 2009[70]	Simple before-after	Poisson regression	pre: 135 (19) post: 213 (13)	•	•		•		
Yoo, Korea - 2001[78]	Simple before-after	Logistic regression	pre: 100 post: 148	•	•	•	•		
Taylor, United States - 2011[73]	Simple before-after	Cox regression	pre: 100 (23) post: 100 (24)	•	•				
Schulman, United States - 2011[59]	Simple before-after	Stepwise Poisson regression		•	•		•		
Burrell, Australia - 2011[75]	Simple before-after	Logistic regression		•		•	•		

Table 7. Specific attributes of organizational change implemented in CLABSI articles that control for confounding or secular trend

Author, Country-Publication Year	Multidisciplinary Team	Team Responsibilities	Hospital Executives on Team	New Protocol or Standards Implemented	Designate Staff Member Responsible for Implementation
Speroff, United States - 2011[60]				•	
Lilly, United States - 2011[53]				•	
Apisarnthanarak, Thailand - 2010[64]	•	Conduct education program, track patients with CVC, monitor adherence with new protocol		•	
Costello, United States - 2008[45]	•	Track nosocomial infections prospectively, to increase awareness of nosocomial infections, to provide education for staff members, and to implement practices changes when indicated	•	•	•
Miller, United States - 2010[65]/[105]	•	Test and implement QI changes to their care practices commensurate with the National Association of Children's Hospitals and Related Institutions (NACHRI) collaborative's recommended CVC guidelines	•	•	•
McKee, United States - 2008[66]	•	Lead team rounds on all PICU patients daily to review patient information and develop a daily care plan	•	•	•
DePalo, United States - 2010[67]	•	Educate staff on evidence-based practices and help implement CLABSI and VAP bundle		•	
Pronovost, United States - 2010[46]	•	Ensure accurate reporting of CLABSI within the ICU and implementation of conceptual model stressing CDC guidelines for reduction in BSI. Education of physicians and creation on central line cart.	•	•	•
Render, United States - 2011[71]				•	
Zingg, Switzerland - 2009[68]				•	•
Kim, United States - 2011[72]				•	
Harris, United States - 2011[74]	•	Led the development of the interventions through the Six Sigma method			
Duane, United States - 2009[70]				•	•
Taylor, United States - 2011[73]	•	The team placed and managed all central lines in the hospital.		•	•
Schulman, United States - 2011[59]	•	To identify bundle elements that were pertinent for the NICU to prevent CLABSI and to implement these items.	•	•	•

Table 8. Methodological quality for CLABSI articles that control for confounding or secular trend

Author, Location-Year	Study Type	Sufficient followup[a]	Adequate control for confounding or secular trend[b]	Change in adherence was analyzed[c]	Change in infection rate was analyzed[d]	Independent of other QI effort[e]	Overall quality rating	Comments
Scales, Canada - 2011[58]	Cluster RCT	-	+	+	-	N/A	***Medium***	Infection rates were not reported.
Speroff, United States - 2011[60]	Cluster RCT	+	+	-	+	N/A	***Higher***	Adherence rates were calculated by followup survey, no baseline data.
Lilly, United States - 2011[53]	Nonrandomized Stepped wedge	-	+	+	+	?	***Medium***	Only 3 of the 7 ICUs had followup one or more yrs
Berenholtz, United States - 2004[49]	Controlled interrupted time series	+	-	-	+	?	***Medium***	The control group received education. Did not compare patient characteristics between the intervention and control ICU or the baseline and postintervention periods.
Khouli, United States - 2011[61]	Controlled before-after	-	-	-	+	?	***Medium***	Adherence rates were not reported.
Perez Parra, Spain - 2010[62]	Controlled before-after	-	-	-	+	+	***Medium***	Adherence rates were not reported.
Barsuk, United States - 2009[63]	Controlled before-after	+	+	-	+	-	***Medium***	Adherence rates were not reported.
Apisarnthanarak, Thailand - 2010[64]	Interrupted time series	+	+	+	+	-	***Medium***	
Costello, United States - 2008[45]	Interrupted time series	+	+	+	+	?	***Medium***	
Miller, United States - 2010[65]/[105]	Interrupted time series	+	+	-	+	?	***Medium***	Adherence rates were reported, but no pre/post statistical comparisons were made.
McKee, United States - 2008[66]	Simple before-after	+	+	-	+	?	***Lower***	Adherence rates were reported, but no pre/post statistical comparisons were made.
Frankel, United States - 2005[76]	Simple before-after	+	-	-	+	?	***Lower***	Used antibiotic-coated catheters in a subset of high risk patients roughly 1 year after starting the Six Sigma program. Did not compare patient characteristics between the baseline and postintervention periods.
Wall, United States - 2005[77]	Simple before-after	+	-	-	+	?	***Lower***	Did not compare patient characteristics between the baseline and postintervention periods.
DePalo, United States - 2010[67]	Simple before-after	+	+	-	+	-	***Lower***	Adherence rates were not reported.
Pronovost, United States - 2010[46]	Simple before-after	+	+	-	+	+	***Lower***	Adherence rates were not reported.
Render, United States - 2011[71]	Simple before-after	+	+	-	+	?	***Lower***	Adherence rates were reported, but no pre/post statistical comparisons were made, but there was an observed inverse correlation between CLABSI rate and overall bundle compliance.
Zingg, Switzerland - 2009[68]	Simple before-after	-	+	+	+	?	***Lower***	
Barrera, Colombia – 2011[48]	Simple before-after	+	+	+	+	?	***Lower***	simple before-after study that controlled for potential confounders

Table 8. Methodological quality for CLABSI articles that control for confounding or secular trend (continued)

Author, Location-Year	Study Type	Sufficient followup[a]	Adequate control for confounding or secular trend[b]	Change in adherence was analyzed[c]	Change in infection rate was analyzed[d]	Independent of other QI effort[e]	Overall quality rating	Comments
Kim, United States - 2011[72]	Simple before-after	+	+	-	+	?	***Lower***	
Harris, United States - 2011[74]	Simple before-after	+	+	-	+	?	***Lower***	
Seguin, France - 2010[69]	Simple before-after	-	+	+	+	?	***Lower***	
Duane, United States - 2009[70]	Simple before-after	?	+	-	+	-	***Lower***	Adherence rates were reported, but no pre/post statistical comparisons were made.
Yoo, Korea - 2001[78]	Simple before-after	-	+	-	+	?	***Lower***	Followup was only 3.5 months.
Taylor, United States - 2011[73]	Simple before-after	+	+	-	+	?	***Lower***	No adherence rates reported. Infection risk was reported rather than infection rates.
Schulman, United States - 2011[59]	Simple before-after	-	+	-	+	?	***Lower***	Adherence rates were reported, but no pre/post statistical comparisons were made.
Burrell, Australia – 2011[75]	Simple before-after	+	-	-	-	?	***Lower***	Study uses a 'lead in period', 1 year from start of intervention, in place of baseline data. This data is compared to last 6 months of followup. Analysis did -t control for patient factors across the 37 ICUs.

Note: All studies used standard and consistent infection definitions. CDC methodology was used in all studies except Seguin et al. (2010).[68]
Infection rates were adjusted for device utilization in all studies.
Independence from other QI efforts was not applicable for randomized controlled trials
[a]Is the length of followup sufficient (at least 12 months) to support the evaluation of primary outcomes and harms?
[b]Were adequate measures taken to control for confounding or secular trend?
[c]Was change in adherence analyzed?
[d]Was change in infection rate analyzed?
[e]Was the intervention performed independent of other QI efforts or other changes?
'+' means 'yes'
'-' means 'no'
'?' means 'uncertain'

Descriptions of Studies That Control for Confounding and Secular Trend

Controlled Studies

Scales et al. (2011)[58]

Summary

In a cluster randomized controlled trial, Scales et al. used audit and feedback, provider education, and provider reminder systems to change adherence to six preventive interventions.[58] Control ICUs implemented a preventive intervention for a different condition. The study was conducted in 15 community hospital ICUs in Canada, and the duration of the each intervention period was 4 months. This cluster randomized, controlled trial found a significant improvement in adherence to a central line insertion bundle. This study did not report infection rates.

Description

The objective of this study was to increase delivery of six practices to improve ICU outcomes for five clinical conditions, including preventive interventions to reduce CLABSI. The five conditions were CLABSI, VAP, deep venous thrombosis, early enteral feeding, and decubitus ulcers. The ICUs were randomized into two groups. Each group was assigned an active intervention targeting a new preventive intervention every 4 months, while serving as control for another, unrelated practice. Thus, one group of ICUs received the intervention to improve adherence to a central line insertion bundle, while another ICU was receiving the intervention for spontaneous breathing trials. The ICU receiving the active intervention for spontaneous breathing trials served as the control unit for central line insertion bundle. After the 12-month study period, control ICUs received the interventions they served as controls for in 3-month blocks. This period was called the decay monitoring period.

Adherence was analyzed as the odds ratio (OR) for improvement in adoption of the preventive intervention by comparing rates in the first month to the fourth month; the two groups were then compared using the summary ratio of ORs.

Results and Limitations

Considering all six preventive interventions, patients in ICUs receiving the active intervention were more likely to receive the preventive interventions than those in the control ICUs; summary ratio of odds ratios 2.79 (95% CI: 1.00 to 7.74; p=0.05; Table 9). Adherence to the central line insertion bundle was the only preventive intervention that had a significant improvement. In the intervention ICUs, adherence significantly improved from 10 percent in the first month of the study period to 70.6 percent in the last month of the study period (OR: 30.1; 95% CI: 11.0 to 82.2; p<0.001). The control ICUs had a nonsignificant change in rates of adherence from the first to last month of the study period with adherence rates of 31.0 percent and 51.7 percent, respectively (OR: 1.71; 95% CI: 0.74 to 3.99; p=0.21). When comparing intervention ICUs with control ICUs, the intervention ICUs had a significant improvement in adherence to the central line insertion bundle (summary OR: 17.55; 95% CI: 4.72 to 65.26; p<0.001).

During the decay monitoring period, the control ICUs did not see a significant improvement in adherence with the insertion bundle. The first month of the decay monitoring period had an

adherence rate of 54.3 percent and the last month had 69.2 percent (OR: 2.05; 95% CI: 0.69 to 6.07; p=0.19).

Even though there were over 4,000 admissions in each group of ICUs, there were only 64 catheter insertions analyzed in the intervention group and 61 in the control group. The authors did find a significant result, but there is large variability in the estimate, most likely due to the small number of insertions analyzed.

Speroff et al. (2011)[60]

Summary

Speroff et al. conducted a cluster randomized controlled trial comparing the use of a virtual collaborative to a toolkit approach.[60] The QI strategies involved were organizational change and provider education. This study was conducted in 60 hospitals across the United States. After 18 months, there was no significant difference in infection rates between the two groups or over time within either group. There were some tools that were used significantly more in the virtual collaborative group compared with the toolkit group.

Description

The objective of this study was to prevent CLABSI and VAP in the ICU by improving adherence to evidence-based practices. The authors compared the use of a virtual collaborative approach to a toolkit approach. The toolkit approach entailed access to evidence-based guidelines and fact sheets for preventing CLABSI and VAP, a review of QI and teamwork methods, standardized data collection tools, standardized charting tools, access to a website that contained educational seminars, clinical tools, and QI tools. In addition, the ICU was allowed to implement other changes to prevent CLABSI and VAP. The collaborative group was given everything the toolkit group was given plus the use of web seminars, teleconferences, individual coaching, monthly educational and troubleshooting conference calls, and an email list-serve to encourage communication among teams.

Data were reported in 3-month intervals and analyzed using hierarchical negative binomial regression models in order to account for change over time, clustering of ICUs within hospitals, and baseline characteristics.

Results and Limitations

During the baseline period, median CLABSI rates were 1.84 (IQR: 0 to 3.83) and 2.42 (IQR: 0.65 to 6.8) infections per 1,000 catheter-days in the virtual collaborative group and the toolkit group, respectively. After 18 months, the rate in the virtual collaborative group increased to 2.76 (IQR: 0 to 4.67) while the rate in the toolkit group decreased to 1.16 (IQR: 0 to 5.46) infections per 1,000 catheter-days. The regression model found that neither the virtual collaborative group nor the toolkit group improved CLABSI rates (p=0.75 and p=0.83, respectively) and there was no difference between the two groups (p=0.71). However, the virtual collaborative group did use data tools significantly more (p=0.004) and implemented the VAP checklist more than the toolkit group (p=0.007).

The floor effect may have limited the possible improvement among the ICUs in this study. The authors list some contextual factors that may have led to the lack of improvement in the study: slow uptake of data driven quality improvement, lack of infrastructure to implement data driven improvement, and differential uptake of general knowledge and implementation

knowledge. Also, giving the toolkit group the ability to implement additional changes at their discretion introduced some bias into the comparison being made.

Lilly et al. (2011)[53]

Summary

Lilly et al. conducted a nonrandomized stepped wedge design study in seven ICUs within an academic medical center in the United States.[53] Organizational change, provider education, and audit and feedback were implemented. After 15 months of implementation, infection rates significantly improved.

Description

Before the initiation of this study the following factors were established: critical care governance, team structure (including intensivist-led closed model), call schedules, interdisciplinary rounds, and staffing models. The focus was on processes of care. Best practices for venous thrombosis, cardiovascular complications, ventilator-associated pneumonia, and stress ulcers were standardized. ICU daily goals and an educational program were initiated before the start of the study.

The study period consisted of initiating the use of a tele-ICU team. The offsite team participated in key critical care delivery 24 hours a day. The team reviewed the care for each patient, conducted real time audit of best practices, performed workstation-assisted care plan reviews, monitored system-generated electronic alerts, audited bedside staff responses to in-room alarms, and intervened when the responses of the bedside staff were delayed and the patient was deemed physiologically unstable. Logistic regression was used to analyze dichotomous outcomes and general linear mixed models were used for continuous outcomes.

Results and Limitations

Adherence rates were not analyzed. During the baseline period, the CLABSI rate was 1 percent while in the postintervention period it was 0.6 percent (OR: 0.50; 95% CI: 0.27 to 0.93; p=0.005). The tele-ICU group was significantly older, sicker, and was not mechanically ventilated or a postoperative case as often as the baseline group. Hospital mortality was the primary outcomes for this study and was rigorously analyzed. It does not seem the same level of analysis was applied to the outcomes that this report is interested in.

Table 9. Outcomes for CLABSI articles that control for confounding or secular trend

Author, country-year	Intervention/ Comparator	Type of outcome	Specific measure	Improve	Worsen	NS	Change in specific measure	Comments
Scales, Canada - 2011[58]	Telemedicine Knowledge Translation program/ Active Control Group	Adherence	Overall insertion bundle	◊			Control: 30.0% → 51.7% Intervention: 10.0% → 70.6% (p=0.02) Ratio of ORs: 17.55 (95% CI: 4.72 to 65.26; p<0.001)	Reflects ratio of odds ratio.
		Infection Rate						
		Costs/Savings						
Speroff, United States - 2011[60]	Virtual Collaborative Group/Toolkit Group	Adherence	Prevention Strategy Use	◊			Virtual Collaborative: 69% Toolkit Group: 54% (p=0.017)	Use of tools and strategies was accomplished by followup survey. Clinical tools were used 61% by the Virtual Collaborative group and 49% by the Toolkit group (p=0.23). Data tools were used 56% by the Virtual Collaborative group and 30% by the Toolkit group (p=0.004).
		Infection	Overall			•	Median Virtual Collaborative: 1.84 (IQR, 0.00 to 3.83) → 2.76 (IQR, 0.00 to 4.67) Median Toolkit: 2.42 (IQR, 0.65 to 6.80) → 1.16 (IQR, 0.00 to 5.46)	
		Cost/Savings						
Lilly, United States - 2011[53]	Tele-ICU (providing care from a remote location)/ Provider education and checklist for best practices	Adherence						The tele-ICU group was significantly older, sicker, and was not mechanically ventilated or a postoperative case as often as the baseline group. It is unclear if these covariates were taken into account for the outcomes of interest.
		Infection	Overall	•			1% → 0.6% (OR=0.50; 95% CI: 0.27 to 0.93; p=0.005)	
		Cost/Savings						
Berenholtz, United States - 2004[49]	Education, CVC cart, nurse empowerment, checklist, and daily assessment of need/ **Education only**	Adherence						During the first month, 32% (12/38) of the checklists used required a nurse intervention. There was no significant difference in the slopes before the interventions were implemented (p=0.80). There does not seem to be a comparison of the slopes after the initiation of the initiative.
		Infection Rate	Overall	•			Control: 5.7 → 1.6 (slope p=0.56) Intervention: 11.3 → 0 (slope p<0.001)	
		Costs/Savings	Annual additional cost savings				$1,945,922 ($1,483,844-$2,408,000)	

Table 9. Outcomes for CLABSI articles that control for confounding or secular trend (continued)

Author, country-year	Intervention/ Comparator	Type of outcome	Specific measure	Improve	Worsen	NS	Change in specific measure	Comments
Khouli, United States - 2011[61]	Simulation-based sterile technique training/ Video-based training (usual care)	Adherence						
		Infection Rate	Overall MICU	•			Mean: 3.5 → 1.0	
			Overall SICU (Control)			•	Mean: 3.6 → 3.4	
			MICU vs. SICU	•			IRR: 0.30 (95% CI: 0.10 to 0.91, p=0.03)	
		Costs/Savings						
Perez Parra, Spain - 2010[62]	Educational Intervention/ No Intervention (usual care)	Adherence						VAP rates were used as a control. P-value for overall CLABSI rate reflects Poisson regression findings. VAP rates were not analyzed, but incidence did increase.
		Infection Rate	Overall CLABSI			•	Mean: 4.22 → 2.94 (p=0.11)	
			General surgery ICU CLABSI	•			Mean: 5.3 → 3.4 (p=0.05)	
			Cardiac surgery ICU CLABSI			•	Mean: 4.2 → 2.7 (p=0.12)	
			Medical ICU CLABSI			•	Mean: 3.4 → 2.6 (p=0.31)	
			Overall VAP (Control)[a]				Mean: 13.34 → 15.82	
		Costs/Savings						
Barsuk, United States - 2009[63]	Simulation Training in CLABSI reduction/ No Intervention (usual care)	Adherence						SICU served as control unit.
		Infection Rate	Overall MICU	•			Mean: 3.20 → 0.5	
			Overall SICU (Control)			•	Mean: 4.86 → 5.26	
			MICU vs. SICU	•			IRR: 0.16 (95% CI: 0.05 to0.44; p=0.001)	
		Costs/Savings						

Table 9. Outcomes for CLABSI articles that control for confounding or secular trend (continued)

Author, country-year	Intervention/ Comparator	Type of outcome	Specific measure	Improve	Worsen	NS	Change in specific measure	Comments
Apisarnthanarak, Thailand - 2010[64]	Period 3: CLABSI bundle + intensified hand hygiene promotion/ Period 1: No Intervention (usual care) Period 2: Bundle - CLABSI	Adherence	Period 2 and 3 vs. period 1 maximal sterile barrier	◊			Period 1 vs. Period 2: 45% → 80% (p<0.05) Period 1 vs. Period 3: 45% → 81% (p<0.05)	Period 1=12 mos (baseline period), Period 2=12 mos (bundle implementation), Period 3=12 mos (bundle implementation + intensified hand hygiene promotion). Level of significance reflects the change in level, not change in slope from segmented regression. Other units included orthopedics, obstetrics/gynecology, and general practice.
			Period 2 and 3 vs. period 1 chlorhexidine skin prep	◊			Period 1 vs. Period 2: 42% → 75% (p<0.05) Period 1 vs. Period 3: 42% → 77% (p<0.05)	
			Period 2 and 3 vs. period 1 avoid femoral vein insertion	◊			Period 1 vs. Period 2: 50% → 64% (p<0.05) Period 1 vs. Period 3: 50% → 66% (p<0.05)	
			Period 2 and 3 vs. period 1 overall hand hygiene	◊			Period 1 vs. Period 2: 8% → 24% (p<0.05) Period 1 vs. Period 3: 8% → 53% (p<0.05)	
		Infection Rate	Medical Ward period 1 vs. period 2	•			Mean: 16 → 6.8 (p=0.03)	
			Medical Ward period 2 vs. period 3	•			Mean: 6.8 → 1.5 (p=0.02)	
			Surgical Ward period 1 vs. period 2	•			Mean: 11 → 5.5 (p=0.001)	
			Surgical Ward period 2 vs. period 3	•			Mean: 5.5 → 0.8 (p=0.05)	
			ICU period 1 vs. period 2	•			Mean: 17 → 7.1 (p=0.005)	
			ICU period 2 vs. period 3	•			Mean: 7.1 → 2.1 (p=0.001)	
			Other Units period 1 vs. period 2	•			Mean: 9 → 5.2 (p=0.04)	
			Other Units period 2 vs. period 3			•	Mean: 5.2 → 0.9 (p=0.14)	
		Costs/Savings						

Table 9. Outcomes for CLABSI articles that control for confounding or secular trend (continued)

Author, country-year	Intervention/ Comparator	Type of outcome	Specific measure	Improve	Worsen	NS	Change in specific measure	Comments
Costello, United States - 2008[45]	Full Intervention: Pediatric Multidisciplinary CLABSI Bundle/ Baseline: Low intensity intervention Partial Intervention: Central venous line (CVL) insertion bundle, CVL access bundle, and CVL maintenance bundle	Adherence	Partial vs. Full Intervention CVL Insertion Bundle	◊			87% → 94% (p<0.001)	
			Partial vs. Full Intervention CVL Maintenance Bundle	◊			85% → 99% (p=0.004)	
			Baseline vs. Full Intervention Hand Hygiene	◊			38% → 85.5% (p<0.001)	
		Infection Rate	Partial Intervention	•			Mean: 7.8 → 4.7 (p=0.029)	
			Full Intervention	•			Mean: 7.8 → 2.3 (p=0.0002)	
		Costs/Savings	Annual attributable cost savings[a]				$236,000 to $782,000	
Miller, United States - 2010[65]/[105]	Bundle - CLABSI/ No Intervention (usual care)	Adherence	Insertion bundle[a]				80% → 89%[b]	After adjusting for region and PICU demographics, the maintenance bundle adherence was the only significant predictor for CLABSI, p=0.017.
			Maintenance bundle[a]				65% → 85%[b]	
		Infection Rate	Overall	•			Mean: 5.4 → 3.1 (p<0.0001)	
		Costs/Savings						
McKee, United States - 2008[66]	CLABSI education, cart, checklist, and nurse empowerment/No Intervention (usual care)	Adherence	Catheter insertion checklist[a]					Percent of cases that needed prompting from a nurse was reported.
		Infection Rate	Overall			•	Mean: 5.2 → 2.7 (p<0.05)	Using statistical process control chart, infection rates marginally improve over the study period, p=0.07. Poisson regression showed significant improvement in infection rates in the post-intervention phase.
		Costs/Savings						

Table 9. Outcomes for CLABSI articles that control for confounding or secular trend (continued)

Author, country-year	Intervention/ Comparator	Type of outcome	Specific measure	Improve	Worsen	NS	Change in specific measure	Comments
Frankel, United States - 2005[76]	Six Sigma Performance Improvement/No Intervention (usual care)	Adherence						Used a statistical process control chart to evaluate the effectiveness of the intervention.
		Infection Rate	Overall	•			11 → 1.7 (p<0.0001)	
			Catheters placed between infections				27 → 175	
		Costs/Savings	Annual cost reduction minus cost of insertion kits and antibiotic coated catheters				$61,000	
Wall, United States - 2005[77]	Continuous quality improvement (CQI) methodology with nurse checklist, provider education, and progress reports/No Intervention (usual care)	Adherence	Hand hygiene				72% → 89%[b]	Used a statistical process control chart to evaluate the effectiveness of the intervention. Points above the upper control limit occurred 3 of 6 times after the intervention.
			Chlorhexidine prep				58% → 100%[b]	
			Maximal sterile barriers				68% → 87%[b]	
			Guidewire exchange				19% → 19%[b]	
		Infection Rate	Overall	•			7.0 → 3.8	
		Costs/Savings						
DePalo, United States - 2010[67]	CLABSI education program and bundle/ No Intervention (usual care)	Adherence						Infection rate was adjusted for hospital size, teaching status, and device-days. Cost savings was calculated using number of lives saved and reduction in ICU days.
		Infection Rate	Overall	•			Mean: 3.73 → 0.97 (p=0.003)	
		Costs/Savings	Cumulative cost savings[a]				$2,016,592	
Pronovost, United States - 2010[46]	Keystone ICU Project/ No Intervention (usual care)	Adherence						Evaluation period=0-18 mos after implementation, Sustainability period=19-36 mos after implementation. Adjusted for clustering within ICUs, hospitals, and regions as well as teaching status and hospital size.
		Infection Rate	Evaluation Period vs. baseline	•			Mean: 7.7 → 1.3 IRR: 0.38 (95% CI: 0.26 to 0.56, p<0.05)	
			Sustainability Period vs. baseline	•			Mean: 7.7 → 1.1 IRR: 0.34 (95% CI: 0.24 to 0.48, p<0.05)	
		Costs/Savings						

Table 9. Outcomes for CLABSI articles that control for confounding or secular trend (continued)

Author, country-year	Intervention/ Comparator	Type of outcome	Specific measure	Improve	Worsen	NS	Change in specific measure	Comments
Render, United States - 2011[71]	CLABSI Bundle collaboration among VA hospitals/ No Intervention (usual care)	Adherence	Complete bundle				85% → 98%	Adherence to the CLABSI bundle had a strong inverse correlation with CLABSI rates (R2=-0.81). Rates for each bundle item were also reported, but adherence was not analyzed. All results compared to 2006 group. 2007: IRR=0.83; 95% CI: 0.73 to 0.94; p=0.0033 2008: IRR=0.65; 95% CI: 0.56 to 0.76; p<0.0001 2009: IRR=0.47; 95% CI: 0.40 to 0.55; p<0.0001 Four of six hospitals with highest rates took part in mentoring and reduced rates by 53% from 2007 to 2008.
		Infection	Overall	•			Mean: 3.84 → 3.19 → 2.44 → 1.85 (all p<0.004)	
		Cost/Savings						
Zingg, Switzerland - 2009[68]	Educational Program for catheter care and hand hygiene/ No Intervention (usual care)	Adherence	Overall hand hygiene			◊	59.1% → 65% (p=0.466)	Patients in the baseline period were significantly more at risk of CLASBI than those in the postintervention period.
			Proper hand disinfection before and after patient contact	◊			22.5% → 42.6% (p=0.003)	
		Infection Rate	Risk of CLABSI	•			3.9 → 1.0 HR: 4.47 (95% CI: 1.86 to 10.2, p<0.001)	
			Time to CLABSI	•			6.5 days → 9 days (p=0.02)	
		Costs/Savings						

Table 9. Outcomes for CLABSI articles that control for confounding or secular trend (continued)

Author, country-year	Intervention/ Comparator	Type of outcome	Specific measure	Improve	Worsen	NS	Change in specific measure	Comments
Barrera, Colombia - 2011[48]	Hand hygiene promotion/ No Intervention (usual care)	Adherence	ABHR use	◊			9.2% annual increase (p<0.001)	CLABSI significantly decreased 12.7% annually. ABHR use is an indirect measure of hand hygiene. Infection rates were controlled for temporary workers and nurse-to-patient ratio. Nurse-to-patient ratio was an independent risk factor for CLABSI (IRR=1.11; 95% CI: 1.07 to 1.16; p<0.001).
		Infection	Overall	•			12 → 7 (IRR=0.89; 95% CI: 0.80 to 0.98; p=0.015)[a]	
		Cost/Savings						
Kim, United States - 2011[72]	CLABSI bundle with cart/ No Intervention (usual care)	Adherence						Total excess cost of CLABSI, regardless of organism, was estimated to be $32,254 (excess LOS + replacement CVL + drug admin cost + drug cost) Authors felt cost of CLABSI bundle was negligible since cart cost $100 for each unit, and staff and equipment already in place.
		Infection	Total	•			9 → 2.7 (RRR=0.70; 95% CI: 0.59 to 0.77; p<0.00001)	
			MICU	•			13.9 → 3.1 (RRR=0.78; 95% CI: 0.66 to 0.85; p<0.0001)	
			SICU	•			4.5 → 1.9 (RRR=0.59; 95% CI: 0.11 to 0.81; p=0.01)	
			CTICU			•	1.8 → 1.4 (RRR=0.28; 95% CI: -3.3 to 0.88; p=0.36)	
			Burn ICU	•			5.2 → 1.2 (RRR=0.76; 95% CI: -0.01 to 0.94; p=0.02)	
			Neuro ICU			•	7 → 3.8 (RRR=0.45; 95% CI: -0.30 to 0.77; p=0.08)	
			CCU			•	8.5 → 5.4 (RRR=0.36; 95% CI: -0.65 to 0.75; p=0.18)	
		Cost/Savings						

Table 9. Outcomes for CLABSI articles that control for confounding or secular trend (continued)

Author, country-year	Intervention/ Comparator	Type of outcome	Specific measure	Improve	Worsen	NS	Change in specific measure	Comments
Harris, United States - 2011[74]	Hand hygiene, VAP bundle, standardizing central line care/ No Intervention (usual care)	Adherence						Outcomes were adjusted for patient's age, sex, and race as well as insurance coverage, comorbidities, and specialty of treating physician. The adjusted average PICU cost during the intervention period was -$3,948 (95% CI: -$10,678 to $2,782). The adjusted average PICU cost during the postintervention period was -$8,826 (95% CI: -$13,950 to -$3,702). The adjusted average cost per hospital stay during the postintervention period was -$12,136 (95% CI: -$19,058 to -$5,214).
		Infection	Overall	•			3.8 → 3.1 → 1.6 (OR=0.86; 95% CI: 0.48 to 1.53; OR=0.42; 95% CI: 0.22 to 0.80; p<0.001; compared to baseline)	
		Cost/Savings	Average PICU cost	◊			$34,365 (SD $2,446) → $30,175 (SD $2,139) → $25,938 (SD $1,146) (compared to baseline p<0.01)	
			Average hospital cost of stay	◊			$54,323 (SD $3,217) → $46,773 (SD $2727) → $42,071 (SD $1,700) (compared to baseline p<0.01)	
			Projected annual cost savings				$12 million	
Seguin, France - 2010[69]	Physician reminder of catheter duration/ No Intervention (usual care)	Adherence	Median CVC duration	◊			5 → 4 (p<0.001)	After adjustment for age, SAPS II, and admission diagnosis, change in infection rate is marginally significant, p=0.051.
			Median time to CVC removal	◊			9 → 2 (p=0.002)	
		Infection Rate	Overall			•	Median: 2.8 → 0.7 (p=0.051)	
		Costs/Savings						

Table 9. Outcomes for CLABSI articles that control for confounding or secular trend (continued)

Author, country-year	Intervention/ Comparator	Type of outcome	Specific measure	Improve	Worsen	NS	Change in specific measure	Comments
Duane, United States - 2009[70]	Group 3: Central venous line (CVL) protocol + CVL supply cart + nurse education + nurse checklist and nurse empowerment/ Group 1: No Intervention (usual care) Group 2: CVL protocol to reduce catheterization duration + resident education	Adherence	Use of checklist[a]				97.6% → 98% → 100%	Lack of CVL protocol and ISS showed to be independent risk factors for CLABSI.
		Infection Rate	Overall	•			Mean: 16.5 → 15.0 → 7.7 Group 1 vs. Group 2: (p=0.08) Group 1 vs. Group 3: (p<0.0001) Group 2 vs. Group 3 (p<0.0044)	
		Costs/Savings	Hospital admissions cost per patient[a]				Group 2: $19,615.70 decrease compared with Group 1 Group 3: $28,391.87 decrease compared with Group 1	
Yoo, Korea - 2001[78]	Infection control week, daily surveillance with checklist, and suggested correction of catheter care by infection control staff/No Intervention (usual care)	Adherence						During the postintervention period, those who had a CLABSI had significantly longer mean duration of catheterization (15 vs. 9.5 days, p<0.01). Duration of ICU admission was found to be a risk factor for CLABSI (OR: 1.05; 95% CI: 1.01 to 1.08; P=0.0008). The intervention period was not found to be associated to CLABSI. There were only 6 infections, 4 during baseline and 2 during postintervention.
		Infection Rate	Overall			•	4.2 → 1.3 (p=0.14)	
		Costs/Savings						

Table 9. Outcomes for CLABSI articles that control for confounding or secular trend (continued)

Author, country-year	Intervention/ Comparator	Type of outcome	Specific measure	Improve	Worsen	NS	Change in specific measure	Comments
Taylor, United States - 2011[73]	Percutaneously inserted central catheters (PICC) team formed/ No Intervention (usual care)	Adherence						In a stratified analysis by tertiles of central line duration patients with a CV for ≥ 30 days had a reduced risk of CLABSI during the intervention period (HR=0.48; 95% CI: 0.25 to 0.91; p=0.025). Other covariates that were associated with decreased CLABSI were postmenstrual age (HR=0.85; 95% CI: 0.25 to 0.91; p=0.025) and fewer respiratory support days (HR=1.01; 95% CI: 1.004 to 1.021; p=0.005).
		Infection				•	24% → 23% (p=0.87)	
		Cost/Savings						
Schulman, United States - 2011[59]	Bundle - CLABSI Insertion and Maintenance/ Low Intensity Intervention	Adherence						Utilization of maintenance checklist was significantly associated to decrease in CLABSI rate.
		Infection Rate	Overall	•			3.5 → 2.1 (p<0.0005)	
		Costs/Savings						

Table 9. Outcomes for CLABSI articles that control for confounding or secular trend (continued)

Author, country-year	Intervention/ Comparator	Type of outcome	Specific measure	Improve	Worsen	NS	Change in specific measure	Comments
Burrell, Australia - 2011[75]	CLABSI Physician + Patient Bundles/ No Intervention (usual care)	Adherence	Physician bundle	◊			74% → 81% (p<0.0001)	Outcomes were controlled for patient bundle, physician bundle and line-days. Line days (RR=1.05; 95% CI: 1.02 to 1.07; p=0.001) and noncompliance with clinician bundle (RR=2.04; 95% CI: 1.1 to 3.6; p=0.016) were found to be significant risk factors for CLABSI. Risk of CLABSI significantly reduced in patients with CVLs inserted by clinicians compliant with both bundles (RR=0.5; 95% CI: 0.4 to 0.8; p=0.004). CVLs inserted by clinicians that did not adhere to the clinician bundle were more likely to be associated with CLABSI (RR=1.62; 95%CI 1.1 to 2.4 p=0.018).
			Patient bundle	◊			81% → 92% (p<0.001)	
		Infection	Overall	•			3.0 (95% CI: 2.0 to 4.3) → 1.2 (95% CI: 0.6 to 2.2) (p=0.0006)	
		Cost/Savings						

Abbreviations: OR = odds ratio; MICU = medical intensive care unit; SICU = surgical intensive care unit; IRR = incidence rate ratio; PICU = pediatric intensive care unit; HR = hazard ratio; SAPS II = simplified acute physiology score II; ISS = Injury Severity Score

• was used for infection rate outcomes

◊ was used for adherence and costs/savings outcomes

[a] Reported, but not analyzed

[b] Numbers were extrapolated from a graph

Berenholtz et al. (2004)[49]

Berenholtz et al.[49] conducted a controlled interrupted time series to test the efficacy of a QI strategy including audit and feedback, organizational change, provider education, and provider reminder systems compared to education alone on reducing hospital infection rate. Details of this study are found in the 2007 report.

Khouli et al. (2011)[61]

Summary

Khouli et al[61] conducted a controlled before-after study to determine the efficacy of simulation-based training with video training versus video training alone of residents. This provider education intervention took place at a university-affiliated hospital in the United States and was followed for 18 months postintervention. Sterile technique improved significantly in the simulation-trained group versus the nonsimulation group. Following this observed improvement, all medical intensive care unit (MICU) residents were trained with this intervention. A comparison of the MICU with the surgical intensive care unit (SICU), which had no video or simulation-based training, showed a significant reduction in the MICU CLABSI rate.

Description

After a baseline evaluation of preparedness in central line sterile technique within a simulation laboratory, residents were randomized to receive either video-based training or simulation-based and video-based training. The training focused on current CDC sterile technique recommendations in the categories of: nonsterile preparation, hand washing, sterile field/supply preparation, sterile gowning, sterile gloving and sterile draping. The simulation-based group showed a statistically significant improvement and subsequently all internal medicine residents in the MICU adopted this training. Sample sizes were not provided. Infection rates were analyzed using a generalized linear model and Poisson regression controlling for ICU type and study period.

Results and Limitations

After randomization, baseline sterile technique test results were not significantly different in any category. A statistically significant improvement in median post-test score in the categories of nonsterile preparation ($p<0.001$), hand washing steps ($p=0.007$), sterile field/supply preparation ($p=0.05$), sterile gowning ($p<0.001$), and sterile draping ($p=0.005$) was observed for the simulation-based and video-based training group compared with the video-based training group (Table 9). An all-or-nothing analysis comparing the number of residents with perfect scores in each of the sterile technique categories showed an identical pattern of statistically significant improvement for the simulation-based training group compared with video training alone. The results of the randomized controlled trial led to the use of combined simulation and video-based training in the medical ICU. All medical ICU residents were trained in this manner while surgical ICU residents received no extra training. Eighteen months after the study intervention, the medical ICU had a CLABSI rate of 1.0 infections per 1,000 catheter-days, which was a significantly lower rate of CLABSI than the surgical ICU with a rate of 3.4 infections per 1,000 catheter-days (IRR: 0.30; 95% CI: 0.10 to 0.91; $p=0.03$) when analyzed with a Poisson regression model. A limitation of this study is adherence rates were not measured during the post-randomized, controlled trial period of the study.

Perez Parra et al. (2010)[62]

Summary

In a controlled before-after study, Perez Parra et al. reported a month-long educational intervention for all ICU staff in three units at a tertiary care university-affiliated hospital in Spain.[62] Adherence rates were not reported and overall infection rates did not change significantly. VAP rates were used as a control in this study and increased over the study period.

Description

The educational intervention was a 15-minute lecture that covered Infectious Disease Society of America and Center for Disease Control and Prevention guidelines for CLABSI prevention. The lecture was given to all ICU workers, physicians, residents, nurses, and students, on all shifts. There was a test before the lecture and a subsequent test 6 months later. Poisson regression was used to analyze infection rates. VAP rates were used as a control, but analysis was not performed on the VAP rates, therefore lessening the effectiveness of the control. Also, there was no analysis done on patient characteristics and no patient characteristics were included in the final regression model.

Results and Limitations

The overall CLABSI rates were nonsignificantly different from the baseline period to the postintervention period (4.22 vs. 2.94 infections per 1,000 catheter-days, p=0.11, (Table 9). While the cardiac surgery (p=0.12) and medical ICUs (p=0.31) did not undergo a significant change, the general surgery ICU did see a significant improvement in infection rates (p=0.05). In comparison, VAP rates were 13.34 infections per 1,000 ventilator-days in the baseline period and 15.82 in the postintervention period.

Barsuk et al. (2009)[63]

Summary

Barsuk et al.[63] compared a simulation-based educational program to a traditional educational program for central line insertion at a tertiary care facility over a 32-month period. A baseline period and a concurrent control group (surgical ICU) served as the comparators for this study. Adherence rates were not reported. The medical ICU received the simulation-based intervention and had significantly lower infection rates than the surgical ICU and the medical ICU during the baseline period.

Description

Residents of both the medical and the surgical ICUs were trained using the traditional method for the first 16 months of the study, serving as the baseline period. Then the residents in the MICU received a baseline test. Thereafter, the residents watched a training video and were given an opportunity for deliberate practice with focused feedback. A post-test was administered and a minimum score was needed to pass. Further training was given to those who did not pass. Poisson regression was used to analyze the infection rates. ICU, period, and catheter-days were also included in the regression model. There was no analysis presented for patient characteristics and no patient characteristics were included in the final model, but there is mention that a significant increase in Charlson score was observed in the postintervention period in the MICU (p=0.009). The diagnosis of sepsis also significantly increased over the study (p=0.02).

Results and Limitations

Infection rates in the medical ICU dropped significantly from 3.2 infections per 1,000 catheter-days to 0.5 ($p=0.001$, Table 9). The infection rate in the surgical ICU was similar in both periods, 4.86 infections per 1,000 catheter-days versus 5.26. The postintervention medical ICU infection rate was also significantly lower than the surgical ICU rate (IRR: 0.16; 95% CI: 0.05 to 0.44). Residents were aware of their involvement in the study, which may have led to a Hawthorne effect in the medical ICU.

Interrupted Time Series

Apisarnthanarak et al. (2010)[64]

Summary

Apisarnthanarak et al. implemented an audit and feedback, organizational change, and provider education intervention over a period of 3 years in a university affiliated, tertiary care hospital in Thailand.[64] The authors found that adherence to maximal sterile barriers, hand hygiene, use of chlorhexidine skin antisepsis at central venous catheter (CVC) insertion site, and avoiding femoral catheterization increased significantly between the baseline and intervention periods. A significant reduction in CLABSI rate was observed in the postintervention period.

Description

A multidisciplinary team from the hospital was created to conduct an education program, track patients with CVC, and monitor adherence to the quality improvement protocol. The study design was broken into three periods. The first period (July 2005 to June 2006) comprised the baseline; period two (July 2006 to June 2007) introduced alcohol dispensers at the patient's bedside and a CLABSI bundle, and period three (July 2007 to June 2008) introduced an intensified hand hygiene intervention. The CLABSI bundle implemented in period two consisted of hospital health care worker education on proper hand hygiene, education on maximal sterile barrier precautions, use of chlorhexidine-based skin preparation, optimization of CVC practices and daily review of catheter necessity. The education component of this intervention was a onetime 45-minute lecture administered to hospital staff. Period three replaced this single education experience with continued education every four months and promoted adherence with posters and newsletters.

Results and Limitations

Overall hand hygiene adherence significantly improved from 8 percent at baseline compared with period two (24%, $p<0.001$) and period three (53%, $p<0.001$, Table 9). Adherence to all components of maximal sterile barrier precautions increased from 45 percent during the baseline period compared with 80 percent ($p<0.05$, compared to baseline) during period two and 81 percent during period three ($p<0.05$, compared to baseline). Correct use of chlorhexidine skin antisepsis increased from a baseline of 42 percent compared with 75 percent ($p<0.05$, compared to baseline) and 77 percent ($p<0.05$, compared to baseline) in periods two and three, respectively. Lastly, adherence to avoiding femoral catheter insertion increased from 50 percent in period one compared with 64 percent ($p<0.05$) in period two and 66 percent ($p<0.05$) in period three.

During period one the overall CLABSI rate per 1,000 catheter-days was 14 compared with 6.4 ($p<0.001$) and 1.4 ($p<0.001$) CLABSI per 1,000 catheter-days in periods two and three respectively. In addition, the mean catheter-days was significantly reduced during period two

(4.9 ± 1.5 days, p<0.001) and period three (4.1 ± 1.1 days, p<0.001) compared with baseline duration of 5.6 ± 2.4 days (Appendix Table G2).

Costello et al. (2008)[45]

Summary

Costello et al. compared full and partial intervention with baseline data on CLABSI at a dedicated pediatric cardiac ICU.[45] The intervention consisted of audit and feedback, financial incentives, regulations, and policy, organizational change, provider education, and a provider reminder system. The duration of both baseline and full intervention periods was 9 months, while the partial intervention period was 15 months. Adherence rates significantly improved between partial and full intervention for adherence to central venous line (CVL) insertion and maintenance bundles. Additionally, hand hygiene showed significant improvement from baseline compared with full intervention. CLABSI rates in the cardiac ICU significantly improved from baseline after both partial and full interventions. The authors estimate an annual attributable savings between $236,000 and $782,000 using previously published cost analysis.

Description

A multidisciplinary team was created to track nosocomial infections, educate staff members, and implement the intervention practice changes. Central venous line insertion, access and practices were reviewed and a pretest was administered to all cardiac ICU members to identify weaknesses. Educational tools were developed with a focus on developing optimal CVL insertion, access, and maintenance technique. Processes for diagnosing patients with possible nosocomial infections were standardized during the study period. Staggered intervention implementation occurred between January 2005 and March 2006 and included: CVL insertion bundle, chlorhexidine based skin preparation, chlorhexidine eluting disk applied to percutaneous insertion sites, real time feedback on infection rates to cardiac ICU staff, mandatory nurse education, creation of cardiac ICU based infection control nurse position, CVL access and maintenance bundle, mandatory physician education, daily goal sheets during rounds, CVL insertion kit, needleless connector system. The sample size during the baseline period, partial implementation period and full implementation period was 911 patients, 1,472 patients, and 936 patients, respectively. A chi-square test or Fisher's exact test was used to analyze adherence with hand hygiene, CVL insertion and maintenance bundles. Segmented regression was used to analyze infection rates.

Results and Limitations

Mean CLABSI rates in the cardiac ICU significantly decreased from 7.8 (95% CI: 5.6 to 10.5) infections per 1,000 catheter-days during the baseline period (April 2004 to December 2004) to 4.7 (95% CI: 3.4 to 6.3) infections per 1,000 catheter-days (p=0.029, Table 9) during the partial intervention period (January 2005 to March 2006). The full intervention (April 2006 to December 2006) had a further reduced CLABSI rate of 2.3 (95% CI: 1.2 to 3.8; p=0.0002). Adherence with the CVL insertion bundle improved from a partial intervention value of 87 percent to 94 percent in the full intervention period (p<0.001). Adherence with the CVL maintenance bundle also improved from a partial intervention value of 85 percent versus 99 percent in the full intervention period (p<0.004). Hand hygiene adherence was also improved from a baseline value of 38 percent to 85.5 percent in the full intervention period (p<0.001).

The authors discuss several limitations of this study. First, is the use of NHSN surveillance definitions for CLABSI which are subject to adjudication bias. Second, there is no existing, validated severity of illness score for pediatric cardiac ICU patients, but indicators of patient acuity tended to increase over the study duration. Lastly, the adherence rates were collected intermittently, rather than systematically.

Miller et al. (2010)[65,105]

Summary

Miller et al. compared a central venous catheter insertion and maintenance bundle intervention to baseline practices among 29 pediatric ICUs in 27 hospitals in the United States.[65,105] Each hospital was a participant in the National Association of Children's Hospitals and Related Institutions quality improvement collaborative and implemented interventions consisting of audit and feedback, organizational change, provider education and provider reminder systems. The authors demonstrated a significant improvement in overall infection rates between the baseline and stable effect periods. An analysis to determine the importance of adherence to insertion and maintenance intervention bundles found that only maintenance bundle adherence was a significant predictor of CLABSI rate decrease.

Description

Baseline data were collected for each ICU from January 2004 to August 2006. A ramp-up period of the first 3 months of the collaborative occurred from October 2006 to December 2006 and there was variation in the intervention bundle element implementation. Following this was a 9-month stable effect period from January 2007 to September 2007, when CLABSI efforts were consistent between ICUs. No sample sizes were reported.

Each ICU selected a multidisciplinary team responsible for testing and implementing CVC insertion and maintenance bundles. The insertion bundle consisted of appropriate hand washing before procedure, use of chlorhexidine gluconate, scrubbing of insertion site for children 2 months of age or older, no iodine skin preparation at insertion site, prepackaged insertion cart, insertion checklist, staff empowerment to stop nonsterile procedures, use of only polyurethane or Teflon catheters, and slide and video based training for all care providers. The maintenance bundle consisted of daily catheter needs assessment, catheter site care, and hub cap and tubing care. While adherence rates were not analyzed, marginal generalized linear models were used to analyze infection rates.

Results and Limitations

The mean baseline CLABSI rate for all pediatric ICUs was 5.4 infections per 1,000 catheter-days. During the ramp up period the mean CLABSI rate decreased to 4.3 infections per 1,000 catheter-days (95% CI: 3.1 to 6.4) which further decreased to a stable effect rate of 3.1 infections per 1,000 catheter-days (95% CI: 2.4 to 4.0; Table 9). Compared with baseline, the stable effect period CLABSI rate significantly decreased ($p<0.0001$). This observed association remained after a more rigorous sensitivity analysis. Miller et al. (2010) also used a hierarchical cluster regression model to determine significant predictors of the observed decrease in CLABSI rate. After adjustment for region and pediatric ICU demographics, the only significant predictor of decreased CLABSI rate was adherence with the CLABSI maintenance bundle (RR: 0.41; 95% CI: 0.20 to 0.85; $p=0.017$).

Update Publication

In 2011, Miller et al. published an update of this study that included another year of data as well as cost savings estimates.[105] In addition to what was reported above, a nested nonrandomized factorial design study was also implemented comparing standard protocols for the use of the following items: (1) chlorhexidine scrub on central line caps and access points, (2) chlorhexidine-impregnated sponges with all central line care, (3) both 1 and 2, or (4) control. There was no significant difference in infection rates between any of the groups. Overall CLABSI rates fell significantly from 5.2 infections per 1,000 catheter-days in the baseline period to 2.3 in the postintervention period (RR: 0.44; 95% CI: 0.37 to 0.53; p<0.0001). There was only one time period, the ramp-up period (October 2006 to December 2006), that had a significant change in slope, 11 percent decrease per month (95% CI: -3% to -18%; p=0.006). The authors estimated that these 29 PICUs saved more than $31 million in CLABSI-attributable health care costs. This is discussed in more detail in key question 1c.

Simple Before-After

McKee et al. (2008)[66]

McKee et al. implemented a 30-month QI initiative through audit and feedback, organizational change, provider education, and provider reminder systems in a tertiary care facility in the United States.[66] Sample size was not reported. Adherence rates were not analyzed, but a statistical process control chart was used to analyze infection rates. A nonsignificant change in infection rates was observed (Table 9) using statistical process control chart methodology and a comparison of incidence rate ratios. During the postintervention period, 10 weeks of zero infections was followed by a dramatic spike in infection rates. An epidemiological investigation occurred and found that a faulty positive displacement mechanical valve was associated with the increased infection rates. As soon as the faulty valves were removed from the hospital, the infection rates decreased dramatically.

Frankel et al. (2005)[76]

Frankel et al.[76] conducted a simple before after study to test the efficacy of six sigma performance improvement strategy on reducing hospital infection rates. Details of this study are found in the 2007 report.

Wall et al. (2005)[77]

Wall et al.[77] conducted a simple before after study to determine the efficacy of a continuous QI strategy on reducing hospital infection rate and increasing compliance with hand hygiene, use of chlorhexidine antisepsis, maximal sterile barriers, and guidewire exchange. Details of this study are found in the 2007 report.

DePalo et al. (2010)[67]

DePalo et al. implemented a 27-month statewide initiative that included audit and feedback, organizational change, and provider education in 11 acute care hospitals in the United States.[67] This initiative targeted both CLABSI and VAP. All adult ICUs in Rhode Island participated in this QI collaborative. Improving patient safety culture and adoption of CLABSI and VAP preventive interventions was the focus of the collaborative. Adherence to CLABSI preventive interventions was not reported. Generalized linear latent and mixed models were used to analyze infection rates. The median CLABSI rate dropped from 1.95 infections per 1,000 catheter-days

in the first quarter to 0 in the last quarter of the study period (Table 9). There was a significant decrease in trend over time for CLABSI (p=0.003). The authors reported an estimated $2,016,592 savings due to the QI collaborative.

Pronovost et al. (2010)[46]

Pronovost et al. invited all hospitals in Michigan to participate in a QI collaborative, the Keystone ICU project.[46] Data were collected on an initial 18-month evaluation period and a subsequent 18-month sustainability period. A total of 103 ICUs from 67 hospitals participated in this study, although baseline data were only available for 55 ICUs. In addition, 13 ICUs elected not to participate during the sustainability period. Generalized linear latent and mixed models were used to analyze infection rates. Adjustment for hospital teaching status and bed size also occurred.

Over a 12-month period, audit and feedback, organizational change, provider education, provider reminder systems, and financial incentives were implemented in three month intervals. A multidisciplinary team was responsible for ensuring accurate reporting of CLABSI in the ICU, implementing CDC guideline conceptual model for reducing CLABSI, and educating physicians on the creation of a central line cart. The median infection rate decreased from 2.7 infections per 1,000 catheter-days (IQR, 0.6 to 4.8) at baseline to 0, which was sustained for every quarter throughout the study's 36-month followup period (Table 9). Mean CLABSI rate decreased significantly from baseline to 18 months postintervention by 12 percent (95% CI: 9% to 15%). The mean CLABSI rate 18 months postintervention versus 36 months postintervention decreased only 1 percent (95% CI: 9% decrease to 7% increase) and was not statistically significant. Forty three ICUs reported data from baseline to the end of the 36-month postintervention period without missing data and were included in a sensitivity analysis. The results of the sensitivity analysis demonstrated a similar 13 percent (95% CI: 9% to 16%) reduction in the mean CLABSI rate comparing baseline to 18 months postintervention and a 1 percent decrease between 18 and 36 months.

Some limitations of this study are the lack of uniformity in surveillance across sites or information pertaining to other contemporaneous QI efforts in the hospitals, and the variability in the sample provided. The hospitals that provided baseline data were not the same as those that provided postintervention data. However, a subgroup analysis was provided of hospitals with complete data and the authors found similar results. In addition to the limitations noted above, the following strengths are worth noting: (1) extensive hospital participation across the state and surrounding area, (2) sustained reductions in majority of the settings, and (3) similar results reported in the subgroup analysis of hospitals with complete data.

Render et al. (2011)[71]

Render et al. reported on a 4-year intervention to reduce CLABSI by implementing organizational change, provider education, audit feedback, and provider reminder systems in 174 VA ICUs in the United States.[71] Overall bundle adherence rose from 85 percent to 98 percent over the study period, but was not analyzed. Sample size was not reported. Poisson (repeat measures GEE) regression was used to analyze infection rates. Pearson's correlation coefficient was used to assess bundle adherence with CLABSI rates. There was a strong inverse correlation between CLABSI rates and bundle adherence ($r2 = -0.81$). Mean infection rates (per 1000 catheter-days) were 3.84 in 2006, 3.19 in 2007, 2.44 in 2008 and 1.85 in 2009 which were all statistically significant. The IRRs for CLABSI were calculated for 2007 (IRR: 0.83; 95% CI:

0.73 to 0.84), 2008 (IRR: 0.065; 95% CI: 0.56 to 0.76) and 2009 (IRR: 0.47; 95% CI: 0.40 to 0.55) using 2006 as the reference group.

Zingg et al. (2009)[68]

Over a 5-month period, Zingg et al. implemented organizational change and provider education in five ICUs in a university hospital in Switzerland.[68] In four teaching phases using multiple modalities, nurses and physicians were educated on proper hand hygiene and catheter care. Adherence with hand hygiene was analyzed using a chi-square test, while infection rates were analyzed using Cox proportional hazards model. During the baseline and postintervention periods, 499 patients and 500 patients were included, respectively. Overall hand hygiene was nonsignificantly different from baseline to the postintervention period (59.1% vs. 65%, p=0.47, Table 9), while correct hand disinfection did improve significantly (22.5% vs. 42.6%, p=0.003). The infection rate improved from 3.9 infections per 1,000 catheter-days in the baseline period to 1.0 (p<0.001). Male sex and residence in the medical ICU were independent risk factors for CLABSI.

Barrera et al. (2011)[48]

Barrera et al. described a 4-year study in six ICUs (general, trauma, neurosurgery, burn, pediatric and neonatology) in Colombia investigating organizational change and provider education.[48] There were 14,516 patients included over the entire study, of which 2,398 acquired a HAI. Risks for CLABSI and HAI were compared using Poisson regression. Alcohol based hand rub was used as an indirect measure of hand hygiene. Use of the hand rub significantly improved 9.2 percent annually (p<0.001). Infection rates for CLABSI significantly decreased 12.5 percent annually (IRR: 0.89; 95% CI: 0.80 to 0.96; p=0.015). Multivariable analysis adjusted for temporary workers and nurse-to-patient ratios. The nurse-to-patient ratio was an independent risk factor for CLABSI (IRR: 1.11, CI: 1.07 to 1.16).

Kim et al. (2011)[72]

Kim et al. assessed CLABSI rates within ICUs when implementing organizational change, provider education, audit and feedback and provider reminder systems.[72] The study assessed a 600 bed public hospital in the United States. Sample size was not reported. A Poisson regression was used to generate relative risk reduction and also to compare study rates with baseline rates. Adherence rates were not reported. Overall infection rates (per 1000 catheter-days) decreased significantly from 9 to 2.7 (RRR: 0.70; 95% CI: 0.59 to 0.77; p<0.00001). Kim et al. (2011) found that total excess cost of any CLABSI, regardless of organism, (excess LOS, replacement CVL, drug administration cost and drug cost) to be $32,254.

Harris et al. (2011)[74]

Harris et al. reported on CLABSI rates in pediatric ICUs within the United States assessing the impact of organizational change, provider education, audit and feedback and provider reminder systems.[74] There were a total of 2,379 patients within this 3-year study. The study was broken up into baseline, intervention and postintervention periods. Infection rates were analyzed using logistic regression. Adherence to intervention was not assessed. Outcomes were adjusted for patient’s age, sex, race, insurance coverage, comorbidities, and specialty of treating physician. Overall infection rate (per 1000 catheter days) decreased from 3.8 to 3.1 to 1.6. The odds ratios for the intervention (OR: 0.86; 95% CI: 0.48 to 1.53) and post-intervention (OR: 0.42; 95% CI: 0.22 to 0.80) were compared to baseline. Average costs of stay decreased from

$34,365 to $30,175 to $25,938 during the three study periods and were statistically significant when compared to baseline. Average costs of hospital stay decreased from $54,323 to $46,773 to $42,071 during the study periods and were also statistically significant when compared to baseline. Adjusted costs were also reported.

Seguin et al. (2010)[69]

Seguin et al. reported on a 9-month intervention in a university-affiliated hospital in France.[69] The intervention included a provider reminder system to reduce the duration of central venous catheterization, as well as indwelling urinary catheterization. During the baseline period, 676 patients were included, and during the postintervention period, 595 patients were included. One-way analysis of variance (ANOVA) was used to analyze duration of catheterization, while Poisson regression was used to analyze the infection rates. Due to group imbalances both outcomes were adjusted for age, Simplified Acute Physiology Score II (SAPS II), and admission diagnosis. A significant change in median duration of central venous catheterization (5 vs. 4 days, p<0.001, Table 9) and median time to central venous catheter removal (9 vs. 7 days, p=0.002) was observed, but after adjustment for patient characteristics, the difference in infection rates was nonsignificant (2.8 vs. 0.7 infections per 1,000 catheter-days, p=0.051).

Duane et al. (2009)[70]

In a 2-phase process over 29 months, Duane et al. implemented organizational change, provider education, and provider reminder systems at a Level 1 trauma center in the United States.[70] One-hundred thirty-five patients were included in the baseline period, 194 in the first phase of the intervention, and 213 patients were included in the last phase of the intervention. Poisson regression was used to compare the infection rates while logistic regression was used to assess independent predictors of CLABSI. Infection rates improved from 16.5 infections per 1,000 catheter-days during the baseline to 15.0 in the first phase to 7.7 infections per 1,000 catheter-days in the last phase of the intervention (Table 9). The baseline period was not significantly different than the first phase of the intervention (p=0.08), but the last phase was significantly better than the baseline period (p<0.0001) and the first phase (p<0.004). Injury severity scores (ISS) and lack of central line protocols were independent predictors of CLABSI (p=0.04 and p=0.01, respectively). Average hospital charges per patient decreased by $28,391.87 in the last phase of the intervention, and by $19,615.70 in the first phase when compared with the baseline period.

Yoo et al. (2001)[78]

Yoo et al.[78] conducted a simple before after study to determine the efficacy of an audit and feedback, organizational change, provider education and provider reminder system QI strategy on reducing the CLABSI rate within a medical-surgical ICU in Korea. Details of this study are found in the 2007 report.

Taylor et al. (2011)[73]

Taylor et al. analyzed the effect of organizational change and provider education on CLABSI risk in extremely low birth-weight infants in NICUs in the United States.[73] The total sample size for the 1-year study was 200 infants. Adherence was not reported. The risk for CLABSI was assessed using Cox regression adjusting for gestational age, central line days, daily census, respiratory support days and premenstrual age at admission. The intervention group had similar risk as the control group (24% versus 23%, respectively; p=0.87). A stratified analysis by tertiles

indicated that patients who have had a central line for at least 30 days had a reduced risk of CLABSI during the intervention period (HR: 0.48, CI: 0.25 to 0.91). Postmenstrual age (HR: 0.85; 95% CI: 0.25 to 0.91; p=0.025) and fewer respiratory support days (HR: 1.01, CI: 1.004 to 1.021; p=0.005) were found to be associated with decreased CLABSI risk.

Schulman et al. (2011)[59]

Schulman et al. implemented organizational change, provider education, and provider reminder systems at 18 New York State neonatal ICUs over a 10-month period.[59] While adherence rates were not reported, Poisson regression was used to analyze infection rates. Overall, statewide CLABSI rates in the neonatal ICUs decreased from a baseline rate of 3.5 to 2.1 infections per 1,000 catheter-days (p<0.0005, Table 9). In a risk factor analysis, checklist utilization was found to decrease CLABSI rate by 16.5 percent (p=0.04).

Burrell et al. (2011)75

Burrell et al. assessed the impact of organizational change, audit and feedback and provider reminder systems on CLABSI rates in public hospital ICUs in Australia.[75] There were ten tertiary, 12 metropolitan and two pediatric ICUs within this 18 month study. A sample size was not reported. Adherence was assessed using a chi-square test. Logistic regression was used to assess the CLABSI rates adjusting for patient bundle, physician bundle and catheter-days. Physician bundle adherence increased significantly from 74 percent to 81 percent (p<0.0001). Patient bundle adherence also significantly increased from 81 percent to 92 percent (p<0.001). The overall infection rate (per 1,000 catheter-days) decreased from 3.0 (95% CI: 2.0 to 4.3) to 1.2 (95% CI: 0.6 to 2.2) and was also statistically significant (p=0.0006). Burrell et al. (2011) found that catheter-days (RR: 1.05; 95% CI: 1.02 to 1.07; p=0.001) and nonadherence with the physician bundle (RR: 2.04; 95% CI: 1.1 to 3.6; p=0.016) were significant risk factors for CLABSI. The risk of CLABSI was significantly reduced in patients with CVLs inserted by physicians adherent with both bundles (RR: 0.5; 95% CI: 0.4 to 0.8; p=0.004). Patients had a higher risk for CLABSI when a CVL was inserted by a clinician that did not adhere to the clinician bundle (RR: 1.62; 95% CI: 1.1 to 2.4; p=0.018).

Studies That Do Not Control for Confounding or Secular Trend

Twenty- seven studies were also identified in the literature search that addressed prevention of central line-associated bloodstream infections and use a simple two sample test to analyze outcomes (Appendix Table F2).[54,79-104] One[79] was a controlled before-after study (as explained in the results overview, this study was demoted due to lack of between group comparisons), while the other 26 were simple before-after studies. Three studies implemented four QI strategies.[80,86,104] Thirteen implemented three QI strategies.[54,79,84,85,87,88,93-96,98,100,101] Six implemented two QI strategies.[81,89,92,97,99,102] Five studies implemented one QI strategy.[82,83,90,91,103] Twenty-one studies used provider education.[79-81,83-96,99,102-104] Seventeen studies used audit and feedback in their QI initiative.[54,79,80,82,84,86-88,93,94,96-101,104] Twenty used organizational change[54,79-81,84-87,89,92-98,100-102,104] Eight implemented a provider reminder system.[54,79,88,95,98,100,101,104]

Strength of Evidence

Audit and Feedback and Provider Reminder Systems With the Base Strategies Compared With Usual Care

The strength of the evidence for the use of audit and feedback and provider reminder systems with the base strategies, compared with usual care is summarized in Table 10. Twelve of the 26 studies reported using this combination of QI strategies.[45,46,49,58,65,66,71,72,74,75,77,78]

Insertion Bundle

Three of the 12 studies reported adherence to an insertion bundle.[45,58,75] As shown in Table 8, two[45,58] of the studies are of medium quality while the third is of lower quality.[75] Because of overall study quality for these two studies, risk of bias was determined to be medium. All 3 studies reported a significant improvement in adherence with the insertion bundle, rising from 10 percent to 70.1 percent ($p<0.005$) in one,[45] 87 percent to 94 percent ($p<0.001$) in another,[58] and 74 percent to 81 percent ($p<0.0001$) in the last study.[75] With similar direction and level of significance, the evidence was judged as consistent. This is a direct measure of adherence to the insertion bundle. The evidence was said to be precise. The quality rating for the cluster randomized, controlled trial[58] was lowered from higher to medium because of several limitations, including short intervention and followup, lack of significant improvement when the initial control group implemented the intervention, and high variability in the estimate. The interrupted time series study[45] adherence results were analyzed using two group tests; only infection rates were analyzed using segmented regression. The strength of the evidence for the use of audit and feedback and provider reminder systems with the base strategies, compared with usual care, to improve adherence to an insertion bundle was determined to be low (Table 10).

Table 10. Audit and feedback and provider reminder systems with the base strategies compared with usual care in CLABSI

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Adherence: insertion bundle	1 controlled study[58] 1 interrupted time series[45] 1 simple before-after[75]	Medium	Consistent	Direct	Precise	***Low***
Adherence: maintenance bundle	1 interrupted time series[45]	Medium	Unknown	Direct	Imprecise	***Insufficient***
Adherence: hand hygiene	1 interrupted time series[45]	Medium	Unknown	Direct	Imprecise	***Insufficient***
Infection rate	1 controlled study[49] 2 interrupted time series[45,65] 8 simple before-after[46,66,71,72,74,75,77,78]	Medium	Consistent	Direct	Precise	***Moderate***
Adherence and infection rates	2 interrupted time series[45,65] 1 simple before-after[75]	Medium	Consistent	Direct	Precise	***Low***

Abbreviation: CLABSI = central line–associated bloodstream infection.

Maintenance Bundle

One of the 12 studies reported data on adherence to a maintenance bundle.[45] As seen in Table 8, the overall study quality was judged to be medium. With only 1 study, consistency is unknown and adherence to the maintenance bundle is a direct measure of adherence. Precision was judged to be imprecise since only 1 medium quality article reported adherence to a maintenance bundle.

The strength of the evidence for the use of audit and feedback and provider reminder systems with the base strategies, compared with usual care, to improve adherence to a maintenance bundle was deemed to be insufficient (Table 10).

Hand Hygiene

One of the 12 studies reported data on adherence to hand hygiene practices.[45] As seen in Table 8, the overall study quality was judged to be medium. With only 1 study, consistency is unknown and adherence to the hand hygiene practices is a direct measure of adherence. Precision was judged to be imprecise since only 1 medium quality article reported adherence to hand hygiene. The strength of the evidence for the use of audit and feedback and provider reminder systems with the base strategies, compared with usual care, to improve adherence to hand hygiene was deemed to be insufficient (Table 10).

Infection Rate

Eleven of the 12 studies reported data on infection rates.[45,46,49,65,66,71,74,75,77,78,106] Three studies[45,49,65] were of medium quality and 8 were of lower quality[46,66,71,72,74,75,77,78] providing a medium risk of bias (Table 8). Nine of 11 studies[45,46,49,65,71,72,74,75,77] found a significant improvement in infection rates and the tenth study[66] reported a nonsignificant reduction in infection rates from the baseline period to the postintervention period. One study reported a nonsignificant decrease in CLABSI rate but included only six cases, four in the preintervention period and two in the postintervention period ($p=0.14$).[78] The baseline infection rates ranged from 3.0 to 11.3 infections per 1,000 catheter-days and dropped to 0 to 3.8 infections per 1,000 catheter-days in the postintervention period. The outcome was judged to be direct and precise. With 9 studies addressing this outcome and improved design and analytical techniques used for infection rather than adherence rates in some studies, the strength of the evidence for the use of audit and feedback and provider reminder systems with the base strategies, compared with usual care, to improve infection rates was determined to be moderate (Table 10).

Adherence and Infection Rate

Three of 12 studies reported data on adherence rates and infection rates.[45,65,75] The adherence rates reported were not analyzed separately for 1 study, but were included in the model for infection rates.[65] In the second study,[45] adherence rates were analyzed using two-group tests. As shown in Table 8, 2 studies were of medium quality while the third was of lower quality.[75] Risk of bias was determined to be medium. Adherence to an insertion and maintenance bundle were reported in 2 studies while the other only reported on an insertion bundle. All three reported significant improvements in adherence rates. One study[65] found a significant association between adherence to the maintenance bundle and improved infection rates. Significant improvements in infection rates were reported in all three studies as well. Based on this, the evidence was determined to be consistent and precise. The outcome is a direct measure. The strength of the evidence for the use of organizational change with or without provider education and audit and feedback and provider reminder systems, compared with usual care, to improve adherence and infection rates was determined to be low (Table 10).

Audit and Feedback or Provider Reminder Systems With the Base Strategies Compared With Usual Care

The strength of the evidence for the use of audit and feedback or provider reminder systems with the base strategies, compared with usual care is summarized in Table 11. Seven of the 26 studies reported using this combination of QI strategies.[48,59,64,67,69,70,76]

Adherence to Multiple Measures

One of 7 studies reported adherence to multiple measures as an outcome.[64] The preventive interventions included maximal sterile barrier, chlorhexidine skin preparation, avoidance of femoral artery, and overall hand hygiene. As shown in Table 8, the quality of this study was judged to be medium and the risk of bias was also determined to be medium. With 1 study the consistency is unknown and the outcome is considered a direct measure of the adherence. The outcome was deemed imprecise. The strength of the evidence for the use of audit and feedback or provider reminder systems with the base strategies, compared with usual care, to improve adherence rates was determined to be insufficient (Table 11).

Hand Hygiene

Only one study reported on this outcome.[48] Thus, strength of evidence is insufficient.

Infection Rate

All 7 studies reported infection rate as an outcome.[48,59,64,67,69,70,76] One[64] was considered of medium quality and 6[48,59,67,69,70,76] were of lower quality (Table 8). The risk of bias was judged to be medium due to the medium quality study and 1[67] of the lower quality studies is a statewide initiative with extended followup time. All 7 studies reported a significant improvement in infection rates leading to a determination of consistent evidence. The outcome is a direct measure and the evidence was judged to be precise. Baseline infection rates ranged from 3.5 to 17.5 infections per 1,000 catheter-days while postintervention infection rates ranged from 0.8 to 7.7 infections per 1,000 catheter-days. In the medium quality study,[64] CLABSI rates fell from 14 to 1.4 per 1,000 catheter days ($p<0.001$) over a 3 year period. The strength of the evidence for the use of audit and feedback or provider reminder systems with the base strategies, compared with usual care, to improve infection rates was determined to be moderate (Table 11).

Table 11. Audit and feedback or provider reminder systems with the base strategies compared with usual care in CLABSI

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Adherence: multiple measures	1 interrupted time series[64]	Medium	Unknown	Direct	Imprecise	***Insufficient***
Adherence: hand hygiene	1 simple before after[48]	High	Unknown	Direct	Imprecise	***Insufficient***
Infection rate	1 interrupted time series[64] 6 simple before-after studies[48,59,67,69,70,76]	Medium	Consistent	Direct	Precise	***Moderate***
Adherence and infection rates	1 interrupted time series[64] 4 simple before-after studies[48,59,69,70]	Medium	Consistent	Direct	Precise	***Low***

Abbreviation: CLABSI = central line–associated bloodstream infection.

Adherence and Infection Rate

Five of 7 studies reported data on adherence rates and infection rates.[48,59,64,69,70] The adherence rates reported were not analyzed separately for 2 studies, but were included in the model for infection rates.[59,70] As shown in Table 8, one study[64] is of medium quality and 4 of lower quality.[48,59,69,70] The risk of bias was considered to be medium. One study[59] found a significant association between utilization of the insertion and maintenance bundle checklists and improved infection rates, while another[70] found the lack of a central venous line was an independent risk factor for CLABSI. A third study [64] reported a significant improvement in adherence to multiple preventive interventions; the fourth reported a significantly greater use of antiseptic rub; and the fifth reported significant improvements in central line duration and time to removal. Four of the 5 studies reported improvements in infection rate, while the change in the fifth was not statistically significant (2.8 to 0.7; p=0.051).[69] Based on this, the evidence was determined to be consistent and precise. The outcome is a direct measure. The strength of the evidence for the use of audit and feedback or provider reminder systems with the base strategies, compared with usual care, to improve adherence and infection rates was determined to be low (Table 11).

Base Strategies Compared With Usual Care

The strength of the evidence for the use of base strategies, compared with usual care is summarized in Table 12. Five of the 26 studies reported using provider education with or without organizational change.[61-63,68,73]

Adherence to Multiple Measures

One of 5 studies reported adherence rates as an outcome.[68] The preventive interventions included hand hygiene and catheter care. As shown in Table 8, the quality of this study was judged to be lower and the risk of bias was determined to be high. With one study, the consistency is unknown and the outcome is considered a direct measure of the adherence. The outcome was deemed imprecise. The strength of the evidence for the use of base strategies, compared with usual care, to improve adherence rates was determined to be insufficient (Table 12).

Table 12. Base strategies compared with usual care in CLABSI

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Adherence: multiple measures	1 simple before-after [68]	High	Unknown	Indirect	Imprecise	***Insufficient***
Infection rate	3 controlled studies[61-63] 1 simple before-after [73]	Medium	Consistent	Direct	Precise	***Moderate***
Risk of infection	1 simple before-after [68]	High	Unknown	Indirect	Imprecise	***Insufficient***
Adherence rate and risk of infection	1 simple before-after [68]	High	Unknown	Indirect	Imprecise	***Insufficient***

Abbreviation: CLABSI = central line–associated bloodstream infection.

Infection Rate

Four of 5 studies reported infection rates as an outcome.[61-63,73] Three studies were of medium quality, and 1 study[73] was of lower quality (Table 8). The risk of bias was judged to be medium. Two[61,63] of 5 studies found a significant improvement in infection rates and the third[62] reported a trend toward significant improvement. One study found no discernible trend in infection rates.[73] The evidence was deemed consistent. The outcome is a direct measure of infection rates. Overall baseline infection rates ranged from 1.84 to 4.2 infections per 1,000 catheter-days while postintervention infection rates ranged from 0.5 to 2.94 infections per 1,000 catheter-days. The evidence was determined to be precise. The strength of the evidence for the use of base strategies, compared with usual care, to improve infection rates was determined to be moderate (Table 12).

Two[61,63] of the 5 studies used a simulation-based provider education strategy. Each of these studies had separate ICUs serve as a contemporaneous control. The intervention ICUs had low infection rates to start with, 3.5 and 3.2 infections per 1,000 catheter-days, but were able to yield a significant improvement, while the nonsimulation-based study did not report a significant change. Both controls had similar infection rates in the baseline and postintervention periods. The evidence for the use of simulation-based provider education compared with traditional provider education strategies suggests that simulations may be more effective at educating clinicians on CLABSI preventive interventions.

Risk of Infection

One of 5 studies reported risk of infection as an outcome.[68] The study looked at change in the risk of infection and not specifically at changes in infection rate. As shown in Table 8, the quality of this study was judged to be lower and the risk of bias was determined to be high. With 1 study the consistency is unknown and the outcome is considered an indirect measure of infection rates. The outcome was deemed imprecise. The strength of the evidence for the use of base strategies, compared with usual care, to improve risk of infection was determined to be insufficient (Table 12).

Adherence and Risk of Infection

One of 6 studies reported adherence rates and a measure of change in infections as an outcome.[68] The strength of the evidence for the use of provider education with or without organizational change compared with usual care to improve adherence and risk of infection separately was determined to be insufficient. Therefore, the strength of the evidence for the use

of base strategies, compared with usual care, to improve adherence and risk of infection was also deemed insufficient (Table 12).

Audit and Feedback With the Base Strategies Compared With a Low Intensity Intervention

One study compared the use of audit and feedback with the base strategies versus provider education and a provider reminder system.[53]

Infection Rate

Lilly et al. (2011) compared a tele-ICU health care delivery system to the use of provider education and a paper checklist. The study showed a 50 percent decrease in odds of developing an infection in the postintervention period (p=0.005). The risk of bias was judged to be medium due to the medium study quality rating. With one study the consistency is unknown and the evidence is imprecise (Table 13).

Table 13. Audit and feedback with the base strategies within CLABSI compared with low intensity intervention

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Infection rate	1 nonrandomized stepped wedge[53]	Medium	Unknown	Direct	Imprecise	***Insufficient***

Abbreviation: CLABSI = central line–associated bloodstream infection.

Base Strategies Compared With a Low intensity Intervention

One study used a combination of organizational change and provider education compared with a low intensity intervention.[60]

Infection Rate

Speroff et al. (2011) compared the use of a virtual collaborative to the use of a toolkit. The study was of higher quality and involved 60 hospitals.[60] Due to the quality of the study, the risk of bias was rated as medium. With only 1 study, the consistency is unknown. Infection rate is a direct measure and the evidence was deemed imprecise. The study showed no differential effect on infection rates (p=0.80). The strength of evidence was considered to be insufficient that the base strategies improve CLABSI rates compared with a low intensity intervention (Table 14).

Table 14. Base strategies within CLABSI compared with low intensity intervention

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Infection rate	1 controlled study[60]	Medium	Unknown	Direct	Imprecise	***Insufficient***

Abbreviation: CLABSI = central line–associated bloodstream infection.

Ventilator-Associated Pneumonia (VAP)

Overview

Nineteen studies were identified in the literature search to reduce rates of ventilator-associated pneumonia (VAP) that met the inclusion criteria and also controlled for confounding or secular trend.[47,48,50,51,53,55-58,60,67,74,107-113] These 19 studies are summarized in Table 15. Four were controlled studies:[58,60,107,108] 2 were cluster randomized, controlled trials[58,60] and 2 were interrupted time series with a control. One used a nonrandomized stepped wedge design.[53] Five others used an interrupted time series design.[50,51,55,57,109] Nine were simple before-after studies that included multivariable analysis.[47,48,56,67,74,110-113]

A variety of QI strategies were used. Seventeen used organizational change;[47,50,51,53,55-57,60,67,74,107-113] 15 used provider education;[47,50,51,55,56,58,60,67,74,108-113] 14 used audit and feedback;[47,48,50,51,53,55-58,67,74,107,109,112] 9 used provider reminder systems;[50,51,56,58,74,107,109,111,112] and 2 used patient (family) education.[47,48] The specific attributes of organizational change that were implemented for these studies are shown in Table 16.

All of the studies used more than one QI strategy to promote change. Seven used four strategies;[47,50,51,56,74,109,112] 5 used three strategies;[55,58,67,107,111] and 7 used two strategies.[48,53,57,60,108,110,113]

Infection and adherence rates were both analyzed in 8 studies.[47,48,51,53,67,107-109] An additional study reported both but compared two different QI strategy combinations.[60] Only adherence with preventive strategies to reduce VAP was reported in 1 study.[58] VAP rates alone were analyzed in 10 studies.[50,55-57,74,110-113] Two studies reported cost/savings information.[74,108]

Fifteen of the 19 were single-center studies[48,50,51,53,55-57,74,107-113] and many of these are just one intensive care unit (ICU) in an academic center. One study[47] was a statewide initiative involving data analysis from 112 ICUs, and another,[67] a statewide project included 23 ICUs. One cluster randomized trial involved multiple ICUs and hospitals but did not specify the number.[60] One of the cluster randomized, controlled trials[58] involved 15 ICUs; the ICUs were randomized into one of two groups. Nine studies[47,50,53,57,60,67,74,107,112] were from the United States, 2[58,111] from Canada, 4[51,56,109,110] from Europe, 2 from Thailand,[108,113] 1 from Colombia,[48] and 1 from Brazil.[55]

The baseline VAP rate varied from 1.9 to 39.7 infections per 1,000 ventilator-days. For single center studies, postintervention sample size ranged from 81 to 4,761 patients and number of VAP infections ranged from 7 to 142. Postintervention infection rates ranged from 0.7 to 22.5 infections per 1,000 ventilator-days. For the four multicenter studies, more than 2 years of postintervention data were available for two of these studies.

The search also identified 25 studies that addressed prevention of VAP but did not control for confounding or secular trend (Appendix Table F1).[80,82,89,91,94,97,103,114-131] These studies are not included in the summary above or in the following analysis due to their weak study designs and potential for biased results.

Methodological Quality of Included Studies

Fourteen studies had followup longer than 1 year after the intervention.[47,48,50,55-57,60,67,74,107-109,112,113] Sixteen were considered to have adequate control for confounding and secular trend.[47,48,53,56-58,60,67,74,107-113] Nine studies analyzed both adherence rates and infection rates.[47,48,51,53,60,67,107-109] For the 17 quasi-experimental studies, only three[108,109,111] explicitly reported being independent of other QI efforts; this dimension was not applicable for the

randomized controlled trials.[58,60] Additional information that was felt to impact study quality is noted as a “Comment” in Table 17. Three studies[60,107,108] were ranked of higher quality, 4[53,57,58,109] of medium quality, and 12 of lower quality.[47,48,50,51,55,56,67,74,110-113]

Table 15. Overview of VAP articles that control for confounding and secular trend

Author, Location-Year	Study Type	Analysis for Infection Rates	Sample Size (Infections)	Organizational Change	Provider Education	Audit and Feedback	Provider Reminder Systems	Patient Education	Financial Incentives
Scales, Canada - 2011[58]	Cluster RCT	Generalized linear mixed model			•	•	•		
Speroff, United States - 2011[60]	Cluster RCT	Hierarchical negative binomial regression		•	•				
Lilly, United States - 2011[53]	Nonrandomized stepped wedge	Logistic regression	pre: 1529 (76) post: 4761 (32)	•		•			
Zaydfudim, United States - 2009[107]	Controlled interrupted time series	Segmented linear regression	study pre: (121) study post: (31)	•		•	•		
Apisarnthanarak, Thailand - 2007[108]	Controlled interrupted time series	Segmented regression	control: (20) study pre: 470 (45) study post: 952 (18)[a]	•	•				
Bouadma, France - 2010[109]	Interrupted time series	Segmented regression with Poisson distribution	pre: 856 (270) post: 835 (142)	•	•	•	•		
Marra, Brazil - 2009[55]	Interrupted time series	Segmented regression	pre: (91) post: (62)	•	•	•			
Papadimos, United States - 2008[57]	Interrupted time series	ARIMA model	pre: 1315 (50) post: 1653 (11)	•		•			
Hawe, United Kingdom - 2009[51]	Interrupted time series	Statistical process control chart	pre: 374 (49) post: 215 (10)	•	•	•	•		
Cheema, United States - 2011[50]	Interrupted time series	u-chart, g-chart		•	•	•	•		
Berenholtz, United States - 2011[47]	Simple before-after	Generalized linear latent and mixed models with Poisson distribution		•	•	•		•	
DePalo, United States - 2010[67]	Simple before-after	Mixed model with Poisson distribution		•	•	•			
Prospero, Italy - 2008[110]	Simple before-after	Time-dependent Cox regression	pre: 104 (27) post: 81 (17)	•	•				
Barrera, Colombia - 2011[48]	Simple before-after	Poisson regression	total: 14,516 (total # HAI: 2,398)			•		•	
Morris, Scotland - 2011[56]	Simple before-after	Poisson regression	pre: 1460 (216) post: 501 (43)	•	•	•	•		
Omrane, Canada - 2007[111]	Simple before-after	Poisson regression	pre: 349 (23) post: 360 (22)	•	•		•		
Harris, United States - 2011[74]	Simple before-after	Logistic regression	pre: 817 (16) intervention: 601 (16) post: 961 (7)	•	•	•	•		
Dubose, United States - 2010[112]	Simple before-after	Logistic regression	pre: 577 (33) post: 570 (25)	•	•	•	•		
Kulvatunyou, Thailand - 2007[113]	Simple before-after	Logistic regression	pre: 85 (42) post: 89 (11)	•	•				

[a]These numbers correspond to the last study period

Table 16. Specific attributes of organizational change that were implemented for VAP articles that control for confounding and secular trend

Author, Country-Publication Year	Multidisciplinary Team	Team Responsibilities	Hospital Executives on Team	New Protocol or Standards Implemented	Designate Staff Member Responsible for Implementation
Speroff, United States - 2011[60]				•	
Lilly, United States - 2011[53]				•	
Zaydfudim, United States – 2009[107]				•	•
Apisarnthanarak, Thailand – 2007[108]	•	Supply feedback from baseline period, design action plan, and monitor educational program	•		•
Bouadma, France – 2010[109]	•	Design education program, select evidence-based recommendations to be implemented		•	
Hawe, United Kingdom – 2009[51]				•	
Cheema, United States - 2011[50]	•	Focused on the adaptation and implementation of a proven pediatric VAP bundle.		•	
Marra, Brazil – 2009[55]				•	•
Papadimos, United States – 2008[57]	•	Implement FASTHUG program		•	
Berenholtz, United States – 2011[47]	•	Implement CUSP program, assist with data collection, standardize protocol, engage and educate staff	•	•	
DePalo, United States – 2010[67]	•	Educate staff on evidence-based practices and help implement CLABSI and VAP bundle		•	
Morris, Scotland - 2011[56]				•	
Omrane, Canada – 2007[111]	•	Develop and implement the protocol		•	
Harris, United States - 2011[74]	•	Led the development of the interventions through the Six Sigma method			
Dubose, United States – 2010[112]	•	Design checklist, audit data, design and implement process changes to address deficiencies		•	•
Kulvatunyou, Thailand – 2007[113]				•	

Table 17. Methodological quality for VAP articles that control for confounding and secular trend

Author, Location-Year	Study Type	Sufficient followup[a]	Adequate control for confounding or secular trend[b]	Change in adherence was analyzed[c]	Change in infection rate was analyzed[d]	Independent of other QI effort[e]	Overall quality rating	Comments
Scales, Canada - 2011[58]	Cluster RCT	-	+	+	-	N/A	***Medium***	Infection rates were not reported. High variability, small number of sites randomized, and there was an active control.
Speroff, United States - 2011[60]	Cluster RCT	+	+	-	+	N/A	***Higher***	Adherence rates were calculated by followup survey, no baseline data. Took place in 59 hospitals.
Lilly, United States - 2011[53]	Nonrandomized Stepped wedge	-	+	+	+	?	***Medium***	Only 3 of the 7 ICUs had followup one or more years
Zaydfudim, United States - 2009[107]	Controlled interrupted time series	+	+	+	+	?	***Higher***	Used BSI as control. There was no baseline adherence rate.
Apisarnthanarak, Thailand - 2007[108]	Controlled interrupted time series	+	+	+	+	+	***Higher***	3-year intervention and followup
Bouadma, France - 2010[109]	Interrupted time series	+	+	+	+	+	***Medium***	
Marra, Brazil - 2009[55]	Interrupted time series	+	-	-	+	-	***Lower***	Adherence rates were reported, but no pre/post statistical comparisons were made. No interrupted time series analysis was conducted.
Papadimos, United States - 2008[57]	Interrupted time series	+	+	-	+	?	***Medium***	
Hawe, United Kingdom - 2009[51]	Interrupted time series	-	-	+	+	-	***Lower***	No interrupted time series analysis was conducted.
Cheema, United States - 2011[50]	Interrupted time series	+	-	-	+	?	***Lower***	Patient characteristics were not assessed.
Berenholtz, United States - 2011[47]	Simple before-after	+	+	+	+	-	***Lower***	Statewide QI initiative.
DePalo, United States - 2010[67]	Simple before-after	+	+	+	+	-	***Lower***	Statewide QI initiative.
Prospero, Italy - 2008[110]	Simple before-after	-	+	-	+	?	***Lower***	
Barrera, Colombia - 2011[48]	Simple before-after	+	+	+	+	?	***Lower***	
Morris, Scotland - 2011[56]	Simple before-after	+	+	-	+	?	***Lower***	Adherence rates were reported, but no pre/post statistical comparisons were made.
Omrane, Canada - 2007[111]	Simple before-after	-	+	-	+	+	***Lower***	
Harris, United States - 2011[74]	Simple before-after	+	+	-	+	?	***Lower***	
Dubose, United States - 2010[112]	Simple before-after	+	+	-	+	?	***Lower***	Adherence rates were reported, but no pre/post statistical comparisons were made.
Kulvatunyou, Thailand - 2007[113]	Simple before-after	+	+	-	+	-	***Lower***	

Note: All studies used standard and consistent infection definitions. CDC methodology was used in all studies except Bouadma et al. (2010),[109] Hawe et al. (2009),[51] and Omrane et al. (2007).[111] Infection rates were adjusted for device utilization in all studies. Independence from other QI efforts was not applicable for randomized controlled trials.
[a]Is the length of followup sufficient (at least 12 months) to support the evaluation of primary outcomes and harms? [b]Were adequate measures taken to control for confounding or secular trend? [c]Was change in adherence analyzed? [d]Was change in infection rate analyzed? [e]Was the intervention performed independent of other QI efforts or other changes?
'+' means 'yes.' '-' means 'no.' '?' means 'uncertain.'

Description of VAP Studies That Control for Confounding and Secular Trend

Controlled Studies

Scales et al. (2011)[58]

Summary

In a cluster randomized, controlled trial, Scales et al. compared change in adherence to preventive interventions in a control ICU where a preventive intervention for a different condition was implemented to intervention ICUs receiving the preventive intervention of interest.[58] Audit and feedback, provider education, and provider reminder systems were used. The study was in 15 community hospital ICUs in Canada and the duration of each intervention period was 4 months. This cluster randomized, controlled trial did not find significant improvements in adherence to head of bed elevation or spontaneous breathing trials. This study did not report infection rates.

Description

In 2011, Scales and colleagues reported on a pragmatic cluster randomized controlled trial among 15 community hospital ICUs in Canada. The objective was to increase delivery of six practices to improve ICU outcomes for five clinical conditions, including VAP (head of bed elevation and daily spontaneous breathing trials), deep venous thrombosis, catheter-related bloodstream infections, early enteral feeding, and decubitus ulcers. The ICUs were randomized into two groups. Each group was assigned an active intervention targeting a new preventive intervention every 4 months, while serving as control for another, unrelated practice. Thus, one group of ICUs received the intervention to improve adherence with head of bed elevation (VAP) while ICUs were receiving the intervention for deep venous thrombosis (DVT) prophylaxis. The ICU receiving the active intervention for DVT prophylaxis served as the control unit for head of bed elevation.

Adherence was analyzed as the odds ratio (OR) for improvement in adoption of the preventive intervention by comparing rates in the first month to the fourth month; the two groups were then compared using the summary ratio of ORs.

Results and Limitations

Considering all six targeted practices, patients in ICUs receiving active intervention were more likely to receive the targeted care practice than those in the control ICUs; summary ratio of ORs of 2.79 and 95% confidence interval (CI) 1.00 to 7.74; p=0.05; Table 18).

Adherence with head of bed elevation in the intervention ICUs improved from 49.8 percent in the first month to 89.6 percent of patient-days in the last month (OR: 6.35; 95% CI: 1.85 to 21.79; p=0.007). In the control units, the rates increased from 80.1 percent to 90.2 percent (OR of 2.04, 95% CI: 0.82 to 5.07; p=0.12). The summary ratio of the two odds ratios was 3.12 (95% CI: 0.79 to 12.41; p=0.11); thus improvement in intervention ICUs was not different from control ICUs.

Adherence with the preventive intervention of daily spontaneous breathing trials in the intervention ICUs improved from 78.8 percent in the first month to 85.1 percent of patient-days in the last month (OR: 1.35; 95% CI: 0.44 to 4.12; p=0.57). In the control units, the rates

changed from 90.9 percent to 89.6 percent with OR of 1.31, 95% CI: 0.34 to 4.97 (p=0.67). The ratio of the two ORs was 1.04 (95% CI: 0.21 to 5.03; p=0.96); thus, change in intervention ICUs were similar to control ICUs.

This randomized, controlled trial had a number of limitations. First, it was limited by the small number (n=15) of units randomized. Second, for head of bed elevation, it was limited by the high variability among units in both baseline adherence (~15 to 100%) and also in final adherence (~65 to 100%). This study also may have been underpowered given the high baseline rates in many of the units randomized. Regarding power, the authors note with a power of 80 percent and alpha of 0.05, the study had adequate power to detect a 30 percent increase when baseline adherence was 50 percent or a 22 percent increase when baseline adherence was 75 percent. For head of bed elevation, all but one control unit had an initial rate of at least 80 percent. For daily spontaneous breathing trials, nearly all ICUs randomized had baseline rates of at least 80 percent. Finally, the short duration of this trial, 4 months, may not have been sufficient to allow for change. An additional limitation includes spillover effect from the control intervention. Most of these limitations lead to an underpowered study or bias the study to accept the null hypothesis. The authors commented that longer intervention phases and inclusion of more centers would likely have narrowed the confidence intervals.

Speroff et al. (2011)[60]

Summary

Speroff et al. conducted a cluster randomized controlled trial comparing the use of a virtual collaborative with a toolkit approach.[60] The QI strategies involved were organizational change and provider education. This study was conducted in 60 hospitals across the United States. After 18 months, there was no significant difference in infection rates between the two groups or over time within either group. There were some tools that were used significantly more in the virtual collaborative group than the toolkit group.

Description

The objective of this study was to prevent CLABSI and VAP in the ICU by improving adherence to evidence-based practices. The authors compared the use of a virtual collaborative approach to a toolkit approach. The toolkit approach entailed access to evidence-based guidelines and fact sheets for preventing CLABSI and VAP, a review of QI and teamwork methods, standardized data collection tools, standardized charting tools, access to a website that contained educational seminars, clinical tools, and QI tools. In addition, the ICU was allowed to implement other changes to prevent CLABSI and VAP. The collaborative group was given everything the toolkit group was given plus the use of web seminars, teleconferences, individual coaching, monthly educational and troubleshooting conference calls, and an email list-serve to encourage communication among teams.

Data were reported in 3-month intervals and analyzed using hierarchical negative binomial regression models in order to account for change over time, clustering of ICUs within hospitals, and baseline characteristics.

Results and Limitations

During the baseline period, median VAP rates were 2.14 (IQR: 0 to 6.09) and 3.49 (IQR: 0 to 7.04) infections per 1,000 ventilator-days in the virtual collaborative group and the toolkit group, respectively. After 18 months, the rate in the virtual collaborative group increased to 2.93 (IQR:

0 to 7.63) while the rate in the toolkit group decreased to 2.06 (IQR: 0 to 6.59) infections per 1,000 ventilator-days. The regression model found that neither the virtual collaborative group nor the toolkit group improved VAP rates (p=0.61 and 0.37, respectively) and there was no difference between the two groups (p=0.8). The virtual collaborative group did use data tools significantly more (p=0.004) and implemented the VAP checklist more than the toolkit group (p=0.007).

The authors list some contextual factors that may have led to the lack of improvement in the study: slow uptake of data driven quality improvement, lack of infrastructure to implement data driven improvement, and differential uptake of general knowledge and implementation knowledge. Also, giving the toolkit group the ability to implement additional changes at their discretion introduced some bias into the comparison being made.

Lilly et al. (2011)[53]

Summary

Lilly et al. conducted a nonrandomized stepped wedge design study in seven ICUs within an academic medical center in the United States.[53] Organizational change, provider education, and audit and feedback were implemented. After 15 months of implementation, infection rates significantly improved.

Description

Before the initiation of this study the following factors were established: critical care governance, team structure (including intensivist-led closed model), call schedules, interdisciplinary rounds, and staffing models. The focus was on processes of care. Best practices for venous thrombosis, cardiovascular complications, ventilator-associated pneumonia, and stress ulcers were standardized. ICU daily goals and an educational program were initiated before the start of the study.

The study period consisted of initiating the use of a tele-ICU team. The offsite team participated in key critical care delivery 24 hours a day. The team reviewed the care for each patient, conducted real time audit of best practices, performed workstation-assisted care plan reviews, monitored system-generated electronic alerts, audited bedside staff responses to in-room alarms, and intervened when the responses of the bedside staff were delayed and the patient was deemed physiologically unstable. Logistic regression was used to analyze dichotomous outcomes and general linear mixed models were used for continuous outcomes.

Results and Limitations

From baseline to postintervention, adherence to “best practice” for prevention of VAP increased from 33% to 51% (OR: 2.2; 95% CI: 1.79 to 2.70; p<0.001). During the baseline period, the VAP rate was 13 percent while in the postintervention period it was 1.6 percent (OR: 0.15; 95% CI: 0.09 to 0.23; p<0.001). The tele-ICU group was significantly older, sicker, and was not mechanically ventilated or a postoperative case as often as the baseline group. Hospital mortality was the primary outcome for this study and was rigorously analyzed. It does not seem the same level of analysis was applied to the outcomes that this report is interested in.

Table 18. Outcomes for VAP articles that control for confounding and secular trend

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Scales, Canada - 2011[58]	Telemedicine Knowledge Translation program/ Active Control Group	Adherence	HOB elevation			◊	Control: 80.1% → 90.2% Intervention: 49.8% → 89.6% (p=0.11) Ratio of ORs: 3.12 (95% CI: 0.79 to 12.41)	Reflects ratio of odds ratio. When all six preventive interventions are pooled together across conditions, a significant improvement in adherence is observed (p=0.05).
			Daily spontaneous breathing trials			◊	Control: 90.9%→89.6% Intervention: 78.8%→85.1% (p=0.96) Ratio of ORs: 1.04 (95% CI: 0.21 to 5.03)	
		Infection						
		Costs/Savings						
Speroff, United States - 2011[60]	Virtual Collaborative Group/Toolkit Group	Adherence	Prevention Strategy Use	◊			Virtual Collaborative: 69% Toolkit Group: 54% (p=0.017)	Use of tools and strategies was accomplished by followup survey. Clinical tools were used 61% by the Virtual Collaborative group and 49% by the Toolkit group (p=0.23). Data tools were used 56% by the Virtual Collaborative group and 30% by the Toolkit group (p=0.004). Collaborative hospitals reported significantly more use of VAP checklist (86% vs. 52%; p=0.007).
		Infection	Overall			•	Median Virtual Collaborative: 2.14 (IQR, 0.00 to 6.09) → 2.93 (IQR, 0.00 to 7.63) Median Toolkit: 3.49 (IQR, 0.00 to 7.04) → 2.06 (IQR, 0.00 to 6.59)	
		Cost/Savings						

Table 18. Outcomes for VAP articles that control for confounding and secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Lilly, United States - 2011[53]	Tele-ICU (providing care from a remote location)/ Provider education and checklist for best practices	Adherence	Overall	◊			33% → 52% (OR=2.20; 95% CI: 1.79 to 2.70; p<0.001)	The tele-ICU group was significantly older, sicker, were not mechanically ventilated or a postoperative case as often as the baseline group. It is unclear if these covariates were taken into account for the outcomes of interest.
		Infection	Overall	•			13% → 1.6% (OR= 0.15; 95% CI: 0.09 to 0.23; p<0.001)	
		Cost/Savings						
Zaydfudim, United States - 2009[107]	VAP electronic dashboard/ No Intervention (usual care)	Adherence	Overall	◊			39% → 89% (p<0.001)	BSI rates were measured as a control. Analysis with pre/post-test for VAP was significantly different, but time series was not.
			Spontaneous breathing trials			◊	86% (95% CI: 75% to 97%) → 97% (95% CI: 95% to 100%)	
			HOB elevation	◊			92% (95% CI: 89% to 95%) → 98% (95% CI: 97% to 99%)	
			Oral care	◊			84% (95% CI: 78% to 90%) → 98% (95% CI: 97% to 98%)	
		Infection	Overall VAP			•	Mean: 15.2 → 9.3 (p=0.37)	
			Overall BSI (Control)			•	Mean: 4.5 → 5.0 (p=0.98)	
		Costs/Savings						

Table 18. Outcomes for VAP articles that control for confounding and secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Apisarnthanarak, Thailand - 2007[108]	Educational program/ No Intervention (usual care)	Adherence	HOB elevation	◊			45% → 84% (p<0.05)	Period 1=12 mos (baseline period), Period 2=12 mos (intervention period), Period 3=24 mos (ongoing intervention and followup period). SICU and CCU served as controls. Level of significance reflects the change in slope, not change in level from time series analysis. Period 3 shows sustained change from period 1 even though it is nonsignificantly different than period 2.
		Infection	MICU period 1 vs. period 2	•			20.6 → 8.5 (p=0.002)	
			MICU period 2 vs. period 3			•	8.5 → 4.2 (p=0.07)	
			SICU all periods (Control)			•	5.4 → 5.6 → 5.5 (p=0.22,p=0.82)	
			CCU all periods (Control)			•	4.4 → 4.8 → 4.6 (p=0.48, p=0.20)	
		Costs/Savings	MICU hospitalization costs per patient	◊			$466 → $293 → $254 (p<0.001)	
			MICU monthly antibiotic cost for VAP	◊			$4769 → $2622 → $2378 (p<0.001)	
			SICU hospitalization costs per patient (Control)			◊	$399 → $384 → $395 (p=NS)	
			SICU monthly antibiotic cost for VAP (Control)			◊	$2901 → $2884 → $2799 (p=NS)	
			CCU hospitalization costs per patient (Control)			◊	$404 → $401 → $415 (p=NS)	
			CCU monthly antibiotic cost for VAP (Control)			◊	$2876 → $2991 → $2994 (p=NS)	
Bouadma, France - 2010[109]	Multifaceted prevention program/ No Intervention (usual care)	Adherence[a]	Complete bundle	◊			0% → 28.8% (p<0.0001)	
			Hand hygiene			◊	68% → 67% (p=0.07)	
			HOB elevation	◊			5% → 58% (p<0.0001)	
			Oral care	◊			47% → 90% (p<0.0001)	
		Infection	Overall	•			22.6 → 13.1 (p=0.001)	
		Costs/Savings						

Table 18. Outcomes for VAP articles that control for confounding and secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Marra, Brazil - 2009[55]	Phase 3: IHI VAP bundle, immediate correction of process measures, provider education, and feedback to providers/ Phase 1: CDC VAP bundle Phase 2: CDC VAP bundle + immediate correction of process measures	Adherence	HOB elevation[b]				74.1% → 89.5% → 96.8%	
			Daily sedation holiday[b]				? → 98.9%	
		Infection	Overall	•			Mean: 16.4 → 15.0 → 10.4 (p=0.05, by ANOVA)	
		Costs/Savings						
Papadimos, United States - 2008[57]	FASTHUG protocol/ Procedural interventions	Adherence						
		Infection	Overall	•			19.3 → 7.3 (p=0.0004)	
		Costs/Savings						
Hawe, United Kingdom - 2009[51]	Active implementation of VAP bundle/ Passive implementation of VAP bundle	Adherence	Overall	◊			0% → 54% (p<0.0001)	Level of significance reflects two samples tests not time series analysis. Statistical process control analysis also showed improvement during the implementation.
			HOB elevation	◊			54% → 94% (p<0.001)	
			Oral care	◊			8% → 100% (p<0.001)	
			Daily weaning plan	◊			52% → 72% (p=0.039)	
			Daily sedation holiday			◊	72% → 82% (p=0.23)	
		Infection	Overall	•			19.2 → 7.5 (p<0.01) Rate Ratio: 0.39 (99% CI, 0.16 to 0.96)	
		Costs/Savings						

Table 18. Outcomes for VAP articles that control for confounding and secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Cheema, United States - 2011[50]	Phase 3: VAP bundle with flow sheet/ Phase 1: Provider education on VAP bundle and VAP prevention; Phase 2: VAP bundle with checklist	Adherence						During the first third of the VAP bundle implementation period, adherence with the VAP bundle ranged from 48% to 59%. During the last third of the VAP bundle implementation period, adherence with the VAP bundle ranged from 65% to 78%.
		Infection	Overall	•			4.2 → 0.7 → 4.8 → 0.8 (p=0.059, p=0.042, p=0.047 respectively compared to prior phase)	
		Cost/Savings						
Berenholtz, United States - 2011[47]	VAP bundle and daily goal sheets/No Intervention (usual care)	Adherence	Overall	◊			32% → 84% (p<0.001)	
		Infection	Overall	•			Median: 5.5 → 0 (p<0.001) Mean: 6.9 to 2.4	
		Costs/Savings						
DePalo, United States - 2010[67]	VAP bundle with daily assessment/ No Intervention (usual care)	Adherence	Complete bundle	◊			60% → 78% (p<0.0001)	Median VAP rate ranged from 0 to 2.76 during the study period. For infection rate, no significant time trend was noted (p=0.60).
		Infection	Overall			•	Median: 0.58 → 0 (p=0.075)	
		Costs/Savings						
Prospero, Italy - 2008[110]	Educational program/No Intervention (usual care)	Adherence						P-value was adjusted for SAPS II, APACHE II, and trauma status.
		Infection	Overall	•			36.9 → 22.5 (p=0.03)	
		Costs/Savings						
Barrera, Colombia - 2011[48]	Hand hygiene promotion/ No Intervention (usual care)	Adherence	ABHR use	◊			9.2% annual increase (p<0.001)	ABHR use is an indirect measure of hand hygiene.
		Infection	Overall			•	9 → 14 (p=0.87)[a]	
		Cost/Savings						

Table 18. Outcomes for VAP articles that control for confounding and secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Morris, Scotland - 2011[56]	VAP bundle - sedation holiday, elevated bed, oral care, with checklist and feedback/ implemented protocols for bed elevation and weaning; intermittent audits with no recording or feedback	Adherence	Complete bundle				? → 70%	Adherence was measured through chart review. Overall relative risk reduction (RRR) was 40% (95% CI: 20% to 67%; p=0.001). RRR was greater for patients that required six or more days in the ICU (RRR=44%; 95% CI: 22% to 67%). RRR for patients that required 14 or more days in the ICU was 35% (95% CI: 13% to 56%).
			HOB elevation and oral care				? → >95%	
		Infection	Overall	•			32 (95% CI: 27 to 35) → 12 (95% CI: 9 to 15) (p<0.001)	
		Cost/Savings						
Omrane, Canada - 2007[111]	VAP prevention protocol/ No Intervention (usual care)	Adherence						Pre-/post-test was significantly different, but adjusted rate ratio using regression analysis was not.
		Infection	Overall			•	25.0 → 22.3 (p=NS) Adjusted rate ratio: 0.86 (95% CI: 0.71 to 1.05)	
		Costs/Savings						
Harris, United States - 2011[74]	Hand hygiene, VAP bundle, standardizing central line care/ No Intervention (usual care)	Adherence						Outcomes were adjusted for patient's age, sex, and race as well as insurance coverage, comorbidities, and specialty of treating physician. The adjusted average PICU cost during the intervention period was -$3,948 (95% CI: -$10,678 to $2,782). The adjusted average PICU cost during the postintervention period was -$8,826 (95% CI: -$13,950 to -$3,702). The adjusted average cost per hospital stay during the postintervention period was -$12,136 (95% CI: -$19,058 to -$5,214).
		Infection	Overall	•			1.9 → 2.6 → 0.7 (OR=1.44; 95% CI: 0.71 to 2.92; OR=0.37; 95% CI: 0.15 to 0.97; p<0.05; compared to baseline)	
		Cost/Savings	Average PICU cost of stay	◊			$34,365 (SD $2,446) → $30,175 (SD $2,139) → $25,938 (SD $1,146) (compared to baseline p<0.01)	
			Average hospital cost of stay	◊			$54,323 (SD $3,217) → $46,773 (SD $2727) → $42,071 (SD $1,700) (compared to baseline p<0.01)	
			Projected annual cost savings				$12 million	

Table 18. Outcomes for VAP articles that control for confounding and secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Dubose, United States - 2010[112]	Quality Rounds Checklist (QRC)/ No Intervention (usual care)	Adherence	HOB elevation[b]				35.2% → 93.2%	P-value was adjusted for age, mechanism of injury, Glasgow Coma Scale, and Injury Severity Score.
			Sedation holiday[b]				77.8% → 94%	
		Infection	Overall	•			12.41 → 8.74 (p=0.008)	
		Costs/Savings						
Kulvatunyou, Thailand - 2007[113]	Educational program/ No Intervention (usual care)	Adherence						P-value was adjusted for age.
		Infection	Overall	•			39.7 → 10.5 (p<0.001)	
		Costs/Savings						

Abbreviations: APACHE II = Acute Physiological and Chronic Health Evaluation II; BSI = bloodstream infection; CCU = cardiac care unit; CDC = Centers for Disease Control; CI = confidence interval; FASTHUG = see Papadimos et al. (2008); HOB = head of bed; MICU = medical ICU; OR = odds ratio; SICU = surgical ICU; SAPS II = Simplified Acute Physiological Score II

• was used for infection rate outcomes

◊ was used for adherence and costs/savings outcomes

[a]Adherence data are from Bouadma et al. Crit Care Med 2010; 38(3): 789-796132

[b]Reported, but not analyzed

Zaydfudim et al. (2009)[107]

Summary

Zaydfudim et al. evaluated a strategy of audit and feedback with organizational change and a provider reminder system.[107] The setting was a United States surgical ICU, and duration of the intervention was 1 year. This controlled interrupted time series found a significant improvement in overall adherence but not in VAP rates. The rate of bloodstream infections (BSI), which did not change during the study, served as the control measure to detect secular trends.

Description

This study used an electronic dashboard system to monitor adherence with a ventilator bundle in a 21-bed surgical intensive care unit (SICU). The dashboard was the default screen saver for SICU clinical workstations that provided access to the electronic medical records. Adherence with the dashboard parameters was reviewed twice daily during interdisciplinary rounds and also in daily reports to physician and nurse leadership. This study was an interrupted time series analysis of VAP rates. Adherence was measured during each of the four quarters of the intervention, but there was no measurement during the baseline period. Quarterly individual parameter adherence was compared using 95% confidence intervals. The change in overall adherence was estimated with linear regression. The effects of the QI strategies on VAP rate were estimated using a segmented linear regression model. The rate of bloodstream infection was used as the control measure.

Results and Limitations

Overall adherence with all six ventilator bundle processes improved from 39 percent during the first quarter of the intervention to 89 percent at the end of 1 year ($p<0.001$). From the first quarter of the intervention to the final quarter, adherence with spontaneous breathing trials increased from 86 percent (95% CI: 75 to 97%) to 97 percent (95% CI: 95 to 100%); head of bed elevation increased from 92 percent (95% CI: 89 to 95%) to 98 percent (95% CI: 97 to 99%), and adherence with oral care improved from 84 percent (95% CI: 78 to 90%) to 98 percent (95% CI: 97 to 98%) as noted in Table 18. Thus, both head of bed elevation and oral care showed significant changes. The mean VAP rate decreased from a baseline of 15.2 (SD, 7.0) to 9.3 (SD, 4.9) per 1,000 ventilator-days in the intervention period ($p=0.01$). Analysis using time series data with segmented linear regression found that the change was not statistically significant ($p=0.37$; see Appendix Table G1). The authors noted there was no evidence of serial autocorrelation (see Methods section for further details). There were 121 cases of VAP during baseline and 31 postintervention. During the study, there was no change in the control measure of bloodstream infections; rates were 4.5 (SD, 3.8) at baseline and then 5.0 (SD, 2.4) per 1,000 catheter-days at postintervention ($p=0.98$). Patients in the postintervention period had higher APACHE II scores ($p<0.002$).

Limitations of this single-center study include the use of bloodstream infection rate as the single control measure and limited details from the time series analysis. The lack of a statistically significant finding on segmented linear regression may have been related to the small number of infections and limited duration of followup subsequent to implementation. Not measuring adherence during the baseline period is also a limitation.

Apisarnthanarak et al. (2007)[108]

Summary

Apisarnthanarak et al. evaluated a strategy of provider education and organizational change to usual care.[108] The setting was a medical ICU (MICU) in Thailand and duration of the intervention was 3 years. This controlled interrupted time series found significant improvements in adherence to head of bed elevation, VAP rate, and hospitalization costs. The rate of VAP in two ICUs (surgical ICU [SICU] and cardiac care unit [CCU]) that served as control units did not change during the study.106

Description

In this study, the educational program was modeled after a successful program developed by Zack et al.;[135] the intervention involved nurses and respiratory therapists and was continuously monitored and reinforced. The quality improvement action plan was designed by a multidisciplinary team; this team included hospital administration. The intervention unit was an 8-bed MICU; control units were an 8-bed SICU and 8-bed CCU.

Data were reported for the baseline period, for year 1 of the intervention, and then for followup during years 2 and 3. Categorical variables were compared using chi-square or Fisher's exact tests and continuous variables with Student's t-test. Trend analysis was performed using segmented regression. Hospital costs were estimated from the Thai insurance and hospital reimbursement systems; costs were converted to U.S. dollars.

Results and Limitations

Adherence improved during the study; maintaining head of bed elevation improved from 45 percent at baseline to 80 percent in year 1 and to 84 percent in years 2 and 3 ($p<0.05$ for each period, compared with baseline). The VAP rates were 20.6 (SD, 4.8) per 1,000 ventilator-days at baseline, 8.5 (SD, 4.2) in year 1, and 4.2 (SD, 3.1) in years 2 and 3; compared with baseline, rates improved ($p<0.001$ for each intervention period). Segmented regression analysis showed a statistically significant change in slope in the MICU VAP rate during the first year of implementation compared with baseline; change in slope of -1.171 (95% CI: -2.128 to -0.214, p=0.0018); change in slope for the final two years of followup compared with the year one was not statistically significant (β = -1.115, 95% CI: -5.867 to 1.643, p=0.07). Change in intercepts between time periods did not show a statistically significant difference, indicating that the initial improvements were sustained (Appendix Table G1). There were 470 patients (45 cases of VAP) during the baseline period and 952 patients (18 infections) in the 3 years postintervention. The authors found no significant differences in patient characteristics or severity of illness from one study period to the next. There were no changes in VAP rates in the two control units: VAP rates for the SICU were 5.4, 5.6, and 5.5 for the 3 periods (p=0.22, p=0.82, year 1 vs. baseline and year 1 vs. year 2 and 3, respectively); the CCU VAP rates were 4.4, 4.8, and 4.6 (p=0.48, p=0.20, year 1 vs. baseline and year 1 vs. year 2 and 3, respectively).

The authors reported a statistically significant decrease in mean hospital stay in MICU patients in periods 2 and 3 compared with the baseline: 5.5 days, 5.1 days, 14 days, respectively, $p<0.001$ for periods 2 and 3 versus baseline (period 1). The authors also report a significant decrease in hospitalization costs for each patient: $293, $254, $466, respectively, $p<0.001$ for periods 2 and 3 versus baseline (period 1).

This study was from a small (8-bed) ICU in a single center in Thailand.

Interrupted Time Series

Bouadma et al. (2010)[109]

Summary

Bouadma et al. evaluated organizational change, provider education, audit and feedback, and provider reminder systems. The setting was a European medical ICU and duration of the intervention was 30 months.[109,132] The interrupted time series showed significant improvement in several adherence rates, including the complete bundle, and a decreased VAP rate.

Description

The QI initiatives in this study included use of technical improvements, such as use of a bicolored ribbon to indicate appropriate head of bed elevation. Adherence was determined using detailed definitions and was based on frequent observations.[132] The Wilcoxon rank sum test was used to compare continuous data and Fisher's exact test for categorical data. The authors calculated both overall VAP rate as well the rate of first VAP episode. The risk of first VAP episode over time was evaluated using segmented regression analysis of quarterly rates using a Poisson model. Adherence was measured at baseline and then 4 times during the study at 1, 6, 12, and 24 months. Analysis with Cochran-Armitage test was used to determine statistical significance of linear trend for adherence rates.

Results and Limitations

Adherence at baseline and at 24 months to head of bed elevation increased from 5 percent to 58 percent ($p<0.0001$) and good oral hygiene from 47 percent to 90 percent ($p<0.0001$).[132] Complete adherence to all six preventive interventions in the bundle increased from 0 to 28.8 percent ($p<0.001$). Hand hygiene was unchanged throughout the study (68% and 67%).

The VAP rates per 1,000 ventilator-days were 22.6 and 13.1, respectively, during baseline (45 month study period) and intervention (30 month study period). Segmented regression analysis was reported as showing a nonsignificant increase in first VAP episode rate during baseline ($p=0.11$) and a significant decrease in the rate during intervention ($p=0.001$)[109] (Appendix Table G1). There were 270 episodes of VAP during the baseline period and 142 during the intervention period. Patients in the intervention period had a higher Simplified Acute Physiological Score II (SAPS II) ($p=0.002$) and greater severity of underlying disease ($p=0.04$).

Marra et al. (2009)[55]

Summary

Marra et al. reported the outcomes with use of a series of increasingly intense, QI interventions implemented in three phases over an 8-year period. The final phase included provider education, organizational change, and audit and feedback. The setting was a medical-surgical ICU in Brazil.[55] This interrupted time series showed a decrease in the VAP rate.

Description

Organizational changes in this study included using new standards/protocols and having designated staff members responsible for implementation. This study was conducted in a 38-bed medical-surgical ICU. Phase 1 (baseline) involved implementing evidence-based measures to reduce VAP and twice yearly audit and feedback for a small number of ventilator patients. In

Phase 2, performance monitoring to improve adherence was done at the patient's bedside; phase 1 activities were continued. Phase 3 occurred following the hospital CEO's statement indicating "zero tolerance for VAP." Added interventions in this phase, which also included new preventive interventions of oral care and subglottic suction, included having an ICU nurse monitor the ventilator bundle each weekday and intervene if nonadherence was noted and providing monthly feedback reports to ICU staff. VAP rates during the 3 periods were compared using ANOVA. Segmented regression analysis of time series data were used only to study changes made within Phase 3 (Appendix Table G1).

Results and Limitations

Adherence to process measures was presented for this study, but statistical analysis was not included. During the study, adherence with head of bed elevation increased from 74.1 percent in Phase 1 (baseline), to 89.5 percent in Phase 2, and 96.8 percent in Phase 3. Adherence with "daily sedation vacations" was 98.9 percent in Phase 3. The mean VAP rate per 1,000 ventilator-days decreased from 16.4 to 15.0 to 10.4 over the three periods (p=0.05 by ANOVA). There were 91 cases of VAP in Phase 1 (baseline), 234 in Phase 2, and 62 in Phase 3. Limitations of this study include lack of a control group, not providing statistical analysis of adherence data, not using interrupted time series analysis to compare the 3 phases, and not comparing patient characteristics for the 3 periods.

Papadimos et al. (2008)[57]

Summary

Papadimos et al. studied the impact of using audit and feedback and organizational change. The setting was a United States-based surgical ICU.[57] Time series analysis showed a significant decrease in VAP rates.

Description

During 2004 and 2005, an intensivist-led multidisciplinary team, including nursing, anesthesiology and respiratory therapy, conducted an improvement project to reduce cases of VAP in a 10-bed SICU. In year 1, procedural interventions were highlighted such as oral care. In year 2 (2005), the emphasis changed to an evaluative intervention, that is, the preventive interventions were emphasized on twice-daily patient rounds by the critical care team. This evaluative approach used the concept of "FASTHUG" for daily assessment of Feeding, Analgesia, Sedation, Thromboembolic prevention, Head of bed elevation, Ulcer prophylaxis, and Glucose control. The year 2 work was in response to lack of significant improvement in the VAP rate during year 1. The authors performed a number of analyses. A two-tailed z-test was used to compare the rates for single years, and followup pairwise comparison was done using a Wilcoxon test. Interrupted time series analysis with ARIMA (autoregressive integrated moving average) modeling was used to test for the impact of intervention on monthly rates of VAP. Consequently, the reduction in VAP may be underestimated.

Results and Limitations

The authors did not report adherence with preventive process measures. The VAP rate decreased from 19.3 per 1,000 ventilator-days at baseline (in 2003 before any intervention) to 7.3 in 2005, the first year of the FASTHUG program (p<0.01; the VAP rate in 2004 was 16.6). The median VAP rate during 2005 (FASTHUG) was lower than both baseline and the less-intensive

year 1 intervention, p=0.028 for both comparisons. There were 24 cases of VAP in 2003, 26 in 2004, and 11 in 2005. A time series analysis was also conducted for preFASTHUG compared with postFASTHUG. This analysis reported a statistically significant drop in VAP rates during the postFASTHUG period (p=0.0004; Appendix Table G1). There was a statistically significant increase in severity of illness during the postFASTHUG period.

Hawe et al. (2009)[51]

Summary

Hawe et al. reported on their intervention using audit and feedback, organizational change, provider education, and provider reminder systems. The setting was a European surgical/medical ICU and the intervention lasted 10 months.[51] This interrupted time series study found a significant increase in adherence to several measures, including overall adherence, and a statistically significant decrease in VAP rate.

Description

The baseline for this study was considered passive implementation and consisted of approving preventive interventions for VAP as ICU policy. Active implementation included the addition of an educational intervention, feedback about adherence and VAP rates, and use of various prompts as reminders of the preventive interventions. VAP rates were compared between the passive and active implementation periods using rate difference and rate ratio tests. In addition, the authors used SPC (statistical process control) analysis of the number of ventilator-days between episodes of VAP. Adherence was measured for 50 consecutive ventilated patients three times during the study, including one measurement during the baseline period.

Results and Limitations

Adherence with all six preventive interventions of the ventilator bundle increased from 0 percent at baseline to 54 percent in the eighth month of the intervention (p<0.0001). Adherence with head of bed elevation increased from 54 percent to 94 percent (p<0.001), daily weaning plan from 52 percent to 72 percent (p=0.039), and daily sedation holiday from 72 percent to 82 percent (p=0.23) over the same interval. VAP rates decreased from 19.2 per 1,000 ventilator-days at baseline to 7.5 during the intervention. The rate ratio was 0.39 (99% CI: 0.16 to 0.96; p=0.01). The SPC analysis of "days since last VAP" showed an increase in days between cases of VAP during active implementation. During this period there were two points above the upper control limit, indicating change consistent with an external cause, that is, active implementation. There were 49 episodes of VAP during the baseline period and 10 episodes during active implementation. The mean Acute Physiology and Chronic Health Evaluation II (APACHE II) score did not change.

The major limitation of this study is lack of a formal interrupted time series analysis.

Cheema et al. (2011)[50]

Summary

Cheema et al. reported on the use of audit and feedback, a provider reminder system, organizational change, and provider education.[50] This took place in a pediatric ICU in the United States and lasted 29 months. This interrupted time series found a significant improvement in infection rates during the final phase.

Description

This intervention was conducted a three phases. The baseline period consisted of 13 months. In the first phase after the baseline period, nurses and respiratory therapists used the VAP prevention checklist everyday on every ventilated patient. The second phase was a 4-month washout phase as the staff found the checklist too cumbersome. In the last phase of the intervention a flow sheet was implemented. This provided cues for VAP prevention bundle practices. Staff was also educated on VAP prevention and the prevention bundle. Statistical process control (SPC) analysis (u-charts, p-charts, and g-charts) were used to analyze the outcomes. The p-values reported originate from a t-test and are comparing the phase to the phase that preceded it.

Results and Limitations

During the baseline period, the VAP rate was 4.2 infections per 1,000 ventilator-days. During the first phase of the intervention it fell to 0.7 (p=0.059), but during the washout period, it rose to 4.8 infections per 1,000 ventilator-days (p=0.042). The VAP rate fell again during the last phase of the intervention period to 0.8 (p=0.047). Self-reported adherence ranged from 48 percent to 59 percent during the first part of the checklist phase and by the end of the checklist phase, adherence ranged from 65 percent to 78 percent.

Number of VAP cases was not provided and the statistical analysis (p-values) was not adjusted for multiple comparisons. In addition, the mean rates in the SPC charts did not correspond to the four study periods.

Simple Before-After Studies

Berenholtz et al. (2011)[47]

Berenholtz et al. reported on use of audit and feedback, organizational change, provider education, and patient (family) education. Data were analyzed from 112 ICUs in 72 hospitals, predominantly in Michigan, as part of the Keystone ICU project. Quarterly data for VAP were reported during the 30-month intervention period; however, only one baseline measurement was obtained.[47] Analysis showed a significant improvement in both overall adherence and VAP rate.

The QI strategies were used to improve adherence with five evidence-based recommendations for patients on ventilators to prevent VAP. The 112 ICUs reported data for 3,228 ICU-months and 550,800 ventilator-days during the entire study period. The data were summarized using median and mean VAP rates. A generalized linear latent and mixed model with Poisson distribution for quarterly number of VAP infections was used to explore the relationship between time since implementation and VAP rates. Overall adherence with the preventive interventions increased from 32 percent at baseline to 84 percent in the final quarter (p<0.001); the "relative risk" of complete adherence was 2.59 (95% CI: 2.49 to 2.69). The overall median VAP rate decreased from 5.5 per 1,000 ventilator-days (mean 6.9) during the 3-month baseline to 0 infections (mean 2.4 infections) at 28-30 months (p<0.001). The multilevel Poisson regression model showed VAP incidence rate ratio of 0.28 (95% CI: 0.24 to 0.34) during the final quarter. This study found a significant decrease in VAP rates at multiple points during the 30-month intervention, even with the relatively low baseline rate. In addition, there was a significant decrease in the VAP incidence rate ratio in all ICU subgroups (such as teaching status, ICU type, and ICU size), except in hospital size of fewer than 200 beds, at 16-18 and 28-30 months after implementation.

Some limitations of this study are the lack of uniformity in surveillance across sites or information pertaining to other contemporaneous QI efforts in the hospitals, and the variability in the sample provided. The hospitals that provided baseline data were not the same as those that provided postintervention data. However, a subgroup analysis was provided of hospitals with complete data and the authors found similar results. In addition to the limitations noted above, the following strengths are worth noting: (1) extensive hospital participation across the state and surrounding area, (2) sustained reductions in majority of the settings, and (3) similar results reported in the subgroup analysis of hospitals with complete data.

DePalo et al. (2010)[67]

DePalo et al. reported on an intervention that included audit and feedback, organizational change, and provider education. This was a statewide (Rhode Island) study in 23 ICUs (263 ICU beds in 11 hospitals) over a 27-month period.[67] There was a significant improvement in overall adherence, but not in the VAP rate.

This study applied the approach from the Michigan Keystone project[46,47] to ICUs in Rhode Island. For VAP, data were available for 679 of 690 months (98.4% complete). During the study, quarterly data were summarized using median and mean VAP rates; a mixed effects model with Poisson distribution was used to examine the number of infections over time. Complete adherence with the VAP preventive interventions showed a statistically significant linear increase from 60 percent in the baseline quarter to 78 percent in the final quarter ($p<0.0001$). Mean VAP rates decreased from 3.44 infections per 1,000 ventilator-days at baseline (median 0.58) to 2.92 (median 0) in the final quarter. Using the mixed model framework, VAP rate during the first year (baseline and intervention) compared with the final year was reported as showing a decreasing trend ($p=0.075$). No overall time trend was noted for VAP ($p=0.60$). While this study found improved adherence, the low baseline VAP rate made it difficult to detect a significant change in this study.

Prospero et al. (2008)[110]

Prospero et al. reported on a 4-month study of an educational program and organizational change to reduce VAP in a 12-bed medical-surgical ICU.[110] The baseline period had 104 ventilator patients and 27 cases of VAP, postintervention there were 81 ventilator patients with 17 cases of VAP. Time-dependent Cox regression models were used to assess the association between potential risk factors and VAP. Adherence was not measured. There was a statistically significant improvement (i.e., decrease) in the VAP rate from 36.9 to 22.5 infections per 1,000 ventilator-days ($p=0.03$).

Barrera et al. (2011)[48]

Barrera et al. described a 4-year study in six ICUs (general, trauma, neurosurgery, burn, pediatric and neonatology) in Colombia investigating organizational change and provider education.[48] There were 14,516 patients included over the entire study of which 2,398 acquired a HAI. Risks for VAP and HAI were compared using Poisson regression. Alcohol-based hand rub was used as an indirect measure of hand hygiene. Use of the hand rub significantly improved 9.2 percent annually ($p<0.001$). There was a nonsignificant increase in VAP rate (per 1000 ventilator-days) from 9 to 14 ($p=0.87$).

Morris et al. (2011)[56]

Morris et al. assessed the impact of organizational change, provider education, audit and feedback, and provider reminder systems on VAP rates in surgical ICUs in Scotland.[56] There were 1,961 patients over the 4-year study period. Data were analyzed using a Poisson regression. The study reported 70 percent adherence to the complete bundle and 95 percent adherence to HOB elevation and oral care. Adherence was measured through chart review. The overall VAP rate (per 1000 ventilator-days) significantly decreased from 32 (95% CI: 27 to 35) to 12 (95% CI: 9 to 15; p<0.001). The overall relative risk reduction was significant (RRR: 40%; 95% CI: 22% to 67%). Patients that required six or more days in the ICU had a greater relative risk reduction (RRR: 44%; 95% CI: 22% to 67%). Patients that required 14 or more days in the ICU had a smaller relative risk reduction (RRR: 35%; 95% CI: 13% to 56%).

Omrane et al. (2007)[111]

Omrane et al. reported on a 6-month intervention to reduce VAP in a 24-bed ICU using organizational change, provider education, and provider reminder systems. The baseline period had 349 ventilator patients and 23 cases of VAP, postintervention there were 360 ventilator patients with 22 cases of VAP.[111] Poisson regression analysis was performed to assess the effect of the intervention on the risk of VAP. Adherence was not reported. While the postintervention VAP rate decreased from 25.0 to 22.3 infections per 1,000 ventilator-days, regression analysis did not demonstrate an association between the intervention and VAP rate (adjusted rate ratio 0.86, 95% CI: 0.71 to 1.05).

Harris et al. (2011)[74]

Harris et al. reported on VAP rates in pediatric ICUs within the United States assessing the impact of organizational change, provider education, audit and feedback and provider reminder systems.[74] There were a total of 2,379 patients within this 3-year study. The study was broken up into baseline, intervention and postintervention periods. Infection rates were analyzed using logistic regression. Adherence to intervention was not assessed. Outcomes were adjusted for patient’s age, sex, race, insurance coverage, comorbidities, and specialty of treating physician. Overall infection rate (per 1000 ventilator-days) changed from 1.9 to 2.6 to 0.7. The odds ratios for the intervention (OR: 1.44; 95% CI: 0.71 to 2.92) and postintervention (OR: 0.37; 95% CI: 0.15 to 0.97) were compared to baseline (p<0.05). Average costs of PICU stay decreased from $34,365 to $30,175 to $25,938 during the three study periods and were statistically significant when compared to baseline (p<0.01). Average costs of hospital stay decreased from $54,323 to $46,773 to $42,071 during the study periods and were also statistically significant when compared to baseline. Adjusted costs were also reported.

Dubose et al. (2010)[112]

Dubose et al. described a 13-month intervention using a Quality Rounds Checklist to reduce VAP in a trauma ICU.[112] The complete intervention included audit and feedback, organizational change, provider education, and provider reminder systems. There were 577 patients with 33 cases of VAP in the baseline period and 570 patients and 25 cases of VAP in the intervention period. Multivariable logistic regression was used to obtain adjusted rates of VAP. Data showing increased rates of adherence were presented but no statistical analysis was reported. There was a statistically significant improvement in the VAP rate decreasing from 12.41 to 8.74 infections per 1,000 ventilator-days (adjusted mean difference 6.652, 95% CI: 4.04 to 9.27; p=0.008).

Kulvatunyou et al. (2007)[113]

Kulvatunyou et al. described their 1-year intervention of provider education and organizational change to reduce VAP in a six bed surgical ICU.[113] There were 85 and 89 patients in the baseline and intervention periods, respectively, requiring ventilator support for 48 hours or more, and there were 42 cases of VAP during baseline and 11 during the intervention. Multiple logistic regression analysis was performed to identify independent risk factors associated with VAP. No data on adherence were presented. The VAP rate decreased from 39.7 to 10.5 infections per 1,000 ventilator-days ($p<0.001$).

Studies That Do Not Control for Confounding or Secular Trend

Twenty-five studies that addressed prevention of ventilator-associated pneumonia used a simple two sample test to analyze outcomes[80,82,89,91,94,97,103,114-131] (Appendix Table F1). All 25 studies were simple before-after study designs. QI strategies to reduce rates of VAP were as follows: 18 used audit and feedback,[80,82,94,97,114,115,117-119,121-125,127,128,130,131] 18 provider education,[80,89,94,103,114-119,121-124,127,128,130,131] 17 organizational change,[80,94,97,114-116,118-121,124-130] and 7 used provider reminder systems.[91,114,122,124,125,129,130] Nineteen studies used 2 or more QI strategies.[80,94,97,114-119,121-125,127-131] The combination of audit and feedback with the base strategies was used in 13 studies;[80,94,97,115,117-119,121,123,125,127,128,131] Five studies[114,122,124,125,130] added provider reminder systems to this combined approach. Fifteen of these studies were from the United States.[80,82,94,97,114-116,119,122-127,129] There were less than 30 postintervention cases of VAP in 8 of 13 studies reporting this information.[80,89,114,115,119,120,124,129]

Strength of Evidence

As noted in the initial section of this chapter, evidence from studies was evaluated based on the combination of QI strategies that were performed. The strength of evidence for the most common combinations of QI strategies to promote adherence to preventive interventions and reduce VAP rates are presented in Table 19 to Table 24. For all of these tables, except for "readiness for weaning," adherence rates are considered direct measures. An objective of this review is to assess whether QI strategies improved adherence to evidence-based practices that have been shown to reduce rates of HAI including VAP. Therefore, adherence to process measures is considered a direct measure for this review.

Audit and Feedback and Provider Reminder Systems With the Base Strategies Compared With Usual Care

Overall, strength of evidence for most outcomes in the eight studies using this combination of strategies is moderate, including adherence rates (overall, head of bed elevation, and oral care) and for studies that measured infection rate and both adherence and infection rate. Strength of evidence is insufficient for the adherence measure of "readiness to wean" (Table 19). One of these studies presented results on costs/savings using this combined QI approach.[74]

Overall Adherence

Three studies reported this outcome.[51,107,109] As shown in Table 17, 1 study[107] is of higher quality, 1 is medium,[109] and 1 is lower.[51] However, the higher-quality study did not measure adherence during the baseline period. These studies are quasi-experimental. The risk of bias is medium. Zaydfudim et al.[107] showed an increase in overall adherence from 39 percent to 89 percent ($p<0.001$), Bouadma et al.[109,132] showed an increase in adherence with the complete

bundle from 0 to 28.2 percent (p<0.0001),and Hawe et al. (2009)[51] showed an increase from 0 percent to 54 percent (p<0.0001). These results are consistent given the similar direction of change. This outcome is a direct measure of adherence. Given the direction and magnitude of change, the evidence is judged to be precise. The strength of evidence is considered to be moderate that audit and feedback and provider reminder systems with the base strategies improves overall adherence to a bundle of VAP preventive interventions compared with usual care.

Table 19. Audit and feedback and provider reminder systems with the base strategies compared with usual care within VAP

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Adherence: overall/summary	1 controlled study[107] 2 interrupted time series[51,109]	Medium	Consistent	Direct	Precise	***Moderate***
Adherence: HOB elevation	2 controlled studies[58,107] 2 interrupted time series[51,109]	Medium	Consistent	Direct	Precise	***Moderate***
Adherence: oral care	1 controlled study[107] 2 interrupted time series[51,109]	Medium	Consistent	Direct	Precise	***Moderate***
Adherence: readiness to wean	2 controlled studies[58,107] 1 interrupted time series[51]	Medium	Consistent	Indirect	Imprecise	***Insufficient***
Infection rate	1 Controlled study[107] 3 interrupted time series[50,51,109] 3 simple before-after [56,74,112]	Medium	Consistent	Direct	Precise	***Moderate***
Adherence and infection rates	1 controlled study[107] 2 interrupted time series[51,109]	Medium	Consistent	Direct	Precise	***Moderate***

Abbreviations: HOB = head of bed; VAP = ventilator-associated pneumonia.
Note: The base strategies are organizational change and provider education.

Head of Bed Elevation

Four studies reported this outcome.[51,58,107,109] As shown in Table 17, 1 study[107] is of higher quality, 2[58,109] are medium, and 1[51] is lower. However, the higher quality study did not measure adherence during the baseline period. Three of the 4 studies are quasi-experimental, and the cluster randomized, controlled trial had limitations (see below); thus this body of evidence was judged to have a medium risk of bias.

Three of the 4 studies showed a statistically significant increase in adherence rate for head of bed elevation: Zaydfudim et al. [107] found an increase from 92 percent (95% CI: 89 to 95%) to 98 percent (95% CI: 97 to 99%) during the intervention; Bouadma et al.[109,132] found an increase of 5 percent to 58 percent (p<0.0001); and Hawe et al.[51] reported an increase from 54 percent to 94 percent (p<0.001). In the cluster randomized, controlled trial, Scales et al.[58] reported an increase in head of bed elevation adherence from 49.8 percent to 89.6 percent in the intervention group; this change during the intervention was statistically significant, but when analyzed compared to the control group, the summary ratio of odds ratios was not statistically significant (3.12; 95% CI: 0.79 to 12.41; p=0.11). Although Scales et al. conducted a cluster randomized, controlled trial, it was limited by the small number of units randomized and it was the shortest in duration, 4 months, compared with 10 months or more for the other studies. As discussed above, Scales et

al.[58] had a number of limitations, many of which may have introduced bias to accept the null hypothesis. These results are judged as consistent given the similar direction of change.

Head of bed elevation is a direct measure of adherence. Based on the direction and magnitude of change, the evidence was judged to be precise. The strength of evidence is considered to be moderate that audit and feedback and provider reminder systems with the base strategies improves adherence to head of bed elevation compared with usual care.

Oral Care

Three studies reported this outcome.[51,107,109] As shown in Table 17, 1 study[107] is of higher quality, 1[109] is medium, and 1[51] is lower. However, the higher-quality study did not measure adherence during the baseline period. These 3 studies are quasi-experimental; thus this body of evidence was judged to have a medium risk of bias.

The 3 studies showed a statistically significant increase in adherence rate for oral care: Zaydfudim et al.[107] found an increase from 84 percent (95% CI: 78 to 90%) to 98 percent (95% CI: 97 to 98%) during the intervention; Bouadma et al.[109,132] found an increase of 47 percent to 90 percent (p<0.0001); and Hawe et al.[51] reported an increase of 8 percent to 100 percent (p<0.001). These results are judged as consistent.

Oral care is a direct measure of adherence. Based on the direction and magnitude of change, the evidence was judged to be precise. The strength of evidence is considered to be moderate that audit and feedback and provider reminder systems with the base strategies improves adherence to oral care compared with usual care.

Assessment of Readiness of Ventilator Weaning

Three studies reported adherence related to this preventive intervention.[51,58,107] The studies report slightly different adherence rates: Zaydfudim et al.[107] and Scales et al.[58] reported adherence to spontaneous breathing trials, while Hawe et al. (2009)[51] reported on adherence to both daily assessment on readiness to wean and daily sedation holidays. As shown in Table 17, 1 study[107] is of higher quality, 1[58] is medium quality, and 1[51] is lower. However, Zaydfudim et al.[107] did not measure adherence during the baseline period. One study[58] is a cluster randomized, controlled trial (with limitations already noted above) and the other 2 are quasi-experimental.[51,107] These studies were judged to have a medium risk of bias.

All measures showed improved adherence; however, only one change was statistically significant. Hawe et al.[51] noted that adherence with daily assessment of readiness to wean improved significantly from 52 percent to 72 percent (p=0.039) but that adherence to daily sedation holiday changed from 72 percent to 82 percent (p=0.23). Zaydfudim et al.[107] noted nonsignificant change in adherence with spontaneous breathing trials of 86 percent to 97 percent; and the cluster randomized, controlled trial from Scales et al.[58] found a change in adherence to spontaneous breathing trials from 78.8 percent to 85.1 percent in the experimental ICUs and from 90.9 to 89.6 percent in the control ICUs. Neither the odds ratio for change during the 4 month intervention (1.35; 95% CI: 0.44 to 4.12; p=0.57) nor the summary ratio of odds ratios for experimental versus control (1.04; 95% CI: 0.21 to 5.03; p=0.96) was statistically significant. These results are judged to be consistent. This outcome is considered indirect because not all of the studies used direct measures of readiness of ventilator weaning.

With the lack of statistically significant change in three of the four measures, this is judged as imprecise. The strength of evidence is considered to be insufficient that audit and feedback and provider reminder systems with the base strategies improves adherence to assessment of readiness of ventilator weaning compared with usual care.

Infection Rate

Seven studies reported this outcome.[50,51,56,74,107,109,112] As shown in Table 17, 1 study[107] is of higher quality, 1[109] is medium, and 5[50,51,56,74,112] are lower. The evidence is quasi-experimental; these studies were judged to have a medium risk of bias. Six of the seven studies showed a statistically significant improvement (i.e., decrease) in VAP rate: Bouadma et al.[109] found a decrease from 22.6 to 13.1 infections per 1,000 ventilator-days (p=0.001); Hawe et al.[51] noted a decrease from 19.2 to 7.5 infections per 1,000 ventilator-days and the rate ratio was 0.39 (99% CI: 0.16 to 0.96); Dubose et al.[112] found a decrease from 12.41 to 8.74 (p=0.008); Cheema at al.[50] found a decrease from 4.2 to 0.8 (p<0.05); Morris et al.[56] reported a decrease from 32 to 12 (p<0.001); and Harris et al.[74] found a decrease from 1.9 to 0.7 (p<0.05). In the seventh study, Zaydfudim et al.[107] noted the mean VAP rate decreased from a baseline of 15.2 (SD, 7.0) to 9.3 (SD, 4.9) per 1,000 ventilator-days in the intervention period (p=0.01), but analysis using the more rigorous segmented linear regression found that the change was not statistically significant (p=0.37). These results are judged as consistent. Infection rate is a direct measure. Again, based on the direction and magnitude of change, the evidence was judged to be precise. The strength of evidence is considered to be moderate that audit and feedback and provider reminder systems with the base strategies improves (i.e., decreases) VAP rate compared with usual care.

Adherence and Infection Rate

Three studies reported this combination of outcomes.[51,107,109] As shown in Table 16, 1 study[107] is of higher quality, one[109] is medium, and 1[51] is lower. Given these quasi-experimental studies, the risk of bias is medium. All of the studies show a statistically significant increase in adherence for at least 2 of the preventive interventions and the two studies that measured overall adherence showed improvement. Two of the three studies also showed an improvement (i.e., decrease) in VAP rates, and in the third study,[107] the decrease was not statistically significant by time series analysis. This evidence is judged to be consistent. As noted above, these are direct measures. Finally, the evidence is judged to be precise given the direction and magnitude of change as described above, even when considering the adherence results for assessing readiness for ventilator weaning. The strength of evidence is considered to be moderate that audit and feedback and provider reminder systems with the base strategies improves both adherence and improves (i.e., decreases) VAP rate compared with usual care.

Cost/Savings

Only 1 study by Harris et al.[74] reported on this outcome, which will be discussed in the section on Key Question 1b.

Audit and Feedback With the Base Strategies Compared With Usual Care

Overall, strength of evidence is moderate related to the 4 studies using this QI approach to reduce infection rates and is low for overall adherence and studies that measure both adherence and infection rate (Table 20). None of these studies reported results for costs/savings related to this QI approach.

Overall Adherence

Two studies reported this outcome.[47,67] As shown in Table 17, both studies are of lower quality.[47,67] The evidence from the 2 lower quality studies comes from large statewide initiatives and is quasi-experimental. The evidence was judged to have a medium risk of bias. Both studies showed a statistically significant improvement in overall adherence: Berenholtz et al.[47] found an

increase from 32 to 84 percent (p<0.001), and DePalo et al.[67] found an increase of 60 to 78 percent (p<0.0001). These results are judged as consistent. Overall adherence is a direct measure. Based on the direction and magnitude of change, as well as the generalizability of these data from statewide initiatives, this evidence was judged to be precise. The strength of evidence is considered to be moderate that audit and feedback with the base strategies improves adherence to overall VAP preventive interventions.

Hand Hygiene

Only 1 study, Barrera et al., reported on this outcome.[48] Thus, strength of evidence is insufficient.

Table 20. Audit and feedback with the base strategies compared with usual care within VAP

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Adherence: overall/Summary	2 simple before-after [47,67]	Medium	Consistent	Direct	Precise	***Moderate***
Adherence: hand hygiene	1 simple before after [48]	High	Unknown	Direct	Imprecise	***Insufficient***
Infection rate	2 interrupted time series[55,57] 3 simple before-after [47,48,67]	Medium	Consistent	Direct	Precise	***Moderate***
Adherence and infection rates	3 simple before-after [47,48,67]	Medium	Consistent	Direct	Precise	***Moderate***

Abbreviation: VAP = ventilator-associated pneumonia.
Note: The base strategies are organizational change and provider education.

Infection Rate

Five studies reported this outcome.[47,48,55,57,67] As shown in Table 17, 1 study[57] is of medium quality and 4[47,48,55,67] are lower quality, although Berenholtz et al.[47] and DePalo et al.[67] represent 2 large statewide initiatives with multiple postintervention measurements. The evidence is quasi-experimental; these studies were judged to have a medium risk of bias. Four of the 5 studies showed a statistically significant improvement (i.e., decrease) in VAP rate: Papadimos et al.[57] found a decrease from 19.3 to 7.3 infections per 1,000 ventilator-days (p=0.0004), Marra et al.[55] noted a decrease from 16.4 to 10.4 infections per 1,000 ventilator-days (p=0.05 by ANOVA), and Berenholtz et al.[47] found a decrease in the median rate from 5.5 to 0 (p<0.001). DePalo et al.[67] noted the median VAP rate decreased from 0.58, the lowest baseline rate, to 0 (p=0.08). Furthermore, Barrera et al.[48] reported a nonsignificant increase in VAP rates over the study period (9 vs. 14 infections per 1,000 ventilator-days, p=0.87) These results are judged as consistent. Infection rate is a direct measure. Based on the direction and magnitude of change, and noting that Berenholtz et al. (2011)[47] and DePalo et al. (2010)[67] are statewide initiatives, the evidence was judged to be precise. The strength of evidence is considered to be moderate that audit and feedback with the base strategies improve (i.e., decrease) the VAP rate compared with usual care.

Adherence and Infection Rate

Three studies reported this outcome.[47,48,67] As shown in Table 17, all 3 studies are of lower quality.[47,48,67] The evidence from 2 of the lower quality studies come from large statewide initiatives.[47,67] The evidence was judged to have a medium risk of bias.

All 3 studies showed a statistically significant improvement in adherence and one[47] of the 3 also showed a significant decrease in VAP rate. The change in VAP rate for the DePalo et al.[67] study was not statistically significant and Barrera et al.[48] reported a nonsignificant increase in VAP rates. These results are judged as consistent. These are direct measures. Based on the direction and magnitude of change from these 2 statewide initiatives, the evidence was judged to be precise. The strength of evidence is considered to be moderate that audit and feedback with the base strategies improves both adherence and improves (i.e., decreases) VAP rate.

Provider Reminder Systems With the Base Strategies Compared With Usual Care

Overall, strength of evidence is insufficient for improving infection rate related to this QI approach.

One study, Omrane et al. (2007),[111] reported on use of this strategy; statistical analysis was only performed for infection rate. The strength of evidence is insufficient (Table 21).

Table 21. Provider reminder systems with the base strategies within VAP compared with usual care

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Infection rate	1 simple before-after study[111]	High	Unknown	Direct	Imprecise	***Insufficient***

Note: The base strategies are organizational change and provider education. VAP = ventilator-associated pneumonia

Base Strategies Compared With Usual Care

Overall, strength of evidence for the 3 studies using the base strategies is insufficient for improving head of bed elevation , and insufficient for improving VAP rate and for studies that measure both adherence and infection rate (Table 22).

Head of Bed Elevation

Only 1 study, Apisarnthanarak et al. (2007), reported on this outcome.[108] Thus, strength of evidence is insufficient.

Table 22. Base strategies within VAP compared with usual care

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Adherence: HOB elevation	1 controlled study[108]	Medium	Unknown	Direct	Imprecise	***Insufficient***
Infection rate	1 controlled study[108] 2 simple before-after studies[110,113]	High	Consistent	Direct	Imprecise	***Insufficient***
Adherence and infection rates	1 controlled study[108]	Medium	Consistent	Direct	Imprecise	***Insufficient***

Abbreviations: HOB = head of bed; VAP = ventilator-associated pneumonia.
Note: The base strategies are organizational change and provider education.

Infection Rate

Three studies reported this outcome.[108,110,113] As shown Table 17, one study[108] is of higher quality and two[110,113] are lower quality. The evidence is quasi-experimental. One of the higher quality studies is from a single 8-bed medical ICU.[108] The two lower quality studies are small simple before-after studies. This evidence was judged to have a high risk of bias. All showed a statistically significant improvement (i.e., decrease) in VAP rate: Apisarnthanarak et al.[108] found a decrease from 20.6 to 8.5 infections per 1,000 ventilator-days (p=0.002), which remained low (4.2 infections per 1,000 ventilator-days) during years 2 and 3; Prospero et al.[110] found a decrease from 36.9 to 22.5 infections per 1,000 ventilator-days (p=0.03), and Kulvatunyou et al.[113] found a decrease in the rate from 39.7 to 10.5 (p<0.001). These results are judged as consistent. Infection rate is a direct measure. The evidence is judged to be imprecise since it is primarily from small simple before-after studies. The strength of evidence is considered to be insufficient that the base strategies improve (i.e., decrease) VAP rate compared with usual care.

Adherence and Infection Rate

Only 1 study, Apisarnthanarak et al. (2007), reported on this outcome.[108] Thus, strength of evidence is insufficient.

Cost/Savings

Only 1 study, Apisarnthanarak et al. (2007), reported on this outcome, which will be discussed in the section on Key Question 1b.[108]

Audit and Feedback With the Base Strategies Compared With a Low Intensity Intervention

One study compared the use of audit and feedback with the base strategies with provider education and a provider reminder system.[53]

Lilly et al. compared a tele-ICU health care delivery system to the use of provider education and a paper checklist.[53] During the postintervention period, patients were more than twice as likely to receive the VAP preventive interventions as those in the baseline period (OR: 2.2; 95% CI: 1.79 to 2.7; p<0.001). The study also showed an 85 percent decrease in odds of developing an infection in the postintervention period (p<0.001). The infection rate decreased from 13 percent to 1.6 percent (p<0.001). The risk of bias was judged to be medium due to the medium study quality rating. With 1 study the consistency is unknown and the evidence is imprecise (Table 23). The strength of evidence is considered to be insufficient that audit and feedback and the base strategies improve (i.e., decrease) VAP rate compared with a low intensity intervention.

Table 23. Audit and feedback with the base strategies within VAP compared with low intensity intervention

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Adherence: Overall Summary	1 Nonrandomized stepped wedge[53]	Medium	Unknown	Direct	Imprecise	***Insufficient***
Infection rate	1 Nonrandomized stepped wedge[53]	Medium	Unknown	Direct	Imprecise	***Insufficient***
Adherence and infection rates	1 Nonrandomized stepped wedge[53]	Medium	Unknown	Direct	Imprecise	***Insufficient***

Base Strategies Compared With Low intensity Intervention

One study used a combination of organizational change and provider education compared with a low intensity intervention.[60]

Speroff et al. compared the use of a virtual collaborative to the use of a toolkit. The study was of higher quality and involved 60 hospitals.[60] Due to the quality of the study, the risk of bias was rated as medium. With only 1 study the consistency is unknown. Infection rate is a direct measure and the evidence was deemed imprecise. The study showed no differential effect on infection rates (p=0.80). The strength of evidence was considered to be insufficient that the base strategies improve (i.e., decrease) VAP rates compared with a low intensity intervention (Table 24).

Table 24. Base strategies within VAP compared with low intensity intervention

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Infection rate	1 Controlled study[60]	Medium	Unknown	Direct	Imprecise	***Insufficient***

Surgical Site Infection (SSI)

Overview

A total of 15 studies, four[133-136] from the 2007 report and an additional 11[52,137-146] identified from the current literature search, used quality improvement (QI) strategies to implement preventive interventions aimed at reducing SSI. These studies controlled for confounding or secular trends, and met all other criteria for inclusion in this systematic review. There were 2 randomized, controlled trials,[52,133] 1 controlled before after study,[134] 1 nonrandomized stepped wedge design,[137] 1 interrupted time series,[138] and 10 simple before-after studies.[135,136,139-146] Most studies used multiple QI strategies: 2 studies implemented four strategies,[137,140] 5 studies implemented three QI strategies,[52,135,138,139,142] 4 studies implemented two strategies,[134,136,144,145] and 4 studies implemented one QI strategy.[133,141,143,146] All but 3 studies used organizational change as one of their strategies.[133,143,145] Nine of the 15 studies included a provider education component.[52,134,135,137-140,142,145] Seven of the 15 studies implemented an audit and feedback

strategy,[52,135-138,140,145] and seven of the 15 studies[133,137,139,140,142-144] included a provider reminder system (Table 25 and Table 26).

Outcomes of interest in this review were adherence rates, infection rates, and cost analyses. Adherence rates most often reported related to appropriate antibiotic prophylaxis use, which in some studies was separated into antibiotic selection, timing of antibiotic administration, and duration of antibiotic. Other adherence rates included maintaining normothermia, appropriate hair removal, and glucose control. Eight of the 15 studies reported both adherence rates and infection rates,[133,135-138,140,142,143] two of the 15 studies reported only adherence rates,[52,139] and five of the 15 studies[134,141,144-146] reported only infection rates . None of the 15 studies reported cost analyses.

Eleven of the 15 studies were conducted in the United States,[52,133,136,137,139-144,146] with one study each from the Netherlands,[138] Germany,[134] Italy,[135] and Israel.[145] There were 7 multicenter studies. One of the randomized, controlled trials involved 44 hospitals,[52] the controlled before-after study from Germany involved eight hospitals,[134] the interrupted time series collected data from 12 hospitals,[138] the nonrandomized stepped wedge study was implemented in two hospitals,[137] the simple before-after study from the US[136] involved 56 hospitals, the simple before-after study from Italy[135] was implemented in 9 wards across several hospitals, and another simple before-after study was implemented in four surgical centers around North America.[144] The remaining 8 studies were implemented in a single site.[133,139-143,145,146] Sample sizes in the postintervention period varied, from 115 to 10,617. Postintervention rates of SSI ranged from 0 to 7.7 percent. Eight of the 15 studies provided baseline SSI rates,[137,138,140-143,145,146] ranging from 1.1 to 15.0 percent.

An additional 34 studies[99,103,147-178] were identified in the literature search which used QI strategies aimed at reducing SSI, but did not perform analyses to control for confounding or secular trends (Appendix Table F3). These studies were not included in the following analyses due to their weak designs and potential for biased results.

Methodological Quality of Included Studies

The 15 included studies were given a rating of higher, medium, or lower, based on the study design and the five dimensions The 2 randomized, controlled trials were rated higher quality,[52,133] the controlled before-after study, the nonrandomized stepped wedge and interrupted time series were rated medium quality,[134,137,138] and the ten simple before-after studies[135,136,139-146] were rated lower quality (Table 27).

Eleven of the 15 studies had followup of at least 1 year,[52,134,137-139,141-146] 11 of the 15 studies controlled for confounding or secular trends in their analyses,[52,133-139,143,145,146] 11 of the 15 studies analyzed change in adherence rates,[52,133,135-140,142-144] and 12 of the 15 studies analyzed change in infection rates.[133-136,138,140-146] One of the 15 studies explicitly stated that the hospitals involved in the study agreed not to introduce other interventions during the study period.[138]

Studies That Control for Confounding or Secular Trend

Controlled Studies

Kritchevsky et al. (2008)[52]

Summary

In a cluster randomized trial, Kritchevsky et al.[52] compared adherence to antimicrobial prophylaxis measures among hospitals receiving audit and feedback reports alone, versus hospitals receiving audit and feedback reports plus support through a QI collaborative. In this particular study, membership in the QI collaborative did not provide a significant incremental improvement in adherence rates. Infection data were not collected.

Description

Forty-four hospitals were matched on adherence to prophylactic antibiotic timing in the baseline period and stratified by average daily census. Twenty-two hospitals were then randomized into the audit and feedback only group and 22 hospitals were assigned to the audit and feedback plus QI collaborative group. The feedback only group received a customized comparative report of five antibiotic performance measures at the beginning of the study and then did not have further communication with the investigators while they implemented changes at their institutions to improve antibiotic prophylaxis. The intervention group received the same customized report, followed by two onsite meetings and several teleconferences with QI experts. Intervention experiences, guidelines, forms, and literature reviews were shared during monthly conference calls among the intervention hospitals. Both study groups kept logs on intervention strategies that were implemented at their facilities. Baseline data were collected from May 2003 to November 2003, on 2,234 patients from the feedback only hospitals and on 2,213 patients from the intervention hospitals. Followup data were collected from February 2005 to July 2005, on 2,238 patients from the feedback only hospitals and on 2,225 patients from the intervention hospitals. To compare the changes in antibiotic administration, the authors used conditional margins, testing treatment group by time interaction and adjusting for type of surgery, hospital size, and region. Logistic regressions with the jackknife design were run.

Results and Limitations

The adjusted difference between the feedback only group and the feedback and QI collaborative group was 6.3 percent (95% CI: -7.3% to 19.8%), showing no incremental improvement through membership in the QI collaborative (Table 28). However, in a pre/post analysis within each study group, significant differences were found within both groups in antibiotic timing and duration (i.e., appropriate discontinuation of antibiotics). For the feedback only group, antibiotic timing improved 10.5 percent (95% CI: 2.7% to 18.3%) and antibiotic duration improved 13.2 percent (95% CI: 2.1% to 24.3%). Adjusted analysis showed that for the feedback and QI collaborative group, antibiotic timing improved 6.7 percent (95% CI: 0.2% to 13.1%) and antibiotic duration improved 21.3 percent (95% CI: 12.5% to 30.1%). Infection data were not reported.

A limitation of this study is that there was overlap in the type of QI strategies implemented in the two study groups. In an appendix to this study, information from the intervention strategy logs showed that common strategies were implemented in both study groups in similar proportions. For example, supplemental education occurred in 71 percent of the feedback only

hospitals and 68 percent of the intervention hospitals, and process changes were implemented in 67 percent of the feedback only hospitals and 64 percent of the intervention hospitals. With similar QI strategies implemented in both groups, differences between the two groups are difficult to detect.

Zanetti et al. (2003)[133]

Zanetti et al.[133] conducted a randomized control trial to test the efficacy of an electronic reminder system to improve antibiotic use. Details of this study are found in the 2007 report.

Gastmeier et al. (2002)[134]

Gastmeier et al.[134] conducted a controlled before-after study to reduce nosocomial infections in surgical patients. Details of this study are found in the 2007 report.

Table 25. Overview of SSI articles that control for confounding or secular trends

Author, location-year	Study type	Analysis for infection rates	Sample size (infections)	Organizational change	Provider education	Audit and feedback	Provider reminder systems	Patient education	Financial incentives
Kritchevsky, United States - 2008[52]	Cluster RCT	Logistic regression	control pre: 2234 control post: 2238 study pre: 2213 study post: 2225	•	•	•			
Zanetti, United States - 2003[133]	Individual RCT	Likelihood ratio test	control: 136 (8) study: 137 (5)				•		
Kao, United States - 2010[137]	Stepped wedge (non-randomized)	Generalized linear model	pre hosp1: 119 (2) post hosp1: 115 (5) pre hosp2: 92 (3) post hosp2: 169 (0)	•	•	•	•		
Gastmeier, Germany - 2002[134]	Controlled before-after	Cox regression	control: 4848 (122[a]) study: 6447 (130[a])	•	•				
Mannien, Netherlands - 2006[138]/[179]	Interrupted time series	Non-linear mixed model	pre: 1668 (90*) post: 1953 (88*)	•	•	•			
Schwann, United States - 2011[143]	Simple before-after	Logistic regression	pre: 9,127 (101*) post: 10,617 (75*)				•		
Dellinger, United States - 2005[136]	Simple before-after	Poisson regression		•		•			
Greco, Italy - 1991[135]	Simple before-after	Mantel-Haenszel relative risks	pre: 4096 (286*) post: 1638 (101*)	•	•	•			
Burkitt, United States - 2009[139]	Simple before-after	Logistic regression	pre: 2550 post: 1779	•	•		•		
Kestle, United States - 2011[144]	Simple before-after	Logistic regression	pre: 896 (79) post: 1571 (89)	•			•		
Salim, Israel - 2011[145]	Simple before-after	Logistic and Poisson regression	pre: 751 (37) post: 865 (18)		•	•			
Hedrick, United States - 2007[140]/[180]	Simple before-after	Logistic regression	pre: 379 (35*) post: 390 (22*)	•	•	•	•		
Kaimal, United States - 2008[141]	Simple before-after	Logistic regression	pre: 800 (51*) post: 516 (13*)	•					
Trussell, United States - 2008[142]	Simple before-after	Logistic regression	pre: 808 (28*) post: 674 (10*)	•	•		•		
Lavu, United States - 2011[146]	Simple before-after	Logistic regression	pre: 233 (35) post: 233 (18)	•					

* Number of infections was estimated from infection rates.
[a]Number of infections reflect the sum of all infections during all three study periods

Table 26. Specific attributes of organizational change implemented in SSI articles that control for confounding or secular trend

Author, Country-Publication Year	Multidisciplinary Team	Team Responsibilities	Hospital Executives on Team	New Protocol or Standards Implemented	Designate Staff Member Responsible for Implementation
Kritchevsky, United States - 2008[52]				•	
Kao, United States - 2010[137]	•	Identify barriers to adherence with SCIP antibiotic prophylaxis adherence		•	•
Mannien, Netherlands - 2006[138]/[179]	•			•	
Gastmeier, Germany - 2002[134]	•	Evaluated infection control measures, developed interventions to improve adherence, and ensured implementation of interventions		•	
Burkitt, United States - 2009[139]	•	Identify obstacles and develop solutions for appropriate antibiotic use		•	
Kestle, United States - 2011[144]				•	
Hedrick, United States - 2007[140]/[180]	•	Develop an aim statement, select a target population, define outcomes and process measures, and begin collecting baseline data		•	•
Kaimal, United States - 2008[141]	•	Define magnitude of SSI problem, develop and implement an action plan	•	•	•
Trussell, United States - 2008[142]	•	Develop protocol		•	•
Lavu, United States - 2011[146]				•	

Table 27. Methodological quality for SSI articles that control for confounding or secular trend

Author, Location-Year	Study Type	Sufficient followup[a]	Adequate control for confounding or secular trend[b]	Change in adherence was analyzed[c]	Change in infection rate was analyzed[d]	Independent of other QI effort[e]	Overall quality rating	Comments
Kritchevsky, United States - 2008[52]	Cluster RCT	+	+	+	-	N/A	***Higher***	Infection rates were not reported.
Zanetti, United States - 2003[133]	Individual RCT	-	+	+	+	N/A	***Higher***	
Kao, United States - 2010[137]	Stepped wedge (non-randomized)	+	+	+	-	-	***Medium***	Infection rates were reported, but no pre-post statistical comparisons were made.
Gastmeier, Germany - 2002[134]	Controlled before-after	+	+	-	+	-	***Medium***	Study hospitals were chosen based on their interest in quality management activities. Control hospitals were allowed to initiate QI efforts and active surveillance if they wished.
Mannien, Netherlands - 2006[138]/[179]	Interrupted time series	+	+	+	+	+	***Medium***	
Schwann, United States - 2011[143]	Simple before-after	+	+	+	+	?	***Lower***	There was a JCHAO visit during the baseline period that may have affected provider behavior. Postdischarge surveillance was limited to positive cultures only.
Dellinger, United States - 2005[136]	Simple before-after	-	+	+	+	?	***Lower***	Many hospitals started surveillance part way through the intervention.
Greco, Italy - 1991[135]	Simple before-after	-	+	+	+	?	***Lower***	Followup was only 6 months. They did not conduct postdischarge surveillance.
Burkitt, United States - 2009[139]	Simple before-after	+	+	+	-	-	***Lower***	Infection rates were not reported.
Kestle, United States - 2011[144]	Simple before-after	+	-	+	+	?	***Lower***	Association between each protocol item and infection rates was assessed, but change in adherence rates was not analyzed.
Salim, Israel – 2011[145]	Simple before-after	+	+	-	+	?	***Lower***	Adherence was not measured.
Hedrick, United States - 2007[140]/[180]	Simple before-after	-	-	+	+	?	***Lower***	
Kaimal, United States - 2008[141]	Simple before-after	+	-	-	+	?	***Lower***	Adherence rates were not reported.
Trussell, United States - 2008[142]	Simple before-after	+	-	+	+	?	***Lower***	
Lavu, United States - 2011[146]	Simple before-after	+	+	-	+	?	***Lower***	Adherence rates were not reported.

Note: All studies used standard and consistent infection definitions. Mannien et al., Hedrick et al., and Trussell et al. used the CDC methodology. Independence from other QI efforts was not applicable for randomized controlled trials.
[a]Is the length of followup sufficient (at least 12 months) to support the evaluation of primary outcomes and harms?
[b]Were adequate measures taken to control for confounding or secular trend?
[c]Was change in adherence analyzed?
[d]Was change in infection rate analyzed?
[e]Was the intervention performed independent of other QI efforts or other changes?
'+' means 'yes' '-' means 'no' '?' means 'uncertain'

Table 28. Outcomes for SSI articles that control for confounding or secular trend

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Kritchevsky, United States - 2008[52]	Joining a quality improvement collaborative + audit and feedback program/ Audit and feedback program	Adherence	All or none' prophylactic measures			◊	Control: 42.5% → 55.7% Intervention: 38.2% → 57.2% (p=NS)	Analysis reflects difference between intervention groups, not baseline and postintervention change. The adjusted difference between the feedback only group and the feedback and QI collaborative group was 6.3% (95% CI: -7.3 to 19.8%).
			Appropriate timing			◊	Control: 74.8% → 85.3% Intervention: 76.3% → 83.2% (p=NS)	
			Appropriate duration			◊	Control: 54.7%→66.8% Intervention: 51.3%→69.5% (p=NS)	
			Appropriate selection			◊	Control: 93.4%→95.4% Intervention: 93.8%→94.7% (p=NS)	
		Infection Rate						
		Costs/Savings						
Zanetti, United States - 2003[133]	Computer automated reminder system for antibiotic prophylaxis/ No intervention (usual care)	Adherence	Received intraoperative redose	◊			Baseline: 27% Control: 40% (p<0.001 compared to baseline) Study: 68% (p<0.001 compared to control)	Adherence in the control group was significantly better than the baseline period (p<0.001) and the study group was significantly better than the control group (p<0.001). Infection rate was not significantly different between groups, but significantly improved from the baseline period (p=0.02).
		Infection Rate	Overall			•	Baseline: 10% Control: 6% Study: 4%	
		Costs/Savings						

Table 28. Outcomes for SSI articles that control for confounding or secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Kao, United States - 2010[137]	Extended timeout for 2 hospitals, 1 with added education, 1 with added preop checklist/ No Intervention (usual care)	Adherence	Appropriate timing, selection, and discontinuation after extended timeout (low intensity intervention):					Hospitals were compared against each other as well as to baseline period. Results to the left represent within hospital comparisons, between baseline and postintervention. Comparisons between hospital 1 and hospital 2: - Hospital 1 had greater overall adherence than hospital 2 (p=0.003). - Patients in hospital 2 were less likely to develop an SSI compared with patients at hospital 1 (OR: 0.23; 95% CI: 0.10 to 0.56; p=0.001). A separate multiple regression analysis demonstrated that nonadherence with the antibiotic guidelines (OR: 2.61; 95% CI: 1.20 to 5.70) and hospital (OR: 0.22; 95% CI: 0.09 to 0.53) were independent predictors of SSI.
			Hospital 1	◊			44% → 70%[a]	
			Hospital 2	◊			28% → 67%[a]	
			Appropriate timing, selection, and discontinuation after intervention:					
			Hospital 1			◊	70% → 80%[a]	
			Hospital 2			◊	67% → 70%[a]	
			Time between antibiotics and incision after extended timeout (low intensity intervention):					
			Hospital 1	◊			74% → 90%[a]	
			Hospital 2	◊			65% → 82%[a]	
			Time between antibiotics and incision after intervention:					
			Hospital 1			◊	90% → 90%[a]	
			Hospital 2	◊			82% → 98%[a]	

Table 28. Outcomes for SSI articles that control for confounding or secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Kao, United States – 2010[137] (continued)	Extended timeout for 2 hospitals, 1 with added education, 1 with added preop checklist/ No Intervention (usual care)	Adherence	Appropriate antibiotic selection after extended timeout (low intensity intervention):					
			Hospital 1	◊			61% → 78%[a]	
			Hospital 2	◊			69% → 80%[a]	
			Appropriate antibiotic selection after intervention:					
			Hospital 1	◊			78% → 90%[a]	
			Hospital 2	◊			80% → 81%[a]	
			Appropriate discontinuation after extended timeout (low intensity intervention):					
			Hospital 1			◊	92% → 95%[a]	
			Hospital 2			◊	85% → 91%[a]	
			Appropriate discontinuation after intervention:					
			Hospital 1			◊	95%→93%[a]	
			Hospital 2			◊	91%→90%[a]	
		Infection Rate					Hospital 1: 2.5% → 10.5% → 4%[a,b] Hospital 2: 4% → 1.5% → 0%[a,b]	
		Costs/Savings						

Table 28. Outcomes for SSI articles that control for confounding or secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Gastmeier, Germany - 2002[134]	Quality circles and increased surveillance efforts/ No intervention (usual care)	Adherence						Cox regression showed the first intervention period to be a protective factor on all nosocomial infections (HR: 0.75; 95% CI: 0.58 to 0.97). The addition of the enhanced surveillance in the second intervention period does not seem to have an additive protective effect on all nosocomial infections (HR: 0.78; 95% CI: 0.60 to 1.01).
		Infection Rate	Overall			•	SSI incidence densities: Control: 2.6 → 2.5 → 2.0 Study: 2.2 → 1.6 → 2.2	
		Costs/Savings						
Mannien, Netherlands - 2006[138]/[179]	Optimized antibiotic prophylaxis/ No Intervention (usual care)	Adherence	Inappropriate administration	◊			Expected/Observed: 93.5%/37.5%	Time series analysis showed improvements in both antibiotic timing and administration post intervention (p<0.01), but adherence did not impact SSI (p=0.99)
			Inappropriate timing	◊			Expected/Observed: 51.8%/39.4%	
		Infection Rate	Overall			•	5.4%→4.5% (p=0.22)	
		Costs/Savings						
Schwann, United States - 2011[143]	Automatic antibiotic administration reminder incorporated into anesthesia information management system/ No Intervention (usual care)	Adherence	Antibiotic timing	◊			62% → 92% (p=0.003)	Outcomes were controlled for inpatient vs. outpatient surgery, location, surgical service, and individual surgeon. ANOVA showed that all postintervention periods are significantly improved from the baseline period for infection rates.
		Infection	Overall	•			1.1% → 0.7% (RR=0.35; 95% CI: 0.13 to 0.52; p=0.003)	
		Cost/Savings						

Table 28. Outcomes for SSI articles that control for confounding or secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Dellinger, United States - 2005[136]	Nationwide collaborative/ No Intervention (usual care)	Adherence	Appropriate antibiotic timing	◊			Quarterly Median: 72% → 82% → 89% → 92% (p<0.0001)	While the trend over time was nonsignificant for infection rates, comparison of the first and last 3 months was significantly different (p=0.0005).
			Appropriate antibiotic selection	◊			Quarterly Median: 90% → 94% → 95% → 95% (p=0.02)	
			Appropriate antibiotic duration	◊			Quarterly Median: 67% → 69% → 74% → 85% (p<0.001)	
			Normothermia	◊			Quarterly Median: 57% → 64% → 69% → 74% (p<0.0001)	
			Avoid shaving	◊			Quarterly Median: 59% → 83% → 90% → 95% (p=0.006)	
			Glucose control	◊			Quarterly Median: 46% → 49% → 53% → 54% (p<0.0001)	
		Infection Rate	Overall			•	2.3% → 1.7%	
		Costs/Savings						
Greco, Italy - 1991[135]	Active surveillance and implementation of new infection control recommendations/ No Intervention (usual care)	Adherence	Shaving	◊			76.8% → 73.5% (p<0.01)	3 units reported a significant reduction, 4 had no change, and 2 reported a significant increase in infection rates. Although the decrease in infection rates started before the initiation of the intervention.
			Postoperative prophylaxis	◊			36.9% → 27.2% (p<0.00001)	
		Infection Rate	Overall (per 100 patients)			•	7.8 → 6.2 (Adjusted RR: 0.85; 95% CI: 0.68 to 1.06)	
			Superficial (per 100 patients)			•	6.7 → 5.7 (Adjusted RR: 0.91; 95% CI: 0.72 to 1.14)	
			Deep (per 100 patients)			•	1.9 → 1.05 (Adjusted RR: 0.63; 95% CI: 0.38 to 1.05)	
		Costs/Savings						
Burkitt, United States - 2009[139]	Toyota Production System - appropriate antibiotic choice and duration/ No Intervention (usual care)	Adherence	Appropriate selection			◊	64.3% → 65.6% → 59.3% → 64.1% → 63.5% (p=0.49)	
			Appropriate duration	◊			39.2% → 46.9% → 45.1% → 47.4% → 67.6% (p<0.01)	
		Infection Rate						
		Costs/Savings						

Table 28. Outcomes for SSI articles that control for confounding or secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Kestle, United States - 2011[144]	Operating room protocol with flow chart/ No Intervention (usual care)	Adherence						Of all of the protocol items, proper hand washing by all team members and double gloving by all team members were significantly associated to lower infection rates (p=0.03 and p=0.04, respectively). Antibiotic-impregnated sutures, and preoperative use of chlorhexidine shampoo were significantly associated with decreased infection rates (3.8% vs. 6.6%; p=0.03 and 3.4% vs. 7.4%; p=0.004, respectively) while BioGlide catheters were associated with significantly higher rates of infection (8.3% vs. 4.5%; p=0.002).
		Infection	Overall	•			8.8% → 5.7% (p=0.003)	
		Cost/Savings						
Salim, Israel - 2011[145]	Refresher courses on infection control and catheter insertion/ No Intervention (usual care)	Adherence						All ORs and IRRs were adjusted for membrane rupture and duration of operation. Results are also further broken down by elective and nonelective cesarean. More significant results were found in the elective cesarean group.
		Infection	Overall	•			4.9% → 2.1% (OR=0.4, 95% CI: 0.23 to 0.72, p=0.002)	
			Incisional	•			3.5% → 0.9% (OR=0.27, 95% CI: 0.12 to 0.59, p=0.001)	
			Organ Space			•	1.6% → 1.2% (OR=0.67, 95% CI: 0.28 to 1.56, p=0.52)	
		Cost/Savings						

Table 28. Outcomes for SSI articles that control for confounding or secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Hedrick, United States - 2007[140]/[180]	Bundle - antibiotic prophylaxis/ No Intervention (usual care)	Adherence	Appropriate antibiotic selection	◊			89%→97% (p≤0.05)	Nonadherence with any of the preventive interventions was not predictive of SSI. Operative time, colorectal surgery, and age were independent risk factors for SSI.
			Appropriate timing	◊			89%→97% (p≤0.05)	
			Appropriate discontinuation			◊	93%→92% (p=NS)	
			Normothermia			◊	85%→90% (p=NS)	
			Glucose control		◊		54%→36% (p≤0.05)	
		Infection Rate	Overall			•	9.2%→5.6% (p=0.07)	
		Costs/Savings						
Kaimal, United States - 2008[141]	Implement policy on timing of antibiotic prophylaxis/ No Intervention (usual care)	Adherence						P-values reflect simple pre-/post-test. Controlling for labor, previous cesarean delivery, parity, maternal age, body mass index, diabetes mellitus, chorioamnionitis and group B streptococcus vaginal culture status, multivariable regression found a significant decrease in overall SSI after the intervention (OR=0.33, 95%CI 0.14 to 0.77).
		Infection Rate	Overall	•			6.4%→2.5% (p=0.02)	
			Cesareans deliveries before labor			•	2.7%→1.1% (p=0.16)	
			Cesareans deliveries during labor	•			10.6%→4.2% (p=0.005)	
		Costs/Savings						
Trussell, United States - 2008[142]	Protocol pathway for appropriate antibiotic use, hair removal, and glucose control/ No Intervention (usual care)	Adherence	Appropriate timing	◊			81%→94% (p=0.001)	Infection rate p-value is adjusted for diabetes mellitus, gender, and NNIS wound class II, all of which were independent predictors of SSI.
			Shaving	◊			60%→20% (p=0.001)	
		Infection Rate	Overall	•			3.5%→1.5% (p=0.001)	
		Costs/Savings						

Table 28. Outcomes for SSI articles that control for confounding or secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Lavu, United States - 2011[146]	Surgical care bundle/ No Intervention (usual care)	Adherence						Infection rate was controlled for estimated blood loss, albumin, and hemoglobin A1c. Estimated blood loss and albumin were independent risk factors for SSI (p=0.01 and p=0.012, respectively).
		Infection	Overall	•			15% → 7.7% (p<0.001)	
		Cost/Savings						

Abbreviations: NS = nonsignificant; OR = odds ratio; CI = confidence interval; NNIS = National Nosocomial Infections Surveillance
• was used for infection rate outcomes
◊ was used for adherence and costs/savings outcomes
[a]Numbers were extrapolated from a graph
[b]Reported, but not analyzed

Kao et al. (2010)[137]

Summary

Kao et al.[137] used a nonrandomized stepped wedge design in two hospitals to compare the effectiveness of an extended timeout period followed by two different QI strategies to improve adherence with antibiotic prophylaxis use. An organizational change was instituted in both hospitals, providing a dedicated time for antibiotic administration and feedback to faculty on antibiotic use. Hospital 1 then added a provider education component in a subsequent study period, and hospital 2 added a provider reminder component in a subsequent study period. Results were as follows:

- Antibiotic selection improved in both hospitals following both the extended timeout period and the period with the additional QI strategy.
- Antibiotic timing improved significantly in both hospitals after the extended timeout, but improved further only in hospital 2 following implementation of the additional QI strategies.
- Antibiotic duration did not improve significantly in either hospital following the extended timeout period or after the period in which additional QI strategies were implemented.
- Infection rates were reported, but baseline versus postintervention analyses on these rates were not conducted.

Description

There was a baseline period from July 2006 to December 2006 (hospital 1: n=119, hospital 2: n=92), followed by three study periods from July 2007 to May 2009. In the first study period (hospital 1: n=100, hospital 2: n=206), a standardized antibiotic prophylaxis form was developed and became available to both hospitals and both hospitals incorporated an extended timeout period. The extended timeout involved administration of the antibiotic during the preoperative period and feedback to faculty on antibiotic use. During period 2 (hospital 1: n=97, hospital 2: n=154), both hospitals continued the extended timeout, and hospital 1 added educational lectures for the anesthesia and general surgery staff. In period 3 (hospital 1: n=115, hospital 2: 169), hospital 1 continued extended timeout and staff education, while hospital 2 continued extended timeout and added a preoperative checklist, nursing documentation of antibiotic choice, and a campaign to increase use of the standardized antibiotic form. Hospital 1 had 14 months of followup for their education component and hospital 2 had 6 months of followup for their checklist, antibiotic documentation, and campaign components. Data on adherence and SSI incidence were collected retrospectively from chart reviews. Chi-square analysis and analysis of variance were used to compare categorical and continuous variables between hospitals and time periods. Logistic regressions were run to determine factors related to nonadherence and SSI rates. General linear modeling examined interaction effects between hospitals and level of intervention.

Results and Limitations

Antibiotic selection improved significantly for both hospitals following both the extended timeout and the periods in which additional QI strategies were implemented ($p<0.001$). Timing of antibiotic improved significantly for both hospitals after the extended timeout. Data collected after the additional QI strategies were implemented showed significant improvements in antibiotic timing only in hospital 2 ($p=0.05$). Antibiotic discontinuation did not significantly

improve in either hospital after any of the study periods. Hospital 1 had greater overall adherence compared with hospital 2 (p=0.003), but hospital 2 experienced fewer SSI compared with hospital 1 (OR: 0.23; 95% CI: 0.10 to 0.56; p=0.001) (Table 28). Limitations of this study include only a 6 month followup for hospital 2 in the final phase and no pre/post analysis of SSI rates. Another limitation is the potential underestimation of infections because SSI were identified through chart review and therefore dependent on the provider documenting the incidence in the chart.

Interrupted Time Series

Mannien et al. (2006)[138]

Summary

Mannien et al.[138] report on a multisite prospective study, the Surgical Prophylaxis and Surveillance project, conducted in the Netherlands[b] Organizational change, provider reminder systems, and audit and feedback were QI strategies implemented in this study. Statistically significant improvements in antibiotic timing and administration following the intervention were reported. Overall SSI rates decreased, but not significantly.

Description

Twelve hospitals, representing different population densities and hospital types, which participated in the Dutch nosocomial surveillance network, volunteered to collect data on antibiotic prophylaxis and SSI rates. At the beginning of the intervention phase, participating hospitals received an auditing report on their use of antibiotic prophylaxis during January 2000 to November 2001 (n=1,668) from the study's supervising committee. The auditing reports and guidelines were discussed with each hospital's multidisciplinary study team. Recommendations for improvement in each hospital were made and educational meetings were conducted. Followup data were collected from July 2001 to November 2002, n=1,953. Logistic regressions were used to compare baseline and intervention SSI rates, adjusting for procedure specific confounders. Segmented time series analysis measured the effect size of the intervention, adjusting for hospital, procedure, and hierarchical structure of the data collected.

Results and Limitations

Time series analysis showed statistically significant improvements in antibiotic timing and administration following the intervention (p<0.01). Overall SSI rates decreased, but not significantly from a baseline rate of 5.4 percent (95% CI: 4.3% to 6.5%) to a postintervention rate of 4.5 percent (95% CI: 3.6% to 5.4%) (Table 28). A limitation of this study is the lack of a control group.

Simple Before-After

Schwann et al. (2011)[143]

Schwann et al. reported on the effect of SSI rates through intervention by provider reminder systems in the United States.[143] Data were collected on 19,744 people over a 3-year period

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[b]This study provides 1 month of additional followup to a report published in 2005 (van Kasteran 2005) that was reviewed in the 2007 Evidence Report on preventing health care-associated infections.

divided by a primary evaluation phase and a sustainability phase. Chi-Square tests were used to determine overall adherence. Bivariate, hierarchical chi-square and logistic regression were also used to assess adherence and SSI rates adjusting for inpatient versus outpatient, location, location of surgical service and individual surgeon. Adherence to antibiotic timing increased from 62 percent to 92 percent and was statistically significant (p=0.003). The overall SSI rate in the study decreased from 1.1 percent to 0.7 percent (RR: 0.35; 95% CI: 0.13 to 0.52) and was statistically significant (p=0.003).

Dellinger et al. (2005)[136]

Fifty-six hospitals joined a collaborative to decrease SSI in this simple before-after study described by Dellinger et al.[136] Details of this study are found in the 2007 report.

Greco et al. (1991)[135]

Greco et al.[135] describe a simple before-after study to reduce SSI, conducted across several hospitals in Italy. Details of this study are found in the 2007 report.

Burkitt et al. (2009)[139]

The Toyota production system, an approach developed by industrial engineers to improve manufacturing quality, was adapted by Burkitt et al.[139] to improve antibiotic prophylaxis in a 146 bed tertiary care Veterans Affairs medical center. Organizational change, provider education, and provider reminder systems were strategies used in this study. Logistic regression analysis, which included a time variable to account for the rolling out of interventions, found significant improvements in the neurosurgical and gastrointestinal departments in antibiotic selection, with adjusted p-values of p<0.01 and p=0.03, respectively, but not in the vascular, genitourinary, or orthopedic departments. The analysis also found significant improvements in antibiotic duration in three of the five participating departments, gastrointestinal, genitourinary, and orthopedic, with adjusted p-values of p=0.04, p<0.01, and p=0.03, respectively. Analysis for all five departments combined showed no significant improvement in antibiotic selection (adjusted p=0.49), but a significant improvement in antibiotic duration (adjusted p<0.01; Table 28).

Kestle et al. (2011)[144]

Kestle et al. investigated the effect of an organizational change and provider reminder systems intervention on SSI rates in pediatric surgical centers within the United States.[144] There were 2,467 patients in this 12-month, multicenter study. Adherence was not reported. Logistic regression was used to assess SSI rates. Overall SSI rate decreased significantly from 8.8 percent to 5.7 percent (p=0.003). Kestle et al. (2011) found that proper hand washing by all team members and double gloving by all team members were associated with lower infection rates (p=0.03 and p=0.04, respectively). Antibiotic-impregnated sutures and preoperative use of shampoo were associated with decreased infection rates (3.8% vs. 6.6%; p=0.03 and 3.4% vs. 7.4%; p=0.04 respectively). BioGlide catheters were significantly associated with higher rates of infection (8.3% vs. 4.5%; p=0.002).

Salim et al. (2011)[145]

Salim et al. reported on the effects of provider education and audit and feedback on SSI rates in women who underwent caesarean delivery in Israel.[145] There were 1,616 patients enrolled in this 2-year study. Adherence was not reported. Infection rates were assessed using logistic and Poisson regression. Overall infection rates decreased significantly from 4.9 percent to 2.1 percent

(OR: 0.4, 95% CI: 0.23 to 0.72; p=0.002). All ORs and IRRs were adjusted for membrane rupture and duration of operation. Salim et al. reported results by elective and nonelective cesarean. There were more significant results found in the elective cesarean group.

Hedrick et al. (2007)[140]

Hedrick et al.[140] report on the implementation of bundled interventions in a single tertiary care 547 bed hospital aimed to improve: (1) antibiotic timing, (2) antibiotic selection, (3) antibiotic discontinuation, (4) normothermia maintenance, and (5) glucose control among patients undergoing intra-abdominal surgery. QI strategies implemented include organizational change, provider education, provider reminder systems, and audit and feedback. Data were compared from the first four months of the study, June 2004 to September 2004, to the last four months of the study, January 2005 to April 2005. Adherence with antibiotic selection and antibiotic timing significantly improved during the study period ($p<0.05$), while discontinuation of antibiotics and maintaining normothermia did not change significantly. Maintaining glucose control worsened significantly ($p<0.05$). Overall SSI rates decreased during the study period, but not significantly (Table 28). In a stepwise logistic regression analysis controlling for select clinical characteristics and illness severity, nonadherence with any of the preventive interventions was not predictive of SSI occurrence.

Kaimal et al. (2008)[141]

In a study focusing on patients undergoing cesarean deliveries in a single university affiliated hospital, Kaimal et al.[141] describe the effect on SSI rates of an organizational change, the institution of a policy requiring prophylactic antibiotics to be administered before skin incision. The baseline period with a low level intervention including provider education was from March 2005 to June 2006, and the postintervention period with the policy change was from June 2006 to June 2007. There were no significant demographic or clinical differences between the two study groups. A multiple logistic regression analysis controlling for potential confounders showed a significant decline in overall SSI following the intervention (OR: 0.33; 95% CI: 0.14 to 0.77)

Trussell et al. (2008)[142]

Trussell et al.[142] describe a bundle of interventions implemented in a single nonuniversity teaching hospital, aimed at reducing SSI for patients undergoing coronary artery bypass grafting procedures. The QI strategies implemented were organizational change, provider education, and provider reminder systems. The baseline and postintervention groups differed significantly in age, American Society of Anesthesiologists score, smoking history, and wound class. Antibiotic timing significantly improved (p=0.001), shaving decreased significantly (p=0.001), and adherence with the tight glucose control protocol was 100 percent. In a logistic regression model including potential confounders identified through stepwise regression, the postprotocol time period was a predictor of fewer SSI (OR: 0.21; 95% CI: 0.09 to 0.51; p=0.001)

Lavu et al. (2011)[146]

Lavu et al. assessed the effects of organizational change on SSI rates in patients within the United States.[146] Data were collected on 466 patients in this 5-year study. Adherence was not reported. Infection rates were assessed by logistic regression and controlled for estimated blood loss, albumin and hemoglobin A1c. Overall infection rates significantly decreased from 15

percent to 7.7 percent ($p<0.001$). Lavu et al. reported that estimated blood loss and albumin were independent risk factors for SSI ($p=0.01$ and $p=0.012$ respectively).

Studies That Do Not Control for Confounding or Secular Trend

There were 34 studies that used QI strategies aimed at reducing SSI, but did not perform analyses to control for confounding or secular trends.[99,103,147-178] Five of the 34 studies used a single QI strategy,[103,147,154,155,161] while the remaining studies implemented combinations of QI strategies. The most common QI strategy implemented among these studies was provider education (28 of the 34).[99,103,148-154,156,157,159-162,164-173,175-177] Seventy-four percent of the studies used organizational change as one of their QI strategies.[148,150-153,155,157-160,162,163,165,167-178] Sixteen of 34 studies implemented provider reminder systems,[147-149,151,152,157-159,166,167,171,173-176,178] 12 of 34 implemented audit and feedback,[99,149,150,156,157,164,167,168172,173,176,177] and none included a patient education component (Appendix Table F3).

Strength of Evidence

Audit and Feedback and the Base Strategies With or Without Provider Reminder Systems Compared With Usual Care

The strength of the evidence for the use of audit and feedback and base strategies with or without provider reminder systems compared with usual care is summarized in Table 29. Six of the 15 studies used this combination of QI strategies.[135-138,140,145]

Antibiotic Selection

Three of the six studies reported antibiotic selection as an outcome.[136,137,140] One study is of medium quality[137] and 2 studies are of lower quality[136,140] (Table 27). Due to the overall quality of the studies, risk of bias was determined as medium. The findings were consistent between studies, with all studies reporting statistically significant improvements in antibiotic selection (Table 28). The measures are direct because antibiotic selection is a component of appropriate antibiotic use. The reported results were precise, with adherence rates improving from 61 percent to 78 percent and 69 percent to 80 percent in the two hospitals in the stepped wedge study,[137] and 89 percent to 97 percent in 1 of the simple before-after studies ($p \le 0.05$)[140] and from 90 percent to 95 percent in the other simple before-after study ($p=0.02$)[136] (Table 28). Use of audit and feedback and base strategies with or without provider reminder systems compared with usual care for improving antibiotic selection has low strength of evidence (Table 29).

Antibiotic Timing

Four of the 6 studies reported antibiotic timing as an outcome.[136-138,140] Two studies are of medium quality[137,138] and 2 studies are of lower quality[136,140] (Table 27), providing a medium risk of bias. The four studies report consistent findings, a significant improvement in antibiotic timing following the interventions (Table 28). The measures are direct because antibiotic timing is a component of appropriate antibiotic use. The reported results are precise, with adherence rates improving from 74 percent to 90 percent and 65 percent to 98 percent in the two hospitals in one study,[137] 72 percent to 92 percent in another study,[136] 89 percent to 97 percent in the third study ($p \le 0.05$),[140] and an observed rate of 60.6 percent compared with an expected rate of 48.2 percent in the fourth study[138] (Table 28). Use of audit and feedback and base strategies with or

without provider reminder systems compared with usual care for improving antibiotic timing has moderate strength of evidence (Table 29).

Table 29. Strength of evidence for audit and feedback and the base strategies with or without provider reminder systems compared with usual care

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Adherence: antibiotic selection	1 stepped wedge[137] 2 simple before-after[136,140]	Medium	Consistent	Direct	Precise	***Low***
Adherence: antibiotic timing	1 interrupted time series[138] 1 stepped wedge[137] 2 simple before-after[136,140]	Medium	Consistent	Direct	Precise	***Moderate***
Adherence: antibiotic duration	1 stepped wedge[137] 3 simple before-after[135,136,140]	Medium	Inconsistent	Direct	Imprecise	***Insufficient***
Adherence: normothermia	2 simple before-after[136,140]	High	Inconsistent	Direct	Imprecise	***Insufficient***
Adherence: glucose control	2 simple before-after[136,140]	High	Unknown	Direct	Imprecise	***Insufficient***
Adherence: shaving	2 simple before-after[135,136]	High	Consistent	Direct	Precise	***Low***
Infection rate	1 interrupted time series[138] 4 simple before-after[135,136,140,145]	Medium	Unknown	Direct	Imprecise	***Insufficient***
Adherence and infection rates	1 interrupted time series[138] 1 stepped wedge[137] 3 simple before-after[135,136,140]	Medium	Unknown	Direct	Imprecise	***Insufficient***

Antibiotic Duration

Four of the 6 studies reported antibiotic duration as an outcome.[135-137,140] One study is of medium quality[137] and 3 studies are of lower quality[135,136,140] (Table 27), providing a medium risk of bias. Two studies report nonsignificant results[137,140] and 2 studies report significant improvements[135,136] (Table 28) for inconsistent findings. The measure is direct. Nonsignificant and significant results are imprecise. Use of audit and feedback and base strategies with or without provider reminder systems compared with usual care for improving antibiotic duration has insufficient evidence (Table 29).

Normothermia Maintenance

Two simple before-after studies with a high risk of bias reported normothermia maintenance as an outcome.[136,140] One study reports nonsignificant findings[140] and 1 study reports significant findings,[136] resulting in inconsistency and imprecision. The strength of evidence for use of audit and feedback and base strategies with or without provider reminder systems compared with usual care for normothermia maintenance is insufficient.

Glucose Control

Two simple before-after studies with a high risk of bias reported glucose control as an outcome.[136,140] One study reports nonsignificant findings[140] and 1 study reports significant findings,[136] resulting in inconsistency and imprecision. The strength of evidence for use of audit

and feedback and base strategies with or without provider reminder systems compared with usual care for glucose control is insufficient.

Shaving

Two simple before-after studies with a high risk of bias reported appropriate hair removal as an outcome.[135,136] A high risk of bias was assigned due to the simple before-after study design, but both studies have large sample sizes, with 1 study involving a collaborative effort among 56 hospitals[136] and the other study involving nine wards in several hospitals across Italy.[135] The findings were consistent between the studies, with both studies reporting statistically significant improvements (Table 28). The measure is direct. The results are precise, with appropriate hair removal improving in one study from 59 percent to 95 percent[136] and a decrease in shaving in the other study from 76.8 percent to 73.5 percent.[135] The strength of evidence for use of audit and feedback and base strategies with or without provider reminder systems for appropriate hair removal compared with usual care is low.

Infection Rate

Five of the 6 studies reported infection rates and conducted statistical analyses to compare the rates.[135,136,138,140,145] The remaining study reported infection rates but did not perform statistical comparisons.[137] Of the 5 studies that conducted statistical analyses, 1 is of medium quality[138] and four are of lower quality,[135,136,140,145] providing a medium risk of bias. The results were nonsignificant in 4 of the 5 studies (Table 28), so consistency is unknown. Infection rate is a direct measure. Because the majority of the results are nonsignificant, they are imprecise. The strength of evidence for use of audit and feedback and base strategies with or without provider reminder systems compared with usual care for improving infection rates is insufficient (Table 29).

Adherence Rate and Infection Rate

Four of the 6 studies reported adherence rates and infection rates and conducted statistical analyses to compare the rates.[135,136,138,140] An additional study did not perform statistical analysis on pre and post infection rates, but conducted a multiple regression analysis including both adherence and infection rates in the model.[137] Of the 4 that conducted analyses comparing rates, 1 study is of medium quality[138] and 3 studies are of lower quality,[135,136,140] providing a medium risk of bias. While adherence rates improved significantly in antibiotic selection, antibiotic timing, and appropriate hair removal, changes in infection rates were nonsignificant (Table 28), so consistency is unknown. The adherence rates and infection rates are direct measures. Because comparisons of adherence to antibiotic duration rates and infection rates are nonsignificant, they are imprecise. Three studies[137,138,140] conducted multivariable analyses to assess whether adherence to preventive interventions was predictive of SSI rates. The nonrandomized stepped wedge study, which did not perform statistical analysis on the infection rates, did run a multiple regression analysis which demonstrated that nonadherence with antibiotic guidelines was a predictor of SSI (OR: 2.61; 95% CI: 1.20 to 5.70) (Table 29).[137] The interrupted time series study used a time series analysis and found that adherence did not impact SSI (p=0.99) (Table 28).[138] The simple before-after study describes a multivariable analysis that found nonadherence with any of the preventive interventions was not predictive of SSI (Table 28).[140] The strength of evidence for use of audit and feedback and base strategies with or without provider reminder systems compared with usual care for improving adherence and infection rates is insufficient (Table 29).

Provider Reminder Systems With the Base Strategies Compared With Usual Care

Five studies used the combination of QI strategies consisting of provider reminder systems with the base strategies compared with usual care.[133,139,142-144] One study is a randomized control trial of higher quality[133] and four studies are simple before-after studies and therefore are of lower quality.

Antibiotic Selection

One of the 5 studies reported adherence to antibiotic selection as an outcome.[139] Risk of bias is high because the study is a simple before-after study, consistency is unknown with only 1 study, the adherence measure (p=0.49) is direct, and because the finding was nonsignificant, the measure is imprecise. The strength of evidence for use of provider reminder systems with the base strategies compared with usual care for antibiotic selection is insufficient (Table 30).

Table 30. Strength of evidence for provider reminder systems with the base strategies compared with usual care

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Adherence: antibiotic selection	1 simple before-after [139]	High	Unknown	Direct	Imprecise	***Insufficient***
Adherence: antibiotic timing	1 controlled study[133] 2 simple before-after [142,143]	Medium	Consistent	Direct	Precise	***Low***
Adherence: antibiotic duration	1 simple before-after study[139]	High	Unknown	Direct	Imprecise	***Insufficient***
Adherence: hair removal	1 simple before-after study[142]	High	Unknown	Direct	Imprecise	***Insufficient***
Infection rate	1 Controlled study[133] 3 Simple before-after studies[142-144]	Medium	Consistent	Direct	Imprecise	***Low***
Adherence and infection rates	1 Controlled study[133] 2 Simple before-after studies[142,143]	Medium	Unknown	Direct	Imprecise	***Insufficient***

Antibiotic Timing

Three of the 5 studies reported adherence to antibiotic timing as an outcome.[133,142,143] Risk of bias is medium because 1 study is a controlled study[133] and 2 studies are simple before-after studies.[142,143] The evidence is consistent, with all three studies reporting significant improvements in antibiotic timing. The measure is direct. The findings are precise, with the controlled study reporting an improvement from 27 percent to 68 percent,[133] 1 simple before-after study reporting an improvement from 81 percent to 94 percent,[142] and the other reporting an improvement from 62 percent to 92 percent. The strength of evidence for use of provider reminder systems with the base strategies compared with usual care for antibiotic timing is low (Table 30).

Antibiotic Duration

One of the 5 studies reported adherence to antibiotic duration as an outcome.[139] Risk of bias is high because the study is a simple before-after study, consistency is unknown with only 1

measure, the adherence measure ($p<0.01$) is direct and imprecise. The strength of evidence for use of provider reminder systems with the base strategies compared with usual care for antibiotic duration is insufficient (Table 30).

Appropriate Hair Removal

One of the 5 studies reported adherence to appropriate hair removal as an outcome.[142] Risk of bias is high because the study is a simple before-after study, consistency is unknown with only one measure, the adherence measure ($p=0.001$) is direct and imprecise. The strength of evidence for use of provider reminder systems with the base strategies compared with usual care for appropriate hair removal is insufficient (Table 30).

Infection Rate

Four of the 5 studies reported infection rates as an outcome.[133,142-144] Risk of bias is medium because 1 study is a controlled study and 3 studies are a simple before-after design. The findings are consistent, with 1 study reporting nonsignificant findings[133] and 3 studies reporting statistical improvements.[142-144] Infection rate is a direct measure. The findings are imprecise. The strength of evidence for use of provider reminder systems with the base strategies compared with usual care for improving infection rates is low (Table 30).

Adherence Rate and Infection Rate

Three of the 5 studies reported both adherence rates and infection rates as outcomes.[133,142,143] Risk of bias is medium because 1 study is a controlled study and 2 studies are a simple before-after design. The findings are inconsistent, with antibiotic timing improving in all 3 studies, but infection rates improving significantly in only 2 of the studies. There was no analysis to assess if adherence to the preventive interventions was predictive of SSI. The strength of evidence for use of provider reminder systems with the base strategies compared with usual care for improving adherence and infection rates is insufficient (Table 30).

Base Strategies Compared With Usual Care

One controlled before-after study and one simple before-after study used a combination of the base strategies compared with usual care.[134,146] Neither study reported any adherence rates, but they provided a comparison of infection rates.

Infection Rate

Three studies addressed infection rates and used a combination of the base strategies, 1 controlled study[134] and 2 simple before-after study.[141,146] Risk of bias is medium. Evidence is of unknown consistency. Infection rate is a direct measure. The findings were imprecise. The strength of evidence for organizational change and provider education compared to usual care is insufficient (Table 31).

Table 31. Strength of evidence for base strategies within SSI compared with usual care

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Infection rate	1 controlled study[134] 2 simple before-after [141,146]	Medium	Unknown	Direct	Imprecise	***Insufficient***

Audit and Feedback With the Base Strategies Compared With Audit and Feedback Alone

One cluster randomized, controlled trial of 44 hospitals compared adherence rates between an audit and feedback group and an audit and feedback with membership in a QI collaborative group.[52] Adherence rates for antibiotic selection, antibiotic timing, and antibiotic duration were reported. Infection rates were not reported.

Antibiotic Selection

Risk of bias for this cluster randomized, controlled trial[52] is medium, consistency is unknown with only one study, the adherence measure is direct and because the measure is nonsignificant, the evidence is imprecise. The strength of evidence for use of audit and feedback with the base strategies compared with audit and feedback alone for antibiotic selection is insufficient (Table 32).

Table 32. Strength of evidence for audit and feedback with the base strategies within SSI compared with lower level of intervention

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Adherence: antibiotic selection	1 controlled[52]	Medium	Unknown	Direct	Imprecise	***Insufficient***
Adherence: antibiotic timing	1 controlled[52]	Medium	Unknown	Direct	Imprecise	***Insufficient***
Adherence: antibiotic duration	1 controlled[52]	Medium	Unknown	Direct	Imprecise	***Insufficient***

Antibiotic Timing

Risk of bias for this cluster randomized, controlled trial[52] is medium, consistency is unknown with only one study, the adherence measure is direct and because the measure is nonsignificant, the evidence is imprecise. The strength of evidence for use of audit and feedback with the base strategies compared with audit and feedback alone for antibiotic timing is insufficient (Table 32).

Antibiotic Duration

Risk of bias for this cluster randomized, controlled trial[52] is medium, consistency is unknown with only one study, the adherence measure is direct and because the measure is nonsignificant, the evidence is imprecise. The strength of evidence for use of audit and feedback with the base strategies compared with audit and feedback alone for antibiotic duration is insufficient (Table 32).

Organizational Change Alone Compared With a Low Intensity Intervention

One simple before-after study compared infection rates between a baseline period with a low level intervention consisting of provider education, to a postintervention period with a QI strategy of organizational change.[141] No adherence rates were reported.

Infection Rate

Risk of bias for this simple before-after study[141] is high, consistency is unknown with only one study, the infection rate (p=0.02) is direct and imprecise. The strength of evidence for use of

organizational change compared with provider education for improving infection rates is insufficient (Table 33).

Table 33. Strength of evidence for organizational change alone within SSI compared with low intensity of intervention

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Infection rate	1 simple before-after[141]	High	Unknown	Direct	Imprecise	***Insufficient***

Catheter-Associated Urinary Tract Infection (CAUTI)

Overview

The literature search identified 11 studies that addressed the prevention of catheter-associated urinary tract infections (CAUTI) and controlled for confounding factors or secular trend (Table 34).[48,69,135,145,181-187] Two[135,185] of the 11 studies are from the 2007 report.[3] The objective of majority of the studies was to reduce indwelling urinary catheter duration and unnecessary catheterization among patients with an indwelling urinary catheter. In addition, the objective of 1 study was to limit use of urinary catheters in postoperative patients.[135] Another study implemented a hand hygiene campaign.[48]

The study designs included 1 randomized stepped wedge design,[186] 1 randomized, controlled trial,[182] 1 controlled before-after study,[185] 2 interrupted time series,[181,183] and 6 simple before-after studies.[48,69,135,145,184,187] Two studies implemented four quality improvement (QI) strategies,[181,187] 2 studies implemented three QI strategies,[135,186] 4 studies implemented two QI strategies[48,145,182,183] and 3 studies[69,184,185] implemented one QI strategy. Provider reminder systems were used in 8 studies while 6 implemented organizational change as well.[48,69,135,145,181-187] Specific attributes of organizational change that were implemented for each study are shown in Table 35.

Infection and adherence rates were reported and analyzed in 6 studies;[48,69,135,182-184] adherence alone was reported in 3 studies;[185-187] and infection rates alone were reported in 2 studies.[145,181] Duration of overall indwelling urinary catheterization was reported as an adherence measure in 5,[64,69,135,184,185] while two[64,182] reported inappropriate indwelling urinary catheterization among patients who had urinary catheters and 1 study[135] reported on rate of urinary catheter use in post-operative patients**.** Three studies reported cost information.[64,185,186]

Seven studies[48,64,69,145,181,184,185] were conducted in single center tertiary care and/or university affiliated hospitals and 4 were a multisite study.[135,182,186,187] Two studies was from the United States,[185,187] 2 were from France,[69,184] 1 from Thailand,[64] 1 in Canada,[182] 1 in the Netherlands,[186] 1 in Brazil,[181] 1 in Colombia,[48] 1 in Israel,[145] and 1 from Italy.[135] Specific hospital settings included seven medical ICUs, one surgical ICU, nine surgical wards, one neurosurgery department, one cardiovascular surgery department, one orthopedic surgery department, one neurology department, one geriatrics department, and one medical-surgical department.

The sample size for the postintervention period ranged from 93 to 1,794 patients, and infection rates in the postintervention period ranged from 1.8 to 12.9 infections per 1,000 catheter-days. Baseline infection rates ranged from 1.7 to 21.5 infections per 1,000 catheter-days.

The search also identified 16 studies that addressed prevention of catheter-associated urinary tract infections that did not control for confounding or secular trend.[80,89,97,103,154,188-198] These studies were not included in the analysis due to their weak designs and potential for biased results (Appendix F4).

Methodological Quality of Included Studies

As displayed in Table 36, 1 study[182] was ranked of higher quality, 3[64,185,186] of medium quality, and 7[48,69,135,145,181,184,187] of lower quality. Six of the 11 had followup longer than 1 year after the intervention.[48,64,145,181,182,187] Given the study designs, adequate measures were taken to control for confounding and secular trend in 8 of 11 studies.[48,64,69,135,145,182,185,186] Six studies analyzed both adherence rates and infection rates.[48,64,69,135,182,184] One study[69] explicitly reported independence from other QI efforts; this dimension was not applicable for the randomized, controlled trials.[182,186]

Table 34. Overview of CAUTI articles that control for confounding or secular trend

Author, location-year	Study type	Analysis for infection rates	Sample size (infections)	Organizational change	Provider education	Audit and feedback	Provider reminder systems	Patient education	Financial incentives
van den Broek, Netherlands - 2011[186]	Stepped wedge design	Time-series analysis	pre: 1149 post: 1794	•	•		•		
Loeb, Canada - 2008[182]	Individual RCT	Logistic regression	control: 345 (51) study: 347 (51)	•			•		
Saint, United States - 2005[185]	Controlled before-after	Poisson regression (for adherence)	control pre: 1,449 control post: 1,202 study pre: 1,546 study post: 1,481				•		
Apisarnthanarak, Thailand - 2007[64]	Interrupted time series	Segmented regression	pre:1105 post: 1307	•			•		
Marra, Brazil - 2011[181]	Interrupted time series	Generalized linear model		•	•	•	•		
Fakih, United States - 2012[187]	Simple before-after	GEE model		•	•	•	•		
Barrera, Colombia - 2011[48]	Simple before-after	Poisson regression	total: 14,516 (total # HAI: 2,398)			•		•	
Salim, Israel - 2011[145]	Simple before-after	Logistic and Poisson regression	pre: 751 (9) post: 865 (3)		•	•			
Seguin, France - 2010[69]	Simple before-after	Poisson regression	pre: 676 (29) post: 595 (18)				•		
Crouzet, France - 2007[184]	Simple before-after	Logistic regression	pre: 141 post: 93				•		
Greco, Italy - 1991[135]	Simple before-after	Mantel-Haenszel relative risks	pre: 4,096 post: 1,638	•	•	•			

Table 35. Specific attributes of organizational change for CAUTI articles that control for confounding or secular trend

Author, Country-Publication Year	Multidisciplinary Team	Team Responsibilities	Hospital Executives on Team	New Protocol or Standards Implemented	Designate Staff Member Responsible for Implementation
van den Broek, Netherlands - 2011[186]	•	Develop the method of implementation that will best suit the hospital and the introduce it to the wards.			
Loeb, Canada - 2008[182]				•	•
Apisarnthanarak, Thailand - 2007[64]	•	Give feedback to the ICU staff, create an action plan, and lead daily bedside discussions with treating physicians	•	•	•
Marra, Brazil - 2011[181]				•	
Fakih, United States - 2012[187]	•	Educate the patient care nurses, triggers the evaluation of catheter necessity, obtain physician support, and address infectious complications related to the urinary catheter.			
Greco, Italy – 1991[135]				•	

Table 36. Study quality for CAUTI articles that control for confounding or secular trend

Author, Location-Year	Study Type	Sufficient followup[a]	Adequate control for confounding or secular trend[b]	Change in adherence was analyzed[c]	Change in infection rate was analyzed[d]	Independent of other QI effort[e]	Overall quality rating	Comments
van den Broek, Netherlands - 2011[186]	Stepped wedge design	-	+	+	-	N/A	***Medium***	Proportion of infected patients were reported but not analyzed and followup was only 5 months for each arm.
Loeb, Canada - 2008[182]	Individual RCT	+	+	+	+	N/A	***Higher***	Randomized at patient level. Contamination of control group was highly possible.
Saint, United States - 2005[185]	Controlled before-after	-	+	+	-	?	***Medium***	Followup was only 8 months. There were large differences in catheterization rates and demographics between the control and study wards, but these were taken into account in the analysis.
Apisarnthanarak, Thailand - 2007[64]	Interrupted time series	+	+	+	+	-	***Medium***	
Marra, Brazil - 2011[181]	Interrupted time series	+	-	-	+	?	***Lower***	Patient characteristics were not compared
Fakih, United States - 2012[187]	Simple before-after	+	-	+	-	?	***Lower***	Authors use GEE model for analysis of inappropriate catheter and time use at the patient-level. Additional covariate data were not collected or used.
Barrera, Colombia - 2011[48]	Simple before-after	+	+	+	+	?	***Lower***	
Salim, Israel - 2011[145]	Simple before-after	+	+	-	+	?	***Lower***	Adherence was not measured.
Seguin, France - 2010[69]	Simple before-after	-	+	+	+	?	***Lower***	
Crouzet, France - 2007[184]	Simple before-after	-	-	+	+	-	***Lower***	Sample size is small and followup is short, and different definition is used.
Greco, Italy - 1991[135]	Simple before-after	-	+	+	+	?	***Lower***	Followup was only 6 months.

Note: All studies used standard and consistent infection definitions. CDC methodology was used in all studies except Seguin et al. (2010).[69]
Infection rates were adjusted for device utilization in all studies except Loeb et al. (2008).[182]
Independence from other QI efforts was not applicable for randomized controlled trials
[a]Is the length of followup sufficient (at least 12 months) to support the evaluation of primary outcomes and harms?
[b]Were adequate measures taken to control for confounding or secular trend?
[c]Was change in adherence analyzed?
[d]Was change in infection rate analyzed?
[e]Was the intervention performed independent of other QI efforts or other changes?
'+' means 'yes'
'-' means 'no'
'?' means 'uncertain'

Studies That Control for Confounding or Secular Trend

Controlled Studies

van den Broek et al. (2011)[186]

Summary

van den Broek et al. conducted a stepped wedge design study in ten Dutch hospitals.[186] Organizational change, provider education, and provider reminder systems were implemented. Hospitals in the intervention group developed tailored approaches to implementing measures to reduce the use of indwelling urinary catheters. After 8 months, both groups were actively participating in the intervention. The proportion of correctly inserted indwelling urinary catheters, duration of catheterization, and prevalence of catheterized patients significantly improved after the intervention.

Description

Ten Dutch hospitals participating in the Dutch surveillance program of nosocomial infections (PREZIES) were randomized to two groups. Each hospital selected as many wards as necessary so that there would be roughly 20 catheterized patients occurring over the 17-month study period in each ward at each hospital. Hospitals chose the changes to implement to reduce indwelling urinary catheter use. In a post hoc summary, the changes were divided into three categories: (1) revision of existing protocols and materials used for catheterization, (2) provider education through various approaches, and (3) changing daily practice by paying closer attention to catheterized patients during daily meetings. Logistic and exponential regressions were used to analyze the outcomes.

Results and Limitations

During the baseline period, there were 1,149 catheterized patients in the ten hospitals. The postintervention population was 1,794 catheterized patients. The prevalence of catheters and the duration of indwelling urinary catheters was significantly lower in the surgery department after the intervention (OR: 0.84; 95% CI: 0.75 to 0.96; OR: 0.80; 95% CI: 0.71 to 0.90, respectively). The neurology departments also saw a significant improvement in duration of indwelling urinary catheterization (OR: 0.81; 95% CI: 0.69 to 0.96; Table 37). The authors found that 460 catheter-days (95% CI: 162 to 761) were eliminated per 100 catheterized patients due to the intervention. Overall measures were not reported for the catheter prevalence or duration of indwelling catheterization. Infection rates were reported but not analyzed; symptomatic CAUTI was 12.6% during baseline and 12.7% during the postintervention period; asymptomatic CAUTI was 37.4% during baseline and 38.3% during the postintervention period.

Table 37. Outcomes for CAUTI articles that control for confounding or secular trend

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
van den Broek, Netherlands - 2011[186]	Revision of existing protocols, introduction of staff education and change to daily practice/ No Intervention (usual care)	Adherence	Correctly inserted UC	◊			64% → 74% (p<0.0001)	Adherence analysis included hospital, ward type and the interaction between hospital and ward.
		Infection	Symptomatic CAUTI				12.6% → 12.7%	
			Asymptomatic CAUTI				37.4% → 38.3%	
		Cost/Savings	Cost of implementing program				€2,638 (95% CI: €1,023 to €3,763)	
			Cost of insertion of UC				€ 28	
			Cost of removal of UC				€ 3	
			Cost of daily care of UC				€ 3	
			Mean amount saved per 100 patients				€ 537	
Loeb, Canada - 2008[182]	Prewritten stop orders for indwelling urinary catheters/ No Intervention (usual care)	Adherence	Duration of inappropriate UC	◊			Control: 3.89 Intervention: 2.20 (p<0.001)	RR was adjusted for sex and antimicrobial use during catheterization. Reinsertion rate was similar in both groups (7.0 vs. 8.6%, p=0.45).
			Duration of overall UC	◊			Control: 5.04 Intervention: 3.70 (p<0.001)	
		Infection Rate	Overall			•	Control: 20% Intervention: 19% RR: 1.04 (95% CI: 0.75 to 1.44, p=0.80)	
		Costs/Savings						

Table 37. Outcomes for CAUTI articles that control for confounding or secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Saint, United States - 2005[185]	Urinary catheter reminder in patient chart and pager reminder/ No Intervention (usual care)	Adherence	Proportion of days catheterized	◊			Control: 27.8% → 32.0% Study (Intent-to-treat): 14.4% → 13.3% (p=0.007) Study (per-protocol): 14.4% → 10.7% (p=NR)	Change in proportion of catheterized days was adjusted for baseline differences in catheterization, age, sex, and length of stay. Recatheterization occurred in 39 patients and was not significantly different between intervention and control ICUs after adjustment for age, sex, and length of stay (p=0.41). Per-protocol analysis was also done, removing cases that were not adherent with reminders.
		Infection Rate						
		Costs/Savings	Annual net savings				\$249-\$5,318 (per-protocol annual net savings: \$50,832)	
Apisarnthanarak, Thailand - 2007[183]	Daily physician reminders to remove unnecessary catheter/ No Intervention (usual care)	Adherence	Percent of Inappropriate UC	◊			20.4% → 11% (p=0.04)	Initial change after intervention was significant, but trend after intervention was not significantly different than baseline trend.
			Duration of overall UC	◊			11 → 3 (p<0.001)	
		Infection Rate	Overall	•			21.5 → 5.2 (p<0.001)	
			Medical Ward	•			21.5 → 6.5 (p=0.04)	
			Surgical Ward	•			19.4 → 7.8 (p=0.03)	
			ICU	•			23.4 → 3.5 (p=0.003)	
		Costs/Savings	Mean monthly hospital costs for antibiotics	◊			\$3,739 → \$1,378 (p<0.001)	
			Mean hospitalization costs per patient	◊			\$366 → \$154 (p<0.001)	

Table 37. Outcomes for CAUTI articles that control for confounding or secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Marra, Brazil - 2011[181]	CAUTI Bundle with nurse empowerment and daily check of UC necessity/ Low intensity Intervention	Adherence	ICU Overall insertion measures				? → 84.3%	
			SDU Overall insertion measures				? → 87.9%	
			ICU appropriate UC indication				? → 87.9%	
			SDU appropriate UC indication				? → 88.3%	
		Infection	Overall ICU	•			7.6 (95% CI: 6.6 to 8.6) → 5.0 (95% CI: 4.2 to 5.8) (p<0.001)	
			Overall SDU	•			15.3 (95% CI: 13.9 to 16.6) → 12.9 (95% CI: 11.6 to 14.2) (p=0.014)	
		Cost/Savings						
Fakih, United States - 2012[187]	CAUTI Bundle with education and feedback/ No Intervention (usual care)	Adherence	Appropriate catheterization	◊			44.3% (95% CI: 40.3% to 48.4%) → 57.6% (95% CI: 51.7% to 63.4%) (p=0.005)	Authors state data reported after week 140 was too unreliable to use due to sparse data collection (8% to 2%) at weeks 152 and 190 respectively. Final appropriate catheterization rate at 190 weeks was 65.3% (95% CI: 44.5% to 81.5%)
		Infection						
		Cost/Savings						
Barrera, Colombia - 2011[48]	hand hygiene promotion/ No Intervention (usual care)	Adherence	ABHR use	◊			9.2% annual increase (p<0.001)	CAUTI significantly increased by 8.0% annually. ABHR use is an indirect measure of hand hygiene.
		Infection	Overall		•		1.7 → 4.5 (p=0.002)[a]	
		Cost/Savings						

Table 37. Outcomes for CAUTI articles that control for confounding or secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Salim, Israel - 2011[145]	Refresher courses on infection control and catheter insertion/ No Intervention (usual care)	Adherence						All ORs and IRRs were adjusted for membrane rupture and duration of operation. These results are also further broken down by elective and nonelective cesarean. More significant results were found in the elective cesarean group.
		Infection	Overall			•	1.2% → 0.3% (OR=0.31, 95% CI: 0.08 to 1.17, p=0.08)	
		Cost/Savings						
Seguin, France - 2010[69]	Physician reminder of catheter duration/ No Intervention (usual care)	Adherence	Duration of overall UC	◊			5 → 4 (p<0.001)	Duration of overall UC and infection rates were adjusted for age, SAPS II, and admission diagnosis.
			Median time to UC removal	◊			14 → 8 (p<0.001)	
		Infection Rate	Overall			•	5.0 → 4.9 (p=0.938)	
		Costs/Savings						
Crouzet, France - 2007[184]	Physician reminder to remove catheter beginning on day 4/ No Intervention (usual care)	Adherence	Duration of overall UC			◊	8.4 → 6.7 (p=0.14)	Overall late CAUTI was adjusted for sex, age, average duration of catheterization, iterative catheter change, and use of antibiotics before or during catheterization. Unit of measure for early CAUTI was frequency of early CAUTI per 100 catheterized patients.
		Infection Rate	Late (>4 days) Overall	•			12.3 →1.8 (p=0.03)	
			Late (>4 days) Orthopedic and cardiovascular surgery	•			17.3 → 0 (p=0.0002)	
			Late (>4 days) Neurology and neurosurgery			•	11.8 → 0 (p=0.06)	
			Late (>4 days) Geriatrics			•	4.1 → 13.4 (p=0.67)	
			Early (≤4 days) Overall			•	7.8 → 13.9 (p=0.13)	
		Costs/Savings						

Table 37. Outcomes for CAUTI articles that control for confounding or secular trend (continued)

Author, Country-Year	Intervention/ Comparator	Type of Outcome	Specific Measure	Improve	Worsen	NS	Change in Specific Measure	Comments
Greco, Italy - 1991[135]	Active surveillance and implementation of new infection control recommendations in postoperative patients/ No Intervention (usual care)	Adherence	Mean duration of overall UC	◊			4.6 → 3.9 (p=0.02)	
			Percent of patients with UC	◊			34.4% → 28.2% (p< 0.0001)	
		Infection Rate	Percentage of patients with UC with UTI			•	12.9% → 11.7% (Adjusted RR: 0.92; 95% CI: 0.69 to 1.23	
		Costs/Savings						

Abbreviations: UC = urinary catheter; RR = relative risk; SAPS II = Simplified Acute Physiological Score II
• was used for infection rate outcomes
◊ was used for adherence and costs/savings outcomes

Loeb et al. (2008)[182]

Summary

Loeb et al. implemented a patient level randomized, controlled trial within seven medical ICUs at three Canadian tertiary care hospitals.[182] Compared with usual care, organizational change and a provider reminder system improved adherence rates, but no significant change in infection rates was observed.

Description

Three-hundred forty-seven patients were randomized to receive a stop order for their urinary catheter while 345 patients were randomized to usual care. The organizational change was to give the nurses the task to review the patients' chart, review the criteria for appropriate use of an indwelling urinary catheter, and assess whether the catheter should be removed. Randomization was stratified by hospital. The individuals assessing the presence of an infection were blinded to study group. Chi-square test and multivariable logistic regression, controlling for sex, antimicrobial use during catheterization, and diabetes, were used to analyze the adherence and infection rates.

Results and Limitations

After 30 months, a significant improvement in both mean duration of inappropriate indwelling urinary catheterization (3.89 days vs. 2.20 days, $p<0.001$) and total indwelling urinary catheterization in the stop order group was observed (5.04 days vs. 3.70 days, $p<0.001$) (Table 37). One-hundred and two CAUTI were identified, 51 in each arm, resulting in a nonsignificant difference between infection frequencies (20% vs. 19%, adjusted $p=0.80$). Reinsertion rates of indwelling urinary catheters were also similar between study groups (7.0% vs. 8.6%, $p=0.45$). Analysis adjusting for covariates showed the stop order was not associated with CAUTI, but female sex was a risk factor ($p=0.047$) and receiving antimicrobials during catheterization ($p<0.0001$) was protective against infection.

Saint et al. (2005)[185]

Saint et al. conducted a controlled before-after study to decrease urinary catheter-days.[185] Details of this study are found in the 2007 report.[3]

Interrupted Time Series

Apisarnthanarak et al. (2007)[183]

Summary

Apisarnthanarak et al. implemented organizational change and a provider reminder system hospitalwide to remove unnecessary indwelling catheters in a tertiary care university affiliated hospital in Thailand.[183] Significant reductions in inappropriate indwelling urinary catheterization and infection rate were observed.

Description

Through the use of a multidisciplinary team, the hospital initiated a provider reminder system to reduce the inappropriate use of catheters in the hospital. Nurses were given the task to identify

patients on catheter day 3 or later. Members of the multidisciplinary team then reviewed the indications for the catheter along with other information and determined if the indwelling urinary catheter was appropriate. If deemed inappropriate, a physician from the multidisciplinary team held a bedside discussion with the patient's treating physician to determine the possibility of discontinuing the indwelling urinary catheter. Continual support for the intervention was provided during monthly staff meetings. A total of 1,105 patients had catheters in a 10-month baseline period and 1,307 had catheters in a 12-month postintervention period. Chi-square test and segmented regression were used to analyze adherence and infection rates, respectively.

Results and Limitations

Proportion of patients with an inappropriate catheter significantly declined from 20.4 percent in the baseline period to 11 percent in the postintervention period (p=0.04; Table 36). Segmented regression showed a significant initial reduction in mean duration of overall indwelling catheterization (p<0.001, Appendix Table G3) and mean infection rate (p<0.001, Appendix Table G3). A nonsignificant change in trend over time was observed for both mean duration of catheterization and infection rates (p=0.24 and p=0.50, respectively). Overall mean infection rates dropped from 21.5 infections per 1,000 catheter-days in the baseline phase to 5.2 infections per 1,000 catheter-days in the postintervention phase. There was also a significant reduction in mean monthly costs for CAUTI-associated antibiotic treatments in this entire Thai hospital ($3,739 vs. $1,378, p<0.001), and mean hospitalization costs per patient also decreased ($366 vs. $154, p<0.001). While segmented regression takes secular trend into account, it does not consider the changes between baseline and postintervention for other factors, such as patient characteristics, that may influence the risk of infection or nonadherence.

Marra et al. (2011)[181]

Summary

Marra et al. implemented a QI initiative using audit and feedback, a provider reminder system, organizational change, and provider education.[181] This took place in three units, one ICU and two step-down units, within a private tertiary care hospital in Brazil. Using this combination of QI strategies, infection rates significantly improved over the study period.

Description

During the intervention period, the hospital CEO declared zero tolerance for CAUTI in the hospital. So a bladder bundle was initiated in addition to the surveillance and other procedures from the baseline period (chlorhexidine skin preparation, no routine change of catheters, and nurses provided feedback to ICU team about adherence to CDC guidelines for insertion). The bladder bundle was accompanied by a catheter insertion cart that held everything needed for a proper indwelling urinary catheter insertion. At the time of performance monitoring, nurses were allowed to address nonadherent bundle elements. A presentation on the protocol and bundle was given. Feedback on adherence was provided via email every month to the ICU team. Posters were also used to display adherence rates. An ICU nurses' group was formed to remove unnecessary catheters every day. ICU nurses were instructed to ask the treating physician daily if the catheter is necessary. Generalized linear models with a Poisson distribution were used to analyze infection rates.

Results and Limitations

Adherence rates were not analyzed, although, adherence rates were between 84 percent and 99 percent in the postintervention period. The step down units had slightly higher adherence rates than the ICU did. Appropriate urinary catheter indications were present in about 88 percent of the patients in the postintervention period. After 19 months, infection rates significantly improved in all three units. In the ICU, infection rates went from 7.6 (95% CI: 6.6 to 8.6) infections per 1,000 catheter-days in the baseline period to 5.0 (95% CI: 4.2 to 5.8) in the postintervention period (p<0.001). In the step-down units, infection rates went from 15.3 (95% CI: 13.9 to 16.6) in the baseline period to 12.9 (95% CI: 11.6 to 14.2) in the postintervention period (p=0.014).

A limitation of this study was the lack of ongoing surveillance. Small audits were conducted once a month at random to observe process measures. In addition, no baseline process measures were reported so the full effect of the intervention was not examined.

Simple Before-After

Fakih et al. (2012)[187]

Fakih et al. investigated the effects of organizational change, provider education, audit and feedback, and provider reminder systems on CAUTI rates in 163 units within 71 acute-care hospitals in the United States.[187] This study was part of the Keystone ICU Project.

The formation of a team designed to disseminate information regarding to the study and promote collection of data were recommended at every participating hospital. Provider education was implemented through multiple webinars that addressed the infectious and noninfectious risks of catheter use ultimately focusing on assessing daily catheter need. Continuous feedback of process measures was provided to each unit. Nurses were encouraged to assess the necessity of indwelling urinary catheters during nursing round and contact the physician if no indication was present. A bladder bundle manual was given to every participating hospital. Further support was available through coaching calls and additional webinars.

A sample size was not reported. Fakih et al. (2012) stated that data reported after week 104 was too unreliable due to sparse data collection (week 104, 48%; week 140, 13%; week 152, 8%; week 190, 2%). Appropriate catheterization rate increased from 44.3 percent (95% CI: 13.9% to 16.6%) at baseline to 57.6 percent (95% CI: 51.7% to 63.4%; p=0.005) at 104 weeks. Overall use of indwelling urinary catheters decreased from 18.1 percent (95% CI: 16.8% to 19.6%) at baseline to 13.8 percent (95% CI: 12.9% to 14.8%; p<0.001) at week 104.

There are some limitations to this study including but not limited to a lack of objective identification of proper catheter use, a failure to account for effects of a multicenter study, adjustment for hospitals that primarily address patients where daily catheter use is required, and the sharp decline in data collection after two years. While two years is a substantial amount of data, this speaks to the sustainability of such a project.

Barrera et al. (2011)[48]

Barrera eta al. described a 4-year study in six ICUs (general, trauma, neurosurgery, burn, pediatric and neonatology) in Colombia investigating organizational change and provider education.[48] There were 14,516 patients included over the entire study of which 2,398 acquired a HAI. Risks for CAUTI and HAI were compared using Poisson regression. Alcohol based hand rub was used as an indirect measure of hand hygiene. Use of the hand rub significantly improved 9.2 percent annually (p<0.001). Infection rates for CAUTI increased from 1.7 to 4.5 and was

statistically significant (p=0.002). Barrera et al. (2011) also reported that CAUTI significantly increased by 8 percent annually.

Salim et al. (2011)[145]

Salim et al. reported on the effects of provider education and audit and feedback on CAUTI rates in women who underwent caesarean delivery in Israel.[145] There were 1,616 patients enrolled in this 2-year study. Adherence was not reported. Infection rates were assessed using logistic and Poisson regression. Overall infection rates decreased from 1.2 percent to 0.3 percent (OR: 0.31; 95% CI: 0.08 to 1.17; p=0.08) and was nonsignificant. All ORs and IRRs were adjusted for membrane rupture and duration of operation. Salim et al. (2011) reported results by elective and non-elective cesarean. There were more significant results found in the elective cesarean group.

Seguin et al. (2010)[69]

Seguin et al. reported on a 9-month intervention in a university affiliated hospital in France.[69] The intervention included a provider reminder system to reduce the duration of indwelling urinary catheterization, as well as central venous catheterization. During the baseline period, 676 patients were included, and during the postintervention period, 595 patients were included. One way analysis of variance (ANOVA) was used to analyze duration of catheterization while Poisson regression was used to analyze the infection rates. Due to group imbalances, both outcomes were adjusted for age, Simplified Acute Physiology Score II (SAPS II), and admission diagnosis. Significant changes in median duration of indwelling urinary catheterization (5 days vs. 4 days, p<0.001) and median time to urinary catheter removal (14 days vs. 8 days, p<0.001) were observed, but the change in infection rates was not statistically significant (5.0 infections per 1,000 catheter-days versus 4.9 infections per 1,000 catheter-days, p=0.94) (Table 37).

Crouzet et al. (2007)[184]

Crouzet et al. reported on a 3-month intervention at a university affiliated hospital in France.[184] The intervention included a provider reminder system to reduce the duration of indwelling urinary catheterization. The baseline sample size was 141 while the postintervention sample size was 93 patients. ANOVA was used to analyze duration of catheterization while logistic regression was used to analyze infection rates. The regression model was adjusted for age, sex, duration of catheterization, systemic antibiotic administration, and repeated catheter replacement. Overall duration of indwelling catheterization was similar in the postintervention period and the baseline period (8.4 days vs. 6.7 days, p=0.14; Table 37). The authors divided CAUTI into two categories in this study, early CAUTI, defined as an infection occurring on or before catheter-day 4, and late CAUTI, defined as an infection occurring after catheter-day 4. Overall incidence of late CAUTI dropped significantly from 12.3 infections per 1,000 catheter-days in the baseline period to 1.8 infections per 1,000 catheter-days in the postintervention period (p=0.03). Analysis adjusting for covariates showed the intervention was significantly protective against late CAUTI occurrence (p=0.01). Limitations of this study are the small sample size and short postintervention period. Overall assessment of outcomes is weakened by Crouzet et al. (2007) reporting early and late CAUTI rates which cannot be aggregated with the overall CAUTI rates in the other studies.

Greco et al. (1991)[135]

Greco et al. conducted a before-after study to decrease urinary catheter-days, decrease urinary catheter use, and decrease UTI in post-operative patients.[135] Details of this study are found in the 2007 report.[3]

Studies That Do Not Control for Confounding or Secular Trend

Sixteen studies that addressed prevention of catheter-associated urinary tract infections used a simple two sample test to analyze outcomes (Appendix Table F4).[80,89,97,103,154,188-198] Fifteen studies were simple before-after study designs and one[191] was a controlled before-after study. The controlled before-after study was demoted due to lack of between group comparisons. Five studies focused on reducing duration of catheterization.[188-190,192,193] Seven studies implemented CAUTI bundles, including standardized protocols that focused both on sterile insertion and necessity of the indwelling catheter.[80,89,97,191,194,196,198] Two studies implemented an educational program to increase awareness of hygiene and hospital acquired infections.[103,154] Two others focused on better educating their residents through novel methods.[195,197] Nine studies[80,97,188,190,191,193,194,196,198] implemented audit and feedback, 9 studies[80,89,97,189,192-194,196,198] implemented organizational change, 15 studies[80,89,103,154,188-198] implemented provider education, and 8 studies[89,188,192-196,198] implemented a provider reminder system.

Strength of Evidence

Audit and Feedback and Provider Reminder Systems and the Base Strategies Compared With Usual Care

Two studies used a combination of audit and feedback and provider reminder systems with the base strategies compared with usual care.[181,187] The strength of evidence for this combination is summarized in (Table 38).

Appropriate Urinary Catheterization

One study reported proportion of appropriately indicated indwelling urinary catheters only.[187] The strength of evidence for this combination was judged as insufficient because there was only one study.

Infection Rate

One study reported only on infection rates.[181] The strength of evidence for this combination was judged as insufficient because there was only one study.
only and Marra et al. (2011) reported.

Table 38. Audit and feedback and provider reminder systems and the base strategies within CAUTI compared with usual care

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Adherence: Appropriate urinary catheterization	1 Simple before-after study[187]	High	Unknown	Indirect	Imprecise	***Insufficient***
Infection rate	1 Interrupted time series[181]	Medium	Unknown	Direct	Imprecise	***Insufficient***

Audit and Feedback and the Base Strategies Compared With Usual Care

The strength of the evidence for the use of this combination to reduce CAUTI compared with usual care is summarized in Table 39. Three studies[48,135,145] used this combination.

Overall Urinary Catheterization

One study reported rate of urinary catheter use and duration of urinary catheters as well as percentage of patients with urinary infection in post-operative patients.[135] The strength of evidence for this combination was judged as insufficient because there was only one study.

Hand Hygiene

One study reported the on the change in hand hygiene through the use alcohol-based hand rub use.[48] The strength of evidence for this combination was judged as insufficient because there was only one study.

Infection Rate

Three simple before-after studies used this combination and analyzed infection rates.[48,135,145] The risk of bias was judged to be high. One study[48] reported a significant worsening in infection rates, while the other two[135,145] reported a nonsignificant change over time. The consistency of the evidence is unknown. Infection rate is a direct measure and the evidence was deemed imprecise. The strength of evidence for this combination was judged as insufficient.

Adherence and Infection Rate

Two simple before-after studies used this combination and analyzed both adherence and infection rates.[48,135] With unknown consistency and imprecise evidence for each outcome separately, the evidence for improving adherence and infection rates is also deemed insufficient.

Table 39. Strength of evidence for audit and feedback and the base strategies within CAUTI compared with usual care

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Adherence: overall urinary catheterization	1 simple before-after [135]	High	Unknown	Indirect	Imprecise	***Insufficient***
Adherence: hand hygiene	1 simple before-after [48]	High	Unknown	Indirect	Imprecise	***Insufficient***
Infection rate	3 simple before-after [48,135,145]	High	Unknown	Direct	Imprecise	***Insufficient***
Adherence and infection rates	2 simple before-after [48,135]	High	Unknown	Direct	Imprecise	***Insufficient***

Provider Reminder Systems Alone or with the Base Strategies Compared With Usual Care

The strength of the evidence for the use of a provider reminder system alone or with the base strategies compared with usual care is summarized in Table 40. Six of 11 studies used this combination of QI strategies.

Duration of Overall Urinary Catheterization

All studies reported duration of overall catheterization as an outcome.[69,182-186] As shown in Table 36, 1 study[182] is of higher quality, 3[183,185,186] are of medium quality, and 2 studies[69,184] are of lower quality. Due to the overall quality of these studies, the risk of bias was determined to be medium. Four of the 6 studies[69,182,183,185] observed a significant improvement in duration of overall indwelling urinary catheterization, and the study[184] with a nonsignificant finding was consistent in direction. The last study had mixed results.[186] There were significant improvements in 2 of the 4 departments . Duration of overall indwelling urinary catheterization, however, is not a direct measure of appropriate catheter use. Therefore, this outcome was deemed to be an indirect measure of adherence. The baseline (or control) duration of overall catheterization ranged from 5.0 to 11.0 days. The postintervention duration ranged from 3.0 to 6.7 days. One controlled study found a significant decrease, from 14.4 to 13.3 percent, in the proportion of days catheterized.[185] Another found that 460 catheter-days (95% CI: 162 to 761) were eliminated per 100 catheterized patients.[186] The evidence was judged to be precise. Use of a provider reminder system alone or with the base strategies for improving duration of overall urinary catheterization as compared with usual care is considered to have a moderate strength of evidence.

Table 40. Strength of evidence for provider reminder system alone or with the base strategies within CAUTI compared with usual care

Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Adherence: overall urinary catheterization	3 controlled studies[182,185,186] 1 interrupted time series[183] 2 simple before-after[69,184]	Medium	Consistent	Indirect	Precise	***Moderate***
Adherence: inappropriate urinary catheterization	1 controlled study[182] 1 interrupted time series[183]	Medium	Consistent	Indirect	Imprecise	***Insufficient***
Adherence: correctly inserted urinary catheters	1 controlled study[186]	Medium	Unknown	Indirect	Imprecise	***Insufficient***
Infection rate	1 controlled study[182] 1 interrupted time series[183] 1 simple before-after[69]	Medium	Inconsistent	Direct	Imprecise	***Insufficient***
Adherence and infection rates	1 controlled study[182] 1 interrupted time series[183] 1 simple before-after[69]	Medium	Inconsistent	Direct	Imprecise	***Insufficient***

Inappropriate Urinary Catheterization

Two studies[182,183] reported measures of inappropriate indwelling urinary catheterization, but each used a different metric. Apisarnthanarak et al. (2007)[183] used proportion of patients with an inappropriate catheter, while Loeb et al. (2008)[182] measured duration of inappropriate catheterization. As shown in Table 36 1 study[182] is of higher quality and 1 is of medium quality.[183] Risk of bias was judged to be medium. The evidence was considered consistent because in both studies a statistically significant improvement was noted. This outcome is

considered indirect given the two approaches to measuring inappropriate urinary catheter use. With only 2 studies and different measurements, this is judged as imprecise. The strength of evidence for use of a provider reminder system alone or with the base strategies for duration of inappropriate urinary catheterization as compared with usual care was considered insufficient.

Correctly Inserted Urinary Catheters

One study reported proportion of correctly inserted urinary catheters.[186] Little can be gleaned from 1 study. The strength of evidence for the use of a provider reminder system alone or with the base strategies to improve correctly inserted urinary catheters is insufficient.

Infection Rate

Three of the 6 studies reported overall infection rates.[69,182,183] While the study by Crouzet et al. (2007)[184] reported on infection rates, it is not included here with the other studies because it reported on early CAUTI and late CAUTI but did not report on the overall CAUTI rate. As shown in Table 36, one study[182] is of higher quality, 1 study[183] of medium quality, and 1 study[69] of lower quality. Risk of bias was judged to be medium. The evidence was considered inconsistent because there was no clear direction of change among all 3 studies. The higher quality study found no change in infection rate, 20 percent versus 19 percent; the medium quality study did not find a change in trend over time although an initial change due to the intervention was observed; and the lower quality study also observed no change in infection rate, 5.0 versus 4.9 infections per 1,000 catheter-days. The evidence for infection rate was judged as imprecise. Therefore, evidence for use of a provider reminder system alone or with the base strategies for improving infection rates as compared with usual care was considered insufficient.

Adherence and Infection Rate

Three of 6 studies reported overall infection and adherence rates.[69,182,183] The strength of evidence for implementing a provider reminder system alone or with the base strategies for improving infection rates was judged to be insufficient. Therefore, the strength of evidence for implementing a provider reminder system alone or with the base strategies to improve adherence and infection rates was judged to be insufficient, as well.

Cost Savings

Two studies reported cost savings information,[183,185] which will be discussed in the section on Key Question 1b.

Key Question 1b. What is the cost, return on investment, or cost-effectiveness of QI strategies to improve HAI?

Costs and Savings Associated With QI Strategies

Fourteen studies[45,49,70,72,74,76,104,105,108,115,159,185,186,199] discussed in the previous sections of Question 1, were identified that provided information related to the implementation costs and/or savings of QI initiatives to reduce HAI. Eleven studies[45,49,70,72,74,76,105,108,185,186,199] adjusted for confounding or secular trend reported information on savings. Three studies that did not adjust for confounding or secular trend provided information on the costs of the QI initiative. Savings reported in studies that did not adjust for confounding or secular trend were not considered in this section given the concerns about the study outcomes as noted previously. The literature

reviewed for this report identified only 1 study that provided a detailed analysis for net savings[185] and no studies provided a comprehensive analysis of return on investment.

Waters et al.[199] conducted an economic analysis of the Keystone ICU Project from the perspective of the hospital using infection data that was reported in 2 studies captured in this report.[46,47] Through the use of activity-based costing techniques, the incremental operational costs of the Keystone ICU Project were calculated. Costs considered were the following: hospital staff salary, equipment costs, supplies costs, laboratory costs, and pharmaceutical costs. A random sample of six hospitals, ranging in size, location, and teaching status, were used. Taking into account initial education and training expenses, capital purchases, ongoing timing spent on the intervention, average annual salary, and product purchases, the total annual cost per hospital was estimated to be $161,584. Table 41 below provides an itemized breakdown of the total cost. Mean baseline CLABSI and VAP rates were 7.7 and 6.9 infections per 1,000 device-days, respectively. After 30 and 36 months of implementation, respectively, the CLABSI rate was 1.1and the VAP rate was 2.4 infections per 1,000 device days. The authors calculated that each year 47.9 infections per hospital were avoided due to this project, 29.9 CLABSI and 18.0 VAP, and the intervention cost was $3,375 per infection avoided.

Apisarnthanarak et al.[108] used provider education and organizational change to reduce ventilator associated pneumonia (VAP) in an 8-bed medical ICU (MICU) in Thailand. In this quasi-experimental study, the surgical ICU and coronary care unit served as control groups. Costs were presented as a reduction in mean cost of antibiotics and hospitalization between the baseline and postintervention periods in the MICU and control groups. Costs were obtained from programmatic, personnel, pharmacy and laboratory data and converted from Thai Baht to U.S. dollars. The authors found a significant reduction in the total cost of antibiotics and cost of hospitalization (MICU hospitalization costs per patient decreased from $466 at baseline to $293 in period 2 to $254 in period 3; $p<0.001$ compared to baseline) for the MICU but no reduction was present for the SICU and CCU (Table 41).

Berenholtz et al.[49] used audit and feedback, organizational change, provider education, and provider reminder systems for the reduction of CLABSI in a SICU in the United States. A concurrent ICU in the same hospital was used as a control group which received provider education alone. Previously published estimates of the extra costs incurred per CLABSI case of $45,254 ($34,508 to $56,000) were multiplied by the estimated number of prevented infections to calculate savings. The authors estimated an annual reduction of 43 CLABSI cases which corresponds to a savings of $1,945,922 ($1,483,844 to $2,408,000). No information on costs of implementation was presented.

Costello et al.[45] used audit and feedback, organizational change, provider education and provider reminder systems for the reduction of CLABSI in a PICU in the United States. Savings were estimated from previously published cost analysis on the price of a CLABSI infection in the PICU and extrapolated based on the author’s estimated reduction of 20 CLABSI cases per year for a total annual savings of $236,000 to $782,000.

Miller et al.[65,105] used audit and feedback, organizational change, provider education, and provider reminder systems to reduce CLABSI rates in 29 pediatric ICUs across the United States. The authors estimated it cost $75,000 per hospital to be a part of the collaborative and that each CLABSI episode cost $45,000. The estimated CLABSI attributable health care cost savings was $31 million. No further details were provided.

Frankel et al.[76] used audit and feedback, organizational change, and provider education for the reduction of CLABSI in a SICU at an academic tertiary care center in the United States.

Savings attributed to the QI strategy were based on an estimate of $3,000 incurred per CLABSI case. The authors estimated that 22 CLABSI cases were prevented each year for a conservative estimated savings of $66,000 per year. The authors state that the costs of purchasing antibiotic-coated catheters and preparing insertion kits cost less than $5,000 per year. No additional information was provided about other costs of implementation, for example, costs of education and supervision.

Kim et al.[72] used audit and feedback, organizational change, provider education, and provider reminder systems to reduce CLABSI rates in the emergency department and ICU of an academic hospital in the United States. The total excess cost was calculated using cost of excess length of stay, cost of replacement of central line including materials for maximal sterile barrier, drug administration costs, and antibiotic costs. The total weighted excess cost for CLABSI, regardless of organism, was $32,354. The authors say the cost of creating the bundle was not considered due to the fact that the overhead costs were negligible. Also, all materials for the bundle were already present in the hospital except for the actual cart, estimated to cost $100 per ICU. No administrative costs were taken into account because the policies did not change.

Harris et al.[74] used audit and feedback, organizational change, provider education, and provider reminder systems to reduce CLABSI and VAP rates in the pediatric ICU of a tertiary academic institution. Costs were estimated using the hospital specific cost-to-charge ratio, reflecting the hospital's point of view, not the payer. Costs were adjusted for patient age, sex, race, insurance coverage, comorbidities, and the primary specialty of the treating physician. Costs were modeled using generalized linear models with a gamma distribution and log link function. Compared to baseline, the adjusted PICU costs during the intervention period was -$3,948 (95% CI: -$10,678 to $2,782) and during the postintervention period PICU costs were −$8,826 (95% CI: -$13,950 to -$3,702; p<0.001). Compared to baseline, the adjusted hospital costs during the intervention period was -$7,697 (95% CI: -$15,990 to $597) and during the postintervention period hospital costs were -$12,136 (95% CI: -$19,058 to -$5,214; p<0.001).

Duane et al.[70] used organizational change, provider education, and provider reminder systems to reduce CLABSI at a Level 1 trauma center in the United States. Savings were based on changes in length of stay between the baseline, partial intervention, and full intervention periods. The average charge for a day in the ICU ($7,249) and outside of the ICU ($2,751) was used to calculate the differences in cost between the patient groups. Length of stay varied significantly from baseline (30.54 days ± 2.08) and the partial (23.41 days ± 1.73; p=0.02) and full interventions (20.22 days ± 2.0; p=0.001) and accounted for an estimated savings of $19,616 per patient when comparing the baseline to partial intervention group and $28,392 when comparing the baseline to full intervention group.

van den Broek et al.[186] used organizational change, provider education, and provider reminder systems to reduce CAUTI rates in ten Dutch hospitals. All health care providers involved in the intervention were asked to record time spent on the intervention. Other costs such as travelling, meetings and material costs were also listed. Cost of catheterization and daily care was estimated using material cost and mean time spend by health care workers. The mean time was estimated by asking 18 nurses as 5 different hospitals. Cost of materials was estimated using hospital purchase prices. The mean cost per hospital of implementing program, with the help of an implementation expert was €2,638 ranging from €1,023 to €3,763. The cost of implementing program without an implementation expert was €1,993. Inserting an indwelling catheter was estimated to cost €28 while the removal of an indwelling catheter cost €3. The cost of daily care was estimated to be €3. All in all, the mean amount saved per 100 hospitalized patients was

€537, ranging from - €369 to €1,666. Two of ten hospitals saw an increase in costs after the implementation of the QI initiative.

Saint et al.[185] used provider reminder systems alone in an effort to reduce the duration of indwelling urethral catheterization in two wards of a university-affiliated hospital in the United States. Two concurrent, non-equivalent wards in the same hospital served as controls. The authors conducted an economic analysis with the following underlying assumptions based on experience and published literature: the daily rate of bacteriuria is 5 percent per day of indwelling catheterization, a nurse can evaluate approximately 360 hospitalized patients per 8-hour workday to assess urinary catheter status, 25 percent of patients will be catheterized at a given time, no cost is present for asymptomatic bacteriuria, the cost of supplies and printing the urinary catheter reminder is $2,000 per year, and the cost of a nurse to ensure the intervention is being followed appropriately is $51,000 for a total cost of $53,200. The cost of a symptomatic CAUTI was estimated as at least $500 per episode. The authors found that the reminder system decreased indwelling catheter duration by 0.9 days (4.6 days for the control wards and 3.7 days for the intervention wards) when conducting an intention to treat analysis and 1.6 days decrease when doing a per-protocol analysis. The net savings were calculated to be $249 per year in the intention to treat analysis and more than $50,832 per year in the per-protocol analysis.

Two additional studies[112,138] that controlled for confounding or secular trend reported cost data but were not included in this section because of a lack of specific information related to the savings from the QI initiative. Mannien et al.[138] report on work to reduce SSI rates in multiple institutions in the Netherlands. This study reports cost savings only briefly and states that the QI initiative led to a 25 percent decreased cost per procedure due to a shorter period of prophylaxis, but did not provide specific values. Dubose et al.[112] implemented a QI strategy to reduce VAP at a trauma ICU in the United States. Results for mean charges were presented for the fully compliant group and the partially compliant group for only the postintervention period. The authors did not provide information on patient factors or comorbid conditions that can directly influence both adherence and costs.

The three studies that did not control for confounding or secular trends[104,115,159] reported data on the costs of implementing aspects of the QI initiative. Kable et al.[159] implemented a QI strategy to increasing adherence with antibiotic guidelines for five common, elective surgical procedures at two teaching hospitals in Australia. Costs of recommended antibiotic prophylaxis by procedure were determined and showed variability among type of procedure (Table 42). Sona et al.[115] put into practice use of oral care to reduce rates of VAP. The authors estimated the total cost of the supplies for the protocol (toothbrushes, toothpaste, and oral antimicrobial solution) was $2,187.49 over a 12-month period and was used to treat about 900 patients on mechanical ventilators. Bakke et al.[104] implemented a CLABSI bundle to reduce the incidence of catheter-related infections in end stage renal disease patients undergoing hemodialysis. The cost-effectiveness of current practice using 4 percent chlorhexidine soap and sodium hypochlorite ($27,771.02 per year) was compared to 3.15 percent chlorhexidine and 70 percent alcohol ($9,266.40 per year) for an estimated dialysis product savings of $18,504.62 over 52 weeks.

Table 41. Savings associated with quality improvement initiatives in studies that control for confounding or secular trend

Author, Country – Year / Intervention	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Provider Education	Provider Reminder Systems	Metric	Statistics for cost savings	Cost/Savings	Savings/Calculations
Waters, United States – 2011[46,47,199] (Keystone ICU Project)	•		•	•	•		VAP rate	None	Startup costs (FY 2004-2005, Beginning of Project): Education and training expenses(per diem): $3,035 Nurses (8 per hospital): $19,534 Physicians (2 per hospital): $33,357 Respiratory therapists: $3,459 Infection control staff: $1,488 Pharmacists: $2,047 Central line insertion cart: $1,500 Startup costs (FY 2008): Education and training expenses(per diem): $691 Nurses (8 per hospital): $4,397 Physicians (2 per hospital): $7,591 Respiratory therapists: $787 Infection control staff: $339 Pharmacists: $466 Central line insertion cart: $341 Ongoing costs (FY 2008): Nurses (8.9% of time on average): $47,652 Physicians (12.2% of time): $64,123 Respiratory therapists (12.5%): $6,666 Infection control staff (7.5%): $4,000 Pharmacists (6.5%): 6,474 Chlorhexidine: $2,058 Oral care kits: $6,000 Sterile central line dressing kits: $10,000 Total costs(FY 2008): $161,584 Cost of intervention per infection avoided: $3,375	A sample of six hospitals that participated in the Keystone ICU Project was asked to participate in this study. Activity based costing techniques were used to estimate the cost of the project. A series of semistructured interviews with staff from each hospital took place to get an idea of how much time was spent on project specific activities. Cases avoided were calculated using the mean CLABSI and VAP rates from each quarter reported in the Keystone Project and comparing that to the baseline. Authors calculated 29.9 CLABSI and 18.0 VAP avoided per year during the study. The cost of the funding from AHRQ was not included in the study.
	•		•		•	•	CLABSI rate			

Table 41. Savings associated with quality improvement initiatives in studies that control for confounding or secular trend (continued)

Author, Country – Year / Intervention	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Provider Education	Provider Reminder Systems	Metric	Statistics for cost savings	Cost/Savings	Savings/Calculations
Apisarnthanarak, Thailand - 2007[108] / Educational Program			•		•		Costs	2-tailed student's t-test	Results reported for period 1 (baseline, 12 months) → period 2 (intervention period, 12 months) → period 3 (ongoing intervention and followup, 12 months) MICU hospitalization costs per patient: $466 → $293 → $254 (p<0.001, compared to period 1) MICU monthly antibiotic cost for VAP : $4769 → $2622 → $2378 (p<0.001, compared to period 1) SICU hospitalization costs per patient (Control): $399 → $384 → $395 (p=NS) SICU monthly antibiotic cost for VAP (Control): $2901 → $2884 → $2799 (p=NS) CCU hospitalization costs per patient (Control): $404 → $401 → $415 (p=NS) CCU monthly antibiotic cost for VAP (Control): $2876 → $2991 → $2994 (p=NS)	Costs for hospitalization were estimated using available programmatic, personnel, pharmacy, and laboratory data. Hospital costs were estimated from the Thai insurance and hospital reimbursement systems. Cost of antibiotics was calculated on the basis of the actual dosage given to the patients and based on the purchase price of the institution without administration costs. All costs were converted from Thai Baht to US Dollars at a conversion rate of 40 to 1.
Berenholtz, United States – 2004[49] / Education, CVC cart, nurse empowerment, checklist, and daily assessment of need	•		•		•	•	CLABSI Rate	None	$1,945,922 (Range $1,483,844-$2,408,000)	The attributable savings were calculated based on published estimates of extra costs per case of CLABSI of $45,254 ($34,508 - $56,000). The annual reduction on CLABSI rates was estimated to be 43 cases. Thus, the estimated savings [$1,945,922 (Range $1,483,844-$2,408,000)] are based on this information.

Table 41. Savings associated with quality improvement initiatives in studies that control for confounding or secular trend (continued)

Author, Country – Year / Intervention	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Provider Education	Provider Reminder Systems	Metric	Statistics for cost savings	Cost/Savings	Savings/Calculations
Costello, United States - 2008[45] / Pediatric multidisciplinary CLABSI bundle	•	•	•		•	•	CLABSI rate	None	$236,000-$782,000	The attributable savings was calculated using estimates from published cost analyses from adult ICUs and general PICUs. The authors assumed approximately 20 CLABSI were prevented each year.
Miller, United States - 2010[65,105] / Bundle - CLABSI	•		•		•	•	CLABSI rate	None	Cost to participate in collaborative: $75,000 per hospital Cost per CLABSI episode: $45,000 CLABSI attributable health care cost savings: $31 million	Authors used literature based adult estimates of CLABSI attributable mortality rates and pediatric-specific CLABSI morbidity information to come up with an estimated per CLABSI episode. Using this and estimated lives saved and CLABSI prevented, the attributable health care cost savings was estimated.
Frankel, United States – 2005[76] / Six Sigma Performance Improvement	•		•		•		CLABSI rate	None	Estimated at least $66,000 per year	The attributable savings were calculated based on cost estimates, the authors estimated each case of CLABSI cost about $3,000. The annual reduction on CLABSI rates was estimated to be 22 cases. Thus, the estimated savings are "at least" $66,000 per year. The incremental costs of preparing insertion kits and purchasing antibiotic-coasted catheters were less than $5,000 per year. No additional information was provided about other costs of implementation, e.g. education and supervision.
Kim, United States – 2011[72] / CLABSI bundle with cart	•		•		•	•		None	Total weighted excess cost for CLABSI: $32,254 Cart cost: $100 per unit	This was calculated by adding up the cost of excess length of stay, replacement of the central line, drug administration costs, and the cost of the drug itself. Excess cost was weighted by type of organism isolated.

Table 41. Savings associated with quality improvement initiatives in studies that control for confounding or secular trend (continued)

Author, Country – Year / Intervention	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Provider Education	Provider Reminder Systems	Metric	Statistics for cost savings	Cost/Savings	Savings/Calculations
Harris, United States – 2011[74] / Hand hygiene, VAP bundle, standardizing central line care	•		•		•	•	Cost of stay	Generalized linear models	Average baseline period PICU cost: $34,365 (SD $2,446) Average intervention period PICU cost: $30,175 (SD $2,139) Average postintervention period PICU cost: $25,938 (SD$1,146)	Adjusted costs were calculated for the intervention and postintervention periods using Adjusted intervention cost: -$3,948 (95% CI: -$10,678 to $2,782) Adjusted postintervention cost: -$8,826 (95% CI: -$13,950 to -$3,702)
Duane, United States - 2009[70] / Group 3: Central venous line (CVL) protocol + CVL supply cart + nurse education + nurse checklist and nurse empowerment; Group 2: CVL protocol to reduce catheterization duration + resident education; Group 1: Usual care			•		•	•	Length of stay	None	Group2 (vs. Group1): $19,615.70 hospital charges per patient; Group3 (vs. Group1): $28,391.87 hospital charges per patient	Costs were calculated by using the length of stay and comparing group 1 with group 2 and 3. Length of stay was adjusted by injury severity score which differed between groups. Adjusted length of stay was multiplied by the average daily charge for hospital stay ($7,249)
van den Broek, Netherlands – 2011[186] / Revision of existing protocols, introduction of staff education and change to daily practice			•		•	•	Cost of implement ation	None	Cost of implementing program per hospital (Includes implementation expert): €2,638 (Range: €1,023 to €3,763) Cost of implementing program per hospital (Without implementation expert): €1,993 Cost of insertion of an indwelling catheter: €28 Cost of removal of an indwelling catheter: €3 Cost of daily care: €3 Mean amount saved per 100 hospitalized patients: €537 (Range: - €369 to €1,666)	All involved in the intervention were asked to record time spent on the intervention. Other costs such as travelling, meetings and material costs were listed. Cost of catheterization and daily care was estimated using material cost and mean time spend by health care workers. Mean time was estimated by asking 18 nurses as 5 different hospitals. Cost of materials was estimated using hospital purchase prices.

Table 41. Savings associated with quality improvement initiatives in studies that control for confounding or secular trend (continued)

Author, Country – Year / Intervention	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Provider Education	Provider Reminder Systems	Metric	Statistics for cost savings	Cost/Savings	Savings/Calculations
Saint, United States - 2005[185] / Urinary catheter reminder in patient chart and pager reminder						•	Reduction in urinary catheter days	None	Intention to treat analysis: $249 per year savings Per-protocol analysis: > $50,832 per year	Their economic analysis was based on the literature and their experience with the intervention. It involved a number of assumptions including the daily rate of bacteriuria with indwelling catheters, the number of patients a nurse can evaluate in an 8-hour workday, percentage of patients who are catheterized at any time, costs of supplies and printing for the reminders, and cost of a nurse with the skills to do the intervention (reminder). Based on an estimated 0.9 day reduction in urinary catheter use, savings were estimated at $53,449 per year while costs were $53,200 per year for a net savings of $249 per year.

Table 42. Implementation costs associated with quality improvement initiatives in studies that did not control for confounding or secular trend

Author, Country – Year / Intervention	Study Design	Infection	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Provider Education	Provider Reminder Systems	Cost of Intervention
Kable, Australia - 2008[159] / Increased adherence to antibiotic prophylaxis guidelines	Simple before-after	SSI					•	•	Costs per patient of recommended prophylactic antibiotics: TURP: $0.62 Cholecystectomy: $2.54 Herniorrhaphy: $0.15 Hysterectomy: $6.24 Joint arthroplasty: $4.30
Sona, United States - 2009[115] / Oral care with tooth brushing and oral chlorhexidine of ventilated patients	Simple before-after	VAP	•		•		•		473-mL bottle of oral antimicrobial solution, $2.11 Floor stock toothbrush, $0.07 Floor stock toothpaste, $0.24 The estimated cost of the protocol was $2187.49 for 12 months.
Bakke, United States – 2010[104] /CLABSI Bundle for end stage renal disease hemodialysis patients	Simple before-after	CLABSI	•		•		•	•	7 swabs for site-care $0.70 Registered Nurse time @ 39/hour with benefits doing site care for 3 minutes: $1.95 Registered Nurse time @ $39/hour with benefits doing HD hub/line care for 1 minute: $0.65 Estimated cost of changing to chlorhexidine 3.15%/alcohol 70% swabs per year: $9266.40

Strength of Evidence

Given the limited number of studies that evaluate costs and/or savings, the limited data on net cost savings, as well as the variation in QI initiatives used in those studies and the varied metrics studied related to costs, the strength of evidence related to the overall cost and savings associated with use of various QI initiatives to reduce HAI is insufficient. Formal tables for strength of evidence were not created.

Furthermore, important questions related to costs and savings were not addressed by the studies; only one study that provided a detailed analysis for net savings and no studies provided a comprehensive analysis of return on investment.

Key Question 1c. Which factors are associated with the effectiveness of QI strategies?

Key Question 1c addresses which factors among the following are associated with the effectiveness of QI strategies: type of QI strategy, duration of intervention, setting of intervention, and staff involved in the implementation of the intervention. We limited this analysis to studies that report and analyze changes in both adherence rates and infection rates because these studies provide the strongest possible causal evidence. To provide a more generalizable and robust synthesis of QI strategies, the analysis in this section combines studies across the four HAI.

The focus of this section is type of QI strategy, for which there is the most evidence. Duration of the QI strategy was a part of the individual study quality appraisals, but will not be an independent factor in this section, with a majority of the studies lasting at least 1 year. Because all of the included studies were in hospital settings, and there were no direct comparisons of QI strategies between multiple units in a single hospital or across hospitals, we were unable to conduct any setting comparisons. Because we combined studies from the four infections, we were also unable to conduct staffing comparisons since different infections require different staffing involvement. For example, reducing VAP rates usually required cooperation from the nursing staff, while reducing SSI rates may have required involvement of the pharmacy and anesthesiology staff.

Combinations of QI Strategies Across HAI

For Key Question 1a, we synthesized strength of evidence for combinations of QI strategies within four HAI: CLABSI, VAP, SSI, and CAUTI. Here we assess the strength of evidence for combinations of QI strategies across HAI.

Twenty-six studies analyzed both adherence and infection rates.[45,47,48,51,53,59,64,65,67-70,75,107-109,133,135-138,140,142,143,182,183] Four of these studies did not separately analyze adherence rates, but adherence was included in the regression analysis for infections.[59,65,70,137] Two studies analyzed adherence and infection rates for two infections each[69,135] and one of these analyzed adherence and infection rates for three infections.[48] These studies will be treated as separate studies, one for each infection, as was done for Key Questions 1 and 1a. Table 43 summarizes the 30 studies included in this section.

Table 43. Overview of studies across HAI

Study Characteristic	Categories	AF + PRS + Base[a]	AF + Base[b]	PRS + Base[c]	Base[d]	All
Infection	CLABSI	3	3	2	1	***8***
	VAP	3	0	4	1	***8***
	SSI	2	3	3	0	***8***
	CAUTI	0	3	2	0	***5***
	TOTAL	***8***	***9***	***11***	***2***	***30***
Study Quality	Higher	1	2	0	1	***4***
	Medium	4	1	3	0	***8***
	Lower	3	6	8	1	***18***
	TOTAL	***8***	***9***	***11***	***2***	***30***

[a]Audit and feedback and provider reminder systems with the base strategies
[b]Audit and feedback with the base strategies
[c]Provider reminder systems with the base strategies
[d]Base strategies alone

The strength of evidence for each combination was determined using the approach described in the Methods chapter and applied to each HAI in section 1a of the Results chapter. All comparisons were to usual care. Table 44 displays the strength of evidence for combinations of QI strategies across HAI.

Table 44. Strength of evidence for combinations of QI strategies

Combination	Outcome	Number/Type of Studies	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
AF + PRS + Base[e]	Adherence and infection rates	1 controlled study[107] 1 stepped wedge[137] 4 interrupted time series[45,51,65,109] 2 simple before-after[75,140]	Medium	Consistent	Direct	Precise	***Moderate***
AF + Base[f]	Adherence and infection rates	1 controlled study[53] [a] 2 interrupted time series[64,138] 8 simple before-after[47,48,67,135,136] [a,b,c]	Medium	Consistent	Direct	Precise	***Moderate***
PRS + Base[g]	Adherence and infection rates	2 controlled studies[133,182] 1 interrupted time series[183] 6 simple before-after[59,69,70,142,143] [d]	Medium	Inconsistent	Direct	Precise	***Low***
Base[h]	Adherence and infection rates	1 controlled study[108] 1 Simple before-after[68]	High	Consistent	Direct	Imprecise	***Insufficient***

[a]One of these studies reported on both CLABSI and VAP, but only reported adherence for VAP. VAP outcomes only are considered for this strength of evidence.
[b]One of these studies reported on both SSI and CAUTI.
[c]One of these studies reported on CLABSI,VAP, and CAUTI.
[d]One of these studies reported on both CLABSI and CAUTI.
[e]Audit and feedback and provider reminder systems with the base strategies
[f]Audit and feedback with the base strategies
[g]Provider reminder systems with the base strategies
[h]Base strategies alone

Audit and Feedback, Provider Reminder Systems, and the Base Strategies Compared With Usual Care

Eight studies reported both adherence and infection rates and used a combination of audit and feedback, provider reminder systems, and the base strategies, compared with usual care.[45,51,65,75,107,109,137,140] Three reported on CLABSI,[45,65,75] 3 reported on VAP,[51,107,109] and 2 reported on SSI.[137,140] One[107] was of higher quality, four[45,65,109,137] were of medium quality, and 3[51,75,140] were of lower quality.

Considering the quality and number of studies using this combination, the risk of bias was judged to be medium. Three studies reported overall adherence measures, all of which showed statistically significant improvement after the intervention.[51,107,109] In the other five studies, 16 of 26 adherence measures demonstrated a statistically significant improvement. In one of those studies, however, one of five measures had a statistically significant decline.[140] Miller et al. did not analyze adherence rates separately, but in multivariable analysis, adherence to the maintenance bundle was protective against CLABSI.[65]

Five of 7 studies reported infection rates as significantly improved.[45,51,65,75,109] One of the two nonsignificant infection rates went from 15.3 in the baseline period to 9.3 in the postintervention period.[107] Kao et al. did not analyze infection rates separately, but the authors reported nonadherence to antibiotic prophylaxis to be predictive of SSI.[137] The evidence was judged to be consistent and precise based on the direction and significance of the results across the eight studies. Adherence and infection rates together are considered a direct measure. There is moderate strength of evidence that the use of this combination improves adherence and infection rates compared with usual care.

Audit and Feedback and the Base Strategies Compared With Usual Care

Eleven studies reported both adherence and infection rates and used a combination of audit and feedback, organizational change, and provider education, compared with usual care.[47,48,53,64,67,135,136,138] Two[48,64] reported on CLABSI, 4[47,48,53,67] reported on VAP, 3 reported on SSI,[135,136,138] and 2[48,135] reported on CAUTI. Three articles[53,64,138] are of medium quality and 5 articles[47,48,67,135,136] are of lower quality.

Considering the quality and number of studies, the risk of bias was judged to be medium. Three of the lower quality studies[47,67,136] contributed strong evidence because they were multisite statewide initiatives that showed a large magnitude of improvement. The fourth lower quality study[135] was also a multisite study. All adherence rates in this set of studies significantly improved. Ten of 17 infection measures showed a statistically significant improvement. Two of the 3 medium quality studies showed statistically significant improvement (for one, it was for 7 of 8 comparisons).[47,64] Two of the studies that had a nonsignificant change in infection rates may have experienced a floor effect.[67,136] DePalo et al. (2010)[67] reported a baseline rate of 0.58 infections per 1,000 catheter-days that dropped to 0 in the postintervention period while Dellinger et al. (2005) found an improvement from 2.3 percent to 1.7 percent over the study period.[136] For one measure, there was a statistically significant decline in CAUTI.[48]

The evidence was judged to be consistent and precise based on the direction and significance of the results across the 11 studies. Adherence and infection rates together are considered a direct measure. There is moderate strength of evidence that the use of this combination improves adherence and infection rates compared with usual care.

Provider Reminder Systems Alone or With the Base Strategies Compared With Usual Care

Nine studies reported both adherence and infection rates and used a combination of provider reminder systems alone, or with the base strategies, compared with usual care.[59,69,70,133142,143,182,183] Three studies[59,69,70] reported on CLABSI, 3 reported on SSI,[133,142,143] and 3 reported on CAUTI.[69,182,183] Two[133,182] are of higher quality, 1[183] is of medium quality, and five articles[59,69,70,142,143] are of lower quality.

Considering the quality and number of studies, the risk of bias was judged to be medium. One of the lower-quality studies[59] contributed strong evidence because it was a multisite statewide initiative with a substantial and highly statistically significant magnitude of change. All adherence rates in this set of studies significantly improved and 5 of 9 studies observed a significant improvement in infection rates.[59,70,142,143,183] Neither of the higher quality studies[133,182] reported a significant improvement in infection rates. Loeb et al. (2008)[182] did have some internal validity issues that have already been discussed in earlier sections of the Results chapter. Seguin et al. (2010) reported on both CLABSI and CAUTI.[69] The CLABSI rate went from 2.8 infections per 1,000 catheter-days to 0.7 (p=0.051) while the CAUTI rate was similar in the baseline and postintervention periods (5.0 vs. 4.9 infections per 1,000 catheter-days, p=0.938). Schulman et al. (2011)[59] did not analyze adherence separately, but utilization of the maintenance checklist was significantly associated with improved CLABSI rates.

Because half of the infection rates demonstrated nonsignificant change, the evidence was judged to be inconsistent. All adherence rates in all studies showed significant improvement. The evidence was judged to be precise. Adherence and infection rates together are considered a direct measure. There is low strength of evidence that the use of this combination improves adherence and infection rates compared with usual care.

Even though this combination of QI strategies was found to have moderate strength of evidence when used to improve CAUTI rates, there were limited data for this combination for the other three infections. Therefore this conclusion was not generalizable across all four infections.

Base Strategies Compared With Usual Care

Two studies reported both adherence and infection rates and used a combination of organizational change with or without provider education, compared with usual care.[68,108] One reported on CLABSI[68] and one reported on VAP.[108] One[108] is of higher quality and the other[68] is of lower quality. Considering the quality and number of studies, the risk of bias was judged to be high. Both studies[68,108] found some improvement in adherence rates and significant improvement in infection rates. The evidence was judged to be consistent and imprecise, because of the paucity of evidence. Adherence and infection rates together are considered a direct measure. There is insufficient strength of evidence that the use of this combination improves adherence and infection rates compared to usual care.

Key Question 2. What is the impact of context on the effectiveness of QI strategies?

The 71 studies that controlled for confounding or secular trend were also evaluated to address the impact of context on the effectiveness of the QI strategies. Context, generally, can be thought of as the "characteristics of the organization and its environment that influence the implementation and effectiveness of the patient safety practice."[24] A major difference between

traditional clinical trials and studies of QI interventions in clinical facilities is that the effectiveness of the latter relies not just on the effect of the intervention but also on the interaction between the intervention and the context. This issue is often discussed when interpreting traditional clinical trials in terms of the generalizability of the results. In the case of healthcare-associated QI strategies, the impact of the context may be as important to the efficacy of the strategy as the inherent features of the strategy itself. A given strategy may work well in a hospital with a strong patient safety culture and executive buy-in, for example, but may not work at all in a hospital with a different context. Understanding the contextual feature(s) which influence QI strategies is essential to translating these initiatives to other settings. Without a clear insight into context it is unclear if a QI strategy can be implemented in a similar or equally impactful fashion given varying environmental characteristics.

The first step in understanding which features of the context are important for a given intervention is to identify which features were present or absent in a given study where the intervention did or did not work. We abstracted the following contextual factors from the included studies, as the authors of the RAND report recommended for use when evaluating the effectiveness of patient safety practices:[20]

- Theory behind patient safety practice
- Existing patient safety infrastructure
- External factors
- Leadership at unit level
- Change in responsibilities at unit level
- Availability of implementation and management tools

Table 45 tabulates the contextual factors reported in the 71 studies that control for confounding or secular trend. While organizational characteristics are easily determined in all studies, reporting on the remaining contextual factors was not complete in most of the studies.

Table 45. Overview of available contextual factors

Contextual Factor	CLABSI	VAP	SSI	CAUTI	Total
Health care setting: Single site	14	15	8	8	***45***
Health care setting: Multiple site[a]	12	4	7	3	***26***
Total	***26***	***19***	***15***	***11***	***71***
United States	18	9	11	2	***40***
Other	8	10	4	9	***31***
Total	***26***	***19***	***15***	***11***	***71***
Theory behind patient safety practice	9	3	4	0	***16***
Existing patient safety infrastructure	8	6	2	4	***20***
External factors	9	7	5	2	***23***
Patient safety culture and teamwork at unit level	14	10	3	4	***31***
Leadership at unit level	17	12	5	3	***37***
Change in responsibilities at unit level	14	11	12	7	***44***
Availability of implementation materials and management tools	19	13	11	6	***49***
0 Contextual factors reported[b]	1	0	1	0	***2***
1 Contextual factors reported[b]	2	2	2	1	***7***
2 Contextual factors reported[b]	4	3	4	7	***18***
3 Contextual factors reported[b]	4	8	3	0	***15***
4 Contextual factors reported[b]	7	1	3	2	***13***
5 Contextual factors reported[b]	7	4	2	1	***14***
6 Contextual factors reported[b]	1	1	0	0	***2***

Abbreviations: CAUTI = catheter-associated urinary tract infection; CLABSI = central line–associated bloodstream infection; VAP = ventilator-associated pneumonia; SSI = surgical site infection.
[a]Of the multiple site studies, the following number were state or country wide initiatives: 5 in CLABSI, 2 in VAP, 3 in SSI, and 1 in CAUTI
[b]Organizational characteristics were reported by all included studies. These capture additional contextual factors reported.

Roughly two-thirds of the studies took place in single sites[45,48-51,53,55-57,61-64,66,68-70,72-74,76-78,107-113,133,139-143,145,146,181,183-185] and about half were from the United States.[45-47,50,52,53,57,60,61,63,65-67,70-74,107,112,137,139-144,146,187] The most commonly reported contextual factor was availability of implementation materials, followed by changes in responsibilities at the unit level, and leadership at the unit level. The contextual factors that were discussed the least were theory behind patient safety practice and patient safety culture and teamwork at the unit level. Two studies reported no additional contextual factors other than organizational characteristics.[62,138] About half of the studies reported at least half of the additional contextual factors of interest (four[53,58,67,74] of which reported on two infections each).[45,46,50,52,53,56,58,59,67,70-77,136,137,140,141,181,186,187] However, no study reported all seven additional contextual factors.

Several multisite studies conducted statistical analyses in an attempt to adjust for contextual factors among the participating sites. For example, Pronovost et al. (2010)[46] included teaching status and hospital size in the regression models and found that neither of those factors was associated with CLABSI rates. Berenholtz et al. (2011)[47] also report that teaching status and hospital size were not associated with infection rates in their study on VAP. They also noted that larger hospitals and teaching hospitals saw a slower decline in VAP rate compared to smaller or nonteaching hospitals initially, though by the end of the 30-month followup VAP rates were

comparable among all hospitals.[47] In a national study on SSI by Mannien et al. (2006),[138] a nonlinear mixed model included the number of surgical procedures and the different mix of surgical procedures among the participating hospitals.

Other studies provided contextual details to inform their discussions on the implementation of the QI strategies. Burkitt et al. (2009)[139] explain that the implementation team for this SSI study focused more of their efforts on the surgical department that performed the most procedures, and then found that this department subsequently had the highest adherence rates compared to the other surgical departments by the end of the study. In a statewide CLABSI initiative, Schulman et al. (2011)[59] explain that some of the differences in CLABSI rates among the participating neonatal ICUs may be due to the different hospital cultures and the different behaviors of the providers.

While contextual factors impact the effectiveness of QI strategy implementation and the sustainability of the interventions, reporting of these factors is neither standardized nor required. Another barrier to reporting such information is the required brevity of publications by journals. Investigators of some studies in this review attempted to control for contextual factors in the analyses, others provided discussions of contextual differences, and still others did not address contextual issues at all. Therefore, our synthesis of context was limited to mapping the frequency with which contextual factors are reported and providing examples of how contextual factors were addressed in some of the studies.

Discussion

Key Findings and Strength of Evidence

This systematic review updates the 2007 Evidence Report: Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies. Volume 6: Prevention of Healthcare-Associated Infections.[3] AHRQ developed the 2007 Evidence Report in response to a 2003 Institute of Medicine (IOM) report, Priority Areas for National Action: Transforming Health Care Quality.[1] Although reduction of healthcare-associated infections (HAI) is a top priority, the human and economic burden of these infections remains unacceptably high. Effective preventive interventions are known. The critical questions are how to achieve provider adherence to these preventive interventions and what is the impact of adherence on infection rates?

This report reviews 71 studies (61 articles) of quality improvement (QI) strategies targeting HAI, ten (nine articles) included in the 2007 review and 61 (52 articles) published subsequently. Four HAI were reviewed: central line-associated bloodstream infections (CLABSI), ventilator-associated pneumonia (VAP), surgical site infections (SSI), and catheter-associated urinary tract infections (CAUTI). Study designs consisted of controlled studies, interrupted time series and simple before-after studies. We limited our synthesis to studies that had statistical analyses that adjusted for confounding or secular trend, without which no causal inference can be made about the reported results. The quality characteristics and also strengths and weaknesses of each of the main types of study design are summarized in Table 3 of the Methods Section.

Six categories of QI strategies were used in these 71 studies: audit and feedback; financial incentives, regulation, and policy; organizational change; patient education; provider education; and provider reminder systems. The most frequent QI strategies used were organizational change and provider education—each was used in 55 and 51 studies, respectively. Two QI strategies were rarely reported: financial incentives, regulation and policy; and patient education. Most studies used multiple QI strategies; only 11 studies used a single QI strategy. Outcomes of interest to the review were adherence to various preventive interventions, change in infection rates, and costs and return on investment. Information was also sought on unintended consequences of QI strategies and contextual factors that might influence the success of a strategy, but data were sparse. Of the studies included in the analysis, none were identified that addressed QI strategies to improve adherence to preventive interventions or reduce HAI rates outside the hospital setting. One study focused on efforts to reduce CLABSI among dialysis patients, but it did not attempt to control for confounding or secular trend and therefore was not included in the main analysis. Most comparisons were with usual care; for 13 studies, the comparison was with a period of low-intensity intervention.[45,49-60]

In analyzing the body of evidence, first we synthesized the evidence within each infection. Then we synthesized results across infections, in an effort to reach stronger and more generalizable conclusions. Evidence synthesis of QI strategies presented considerable challenges. It was not possible to disaggregate the data into individual strategies or to systematically assess the incremental effects of adding a particular strategy to a combination of strategies. Moreover, various combinations of specific strategies were used in the studies, making it challenging to categorize consistent combinations of QI strategies or to compare such combinations with each other.

As discussed in the Results, to develop a workable classification of QI strategy combinations, we hypothesized that organizational change and provider education constitute base strategies. Face validity is the initial rationale for the hypothesis. It is difficult to imagine how any

preventive intervention can be implemented without at least some level of organizational change and/or provider education. In fact, 90 percent of studies report at least one of these strategies. Indeed, it is plausible that those studies that did not report use of organizational change or provider education simply took these elements for granted. While this hypothesis is open to debate, the use of these strategies was ubiquitous, so in practical terms, little distinction could be made between those studies that used these two strategies and those that did not.

We, therefore, refer to organizational change, provider education or the combination of both, as base strategies. This simplifying concept allowed us to organize our data into categories of strategies used in combination with the base case. These additional strategies are: (1) audit and feedback plus provider reminder systems, (2) audit and feedback only, (3) provider reminder systems only. This approach mirrors common practice, which relies on bundles of QI strategies, and can therefore potentially yield practical insights.

Key Findings Across Infections

Our key findings, shown in Table 46, assess the evidence across all four infections, applying the framework for grading strength of evidence described in Methods Guide for Effectiveness and Comparative Effectiveness Reviews,[43,44] Only studies that reported on both adherence and infection rates are included in our key findings across infections: 30 of the 71 studies (42%). All comparisons are with usual care.

- There is moderate strength of evidence that adherence and infection rates improve when these strategies are used with the base strategies:
    - Audit and feedback plus provider reminder systems
    - Audit and feedback alone
- There is low strength of evidence that adherence and infection rates improve when this strategy is used with the base strategies:
    - Provider reminder systems alone
- There is insufficient evidence that the base strategies alone (listed below) improve adherence and infection rates:
    - Organizational change plus provider education
    - Provider education only

We consider these to be our most robust and generalizable findings. Note that the strength-of-evidence analysis describes the evidence for only the specified combination of QI strategies compared with usual care. The conclusions do not imply that one combination is superior to another. We can only describe the strength of evidence that is available for each combination of QI strategies. Furthermore, the finding of moderate strength of evidence, given a heterogeneous incomplete literature, is noteworthy and suggests that these implementation strategies can be effective in reducing HAI, which is the ultimate objective of the QI efforts.

Table 46. Strength of evidence for combinations of QI strategies across healthcare-associated infections

Strength of Evidence	Combination	Outcome	Number/Type of Studies
Moderate	Base strategies* + Audit and Feedback + Provider Reminder System	Adherence and infection rates	1 controlled study[107] 1 stepped wedge[137] 4 interrupted time series[45,51,65,109] 2 simple before-after[75,140]
	Base strategies + Audit and Feedback	Adherence and infection rates	1 controlled study[53] 2 interrupted time series[64,138] 8 simple before-after[47,48,67,135,136] [a,b]
Low	Base strategies + Provider Reminder Systems	Adherence and infection rates	2 controlled study[133,182] 1 interrupted time series[183] 6 simple before-after [59,69,70,142,143] [c]
Insufficient	Base strategies	Adherence and infection rates	1 controlled study[108] 1 simple before-after[68]

*The base strategies are organizational change and provider education.
[a]One of these studies reported on both SSI and CAUTI. (Greco et al. (1991)[135]
[b]One of these studies reported on CLABSI, VAP, and CAUTI. (Barrera et al. (2011)[4]
[c]One of these studies reported on both CLABSI and CAUTI. (Seguin et al. (2010)[69]

Findings and Strength of Evidence for Each Infection

Table 47 displays moderate-strength findings for each infection. There were no QI strategy combinations for which the strength of evidence was rated high, which is not surprising since these studies are implemented in real world settings and the strongest quasi-experimental designs and statistical analyses often were not used. Studies that reported on adherence rates, infection rates or both were included to assess strength of evidence for QI strategies for each infection. Of the 71 studies, 26 addressed CLABSI, 19 addressed VAP, 15 addressed SSI, and 11 addressed CAUTI. For each infection, studies varied in the adherence rates reported and whether significant improvements were found. Thus, Table 47 shows the specific adherence rates that were improved with each combination of QI strategies.

Table 47. Combinations of QI strategies with moderate strength of evidence for each infection

Infection	Combination	Outcome
CLABSI	Base strategies* + Audit and Feedback + Provider Reminder Systems	Infection rate
	Base strategies + Audit and Feedback or Provider Reminder Systems	Infection rate
	Base strategies	Infection rate
VAP	Base strategies + Audit and Feedback + Provider Reminder Systems	Adherence: overall
		Adherence: HOB elevation
		Adherence: oral care
		Infection rate
		Adherence and infection rates
	Base strategies + Audit and Feedback	Adherence: overall/summary
		Infection rate
		Adherence and infection rates
SSI	Base strategies + Audit and Feedback with or without Provider Reminder Systems	Adherence: antibiotic timing
CAUTI	Provider Reminder Systems with or without Base strategies	Adherence: duration of overall urinary catheterization

Abbreviations: CAUTI = catheter-associated urinary tract infection; CLABSI = central line–associated bloodstream infection; HOB = head of bed; QI = quality improvement; VAP = ventilator-associated pneumonia; SSI = surgical site infection.
Note: The base strategies are organizational change and provider education.

In general, within-infection results concur with the key results across infections displayed in Table 46. There is moderate strength of evidence to support audit and feedback plus provider reminder systems with the base strategies, as well as audit and feedback alone with the base strategies. Two differences are worth noting.

1. Studies of CLABSI demonstrate the impact of differing approaches to the QI strategy on the outcome. Two studies compared simulation-based provider education with traditional provider education (lecture and/or video-based education).[26,28] Both studies found the simulation-based approach to provider education to be superior to the traditional method. This finding may warrant further confirmatory research.
2. Studies of CAUTI focused on provider reminder systems as the main strategy for reducing duration of urinary catheterization. There was moderate strength of evidence that provider reminder systems alone or used the base strategies improve adherence related to duration of overall urinary catheterization, compared with usual care. This finding was not generalizable to other infections given the current body of evidence.

Alternative interpretations may account for these CLABSI and CAUTI results, which cannot be empirically verified from the evidence available from this review. Simulation-based provider education probably has a greater impact than traditional, more passive teaching techniques. Alternatively, however, simulation may have attributes that are similar to audit and feedback, and may even, under some circumstances, constitute a form of audit and feedback. With respect to CAUTI, might audit and feedback enhance the results of provider reminder systems? Moreover, in the setting of initiating urinary catheterization, which is addressed by only 3 of 11 studies, audit and feedback might be more relevant than provider reminders. These alternative interpretations remind us that it is important to understand the potential synergies among QI strategies and that certain QI strategies may be more effective for some preventive interventions

than others. For example, if the preventive intervention is to remove hair from an incision site using scissors rather than clippers, simply removing all scissors from the operating room may be quite effective. In this report, such a change would be designated an organizational change. But if the goal is to have clinical staff use proper sterile techniques when inserting a central line, a checklist—a type of provider reminder system—might be more effective, as well as making sure the tray has the recommended type of antiseptic.

Key Questions With Insufficient Data

As discussed in the results section, there were several questions posed by this report that could not be answered because the data were insufficient. These included the following:

- How effective are QI strategies in reducing HAI in nonhospital settings, such as ambulatory surgical centers, freestanding dialysis centers, or long-term care facilities,
- What is the impact of the following QI strategies: patient education; financial incentives, regulation, and policy; and promotion of self-management?
- What are the savings or costs from the intervention and what is the return on investment related to use of these QI strategies, and
- How does context impact the outcome and success of the QI strategies?

Findings in Relationship to What Is Already Known

2007 Evidence Report

Authors of the 2007 Evidence Report[3] identified several strategies with potential benefit, but for which further research is needed: (1) Printed or computer-based reminders with use of automatic stop orders may reduce unnecessary urethral catheterization. (2) Printed or computer-based reminders may improve adherence to recommendations for timing and duration of surgical antibiotic prophylaxis. (3) Staff education using interactive tutorials (including video and Web-based tutorials) and checklists may improve adherence to insertion practices for placement of central venous catheters. (4) Staff education, including use of interactive tutorials, may improve adherence to interventions to prevent VAP. The report concluded that the evidence for QI strategies to improve preventive interventions for HAI was generally of suboptimal quality, and therefore they were unable to reach firm conclusions.[3]

Evidence on the results of QI strategies to reduce HAI has shown improvement since the 2007 report. There was improved methodological quality in the included studies of the current report compared with the previous report. Of the 42 studies included in the 2007 report, only 14 (33%) had a control group or more sophisticated statistical analysis than a two-group test. Of the 173 studies included in the current systematic review, 71 (41%) had a control group or more sophisticated statistical analysis. Both the absolute number of studies and the proportion of studies with statistical analysis to control for confounding and secular trend increased. We were therefore able to reach firmer conclusions. We found moderate strength of evidence to support several combinations of strategies across all four infections, and for specific infections.

In addition, the number of relevant publications per year has increased. This trend continued while the systematic review was being prepared. An update of the literature search from April 2011 to January 2012 yielded 40 included articles, compared with 103 articles between January 2006 and April 2011.

The 2007 report concluded that:

> Investigators should attempt to perform controlled trials of QI strategies when possible, and should report both adherence rates and infection rates. If performing a controlled trial is impractical, investigators should perform interrupted time series studies, involving reporting data for at least 3 time points before and after the intervention and formal time series statistical analysis.[3]

We are in complete agreement with the authors' conclusions. While the quality of the literature has improved markedly since 2007, the majority of studies published have designs and statistical analyses that are inadequate to support causal inference. Thus there is potential to mislead clinical and policy decision makers, with resulting harm to patients. Even where no active harm ensues, the opportunity cost of implementing ineffective programs is harm in itself. However, relatively small changes in research design and statistical analysis—such as collecting data for three time points before the intervention and using interrupted time series statistical analysis—could substantially strengthen the body of evidence.

Other Studies and Systematic Reviews

Comparing the results of this systematic review with the published literature is challenging. First, the effectiveness of quality improvement strategies may vary with the context and with the clinical issue being addressed. A number of other studies, including several Cochrane reviews, address efforts to change clinical practice regarding use of preventive services, implementation of guidelines, and prescribing patterns (e.g., Shojania and colleagues,[200] Jamal and colleagues,[32] Grimshaw and colleagues[29]). The impact may also vary with the context, and as this report concludes, the usable information available on context remains sparse. Another recent systematic review of the influence of context on the success of QI efforts in health care concludes that the current body of work is in an early stage of development (Kaplan and colleagues[201]). The present report relies on the concepts developed by a blue ribbon panel of experts and reported in the RAND report.[20] The definition and scope of QI strategies also varies (e.g., Scott[202] Grimshaw and colleagues[29]). For example, in this report, provider education is treated as a single entity, in accordance with the categorization used in the 2007 report.[3] A report focusing on education might break it down into distribution of educational visits, educational meetings, and educational outreach materials (Grimshaw et al.[29]). As noted, examining the difference between simulation-based provider education and traditional provider education might also be worthwhile.

Finally, the approaches to analyzing individual QI strategies, such as audit and feedback, vary because they often form part of a bundle of QI strategies. Should the focus be on individual strategies, even if they form part of a bundle of interventions that may vary from study to study? The advantage is the ability to focus on specific components that may be critical to the success of an intervention. The disadvantage is the inability to disentangle the effects of different strategies grouped together. The focus on individual strategies was used in the 2007 report and a number of other studies.[3,31] The current report groups bundles of similar strategies, which will help to account for interactions among individual QI strategies. However, because of the large number of different QI strategy combinations, the groupings are not entirely homogeneous, and there are fewer studies per combination. The results are also more challenging to present (e.g., base strategies and audit and feedback or provider reminder systems). Nevertheless, we think this approach produces more valid and generalizable conclusions because it allows for interaction effects to a greater degree. Furthermore, in actual practice, bundles of QI strategies are frequently used.

Focusing on the effectiveness of specific QI strategies, in a Cochrane Review Grimshaw et al.[29] examined guideline dissemination and implementation strategies and compared audit and feedback and reminders with other interventions. When comparing audit and feedback alone to no intervention, there were modest improvements in care (modest describes effect sizes >5% and ≤10%). For reminders, there were moderate improvements in care (moderate describes effect sizes >10% and ≤20%). There were fewer evaluations of audit and feedback than reminders. In general, the impact of the QI strategy was larger when a single strategy was compared to a no intervention control group, rather than comparing one multifaceted intervention to another. However, this study is based on literature published before 2000.

In another Cochrane review, Jamtvedt et al.[31] focused on audit and feedback. The literature search covered randomized controlled trials up to January 2004. They distinguished among different types of audit and feedback and graded the overall intensity of the strategy. They concluded that audit and feedback can be effective in improving professional practice, but there were studies in which use of audit and feedback had a negative effect. As with other studies, the target of the quality improvement effort varied from prevention to test ordering, prescribing, and general management of care. Their comparisons included any combination of QI strategies in which audit and feedback was included, but they did not find that audit and feedback alone was more effective than when included in a bundle of strategies.

De Vos and colleagues[203] conducted a systematic review of controlled studies on the impact of implementing quality indicators in hospitals. They noted that they had not found any overview on implementation and impact of quality indicators in hospitals in general. The article included 21 studies from 1994 to 2008, none of which focused on efforts to reduce HAI. They grouped implementation strategies as follows: educational meeting, educational outreach, audit and feedback, development of a QI plan, and financial incentives. Supporting activities included distribution of educational material, involvement of local opinion leaders, and quality improvement facilities. Most studies used multiple implementation strategies, and the most commonly used strategy for incorporating information on quality indicators was audit and feedback. Process measures were reported more frequently than outcomes. Fourteen of the studies adjusted for potential confounders, and they showed less effectiveness than unadjusted studies did. Studies showing effectiveness or partially effectiveness (defined by the proportion of improved measures) appeared to use audit and feedback together with other implementation strategies. Despite the differences between this article and the current systematic review, the findings appear to be congruent.

The systematic reviews on provider reminder systems tended to focus on specific types of reminder systems, e.g., on-screen point-of-care computer reminders (Shojania et al.[200]). Given the diversity of provider reminder systems used in the studies included in the current report, the findings for these disparate types of reviews were not compared. One meta-analysis focused on reminder systems to reduce urinary tract infections and urinary catheter use in hospital patients.[204] Based on a review of 14 articles published before September 2008, the authors found that the rate of CAUTI fell by 52 percent (p<.001) when reminders or stop orders were used. There was overlap between the studies included in this article and in the current report, but Meddings and colleagues[204] appear to have included simple before-after studies. Their overall conclusion is therefore similar to that in the current report, but the size of the effect is likely to be overestimated.

Comparing the results of the current systematic review with other findings echoes the challenges encountered in conducting this review. Specifically, the heterogeneity encountered in

articles on implementation of preventive interventions to reduce HAI is magnified in the literature on QI strategies in general. Overall, however, the results of the current review appear to be congruent with those of other studies and systematic reviews. They suggest that improvements in adherence and infection rates may result from use of audit and feedback as well as provider reminder systems.

Applicability

We believe that the results of QI strategies graded moderate strength of evidence are generalizable to other hospital settings. However, there is insufficient evidence to address the extent to which specific contextual factors at an institution influence the success of QI strategies and thus what heterogeneity of outcomes might exist across various hospital settings. The sustainability of a QI strategy is essential to success in clinical practice. Many studies did not measure outcomes for more than 1 year postintervention, which is the minimum needed to evaluate sustainability. Thus the applicability of our results to long term quality improvement is uncertain. Finally, given the paucity of published studies in nonhospital settings, these findings are not applicable to the success of QI strategies in other important health care settings, such as long-term care facilities.

For decision makers, knowledge of costs, benefits and trade-offs of implementing a new program is critical to the decision of whether to adopt a QI strategy. This review did not find evidence related to either downside risk from use of these QI strategies or to the return on investment (ROI) from implementing them. Lack of such evidence to inform decision making may also limit applicability of results.

Limitations of the Present Review

The limitations of this review are those that are generally encountered in assessments of complex interventions that are used in complex settings. Such studies are typically heterogeneous in design, setting, measurement, outcomes, and reporting. The resulting data are not amenable to quantitative analysis, thus requiring a qualitative approach. As noted above, evidence synthesis of QI strategies presented considerable challenges. To develop a workable classification of QI strategy combinations, we hypothesized that organizational change and provider education constitute base strategies and categorized other QI strategies that were combined with organizational change and provider education. As is often the case in qualitative research, the validity of the classification must be demonstrated by its application. Is it a useful way to organize the evidence? Most importantly, and as yet unknown, is the issue of whether the classification can be used prospectively to predict success of QI strategies.

Moreover, this review adopted the existing classification system of QI strategies, with whatever limitations may be inherent in this system. One limitation that is apparent to us is that the same strategy may in fact incorporate very different interventions. For example, as noted above, the different provider education methods may vary in intensity, and thus their potential effect on the outcomes of interest may vary. To this end, the recommendations of Shekelle and colleagues to advance the science of patient safety include "more detailed descriptions of interventions and their implementation."[25]

Future Research Needs

This report is a systematic review of the evidence on the use of QI strategies to improve adherence to preventive interventions and to reduce rate of infection. We found both critical methodologic weaknesses in the literature and gaps in evidence to address the Key Questions of our review. The most striking weakness of the literature was the prevalence of deficiencies in study design that precluded causal inference between intervention and reported results. A second weakness was the dearth of systematic collection and reporting of factors that may contribute to the generalizability of QI strategies, that is, information on context. Another weakness was the limited comparability of process measures across studies using the same preventive interventions. There are evidence gaps for the use of QI strategies in nonhospital settings, cost savings and return on investment, and sustainability of results.

Methodologic Weakness: Causal Inference

Studies selected for this systematic review used either an experimental design with a control group or a quasi-experimental design. Most studies of QI strategies are effectiveness studies, rather than efficacy studies. The interventions are implemented in a "real-world" setting rather than using the highly controlled designs that are the standard for efficacy studies.

The factors that can confound the results of such quasi-experimental studies are well known. Unlike most clinical trials, QI studies often do not follow the same patients over time. The patients in the baseline group may be different than those in the postintervention group with respect to their risk of infection. For example, infection risk may be subject to seasonal variation and demographic mix of patients may change. Infection rates may also change over time for reasons unrelated to the QI intervention. The trend may have begun prior to the QI intervention perhaps related to national attention to reducing preventable infections. Also, other QI interventions may be introduced into the institution in overlapping time periods. Among the studies included in this report, most of them either did not explicitly state if the QI strategies were "independent" of other QI efforts or indicated that other QI efforts were introduced. The phenomenon of regression to the mean may account for the more favorable outcomes observed postintervention. While regression analysis and time series analysis can control for confounders and time trends, two-group tests, which are commonly used, cannot.

Although 173 studies met initial selection criteria for this review, 102 were excluded from our synthesis because they used statistical analyses that did not control for confounding or secular trend. While these studies reported an association between QI strategy and outcome, they do not support causal inference and have higher potential to introduce bias into the evidence base. It is more likely that the studies that do not control for confounding will find significant results. Moreover, our classification of studies as using adequate statistical analyses was generous. For example, not all of the studies that used an interrupted time series design used appropriate statistical analysis to evaluate changes due to the intervention. In addition, adjustments related to changes in the patient population were not always completed.

Most publications did not provide analyses of statistical power. Although we limited inclusion to studies with a minimum of 100 participants, infection events could easily be too infrequent in the population to yield sufficient sample to detect a difference. Baseline adherence and infection rates varied markedly among studies. Some studies had high adherence rates and others had low infection rates, resulting in ceiling and floor effects that would make it difficult to detect a statistically significant improvement. In one of the most rigorously designed studies, a

cluster randomized trial, imbalances in baseline rates across study arms might explain nonsignificant findings. While a cluster randomized trial is the most rigorous design suited to assessing QI strategies, randomization by institution limits the number of groups allocated to each arm and may result in imbalances between study arms.

To advance the science of using QI strategies to reduce HAI, studies need to demonstrate a causal linkage between improved adherence and reduced infection rate. To evaluate this, studies should report both adherence with the preventive interventions and infection rates. Many studies only reported infection rates, a few reported just adherence; this gives an incomplete picture of the outcome. A few studies presented rates of adherence but did not conduct a statistical analysis.

Although we found no specific suggestion of publication bias, there are some causes for concern. One is the lack of studies reporting negative results. While it is possible that efforts to implement QI measures do no harm, it is also possible that failures are not being reported. Another concern is that the failure to use adequate study design and statistical controls biases toward significantly favorable results, which creates an unwarranted impression of success. Our findings suggest that journals can improve statistical review of QI strategy studies, which would in turn strengthen the quality of evidence available to decision makers and provide an incentive to investigators to conduct more rigorous studies.

Finally the circumstances under which studies of QI strategies are conducted merit a thoughtful approach to improving the development of evidence. Conducting a rigorous evaluation of a complex intervention is a challenging undertaking. Most studies of QI strategies are effectiveness studies, rather than efficacy studies. The usual call to improve the quality of evidence by producing randomized controlled trials may not pertain to this issue. A more productive approach would be to improve the quality of quasi-experimental studies through (1) conducting more rigorous study designs, (2) taking into account secular trends and potential confounders, and (3) reporting and analyzing both adherence and infection rates. The enthusiasm of institutions and institutional collaborations might be harnessed by creating tool kits and accessible consultation so that organizations that are engaged in QI initiatives can make a meaningful contribution to the accumulation of knowledge about successful QI strategies.

Methodologic Weakness: Collection and Reporting of Factors That May Influence Generalizability

Shekelle and colleagues recently proposed a framework to advance the science of patient safety.[25] Their recommendations include "greater use of theory and logic models, more detailed descriptions of interventions and their implementation, enhanced explanation of intended and desired outcomes, and better description of measurements of context and how context influences interventions." Although we abstracted contextual factors from the studies included in this review, the available data were too disparate to be synthesized in a meaningful fashion. This is not surprising, as available studies largely pre-date the dissemination of recommendations to advance the science of patient safety. Presently, the approach to collecting and reporting on factors that may influence generalizability is not sufficiently standardized to produce a robust evidence base. We suggest that availability of tool kits and consultation for organizations undertaking QI evaluation studies could assist this effort.

Above all, however, we caution that efforts to systematize the framework cannot succeed unless pervasive methodologic weaknesses related to causal inferences that we describe above are remedied. The most granular and reproducible descriptions of contextual factors are useless if overlaid on studies where reports of the outcome of QI strategies are unreliable.

Methodologic Weakness: Comparability in Audit of Process Measures

The studies included in the current report had to implement QI strategies that addressed evidence-based preventive interventions. While there is a very clear list of these preventive interventions, the way in which adherence is measured varied greatly from study to study. The inconsistency does reduce the comparability of process measures across studies. Another potential confounder is that studies varied in how preventive interventions were implemented, for example, in the frequency of oral care for ventilated patients or the use of antibiotic-impregnated catheters. Adopting more standardized approaches to measuring adherence would strengthen the body of evidence.

Evidence Gaps

Three key evidence gaps that merit future research.

Only one study, which did not control for confounding or secular trend, was found on the use of QI strategies to reduce HAI in nonhospital settings such as ambulatory surgical centers, freestanding dialysis centers, and long-term care facilities. Yet, a substantial proportion of health care is delivered outside hospitals.

The studies on using QI strategies to reduce HAI were very limited in providing data about the implementation costs, cost savings from the implementation, and return on investment from implementing the QI strategies. The data related to savings are weakened by the number of simple before-after studies that present information on cost-savings when the impact on infections rates is uncertain. One reason for not adopting successful QI strategies is that they are "too expensive," so the lack of data related to this measure is a major deficiency.

Finally, there are limited data related to the long-term durability and sustainability of the impact of the QI strategies over time. Many studies lasted only 1 year postintervention or less. To eliminate, or at least reduce, HAI, the QI strategies must show sustained effectiveness over several years.

Conclusions

The magnitude of the potential harm caused by HAI and their ubiquity, as well as the recent reduction in infection rates, highlight the importance and feasibility of identifying the most effective ways for healthcare institutions to address their prevention. Although the practical challenges in measuring the effectiveness of different strategies in a real-world environment are many, the results of this systematic review demonstrate that it can be done and that practical lessons can be gleaned even from a less than ideal evidence base. In this update of the 2007 AHRQ report (Ranji and colleagues, 2007)[3], there is moderate strength of evidence across all four infections examined that both adherence and infection rates improve when either audit and feedback plus provider reminder systems or audit and feedback alone are added to the base strategies of organizational change and provider education. There is low strength of evidence that adherence and infection rates improve when provider reminder systems alone are added to the base strategies. There is insufficient evidence for reduction of HAI in nonhospital settings, cost/savings for QI strategies, and the nature and impact of the clinical context. Relatively modest improvements in research approaches have the potential to substantially strengthen the evidence and provide further insight into how to protect patients from healthcare-associated infections.

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Abbreviations

AHRQ	Agency for Healthcare Research and Quality
ANOVA	analysis of variance
APACHE II	Acute Physiological and Chronic Health Evaluation II
APIC	Association for Professionals in Infection Control and Epidemiology, Inc.
ARIMA	autoregressive integrated moving average
BSI	bloodstream infection
CAUTI	catheter-associated urinary tract infection
CCU	cardiac care unit
CDC	Centers for Disease Control and Prevention
CI	confidence interval
CLABSI	central line-associated bloodstream infection
CPI	Consumer Price Index
CUSP	Comprehensive Unit based Safety Program
CVC	central venous catheter
CVL	central venous line
DHQP	Division of Healthcare Quality Promotion
DVT	deep vein thrombosis
EPOC	Cochrane's Effective Practice and Organisation of Care Group
FASTHUG	Feeding, Analgesia, Sedation, Thromboembolic prevention, Head of bed elevation, Ulcer prophylaxis, and Glucose control
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
HAI	healthcare-associated infection
HICPAC	Healthcare Infection Control Practices Advisory Committee
HOB	head of bed
HR	hazard ratio
ICU	intensive care unit
IDSA	Infectious Diseases Society of America
IOM	Institute of Medicine
IRR	incidence rate ratio
ISS	Injury Severity Score
KQ	Key Question
MICU	medical intensive care unit
mos	months
NACHRI	National Association of Children's Hospitals and Related Institutions
NHSN	National Healthcare Safety Network
NICU	neonatal intensive care unit
NNIS	National Nosocomial Infections Surveillance
NS	nonsignificant
OR	odds ratio
PDMV	positive displacement mechanical valve
PICU	pediatric intensive care unit
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSP	patient safety practice
QI	quality improvement

RAND	Research and Development
RCT	randomized controlled trial
RR	relative risk
RTI	Research Triangle Institute
SAPS II	Simplified Acute Physiological Score II
SD	standard deviation
SHEA	Society for Healthcare Epidemiologists of America
SICU	surgical intensive care unit
SIR	standardized infection ratios
SOE	strength of evidence
SPC	statistical process control
SSI	surgical site infection
TEP	Technical Expert Panel
UC	urinary catheter
VAP	ventilator-associated pneumonia

Appendix A. Search Strategy

(Source: Ranji et al. 2007)

#1

targets QI strategies that tend to be multi-factorial using relevant MeSH terms and title words

Patient-Centered Care [mh] or Progressive Patient Care [mh] or Critical Pathways [mh] or Delivery of Health Care, Integrated [mh] or Patient Care Team [mh] or Behavior Control [mh] or ((coordination [tw] or coordinated [tw] or Multifactorial [tw] or Multi-factorial [tw] or Multicomponent [tw] or Multi-component [tw] or multidisciplinary [tw] or multi-disciplinary [tw] or interdisciplinary [tw] or interdisciplinary [tw] or integrated [tw] or community-based [tw] or organized [tw] or comprehensive [tw]) and program*[tw] or care [tw] or approach [tw] or intervention [tw] or strategy[tw] or strategies [tw] or management [tw] or managing [tw] or center*[tw])) or Organization and Administration [mh] or bundle*[tw]

#2

targets TQM and CQI

Total Quality Management [mh] OR Quality control [mh] OR TQM [tw] OR CQI [tw] OR (quality [tw] AND (continuous [tw] OR total [tw]) AND (management [tw] OR mprovement [tw]))

#3

targets provider education

Education, Continuing [mh] OR Education, Nursing [mh] OR Education, Medical [mh] OR Inservice Training [mh] OR Programmed Instruction [mh] OR ((Education [tw]AND Continuing [tw]) AND (medical [tw] OR professional* [tw] OR nursing [tw] OR physician* [tw] OR nurse* [tw])) OR (outreach [tw] AND (visit* [tw] OR educational [tw]) OR (academic [tw] AND detailing [tw]))

#4

targets diffusion of innovation

Diffusion of Innovation [mh] OR (Diffusion [ti] AND (Innovation [ti] OR technology [ti]))

#5

targets audit & feedback, reminder systems, and financial incentives

Medical audit [mh] OR ((Audit [tw] OR feedback [tw] OR compliance [tw] OR adherence [tw] OR training [tw]) AND (improvement* [tw] OR improving [tw] OR improves [tw] OR improve [tw] OR guideline* [tw] OR practice* [tw] OR medical [tw] OR provider* [tw] OR physician* [tw] OR nurse* [tw] OR clinician* [tw] OR academic [tw] OR visit* [tw])) OR Reminder Systems [mh] OR Reminder* [tw] OR ((financial [tw] OR economic [tw] OR physician* [tw] OR patient*) AND incentive* [tw]) OR Reimbursement Mechanisms [mh] or Guideline Adherence [mh] OR practice guidelines [mh]

#6

Medical Informatics [mh] OR computer [tw] OR (decision [tw] AND (support [tw] or analysis [tw))

#7
All QI studies
#1 or #2 or #3 Or #4 or #5 or #6

#8
Surgical site infection terms
Surgical wound infection[mh] OR surgical site infection*[tiab] OR postoperative infection*[ti] OR postsurgical infection*[ti] OR wound infection*[ti] OR sternal wound infection*[tiab] OR postoperative[ti] OR postsurgical[ti]

#9
Combination of QI terms with SSI terms
#7 AND #8

#10
RCT search
Randomised [ti] OR Randomized [ti] OR Controlled [ti] OR intervention [ti] OR evaluation [ti] OR impact [ti] OR effectiveness [ti] OR Evaluation [ti] OR Studies [ti] OR study [ti] Comparative [ti] OR Feasibility [ti] OR Program [ti] OR Design [ti] OR Clinical Trial [pt] OR Randomized Controlled Trial [pt] OR Epidemiologic Studies [mh] OR Evaluation Studies [mh] OR Comparative Study [mh] OR Feasibility Studies [mh] OR Intervention Studies [mh] OR Program Evaluation [mh] OR Epidemiologic Research Design [mh]

#11
Meta-analysis, systematic review search
((meta-analysis [pt] OR meta-analysis [tw] OR metanalysis [tw]) OR ((review [pt] OR guideline [pt] OR consensus [ti] OR guideline* [ti] OR literature [ti] OR overview [ti] OR review [ti] OR Decision Support Techniques [mh]) AND ((Cochrane [tw] OR Medline [tw] OR CINAHL [tw] OR (National [tw] AND Library [tw])) OR (handsearch* [tw] OR search* [tw] OR searching [tw]) AND (hand [tw] OR manual [tw] OR electronic [tw] OR bibliographi* [tw] OR database* OR (Cochrane [tw] OR Medline [tw] OR CINAHL [tw] OR (National [tw] AND Library [tw]))))) OR ((synthesis [ti] OR overview [ti] OR review [ti] OR survey [ti]) AND (systematic [ti] OR critical [ti] OR methodologic [ti] OR quantitative [ti] OR qualitative [ti] OR literature [ti] OR evidence [ti] OR
evidence-based [ti]))) BUTNOT (editorial [pt] OR comment [pt] OR letter [pt])

#12
All original research
#10 OR #11

#13
Combination of QI terms with SSI terms, limited to original research only
#9 AND #12

#14

#SSI/QI search limited to English only
#13 AND Limits: English

#15
CLABSI search (restrict to English only)
(Catheterization, Central Venous [MeSH] OR central line*[ti] OR central venous catheter*[ti]) AND (Cross infection [mh] OR bacteremia [mh] OR nosocomial [tiab] OR “healthcare associated”[tiab] OR “hospital acquired”[tiab] OR bundle[tiab])

#16
VAP search (restrict to English only)
(Respiration, Artificial[mh] OR mechanically ventilated*[ti] OR intubated*[ti] OR mechanical ventilation*[ti] or ventilator associated*[ti]) AND (Cross infection [mh] OR bacteremia [mh] OR nosocomial [tiab] OR “healthcare associated”[tiab] OR “hospital acquired”[tiab] OR bundle[tiab])

#17
UCUTI search (restrict to English only)
(Urinary catheterization[mh] OR urinary catheter*[tiab]) AND (Cross infection [mh] OR bacteremia [mh] OR nosocomial [tiab] OR “hospital-acquired”[tiab] OR healthcareassociated”[tiab] OR bundle[tiab])

Supplemental Searches

#S1
Nosocomial infection systematic reviews (limited to English only)
Cross infection[mh] AND systematic[sb]

#S2
Handwashing systematic reviews (limited to English only)
Handwashing[mh] AND systematic[sb]

#S3
Author searches
Pronovost p[au] OR Gastmeier P[au] OR Gyssens IC[au]

Appendix B. Excluded Studies

[No Author]. Case study. Implementing IHI's six interventions: contributing to the campaign to save 100,000 lives. Joint Commission Perspectives on Patient Safety 2006 6(2):9-10. Exclusion Codes: COMMENTARY

[No Author]. New York hospitals cut central line infections in half. Perform Improv Advis 2006 10(6):61-7. Exclusion Codes: NOT RELEVANT OUTCOME

[No Author]. Using computer's data to guide OR QI. OR Manager 2006 22(7):18. Exclusion Codes: GUIDELINE

[No Author]. Decreasing surgical site infections in ambulatory care: using data to identify and address issues. Joint Commission Perspectives on Patient Safety 2007 7(2):9. Exclusion Codes: NOT RELEVANT QUESTION

[No Author]. Hospital factors bigger than patient severity of illness: HAIs 'not necessarily inevitable'. Hospital Infection Control 2007 34(1):3-3. Exclusion Codes: COMMENTARY

[No Author]. Link seen between working conditions, infections: higher staffing numbers yield improved outcomes. Healthcare Benchmarks & Quality Improvement 2007 14(9):106-108. Exclusion Codes: COMMENTARY

[No Author]. Ventilator-associated pneumonia. Crit Care Nurse 2008 28(3):83-5. Exclusion Codes: GUIDELINE

[No Author]. Antimicrobial prophylaxis for surgery. Treat Guidel Med Lett 2009 7(82):47-52. Exclusion Codes: GUIDELINE

[No Author]. Intervention leads to reduction in central venous catheter-associated blood stream infections for pediatric patients. AHRQ Research Activities 2009 (351):4-5. Exclusion Codes: COMMENTARY

[No Author]. Quality improvement collaborative fails to improve infection prevention in surgical patients. AHRQ Research Activities 2009 (344):6-6. Exclusion Codes: LETTER

[No Author]. Methodology for a study of structured co-management of high-risk postoperative patients in a teaching hospital. Crit Care Resusc 2010 12(4):277-86. Exclusion Codes: NOT RELEVANT QUESTION

[No author]. In brief. Nursing Standard 2011 26(4): 8-8. Exclusion Codes: LETTER TO EDITOR

[No author]. University of Kansas Improves compliance with the SCIP Infection Antibiotic Core Measures. Joint Commission Benchmark 2011 13(4): 4-6. Exclusion Codes: EDITORIAL

Abdel-Galil, K. The WHO Surgical Safety Checklist: are we measuring up? British Journal of Oral and Maxillofacial Surgery 2010 48(5):397-398. Exclusion Codes: LETTER

Abouzari, M., Sodagari, N., Hasibi, M., et al. Re: Nonshaved cranial surgery in black Africans: a short-term prospective preliminary study (Adeleye and Olowookere, Surg Neurol 2008;69-72). Effect of hair on surgical wound infection after cranial surgery: a 3-armed randomized clinical trial. Surgical Neurology 2009 71(2):261-262. Exclusion Codes: NOT RELEVANT OUTCOME

Abreu, M., Kawagoe, J. Y., De Menezes, F. G., et al. Continuous quality improvement program on healthcare-associated infections in a neonatal intensive care unit: A 16-year experience. American Journal of Infection Control 2011 39(5): E84-E85. Exclusion Codes: NO STATISTICAL ANALYSIS

Acosta-Escribano, J., Fernandez-Vivas, M., Grau et al. Gastric versus transpyloric feeding in severe traumatic brain injury: A prospective, randomized trial. Intensive Care Medicine 2010 36(9):1532-1539. Exclusion Codes: NOT RELEVANT INTERVENTION

Agodi, A., Auxilia, F., Barchitta, M., et al. Risk factors for surgical site infections in hip and knee arthroprosthesis: Role of microbial air contamination and adherence to guidelines for antimicrobial prophylaxis. Clinical Microbiology and Infection 2011 17(): S757-S758. Exclusion Codes: ABSTRACT ONLY

Agrawal, S., Williams, A. Implementing the ventilator bundle from Patient Safety First to improve critical care. Nurs Times 2009 105(36):19. Exclusion Codes: GUIDELINE

Aguilar-Nascimento, J. E., Marra, J. G., Slhessarenko, N., et al. Efficacy of National Nosocomial Infection Surveillance score, acute-phase proteins, and interleukin-6 for predicting postoperative infections following major gastrointestinal surgery. Sao Paulo Med J 2007 125(1):34-41. Exclusion Codes: NOT RELEVANT INTERVENTION

Aguilar-Nascimento, J. E., Salomao, A. B., Caporossi, C., et al. Clinical benefits after the implementation of a multimodal perioperative protocol in elderly patients. Arq Gastroenterol 2010 47(2):178-83. Exclusion Codes: NOT RELEVANT INTERVENTION

al Awa, B., de Wever, A., Almazrooa, A., et al. The impact of accreditation on patient safety and quality of care indicators at King Abdulaziz University Hospital in Saudi Arabia. Research Journal of Medical Sciences 2011 5(1):43-51. Exclusion Codes: NOT RELEVANT QUESTION

Al Raiy, B., Fakih, M. G., Bryan-Nomides, N., et al. Peripherally inserted central venous catheters in the acute care setting: a safe alternative to high-risk short-term central venous catheters. American Journal of Infection Control 2010 38(2):149-153. Exclusion Codes: NOT RELEVANT QUESTION

Alberato, Holly Delatte., Rosalind, Steele-Moses, Susan, Murphree, Paul. Decreasing urinary tract infections one indwelling catheter at a time: a hospital based skilled nursing unit performance improvement program. Pelican News 2010 66(4):8-8. Exclusion Codes: NOT RELEVANT STATISTICAL ANALYSIS

Alexandrou, E., Spencer, T., Davidson, P. Nursing central line service prevents catheter related infections. Australian Nursing Journal 2008 15(11):49-49. Exclusion Codes: EDITORIAL

Alexiou, V. G., Ierodiakonou, V., Dimopoulos, G., et al. Impact of patient position on the incidence of ventilator-associated pneumonia: a Meta-analysis of randomized controlled trials. J Crit Care 2009 24(4):515-22. Exclusion Codes: META-ANALYSIS

Alp, E., Leblebicioglu, H., Doganay, M., et al. Infection control practice in countries with limited resources. Annals of Clinical Microbiology and Antimicrobials 2011 10(): Exclusion Codes: SYSTEMATIC REVIEW

Al-Momany, N. H., Al-Bakri, A. G., Makahleh, Z. M., et al. Adherence to international antimicrobial prophylaxis guidelines in cardia surgery: A Jordanian study demonstrates need for quality improvement. Journal of Managed Care Pharmacy 2009 15(3):262-271. Exclusion Codes: DUPLICATE PATIENT POPULATION OR PUBLICATION

Al-Momany, N. H., Al-Bakri, A. G., Makahleh, Z. M., et al. Adherence to international antimicrobial prophylaxis guidelines in cardiac surgery: a jordanian study demonstrates need for quality improvement. Journal of Managed Care Pharmacy 2009 15(3):262-271. Exclusion Codes: EDITORIAL

Alsaghir, A. H., Martin, C. M. Effect of prone positioning in patients with acute respiratory distress syndrome: a Meta-analysis. Crit Care Med 2008 36(2):603-9. Exclusion Codes: META-ANALYSIS

Al-Tawfiq, J. A., Abed, M. S. Decreasing ventilator-associated pneumonia in adult intensive care units using the Institute for Healthcare Improvement bundle. Am J Infect Control 2010 38(7):552-6. Exclusion Codes: NOT RELEVANT STATISTICAL ANALYSIS

Aly, H., Badawy, M., El-Kholy, A., et al. Randomized, controlled trial on tracheal colonization of ventilated infants: can gravity prevent ventilator-associated pneumonia? Pediatrics 2008 122(4):770-4. Exclusion Codes: NOT RELEVANT QUESTION

Amarasingham, R., Pronovost, P. J., Diener-West, M., et al. Measuring clinical information technology in the ICU setting: application in a quality improvement collaborative. J Am Med Inform Assoc 2007 14(3):288-94. Exclusion Codes: NOT RELEVANT INTERVENTION

Ames, N. J. Evidence to support tooth brushing in critically ill patients. Am J Crit Care 2011 20(3): 242-50. Exclusion Codes: SYSTEMATIC REVIEW

Anchalia, M. M. and D'Ambruoso, L. Seeking solutions: scaling-up audit as a quality improvement tool for infection control in Gujarat, India. Int J Qual Health Care 2011 23(4): 464-70. Exclusion Codes: NO STATISTICAL ANALYSIS

Anderson, D. J., Kaye, K. S., Classen, D., et al. Strategies to prevent surgical site infections in acute care hospitals. Infect Control Hosp Epidemiol 2008 29 Suppl 1:S51-61. Exclusion Codes: GUIDELINE

Anderson, Deverick J., Miller, Becky A., Chen, Luke F., et al. The network approach for prevention of healthcare-associated infections: long-term effect of participation in the duke infection control outreach network. Infection Control & Hospital Epidemiology 2011 32(4):315-322. Exclusion Codes: NO BASELINE DATA

Anderson, D. J., Miller, B. A., Chen, L. F., et al. The network approach for prevention of healthcare-associated infections: Long-term effect of participation in the Duke Infection Control Outreach Network. Infection Control and Hospital Epidemiology 2011 32(4):315-322. Exclusion Codes: DUPLICATE STUDY/PATIENT POPULATION

Andrews, A., Valente, A. Accelerating best care in Pennsylvania: the Hazleton General Hospital experience. American Journal of Medical Quality 2008 23(4):259-265. Exclusion Codes: COMMENTARY

Ang, L., Laskar, R., Gray, J. W. A point prevalence study of infection and antimicrobial use at a UK children's hospital. Journal of Hospital Infection 2008 68(4):372-374. Exclusion Codes: NOT RELEVANT OUTCOME

Anthony, T., Murray, B. W., Sum-Ping, J. T., et al. Evaluating an evidence-based bundle for preventing surgical site infection: a randomized trial. Arch Surg 2011 146(3):263-9. Exclusion Codes: NOT RELEVANT QUESTION

Apisarnthanarak, A., Srichomkwun, P., Sutepvarnon, A., et al. The long-term outcomes of an antibiotic control program with and without education [6]. Clinical Infectious Diseases 2007 45(9):1245-1247. Exclusion Codes: NOT RELEVANT QUESTION

Apisarnthanarak, A., Suwannakin, A., Maungboon, P., et al. Long-term outcome of an intervention to remove unnecessary urinary catheters, with and without a quality improvement team, in a Thai tertiary care center. Infect Control Hosp Epidemiol 2008 29(11):1094-5. Exclusion Codes: LETTER

Arabi, Y., Haddad, S., Hawes, R., et al. Changing sedation practices in the intensive care unit--protocol implementation, multifaceted multidisciplinary approach and teamwork. Middle East J Anesthesiol 2007 19(2):429-47. Exclusion Codes: NOT RELEVANT INTERVENTION

Arriaga, A. F., Lancaster, R. T., Berry, W. R., et al. The better colectomy project: Association of evidence-based best-practice adherence rates to outcomes in colorectal surgery. Annals of Surgery 2009 250(4):507-512. Exclusion Codes: NOT RELEVANT DESIGN

Arroliga, A. C., Pollard, C. L., Wilde, C. D., et al. Reduction in the Incidence of Ventilator-Associated Pneumonia (VAP): A Multidisciplinary Approach. Respir Care 2011 (): . Exclusion Codes: NOT RELEVANT DESIGN

Astle, C. M., Jensen, L. A trial of EXSEPT for hemodialysis central venous catheters. Nephrology Nursing Journal 2005 32([5]):517-525. Exclusion Codes: NOT RELEVANT QUESTION

Augustyn, B. Ventilator-associated pneumonia: risk factors and prevention. Crit Care Nurse 2007 27(4):32-6, 38-9; quiz 40. Exclusion Codes: REVIEW ARTICLE

Babayan, R. K. Re: Evaluating an evidence-based bundle for preventing surgical site infection: a randomized trial. J Urol 2011 186(6): 2266. Exclusion Codes: COMMENTARY

Babayan, R. K. Improving surgical site infections: Using national surgical quality improvement program data to institute surgical care improvement project protocols in improving surgical outcomes. Journal of Urology 2011 185(2):541. Exclusion Codes: LETTER

Balamongkhon, B., Thamlikitkul, V. Implementation of chlorhexidine gluconate for central venous catheter site care at Siriraj Hospital, Bangkok, Thailand. Am J Infect Control 2007 35(9):585-8. Exclusion Codes: NOT RELEVANT QUESTION

Balonov, K., Miller, A. D., Lisbon, A., et al. A novel Method of continuous measurement of head of bed elevation in ventilated patients. Intensive Care Med 2007 33(6):1050-4. Exclusion Codes: NOT RELEVANT QUESTION

Banerjee, S., Shen, B., Baron, T. H., et al. Antibiotic prophylaxis for GI endoscopy. Gastrointest Endosc 2008 67(6):791-8. Exclusion Codes: GUIDELINE

Barie, P. S. Breaking with tradition: Evidence-based antibiotic prophylaxis of open fractures. Surgical Infections 2006 7(4):327-329. Exclusion Codes: EDITORIAL

Barie, P. S. Infection control practices in ambulatory surgical centers. JAMA - Journal of the American Medical Association 2010 303(22):2295-2297. Exclusion Codes: LETTER

Barrell, C., Covington, L., Bhatia, M., et al. Preventive strategies for central line-associated bloodstream infections in pediatric hematopoietic stem cell transplant recipients. Am J Infect Control 2011 (): . Exclusion Codes: SAMPLE SIZE UNDER 100

Barria, R. M., Lorca, P., Munoz, S. Randomized controlled trial of vascular access in newborns in the neonatal intensive care unit. J Obstet Gynecol Neonatal Nurs 2007 36(5):450-6. Exclusion Codes: NOT RELEVANT INTERVENTION

Barrow, C. A patient's journey through the operating department from an infection control perspective. J Perioper Pract 2009 19(3):94-8. Exclusion Codes: EDITORIAL

Barwolff, S., Sohr, D., Geffers, C., et al. Reduction of surgical site infections after Caesarean delivery using surveillance. J Hosp Infect 2006 64(2):156-61. Exclusion Codes: NOT RELEVANT INTERVENTION

Battistella, M., Bhola, C., Lok, C. E. Long-term follow-up of the Hemodialysis Infection Prevention with Polysporin Ointment (HIPPO) study: A quality improvement report. American Journal of Kidney Diseases 2011 57(3):432-441. Exclusion Codes: NOT RELEVANT INTERVENTION STRATEGY

Bearfield, P., McDonald, I., Carrington, M., et al. Ventilator associated pneumonia and adherence to a high impact ventilator care bundle-an observational study. Intensive Care Medicine 2011 37(): S275. Exclusion Codes: ABSTRACT ONLY

Bearman, L, G. M., Munro, C., Sessler, C. N., Wenzel, R. P. Infection control and the prevention of nosocomial infections in the intensive care unit. Seminars in Respiratory and Critical Care Medicine 2006 27(3):310-324. Exclusion Codes: GUIDELINE

Bearman, L, G. M., Marra, A. R., Sessler, C. N., Smith, W. R., Rosato, A., Laplante, J. K., Wenzel, R. P., Edmond, M. B. A controlled trial of universal gloving versus contact precautions for preventing the transmission of multidrug-resistant organisms. American Journal of Infection Control 2007 35(10):650-655. Exclusion Codes: NOT RELEVANT INTERVENTION

Behta, M., Ross, B., Hong, F., et al. Automated identification, tracking and reporting of central line-associated blood streams infection to comply with required New York State reporting. AMIA Annu Symp Proc 2007:869. Exclusion Codes: NOT RELEVANT INTERVENTION

Beldi, G., Bisch-Knaden, S., Banz, V., et al. Impact of intraoperative behavior on surgical site infections. Am J Surg 2009 198(2):157-62. Exclusion Codes: focus on preventative intervention

Bellissimo-Rodrigues, F., Bellissimo-Rodrigues, W. T., Viana, J. M., et al. Effectiveness of oral rinse with chlorhexidine in preventing nosocomial respiratory tract infections among intensive care unit patients. Infection Control and Hospital Epidemiology 2009 30(10):952-958. Exclusion Codes: NOT RELEVANT QUESTION

Beltramini, A. M., Salata, R. A. and Ray, A. J. Thermoregulation and risk of surgical site infection. Infection Control & Hospital Epidemiology 2011 32(6): 603-610. PMID: 21558774. Exclusion Codes: SYSTEMATIC REVIEW

Berenholtz, S. M., Pham, J. C., Thompson, D. A., et al. Collaborative cohort study of an intervention to reduce ventilator-associated pneumonia in the intensive care unit. Infection Control & Hospital Epidemiology 2011 32(4): 305-314. 21460481Exclusion Codes: DUPLICATE PATIENT POPULATION OR PUBLICATION

Berger, E. Value over volume: Value-based purchasing brings financial incentives for 13 core quality measures. Annals of Emergency Medicine 2011 58(6): 19A-21A. Exclusion Codes: LETTER TO EDITOR

Berger, R. E. Evaluating an evidence-based bundle for preventing surgical site infection: A randomized trial. Journal of Urology 2011 185(6): 2178. Exclusion Codes: COMMENTARY

Bernstein, J., Meller, M. M. Antimicrobial prophylaxis to prevent surgical site infection. J Bone Joint Surg Am 2006 88(5):1149-50; discussion 1150-2. Exclusion Codes: LETTER

Berra, L., Cressoni, M., Li Bassi, G., et al. Continuous lateral rotation therapy to prevent ventilator-associated pneumonia: the neglected effects of gravity on pathogenesis of ventilator-associated pneumonia. Crit Care Med 2010 38(3):1018-9; author reply 1019. Exclusion Codes: NOT RELEVANT INTERVENTION

Berriel-Cass, D., Adkins, F. W., Jones, P., et al. Clinical excellence series. Eliminating nosocomial infections at Ascension Health. Joint Commission Journal on Quality & Patient Safety 2006 32(11):612-620. Exclusion Codes: DUPLICATE STUDY/PATIENT POPULATION

Betts, P., Brink, S., Silink, M., et al. Management of children and adolescents with diabetes requiring surgery. Pediatr Diabetes 2009 10 Suppl 12:169-74. Exclusion Codes: GUIDELINE

Biese, K. J., Roberts, E., LaMantia, M., et al. Effect of a geriatric curriculum on emergency medicine resident attitudes, knowledge, and decision-making. Acad Emerg Med 2011 18 Suppl 2(): S92-6. Exclusion Codes: DUPLICATE PATIENT POPULATION OR PUBLICATION

Bigsby, E., Lindsay, W., Pentlow, A., et al. Communication and adherence to prophylactic antibiotic guidelines in patients with a proximal femoral fracture. J Hosp Infect 2010 76(2):185-7. Exclusion Codes: LETTER TO EDITOR

Bingham, M., Ashley, J., De Jong, M., et al. Implementing a unit-level intervention to reduce the probability of ventilator-associated pneumonia. Nurs Res 2010 59(1 Suppl):S40-7. Exclusion Codes: NOT RELEVANT STATISTICAL ANALYSIS

Birch, P., Ogden, S., Hewson, M. A randomised, controlled trial of heparin in total parenteral nutrition to prevent sepsis associated with neonatal long lines: the Heparin in Long Line Total Parenteral Nutrition (HILLTOP) trial. Arch Dis Child Fetal Neonatal Ed 2010 95(4):F252-7. Exclusion Codes: NOT RELEVANT QUESTION

Bizzarro, M. J., Sabo, B., Noonan, M., et al. A quality improvement initiative to reduce central line-associated bloodstream infections in a neonatal intensive care unit. Infection Control & Hospital Epidemiology 2010 31(3):241-248. Exclusion Codes: DUPLICATE STUDY/PATIENT POPULATION

Blot, F., Gachot, B., Nitenberg, G. Are urokinase rinses needed to reduce catheter-related bloodstream infections when standard preventive guidelines are observed? J Clin Oncol 2008 26(14):2415-6; author reply 2416. Exclusion Codes: EDITORIAL

Blot, S., Labeau, S., Vandijck, D. Implementation of guidelines for the prevention of ventilator-associated pneumonia. Am Surg 2008 74(2):183-4; author reply 184. Exclusion Codes: LETTER

Boltz, M. M., Hollenbeak, C. S., Julian, K. G., et al. Hospital costs associated with surgical site infections in general and vascular surgery patients. Surgery 2011 150(5): 934-42. Exclusion Codes: NOT RELEVANT OUTCOME

Bonello, R. S., Fletcher, C. E., Becker, W. K., et al. An intensive care unit quality improvement collaborative in nine Department of Veterans Affairs hospitals: reducing ventilator-associated pneumonia and catheter-related bloodstream infection rates. Joint Commission Journal on Quality & Patient Safety 2008 34(11):639-645. Exclusion Codes: NOT RELEVANT STATISTICAL ANALYSIS

Bonten, M. J. Prevention of ventilator-associated pneumonia: bugs or drugs? Am J Respir Crit Care Med 2010 182(8):993-4. Exclusion Codes: EDITORIAL

Bopp, M., Darby, M., Loftin, K. C., Broscious, S. Effects of daily oral care with 0.12% chlorhexidine gluconate and a standard oral care protocol on the development of nosocomial pneumonia in intubated patients: a pilot study. J Dent Hyg 2006 80(3):9. Exclusion Codes: NOT RELEVANT QUESTION

Borghesi, A., Stronati, M. Strategies for the prevention of hospital-acquired infections in the neonatal intensive care unit. Journal of Hospital Infection 2009 71(1):96-97. Exclusion Codes: LETTER

Boriboonhirunsarn, D., Lauwahutanont, P., Kaewmanee, K., et al. Usage of prophylactic antibiotics in uncomplicated gynecologic abdominal surgery in Siriraj hospital. J Med Assoc Thai 2007 90(6):1068-73. Exclusion Codes: NOT RELEVANT INTERVENTION

Borschel, D. M., Chenoweth, C. E., Kaufman, S. R., et al. Are antiseptic-coated central venous catheters effective in a real-world setting? Am J Infect Control 2006 34(6):388-93. Exclusion Codes: NOT RELEVANT INTERVENTION

Bouadma, L., Mourvillier, B., Deiler, V., et al. Changes in knowledge, beliefs, and perceptions throughout a multifaceted behavioral program aimed at preventing ventilator-associated pneumonia. Intensive Care Med 2010 36(8):1341-7. Exclusion Codes: NOT RELEVANT QUESTION

Bouadma, L., Mourvillier, B., Deiler, V., et al. A multifaceted program to prevent ventilator-associated pneumonia: impact on compliance with preventive measures. Crit Care Med 2010 38(3):789-96. Exclusion Codes: DUPLICATE STUDY/PATIENT POPULATION

Bowater, R. J., Stirling, S. A., Lilford, R. J. Is antibiotic prophylaxis in surgery a generally effective intervention? Testing a generic hypothesis over a set of Meta-analyses. Ann Surg 2009 249(4):551-6. Exclusion Codes: META-ANALYSIS

Bowton, D. L. Resolution of ventilator-associated pneumonia: is my patient getting better? Crit Care Med 2010 38(1):308-9. Exclusion Codes: EDITORIAL

Boyer, D. R., Steltzer, N., Larrabee, J. H. Implementation of an evidence-based bladder scanner protocol. J Nurs Care Qual 2009 24(1):10-6. Exclusion Codes: NOT RELEVANT QUESTION

Bozikis, M. R., Braun, B. I., Kritchevsky, S. B. How accurately are starting times documented in the medical record? Implications for surgical infection prevention performance measurement. Infection Control and Hospital Epidemiology 2010 31(3):307-309. Exclusion Codes: NOT RELEVANT OUTCOME

Brandt, C., Sohr, D., Behnke, M., et al. Reduction of surgical site infection rates associated with active surveillance. Infect Control Hosp Epidemiol 2006 27(12):1347-51. Exclusion Codes: NOT RELEVANT INTERVENTION

Brandt, C., Hott, U., Sohr, D., et al. Operating room ventilation with laminar airflow shows no protective effect on the surgical site infection rate in orthopedic and abdominal surgery. Ann Surg 2008 248(5):695-700. Exclusion Codes: NOT RELEVANT INTERVENTION

Brandt, C., Ruden, H., Gastmeier, P. Protective Effect of HEPA-Filtered Operating Room Air Ventilation With or Without Laminar Airflow on Surgical Site Infections. Ann Surg 2009. Exclusion Codes: NOT RELEVANT INTERVENTION

Braudis, N., Franey, K., Ahern, J., et al. Establishing nurse-sensitive quality metrics for the pediatric cardiovascular ICU. Pediatric Critical Care Medicine 2011 12(4): S91. Exclusion Codes: ABSTRACT ONLY

Brilli, R. J., Sparling, K. W., Lake, M. R., et al. The business case for preventing ventilator-associated pneumonia in pediatric intensive care unit patients. Jt Comm J Qual Patient Saf 2008 34(11):629-38. Exclusion Codes: NOT RELEVANT DESIGN

Brito, V., Niederman, M. S. Standardized care for nosocomial pneumonia is a valuable tool to improve patient outcomes: How do we get intensivists to listen? Critical Care Medicine 2009 37(1):350-352. Exclusion Codes: COMMENTARY

Brokenshire, E., Plank, L. D., Gillanders, L. K., et al. Adult total parenteral nutrition at Auckland City Hospital: a 6-year review. N Z Med J 2009 122(1297):17-24. Exclusion Codes: NOT RELEVANT INTERVENTION

Brooke, B. S., Meguid, R. A., Makary, M. A., et al. Improving surgical outcomes through adoption of evidence-based process measures: intervention specific or associated with overall hospital quality? Surgery 2010 147(4):481-90. Exclusion Codes: NOT RELEVANT QUESTION

Brun-Buisson, C. Preventing ventilator associated pneumonia. BMJ 2007 334(7599):861-2. Exclusion Codes: EDITORIAL

Brungs, S. M., Render, M. L. Using evidence-based practice to reduce central line infections. Clin J Oncol Nurs 2006 10(6):723-5. Exclusion Codes: GUIDELINE

Buffet-Bataillon, S., Haegelen, C., Riffaud, L., et al. Impact of surgical site infection surveillance in a neurosurgical unit. Journal of Hospital Infection 2011 77(4):352-355. Exclusion Codes: NOT RELEVANT QUESTION

Bull, A. L., Russo, P. L., Friedman, N. D., et al. Compliance with surgical antibiotic prophylaxis--reporting from a Statewide surveillance programme in Victoria, Australia. J Hosp Infect 2006 63(2):140-7. Exclusion Codes: NOT RELEVANT OUTCOME

Burden, N. Some is not a number, soon is not a time: saving lives in America's health care facilities. J Perianesth Nurs 2006 21(3):200-3. Exclusion Codes: NOT RELEVANT INTERVENTION

Burger, C. D., Resar, R. K. “Ventilator bundle” approach to prevention of ventilator-associated pneumonia. Mayo Clin Proc 2006 81(6):849-50. Exclusion Codes: LETTER

Burgher, A. H., Barnett, C. F., Obray, J. B., et al. Introduction of infection control measures to reduce infection associated with implantable pain therapy devices. Pain Pract 2007 7(3):279-84. Exclusion Codes: N<100

Burns, A., Bowers, L., Pak, N., et al. The excess cost associated with healthcare-associated bloodstream infections at Auckland City Hospital. New Zealand Medical Journal 2010 123(1324):17-24. Exclusion Codes: NOT RELEVANT QUESTION

Burton, D. C., Edwards, J. R., Srinivasan, A., et al. Trends in catheter-associated urinary tract infections in adult intensive care units-United states, 1990-2007. Infection Control & Hospital Epidemiology 2011 32(8): 748-756. 21768757Exclusion Codes: NOT RELEVANT QUESTION

Butler, T. Professional nurses can and must prevent urinary tract infections. Okla Nurse 2010 55(4):10. Exclusion Codes: COMMENTARY

Butler-O’Hara, M., D’Angio, C. T., Hoey, H., et al. An Evidence-Based Catheter Bundle Alters Central Venous Catheter Strategy in Newborn Infants. Journal of Pediatrics 2012 (): . Exclusion Codes: NOT RELEVANT OUTCOME

Cabassa, Sylvia Colon. Nurse-generated reminder system to reduce catheter associated urinary tract infection. 2010 D.N.P.:48 p. Exclusion Codes: NOT RELEVANT QUESTION

Caffrey, A. R., Woodmansee, S. B., Crandall, N., et al. Low Adherence to Outpatient Preoperative Methicillin-Resistant Staphylococcus aureus Decolonization Therapy. Infection Control & Hospital Epidemiology 2011 32(9): 930-932. 21828980Exclusion Codes: LETTER TO EDITOR

Calfee, D. P., Salgado, C. D., Classen, D., et al. Strategies to prevent transmission of Methicillin-resistant Staphylococcus aureus in acute care hospitals. Infect Control Hosp Epidemiol 2008 29 Suppl 1:S62-80. Exclusion Codes: NOT RELEVANT INFECTION

Callcut, R. A. What is the best position for preventing ventilator-associated pneumonia? Respir Care 2010 55(3):353-4. Exclusion Codes: COMMENTARY

Campbell Jr, D. A., Kubus, J. J., Henke, P. K., et al. The Michigan Surgical Quality Collaborative: a legacy of Shukri Khuri. American Journal of Surgery 2009 198(5 SUPPL):S49-S55. Exclusion Codes: NOT RELEVANT OUTCOME

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Willson, M., Wilde, M., Webb, M. L., et al. Nursing interventions to reduce the risk of catheter-associated urinary tract infection: part 2: staff education, monitoring, and care techniques. J Wound Ostomy Continence Nurs 2009 36(2):137-54. Exclusion Codes: DUPLICATE STUDY/PATIENT POPULATION

Wilson, A. P., Hodgson, B., Liu, M., et al. Reduction in wound infection rates by wound surveillance with postdischarge follow-up and feedback. Br J Surg 2006 93(5):630-8. Exclusion Codes: NOT RELEVANT INTERVENTION

Wirtschafter, D. D., Pettit, J., Kurtin, P., et al. A Statewide quality improvement collaborative to reduce neonatal central line-associated blood stream infections. Journal of Perinatology 2010 30(3):170-181. Exclusion Codes: NOT RELEVANT STATISTICAL ANALYSIS

Wirtschafter, D. D., Powers, R. J., Pettit, J. S., et al. Nosocomial infection reduction in VLBW infants with a Statewide quality-improvement model. Pediatrics 2011 127(3):419-426. Exclusion Codes: NOT RELEVANT INFECTION

Wise, M. P., Cole, J. M., Williams, D. W., et al. Efficacy of oral chlorhexidine in critical care. Crit Care 2008 12(3):419; auhtor reply 419. Exclusion Codes: LETTER

Woeltje, K. F., McMullen, K. M., Butler, A. M., et al. Electronic surveillance for healthcare-associated central line-associated bloodstream infections outside the intensive care unit. Infection Control and Hospital Epidemiology 2011 32(11): 1086-1090. Exclusion Codes: NOT RELEVANT QUESTION

Wojkowska-Mach, J., Bulanda, M., Kochan, P., et al. Surgical site infections surveillance and quality management in Polish hospitals. Chirurgia Polska 2006 8(2):136-145. Exclusion Codes: NOT RELEVANT INTERVENTION

Woodward, C. S., Son, M., Calhoon, J., et al. Sternal wound infections in pediatric congenital cardiac surgery: A survey of incidence and preventative practice. Annals of Thoracic Surgery 2011 91(3):799-804. Exclusion Codes: NOT RELEVANT OUTCOME

Woolley, I., Jones, P., Spelman, D., et al. Cost-effectiveness of a post-splenectomy registry for prevention of sepsis in the asplenic. Australian and New Zealand Journal of Public Health 2006 30(6):558-561. Exclusion Codes: NOT RELEVANT INTERVENTION

Wren, S. M., Martin, M., Yoon, J. K., et al. Postoperative pneumonia-prevention program for the inpatient surgical ward. J Am Coll Surg 2010 210(4):491-5. Exclusion Codes: NOT RELEVANT INFECTION

Wright, M.-O., Hebden, J. N., Allen-Bridson, K., et al. Health Care-Associated Infections Studies Project: An American Journal of Infection Control and National Healthcare Safety Network Data Quality Collaboration Case Study 6. American Journal of Infection Control 2011 39(6): 515-516. 21704430Exclusion Codes: NOT RELEVANT INFECTION

Wu, A. W., Sexton, J. B., Pronovost, P. J. Partnership with patients: a prescription for ICU safety. Chest 2006 130(5):1291-3. Exclusion Codes: COMMENTARY

Wu, S. C., Crews, R. T., Zelen, C., et al. Use of chlorhexidine-impregnated patch at pin site to reduce local morbidity: the ChIPPS Pilot Trial. Int Wound J 2008 5(3):416-22. ,Exclusion Codes: NOT RELEVANT QUESTION

Wunderink, R. G., Brun-Buisson, C. Ventilator-associated pneumonia: Lessons learned from clinical trials. J Crit Care 2008 23(1):2-4. Exclusion Codes: EDITORIAL

Xiao, Y., Seagull, F. J., Bochicchio, G. V., et al. Video-based training increases sterile-technique compliance during central venous catheter insertion. Critical Care Medicine 2007 35(5):1302-1306. Exclusion Codes: INSUFFICIENT SAMPLE SIZE

Yahav, D., Rozen-Zvi, B., Gafter-Gvili, A., et al. Antimicrobial lock solutions for the prevention of infections associated with intravascular catheters in patients undergoing hemodialysis: systematic review and Meta-analysis of randomized, controlled trials. Clin Infect Dis 2008 47(1):83-93. Exclusion Codes: META-ANALYSIS

Yap, E. L., Levine, A., Strang, T., et al. Should additional antibiotics or an iodine washout be given to all patients who suffer an emergency re-sternotomy on the cardiothoracic intensive care unit? Interact Cardiovasc Thorac Surg 2008 7(3):464-9. Exclusion Codes: REVIEW ARTICLE

Yngström, D., Linström, K., Nyström, K., et al. Healthcare-associated infections must stop: a breakthrough project aimed at reducing healthcare-associated infections in an intensive-care unit. BMJ Quality & Safety 2011 20(7): 631-636. 21642444Exclusion Codes: NO STATISTICAL ANALYSIS

Yoko Furuya, E., Dick, A., Perencevich, E. N., et al. Central line bundle implementation in US intensive care units and impact on bloodstream infections. PLoS One 2011 6(1). Exclusion Codes: DUPLICATE STUDY/PATIENT POPULATION

You, S, J. H., Ip, D. N. C., Wong, C. T. N., et al. Meticillin-resistant Staphylococcus aureus bacteraemia in Hong Kong. Journal of Hospital Infection 2008 70(4):379-381. Exclusion Codes: NOT RELEVANT INFECTION

Young, B. C., Hacker, M. R., Dodge, L. E., et al. Timing of antibiotic administration and infectious morbidity following cesarean delivery: incorporating policy change into workflow. Archives of Gynecology and Obstetrics 2011 (): 1-6. Exclusion Codes: NOT RELEVANT QUESTION

Young, E. M., Commiskey, M. L., Wilson, S. J. Translating evidence into practice to prevent central venous catheter-associated bloodstream infections: A systems-based intervention. American Journal of Infection Control 2006 34(8):503-506. Exclusion Codes: reason

Young, L. S., Winston, L. G. Preoperative use of mupirocin for the prevention of healthcare-associated Staphylococcus aureus infections: a cost-effectiveness analysis. Infect Control Hosp Epidemiol 2006 27(12):1304-12. Exclusion Codes: NOT RELEVANT QUESTION

Young, P., Wyncoll, D. PEEP is protective against pulmonary microaspiration. Crit Care Med 2009 37(1):380; author reply 381-2. Exclusion Codes: LETTER

Young, P. J., Wyncoll, D. L. Continuous cuff pressure control and the prevention of ventilator-associated pneumonia. Crit Care Med 2007 35(10):2470-1; author reply 2471. Exclusion Codes: NOT RELEVANT INTERVENTION

Youngquist, P., Carroll, M., Farber, M., et al. Implementing a ventilator bundle in a community hospital. Jt Comm J Qual Patient Saf 2007 33(4):219-25. Exclusion Codes: NOT RELEVANT STATISTICAL ANALYSIS

Yousefshahi, F., Khajavi, M. R., Anbarafshan, M., et al. Sanosil, a more effective agent for preventing the hospital-acquired ventilator associated pneumonia. Int J Health Care Qual Assur 2010 23(6):583-90. Exclusion Codes: NOT RELEVANT INTERVENTION

Zabramski, J. M., Spetzler, R. F. and Sonntag, V. K. H. Impact of a standardized protocol and antibiotic-impregnated catheters on ventriculostomy infection rates in cerebrovascular patients. Neurosurgery 2011 69(1): E260. Exclusion Codes: LETTER TO EDITOR

Zacharias, S., Dwarakanath, S., Agarwal, M., et al. A comparative study to assess the effect of amikacin sulfate bladder wash on catheter-associated urinary tract infection in neurosurgical patients. Indian J Crit Care Med 2009 13(1):17-20. Exclusion Codes: NOT RELEVANT INTERVENTION

Zack, J. Zeroing in on zero tolerance for central line-associated bacteremia. American Journal of Infection Control 2008 36(10):S176.e1-2. Exclusion Codes: REVIEW ARTICLE

Zanotto, A. R., Heineck, I., Ferreira, M. B. Antibiotic prophylaxis in cholecystectomies in a teaching hospital in Brazil. Ann Pharmacother 2006 40(11):2003-7. Exclusion Codes: NOT RELEVANT OUTCOME

Zhang, Y., Harvey, K. Rational antibiotic use in China: Lessons learnt through introducing surgeons to Australian guidelines. Australia and New Zealand Health Policy 2006 3(1). Exclusion Codes: NOT RELEVANT OUTCOME

Zhou, Z. J., Zheng, Y. L., Hu, Y. H. Effect and cost of perioperative use of antibiotics in coronary artery bypass grafting: A randomized controlled study. Chinese Medical Journal 2011 124(5):699-703. Exclusion Codes: NOT RELEVANT INTERVENTION

Zilberberg, M. D. and Shorr, A. F. Economic Aspects of Preventing Health Care-Associated Infections in the Intensive Care Unit. Critical Care Clinics 2012 28(1): 89-97. Exclusion Codes: NOT RELEVANT OUTCOME

Zywiel, M. G., Daley, J. A., Delanois, R. E., et al. Advance pre-operative chlorhexidine reduces the incidence of surgical site infections in knee arthroplasty. International Orthopaedics 2011 35(7): 1001-1006. Exclusion Codes: NOT RELEVANT INTERVENTION STRATEGY

Appendix C. Evidence Tables[3]

Appendix Table C1a. Study characteristics for VAP which control for secular trend or confounding

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Apisarnthanarak, Thailand - 2007	Controlled interrupted time series	VAP	Tertiary care or university hospital	Medical Intensive Care Unit Coronary Care Unit	2004 - 2006	36	CDC definition was used. Baseline period (Period 1) was from January 1, 2003 through December 31, 2003. Intervention (Period 2) was implemented from January 1, 2004 through December 31, 2004. Follow-up period (Period 3) was from January 1, 2005 through December 31, 2006. The surgical ICU and coronary care unit served as controls.
Berenholtz, United States - 2011	Simple before-after	VAP	More than one hospital of different types	Medical Intensive Care Unit Mixed ICU, Surgical/Trauma ICU, Cardiac ICU	2004 - 2006	30	CDC definition was used. 112 ICUs from 72 hospitals participated. March 2004 ICUs began implementing patient safety interventions.
Bouadma, France - 2010	Interrupted time series	VAP	Tertiary care or university hospital	Medical Intensive Care Unit	2005 - 2008	30	VAP definition is spelled out on page 1117. Baseline period was from January 1, 2002 through September 30, 2005. Intervention was implemented from October 1, 2005 through December 31, 2005. Follow-up period was from January 1, 2006 through June 30, 2008. Baseline period for VAP rates was 45 months long while baseline period for compliance was one time point before the intervention.
DePalo, United States - 2010	Simple before-after	CLABSI; VAP		coronary ICU, respiratory ICU, intermediate care ICU, neurosurgery ICU, trauma ICU	2005 - 2008	27	23 adult ICUs total. All ICUs in Rhode Island were included. CLABSI Education intervention began November 2005. Baseline data collected January 2006 to March 2006 which was during the intervention period. Education intervention for VAP began March 2006. CLABSI and VAP Intervention dates: April 1, 2006 to June 30 2008.
Dubose, United States - 2010	Simple before-after	VAP	Tertiary care or university hospital	Trauma ICU		14	CDC/NNIS definition was used. Specific dates were not given. First month was used as baseline for process measures and year prior to study was used as baseline for infection rates.

[3] Tables for studies identified during the updated search are found in the tables at the end of this appendix.

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Hawe, United Kingdom - 2009	Interrupted time series	VAP	Community hospital with residents	Medical/Surgical ICU	2007 - 2007	10	Hospitals in Europe Links for Infection Control Surveillance (HELICS) definition was used. Passive Implementation was from September 2005 through February 28, 2007. Active Implementation was from March 1, 2007 through December 31, 2007.
Kulvatunyou, Thailand - 2007	Simple before-after	VAP			2003 - 2003	12	Used CDC definition. Baseline period was from July 1, 2002 through June 30, 2003. The intervention was given April 2003. Follow-up period was from July 1, 2003 through June 30, 2004.
Marra, Brazil - 2009	Interrupted time series	VAP	Tertiary care or university hospital	Medical/Surgical ICU	2001 - 2008	90	CDC definition was used. Phase 1 was from March 2001 through December 2002. Phase 2 was from January 2003 through December 2006. Phase 3 was from January 2007 through September 2008.
Omrane, Canada - 2007	Simple before-after	VAP	Tertiary care or university hospital	Mixed ICU	2004 - 2005	6	Definition from Zack et al (Crit Care Med 2002; 30: 2407-12) and Babcock et al (Chest 2004; 125: 2224-31) was used. Baseline period was from November 8, 2003 through May 8, 2004. The education and protocol was initiated in October 2004. The follow-up period was from November 8, 2004 through May 8, 2005.
Papadimos, United States - 2008	Interrupted time series	VAP	Tertiary care or university hospital	Surgical Intensive Care Unit	2004 - 2005	54	CDC definition was used. Baseline period was from January 1, 2003 through December 31, 2003. The Pre-FASTHUG period was from January 1, 2004 through December 31, 2004. The post-FASTHUG period was from January 1, 2005 through June 30, 2007. Infection rates were not reported for the overall pre-intervention period. It is broken into 2 time periods.
Prospero, Italy – 2008	Simple before-after	VAP	Tertiary care or university hospital	Medical/Surgical ICU	2006 - 2006	4	CDC definition was used. Baseline period was from January 2006 through April 2006. The intervention was given in April of 2006. Post-intervention period was from May 2006 through August 2006.

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Scales, Canada - 2011	RCT – Location	CLABSI;VAP	More than one hospital of different types	Medical/Surgical ICU	2005 - 2007	4	15 ICUs, one per hospital, took part in this study. All hospitals were community hospitals. Trial ran from November 1, 2005 to October 31, 2006. From December 1, 2006 through August 31, 2007, ICU's received interventions that they had not received during the trial. The study design details are outlined in Scales et al. Implement Sci 2009; 4:5.; Only adherence rates
Zaydfudim, United States - 2009	Controlled interrupted time series	VAP	Tertiary care or university hospital	Surgical Intensive Care Unit	2007 - 2008	12	Pre-intervention period was from January 2005 through June 2007. Post-intervention period was from August 2007 through July 2008.

Appendix Table C1b. Study characteristics for CLABSI which control for secular trend or confounding

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Apisarnthanarak, Thailand - 2010	Interrupted time series	CLABSI	Tertiary care or university hospital	All units of the hospital	2006 - 2008	24	Although this is a Thai study, CDC definitions of CLABSI were used.; Baseline: July 1, 2005, to June 30, 2006; Intervention: July 1, 2006, to June 30, 2007 -CLABSI bundle only; July 1, 2007, to June 30, 2008 - CLABSI bundle with intensified hand hygiene intervention; Central venous catheters (CVCs) were placed by internists, intensivists, surgeons, and resident physicians throughout all units in the hospital.
Barsuk, United States - 2009	Controlled before-after	CLABSI	Tertiary care or university hospital	Medical Intensive Care Unit	2006 - 2008	16	CDC/NNIS definitions were used.
Costello, United States - 2008	Interrupted time series	CLABSI	Quaternary Care Pediatric Institution	Pediatric Cardiac Intensive Care Unit	2005 - 2006	24	CDC/NHSN definition was used. Baseline: April 2004 to December 2004. Partial Intervention: January 2005 to March 2006. Full Intervention: April 2006 to December 2006.
DePalo, United States - 2010	Simple before-after	CLABSI;VAP		coronary ICU, respiratory ICU, intermediate care ICU, neurosurgery ICU, trauma ICU	2005 - 2008	27	23 adult ICUs total. All ICUs in Rhode Island were included. CLABSI Education intervention began November 2005. Baseline data collected January 2006 to March 2006 which was during the intervention period. Education intervention for VAP began March 2006. CLABSI and VAP Intervention dates: April 1, 2006 to June 30 2008.
Duane, United States - 2009	Simple before-after	CLABSI	Tertiary care or university hospital	Surgical trauma intensive care unit (STICU)	2004 - 2006	30	Study was prospectively conducted in three sequential "groups": Group 1 (pre-protocol): Jan 2003 - June 2004; Group 2 (Post-protocol): July 2004-June 2005; up 3 (Post-protocol, amplified): Jan 2003-June 2004. CDC definition BSI was used.
Khouli, United States - 2011	Controlled before-after	CLABSI	Tertiary care or university hospital	Medical Intensive Care Unit, Surgical Intensive Care Unit	2007 - 2009	6	CDC/NNIS definitions were used.
McKee, United States - 2008	Simple before-after	CLABSI	Tertiary care or university hospital	Pediatric Intensive Care Unit	2004 - 2006	31	CDC/NNIS definitions were used.
Miller, United States - 2010	Interrupted time series	CLABSI	More than one hospital of different types	Pediatric Intensive Care Unit	2006 - 2007	11	CDC definition was used.

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Perez Parra, Spain - 2010	Controlled before-after	CLABSI	Tertiary care or university hospital	Medical, General postsurgery, Cardiac postsurgery ICU	2006 - 2007	9	Used CDC definition (Horan, 2004). roll-plate technique of Maki et al (N Engl J Med 1977; 296: 1305 1309) and interpretative criteria for culturing CVC tip samples
Pronovost, United States - 2010	Simple before-after	CLABSI	More than one hospital of different types	Adult ICUs	2004 - 2005	36	CDC definition was used. 90 adult ICUs from 61 hospitals participated. March 2004 was the beginning of the intervention implementation. Baseline rate was taken during March through May 2004 from ICUs that had not started implementation of the interventions yet.
Scales, Canada - 2011	RCT – Location	CLABSI;VAP	More than one hospital of different types	Medical/Surgical ICU	2005 - 2007	4	15 ICUs, one per hospital, took part in this study. All hospitals were community hospitals. Trial ran from November 1, 2005 to October 31, 2006. From December 1, 2006 through August 31, 2007, ICU's received interventions that they had not received during the trial. The study design details are outlined in Scales et al. Implement Sci 2009; 4:5.; Only adherence rates
Schulman, United States - 2011	Simple before-after	CLABSI	More than one hospital of different types	NICU	2007 - 2009		CDC definitions for CLABSI.; 18 Regional Perinatal Care Center (RPC) NICUs.
Seguin, France - 2010	Simple before-after	CAUTI; CLABSI	Tertiary care or university hospital	Surgical Intensive Care Unit	2006 - 2007	9	International definitions were used. Baseline period was from August 2005 through May 2006. Patients were only followed while in the ICU.
Zingg, Switzerland - 2009	Simple before-after	CLABSI	Tertiary care or university hospital	Medical Intensive Care Unit, Surgical Intensive Care Unit Cardiovascular ICU, Trauma ICU, Neurosurgery ICU	2004 - 2004	5	CDC/NHSN definition was used. Baseline was from September 2003 through December 2003. Took place in 5 ICUs at 1 hospital.

*Articles by Berenholtz et al. (2004), Frankel et al. (2005), Wall et al. (2005), and Yoo et al. (2001) were from the 2007 Report (Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies: Volume 6—Prevention of Healthcare-Associated Infections) and were included only in the tables within the comparative effectiveness review. For further information on these studies please refer to the 2007 report.

Appendix Table C1c. Study characteristics for SSI which control for secular trend or confounding

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Burkitt, United States - 2009	Simple before-after	SSI	one surgical unit in one Veterans Affairs hospital	Operating Room pharmacy	2001 - 2004	12	Only adherence rates reported, no SSI. Interventions were rolled out over the course of several yrs. 2000 is a pre-period for all interventions. In 2001-2002, an intervention to reduce MRSA was initiated. In 2002-2003, this evolved into an intervention to improve antibiotic administration. SSI rates are presented for all yrs, comparing all yrs data, but with special analysis performed comparing 2004 data to the previous yrs since 2004 was the 1st yr after all interventions were implemented.
Hedrick, United States - 2007	Simple before-after	SSI	Tertiary care or university hospital	Operating Room, Surgical Intensive Care Unit	2004 - 2005	10	Many interventions were rolled out at different times during the course of the study period, some implemented while the pre-data was being collected. Because of this overlap, the effect of the intervention may be underestimated. SSI defined according to Surgical Wound Infection Task Force guidelines, which is a modification of the CDC criteria.
Kaimal, United States - 2008	Simple before-after	SSI	Tertiary care or university hospital	Operating Room	2006 - 2007	12	Uncertain how SSI defined.; 1 Institution, 1316 term C-Sections. They define the pre-period from Jan03-Mar05 and that is the baseline. There is an in-between period, from Mar05-Jun06, when they tried several interventions that they say did not work, so they tried a new intervention beginning in Jun06. The post-period is Jun06-Jun07 and they compare this period of time to the baseline, Jan03-Mar05
Kao, United States - 2010	Stepped wedge (non-randomized)	SSI	Tertiary care or university hospital	Operating Room Pre-op area	2007 - 2009	14	The study design was a modified step-wedge design which they called a staggered cohort design. One hospital received the intervention at the beginning, and then 6 months later, the second hospital received the intervention. Hospital 1 had 14 months of follow-up and hospital 2 had 6 months of follow-up. Uncertain how SSI were defined.
Kritchevsky, United States - 2008	RCT – Location	SSI	More than one hospital of different types	Operating Room varied among intervention hospitals	2003 - 2005	18	No SSI rates reported, only adherence rates.; 44 Acute Care Hospitals
Mannien, Netherlands - 2006	Interrupted time series	SSI	More than one hospital of different types	Operating Room	2001 - 2002	11	Follow-up time varied for different hospitals, 6-11 mos. Pre-intervention period from January 2000 to November 2001; CDC definition was used
Trussell, United States - 2008	Simple before-after	SSI	Tertiary care or university hospital	Operating Room, Surgical Intensive Care Unit Pre-op area	-		The study took place in a 39-month period, with the intervention implemented “in the middle”. No dates were given. SSI determined using NNIS definition.

*Articles by Zanetti et al. (2003), Gastmeier et al. (2002), Greco et al. (1991), Dellinger et al. (1991) were from the 2007 Report (*Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies: Volume 6—Prevention of Healthcare-Associated Infections)* and were included only in the tables within the comparative effectiveness review. For further information on these studies please refer to the 2007 report.

Appendix Table C1d. Study characteristics for CAUTI which control for secular trend or confounding

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Apisarnthanarak, Thailand - 2007	Interrupted time series	CAUTI		Medical Inpatient Ward, Surgical Inpatient Ward, ICU	2005 - 2006	12	Baseline: July 1, 2004 - June 30, 2005; f/u: July 1, 2005 - June 30, 2006; NNIS definition used for UTI.
Crouzet, France - 2007	Simple Before-after	CAUTI	Tertiary care or university hospital	neurosurgery, cardiovascular surgery, orthopedic surgery, neurology, and geriatric departments	2005 - 2005	3	Study consisted of 3-month prospective observational phase followed by a 3-month prospective intervention phase (1 Jan 2005 - 30 June 2005). CDC's definition of CAUTI was used. There is no overall CAUTI rate, just early and late CAUTI.
Loeb, Canada - 2008	RCT – Patient	CAUTI	More than one hospital of different types	General Inpatient Ward (non-ICU)	2004 - 2006	30	CDC definition was used to define symptomatic UTI.; Trial conducted among patients admitted to one of seven general medical units in 3 hospitals. Cultures were taken 7 days after UC removal.
Seguin, France - 2010	Simple before-after	CAUTI;CLABSI	Tertiary care or university hospital	Surgical Intensive Care Unit	2006 - 2007	9	International definitions were used. Baseline period was from August 2005 through May 2006. Patients were only followed while in the ICU.

*Articles by Greco et al. (1991),and Saint et al. (2005) were from the 2007 Report (Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies: Volume 6—Prevention of Healthcare-Associated Infections) and were included only in the tables within the comparative effectiveness review. For further information on these studies please refer to the 2007 report.

Appendix Table C2a. Patient characteristics for VAP which control for secular trend or confounding

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Apisarnthanarak, Thailand - 2007	VAP	Educational Program	Provider Education	Intervention Team	Nurses, Respiratory Therapists	1	pre: 470; post1: 482; post2: 952
Berenholtz, United States - 2011	VAP	Comprehensive Unit-Based Safety Program (CUSP)	Organizational Change, Provider Education	Team of Frontline Staff	All Clinical Staff	72	
Berenholtz, United States - 2011	VAP	VAP Bundle and Daily Goal Sheets	Audit and Feedback, Organizational Change, Patient Education, Provider Education	Local ICU Improvement Team	All Clinical Staff	72	
Bouadma, France - 2010	VAP	Multifaceted Prevention Program	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	Multidisciplinary Task Force	All Clinical Staff	1	pre: 856; post1: 74; post2: 835
DePalo, United States - 2010	CLABSI;VAP	VAP Education Program and Bundle				11	
Dubose, United States - 2010	VAP	Quality Rounds Checklist (QRC)	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	Multidisciplinary team	All Clinical Staff	1	pre: 577; post: 570
Hawe, United Kingdom - 2009	VAP	Active Implementation	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	Study Staff	All Clinical Staff	1	passive: 374; active: 215
Hawe, United Kingdom - 2009	VAP	Passive Implementation	Organizational Change	Critical Care Development Group	All Clinical Staff	1	374
Kulvatunyou, Thailand - 2007	VAP	Educational Program		Study Staff		1	Pre-intervention: 85; Post-intervention: 89
Marra, Brazil - 2009	VAP	VAP Bundle	Audit and Feedback, Organizational Change, Provider Education	Study Staff	All Clinical Staff	1	
Omrane, Canada - 2007	VAP	VAP Prevention Protocol	Organizational Change, Provider Education, Provider Reminder Systems	Multidisciplinary team	All Clinical Staff	1	pre: 349; post: 360
Papadimos, United States - 2008	VAP	FASTHUG protocol	Audit and Feedback, Organizational Change	Intensivist-led Critical Care Team	All Clinical Staff	1	pre: 1315; post: 1653
Prospero, Italy - 2008	VAP	Educational Program	Provider Education	Hospital Hygiene Service	All Clinical Staff	1	pre: 104; post: 81

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Scales, Canada - 2011	CLABSI;VAP	Bundle - CLABSI, VAP	Audit and Feedback, Provider Education, Provider Reminder Systems	Study Staff	All Clinical Staff	15	intervention: 4651; control: 4618
Zaydfudim, United States - 2009	VAP	VAP Electronic Dashboard	Audit and Feedback, Organizational Change, Provider Reminder Systems	Critical care team	All Clinical Staff	1	

Appendix Table C2b. Patient characteristics for CLABSI which control for secular trend or confounding

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Apisarnthanarak, Thailand - 2010	CLABSI	Period 3: Intensified hand hygiene promotion plus CLABSI bundle	Audit and Feedback, Organizational Change, Provider Education	Multidisciplinary Team	All clinical staff	1	pre: 1115; post1: 1050; post2: 1204
Barsuk, United States - 2009	CLABSI	CVC Insertion Simulation	Provider Education	Study Staff	Medical Residents	1	
Costello, United States - 2008	CLABSI	Full Intervention: Pediatric Multidisciplinary CLABSI Bundle	Audit and Feedback, Financial incentives, Organizational Change, Provider Education, Provider Reminder Systems	Multidisciplinary team	Nurses, Physicians	1	pre: 911; post1: 1472; post2: 936
DePalo, United States - 2010	CLABSI;VAP	CLABSI Education Program and Bundle		Rhode Island Quality Institute		11	
Duane, United States - 2009	CLABSI	Group 3: Central venous line (CVL) protocol + CVL supply cart + nurse education + nurse checklist and nurse empowerment	Organizational Change, Provider Education, Provider Reminder Systems	Study Staff	Nurses, Physicians	1	Group 1: 135; Group 2: 194; Group 3: 213
Khouli, United States - 2011	CLABSI	Simulation-based sterile technique training	Provider Education	Study Staff	Medical Residents	1	
McKee, United States - 2008	CLABSI	CLABSI education, cart, checklist, and nurse empowerment	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	Study Staff	Nurses, Physicians	1	
Miller, United States - 2010	CLABSI	Bundle - CLABSI	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	Multidisciplinary team	All Clinical Staff	27	
Perez Parra, Spain - 2010	CLABSI	CLABSI Education	Provider Education	Study Staff	Nurses, Physicians Residents and nursing students	1	
Pronovost, United States - 2010	CLABSI	Conceptual Model - CDC CLABSI Bundle	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems; Financial Incentives, Regulation, and Policy	MHA Keystone Center for Patient Safety and Quality, ICU team	All Clinical Staff	61	

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Scales, Canada - 2011	CLABSI;VAP	Bundle - CLABSI, VAP	Audit and Feedback, Provider Education, Provider Reminder Systems	Study Staff	All Clinical Staff	15	intervention: 4651; control: 4618
Schulman, United States - 2011	CLABSI	Bundle - CLABSI	Organizational Change, Provider Education, Provider Reminder Systems	Study staff	All Clinical Staff	18	
Seguin, France - 2010	CAUTI;CLABSI	Physician reminder of catheter duration	Provider Reminder Systems	Study Staff	Nurses, Physicians	1	pre: 676; post: 595
Zingg, Switzerland - 2009	CLABSI	Educational Program for catheter care and hand hygiene	Organizational Change, Provider Education	Study Staff	All Clinical Staff	1	pre: 499; post: 500

Appendix Table C2c. Patient characteristics for SSI which control for secular trend or confounding

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Burkitt, United States - 2009	SSI	Toyota Production System- appropriate antibiotic choice and duration	Organizational Change, Provider Education, Provider Reminder Systems	Administration	All Clinical Staff pharmacists	1	pre: 2550; post:1779
Hedrick, United States - 2007	SSI	bundle - antibiotic prophylaxis	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	multidisciplinary team	All Clinical Staff pharmacists	1	pre: 379; post: 390
Hedrick, United States - 2007	SSI	bundle - normothermia	Organizational Change	multidisciplinary team	All Clinical Staff	1	pre: 379; post: 390
Hedrick, United States - 2007	SSI	bundle - glucose control	Organizational Change	multidisciplinary team	All Clinical Staff	1	pre: 379; post: 390
Kaimal, United States - 2008	SSI	implement policy on timing of antibiotic prophylaxis	Organizational Change	task force comprised of physicians, nurses, administrators, and personnel from hospital infection control service	All Clinical Staff pharmacists	1	pre: 800; post: 516
Kao, United States - 2010	SSI	extended timeout for 2 hospitals, 1 with added education, 1 with added preop checklist	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	multidisciplinary team from 2 hospitals	All Clinical Staff	2	HOSP 1: pre: 119; period 1: 100; period 2: 97; period 3: 115; HOSP 2: pre: 92; period 1: 206; period 2: 154; period 3: 169
Kritchevsky, United States - 2008	SSI	joining a quality improvement collaborative	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	investigators who designed TRAPE (Trial to Reduce Antimicrobial Prophylaxis Errors)	All Clinical Staff pharmacists	feedback only: 22; feedback and intervention: 22	pre feedback only: 2234; pre feedback and intervention: 2213; post feedback only: 2238; post feedback and intervention: 2225
Mannien, Netherlands - 2006	SSI	Optimized antibiotic prophylaxis	Audit and Feedback, Organizational Change, Provider Education	The CHIPS study group	All Clinical Staff	12	pre: 1668; post: 1953
Trussell, United States - 2008	SSI	protocol pathway for appropriate antibiotic use, hair removal, and glucose control	Organizational Change, Provider Education, Provider Reminder Systems	Team of cardiovascular surgeons, intensivists, clinical nurse specialists, and infection control personnel	All Clinical Staff	1	pre: 808; post: 674

Appendix Table C2d. Patient characteristics for CAUTI which control for secular trend or confounding

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Apisarnthanarak, Thailand - 2007	CAUTI	Daily physician reminders to remove unnecessary catheter		Intervention team		1	Pre: 1105; post: 1307
Crouzet, France - 2007	CAUTI	Physician reminder to remove catheter beginning on day 4	Provider Reminder Systems	Study Staff	Nurses, Physicians	1	pre: 141; post: 93
Loeb, Canada - 2008	CAUTI	Stop orders for indwelling urinary catheters	Organizational Change, Provider Reminder Systems	Study Staff	Nurses, Physicians	3	control: 345; study: 347
Seguin, France - 2010	CAUTI;CLABSI	Physician reminder of catheter duration	Provider Reminder Systems	Study Staff	Nurses, Physicians	1	pre: 676; post: 595

Appendix Table C3a. Intervention characteristics for VAP which control for secular trend or confounding

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Apisarnthanarak, Thailand - 2007	VAP	Feedback of baseline data was first given to the MICU staff and an action plan was developed. In period 2, an educational program began and was continuously monitored throughout period 3. A 10-page self-study module was given to the MICU staff to be completed. Before and after administration of the self-study module a 20 question exam was given. Staff who scored below an 80% were required to retake the module. The self-study module was encouraged for all nurses and respiratory staff, but not deemed mandatory. In addition to the educational module, posters, fact sheets, and in-service training sessions for nurses and respiratory therapists were used. The educational program was repeated every 6 months during periods 2 and 3 for the nurses and respiratory therapists. In-service sessions were provided for the first 3 months during period 2, then during month 6, and then every 6 months after that by the infectious disease specialist and focused on VAP prevention practices. Attendance was highly encouraged, but not mandatory. The surgical ICU and coronary care unit were used as controls and did not receive any new interventions for reducing VAP.		The baseline data was given to the MICU staff as feedback. The intervention team required MICU staff who scored under 80% to retake the educational module

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Berenholtz, United States - 2011	VAP	Toolkit was provided along with a slideshow to educate and engage all ICU staff. The VAP bundle implemented included HOB elevation > 30 degrees, appropriate sedation, stress ulcer prophylaxis, deep vein thrombosis prophylaxis, and daily assessment for extubation. Local ICU Improvement teams were trained through semimonthly conference calls, coaching by study investigators, and semiannual statewide meetings. Improvement teams were instructed to partner with their hospital's infection preventionist to help with data collection. ICU Improvement teams posted compliance and VAP rates in the ICU to engage ICU staff. Study investigators reviewed published guidelines for VAP prevention and other supportive evidence during conference calls to educate local ICU teams. The toolkit given to the teams also included a one page "fact-sheet" summary and references to be used to educate their staff. ICU staff used a standardized tool, "Daily Goals" checklists to execute the intervention. Teams were advised to make protocols and standard order sets. Families were told to ask whether the patient was receiving the bundle items. Teams received monthly compliance and VAP rates for their ICU and all other participating ICUs. The reports were de-identified.		Monthly compliance and VAP rates were supplied to the ICU improvement teams. ICUs received de-identified reports from other participating ICUs as well to compare their performance.
Bouadma, France - 2010	VAP	A multidisciplinary task force was formed which included five physicians and five nurses. They reviewed the literature and recent guidelines for preventing VAP and designed an educational program to promote 8 target recommendations among ICU nursing staff. The task force developed a 3-hour mandatory slide presentation with interactive discussion. Each participant was given a booklet with summary information. This was repeated for every 24 new employees. Screen savers were used as reminders and posters were put up around the ICU. Oral care, HOB elevation, and hand hygiene were some of the targeted preventive measures. A simple color-coded visual reminder was placed at the head of the bed to help staff visualize the optimal bed position.		Five performance assessments took place at baseline, 1 month, 6 months, 12 months, and 24 months. They were conducted by ten MICU physicians, nurses, and head nurses not affiliated with caring for ICU patients. After each assessment feedback was given to the MICU staff during regular meetings in the form of graphs documenting compliance and VAP rates. Screensavers also displayed these rates.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
DePalo, United States - 2010	CLABSI; VAP	11 hospitals with 23 ICU units total; one of the hospitals have 4 ICU units and another have 10 units. The JHQSRG served as consultants communicating content for the educational sessions and conference calls. The content and coaching calls reinforced strategies. Education program content: educating staff on the science of safety, identifying hazards, identifying senior executive partners, learning from defects and implementing teamwork tools. Team members were empowered with the ability to stop procedures if safety was compromised. The CLABSI best-practice strategies targeted the clinician's use of five evidence-based behaviors recommended by the CDC, identified as being the most effective at reducing CLABSI. These behaviors included hand-washing, using full barrier precautions when inserting central access catheters, chlorhexidine skin-cleansing, avoiding the femoral site if possible and removing unnecessary catheters. All unit teams educated their bedside staff to best practice strategies and implemented processes by the end of the first quarter.		Throughout study period, teams received feedback on infection rates by accessing database reports and review with the project manager. Subcommittees had quarterly conference calls with physician champions.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Dubose, United States - 2010	VAP	A multidisciplinary team reviewed best-practices data and chose 16 prophylactic measures, 4 of which were for VAP. Then a tool was designed, the Quality Rounds Checklist (QRC), to quantify these prevention measures. The on-duty trauma ICU fellow and ICU team used the QRC daily during rounds to assess if compliance to the VAP bundle was being met. Nurses were in charge of pain assessment, restraint need, oral care, and daily CVC site evaluation. The nurse manager was in charge of checking completion of these measures. The QRC was also used to check compliance. Any components that were deemed non-compliant were highlighted for immediate correction. New fellows were trained in the appropriate use of the QRC. Regular in-services were conducted for the nursing staff discussing the importance of the prophylactic measures. A monthly multidisciplinary meeting was held to assess systemic deficiencies and develop strategies to improvement those areas. The fellow was in charge of presenting the data at the monthly meetings. From these meetings changes such as nursing and staff education on HOB elevation, laminated signs in patient rooms reminding providers of HOB elevation were initiated.		Monthly feedback meetings were conducted by the multidisciplinary team and used to relay compliance and VAP rates from the previous month as well as discuss changes that could improve compliance and infection rates.
Hawe, United Kingdom - 2009	VAP	Educational workshops started in March 2007 and covered various topics pertaining to VAP. The evidence base for the bundle was discussed. Written material was distributed for self-study. Compliance and VAP rates were displayed on the walls of the ICU and at multidisciplinary educational meetings. The pattern of VAP acquisition was frequently updated and discussed at educational meetings as well. When barriers to providing the bundle were met an iterative process to improve these took place. Adherence to the bundle was also promoted during daily rounds to increase collective ownership.		Compliance rates and VAP rates were hung up around the ICU as well as presented at educational meetings.
Kulvatunyou, Thailand - 2007	VAP	The educational program was modeled after Zack et al's paper, Crit Care Med 2002; 30: 2407-12. A 1-hour formal lecture was given to the ICU nursing staff. They were also given a handout with information about VAP. A 10 question pre-, post-lecture exam was given before and after the initial lecture and the second formal lecture six months later. Daily formal discussion rounds were also implemented and posters were hung up around the ICU.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Marra, Brazil - 2009	VAP	During phase 1, a CDC VAP bundle was implemented and audited twice annually by the study staff. The bundle included HOB elevation, no routine changing of humidified ventilator circuits, periodically draining and discarding condensate, and changing the heat-and-moisture exchangers. Study staff provided compliance feedback to all ICU staff through email. During phase 2, immediate correction of non-compliance was added to the aspects of phase 1. Feedback was still being provided. During phase 3,the hospital CEO decided zero tolerance for VAP. In response, the study staff intensified QI efforts monthly. The IHI VAP bundle (HOB elevation, daily sedation vacations, peptic ulcer prophylaxis, deep vein thrombosis prophylaxis, and daily assessment of extubation) was also implemented, staff education was initiated, and posters were hung around the ICU displaying compliance rates. In October 2007, oral care was added to the bundle. In February 2008, continuous aspiration of subglottic secretions was implemented. The bundle was monitored each weekday by an ICU nurse. The nurse would intervene at the same time if the bundle was found to be non-compliant.		Monthly feedback on compliance was given during all three phase. Posters around the ICU also provided feedback on VAP rates and compliance
Omrane, Canada - 2007	VAP	Nurses, respiratory therapists, intensivists, and pharmacists were involved in developing and implementing the protocol. The VAP protocol focused on nutrition, patient positioning, hand hygiene, stress ulcer prophylaxis, and ventilator circuit. A laminated copy of the protocol was included in the patient's chart. At the time of introduction of the protocol an educational session was held. In addition to the protocol, 12 in-service trainings were held for all ICU staff the two weeks preceding the protocol adoption. Additional in-service programs were held throughout the study period. Posters were also hung around the ICU.		Two investigators evaluated protocol compliance and provide feedback to the ICU staff.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Papadimos, United States - 2008	VAP	FASTHUG is an acronym for daily evaluation of Feeding, Analgesia, Sedation, Thromboembolic prophylaxis, elevation of the Head of the bed, Ulcer prophylaxis, and Glucose control. Oral care and hand hygiene were also a part of the protocol. In November 2003 an intensivist-led critical care team model was adopted in the SICU. The team consisted of faculty physicians, anesthesiologists, surgery residents, medical students, nurses, a pharmacist, and respiratory therapists. In 2004, interventions were asked to be implemented, but not enforced except for hand washing. Hand washing was highly enforced by 'secret shoppers' (infection control department officials pretending to not be from the IC department). In 2005, FASTHUG was added to the daily patient evaluation and emphasized during rounds by the critical care team. Its information was used to adjust daily patient care plans.		
Prospero, Italy - 2008	VAP	In March 2006, the ICU staff contacted the Hospital Hygiene Service for help with improving their infection control practices. In April an educational program on CDC Guidelines for preventing VAP was presented to all physicians and nurses. During April and May alcohol-based hand sanitizer was introduced to the ICU staff.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Scales, Canada - 2011	CLABSI;VAP	The 15 ICUs were split into 2 groups and were randomized to receive an intervention while acting as a control for an ICU in the other group. There were 3 phases, each phase was 4 months long. Each ICU received a different intervention in each phase. At the end of the trial, the ICUs would receive the interventions that they acted as controls for in 3 month phases. This was called the decay-monitoring period. A central coordinating office conducted the interventions, disseminated the educational and promotional materials, arranged videoconferences, and analyzed the data. All participating ICUs were given videoconference equipment. An expert advisory panel generated a list 15 best practices which were given to the ICU directors. The ICU directors rated which ones they found most applicable and the top six were the ones implemented in this study. For each best practice, a bibliography of relevant literature was generated and presented in easy-to-read bulletins. A content expert provided the interactive educational sessions through videoconference. The presentations were available on a website for reference. ICUs were also encouraged to provide their own in-services and educational programs. Process measures were audited daily and monthly feedback reports were given to the ICU staff. De-identified information for all participating hospitals were included in the feedback reports. ICUs were encouraged to use posters and lapel pins to remind clinicians of the best practices. Examples of pre-printed order sets and checklists were also supplied to the ICUs. The Ontario Telemedicine Network videoconferencing infrastructure was used to provide the educational sessions from the content experts, conduct monthly network meetings, and host training sessions for data collectors and site educators.		Monthly feedback reports were provided to each ICU. The report included identified data for the ICU and de-identified data for the rest of the participating ICUs.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Zaydfudim, United States - 2009	VAP	An electronic dashboard was designed to display real-time VAP compliance for each parameter. If the parameter was green then it was in compliance. If it was yellow then the parameter was soon due. If it was red then the parameter was not in compliance. The dashboard was the screensaver for all of the computers in the ICU. Compliance with dashboard parameters were reviewed twice daily at during rounds. Physician and nursing leadership received daily compliance reports. The VAP bundle had been initiated in January 2002 in this ICU, but had poor compliance and no change in VAP rates. The respiratory therapist team was in charge of performing spontaneous breathing trials. The sedation score goal was set by the critical care team. Bedside nurses were in charge of titrating the sedatives in order to achieve sedation score goal. Bedside nurses also implemented HOB elevation, oral care, and hypopharyngeal suctioning.		The dashboard allows for instant compliance feedback and ICU leadership were given daily compliance reports.

Appendix Table C3b. Intervention characteristics for CLABSI which control for secular trend or confounding

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Apisarnthanarak, Thailand - 2010	CLABSI	Each intervention and baseline period consisted of 12 months. From June 1 to 30, 2006, the team provided feedback on baseline data to the hospital nursing staff and physician, and an action plan was developed. During period 2 (July 1, 2006, to June 30, 2007), alcohol- based hand rub (75% isopropyl alcohol) dispensers were attached to the rails of all patient beds, and the CA-BSI prevention bundle was implemented. Components of CA BSI bundle included (1) hospital-wide HCW education on proper hand hygiene practices following the World Health Organization's (WHO) ''Five Moments for Hand Hygiene'' campaign,9 (2) education of physicians on the use of maximum sterile barrier precautions during CVC insertion, (3) use of a chlorhexidine- based skin preparation, (4) optimization of CVC insertion practices (e.g., avoidance of femoral insertion sites), and (5) daily review of the need for CVC in each patient. The CVC dressing was changed every 48 hours if using a gauze dressing and tape and every 7 days if using a transparent dressing. The educational program on hand hygiene and maximum sterile barrier precautions consisted of a single 45-minute interactive educational session and was repeated every 4 months. During period 3 (July 1, 2007, to June 30, 2008), an intensified hand hygiene intervention was introduced. As part of this education, all HCWs were required to demonstrate proper hand hygiene practice and confirm adequate practice with the fluorescence dye test. After the presentation, we distributed a hand hygiene fact sheet. All patients admitted to the hospital were prospectively followed by the intervention team, comprising the head nurse, an ICS, an infectious disease consultant, and a hospital epidemiologist, throughout the entire study period.		During the period 3, feedback on hand hygiene compliance rates and maximum sterile barrier precaution use were provided to each nursing unit through a monthly infection control newsletter and posters. Feedback was not available for health care workers during the period 2.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Barsuk, United States - 2009	CLABSI	Residents in the simulator-trained group took a baseline test (pretest) in CVC insertion using a simulator and a 27-item CVC skills checklist. Subsequently, these residents completed 2-two hour education sessions. The first hour contained a videotaped lecture on the technique, indications, contraindications, and complications of CVC insertion and a step-by-step demonstration of CVC insertion technique. Evidence-based guidelines for CRBSI reduction were emphasized (hand washing, full sterile barrier technique, chlorhexidine skin preparation, avoidance of the femoral site, and prompt CVC removal). The remaining 3 hours of education featured training with an ultrasonographic device and the opportunity for deliberate practice on the simulator with focused feedback. After training, residents underwent a posttest using the CVC skills checklist and were expected to meet or exceed a minimum passing score (MPS) set by an expert panel in both internal jugular and subclavian CVC insertion. Residents who did not achieve the MPS underwent more deliberate practice and were retested until the MPS was reached. Traditionally trained internal medicine and emergency medicine residents attended a lecture series on bedside procedures at the beginning of the academic year and did not undergo training on the CVC simulator. Central venous catheter patient care bundles were used throughout NMH during the study period. The bundles mandate sterile technique, full barrier drapes, and insertion site disinfection with chlorhexidine, 2%, according to recommendations of the Institute for Healthcare Improvement (IHI). In the last 4 months of the 32-month study period, chlorhexidine impregnated body wipes were used for most patients in the MICU.		During the simulator training, residents were given very focused feedback on their technique. If the residents didn't meet or exceed the minimum passing score, they underwent more practice and retested.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
		Partial intervention period (January 2005 through March 2006): A CICU based infection control nurse position (0.75 full-time equivalent) was established to facilitate the intervention. The manager of the hospital's infection control program provided mentoring and instruction critical to the development of this position. This nurse collaborated closely with the hospital's infection control staff members and assumed primary responsibility for prospective CLABSI surveillance, instruction during educational sessions, and implementation of evidence-based practice changes. Mandatory, detailed, educational sessions regarding CLAB prevention were conducted for all CICU nursing and physician staff members and included PowerPoint presentations, a 15-page handout, question-and answer periods and, for nursing staff members, hands-on demonstrations of CVL access and maintenance techniques. A CVL insertion bundle (January 2005) was implemented in the CICU, cardiac catheterization laboratory, and cardiac operating rooms. Insertion bundle consisted of the following steps: Whether CVL necessity was confirmed with attending physician; CVL checklist for insertion was reviewed; Use of hand hygiene before donning and after removing gloves; Use of CVL insertion kit with maximal sterile barriers (Skin antisepsis: 2% chlorhexidine if patient of EGA of >37 wk or 70% alcohol X 3 if patient of EGA of <37 wk) and an included CVL insertion "observer" with a documented signature for sign-off. March 2005, both the access and maintenance bundle were initiated standardizing the technique for maintaining and changing CVL dressings. The access bundle emphasized sterile technique, including a 10-second alcohol scrub before each entry into a CVL hub. (Exact details of access and maintenance bundles on page 918 of paper). A hand hygiene campaign was simultaneously implemented. A daily goal sheet that emphasized the timely removal of CVLs once they were no longer clinically needed was introduced for use during morning rounds. Feedback on infection rates and reminders regarding compliance with existing initiatives were commonly provided during bedside rounds; feedback of current CLABSI rates and initiatives was provided to all CICU physician and nursing staff members through educational sessions, morbidity and mortality conferences, and electronic communications. Compliance with use of the CVL		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
DePalo, United States - 2010	CLABSI;VAP	11 hospitals with 23 ICU units total; one of the hospitals have 4 ICU units and another have 10 units. The JHQSRG served as consultants communicating content for the educational sessions and conference calls. The content and coaching calls reinforced strategies. Education program content: educating staff on the science of safety, identifying hazards, identifying senior executive partners, learning from defects and implementing teamwork tools. Team members were empowered with the ability to stop procedures if safety was compromised. The CLABSI best-practice strategies targeted the clinician's use of five evidence-based behaviors recommended by the CDC, identified as being the most effective at reducing CLABSI. These behaviors included hand-washing, using full barrier precautions when inserting central access catheters, chlorhexidine skin-cleansing, avoiding the femoral site if possible and removing unnecessary catheters. All unit teams educated their bedside staff to best practice strategies and implemented processes by the end of the first quarter.		Throughout study period, teams received feedback on infection rates by accessing database reports and review with the project manager. Subcommittees had quarterly conference calls with physician champions.
Duane, United States - 2009	CLABSI	In Group 2, the CVL protocol included minimizing CVL use, removal of the CVL ASAP, elimination of routine CVL changes and guidewire exchanges, strict universal precautions including maximal barrier precautions, and an educational program for rotating STICU residents. Group 3 (amplified protocol) included the CVL protocol from Group 2 plus a line supply cart, nursing education on the impact of BSI and their role in the prevention of BSI, a nursing checklist to ensure proper sterile technique, and nurse empowerment to stop the line placement in case of any violation of checklist.		
Khouli, United States - 2011	CLABSI	Baseline assessment of performance in CVC simulation was conducted first for both groups of residents. Residents then received either training from a 20-minute video or simulation-based training plus video. After completion of training, the residents were scored again. After this, the authors compared rates of CLABSI in the MICU and SICU.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
McKee, United States - 2008	CLABSI	The improvement model included six interventions: 1) administering a pre-intervention survey of PICU attending and fellow physicians and nurses to assess current central catheter insertion practices; 2) implementing an educational intervention to increase provider and nurse awareness of evidence-based infection control practices for inserting and maintaining central catheters; 3) creating a dedicated catheter insertion/procedure cart to make it easier for providers to follow guidelines for sterile central venous catheter insertion; 4) implementing a checklist to ensure adherence to evidence-based guidelines for central catheter insertion and provide independent double-checking of adherence; 5) empowering nurses to stop the procedure if evidence- based guidelines were not followed; and 6) providing real-time weekly feedback to ICU doctors and leaders on performance. The educational program was a web-based training module, similar to the one already being used for the adult ICUs. Attendance was tracked and staff providers were reeducated on proper techniques for maintenance of central catheters, such as changing soiled or nonadherent dressings. The cart was restocked daily by the PICU support staff. An in-service conducted by the PICU nursing administration was provided to the nurses on how to fill out the checklist. Physicians were also educated that this intervention was a partnership between them and the nurses. During insertion of a central catheter, if a guideline is non-compliant, the nurse will ask for it to be corrected and then the procedure can continue. If the physician still does not comply, then they are referred to the PICU medical director. Weekly feedback was sent via email to all ICU directors and senior leaders in the hospital.		Feedback was given weekly to ICU directors and senior leaders via email. This allowed participants to see each ICU's performance as well as their own.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Miller, United States - 2010	CLABSI	Each PICU team selected a ‘champion’ to promote the unit. The multidisciplinary team attended 4 face-to-face learning workshops, over the first year with monthly conference calls and monthly collection of infection data with PICU-wide submission. Implementation of an insertion bundle and a maintenance bundle. The insertion bundle consisted of: washing hands before the procedure, for children aged greater than or equal to 2 mo, chlorhexidine was used scrubbed at the insertion site for 30s with the exception of the groin which was scrubbed for 2 minutes. No iodine skin prep or ointment was used at the insertion site. Insertion cart was prepackaged using full sterile barriers. A checklist was created to empower staff to stop a procedure not following sterile techniques. Use of only polyurethane or Teflon catheters. Insertion training including videos and slides. The maintenance bundle consisted of: daily assessment of whether catheter is needed, catheter-site care, catheter hub, cap and tube care. Both bundles were in line with CDC recommendations.		Monthly collection of CLABSI rates for each PICU were gathered and shared with all 29 PICU.
Perez Parra, Spain - 2010	CLABSI	A short lecture covering the following 10 main points was given 30 times to cover all ICU workers on all shifts: 1. Use of a full sterile sheet when preparing the CVC insertion site, 2. Choice of the subclavian vein as the preferred site of insertion, 3. Use of closed needleless catheter connection systems, 4. Disinfection of clean skin with 2% chlorhexidine gluconate solution before CVC insertion, 5. CVC site dressing regimens, 6. Aseptic technique during CVC care and maintenance (hand washing and use of gloves), 7. Optimal frequency of CVC dressing replacement, 8. Use of parenteral nutrition through a multi-lumen CVC, 9. Management of suspected CLABSI (change avoiding guide wire technique), 10. Replacement of administration sets, needleless systems, and parenteral fluids). A pre-test was given to healthcare staff shortly before the lecture and then 6 months later. No other changes to reduce CLABSI and VAP were implemented at this time.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Pronovost, United States - 2010	CLABSI	An intensive care unit team was formed and included a senior executive, the intensive care unit director and nurse manager, and a physician and nurse in the ICU who can dedicate 20% of their time to the project. Training of the team leaders was accomplished through conference calls every other week, coaching by research staff, and statewide meetings twice a year. The teams received supporting information on the efficacy of each component of the intervention, suggestions for implementing it, and instruction in methods of data collection. During the initial implementation, the individual ICUs implemented 2 cultural interventions and 2 patient safety interventions. These interventions were implemented in 3 month intervals. The interventions were integrated into staff orientation. The ICUs also implemented daily goal sheets to improve communication between clinicians. The intervention was trying to increase compliance with the following CDC recommendations: hand washing, using full-barrier precautions during the insertion of central venous catheters, cleaning the skin with chlorhexidine, avoiding the femoral site if possible, and removing unnecessary catheters. Clinicians were educated on these practices. A central-line cart with necessary supplies was created, a checklist was used to ensure adherence to infection-control practices, and providers were stopped if practices were not being conducted. Removal of catheters were discussed at daily rounds. Teams received feedback on number and rates of CLABSI at monthly and quarterly meetings, respectively.	BCBS-MI supplied a financial incentive if the hospital submitted 90% of their CLABSI data in the first year. In subsequent years, the incentive was based on performance benchmarks created from year 1's data.	Number and rates of CLABSI were given to teams at monthly and quarterly meetings, respectively.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Scales, Canada - 2011	CLABSI;VAP	The 15 ICUs were split into 2 groups and were randomized to receive an intervention while acting as a control for an ICU in the other group. There were 3 phases, each phase was 4 months long. Each ICU received a different intervention in each phase. At the end of the trial, the ICUs would received the interventions that they acted as controls for in 3 month phases. This was called the decay-monitoring period. A central coordinating office conducted the interventions, disseminated the educational and promotional materials, arranged videoconferences, and analyzed the data. All participating ICUs were given videoconference equipment. An expert advisory panel generated a list 15 best practices which were given to the ICU directors. The ICU directors rated which ones they found most applicable and the top six were the ones implemented in this study. For each best practice, a bibliography of relevant literature was generated and presented in easy-to-read bulletins. A content expert provided the interactive educational sessions through videoconference. The presentations were available on a website for reference. ICUs were also encouraged to provide their own in-services and educational programs. Process measures were audited daily and monthly feedback reports were given to the ICU staff. De-identified information for all participating hospitals were included in the feedback reports. ICUs were encouraged to use posters and lapel pins to remind clinicians of the best practices. Examples of pre-printed order sets and checklists were also supplied to the ICUs. The Ontario Telemedicine Network videoconferencing infrastructure was used to provide the educational sessions from the content experts, conduct monthly network meetings, and host training sessions for data collectors and site educators.		Monthly feedback reports were provided to each ICU. The report included identified data for the ICU and de-identified data for the rest of the participating ICUs.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Schulman, United States - 2011	CLABSI	Two bundled were implemented an insertion bundle and a maintenance bundle. The insertion bundle consisted of: creating central line kit or carts to consolidate items necessary for insertion, hand hygiene with appropriate alcohol-based product or antiseptic soap after palpating insertion sites and before and after inserting the central line, use of maximal barrier precautions, disinfecting skin with antiseptic (chlorhexidine 2%, alcohol 70%) before insertion, and using a sterile semipermeable dressing or gauze to cover the insertion site. Maintenance bundle consisted of: hand hygiene with appropriate antiseptic soap or alcohol-based product, evaluation of catheter insertion site daily for infection and dressing integrity, changing damp soiled or loose dressings aseptically and disinfecting site with chlorhexidine, develop and use standard IV tubing setup and changes, maintain aseptic technique when changing IV tubing and when entering the catheter, daily review of catheter necessity with prompt removal. The hospitals also implemented a checklist to promote the bundle behaviors, with workshops geared toward reducing CLABSI as well as periodic surveys and conference calls.		
Seguin, France - 2010	CAUTI;CLABSI	During Period 2, a red square was added to the patient's daily care sheet. The box asked the physician if the CVC or urinary catheter was useful or needed. If the physician marked no then the nurse was instructed to remove the catheter.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Zingg, Switzerland - 2009	CLABSI	All protocols were reviewed and check for completeness and plausibility by two study physicians. An educational program targeting hand hygiene and catheter care was implemented in 4 phases and each phase had 4 modules that were done in a fixed order. Phase 1 was used to train head nurses and nursing instructors through 12 interactive training sessions. Phase 2 included five-45 min general teaching sessions for all ICU nurses in which a short review of the literature and practical demonstrations were provided. Phase 3 included 80-15 min bedside teaching workshops for small groups of ICU nurses. Phase 4 was targeted at physicians and covered hand hygiene more than CVC care. The four modules within each phase were 1) hand hygiene, 2) dressing of the insertion site, 3) manipulation of tubing and stopcocks, and 4) aseptic preparation of infusates. Two infection control nurses were in charge of all of the educational sessions. For hand hygiene, the focus wasn't so much on increased compliance, but and increase proper technique of hand hygiene.		

Appendix Table C3c. Intervention characteristics for SSI which control for secular trend or confounding

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Burkitt, United States - 2009	SSI	TPS team leader (staff nurse) worked with unit staff to identify obstacles in choosing appropriate antibiotic and duration of perioperative antibiotic. Staff identified 4 key barriers: 1) reliance on computerized bar code medication system that was frequently nonfunctional, 2) lack of antibiotic standardization orders, 3) reliance on paper-based medication records, and 4) monthly new surgical residents responsible for antibiotic orders. An iterative process guided by TPS came up with the following solutions: 1) a backup battery pack was purchased so bar code system always functional, 2) pharmacists developed list of appropriate antibiotics for each procedure based on latest guidelines and approved by head of infectious diseases, 3) guidelines for antibiotic prophylaxis were made available on computerized VA order entry system and printed on cards for all physicians and residents, 4) computerized standing order automatically discontinued antibiotics 24 hrs after surgery. Also, education provided to new attending physicians and residents on a regular basis.		
Hedrick, United States - 2007	SSI	The hospital joined the Surgical Infection Prevention project in 2004. Following participation in the collaborative, a multidisciplinary team formed with members from surgical and anesthesia depts., OR staff, and staff from office of performance improvement, led by team champion. Members met with and had frequent teleconferences with the Virginia Healthcare Quality Center. Team chose target population, defined outcomes and process measures and began collecting baseline data. One person designated to have key accountability for antibiotic prophylaxis measures, which included standardizing administration and duration, documenting on pt charts, providing visible reminders and checklists, and involving pharmacy staff.		Monthly compliance statements were provided to the Virginia Healthcare Quality Center.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Kaimal, United States - 2008	SSI	A task force comprised of physicians, nurses, administrators, and personnel from hospital infection control service was formed to define magnitude of SSI problem among pts undergoing cesarean deliveries and identify solutions. They developed an action plan that included retraining nurses in aseptic technique, instituting a new surgical prep routine, implementing pt warming and oxygen administration guidelines, reducing OR traffic, and improving scrub technique. After 1 yr no change in SSI, and task force reviewed antibiotic administration and decided to implement policy regarding timing of administration to be prior to incision rather than at cord clamp. The new action plan involved staff from neonatology, anesthesia, and obstetrics to define and implement the change. Communication and dissemination to staff was made verbally and electronically, with multiple messages sent for reinforcement. Nurses became primary communicators of the policy.	Starbucks cards were offered as incentives to report SSI to task force.	
Kao, United States - 2010	SSI	The multidisciplinary teams from 2 hospitals identified barriers to compliance with SCIP antibiotic prophylaxis compliance. Both hospitals incorporated an extended timeout in which antibiotics were administered preoperatively and both provided feedback to faculty. Hospital 1 added educational lectures to the anesthesiologists and surgeons. Hospital 2 added an educational campaign and a preop checklist for nurses to document antibiotic choice. Both hospitals had a standardized preop form prior to the intervention, which standardized which antibiotics were ordered for which procedure. There were 4 phases of the study: 1) baseline, 2) attention only for both hospitals (no intervention used, but SCIP compliance was measured), 3) intervention for hospital 1, attention only for hospital 2, and 4) intervention for both hospitals.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Kritchevsky, United States - 2008	SSI	Hospitals volunteered to be part of the collaborative, and were then randomized into either a feedback only group or an intervention group which received feedback and an intervention. Hospitals were matched on size, as well as adherence to prophylactic antibiotic timing in the pre period. Two staff members from all hospitals were trained to collect and report the following on a random sample of 100 surgery cases: method of ordering antibiotic, professional background of person ordering antibiotic, pt location when antibiotic administered, professional background of person administering antibiotic, incision times, and antibiotic administration times. The feedback only group received a customized comparative report of 5 performance measures: timing, receipt of antibiotic, duration, selection, and single preoperative dose. The intervention group received the same comparative report, as well as an initial in-person meeting with improvement experts, followed by 8 monthly telephone calls to share strategies, obstacles, and successes, and then a final in-person meeting with experts with advice on how to overcome obstacles. There were also monthly 90-minute conference calls with all intervention hospitals to share intervention experiences, guidelines, forms, and literature reviews. Both intervention and feedback only groups kept logs on intervention strategies that they implemented at their own facilities. Additional QI strategies were selected by each hospital, and there was substantial overlap in additional QI strategies selected by the feedback only grps and the feedback and intervention collaborative grps. Details available in appendix.		Hospitals received a comparative report with 5 performance measures: timing, receipt of antibiotics, duration, selection, and single preoperative dose. Intervenees met twice with quality improvement experts and received advice on interventions to be implemented at individual hospitals.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Mannien, Netherlands - 2006	SSI	As part of the prospective, multisite, Surgical Prophylaxis and Surveillance (CHIPS) project, an optimized and restrictive antibiotic policy based on the national guideline was implemented. The guideline recommends prophylaxes with a single dose of antimicrobial administered intravenously within 30 minutes before the first incision. The hospitals participated voluntarily in CHIPS. The policy was based on the national guideline for surgical prophylaxis issued by the Dutch Working Party on Antibiotic Policy (SWAB). From a previous publication on the CHIPS project (van Kasteren 2005), additional details on the project were described. Following the pre-intervention period, every hospital received feedback on their antibiotic prophylaxis data. Educational mtgs were organized for medical specialists and nurses.		Following the pre-intervention period, participating hospitals received feedback on their antibiotic prophylaxis data.
Trussell, United States - 2008	SSI	A team of cardiovascular surgeons, intensivists, clinical nurse specialists, and infection control personnel constructed a simple protocol pathway to improve timely administration of antibiotics, maintain glucose control, and remove hair appropriately. In the pathway, cardiac anesthesiologists were designated the responsibility of administering antibiotics en route to the OR. Large colored stamps requiring documentation of dosing served as a reminder. Endocrinology and pharmacy staff assisted in devising a protocol wherein all pts were placed on IV insulin post-operative, monitored hourly with finger sticks, and infusion rates adjusted accordingly. Shaving utensils were removed from pre-operative area and replaced with electric clippers and an in-service was conducted for nurses.	The article cited legislation allowing CMS to adjust hospital reimbursement down in pt cases complicated by HAIs, as an incentive to reduce SSIs.	

Appendix Table C3d. Intervention characteristics for CAUTI which control for secular trend or confounding

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Apisarnthanarak, Thailand - 2007	CAUTI	The intervention team reviewed the literature and collected baseline data. During the time between study periods the intervention team provided feedback from the baseline data to the nurses and physicians. An action plan was developed. Nurse-generated daily reminders were given to physicians to remove unnecessary urinary catheters. Nursing staff identified patients with indwelling catheters >= 3 days and notified investigators. If catheterization was determined to be inappropriate by an ID physician, a physician from the intervention team held a bedside discussion with the treating physician regarding reasons for catheterization and the possibility of discontinuing it, upon which the treating physician made a decision. This intervention was promoted at monthly staff meetings. The intervention team held monthly meetings to discuss problems and to identify modifiable risk factors for each patient who developed CAUTI in the previous month.		Feedback on the baseline data were given to nursing staff and physician by the intervention team prior to the initiation of the intervention. No feedback mechanism existed during the intervention period.
Crouzet, France - 2007	CAUTI	Nursing staff reminded physicians to remove any unnecessary urinary catheter after four days of the catheter being in situ and on a daily basis thereafter.		
Loeb, Canada - 2008	CAUTI	Prior to beginning the trial, information sessions were conducted for nursing staff on participating units to introduce them to the study and explain the stop orders. Attending physicians received a letter notifying them of the stop orders. Prewritten orders were placed in the chart of participants randomized to the stop-order group. Stop orders listed the following six criteria as acceptable for a urinary catheter: urinary obstruction, neurogenic bladder and urinary retention, urological surgery, fluid challenge for acute renal failure, open sacral wound care for incontinent patients, and comfort care for urinary incontinence in terminal illness. Nurses were required to review participants' medical history and the results of any tests ordered by the attending physician to determine if the required criteria were met and remove catheters in their absence. The research nurse did regular follow-up with nursing staff to ensure that the automatic stop orders were followed.		
Seguin, France - 2010	CAUTI;CLABSI	During Period 2, a red square was added to the patient's daily care sheet. The box asked the physician if the CVC or urinary catheter was useful or needed. If the physician marked no then the nurse was instructed to remove the catheter.		

Appendix Table C4a. Study context for VAP which control for secular trend or confounding

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Apisarnthanarak, Thailand - 2007	VAP	Pratumthani, Thailand/3 8-Bed ICUs; 450 bed hospital					The intervention team consisted of a representative from the hospital administration, an infectious disease physician, a clinical microbiologist, a MICU physician, a MICU chief nurse, 2 infection control specialists, and a hospital epidemiologist. The infectious disease specialists were in charge of the staff in-service trainings throughout the study period.	The educational program was self-directed.
Berenholtz, United States - 2011	VAP	Michigan/112 ICUs	Larger and teaching hospitals saw a slower decline in VAP rates than small or non-teaching hospitals. By the end of the follow-up period VAP rates were comparable across all contexts		This study was a part of the Keystone Project. There was also work to improved patient safety culture and communication in these ICUs. Some hospitals may have been implementing VAP preventive measures as well.		An ICU Improvement Team was made in all the participating ICUs to help keep the ICU working to the study goals. The team consisted of the ICU director, ICU nurse manager, an ICU physician and nurse, and the senior hospital executive.	The study investigators made a website with all the toolkits, educational materials, as well as other useful information for the ICU improvement teams.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Bouadma, France - 2010	VAP	Paris, France/1000 bed hospital			HAI surveillance since 1995; alcohol rub introduced in 2000; standardized weaning protocol introduced in 2001; ongoing long-term program to improve hand-hygiene and precautions for controlling multi-drug resistant bacteria		A standardized weaning protocol was implemented in the ICU in 2001 and was not changed during the study period. Heat and moisture exchangers were changed every 7 days or when visibly soiled, and keeping the same ventilator circuit in a given patient unless visibly soiled or malfunctioning. HAI surveillance in the ICU has occurred since 1995. The multidisciplinary included four intensivists, one infection control physician, three ICU nurses, and two infection control nurses.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
DePalo, United States - 2010	CLABSI;VAP	Rhode Island/263 beds in 23 adult ICUs in 11 hospitals		They used the Michigan Keystone collaborative approach which found that it was more efficient to centralize the technical work such as data collection and evidence summaries, but have individual hospital units work out how to implement the preventive strategies.	One unit in a mid-size hospital and one unit in the smallest hospital began using silver-coated endotracheal tubes to help reduce VAP during the course of the project. 3 ICUs added antibacterial-impregnated catheters to their CLABSI reducing strategies.	The Michigan Keystone Project, pay-for-performance, regulatory measures, and mandated infection reporting all had some influence on the initiation and propagation of this project.	The multidisciplinary team consisted of the following leaders: MD and nurse leaders of each ICU, CEO of each hospital. The CEO provided a formalized commitment letter.	funding was provided for a shared database across hospitals and to pay for speakers at the learning sessions
Dubose, United States - 2010	VAP	Los Angeles, CA/				Medicare declining to reimburse for HAI-related costs.	The multidisciplinary team included intensivists, trauma surgeons, nursing staff, and a biostatistician. The multidisciplinary team made the QRC and chose the prevention measures on the QRC. The fellow was in charge of presenting the data at the monthly meetings.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Hawe, United Kingdom - 2009	VAP	Livilands Stirling, UK/S/MICU serves a population of about 270,000					Hand hygiene campaign, basic infection control techniques, and a CLABSI prevention intervention were already in place in the hospital. The ICU had an ongoing culture supporting staff education.	
Kulvatunyou, Thailand - 2007	VAP	Bangkok, Thailand/1000 hospital beds					The study staff had also implemented a ventilator weaning protocol during the study period.	All nurses were given an educational pamphlet.
Marra, Brazil - 2009	VAP	Sao Paulo, Brazil/38 bed medical-surgical ICU				Hospital CEO expressed zero tolerance for VAP in phase 3.	An ICU nurse was in charge of monitoring compliance daily.	
Omrane, Canada - 2007	VAP	Montreal, Canada/24 bed mixed ICU					Nutrition, stress ulcer prophylaxis, hand hygiene, and change in ventilator circuit were already in place, but added to the protocol for emphasis. The team that designed and implemented the protocol consisted of respiratory therapists, intensivists, pharmacists, and nurses.	A laminated copy of the protocol was included in every patient chart.
Papadimos, United States - 2008	VAP	Toledo, OH/319 bed hospital			Hand hygiene was already being strictly enforced throughout the entire hospital.	Authors mentioned IHI’s 100,000 Lives campaign’s and the JCAHO’s goal of reducing HAI rates.	The establishment of the intensivist-led critical care team was to promote teamwork and communication between the disciplines to improve patient care.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Prospero, Italy - 2008	VAP	Ancona, Italy/917 bed hospital					Hospital Hygiene Service had come up with the educational program for the ICU staff.	
Scales, Canada - 2011	CLABSI;VAP	Ontario, Canada/15 ICUs (range of ICU beds: 4-19)	ICUs that had a dedicated intensivist staff, more than 10 staffed ICU beds, and had not collected previous data for quality purposes had higher compliance with HOB elevation.			The Ministry of Health and Long-Term Care sought proposals for development and evaluation of strategies to improve effectiveness of care in Ontario's healthcare system.	A panel of experts and ICU directors were used to decide on the best practices to be implemented in this study. Content experts were in charge of the interactive educational sessions. Site educators gave in-services and ICU-specific educational programs. A central coordinating office was in charge of distributing all of the intervention materials, scheduling meetings, and analyzing data.	The interactive educational sessions were posted on the website. Guidelines were summarized into easy-to-read formats.
Zaydfudim, United States - 2009	VAP	Nashville, TN/832 bed hospital			The CDC VAP prevention recommendations were already being implemented.		The respiratory therapist team was in charge of performing spontaneous breathing trials. The sedation score goal was set by the critical care team. Bedside nurses were in charge of titrating the sedatives in order to achieve sedation score goal. Bedside nurses also implemented HOB elevation, oral care, and hypopharyngeal suctioning.	Since the hospital uses electronic medical records, there are computers all throughout the ICU and the dashboard is displayed on every computer.

Appendix Table C4b. Study context for CLABSI which control for secular trend or confounding

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Apisarnthanarak, Thailand - 2010	CLABSI	Thammasat University Hospital/500 bed hospital	Intervention worked in a “resource-limited” setting. All cases were reviewed by same ICS throughout the study. There was no significant difference among the various nursing units with respect to adherence.		Interventions to reduce MDR A baumannii transmission in ICUs middle of period 1.		All patients admitted to the hospital were prospectively followed by an intervention team comprised of the head nurse, an Infection Control Specialist, an infectious disease consultant, and a hospital epidemiologist during both intervention periods. The intervention team however, provided feedback during period 3 only.	
Barsuk, United States - 2009	CLABSI	Chicago, IL/897 bed hospital			Catheter care bundles were used throughout the study in both ICUs.	CMS has refused reimbursing HAI-associated costs.	During the last 4 months of the post-intervention period, chlorhexidine impregnated body wipes were used on most patients in the MICU.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Costello, United States - 2008	CLABSI	Boston, Massachusetts/24 ICU beds			March 2005, hospital participated in the Child Health Corporation of America national collaborative to reduce CLABSI		The cardiovascular program nosocomial infection committee consisted of representatives from the CICU's medical and nursing staff, cardiac anesthesia service, cardiac surgery service, cardiac catheterization laboratory, inpatient cardiac floor, and outpatient cardiac clinic and the hospital's Division of Infectious Diseases, infection control program, respiratory therapy service, and pharmacy. A new position was made in the ICU to accommodate the change being made to increase patient safety culture. Also, hospital administration provided a commitment to this effort.	Infection control nurse was available (three 12-hour shifts per week) for all of 2005 and quarterly during 2006. administrative support was provided by the hospital's program for safety and quality.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
DePalo, United States - 2010	CLABSI;VAP	Rhode Island/263 beds in 23 adult ICUs in 11 hospitals		They used the Michigan Keystone collaborative approach which found that it was more efficient to centralize the technical work such as data collection and evidence summaries, but have individual hospital units work out how to implement the preventive strategies.	One unit in a mid-size hospital and one unit in the smallest hospital began using silver-coated endotracheal tubes to help reduce VAP during the course of the project. 3 ICUs added antibacterial-impregnated catheters to their CLABSI reducing strategies.	The Michigan Keystone Project, pay-for-performance, regulatory measures, and mandated infection reporting all had some influence on the initiation and propagation of this project.	The multidisciplinary team consisted of the following leaders: MD and nurse leaders of each ICU, CEO of each hospital. The CEO provided a formalized commitment letter.	funding was provided for a shared database across hospitals and to pay for speakers at the learning sessions
Duane, United States - 2009	CLABSI	Richmond, VA/			All lines placed were antibiotic-coated catheters. There was also a simultaneous initiative to decrease antimicrobial therapy.	CMS eliminates reimbursement for HAI-related costs.	Nurses were empowered to stop procedures if the protocol was not being met.	CVL protocol, nursing checklist, line supply cart were all added to the standard of care.
Khouli, United States - 2011	CLABSI	New York, NY/885 bed hospital		Simulation training allows for repetitive and deliberate practice in a realistic and interactive environment that can provide feedback on performance and mistakes.				

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
McKee, United States - 2008	CLABSI	Baltimore, MD/926 bed hospital; 22-bed PICU					Nurses were able to stop any procedure not adhering to CLABSI control guidelines. Study staff was trying to emphasize that placement of central catheters was a partnership between physicians and nurses.	The central line cart was mobile so it could be rolled into the patients room when needed. The checklists were placed on the cart so they were easy to find.
Miller, United States - 2010	CLABSI	Multi-center/29 ICUS in 27 hospitals; 10-16 bed ICU: 12; 17-27 bed ICU: 13; 28-36 bed ICU: 4	Physicians were more involved with central line insertion while nurses were more involved with maintenance. Risk factors differ in pediatric and adult populations.	Small tests of change were used to achieve quality improvement		This study was a part of the QI collaborative of the National Association of Children's Hospitals and Related Institutions (NACHRI).	Each unit appointed a 'champion' to steer QI intervention in the PICU. The multidisciplinary team included a senior PICU leader/physician champion, QI leaders, infectious disease physicians, PICU nursing leaders, and/or infection control professionals.	
Perez Parra, Spain - 2010	CLABSI	Madrid, Spain/60 beds in 3 study ICUs						

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Pronovost, United States - 2010	CLABSI	Michigan state/61 hospitals	Teaching status and hospital size were found to be non-significantly associated to CLABSI, p=0.35 and p=0.33, respectively. Clinicians identified the following as important to sustaining the project: 1) continued feedback, 2) improvements in safety culture, 3) belief that CLABSI is preventable, 4) Involvement of senior leaders, 5) a shared goal rather than competition to reduce infection rates.	The comprehensive unit-based safety program was used to improve patient safety culture and compliance with evidence-based interventions. In an earlier publication, Pronovost et al. state that employees are guided by an organization-wide commitment to safety, in which each member upholds their own safety norms and those of their coworkers. (Ref 10)	An intervention for VAP was taking place simultaneously in this network of hospitals	The IOM report 'To Err is Human' motivated the beginning of this project to transform patient safety culture in healthcare settings.	A team that included a senior executive, the intensive care unit director and nurse manager, and a physician and nurse from the ICU was formed at each hospital.	A central-line cart and checklist were made available to increase compliance.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Scales, Canada - 2011	CLABSI;VAP	Ontario, Canada/15 ICUs (range of ICU beds: 4-19)	ICUs that had a dedicated intensivist staff, more than 10 staffed ICU beds, and had not collected previous data for quality purposes had higher compliance with HOB elevation.			The Ministry of Health and Long-Term Care sought proposals for development and evaluation of strategies to improve effectiveness of care in Ontario's healthcare system.	A panel of experts and ICU directors were used to decide on the best practices to be implemented in this study. Content experts were in charge of the interactive educational sessions. Site educators gave in-services and ICU-specific educational programs. A central coordinating office was in charge of distributing all of the intervention materials, scheduling meetings, and analyzing data.	The interactive educational sessions were posted on the website. Guidelines were summarized into easy-to-read formats.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Schulman, United States - 2011	CLABSI	New York State/18 NICUs	Creating a culture wherein the NICU staff, a physician 'champion', and the ICPs consider themselves a single team working to prevent CLABSI seemed to produce greater improvement. Authors also mentioned that there was a lot of variability from NICU to NICU and that was most likely due to influence of context.			In 2007, New York mandated reporting of CLABSI rates in all ICUs.	Having 2 staff members in charge of central line placement, changing catheter tubes by nursing pairs, and assessing daily need of central line seemed to yield greater improvement.	Placing hand sanitizer dispensers at each bedside seemed to increase adherence to hand hygiene practices.
Seguin, France - 2010	CAUTI;CLABSI	Rennes, France/60-bed ICU			CVC and urinary catheter management did not change during this study period.			The box was added to the paperwork already being used for tracking patient care.
Zingg, Switzerland - 2009	CLABSI	Zurich, Switzerland/960 bed hospital	MICU had significantly higher CLABSI rates than the SICU for both phases of the study.		Use of maximal sterile barriers and skin disinfection with povidone-iodine and octenidine were already being implemented.		Two infection control nurses were in charge of all of the educational sessions. A standardized protocol for catheter care was created.	

Appendix Table C4c. Study context for SSI which control for secular trend or confounding

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Burkitt, United States - 2009	SSI	Pittsburgh, PA/36 bed surgery unit; 146 bed tertiary care for veterans	Improvements across the 5 classes of surgery differed. The TPS focused their efforts on the more common surgical procedures. Most common were orthopedic, so those physicians had more discussions with the TPS team and also had the high-test compliance percentages.	In the TPS model, frontline work groups identify problems, experiment with possible solutions, measure the results, and implement strategies to improve quality, resulting in a “ground up” rather than “top down” approach.	This intervention evolved from efforts to reduce MRSA.		TPS team leader was a staff nurse, who worked with all staff to identify problems and develop solutions.	All staff are involved. Battery packs were purchased and a computerized medication system was available.
Hedrick, United States - 2007	SSI	Charlottesville, VA/547 bed hospital; 29,000 admissions/yr				In 2003, Virginia Healthcare Quality Center (VHQC) asked medical centers in the state to choose a target population for which they want to lower SSI rates. The VHQC began this program in response the CMS Surgical Infection Prevention project.	A multidisciplinary team defined the scope of the problem and designed interventions to lower SSI rates. Specific nurses were designated responsible for implementation.	coordination among multiple disciplines, designated enforcers of intervention were assigned, standardization of procedures

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Kaimal, United States - 2008	SSI	San Francisco, CA/		Systems of pt care are complex and require multidisciplinary problem-solving in order to make improvements. Understanding the nature of the system and the roles of the participants is essential for policy change.	The authors had tried some initial policy changes regarding retraining RNs, new surgical prep, supplemental O2, pt warming, and improving scrub technique, but none had lowered the SSI rate prior to the intervention of this study.		A multidisciplinary task force worked with members of different depts. Nurses were designated as communicators and enforcers of the policy change.	The policy change was communicated verbally and electronically.
Kao, United States - 2010	SSI	both hospitals in Houston, TX/2 county hospitals	Hospital 1 scored lower on the Safety Attitudes Questionnaire in safety domains and teamwork compared to hospital 2. Hospital 1 had lower compliance with antibiotic timing, but had better compliance with antibiotic discontinuation and overall compliance compared to hospital 2. Hospital 1 had higher SSI rates compared to hospital 2.		A standardized antibiotic form was available to both hospitals prior to intervention, however it was not implemented extensively.	Preintervention data had been reported previously as part of a study on factors predicting compliance with SSI prophylaxis guidelines. The hospitals’ district was collecting SSI rates from hospitals during the study period, so lowering SSI was a concern. Hospital 2 had proportionately more abdominal vascular cases.	In hospital 2, nurses were responsible for completing a pre-op checklist.	multidisciplinary team, standardized forms

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Kritchevsky, United States - 2008	SSI	/44 acute care hospitals		Quality improvement collaborative bring together groups of practitioners in a series of meetings to share and implement practical solutions for rapid improvement of processes for which the gap between knowledge and practice in health care is substantial.		During the study, there was national interest in the antibiotic prophylaxis process because of the creation of SIP (National Surgical Infection Prevention Project) by the Centers for Medicare and Medicaid Services. During study period, antibiotic prophylaxis use improved nationally.	2 staff from each hospital were trained to collect data, then each hospital was responsible for developing their own intervention strategies.	The collaborative requires extensive involvement from multidisciplinary staff. There were no details on the specific interventions that each hospital chose to implement.
Mannien, Netherlands - 2006	SSI	The Netherlands/<400 beds: 3 hospitals; 400-800 beds: 6 hospitals; >800 beds: 3 hospitals			All hospitals were part of a larger national surveillance network that monitored nosocomial infections, PREZIES.		The CHIPS study group developed the antibiotic recommendations and provided each hospital with an audit report at the start of the intervention. The study group also organized educational mtgs for medical specialists and nurses.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Trussell, United States - 2008	SSI	Phoenix, AZ/					For the antibiotic prophylaxis arm of the pathway, cardiac anesthesiologists were designated responsibility of following the protocol. Nurses were responsible for maintaining glucose control through the whole ICU stay and for appropriate hair removal.	The protocol pathway is relatively non-labor intensive, requires no pt compliance, includes emergency cases, and places no added stress to surgeons. Glucose control did place a heavier labor burden on ICU nurses.

Appendix Table C4d. Study context for CAUTI which control for secular trend or confounding

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Apisarnthanarak, Thailand - 2007	CAUTI	Pratumthani, Thailand/450 hospital beds			hospitalwide quality improvement program for prevention VAP		Multidisciplinary intervention team organized and consisted of a representative from hospital admin, an ID physician, a clinical microbiologist, 2 internists, 2 infection control specialists, chief nurses from all units, and an epidemiologist. Ongoing routine infection control policies included aseptic catheter insertion technique, use of closed urinary catheters, and education of nursing staff of catheter use.	
Crouzet, France - 2007	CAUTI	Besancon, France/1205 bed hospital	Inconsistencies in results (significant decrease in the duration of catheterization in orthopedic and CV surgery departments vs. the other 3) between various departments were observed.		Closed drainage was maintained in all patients following insertion of catheter.		Nurses were now asked to remind physicians daily to assess the necessity of the patient's catheter.	
Loeb, Canada - 2008	CAUTI	Hamilton, Ontario, Canada/7 medical units in 3 hospitals					Nurses were required to review patients' medical history and any test results to determine if the required criteria were met and remove catheters in their absence. The research nurse did regular f/u with nursing staff to ensure that the automatic stop orders were followed.	Prewritten stop orders listing 6 urinary catheter criteria were available for nurses to place in patient charts.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Seguin, France - 2010	CAUTI;CLABSI	Rennes, France/60-bed ICU			CVC and urinary catheter management did not change during this study period.			The box was added to the paperwork already being used for tracking patient care.

Appendix Table C5a(1). Infection rate outcomes for VAP which control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention infection rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Unit of Measure	Follow-up (months)
Apisarnthanarak, Thailand - 2007	VAP	Educational Program	MICU: 20.6; SICU: 5.4; CCU: 4.4	post1 MICU: 8.5; post1 SICU: 5.6; post1 CCU: 4.8; post2 MICU: 4.2; post2 SICU: 5.5; post2 CCU: 4.6;	MICU pre vs. post1 Student's ttest: p=0.002; MICU post1 vs. post2 ttest: p=0.07; SICU pre vs. post1 ttest: p=0.227; SICU post1 vs. post2 ttest: p=0.82; CCU pre vs. post1 ttest: p=0.481; CCU post1 vs. post2 ttest: p=0.20	infections/1000 device-days	36
Berenholtz, United States - 2011	VAP	VAP Bundle and Daily Goal Sheets	median: 5.5	post1 median: 0; post2 median: 0	Wilcoxon rank sum post1 vs baseline and post2 vs baseline for medians: p<0.001; ; post1 vs baseline incidence rate ratio: 0.51 (95% CI .41-.65); post2 vs baseline: .29 (95% CI .24-.34)	infections/1000 device-days	30
Bouadma, France - 2010	VAP	Multifaceted Prevention Program	overall: 22.6; 1st VAP episode: 26.1	overall: 13.1; 1st VAP episode: 14.9	overall p<0.001; 1st VAP episode p<0.001	infections/1000 device-days	30
DePalo, United States - 2010	CLABSI, VAP	CLABSI Education Program and Bundle	median CLABSI Q1 2006: 1.95; median VAP Q1 2006: 0.58	median CLABSI Q2 2008: 0; median VAP Q2 2008: 0	mixed model: comparison of 1st 4 quarters to last 4 quarters: CLABSI: p=0.003; VAP: p=0.075	Infections/1000 device-days	27
Dubose, United States - 2010	VAP	Quality Rounds Checklist (QRC)	12.41	8.74; VAP rate (%) for fully compliant QRC: 3.5%; VAP rate (%) for partially compliant: 13.4%	After multivariable adjustments for age, GCS score, ISS and mechanism of injury the mean difference in VAP rate was 6.65 (95% CI 4.04-9.27) with a p-value of 0.008; Chi-square for full vs partial compliant VAP p=.04	infections/1000 device-days	12
Hawe, United Kingdom - 2009	VAP	Active Implementation	19.2	7.5		infections/1000 device-days	10
Kulvatunyou, Thailand - 2007	VAP	Educational Program	39.7	10.5; Intervention OR = 9.03 (95% CI 3.94-20.67)	non-parametric bootstrap test with 10000 resamples: p< 0.001; logistic regression: p<0.001	Infections/1000 ventilator-days	12
Marra, Brazil - 2009	VAP	VAP Bundle		Phase 1: 16.4 (SD 7.6); Phase 2: 15.0 (SD 9.2); Phase 3: 10.4 (SD 8.1)	0.05	Infections/1000 ventilator-days	78
Omrane, Canada - 2007	VAP	VAP Prevention Protocol	25.0	22.3	Chi-square: p< 0.001; Crude RR for post vs pre-intervention VAP: 0.90 (95% CI 0.87-0.92); Adjusted RR for post vs pre-intervention VAP: 0.86 (95% CI 0.71-1.05)	infections/1000 device-days	6

Study	Infection	Intervention(s)	Pre-intervention infection rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Unit of Measure	Follow-up (months)
Papadimos, United States - 2008	VAP	FASTHUG protocol	19.3	post1: 16.6; post2: 7.3	p< 0.01	infections/1000 device-days	24
Prospero, Italy - 2008	VAP	Educational Program	36.9	22.5	Student's ttest: p=0.049; Rate ratio: 0.61; Unadjusted Cox regression Hazard Ratio: 0.761 (p-value 0.087); Adjusted HR for period 2: 0.70 (p-value = 0.03)	infections/1000 device-days	4
Scales, Canada - 2011	CLABSI, VAP	Bundle - CLABSI, VAP					
Zaydfudim, United States - 2009	VAP	VAP Electronic Dashboard	15.2	9.3	t test, p=0.01	infections/1000 device-days	12

Appendix Table C5a(2). Infection rate outcomes for CLABSI which control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-cost	Post-cost	Cost statistical analysis	Savings due to intervention	Savings statistical analysis
Apisarnthanarak, Thailand - 2010	CLABSI	Period 3: Intensified hand hygiene promotion plus CLABSI bundle	medical:16 (SD 7.6); surgical: 11 (SD 5.4); ICU: 17 (SD 6.5); other units: 9 (SD 3.6)	post1 medical: 6.8 (SD 3.5); post1 surgical: 5.5 (SD 2.4); post1 ICU: 7.1 (SD 3.9); post1 other units: 5.2 (SD 1.1); post2 medical: 1.5 (SD 0.4); post2 surgical: 0.08 (SD 0.1); post2 ICU: 2.1 (SD 1.1); post2 other units: 0.9 (SD 0.2)	all t-test: p<0.05; See segmented results below	mean infections/1000 device-days	12 and 24 months
Barsuk, United States - 2009	CLABSI	CVC Insertion Simulation	MICU traditional: 3.2; SICU traditional: 4.86	MICU simulation-based: 0.5; SICU traditional: 5.26	Poisson Regression: IRR=0.16; 95% CI, 0.05-0.44, p=0.001 (comparison reflects post-MICU vs pre-MICU and SICU)	infections/1000 device-days	16
Costello, United States - 2008	CLABSI	Full Intervention: Pediatric Multidisciplinary CLABSI Bundle	mean: 7.8 (95% CI 5.6-10.5)	post1 mean: 4.7 (95% CI 3.4-6.3); post2 mean: 2.3 (95% CI 1.2-3.8)	post1 Wald test: p=0.029; post2 Wald test: p=0.0002	infections/1000 device-days	24
DePalo, United States - 2010	CLABSI, VAP	CLABSI Education Program and Bundle	median CLABSI Q1 2006: 1.95; median VAP Q1 2006: 0.58	median CLABSI Q2 2008: 0; median VAP Q2 2008: 0	mixed model: comparison of 1st 4 quarters to last 4 quarters: CLABSI: p=0.003; VAP: p=0.075	Infections/1000 device-days	27
Duane, United States - 2009	CLABSI	Group 3: Central venous line (CVL) protocol + CVL supply cart + nurse education + nurse checklist and nurse empowerment	16.5	Group2: 15.0; Group3: 7.7	Poisson regression of quarterly infection rates Group1 vs. Group3 p<0.0001; Group2 vs. Group3 p<0.004; Group1 vs. Group2 p=0.08	infections/1000 device-days	Group2: 12; Group3: 6 (18 mos since CVL protocol implementation)
Khouli, United States - 2011	CLABSI	Simulation-based sterile technique training	video: 3.6; simulation; 3.5	video: 3.4; simulation; 1.0	Poisson Regression incidence rate ratio: 0.30 (95% CI: 0.10-0.91) p=0.03	infections/1000 device-days	

Study	Infection	Intervention(s)	Pre-cost	Post-cost	Cost statistical analysis	Savings due to intervention	Savings statistical analysis
McKee, United States - 2008	CLABSI	CLABSI education, cart, checklist, and nurse empowerment	Monthly mean: 5.2	Monthly mean before faulty PDMV was recognized: 6.6; Monthly mean for non-contaminated post-intervention period: 2.7	Poisson regression p<0.05; Statistical process control chart methodology p=0.07	infections/1000 device-days	31
Miller, United States - 2010	CLABSI	Bundle - CLABSI	mean: 5.4 (95% CI 4.5-6.4)	mean: 3.1 (95% CI 2.4-4.0)	Hierarchical regression: relative rate=0.57, 95%CIs 0.45-0.74, p<0.0001	infections/1000 device-days	12
Perez Parra, Spain - 2010	CLABSI	CLABSI Education	Overall: 4.22; General SICU: 3.4; Cardiac SICU:	Overall: 2.94; General SICU: 5.3	Wilcoxon rank sum test: Overall: p=0.03; General SICU: p=0.05; Cardiac SICU: p=0.12; MICU: p=0.31; Poisson Regression: RR= 0.69 (95% CI 0.44-1.08), p= 0.11	infections/1000 device-days	9
Pronovost, United States - 2010	CLABSI	Conceptual Model - CDC CLABSI Bundle	median: 2.7 (IQR 06.-4.8)	Implementation median: 1.6 (IQR 0-4.4); 0-3mos post-implementation median: 0 (IQR 0-3); 34-36mos post-implementation median: 0 (IQR 0-1.2)	generalized linear latent and mixed models Implementation IRR: 0.81 (95% CI 0.61-1.08); 0-3mos IRR: 0.68 (95% CI 0.53-0.88); 34-36mos IRR: 0.34 (95% CI 0.24-0.48)	infections/1000 device-days	36
Scales, Canada - 2011	CLABSI, VAP	Bundle - CLABSI, VAP					
Schulman, United States - 2011	CLABSI	Bundle - CLABSI	old CDC definition mean: 6.4; new CDC definition mean: 3.5	new CDC definition 2.1	Chi-square result (unit of analysis NICU) p<.0005 for both definitions; Poisson regression old definition risk ratio: 0.33 (95% CI 0.27-0.41) p<.0005; Poisson regression new definition risk ratio: 0.6 (95% CI 0.48-0.75) p<.0005	infections/1000 device-days	10

Study	Infection	Intervention(s)	Pre-cost	Post-cost	Cost statistical analysis	Savings due to intervention	Savings statistical analysis
Seguin, France - 2010	CAUTI, CLABSI	Physician reminder of catheter duration	CLABSI: 2.8; CAUTI: 5.0	CLABSI: 0.7; CAUTI: 4.9	Adjusted CLABSI Poisson Regression: p=0.051; Adjusted CAUTI Poisson Regression: p=0.938	infections/1000 device-days	9
Zingg, Switzerland - 2009	CLABSI	Educational Program for catheter care and hand hygiene	overall: 3.9; MICU: 9; SICU: 3	overall: 1.0; MICU: 3.9; SICU: 0.2	chi square: overall p<0.001, MICU vs SICU p<0.001 for both periods; Cox, overall HR=4.47 (95% CI 1.86-10.2, p<0.001)	infections/1000 device-days	5

Appendix Table C5a(3). Infection rate outcomes for SSI which control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)	Study
Burkitt, United States - 2009	SSI	Toyota Production System- appropriate antibiotic choice and duration					
Hedrick, United States - 2007	SSI	bundle - glucose control	9.2%	5.6%	p=0.07	infection/100 operations	10
Hedrick, United States - 2007	SSI	bundle - normothermia	9.2%	5.6%	p=0.07	infection/100 operations	10
Hedrick, United States - 2007	SSI	bundle - antibiotic prophylaxis	9.2%	5.6%	t-test, p=0.07	infection/100 operations	10
Kaimal, United States - 2008	SSI	implement policy on timing of antibiotic prophylaxis	for all cesarean deliveries: 6.4; for cesarean deliveries before labor: 2.7; for cesarean deliveries during labor: 10.6	for all cesarean deliveries: 2.5; for cesarean deliveries before labor: 1.1; for cesarean deliveries during labor: 4.2	for all cesarean deliveries, chi square: p=0.002; for cesarean deliveries before labor, chi square: p=0.16; for cesarean deliveries during labor, chi square: p=0.005. logistic regression overall SSI: adjusted OR = 0.33, 95% CI=0.14-0.77	infection/100 cesarean deliveries	12
Kao, United States - 2010	SSI	extended timeout for 2 hospitals, 1 with added education, 1 with added preop checklist	hosp 1 pre: 1.7%; hosp 2 pre: 3.3%; hosp 1 period 1: 11%; hosp 2 period 1: 1.5%; hosp 2 period 2: 0.6%	hosp 1 period 2: 2.1%; hosp 1 period 3: 4.3%; hospital 2 period 3: 0%	No pre/post statistical analysis on SSI Patients operated on at hospital 2 were less likely to develop an SSI compared with those at hospital 1 (odds ratio [OR], 0.23; 95% confidence interval [CI], 0.10--0.56; P = .001).	infection/100 procedures	hospital 1: 12; hospital 2: 6
Kritchevsky, United States - 2008	SSI	joining a quality improvement collaborative					
Mannien, Netherlands - 2006	SSI	Optimized antibiotic prophylaxis	5.4% (95% CI 4.3-6.5%)	4.5% (95% CI 3.6-5.4%)	logistic regression, p=0.22	percentage of procedures with SSIs	6-11
Trussell, United States - 2008	SSI	protocol pathway for appropriate antibiotic use, hair removal, and glucose control	3.5%	1.5%	t test, p=0.001; stepwise logistic regression results: post-protocol OR and 95% CI: 0.21 (0.09-0.51), p=.001	infections/100 operations	estimate: 13

Appendix Table C5a(4). Infection rate outcomes for CAUTI which control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-cost	Post-cost	Cost statistical analysis	Savings due to intervention	Savings statistical analysis
Apisarnthanarak, Thailand - 2007	CAUTI	Daily physician reminders to remove unnecessary catheter	Mean(SD): overall: 21.5 (5.5); medical: 21.5 (10); surgical: 19.4 (5.4); ICU: 23.4 (13.7)	Mean(SD): overall: 5.2 (2.1); medical: 6.5 (4.3); surgical: 7.8 (6.1); ICU: 3.5 (6.4)	t test, all p<0.05	Infections/1000 catheter-days	12
Crouzet, France - 2007	CAUTI	Physician reminder to remove catheter beginning on day 4	Late CAUTI (>4 days): 12.3; Early CAUTI: 7.8	Late CAUTI (>4 days): 1.8; Early CAUTI: 13.9	LCAUTI log rank test: p=0.03; ECAUTI log rank test: p=0.13	infections/1000 device-days	3
Loeb, Canada - 2008	CAUTI	Stop orders for indwelling urinary catheters		study: 19%; control: 20%	RR=0.94, 95% CI 0.66-1.33, p=0.71	Frequency of infections	
Seguin, France - 2010	CAUTI, CLABSI	Physician reminder of catheter duration	CLABSI: 2.8; CAUTI: 5.0	CLABSI: 0.7; CAUTI: 4.9	Adjusted CLABSI Poisson Regression: p=0.051; Adjusted CAUTI Poisson Regression: p=0.938	infections/1000 device-days	9

Appendix Table C5b(1). Adherence outcomes for VAP which control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Apisarnthanarak, Thailand - 2007	VAP	Educational Program	HOB elevation: 45%; Mean percentage of correct answers: 78.5%	post1 HOB elevation: 80%; post2 HOB elevation: 84%; Mean percentage of correct answers: 90.8%	post1 Chi-square: p<0.05; post2 Chi-square: p<0.05; mean percentage Chi-square: p<0.001	36
Berenholtz, United States - 2011	VAP	VAP Bundle and Daily Goal Sheets	composite: 32%	post1 composite: 75%; post2 composite: 84%	Pearson Chi-square post1 vs baseline and post2 vs baseline: p<0.001	30
Bouadma, France - 2010	VAP	Multifaceted Prevention Program	hand hygiene: 68%; glove and gown use: 80%; HOB elevation: 5%; oral care: 47%	hand hygiene: 67%; glove and gown use: 82%; HOB elevation: 58%; oral care: 90%	hand hygiene p=0.70; glove and gown use p=0.80; HOB elevation p<0.0001; oral care p< 0.0001	24
DePalo, United States - 2010	CLABSI;VAP	CLABSI Education Program and Bundle	Complete Bundle VAP: 60%	Complete Bundle VAP: 78%	p=<0.0001	27
Dubose, United States - 2010	VAP	Quality Rounds Checklist (QRC)	HOB: 35.2%; peptic ulcer prophylaxis: 76.2%; thrombolytic prophylaxis: 91.4%; sedation holiday: 77.8%	HOB: 93.2%; peptic ulcer prophylaxis: 90.4%; thrombolytic prophylaxis: 93.5%; sedation holiday: 94.0%		12
Hawe, United Kingdom - 2009	VAP	Active Implementation		post1 full compliance: 0%; post2 full compliance: 48%; post3 full compliance: 54%	p<0.0001	10
Kulvatunyou, Thailand - 2007	VAP	Educational Program				
Marra, Brazil - 2009	VAP	VAP Bundle		Phase 1 HOB Elevation: 74.1%; Phase 2 HOB Elevation: 89.5%; Phase 3 HOB Elevation: 96.8%; Phase 3 Daily sedation vacation: 98.9%; Phase 3 oral care: 100%		
Omrane, Canada - 2007	VAP	VAP Prevention Protocol				
Papadimos, United States - 2008	VAP	FASTHUG protocol				
Prospero, Italy - 2008	VAP	Educational Program				

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Scales, Canada - 2011	CLABSI;VAP	Bundle - CLABSI, VAP	intervention HOB elevation: 50.2%; intervention CLABSI bundle: 10%; intervention daily spontaneous breathing trial: 78.8%; control HOB elevation: 80.1%; control CLABSI bundle: 31%; control daily spontaneous breathing trial: 90.9%	intervention HOB elevation: 89.6%; intervention CLABSI bundle: 70.6%; intervention daily spontaneous breathing trial: 85.1%; control HOB elevation: 90.2%; control CLABSI bundle: 51.7%; control daily spontaneous breathing trial: 89%	Ratio of random effects ORs (active OR/control OR) for: HOB elevation: 3.12 (95% CI .79-12.41); CLABSI bundle: 17.55 (95% CI 4.72-65.26);daily spontaneous breathing trials: 1.04 (95% CI 0.21-5.03); overall: 2.79 (95% CI 1.00-7.74, p=0.049)	4-12
Zaydfudim, United States - 2009	VAP	VAP Electronic Dashboard		post1: 39%; post2: 89%	linear regression, p<0.001	12

Appendix Table C5b(2). Adherence outcomes for CLABSI which control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Apisarnthanarak, Thailand - 2010	CLABSI	Period 3: Intensified hand hygiene promotion plus CLABSI bundle	overall complete maximal sterile barrier: 45%; Chlorhexidine skin prep: 42%; Avoid femoral catheter: 50%	post1 overall complete maximal sterile barrier: 80%; post2 overall complete maximal sterile barrier: 81%; post1 chlorhexidine skin prep: 75%; post2 chlorhexidine skin prep: 77%; post1 avoid femoral catheter: 64%; post2 avoid femoral catheter: 66%	all t-test: p<0.05	12 and 24 months
Barsuk, United States - 2009	CLABSI	CVC Insertion Simulation				
Costello, United States - 2008	CLABSI	Full Intervention: Pediatric Multidisciplinary CLABSI Bundle		post1 insertion bundle: 87%; post1 maintenance bundle: 85%; post1 hand hygiene: 38%; post2 insertion bundle: 94%; post2 maintenance bundle: 99%; post2 hand hygiene: 85.5%	insert bundle χ2/Fishers exact: p=<0.001; maintenance bundle χ2/Fishers exact: p=0.004; hand hyg χ2/Fishers exact: p=< 0.001	24
DePalo, United States - 2010	CLABSI;VAP	CLABSI Education Program and Bundle	Complete Bundle VAP: 60%	Complete Bundle VAP: 78%	p=<0.0001	27
Duane, United States - 2009	CLABSI	Group 3: Central venous line (CVL) protocol + CVL supply cart + nurse education + nurse checklist and nurse empowerment		% compliant with checklist: Oct 2005: 97.6%; March 2006: 98%; June 2006: 100%		Oct 2005: 3; Mar 2006: 9; June 2006: 12
Khouli, United States - 2011	CLABSI	Simulation-based sterile technique training	median sterile technique score: video: 13.0; simulation: 12.5	median sterile technique score: video: 18.0; simulation: 22.0	Wilcoxon signed rank test difference in total score b/w groups phase 1: p<0.95; Wilcoxon signed rank test difference in total score b/w groups phase 2; p<.001	
McKee, United States - 2008	CLABSI	CLABSI education, cart, checklist, and nurse empowerment		Cases needed prompting by nurse: to wash hands before procedure: 0%; have all hair under cap, sterile gown, and sterile gloves: 3%; chlorhexidine skin prep: 3%; large sterile drape: 5%; Apply sterile dressing after procedure: 0%		

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Miller, United States - 2010	CLABSI	Bundle - CLABSI		October 2007: Insertion bundle: 84%; Maintenance bundle: 82%	Hierarchical regression model: Maintenance bundle on CLABSI relative rate=0.41, 95%CI 0.2-0.85, p=0.017	12
Perez Parra, Spain - 2010	CLABSI	CLABSI Education				
Pronovost, United States - 2010	CLABSI	Conceptual Model - CDC CLABSI Bundle				
Scales, Canada - 2011	CLABSI;VAP	Bundle - CLABSI, VAP	intervention HOB elevation: 50.2%; intervention CLABSI bundle: 10%; intervention daily spontaneous breathing trial: 78.8%; control HOB elevation: 80.1%; control CLABSI bundle: 31%; control daily spontaneous breathing trial: 90.9%	intervention HOB elevation: 89.6%; intervention CLABSI bundle: 70.6%; intervention daily spontaneous breathing trial: 85.1%; control HOB elevation: 90.2%; control CLABSI bundle: 51.7%; control daily spontaneous breathing trial: 89%	Ratio of random effects ORs (active OR/control OR) for: HOB elevation: 3.12 (95% CI .79-12.41); CLABSI bundle: 17.55 (95% CI 4.72-65.26);daily spontaneous breathing trials: 1.04 (95% CI 0.21-5.03); overall: 2.79 (95% CI 1.00-7.74, p=0.049)	4-12
Schulman, United States - 2011	CLABSI	Bundle - CLABSI				
Seguin, France - 2010	CAUTI;CLABSI	Physician reminder of catheter duration	median CVC duration: 5 days (IQR 3-9 days); median UC duration: 5 (IQR 3-11); median time to CVC removal: 9 (95% CI 8-10); median time to UC removal: 14 (95% CI 12-15)	median CVC duration: 4 (3-7); median UC duration: 4 (IQR 3-8); median time to CVC removal: 7 (95% CI 6-8); median time to UC removal: 8 (95% CI 6-9)		9
Zingg, Switzerland - 2009	CLABSI	Educational Program for catheter care and hand hygiene	overall hand hygiene: 59.1%; proper hand disinfection: 22.5%; hand hygiene before patient contact: 26%; hand hygiene after patient contact: 21%	overall hand hygiene: 65%; proper hand disinfection: 42.6%; hand hygiene before patient contact: 45%; hand hygiene after patient contact: 56%	chi square: overall p=0.47; proper disinfection p=0.003; hand hygiene before patient contact p=0.007; hand hygiene after patient contact p<0.001	5

Appendix Table C5b(3). Adherence outcomes for SSI which control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Burkitt, United States - 2009	SSI	Toyota Production System- appropriate antibiotic choice and duration	appropriate selection and duration: 2000: 25.5%; 2001: 29.8%; 2002: 23.4%; 2003: 27.4%	appropriate selection and duration: 2004: 44.0%	adjusted p from logistic regression, p<0.01	12
Hedrick, United States - 2007	SSI	bundle - glucose control	glucose control: 54%	glucose control: 36%	p<=.05	10
Hedrick, United States - 2007	SSI	bundle - normothermia	85%	90%	NS	10
Hedrick, United States - 2007	SSI	bundle - antibiotic prophylaxis	appropriate antibiotic selection: 89%; appropriate antibiotic timing: 89%; appropriate discontinuation of antibiotics: 93%	appropriate antibiotic selection: 97%; appropriate antibiotic timing: 97%; appropriate discontinuation of antibiotics: 92%%	appropriate antibiotic selection and appropriate antibiotic timing: chi square, p<0.05; appropriate discontinuation of antibiotics: NS	10
Kaimal, United States - 2008	SSI	implement policy on timing of antibiotic prophylaxis				
Kao, United States - 2010	SSI	extended timeout for 2 hospitals, 1 with added education, 1 with added preop checklist	overall compliance: hosp 1: 42%; hosp 2: 26%	overall compliance: post 1: hosp 1:70%, hosp 2: 68%; post 2: hosp 1: 80%, hosp 2: 69%	overall combined compliance, chi square: p=.003; separated by post periods, after post 1, chi square: p=<.001, after post 2, NS	hospital 1: 12; hospital 2: 6
Kritchevsky, United States - 2008	SSI	joining a quality improvement collaborative	For intervention grp: timing: 76.3; receipt of antibiotic: 97.4; duration: 51.3; selection: 93.8; single dose: 85.1; overall: 38.2	For intervention grp: timing: 83.2; receipt of antibiotic: 98.9; duration: 69.5; selection: 94.7; single dose: 80.2; overall: 57.2	For intervention grp: adjusted change: timing: 6.7 (0.2-13.1); receipt of antibiotic: 1.1 (0.0-1.9); duration: 21.3 (12.5-30.1); selection: 0.5 (-0.9-1.9); single dose: -4.6 (-10.3-1.2); overall: 20.3 (12.0-28.6)	
Mannien, Netherlands - 2006	SSI	Optimized antibiotic prophylaxis	inappropriate abx admin: 93.5%; admin abx after incision: 46.8%; inappropriate timing of abx: 51.8%	inappropriate abx admin: 37.5%; admin abx after incision: 31.4%; inappropriate timing of abx: 39.4%	segmented time series analysis: all p<0.01	6-11
Trussell, United States - 2008	SSI	protocol pathway for appropriate antibiotic use, hair removal, and glucose control	timing of antibiotics: 81%; glucose control: no pre-measurement since protocol was new; shaving: 60%	timing of antibiotics: 94%; glucose control: 100%; shaving: 20%	timing of antibiotics, t test: p=0.001; glucose control: NA; shaving: t-test, p=0.001	estimate: 13

Appendix Table C5b(4). Adherence outcomes for CAUTI which control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Apisarnthanarak, Thailand - 2007	CAUTI	Daily physician reminders to remove unnecessary catheter				
Crouzet, France - 2007	CAUTI	Physician reminder to remove catheter beginning on day 4				
Loeb, Canada - 2008	CAUTI	Stop orders for indwelling urinary catheters				
Seguin, France - 2010	CAUTI;CLABSI	Physician reminder of catheter duration	median CVC duration: 5 days (IQR 3-9 days); median UC duration: 5 (IQR 3-11); median time to CVC removal: 9 (95% CI 8-10); median time to UC removal: 14 (95% CI 12-15)	median CVC duration: 4 (3-7); median UC duration: 4 (IQR 3-8); median time to CVC removal: 7 (95% CI 6-8); median time to UC removal: 8 (95% CI 6-9)		9

Appendix Table C5c(1). Cost/savings outcomes for VAP which control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention Cost	Post-Intervention Cost	Cost Statistical Analysis	Savings from QI Intervention	Follow-up (months)
Apisarnthanarak, Thailand - 2007	VAP	Educational Program	MICU Hospitalization cost/patient: $466 (SD $108); SICU hospitalization cost/patient: $399 (SD 93); CCU hospitalization cost/patient: $404	post1 MICU hosp cost/patient: $293 (SD 88); post1 SICU hosp cost/patient: $384 (SD 95); post1 CCU hosp cost/patient: $401 (SD 104); post2 MICU hosp cost/patient: $254 (SD 92); post2 SICU hosp cost/patient: $395 (sd 83); post2 CCU hosp cost/patient: $415	MICU pre vs. post1: p<0.001; MICU pre vs. post2: p<0.001		
Berenholtz, United States - 2011	VAP	VAP Bundle and Daily Goal Sheets					
Bouadma, France - 2010	VAP	Multifaceted Prevention Program					
DePalo, United States - 2010	CLABSI;VAP	CLABSI Education Program and Bundle				Cumulative cost savings: $2,016,592	
Dubose, United States - 2010	VAP	Quality Rounds Checklist (QRC)		Hospital charges for fully compliant QRC: $143,554; Hospital charges for partially compliant QRC: $311,930	Student's t or Mann-Whitney U test p-value <0.001		
Hawe, United Kingdom - 2009	VAP	Active Implementation					
Kulvatunyou, Thailand - 2007	VAP	Educational Program					
Marra, Brazil - 2009	VAP	VAP Bundle					
Omrane, Canada - 2007	VAP	VAP Prevention Protocol					
Papadimos, United States - 2008	VAP	FASTHUG protocol					
Prospero, Italy - 2008	VAP	Educational Program					
Scales, Canada - 2011	CLABSI;VAP	Bundle - CLABSI, VAP					
Zaydfudim, United States - 2009	VAP	VAP Electronic Dashboard					

Appendix Table C5c(2). Cost/savings outcomes for CLABSI which control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention Cost	Post-Intervention Cost	Cost Statistical Analysis	Savings from QI Intervention	Follow-up (months)
Apisarnthanarak, Thailand - 2010	CLABSI	Period 3: Intensified hand hygiene promotion plus CLABSI bundle					
Barsuk, United States - 2009	CLABSI	CVC Insertion Simulation					
Costello, United States - 2008	CLABSI	Full Intervention: Pediatric Multidisciplinary CLABSI Bundle				$236,000-$782,000	
DePalo, United States - 2010	CLABSI;VAP	CLABSI Education Program and Bundle				Cumulative cost savings: $2,016,592	
Duane, United States - 2009	CLABSI	Group 3: Central venous line (CVL) protocol + CVL supply cart + nurse education + nurse checklist and nurse empowerment				Group2 (vs. Group1): $19,615.70 hospital charges per patient; Group3 (vs. Group1): $28,391.87 hospital charges per patient	
Khouli, United States - 2011	CLABSI	Simulation-based sterile technique training					
McKee, United States - 2008	CLABSI	CLABSI education, cart, checklist, and nurse empowerment					
Miller, United States - 2010	CLABSI	Bundle - CLABSI					
Perez Parra, Spain - 2010	CLABSI	CLABSI Education					
Pronovost, United States - 2010	CLABSI	Conceptual Model - CDC CLABSI Bundle					
Scales, Canada - 2011	CLABSI;VAP	Bundle - CLABSI, VAP					
Schulman, United States - 2011	CLABSI	Bundle - CLABSI					
Seguin, France - 2010	CAUTI;CLABSI	Physician reminder of catheter duration					
Zingg, Switzerland - 2009	CLABSI	Educational Program for catheter care and hand hygiene					

Appendix Table C5c(3). Cost/savings outcomes for SSI which control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention Cost	Post-Intervention Cost	Cost Statistical Analysis	Savings from QI Intervention	Follow-up (months)
Burkitt, United States - 2009	SSI	Toyota Production System- appropriate antibiotic choice and duration				LOS not significantly different among all yrs. Significance found between 2003 and 2004, but significance disappeared after adjustment for surgical procedure, admission source, age, comorbidities.	
Hedrick, United States - 2007	SSI	bundle - glucose control					
Hedrick, United States - 2007	SSI	bundle - normothermia					
Hedrick, United States - 2007	SSI	bundle - antibiotic prophylaxis					
Kaimal, United States - 2008	SSI	implement policy on timing of antibiotic prophylaxis					
Kao, United States - 2010	SSI	extended timeout for 2 hospitals, 1 with added education, 1 with added preop checklist					
Kritchevsky, United States - 2008	SSI	joining a quality improvement collaborative					
Mannien, Netherlands - 2006	SSI	Optimized antibiotic prophylaxis				35% decrease in use of prophylactic antibiotics and 25% decrease in antibiotic costs per procedure	
Trussell, United States - 2008	SSI	protocol pathway for appropriate antibiotic use, hair removal, and glucose control					

Appendix Table C5c(4). Cost/savings outcomes for CAUTI which control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention Cost	Post-Intervention Cost	Cost Statistical Analysis	Savings from QI Intervention	Follow-up (months)
Apisarnthanarak, Thailand - 2007	CAUTI	Daily physician reminders to remove unnecessary catheter	Hospitalization per patient, mean(SD): $366 (62)	Hospitalization per patient, mean(SD): $154 (34)	t test, p<0.001		
Crouzet, France - 2007	CAUTI	Physician reminder to remove catheter beginning on day 4					
Loeb, Canada - 2008	CAUTI	Stop orders for indwelling urinary catheters					
Seguin, France - 2010	CAUTI; CLABSI	Physician reminder of catheter duration					

Appendix Table C6a(1). Quality ratings for nonrandomized studies on VAP which control for secular trend or confounding

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	AdherenceReported	InfectionCDC	DeviceAdju	QE_IndependentQI	QE_DataTimePoint	QE_InfectionRate	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
DePalo, United States - 2010	CLABSI;VAP	No	Yes*	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	No	No	Yes	TRUE	non-parametric methods	TRUE	Mixed effects model with Poisson distribution	hospital size, teaching status, effect of multiple ICUs within hospitals, repeated quarterly measures, and device-days
Kulvatunyou, Thailand - 2007	VAP	Uncertain	Uncertain	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	TRUE	t-test, chi-square test, Wilcoxon rank sum test, multiple logistic regression, and non-parametric bootstrap test	FALSE		
Berenholtz, United States - 2011	VAP	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	TRUE	Wilcoxon Rank-Sum and Pearson chi-square test	TRUE	Generalized Linear latent and Mixed Models with a Poisson distribution	teaching status, hospital size, ICU type

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	AdherenceReported	InfectionCDC	DeviceAdju	QE_IndependentQI	QE_DataTimePoint	QE_InfectionRate	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Dubose, United States - 2010	VAP	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	TRUE	Student's t-test; Mann-Whitney U test; chi-square test; Fisher's exact test	TRUE	Multivariable Logistic Regression	Age > 55; Glasgow Score < 8; Injury Severity Score > 20; mechanism of injury
Hawe, United Kingdom - 2009	VAP	No	Yes	Yes	No	No	No	Yes	No	Yes	No	Yes	Yes	TRUE	chi-square, Mann-Whitney U-test	FALSE		
Apisarnthanarak, Thailand - 2007	VAP	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	TRUE	Chi-square test; Fisher exact test; interrupted time series with segmented regression analysis	FALSE		
Bouadma, France - 2010	VAP	No	Yes	Uncertain	Yes	No	No	Yes	Uncertain	Yes	Yes	Yes	Yes	TRUE	Wilcoxon Rank-sum Test; Fisher's exact test; segmented Poisson regression; Cox proportional hazards	TRUE	Cox proportional hazards	gender, having a fatal disease, arterial catheter before VAP, and study period

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	AdherenceReported	InfectionCDC	DeviceAdju	QE_IndependentQI	QE_DataTimePoint	QE_InfectionRate	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Omrane, Canada - 2007	VAP	No	Uncertain	Uncertain	No	Yes	No	No	No	Yes	Yes	No	No	TRUE	Student's t-test, Wilcoxon rank sum test, chi-square test	FALSE	Poisson regression	Poisson regression was adjusted for age, gender, APACHE II Score, GCS Score, service the patient originated from (surgical, trauma, etc)
Papadimos, United States - 2008	VAP	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	TRUE	Wilcoxon rank sum test, Auto-regressive integrated moving average (ARIMA) model, t-test, and chi-square test	FALSE		
Prospero, Italy - 2008	VAP	No	No	Yes	No	Yes	No	No	Yes	Yes	Yes	No	No	TRUE	Student's t-test	FALSE	time-dependent Cox regression	Cox was controlled for SAPS II score, APACHE II score and being a trauma patient

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	AdherenceReported	InfectionCDC	DeviceAdju	QE_IndependentQI	QE_DataTimePoint	QE_InfectionRate	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Zaydfudim, United States - 2009	VAP	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	TRUE	t-test, Wilcoxon rank sum test, linear regression, piecewise linear regression	FALSE		
Scales, Canada - 2011	CLABSI;VAP	No	Yes	No	No	Yes	Yes							FALSE		TRUE	generalized linear mixed model with random effects	group, time, group*time (interaction term)
Marra, Brazil - 2009	VAP	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	TRUE	Chi-square test, ANOVA, segmented regression of interrupted time series	FALSE		

All_Vary	Did the execution of the study vary from the original protocol?
All_Valid	Is the intervention assessed using valid and reliable measures, implemented consistently across all study participants?
All_Consist	Are outcomes assessed using valid and reliable measures, implemented consistently across all study participants?
All_PrimOut	Is the length of followup sufficient to support the evaluation of primary outcomes and harms?
All_ImpOut	Are any important primary outcomes missing from the results?
All_FundSource	Is the Source of funding Identified?
AdherenceReported	If infection rates reported, did study also report adherence rates?
InfectionCDC	If infection rates reported, was CDC/NNIS* methodology used?
DeviceAdju	For CLABSI, VAP, CAUTI: were infection rates adjusted for device utilization?
Postsurveillance	For SSI: was post-discharge surveillance for infections performed?
QE_IndependentQI	Was the intervention performed independent of other QI efforts or other changes?
QE_DataTimePoint	Did the study report data at more than one time point both before and after the intervention?
QE_InfectionRate	If the study reported infection rates, were process measurements also reported?
UnivarYN	Was Univariate Analysis Conducted?
UnivarModel	What model was used?
UnivarControl	What variables were controlled for?
MultivarYN	Was Multivariate Analysis Conducted?
MultivarModel	What model was used?

Appendix Table C6a(2). Quality ratings for randomized study on VAP

Study	Infections	CON_Rand	CON_RandDesc	CON_ NonRandRationale	CON_Assessor	CON_Unit	CON_Corrected
Scales, Canada - 2011	CLABSI;VAP	No	Yes		Uncertain	No	Yes

CON_Rand Were study subjects randomized
CON_RandDesc was randomization process described?
CON_NonRandRationale For non-randomized studies, was rationale for comparison group selection explained?
CON_Assessor Were outcome assessor blinded to treatment group assignment?
CON_Unit Was a unit of analysis error present?
CON_Corrected Was a unit of analysis error present and corrected by appropriate statistical methods?

Appendix Table C6b(1). Quality ratings for nonrandomized studies on CLABSI which control for secular trend or confounding

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	InfectionCDC	DeviceAdju	QE_IndependentQI	QE_DataTimePoint	QE_InfectionRate	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
DePalo, United States - 2010	CLABSI;VAP	No	Yes*	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	No	No	Yes	TRUE	non-parametric methods	TRUE	Mixed effects model with Poisson distribution	hospital size, teaching status, effect of multiple ICUs within hospitals, repeated quarterly measures, and device-days
Schulman, United States - 2011	CLABSI	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Uncertain	Yes	No	TRUE	Chi-Squared	TRUE	stepwise Poisson regression	NICU
Miller, United States - 2010	CLABSI	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Uncertain	Yes	Yes	FALSE		TRUE	Generalized Linear Model (log-link); Hierarchical regression modeling for compliance comparison	Geographic region; average length of stay; bed capacity
McKee, United States - 2008	CLABSI	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Uncertain	Yes	Yes	TRUE	Poisson regression	TRUE	Statistical process control chart	

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	InfectionCDC	DeviceAdju	QE_IndependentQI	QE_DataTimePoint	QE_InfectionRate	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Khouli, United States - 2011	CLABSI	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Uncertain	No	Yes	TRUE	Fischer Exact Test for all-or-none analysis. Two-sample t-test was used to compare scores between intervention periods	TRUE	GLM for CRBSI rate, likelihood of infection by ICU type used Poisson regression model.	
Apisarnthanarak, Thailand - 2010	CLABSI	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	TRUE	2 tailed Chi Square or Fisher exact test used, student t-test	TRUE	Segmented regression	
Barsuk, United States - 2009	CLABSI	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	No	FALSE		TRUE	Poisson regression	ICU location and period
Duane, United States - 2009	CLABSI	No	No	Yes	Uncertain	No	No	Yes	Yes	Yes	No	Yes	Yes	TRUE	Wilcoxon rank sum, fisher's exact, ANCOVA	TRUE	Logistic, Poisson regression	CVL protocol, Injury Severity Score
Seguin, France - 2010	CAUTI;CLABSI	Uncertain	Yes	No	No	No	Yes	Yes	No	Yes	Uncertain	No	Yes	TRUE	Chi-square test, Fisher's exact test, Student's t-test, Wilcoxon rank sum test, ANOVA	TRUE	logistic regression, Poisson regression, time-to-event analysis	age, SAPS-II score, and admissions diagnosis

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	InfectionCDC	DeviceAdju	QE_IndependentQI	QE_DataTimePoint	QE_InfectionRate	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Costello, United States - 2008	CLABSI	Uncertain	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Uncertain	Yes	Yes	TRUE	Chi-Square test, Fisher's exact tests, Wald test	TRUE	Interrupted time series segmented regression (data transformed)	Time and study period
Perez Parra, Spain - 2010	CLABSI	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	No	TRUE	Chi-square test, Fisher Exact Test, T-test, Wilcoxon rank sum test	TRUE	Poisson Regression	Authors mention controlling for confounding effects and secular trends but do not describe model.
Scales, Canada - 2011	CLABSI;VAP	No	Yes	No	No	Yes	Yes							FALSE		TRUE	generalized linear mixed model with random effects	group, time, group*time (interaction term)
Pronovost, United States - 2010	CLABSI	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	TRUE		FALSE	Generalized linear latent and mixed models with Poisson distribution	teaching status and hospital size

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	InfectionCDC	DeviceAdju	QE_IndependentQI	QE_DataTimePoint	QE_InfectionRate	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Zingg, Switzerland - 2009	CLABSI	No	Yes	Yes	No	No	No	Yes	Yes	Yes	Uncertain	No	Yes	TRUE	chi-square test, Wilcoxon rank sum test	TRUE	Cox proportional hazards model	period, sex, stay in medical ICU, diabetes, McCabe fatal <6 mo, Charlson score>3, SAPS score, cardiosurgery, intubation, insertion in ER or ICU

All_Vary Did the execution of the study vary from the original protocol?
All_ValidIs the intervention assessed using valid and reliable measures, implemented consistently across all study participants?
All_Consist Are outcomes assessed using valid and reliable measures, implemented consistently across all study participants?
All_PrimOut Is the length of followup sufficient to support the evaluation of primary outcomes and harms?
All_ImpOut Are any important primary outcomes missing from the results?
All_FundSource Is the Source of funding Identified?
AdherenceReportedIf infection rates reported, did study also report adherence rates?
InfectionCDC If infection rates reported, was CDC/NNIS* methodology used?
DeviceAdju For CLABSI, VAP, CAUTI: were infection rates adjusted for device utilization?
Postsurveillance For SSI: was post-discharge surveillance for infections performed?
QE_IndependentQI Was the intervention performed independent of other QI efforts or other changes?
QE_DataTimePointDid the study report data at more than one time point both before and after the intervention?
QE_InfectionRate If the study reported infection rates, were process measurements also reported?
UnivarYN Was Univariate Analysis Conducted?
UnivarModel What model was used?
UnivarControl What variables were controlled for?
MultivarYN Was Multivariate Analysis Conducted?
MultivarModel What model was used?

Appendix Table C6b(2). Quality ratings for randomized study on CLABSI

Study	Infections	CON_Rand	CON_RandDesc	CON_NonRandRationale	CON_Assessor	CON_Unit	CON_Corrected
Scales, Canada - 2011	CLABSI;VAP	No	Yes		Uncertain	No	Yes

CON_Rand Were study subjects randomized
CON_RandDesc was randomization process described?
CON_NonRandRationale For non-randomized studies, was rationale for comparison group selection explained?
CON_Assessor Were outcome assessor blinded to treatment group assignment?
CON_Unit Was a unit of analysis error present?
CON_Corrected Was a unit of analysis error present and corrected by appropriate statistical methods?

Appendix Table C6c(1). Quality ratings for nonrandomized studies on SSI which control for secular trend or confounding

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	InfectionCDC	postsurveillance	QE_IndependentQI	QE_DataTimePoint	QE_InfectionRate	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Hedrick, United States - 2007	SSI	No	Yes	Yes	No	No	No	Yes	Yes	Yes	Uncertain	No	Yes	TRUE	student's t-test for continuous variables; chi-sq with Yates correction for dichotomous variables	TRUE	stepwise logistical regression with Wald statistic	operative site, laparoscopy, age, hypoalbuminemia, BMI, wound classification, ASA score, operative time
Kaimal, United States - 2008	SSI	Yes	Yes	Uncertain	Yes	Yes	Yes	No	Uncertain	Yes	Uncertain	No	No	TRUE	chi-square	TRUE	logistic regression	labor, previous cesarean, parity, age, BMI, diabetes, chorioamnionitis, strep B culture status
Kritchevsky, United States - 2008	SSI	No	Yes	Yes	Yes	Yes	Yes							FALSE		TRUE	jackknife design	type of surgery, hospital size, region
Trussell, United States - 2008	SSI	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Uncertain	No	Yes	TRUE	t-test or Mann-Whitney for continuous variables; Fisher exact test for categorical variables	TRUE	stepwise logistic regression	diabetes, gender, NNIS wound class
Kao, United States - 2010	SSI	No	Yes	Uncertain	Yes	No	Yes	Yes	Uncertain	No	No	Yes	Yes	TRUE	chi-sq for categorical; ANOVA for continuous	TRUE	general linear modeling to look at interaction effect between hosp and level of intervention	

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	InfectionCDC	postsurveillance	QE_IndependentQI	QE_DataTimePoint	QE_InfectionRate	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Mannien, Netherlands - 2006	SSI	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	TRUE	Chi-square, Student t test, segmented time series analysis	TRUE	segmented time series analysis; Logistic regression, non-linear mixed model analysis	Sex, age (>=65 yrs), university hospital, Duration of surgery (>P75), ASA classification (>=3)
Burkitt, United States - 2009	SSI	No	Yes	Yes	Yes	Yes	Yes				No	No		TRUE	chi-sq for categorical variables; Wilcoxon rank sum for continuous variables	TRUE	logistic regression	type of surgical procedure, admission source, age, # comorbid conditions

All_Vary Did the execution of the study vary from the original protocol?
All_Valid Is the intervention assessed using valid and reliable measures, implemented consistently across all study participants?
All_Consist Are outcomes assessed using valid and reliable measures, implemented consistently across all study participants?
All_PrimOut Is the length of followup sufficient to support the evaluation of primary outcomes and harms?
All_ImpOut Are any important primary outcomes missing from the results?
All_FundSource Is the Source of funding Identified?
AdherenceReported If infection rates reported, did study also report adherence rates?
InfectionCDC If infection rates reported, was CDC/NNIS* methodology used?
DeviceAdju For CLABSI, VAP, CAUTI: were infection rates adjusted for device utilization?
Postsurveillance For SSI: was post-discharge surveillance for infections performed?
QE_IndependentQI Was the intervention performed independent of other QI efforts or other changes?
QE_DataTimePoint Did the study report data at more than one time point both before and after the intervention?
QE_InfectionRate If the study reported infection rates, were process measurements also reported?
UnivarYN Was Univariate Analysis Conducted?
UnivarModel What model was used?
UnivarControl What variables were controlled for?
MultivarYN Was Multivariate Analysis Conducted?
MultivarModel What model was used?

Appendix Table C6c(2). Quality ratings for randomized study on SSI

Study	Infections	CON_Rand	CON_RandDesc	CON_NonRand Rationale	CON_Assessor	CON_Unit	CON_Corrected
Kritchevsky, United States - 2008	SSI	Yes	Yes		No	Uncertain	Uncertain

CON_Rand Were study subjects randomized
CON_RandDesc was randomization process described?
CON_NonRandRationale For non-randomized studies, was rationale for comparison group selection explained?
CON_Assessor Were outcome assessor blinded to treatment group assignment?
CON_Unit Was a unit of analysis error present?
CON_Corrected Was a unit of analysis error present and corrected by appropriate statistical methods?

Appendix Table C6d(1). Quality ratings for nonrandomized studies on CAUTI which control for secular trend or confounding

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	InfectionCDC	DeviceAdju	QE_IndependentQI	QE_DataTimePoint	QE_InfectionRate	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Apisarnthanarak, Thailand - 2007	CAUTI	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	TRUE	chi-squared, fisher's exact test, student t-test	TRUE	interrupted time series with segmented regression analysis; Pearson correlation	
Crouzet, France - 2007	CAUTI	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	No	Yes	TRUE	chi-squared, t-test, ANOVA	TRUE	KM analysis with log-rank test; logistic regression	age, sex, duration of catheterization, systemic antibiotic administration for diseases other than UTI, repeated catheter replacement, study intervention
Loeb, Canada - 2008	CAUTI	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No	N/A	N/A	N/A	TRUE	chi-square test, Student's t-test	TRUE	logistic regression	male sex, diabetes, intervention, and antibiotic exposure
Seguin, France - 2010	CAUTI;CLABSI	Uncertain	Yes	No	No	No	Yes	Yes	No	Yes	Uncertain	No	Yes	TRUE	Chi-square test, Fisher's exact test, Student's t-test, Wilcoxon rank sum test, ANOVA	TRUE	logistic regression, Poisson regression, time-to-event analysis	age, SAPS-II score, and admissions diagnosis

All_Vary Did the execution of the study vary from the original protocol?
All_Valid Is the intervention assessed using valid and reliable measures, implemented consistently across all study participants?

All_Consist	Are outcomes assessed using valid and reliable measures, implemented consistently across all study participants?
All_PrimOut	Is the length of followup sufficient to support the evaluation of primary outcomes and harms?
All_ImpOut	Are any important primary outcomes missing from the results?
All_FundSource	Is the Source of funding Identified?
AdherenceReported	If infection rates reported, did study also report adherence rates?
InfectionCDC	If infection rates reported, was CDC/NNIS* methodology used?
DeviceAdju	For CLABSI, VAP, CAUTI: were infection rates adjusted for device utilization?
Postsurveillance	For SSI: was post-discharge surveillance for infections performed?
QE_IndependentQI	Was the intervention performed independent of other QI efforts or other changes?
QE_DataTimePoint	Did the study report data at more than one time point both before and after the intervention?
QE_InfectionRate	If the study reported infection rates, were process measurements also reported?
UnivarYN	Was Univariate Analysis Conducted?
UnivarModel	What model was used?
UnivarControl	What variables were controlled for?
MultivarYN	Was Multivariate Analysis Conducted?
MultivarModel	What model was used?

Appendix Table C6d(2). Quality ratings for randomized study on CAUTI

Study	Infections	CON_Rand	CON_RandDesc	CON_NonRandRationale	CON_Assessor	CON_Unit	CON_Corrected
Loeb, Canada - 2008	CAUTI	Yes	Yes		Yes	No	

CON_Rand Were study subjects randomized
CON_RandDesc was randomization process described?
CON_NonRandRationale For non-randomized studies, was rationale for comparison group selection explained?
CON_Assessor Were outcome assessor blinded to treatment group assignment?
CON_Unit Was a unit of analysis error present?
CON_Corrected Was a unit of analysis error present and corrected by appropriate statistical methods?

Appendix Table C1-LQ-a. Study characteristics for VAP which do not control for secular trend or confounding

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Abbott, United States - 2006	Simple Before-after	VAP	More than one hospital of different types	Medical Intensive Care Unit, Surgical Intensive Care Unit Burn ICU, Trauma ICU	2004 - 2004	3	CDC/NNIS definition was used. Baseline was from April 2002 through June 2002. 5 ICUs within 2 hospitals participated.
Assanasen, - 2008	Simple Before-after	CLABSI;VAP	Tertiary care or university hospital	Medical Intensive Care Unit, Surgical Intensive Care Unit	2004 - 2006	24	CDC definitions were used. Baseline period was from April 2004 through June 2004
Berriel-Cass, United States - 2006	Simple Before-after	CLABSI;VAP	More than one hospital of different types	Medical Intensive Care Unit, Surgical Intensive Care Unit Cardiac ICU; Cardiovascular ICU; Medical/Surgical ICU	2004 - 2006	23	CDC/NNIS definition was used.; 1 hospital, with a MICU, SICU, Cardiac ICU and Cardiovascular ICU, implemented the CLABSI bundle and the other, with a Medical/Surgical ICU and Cardiovascular ICU, implemented the VAP bundle. In total there were 6 ICUS. Baseline CLABSI: July 2003 to January 2004. Baseline VAP: January 2003 to January 2004.
Bigham, United States - 2009	Simple Before-after	VAP	Tertiary care or university hospital	Pediatric Intensive Care Unit	2005 - 2005	28	CDC/NNIS definition was used. Pre-implementation period was from January 1, 2004 through December 31, 2004. Implementation period was from January 1, 2005 through August 31, 2005. Post-implementation period was from September 1, 2005 through December 31, 2007.
Bird, United States - 2010	Simple Before-after	VAP	Tertiary care or university hospital	Trauma/General Surgery ICU, Subspecialty surgery ICU	2006 - 2009	31	CDC definition was used. Baseline period was from March 1, 2006 through September 30, 2006. The implementation and follow-up period was from October 1, 2006 through May 31, 2009. Study included 2 ICUs.
Blamoun, United States - 2009	Simple Before-after	VAP	Tertiary care or university hospital	Medical Intensive Care Unit	2004 - 2007	30	Baseline: 2003 to 2004 for a total of 18 months.
Bloos, Germany - 2009	Simple Before-after	VAP	Tertiary care or university hospital	Surgical Intensive Care Unit	2005 - 2005	4	Clinical Pulmonary Infection Score (CPIS) was used. Baseline period (Audit I) was from June 2005 through September 2005. The intervention was implemented from October 2005 through November 2005. Follow-up period (Audit II) was from March 2006 through June 2006

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Cocanour, United States - 2006	Simple Before-after	VAP	Tertiary care or university hospital	Shock Trauma ICU (STICU)	2002 - 2003	12	NNIS definition was used. Baseline period was from January 2002 through May 2002. VAP bundle began in June 2002. Audit and feedback began in October 2002. Follow-up period was from June 2002 through June 2003.
Garcia, United States - 2009	Simple Before-after	VAP	Tertiary care or university hospital	Medical Intensive Care Unit	2002 - 2004	24	CDC definition was used. Baseline: January 1, 2001, to December 31, 2002.
Gurskis, Lithuania - 2009	Simple Before-after	CAUTI, CLABSI, VAP	Tertiary care or university hospital	Pediatric Intensive Care Unit	2005-2007	12	Preintervention from January 2005 through 2006. In 3 pediatric ICUs.
Heimes, United States - 2011	Simple Before-after	VAP	Tertiary care or university hospital	Trauma ICU	2004 - 2008	54	CDC definition was used. Baseline period was from January 2003 through December 2003. Implementation period was January 2004 to December 2005. Strict implementation of the VAP protocol was from January 2006 through June 2008. Record 58600 was published in 2007 and only presents d
Jain, United States - 2006	Simple Before-after	CAUTI;CLABSI;VAP	Hospital type unspecified	Medical/Surgical ICU	2002 - 2003	12	CDC definitions were used. Baseline period was from October 2000 through September 2002.
Jimenez, United States - 2009	Simple Before-after	VAP	Tertiary care or university hospital	Neurosurgical ICU	2007 - 2007	4	Infection rates were not observed. 14 consecutive days in July/August 2007 were used as pre-intervention adherence and 14 consecutive days in December 2007 were used as post-intervention adherence
Landrum, Afghanistan - 2008	Simple Before-after	VAP	Combat Support Hospital	Mixed ICU	2006 - 2006	6	CDC definition is used. This is a USO field hospital. Baseline period was from May 1, 2006 through May 31, 2006; Intervention period was from June 1, 2006 through August 31, 2006; Targeted surveillance took place in November and December of 2006
Quenot, France - 2007	Simple Before-after	VAP	Tertiary care or university hospital	Medical Intensive Care Unit	2001 - 2003	24	Definition is spelled out on pg 2033. Baseline period is from May 1999 through May 2001. The intervention period was from December 2001 through December 2003.
Rogers, Ireland - 2010	Simple Before-after	CLABSI;VAP	More than one hospital of different types	Neonatal ICU		6	CDC definition was used. Years of the study period were not included. 6 months of baseline data collection occurred, then a 3 month intervention then 6 more months of

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
							post-intervention surveillance took place.
Rosenthal, Argentina - 2006	Simple Before-after	VAP	More than one hospital of different types	Medical/Surgical ICU, Coronary ICU	2002 - 2002	12	CDC definition was used. Baseline period (Phase 1) was from January 2001 through December 2001. The Intervention/Follow-up period (Phase 2) was from January 2002 through December 2002.
Ross, United States - 2007	Simple Before-after	VAP	Tertiary care or university hospital	Surgical Intensive Care Unit Pulmonary/Medicine ICU, Vascular Surgery ICU, Cardiothoracic Surgery ICU, Neurosurgery ICU, Trauma ICU		2	CDC/NNIS definition was used. No dates were reported.
Sona, United States - 2009	Simple Before-after	VAP	Tertiary care or university hospital	Surgical Intensive Care Unit	2004 - 2005	12	NNIS criteria were used to diagnose VAP. Pre-intervention period was from June 2003 through May 2004. The post-intervention period was from June 2004 through May 2005.
Venkatram, United States - 2010	Simple Before-after	CAUTI;CLABSI;VAP	Tertiary care or university hospital	Medical Intensive Care Unit	2005 - 2007	36	CDC/NNIS definitions were used. 2004 was the pre-intervention period for CLABSI and CAUTI. 2005 was the pre-intervention period for VAP.

Appendix Table C1-LQ-b. Study characteristics for CLABSI which do not control for secular trend or confounding

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Assanasen, - 2008	Simple Before-after	CLABSI;VAP	Tertiary care or university hospital	Medical Intensive Care Unit, Surgical Intensive Care Unit	2004 - 2006	24	CDC definitions were used. Baseline period was from April 2004 through June 2004
Berriel-Cass, United States - 2006	Simple Before-after	CLABSI;VAP	More than one hospital of different types	Medical Intensive Care Unit, Surgical Intensive Care Unit Cardiac ICU; Cardiovascular ICU; Medical/Surgical ICU	2004 - 2006	23	CDC/NNIS definition was used.; 1 hospital, with a MICU, SICU, Cardiac ICU and Cardiovascular ICU, implemented the CLABSI bundle and the other, with a Medical/Surgical ICU and Cardiovascular ICU, implemented the VAP bundle. In total there were 6 ICUS. Baseline CLABSI: July 2003 to January 2004. Baseline VAP: January 2003 to January 2004.
Bhutta, United States - 2007	Simple Before-after	CLABSI	Tertiary care or university hospital	Pediatric Intensive Care Unit	1998 - 2003	36	Baseline: 1994-1997 with 1997 rate compared to end of follow-up rate in 2005. Stepwise intervention starting November 1998 with the introduction of maximal barrier precautions followed with catheters impregnated with antibiotics in July 1999, an annual hand washing campaign in March 2000, physical barriers between patients beds in new units in April 2003 and Chlorhexidine skin disinfectant in May 2003. The Raad and Hanna's definition for blood stream infection with catheters was used (see citation number 17).
Bizzarro, United States - 2010	Simple Before-after	CLABSI	Tertiary care or university hospital	NICU	2007 - 2007	15	NHSN definitions used. Baseline: July 1, 2005 to June 30, 2007. Intervention: July 1, 2007 to December 31, 2007. Follow-up: January 1, 2008 to March 31, 2009.
Galpern, United States - 2008	Simple Before-after	CLABSI	Community hospital with residents	Medical Intensive Care Unit, Surgical Intensive Care Unit	2005 - 2007	19	CDC/NNIS definition was used. Baseline: February 2005 to June 2005 (5 months). Intervention: July 2005 to April 31, 2007. Information available in this study is very vague.
Guerin, United States - 2010	Simple Before-after	CLABSI	Tertiary care or university hospital	Hospital-wide	2008 - 2009	12	CLABSI definition by CDC/NHSN was used. Baseline: October 1, 2006, to September 30, 2008. Post-intervention period: October 1, 2008, to September 30, 2009
Jain, United States - 2006	Simple Before-after	CAUTI;CLABSI;VAP	Hospital type unspecified	Medical/Surgical ICU	2002 - 2003	12	CDC definitions were used. Baseline period was from October 2000 through September 2002.
Gurskis, Lithuania -	Simple Before-	CAUTI, CLABSI, VAP	Tertiary care or university	Pediatric Intensive Care Unit	2005-2007	12	Preintervention from January 2005 through 2006. In 3 pediatric ICUs.

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
2009	after		hospital				
Jeffries, United States - 2009	Simple Before-after	CLABSI	More than one hospital of different types	Pediatric Intensive Care Unit Cardiac ICU	2005 - 2005	12	CDC/NNIS definition was used. 26 hospitals participated. Baseline was July 2004 through March 2005. Intervention was April 2005 through December 2005.
Koll, United States - 2008	Simple Before-after	CLABSI	More than one hospital of different types	adult ICUs	2005 - 2008	33	49 adult ICUs at 36 hospitals in partnership with GNYHA and UHF. A minimum of 3 months of baseline data were required at each hospital. The intervention period was from July 2005 to March 2008. CDC/NHSN definitions of CLABSI were used.
Lobo, Brazil - 2010	Controlled Before-after	CLABSI	Tertiary care or university hospital	Medical Intensive Care Unit	2005 - 2007	17	CDC/NNIS definitions were used.
Marra, Brazil - 2010	Simple Before-after	CLABSI	Tertiary care or university hospital	Medical-Surgical ICU, step-down units	2005 - 2009		No Baseline period. Two intervention phases: phase 1, March 2005 to March 2007 and phase 2, April 2007 to April 2009. No Follow-up period. CDC definitions were used. Study was never reviewed by the IRB. One medical surgical ICU and two step-down units in the same hospital.
Render, United States - 2006	Simple Before-after	CLABSI	More than one hospital of different types	Medical Intensive Care Unit	2004 - 2005	24	CDC definition for CLABSI was used. 10 hospitals were randomized to either CLABSI or SSI project in the first year and then adding the alternative project in year 2. The CLABSI project began in 4 hospitals (ICUs) in 2004 and continued for 2 years. However, the post intervention data are only reported for 2004 (vs. 2003 as the baseline).
Rogers, Ireland - 2010	Simple Before-after	CLABSI;VAP	More than one hospital of different types	Neonatal ICU		6	CDC definition was used. Years of the study period were not included. 6 months of baseline data collection occurred, then a 3 month intervention then 6 more months of post-intervention surveillance took place.
Sannoh, United States - 2010	Simple Before-after	CLABSI	Tertiary care or university hospital	Neonatal ICU	2006 - 2007	13	CDC definitions used.; Baseline: June 2005 to end of January 2006 Intervention: February 2006 (1 month education program adherence measured before and after then organizational and policy changes) to March 2007.

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Santana, Brazil - 2008	Simple Before-after	CLABSI	Tertiary care or university hospital	2 medical-surgical ICU's	2005 - 2005	4	Baseline: September 2004 to December 2004; Intervention: January 2005 to March 2005; Follow-up: April 2005 to July 2005. NNIS definitions were used.
Shannon, United States - 2006	Simple Before-after	CLABSI	Tertiary care or university hospital	Medical Intensive Care Unit Cardiac Intensive Care	2003 - 2006	34	Preintervention period from July 2002 to June 2003.
Venkatram, United States - 2010	Simple Before-after	CAUTI;CLABSI;VAP	Tertiary care or university hospital	Medical Intensive Care Unit	2005 - 2007	36	CDC/NNIS definitions were used. 2004 was the pre-intervention period for CLABSI and CAUTI. 2005 was the pre-intervention period for VAP.
Warren, United States - 2006	Simple Before-after	CLABSI	More than one hospital of different types	Medical Intensive Care Unit, Surgical Intensive Care Unit Mixed ICUs	2002 - 2003	15	12 ICUs and 1 bone marrow transplantation unit at 6 academic medical centers participating in the CDC Prevention Epicenter Program. Baseline: Jan 2002 until intervention began 5-7 months later. The intervention was implemented over a 3-month period in each unit. F/u data collection lasted anywhere from 15-18 months after the intervention in each study unit (until Dec 2003). CDC definition was used.
Wicker, United States - 2011	Simple Before-after	CLABSI	Tertiary care or university hospital	Neonatal ICU	2005 - 2008	48	patients were preterm infants with birth weight <=1500. Baseline from January 2001 to December 2004.
Yilmaz, Turkey - 2007	Simple Before-after	CLABSI	Tertiary care or university hospital	Hospital-wide	2004 - 2004	6	CDC definition was used.; Pediatric patients were excluded from this study.

Appendix Table C1-LQ-c. Study characteristics for SSI which do not control for secular trend or confounding

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Acklin, Switzerland - 2011	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room Pre-op area	2000 - 2001	12	Authors used CDC definitions for SSI.
Awad, United States - 2009	Simple Before-after	SSI	Tertiary care or university hospital	General Inpatient Ward (non-ICU), Operating Room	2006 - 2007	24	MRSA bundle initiated in 1 medical unit in Oct 2006, and hospital-wide by Oct 2007
Berenguer, United States - 2010	Simple Before-after	SSI	Tertiary care or university hospital	General Inpatient Ward (non-ICU), Operating Room, Surgical Intensive Care Unit	2007 - 2008	12	SSI defined using NSQIP guideline
Berry, United States - 2009	Simple Before-after	SSI	Tertiary care or university hospital Tertiary/Quaternary	Operating Room, Surgical Intensive Care Unit Pre-operative-area	2006 - 2007	12	Reducing surgical site infections was a small part of a larger new system called ProvenCare in which methods to provide evidence-based recommended care were initiated. Uncertain what infection definition was used.
Carles, France - 2006	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room hospital pharmacy		2	No SSI rates reported, only adherence rates.
Forbes, Canada - 2008	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room pre-op unit	2006 - 2007	11	SSI defined by CDC criteria.
Gomez, Argentina - 2006	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room Pre-op area	2002 - 2005	36	CDC definition used to identify SSI.
Graf, Germany - 2009	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room, Surgical Intensive Care Unit	2006 - 2008	27	In addition to the prospective study, the investigators conducted a case-control study to identify risk factors for deep sternal surgical site infections. Because this part of the study was not quality improvement, I only abstracted information relating to the prospective study. SSI were defined using the CDC criteria.
Hermsen, United States - 2008	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room	2005 - 2006	9	Pre-intervention period March through August 2005. No SSIs measured, only adherence rates. Study is a mixture of retrospective (pre period) and prospective (post period).
Ichikawa, Japan - 2007	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room	2004 - 2005	15	Pre-intervention period was from January to December 2003. SSIs defined by CDC guidelines.
Kable, Australia - 2008	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room Pre-op area	1999 - 2000	6	SSIs defined by New South Wales Hospital Infection Epidemiology and Surveillance Unit.

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Kramer, United States - 2008	Simple Before-after	SSI	Tertiary care or university hospital	General Inpatient Ward (non-ICU), Operating Room, Surgical Intensive Care Unit	2005 - 2006	18	Deep sternal wound infection defined by Northern New England Cardiovascular Diseases Study Group
Liau, Singapore - 2010	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room Post-anesthesia care unit	2006 - 2007	24	SSIs classified using CDC definitions.
Nemeth, United States - 2010	Simple Before-after	SSI	Pre-op area		2006 - 2006	0.16	Only a 5 day post-intervention period. No SSI's measured, only timely antibiotic administration measured.
Ozgun, Turkey - 2010	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room, Surgical Intensive Care Unit	2007 - 2007	3	Definition unclear.; No SSI rates reported, only adherence rates.; Baseline: between November 2006 to January 2007. Intervention: January 2007 to September 2007. Education program lasted for "more than 1 month." The post-intervention period began 1 month after the intervention ended so November 2007 to January 2008 to coincide with the same months as the pre-intervention period. Surgical procedures are distributed among the following disciplines: orthopedic surgery, vascular surgery, skin and deep tissue surgery, and endocrine and abdominal surgery including intestinal, gynecologic, and urologic procedures.
Parker, United States - 2007	Simple Before-after	SSI	Tertiary care or university hospital	Pre-op area	2005 - 2006	8	Infection rates not reported. Retrospective audit from 2001-2005 gave baseline compliance rate.
Pastor, United States - 2010	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room, Surgical Intensive Care Unit Pre-op area	2007 - 2008	14	SSI defined by NNIS criteria.
Paull, United States - 2010	Simple Before-after	SSI	Veterans Health Administration hospitals	Operating Room Pre-op area	2009 - 2010	12	No SSI rates reported, only adherence rates.
Potenza, United States - 2009	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room, Surgical Intensive Care Unit Pre-op area	2006 - 2008	27	No SSI rates reported, only adherence rates.
Rauk, United States - 2010	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room Pre-op area	2006 - 2006	6	Definition for SSI uncertain.

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Shimoni, Israel - 2009	Simple Before-after	SSI	Hospital - type not specified	Operating Room	2007 - 2007	12	Definition of infection not given. Month of intervention not stated. Pre and post intervention periods only defined as 2006 and 2007.
Suchitra, India - 2009	Simple Before-after	CAUTI;SSI	More than one hospital of different types		2004 - 2005	6	Preintervention was 6 months from January 2004 to end of June 2004
Takahashi, Japan - 2010	Simple Before-after	SSI	Tertiary care or university hospital	15 different surgical departments	2007 - 2007	3	Describes outcome as ‘isolation of p. aeruginosa among all gram-negative organisms and isolation of MRSA among all gram-positive organisms’. pre-intervention period from Feb 2006 to April 2006.
Wax, United States - 2007	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room	2005 - 2005	10	Baseline was from June 2004 to December 2004
Whitman, United States - 2008	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room	2006 - 2007	18	Period 1 was from March 2005 through December 2005. This is the baseline and was used for comparisons with period 2, 3 and 4. Only adherence rates reported, no SSI rates.
Willemsen, Netherlands - 2007	Simple Before-after	SSI	Tertiary care or university hospital	Operating Room Pre-op area	2006 - 2006	2	No SSI rates reported, only adherence rates.
Zvonar, Canada - 2008	Simple Before-after	SSI	Tertiary care or university hospital	Pre-op area	2003 - 2005	39	Infection rates were not reported. Baseline was from Jan 2002 through March 2002.

Appendix Table C1-LQ-d. Study characteristics for CAUTI which do not control for secular trend or confounding

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up (months)	Comment
Gokula, United States - 2007	Simple Before-after	CAUTI	Community hospital with residents	Emergency Department	2003 - 2003	24	Definition used is unclear.
Gurskis, Lithuania - 2009	Simple Before-after	CAUTI, CLABSI, VAP	Tertiary care or university hospital	Pediatric Intensive Care Unit	2005-2007	12	Preintervention from January 2005 through 2006. In 3 pediatric ICUs.
Jain, United States - 2006	Simple Before-after	CAUTI;CLABSI;VAP	Hospital type unspecified	Medical/Surgical ICU	2002 - 2003	12	CDC definitions were used. Baseline period was from October 2000 through September 2002.
Rothfeld, United States - 2010	Simple Before-after	CAUTI	Non-teaching community hospital	Definitive observation unit, telemetry unit		5	Definition used is spelled out on page 569. No dates were provided. There was a 7 month control period and a 5 month intervention period.
Stephan, Switzerland - 2006	Controlled Before-after	CAUTI	Tertiary care or university hospital	orthopedic and abdominal surgery departments	2002 - 2004	7	Preintervention from November 2001 to January 2002; Phase 1 follow up from March to June 2002; Phase 2 follow up from April to June 2004. “Infections were prospectively identified according to standard definitions” which were not specified
Suchitra, India - 2009	Simple Before-after	CAUTI;SSI	More than one hospital of different types		2004 - 2005	6	Preintervention was 6 months from January 2004 to end of June 2004
Venkatram, United States - 2010	Simple Before-after	CAUTI;CLABSI;VAP	Tertiary care or university hospital	Medical Intensive Care Unit	2005 - 2007	36	CDC/NNIS definitions were used. 2004 was the pre-intervention period for CLABSI and CAUTI. 2005 was the pre-intervention period for VAP.
Wald, United States - 2011	Simple Before-after	CAUTI	Tertiary care or university hospital	Orthopedic surgery unit, general surgery unit	2008 - 2008	4	Baseline period: Sept 1, 2007 - Jan 31, 2008; F/u period: April 1, 2008 - July 31, 2008. The definition for CAUTI was based on that used by the NHSN and included both symptomatic CAUTI and symptomatic bacteriuria.

Appendix Table C2-LQ-a. Patient characteristics for VAP which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Abbott, United States - 2006	VAP	Academic Center of Evidence-based Practice (ACE) Star Model	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	Multidisciplinary Team	All Clinical Staff	2	total: 106
Assanasen, - 2008	CLABSI;VAP	Feedback Program	Audit and Feedback	Hospital Infection Control Professionals	Nurses, Physicians	1	
Berriel-Cass, United States - 2006	CLABSI;VAP	CLABSI Bundle	Audit and Feedback, Organizational Change, Provider Education	Administration Infection Control Department	Nurses, Physicians	1	
Berriel-Cass, United States - 2006	CLABSI;VAP	VAP Bundle	Audit and Feedback, Organizational Change, Provider Education	Administration Multidisciplinary rounds (MDR) team	All Clinical Staff	1	
Bigham, United States - 2009	VAP	VAP Bundle	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	Critical Care Unit Quality Improvement Collaborative-VAP Prevention Collaborative	Nurses, Respiratory Therapists	1	pre: 617; post1: 447; post2: 1782
Bird, United States - 2010	VAP	VAP Bundle	Audit and Feedback, Organizational Change, Provider Reminder Systems	Multidisciplinary Team	Nurses	1	
Blamoun, United States - 2009	VAP	Expanded VAP bundle	Organizational Change	Study staff	Nurses, Respiratory Therapists	1	
Bloos, Germany - 2009	VAP	Educational Program	Audit and Feedback, Organizational Change, Provider Education	Multidisciplinary Team (Change Team)	Nurses, Physicians	1	pre: 133; post: 141
Cocanour, United States - 2006	VAP	VAP Bundle	Audit and Feedback, Organizational Change, Patient Education, Provider Education	Multidisciplinary Team	All Clinical Staff	1	
Garcia, United States - 2009	VAP	VAP Education and Oral Care Protocol	Organizational Change, Provider Education	VAP Prevention Team	Nurses, Physicians, Respiratory Therapists Anesthesiologists	1	pre: 779; post: 759

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	VAP Bundle	Organizational Change, Provider Education	Pediatric Intensive Care Staff	All Clinical Staff	1	Preintervention: 270; Postintervention : 322
Heimes, United States - 2011	VAP	VAP Prevention Protocol (VAPP)	Audit and Feedback, Organizational Change, Provider Education	Study Staff	All Clinical Staff	1	pre: 215; post1: 240; post2 : 241
Jain, United States - 2006	CAUTI;CLABSI;VAP	IMPACT initiative	Audit and Feedback, Organizational Change	Administration	All Clinical Staff	1	
Jimenez, United States - 2009	VAP	VAP Bundle	Audit and Feedback, Provider Education, Provider Reminder Systems	Study Staff	All Clinical Staff	1	pre: 102; post: 86
Landrum, Afghanistan - 2008	VAP	Infection Control Protocol	Organizational Change, Provider Education	ICU Staff	All Clinical Staff	1	total: 475
Quenot, France - 2007	VAP	Nurse-Implemented Sedation Protocol	Organizational Change	Multidisciplinary Team	Nurses	1	pre: 226; post: 197
Rogers, Ireland - 2010	CLABSI;VAP	Plan-Do-Study-Act (PDSA)cycle	Provider Education	Multidisciplinary team	All Clinical Staff	5	
Rosenthal, Argentina - 2006	VAP	Multifaceted Infection Control Program	Audit and Feedback, Provider Education	Study Staff	All Clinical Staff	2	pre: 435; post: 366
Ross, United States - 2007	VAP	Educational Program	Audit and Feedback, Provider Education	Study Staff	Nurses Certified Nurse Assistants	1	pre: 55; post:61
Sona, United States - 2009	VAP	Oral Care Protocol	Audit and Feedback, Organizational Change, Provider Education	Quality Improvement Team	Nurses	1	pre: 777; post: 871
Venkatram, United States - 2010	CAUTI;CLABSI;VAP	CAUTI bundle	Audit and Feedback, Organizational Change, Patient Education, Provider Education	Health and Hospital Corporation (HHC) Collaborative	All Clinical Staff	1	pre: 1096; post: 3749

Appendix Table C2-LQ-b. Patient characteristics for CLABSI which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Assanasen, - 2008	CLABSI; VAP	Feedback Program	Audit and Feedback	Hospital Infection Control Professionals	Nurses, Physicians	1	
Berriel-Cass, United States - 2006	CLABSI; VAP	CLABSI Bundle	Audit and Feedback, Organizational Change, Provider Education	Administration Infection Control Department	Nurses, Physicians	1	
Berriel-Cass, United States - 2006	CLABSI; VAP	VAP Bundle	Audit and Feedback, Organizational Change, Provider Education	Administration Multidisciplinary rounds (MDR) team	All Clinical Staff	1	
Bhutta, United States - 2007	CLABSI	Bundle CLABSI	Organizational Change, Provider Education, Provider Reminder Systems	Administration	All Clinical Staff	1	
Bizzarro, United States - 2010	CLABSI	Bundle - CLABSI	Audit and Feedback, Organizational Change, Promotion of Self-Management, Provider Education	Multidisciplinary Team	postdoctoral neonatology fellows	1	pre: 417; post: 159
Galpern, United States - 2008	CLABSI	CLABSI Bundle	Audit and Feedback, Organizational Change, Provider Education	Multidisciplinary team	Nurses, Physicians	1	
Guerin, United States - 2010	CLABSI	Post-insertion CVC care bundle	Organizational Change, Provider Education	Administration	Nurses	1	
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	CLABSI Education	Organizational Change, Provider Education	Pediatric Intensive Care Staff	All Clinical Staff	1	eintervention: 270; postintervention: 322
Jain, United States - 2006	CAUTI; CLABSI; VAP	IMPACT initiative	Audit and Feedback, Organizational Change	Administration	All Clinical Staff	1	
Jeffries, United States - 2009	CLABSI	CVC Insertion and Maintenance Bundle	Audit and Feedback, Organizational Change, Provider Education	Children's Health Corporation of America directors and advisors from National Initiative for Children's Healthcare Quality advisors	Nurses, Physicians	26	
Koll, United States - 2008	CLABSI	Central line bundle	Audit and Feedback, Organizational Change, Provider Education	Interdisciplinary team at each participating hospital, steering committee of GNYHA Infection Control Work Group	All Clinical Staff	36	

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Lobo, Brazil - 2010	CLABSI	Continuous Education	Audit and Feedback, Provider Education, Provider Reminder Systems	Study Staff	Nurses, Physicians	1	pre: 141; post: 41
Lobo, Brazil - 2010	CLABSI	Single lecture	Provider Education	Study Staff	All Clinical Staff	1	pre: 378; post: 262
Marra, Brazil - 2010	CLABSI	IHI Bundle - CLABSI	Audit and Feedback, Organizational Change, Provider Reminder Systems	Study Staff	Nurses, Physicians	1	
Render, United States - 2006	CLABSI	CLABSI bundle	Audit and Feedback, Organizational Change, Provider Reminder Systems	Administration Each hospital's CEO and leaders identified a project leader and team members (often led by hospital infection control professionals and consisted of the nurse manager of the ICU, staff nurses, a physician champion, and a supply manager)	Nurses, Physicians	10	
Rogers, Ireland - 2010	CLABSI; VAP	Plan-Do-Study-Act (PDSA)cycle	Provider Education	Multidisciplinary team	All Clinical Staff	5	
Sannoh, United States - 2010	CLABSI	Bundle - CLABSI	Audit and Feedback, Provider Education, Provider Reminder Systems	Study Staff	All Clinical Staff	1	pre: 163; post: 210
Santana, Brazil - 2008	CLABSI	Education	Provider Education	Unclear, study staff	All Clinical Staff	1	total: 186
Shannon, United States - 2006	CLABSI	Toyota Production System adaptation	Organizational Change, Provider Education	Multidisciplinary team	All Clinical Staff	1	pre: 1067; post1: 1798; post2: 1829; post3: 1832
Venkatram, United States - 2010	CAUTI; CLABSI; VAP	CAUTI bundle	Audit and Feedback, Organizational Change, Patient Education, Provider Education	Health and Hospital Corporation (HHC) Collaborative	All Clinical Staff	1	pre: 1096; post: 3749
Warren, United States - 2006	CLABSI	Multifaceted, education-based intervention	Provider Education	Multi-center research team (CDC Prevention Epicenter Program)	Nurses, Physicians	6	
Wicker, United States - 2011	CLABSI	Comprehensive Infection Control Measures	Audit and Feeback, Organizational Change, Provider Education	NICU staff	NICU staff	1	pre: 334; post: 303

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Yilmaz, Turkey - 2007	CLABSI	Education	Audit and Feedback, Organizational Change, Provider Education	Not specified, study staff	All Clinical Staff	1	pre: 241; post: 193

Appendix Table C2-LQ-c. Patient characteristics for SSI which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Acklin, Switzerland - 2011	SSI	bundle - antibiotic prophylaxis, skin prep, sterile dressing	Audit and Feedback, Provider Education	independent hospital epidemiology team	Nurses, Physicians	1	pre: 217; post: 153
Awad, United States - 2009	SSI	MRSA bundle	Organizational Change, Provider Education	not specified who initiated intervention plans and implementation	All Clinical Staff	1	
Berenguer, United States - 2010	SSI	implementing SCIP measures	Organizational Change, Provider Education	Administration	All Clinical Staff	1	pre: 113; post: 84
Berry, United States - 2009	SSI	ProvenCare	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	Geisinger Health System	All Clinical Staff	3	pre: 137; post: 117
Carles, France - 2006	SSI	surgical antibiotic prophylaxis kit (SAPK)	Organizational Change	department of anesthesiology	hospital pharmacists, anesthesiologists;	1	pre: 210; post: 210
Forbes, Canada - 2008	SSI	bundle - antibiotic administration in OR, pre-printed order form to standardize choice of antibiotic, monthly performance figures posted in OR	Audit and Feedback, Organizational Change, Provider Education	Surgical Site Infection Working Group at McMaster University	All Clinical Staff	1	pre: 105; post: 103
Forbes, Canada - 2008	SSI	bundle - glucose control by screening all pts prior to surgery, administering weight-based regimen of insulin to diabetics, monthly performance figures posted in OR	Audit and Feedback, Organizational Change, Provider Education	Surgical Site Infection Working Group at McMaster University	All Clinical Staff	1	pre: 105; post: 103
Forbes, Canada - 2008	SSI	bundle - maintain normothermia by warming OR to 22 C, standardizing IV warmers and forced air devices, monthly performance figures posted in OR	Audit and Feedback, Organizational Change, Provider Education	Surgical Site Infection Working Group at McMaster University	All Clinical Staff	1	pre: 105; post: 103
Gomez, Argentina - 2006	SSI	automatic stop prophylaxis form	Organizational Change, Provider Education, Provider Reminder Systems	multidisciplinary team	All Clinical Staff	1	pre: 3496; post: 3982

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Graf, Germany - 2009	SSI	bundle - SSI	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	infection control team	All Clinical Staff	1	pre: 3150; post: 980
Hermsen, United States - 2008	SSI	Standardized order form	Audit and Feedback, Organizational Change, Provider Education	Study staff	Nurses, Physicians Pharmacists	1	pre: 406; post: 396
Ichikawa, Japan - 2007	SSI	Implementation of Antibiotic Protocols	Audit and Feedback, Provider Education	Infection Control Team, Study Staff	Nurses anesthesiologists, attending surgeons	1	pre: 721; post: 1313
Kable, Australia - 2008	SSI	bundle - antibiotic prophylaxis	Provider Education, Provider Reminder Systems	researchers of the Newcastle Surgical Outcomes Study of Adverse Events	All Clinical Staff	2	pre: 659; post: 518
Kramer, United States - 2008	SSI	nomogram for glycemic control	Organizational Change, Provider Education, Provider Reminder Systems	Multidisciplinary team	Nurses, Physicians	1	pre: 1677; post: 1388
Liau, Singapore - 2010	SSI	bundle - antibiotic, glucose control, clippers, normothermia	Organizational Change, Provider Education, Provider Reminder Systems	multidisciplinary team	All Clinical Staff	1	post: 2408
Martin, United States - 2010	SSI	surgical wear changes in Mohs surgery	Organizational Change	physician	Nurses, Physicians	1	pre: 365; post: 585
Nemeth, United States - 2010	SSI	Education program	Provider Education, Provider Reminder Systems	Study staff	Anesthesia, nursing and surgical staff	1	baseline: 97; intervention: 193
Ozgun, Turkey - 2010	SSI	antibiotic prophylaxis education	Provider Education	not specified who carried out educational intervention	Nurses, Physicians	1	pre: 312; post: 322
Parker, United States - 2007	SSI	Six Sigma methodology and antibiotic prophylaxis	Organizational Change, Provider Education, Provider Reminder Systems	Multidisciplinary team	All Clinical Staff	1	pre: 615; post: 1716
Pastor, United States - 2010	SSI	task force to meet SCIP process measures	Organizational Change, Provider Education	multidisciplinary task force	All Clinical Staff	1	pre: 238; post: 253
Paull, United States - 2010	SSI	The Briefing Guide (BiG)	Organizational Change, Provider Education, Provider Reminder Systems	Veterans Health Administration National Center for Patient Safety (NCPS)	All Clinical Staff	74	

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Potenza, United States - 2009	SSI	bundle - antibiotic prophylaxis	Organizational Change, Provider Education, Provider Reminder Systems	Team assembled to respond to SCIP guidelines	All Clinical Staff	1	total: 1359
Potenza, United States - 2009	SSI	bundle - normothermia	Organizational Change, Provider Education, Provider Reminder Systems	a team addressing SCIP guidelines	All Clinical Staff	1	1359
Potenza, United States - 2009	SSI	bundle - glucose control	Organizational Change, Provider Education, Provider Reminder Systems	a team to address SCIP guidelines	All Clinical Staff	1	1359
Potenza, United States - 2009	SSI	bundle - appropriate hair removal	Organizational Change, Provider Education, Provider Reminder Systems	team responding to SCIP guidelines	All Clinical Staff	1	1359
Rauk, United States - 2010	SSI	bundle - skin prep and instrument sterilization	Organizational Change, Provider Education	multidisciplinary team	All Clinical Staff	1	pre: 441; post: 436
Shimoni, Israel - 2009	SSI	Empowering surgical nurses	Organizational Change	heads of the obstetrics and anesthesia departments	Nurses		pre: 1104; post: 1089
Suchitra, India - 2009	CAUTI; SSI	Education Program	Provider Education	staff study	Nurses, Physicians ward aides	3	pre: 1125; post: 1119
Takahashi, Japan - 2010	SSI	Departmental Education	Audit and Feedback, Organizational Change, Provider Education	Antimicrobial stewardship team, study staff	All Clinical Staff	1	pre: 1627; post: 1627
Wax, United States - 2007	SSI	Electronic reminder for provider	Provider Reminder Systems	Study staff	anesthesia practitioners	1	pre: 4987; post: 9478
Whitman, United States - 2008	SSI	Multiple ‘forced functions’	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	Temple University Hospital administration, surgical chairs, study staff	Nurses, Physicians residents, faculty	1	total: 1622
Willemsen, Netherlands - 2007	SSI	standardized antibiotic protocol	Organizational Change, Provider Education	multidisciplinary team	All Clinical Staff	1	pre: 153; post: 147
Zvonar, Canada - 2008	SSI	Appropriate antibiotic prophylaxis administration	Audit and Feedback, Organizational Change, Provider Education	Multidisciplinary team	All Clinical Staff Anesthesiology providers	1	

Appendix Table C2-LQ-d. Patient characteristics for CAUTI which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Type of QI Strategy	Interventionists	Participants	Number of Hospitals	Number of Patients
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	CAUTI Education	Organizational Change, Provider Education	Pediatric Intensive Care Staff	All Clinical Staff	1	preintervention: 270; postintervention: 322
Gokula, United States - 2007	CAUTI	Education and indications checklist	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	Study Staff	Nurses, Physicians	1	pre: 100; post: 100
Jain, United States - 2006	CAUTI;CLABSI;VAP	IMPACT initiative	Audit and Feedback, Organizational Change	Administration	All Clinical Staff	1	
Rothfeld, United States - 2010	CAUTI	Appropriate Catheter Use Protocol	Organizational Change, Provider Education	Study Staff	Nurses	1	
Stephan, Switzerland - 2006	CAUTI	CAUTI guidelines, education and posters	Audit and Feedback, Provider Education	Study staff, Multidisciplinary team	All Clinical Staff	1	pre: 280; post1: 259; post2: 300
Suchitra, India - 2009	CAUTI;SSI	Education Program	Provider Education	staff study	Nurses, Physicians ward aides	3	pre: 1125; post: 1119
Venkatram, United States - 2010	CAUTI;CLABSI;VAP	CAUTI bundle	Audit and Feedback, Organizational Change, Patient Education, Provider Education	Health and Hospital Corporation (HHC) Collaborative	All Clinical Staff	1	pre: 1096; post: 3749
Wald, United States - 2011	CAUTI	Audit and feedback on catheter duration	Audit and Feedback, Provider Education	Study Staff	Nurses	1	orthopedic pre: 206; orthopedic post: 290; general pre: 167; general post: 183

Appendix Table C3-LQ-a. Intervention characteristics for VAP which do not control for secular trend or confounding

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Abbott, United States - 2006	VAP	The researchers used the Academic Center of Evidence-based Practice (ACE) Star Model to guide and implement evidence-based practices. The 5 stages of knowledge transformation used are 1) knowledge discovery, 2) evidence summary, 3) translation into practice recommendations, 4) integration into practice, and 5) evaluation. For knowledge discovery, monthly meetings were held by critical care clinicians to brainstorm strategies to reduce and prevent VAP. Collaboration with a nearby hospital also took place. For evidence summary, a systematic review was conducted and published. From that, the researchers found 5 EBPs that have been shown to be most effective against VAP, 1) HOB elevation, 2) oral care, 3) condensate management, 4) hand hygiene, and 5) proper glove use. The summarized evidence was then interpreted and combined with clinical expertise and theoretical guides and then contextualized to the patient population and setting. The researchers used the PRECEDE-PROCEED and diffusion of innovation models to integrate the aforementioned EBPs into clinical practice. The PRECEDE-PROCEED model was used to evaluate predisposing factors such as attitudes, beliefs, and perceptions that motivate people to change. The diffusion of innovation model was used to evaluate elements of innovation that facilitate change at the unit level. A multidisciplinary education team was formed. The nurses, techs, and respiratory therapists were given a self-learning packet about VAP at orientation. Staff physicians, residents, interns, respiratory therapists, and housekeeping staffed were briefed on the EBP changes. Educational storyboards were developed and displayed. The storyboards contained the EBPs, audit data, as well as the change process. Reminders were placed at every bedside. One-on-one bedside teachings and verbal reminders were used to reinforce the change. Weekly email reminders with audit data were sent to all staff. Frequent communication with hospital leadership took place.		Feedback was provided through storyboard posters and weekly emails.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Assanasen, - 2008	CLABSI; VAP	During phase 2, the nurse managers and physician directors received unit-specific quarterly feedback on compliance and infection rates via email from the hospital's infection control professionals. It also contained trends and compliance targets for each process measure. The nurse director of epidemiology and infection control provided informal feedback to unit leaders. During phase 3, dashboard-like posters were hung in ICU staff only areas. They displayed quarterly compliance and infection rates. Compliance was color coded. Poor compliance was red, borderline compliance was yellow and adequate compliance was green. The poster also had a brief summary of infection control practices to improve compliance. Target compliance rates were also displayed. A self-administered questionnaire was given at the end of the study to assess changes in behavior.		During phase 2, the nurse managers and physician directors received unit-specific quarterly feedback on compliance and infection rates via email. It also contained trends and compliance targets for each process measure. The nurse director of epidemiology and infection control provided informal feedback to unit leaders. During phase 3, dashboard-like posters were hung in ICU staff only areas. They displayed quarterly compliance and infection rates. Compliance was color coded. Poor compliance was red, borderline compliance was yellow and adequate compliance was green.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Berriel-Cass, United States - 2006	CLABSI; VAP	The infection control department met with the senior vice president of quality and the hospital CEO to describe the process to improve patient care and reduce costs. Senior leadership's support was key to ensuring availability of resources and enhancing the visibility of the initiative. The infection control department put together the educational component for physicians and nurses, with its medical director providing education to physicians, and the infection control practitioners (ICPs) providing it to nursing. ICPs educated rotating resident physicians in the ICU monthly. The educational program addressed many issues relating to CLABSI such as best practices, morbidity, mortality, cost, definitions, new tools being used, and potential barriers to implementation. Best practices that were included in the bundle were avoiding femoral lines, use of chlorhexidine for skin preparation, hand hygiene, and maximum sterile barrier use. A checklist was developed for CL insertions that would be utilized to assess compliance with this protocol. The checklist forced compliance with the components of the procedure by not allowing the operator to proceed without following the best practices. The checklist did not allow "no" as one of the answers. The two options were either "yes" or "yes after correction." Nursing and physician champions were designated. The nursing champion was defined as a nurse well known in the ICU who was involved in training nurses on his or her unit on using the checklist to document the correct placement of central catheters and was responsible for compliance with the checklist on all lines placed. The unit nurse manager acted as the nurse champion and supported the nurses' stopping of the procedure at any time if the physician was not complying with the established protocol. The physician champion was chosen based on being well known in the ICU, being involved in training residents for catheter placement, directing in-services for resident physicians (medical and surgical) on appropriate line placement and the use of the tool, and serving as a contact person if problems occur between operator (physician) and nursing. ICP's rounded in the ICU daily to collect the checklist and provide feedback if the form was missing information or not completed correctly. All components of the bundle needed to be present or the operator was considered noncompliant. To decrease barriers, a central line cart was also made that contained the necessary supplies for insertion.		The ICPs rounded in the ICUs daily to collect the checklist and provide feedback if the form was missing information or not completed correctly. Monthly CLABSI rates were given to each ICU. Unit rates were compared to historical rates as well as NNIS rates.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Berriel-Cass, United States - 2006	CLABSI; VAP	An implementation team was established to develop changes and goals. The team was called the MDR team. The MDR team educated the charge nurses who in turn educated the staff on their shifts. The ICU managers attended nurse orientation to educate the new nurses on MDR, bundles, and other changes in the ICU. The same approach was used with all new employees and with continuing education for staff. Physicians were educated on the changes underway and were encouraged to participate. Impediments to educating all staff included the use of traveling nurses and temporary staff as well as the normal turnover rate among staff nurses. The MDR team designed a daily goal sheet, developed a VAP bundle, defined methodology for data collection and reporting, and determined an implementation date. An IHI VAP bundle was implemented and consisted of HOB elevation, deep vein thrombosis prophylaxis, peptic ulcer disease prophylaxis, oral care every two hours, and hand washing. Sedation vacation and the weaning protocol were implemented later. The ICU staff nurse measured DVT and PUD prophylaxis compliance and reported findings in the daily MDR meeting. If no order was obtained for the appropriate prophylaxis, the staff nurse followed up with the physician to determine why prophylaxis was omitted. Kits containing the material for every-two-hour oral care were placed in the patient room each morning and inventoried the next day by the staff nurse to determine use. Compliance was reported in the daily meeting.		The ICU staff nurse measured DVT and PUD prophylaxis compliance and reported findings in the daily MDR meeting. If no order was obtained for the appropriate prophylaxis, the staff nurse followed up with the physician to determine why prophylaxis was omitted. The daily goal sheet was used to document recommended changes or feedback that needed to be communicated to the physician and other team members. Staff nurses also reported compliance with oral care at the MDR meetings.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Bigham, United States - 2009	VAP	A multidisciplinary task force, the Critical Care Unit Quality Improvement Collaborative-VAP Prevention Collaborative, was established and defined specific aims for VAP reduction. The collaborative included physicians, nurses, respiratory therapists, infection control staff, and quality improvement consultants. Using IHI recommendations, a targeted literature review, and intra-institutional expert clinician consensus, a pediatric-specific VAP bundle was designed. Implementation of the bundle was led by the PICU respiratory therapist. Nurses and respiratory therapists used rapid cycles of change (Plan-Do-Study-Act) to find the best methods to achieve reliable compliance with the bundle. Clinical staff education and implementation of the VAP bundle occurred midway through the implementation period. VAP bundle included hand hygiene, HOB elevation, mouth care, oral suction, changing soiled catheters, ventilator circuit inspection, and draining condensate. In addition, the use of bundle compliance checklists were used to educate, remind, and measure compliance with the bundle. These were later incorporated into the standard documentation. Oral care packages were placed in each patient room to make more convenient and serve as a reminder. Posters were placed around the ICU displaying compliance rates, VAP rates, and “days since” last VAP. Real time reporting of VAP cases was initiated. ICU leadership was notified within a day of the VAP diagnosis. Monthly ICU leadership meetings were used to review the data and guide and facilitate the work of the frontline staff. VAP bundle education was added to the orientation for float nursing staff. Compliance was also added to leadership and staff evaluations. Periodically compliance was assessed at random and unannounced.		Monthly ICU leadership meetings were held to review data and make changes if necessary. Posters in the ICU also displayed compliance rates, VAP rates, and “days” since last VAP case. The authors say appropriate disciplinary actions were still being evaluated.
Bird, United States - 2010	VAP	A multidisciplinary team was organized and a VAP bundle was implemented that included HOB elevation, daily sedation break, daily assessment for extubation, peptic ulcer prophylaxis, and deep vein thrombosis prophylaxis. Compliance was assessed twice daily by the respiratory care service. Monthly a multidisciplinary team reviewed the compliance data and supplied feedback to the nursing staff.		Data was reviewed monthly by a multidisciplinary team and feedback was provided to the SICU nursing staff
Blamoun, United States - 2009	VAP	Procedures done during and prior to baseline and then more highly enforced at the intervention: Patients are screened for infection on admission and monitored for signs of developing infection after admission. Criteria for infection surveillance include temperature; 90 beats/min respiratory rate or 20 breaths/min or PaCO2 # 32 mmHg, and white cell count of 12,000 cells/mm3 or . 10% bands. The decision is based on the presence of 2 or more of these criteria. The protocol also includes the use of broad-spectrum antibiotics until the pathogen is isolated. Patients suspected of sepsis on admission or first temperature spike.100.4 degrees F (whichever comes first) are immediately tested for pathogens.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
		The laboratory technician provides a prompt verbal alert to the nurse caring for the patient on the detection of any pathogens, followed by notification of the physician by the nurse and decision regarding initiation of treatment. Implementation of negative pressure, airborne, droplet, or contact isolation precautions, depending on the patient's symptoms and suspected organisms. The patient is placed in a specially designated isolation room with negative pressure used for respiratory isolation, including airborne and droplet isolation. The use of gloves, gowns, and face shields before expected contact with patients on contact isolation is strictly enforced, as is the use of face masks for patients on respiratory isolation. Canisters are readily available for dull objects contaminated with body fluids, and designated ''sharps'' containers are made available for contaminated sharps. All central venous access lines are placed under complete sterile conditions, and lines that had been placed under emergency (non-sterile) conditions are replaced on admission to the MICU. Daily inspection and care of lines are instituted to prevent catheter-related infections. Nasal swabs are performed for all patients in the MICU to screen for nasal MRSA colonization. A hand washing procedure is in place for patients on isolation that mandates hand washing before and after patient contact by any and all health care personnel. For patients not on isolation, staff can use a sterilizing, alcohol-based gel. ''Hands-free'' faucets are installed on sinks in patient rooms. Nurse VAP Bundle components: Use of an oropharyngeal cleansing kit (Q-Care; Sage Products, Cary, IL) every 4 hours, Frequent (every 4 hours) suctioning of both the oropharynx and the endotracheal tube. Respiratory-therapists VAP Bundle procedures: Use of the "Sedation Vacation" (SV) on a daily basis. Trial of spontaneous breathing (SBT) after use of the SV by changing the ventilator mode to a pressure support setting of 5 cm H2O for 30 to 120 minutes. Obtaining and documenting weaning parameters during the SBT, including respiratory rate, tidal volume, negative inspiratory force, and minute ventilation, to assess the readiness for weaning. Notification of the intensivist when the patient is considered to have passed the SBT and is extubated. Early tracheostomy (, 12 days) for patients repeatedly failing SBT, especially those expected to be ventilator-dependent for an extended period, and tracheostomy for all patients beyond 12 days. Head-of-bed elevation of 30 degrees to 45 degrees for all patients on ventilators. (CDC Guidelines approved)		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Bloos, Germany - 2009	VAP	A change team was formed. During Audit I a specially trained task force visited patients' rooms randomly between 8AM and 8PM and recorded compliance to modified-IHI VAP bundle. The change team taught all nurses and residents through daily seminars about the VAP bundle as well as gave feedback from Audit I. The VAP bundle included lung protective ventilation for patients with acute lung injury (ALI), HOB elevation, stress ulcer prophylaxis, and deep vein thrombosis prophylaxis. Red marks were put on the walls to indicate the correct HOB elevation. Prescriptions for prophylaxis had to be made by physicians and administration had to be signed by a nurse to be considered compliant. The change team monitored daily compliance and individually trained nurses and staff that were still non-compliant after 2 months. Audit II was conducted in the same manner as Audit I.		Feedback was given by the change team for the 2 months following the education program. Individual nurses and residents were trained again if the bundle was not being implemented correctly.
Cocanour, United States - 2006	VAP	A VAP bundle, which included HOB elevation, peptic ulcer prophylaxis, endotracheal tube suctioning, hand washing (includes use of alcohol-based hand sanitizer), oral care, use of personal protective gear, use of sleeved Yankauers, changing nasogastric irrigation fluids daily, chlorhexidine baths twice weekly revised insulin control protocol were implemented first under the advisement of a multidisciplinary team. A daily audit/feedback program was implemented three months after the bundle began due to low compliance rates. The infection control practitioner (ICP) evaluated each patient daily for compliance with the bundle components. Feedback was given weekly to the STICU staff by the ICP. In-service education programs were provided by the ICP. Posters, graphs, and charts were also used to relay information. Patient families were educated and encouraged to provide simple care. Faculty were given monthly infection rates and weekly compliance rates. Faculty were encouraged to remind residents and nurses to comply with bundle components. Residents had a monthly orientation where the VAP bundle was reviewed.		The Infection Control Practitioner gave weekly compliance feedback and provided in-service education accordingly.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Garcia, United States - 2009	VAP	During baseline two experienced infection control professionals used staff interviews and observations of practice to identify barriers to best practice in VAP prevention. Respiratory therapists, nurses, and physicians were included in the review. During baseline MICU protocols required "standard" oral care, which included suctioning of the oral cavity with suction catheters or Yankauer suctioning devices and glycerin swabs for tissue and lip care. No specific time frames for using these items was established. Dental care products were not used for patients receiving mechanical ventilation. The infection control department held a series of meetings with staff from the MICU, ED, materials management, and performance department. Information from the interviews and a review of policies and available products for patient care was shared. A list of oral care needs was made and actions needed to make this successful were outlined. The education program was conducted by the infection control professionals and covered the following topics: morbidity, mortality, and costs associated with VAP; MICU rates vs. national benchmarks; procedure and timing of hand washing; intubation procedures; review of protocols for ventilator circuits, closed suction devices, and changes of heat moisture exchange filters; medication administration; care of equipment; review of weaning protocols; and review of policies addressing elevating the head of the bed. The infection control committee and the products evaluation and standardization committee approved the implementation of a comprehensive oral and dental care system in which nurses were supposed to use on all ventilated patients. Nursing knowledge of the protocol details was tested twice per year as part of the nursing education competency requirements.		
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	•Patient-based NI surveillance protocol adapted from the Hospitals in Europe Link for Infection Control through Surveillance (HELICS) was used. Patients in the units were assessed by physicians on duty, and standard data collection form was filled out. The multimodal intervention (i.e. an infection control program) was designed depending on the NI surveillance data analysis in the control group and the data gathered from the evaluation form of NI prevention methods. The intervention included education of the ICU staff (6 hours) about NI prevention and implementation or correction of daily routine procedures, according to the evidence-based recommendations. Prevention of bloodstream infection •Emphasize hand washing for ICU staff, consultants, and parents •Use only single use towels in the ICU •Educate health-care workers regarding the indications for intravascular catheter use, proper procedures for the insertion and maintenance of intravascular catheters, and appropriate infection control measures to prevent intravascular catheter-related infections		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
		•Use of gloves does not obviate the need for hand hygiene •Record the operator, date, and time of catheter insertion and removal, and dressing changes on a standardized form •Observe hand hygiene before and after palpating catheter insertion sites, as well as before and after inserting, replacing, accessing, repairing, or dressing an intravascular catheter •Encourage patients to report to their health care provider any changes in their catheter site or any new discomfort •Maintain aseptic technique for the insertion and care of intravascular catheters •Wearing clean gloves rather than sterile gloves is acceptable for the insertion of peripheral intravascular catheters if the access site is not touched after the application of skin antiseptics. Sterile gloves should be worn for the insertion of arterial and central catheters •Wear clean or sterile gloves when changing the dressing on intravascular catheters •Do not routinely use arterial or venous cutdown procedures as a method to insert catheters •Leave peripheral venous catheters in place in children until IV therapy is completed, unless complications (e.g. phlebitis and infiltration) occur •When adherence to aseptic technique cannot be ensured (i.e. when catheters are inserted during a medical emergency), replace all catheters as soon as possible and after no longer than 48 hours •Replace catheter-site dressing if the dressing becomes damp, loosened, or visibly soiled •Consider reduction of CV catheter utilization		
Heimes, United States - 2011	VAP	VAPP protocol included HOB elevation, oral care, extubation assessment, use of nasogastric tubes, sedation holiday, stress ulcer prophylaxis, ventilator weaning, and deep vein thrombosis prophylaxis. Later on the protocol was enforced daily through rounds by trauma ICU case manager and infection control officer and documented in the patients' charts. Respiratory therapists attempted weaning from ventilation daily. Physicians made the final decision on extubation of the patient.	The authors mention the Deficit Reduction Act and the financial incentives to implement quality improvement programs	

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Jain, United States - 2006	CAUTI;CLABSI;VAP	Physician led multidisciplinary rounds were initiated in October 2002. The team included in these rounds consisted of the patient's nurse, ICU charge nurse, pharmacist, dietician, respiratory therapist, case manager, social worker, physical therapist, and palliative care nurse. This team would set daily goals and use trigger tools to define adverse ICU events. Daily bed flow meetings were also implemented which happened twice daily. They were 20 minutes long and discussed facility status, intervention priorities, historical data, and daily goal setting. The meeting was led by the administrative house supervisor. After October 2002 bundles for VAP, CLABSI, and CAUTI were implemented. The bundles were developed using published guidelines, CDC recommendations, and local staff recommendations. Feedback was provided to the physicians.	Intensivists were reimbursed for doing rounds.	Feedback was provided to physicians.
Jimenez, United States - 2009	VAP	A 1 week educational program on IHI ventilator bundle protocol included lectures, pamphlets, and reminder cards. The bundle included HOB elevation, sedation vacations, peptic ulcer prophylaxis, and deep vein thrombosis prophylaxis. Feedback was provided to the nursing staff and their supervisor through graphs and reports.		Staff was provided graphical feedback at unknown time points
Landrum, Afghanistan - 2008	VAP	A VAP bundle was implemented (HOB elevation, oral care, and daily sedation holiday) in addition to placing alcohol-based hand sanitizer at each bedside, requiring hand washing before and after patient contact, wearing gloves and gowns when treating a patient with certain pathogens, reducing use of certain medications, cleaning equipment on a regular basis as well as after each patient transfer. Preprinted forms for all ICU admissions were created to track these added measures. Antibiotic control measures were also implemented. Staff education of nurses and physicians was done and reeducation occurred on a regular basis during daily morning briefings. The infectious disease physician inspected the facility multiple times a day providing education and reinforcement of procedures.		Infectious disease physician inspected the facility daily and gave feedback as needed
Quenot, France - 2007	VAP	The protocol was designed by a multidisciplinary team of nurses and physicians. The staff was then trained on how to use the protocol. The bedside nurse first administers the sedative according to the physicians' prescription. Every 3 hours, level of sedation and dose of sedative given was to be documented on the patient's chart. The nurse would adjust the dose if necessary unless poor tolerance or no improvement occurs. Then the physician is alerted. Nurses were given a table with the doses of sedative to be administered according to weight, previous doses given, and adjustments to occur later on.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Rogers, Ireland - 2010	CLABSI; VAP	A multidisciplinary team designed an educational package to promote hand hygiene in addition to current infection control measures. A 3 month education intervention included a presentation of evidence-based hand hygiene guidelines, new infection related posters, and demonstration of a six step hand hygiene technique using Glo Germ. Questionnaires were also sent out to ICU staff before and after the intervention to compare attitudes, knowledge and personal practices associated with hand hygiene.		
Rosenthal, Argentina - 2006	VAP	During phase 1, active surveillance of VAP without feedback was carried out. 1 hour educational programs were given monthly from the last 2 months of Phase 1 all the way through Phase 2. Attendance was not mandatory. Each program was self-contained and covered 1997 CDC Nosocomial Pneumonia Prevention Guidelines. Monthly feedback was also provided to ICU staff during Phase 2. Feedback was also presented at infection control meetings in the form of bar charts. A formal report was forwarded to the administrators of each ICU.		Monthly VAP rates were given to the ICU staff at the infection control meetings in the form of bar charts.
Ross, United States - 2007	VAP	The literature was reviewed to develop an evidence-based education program for oral care and a competency checklist. Critical care nurse specialists used the Oral Assessment Guide (OAG) to assess oral hygiene. These were conducted unannounced and during both shifts in all units. The assessments occurred eleven times over a one week period during the pre- and post-intervention periods. The educational program consisted of posters highlighting the best-practice oral care protocol, storyboards outlining the role of oral care in preventing VAP, and research studies to show the evidence supporting the protocol changes. Storyboards were used for self-learning as well as for individualized and small group in-services. The critical care nurse specialists or the unit based educators provided the education programs. The storyboards were posted on the hospital's intranet. Nurses and CNAs were required to complete the competency checklist with observed performance of the oral care protocol. Direct feedback was given on their performance. 2 months later the assessments took place again.		All of the nurses and CNAs in every ICU were required to complete the oral care protocol while being observed. Critical care nurse specialists provided feedback afterwards.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Sona, United States - 2009	VAP	A preprinted order set was designed and placed in the admissions packet. The attendings and fellows were educated on the protocol through QI meetings. All incoming residents were also updated on the oral care protocol and order set. Clinical nurse specialists (CNS) and nurse educators educated the ICU nursing staff on the oral care protocol and the documentation in three groups. The nurses were given pictorials displaying the oral care protocol. These pictorials were laminated and paced in resource manuals at every patient's bedside. The two CNSs audited compliance rates through a biweekly review of the medication administration and oral care supplies. If a patient did not have an order for the oral care protocol, the medical team was approached to get one. If the patient did have an order, but the protocol had not been performed then the CNS would discuss it with the patient's nurse. VAP rates were reported monthly at the unit's multidisciplinary QI meeting.		The two CNSs audited compliance rates through a biweekly review of the medication administration and oral care supplies. If a patient did not have an order for the oral care protocol, the medical team was approached to get one. If the patient did have an order, but the protocol had not been performed then the CNS would discuss it with the patient's nurse.
Venkatram, United States - 2010	CAUTI; CLABSI; VAP	The HHC collaborative was comprised of participating institution's medical directors, nursing directors, chiefs of medical and surgical departments, directors of critical care units, and respiratory therapy and nursing supervisors. The directors of critical care met monthly and emphasized the use of the bundle strategies. Data from the participating hospitals was shared both on the critical care collaborative website as well as during learning sessions. Focused learning sessions were conducted by intensivists periodically. The MICU director served as the champion and held monthly sessions for all ICU staff to reinforce the procedures involved in the bundled approach. Nurses collected compliance data and shared it with the MICU team at the performance improvement committee meetings. Data was also shared with other HHC hospitals. 'Zero Infection Rate' certificates were given by the infection control staff monthly as positive feedback. A CAUTI bundle was implemented in January 2005. It included daily assessment of need, sterile technique when inserting, and use of silver-coated catheters. In addition nurses monitored for breaches in infection control. The MICU nurse was also empowered to stop a procedure if there was a deviation from the recommendations. Evaluation of the necessity of the urinary catheter was integrated into the daily goals and discussed at bedside rounds daily.		The ICU was awarded monthly 'Zero Infection Rate' certificates based on outcomes by the infection control staff. Nurses collected compliance data and shared it at the MICU performance improvement committee meetings.

Appendix Table C3-LQ-b. Intervention characteristics for CLABSI which do not control for secular trend or confounding

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Assanasen, - 2008	CLABSI; VAP	During phase 2, the nurse managers and physician directors received unit-specific quarterly feedback on compliance and infection rates via email from the hospital's infection control professionals. It also contained trends and compliance targets for each process measure. The nurse director of epidemiology and infection control provided informal feedback to unit leaders. During phase 3, dashboard-like posters were hung in ICU staff only areas. They displayed quarterly compliance and infection rates. Compliance was color coded. Poor compliance was red, borderline compliance was yellow and adequate compliance was green. The poster also had a brief summary of infection control practices to improve compliance. Target compliance rates were also displayed. A self-administered questionnaire was given at the end of the study to assess changes in behavior.		During phase 2, the nurse managers and physician directors received unit-specific quarterly feedback on compliance and infection rates via email. It also contained trends and compliance targets for each process measure. The nurse director of epidemiology and infection control provided informal feedback to unit leaders. During phase 3, dashboard-like posters were hung in ICU staff only areas. They displayed quarterly compliance and infection rates. Compliance was color coded. Poor compliance was red, borderline compliance was yellow and adequate compliance was green.
Berriel-Cass, United States - 2006	CLABSI; VAP	The infection control department met with the senior vice president of quality and the hospital CEO to describe the process to improve patient care and reduce costs. Senior leadership's support was key to ensuring availability of resources and enhancing the visibility of the initiative. The infection control department put together the educational component for physicians and nurses, with its medical director providing education to physicians, and the infection control practitioners (ICPs) providing it to nursing. ICPs educated rotating resident physicians in the ICU monthly. The educational program addressed many issues relating to CLABSI such as best practices, morbidity, mortality, cost, definitions, new tools being used, and potential barriers to implementation. Best practices that were included in the bundle were avoiding femoral lines, use of chlorhexidine for skin preparation, hand hygiene, and maximum sterile barrier use. A checklist was developed for CL insertions that would be utilized to assess compliance with this protocol. The checklist forced compliance with the components of the procedure by not allowing the operator to proceed without following the best practices. The checklist did not allow no as one of the answers. The two options were either yes or yes after correction. Nursing and physician champions were designated. The nursing champion was defined as a nurse well known in the ICU who was involved in training nurses on his or her unit on using the checklist to document the correct placement of central catheters and was responsible for compliance with the checklist on all lines placed. The unit nurse manager acted as the nurse champion and supported the nurses' stopping of the procedure at any time if the physician was not complying with the established protocol. The physician champion was chosen based on being well known in the ICU, being involved in training residents for		The ICPs rounded in the ICUs daily to collect the checklist and provide feedback if the form was missing information or not completed correctly. Monthly CLABSI rates were given to each ICU. Unit rates were compared to historical rates as well as NNIS rates.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
		catheter placement, directing in-services for resident physicians (medical and surgical) on appropriate line placement and the use of the tool, and serving as a contact person if problems occur between operator (physician) and nursing. ICP's rounded in the ICU daily to collect the checklist and provide feedback if the form was missing information or not completed correctly. All components of the bundle needed to be present or the operator was considered noncompliant. To decrease barriers, a central line cart was also made that contained the necessary supplies for insertion.		
Berriel-Cass, United States - 2006	CLABSI; VAP	An implementation team was established to develop changes and goals. The team was called the MDR team. The MDR team educated the charge nurses who in turn educated the staff on their shifts. The ICU managers attended nurse orientation to educate the new nurses on MDR, bundles, and other changes in the ICU. The same approach was used with all new employees and with continuing education for staff. Physicians were educated on the changes underway and were encouraged to participate. Impediments to educating all staff included the use of traveling nurses and temporary staff as well as the normal turnover rate among staff nurses. The MDR team designed a daily goal sheet, developed a VAP bundle, defined methodology for data collection and reporting, and determined an implementation date. An IHI VAP bundle was implemented and consisted of HOB elevation, deep vein thrombosis prophylaxis, peptic ulcer disease prophylaxis, oral care every two hours, and hand washing. Sedation vacation and the weaning protocol were implemented later. The ICU staff nurse measured DVT and PUD prophylaxis compliance and reported findings in the daily MDR meeting. If no order was obtained for the appropriate prophylaxis, the staff nurse followed up with the physician to determine why prophylaxis was omitted. Kits containing the material for every-two-hour oral care were placed in the patient room each morning and inventoried the next day by the staff nurse to determine use. Compliance was reported in the daily meeting.		The ICU staff nurse measured DVT and PUD prophylaxis compliance and reported findings in the daily MDR meeting. If no order was obtained for the appropriate prophylaxis, the staff nurse followed up with the physician to determine why prophylaxis was omitted. The daily goal sheet was used to document recommended changes or feedback that needed to be communicated to the physician and other team members. Staff nurses also reported compliance with oral care at the MDR meetings.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Bhutta, United States - 2007	CLABSI	Stepwise introduction of interventions designed to reduce infection rates, including maximal barrier precautions, transition to antibiotic impregnated central venous catheters, annual hand washing campaigns, and changing the skin disinfectant from povidone-iodine to chlorhexidine.		An indicator is displayed, showing status with regard to the desired intervention. A simple color scheme of red, yellow, and green represents various states of compliance with process steps. Red indicates out of compliance, yellow indicates in compliance but the item is coming due, and green indicates compliance. A grace period is built in to each item to allow for patient variability. The dashboard was designed to aid in supporting clinician work flow. Online checklists began in 2007; The nursing staff completed checklists for each ventilated patient at least two times per day to document compliance with VAP reduction strategies. Nursing leadership periodically audited compliance, and followed up with staff if targeted compliance levels were not achieved or if the checklists were not completed. The CAUTI tracking system in early 2008 provided real-time reports of urinary catheter insertion dates and duration on a patient-by-patient basis, with color-coded visual cues identifying those patients having extended duration of catheterization.; Infection control staff reported quarterly data to the nursing and medical directors of the unit.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Bizzarro, United States - 2010	CLABSI	Mandatory yearly lectures, hands-on training sessions, and observed competency assessments for proper CVC placement and management techniques for all new personnel. Those who are formally trained may independently perform and assist in the training of incoming personnel. Mandatory yearly lecture, hands-on training session, and observed competency assessments for proper hand washing and aseptic techniques for CVC placement and management for all new personnel. Povidone iodine with 70% isopropyl alcohol for cutaneous antisepsis and dressing changes. Dressings are not to be changed routinely and are to be changed only under the following conditions: when the integrity of the dressing is compromised; when the dressing is visibly soiled; and/or when the catheter position needs to be readjusted (out only). Daily discussion during attending physician rounds regarding need for CVC; removal of CVC the day before or the day neonate achieves complete enteral feeding; ensure removal of surgical lines within 48 hours of discontinuation of use. Surveillance conducted and made available to the staff quarterly; the CVC Initiative Committee meets semiannually, at a minimum, to review data and new medical literature and to update protocols.		Rates of CLABSI were reported quarterly to the staff in graphic and tabular form, and post initiative data were compared with pre-initiative and NHSN data. A daily chart was kept in the NBSCU staff room to display the number of days between consecutive cases of CLABSI in the NBSCU.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Galpern, United States - 2008	CLABSI	Resident physicians and nurses were educated on bloodstream-infection--control practices, which included discussions about proper hand washing, use of full-barrier precautions during the central line insertion, appropriate preparation of the skin with ChloraPrep, avoiding the femoral site if possible, and early removal of all central lines. Organizational change: A central line cart was created that contained all the equipment needed to comply with evidence-based guidelines for central line insertions. A policy was instituted that required nurses to assist in central line insertion. Previously, central lines were placed by the critical care physicians without assistance, unless requested. All central lines were secured using a 3.0 silk stitch. They did not use a noninjurious method, such as the stat lock mechanism. After placement of the central line, a form was filled out by the physician and nurse to ensure the protocol was not violated. On a daily basis, justification for the need of the central line needed to be documented in the chart. If no justification could be found, the central line was removed by the physician. A trained infection-control nurse examined each patient every day to determine whether a bloodstream infection had occurred to remove the possibility that another health-care provider might not report the infection. Data were collected on a monthly basis, which included the number of critical-care beds in use at the time, the number of catheters placed, the number of days the catheters were left in place expressed as catheter days, and the number of line-associated infections. Data were reported to the directors of the surgical and medical ICUs, which allowed for real-time feedback to the staff on how the intervention was proceeding. No change in the materials was used during the time of the study. The catheter kits, drapes, gowns, gloves, and caps were all kept the same during the study period.		On a monthly basis feedback to the staff was provided as a means of data on the number of critical-care beds in use at the time, the number of catheters placed, the number of days the catheters were left in place expressed as catheter days, and the number of line-associated infections.
Guerin, United States - 2010	CLABSI	During the intervention period, an IV team was assembled to provide insertion and site care for PICC lines as well as monitoring site care and dwell time for all IVs in the hospital. The nursing staff created and implemented (by each nursing unit's IV champion) a post insertion care bundle consisting of daily inspection of the insertion site; site care if the dressing was wet, soiled, or had not been changed for 7 days; documentation of ongoing need for the catheter; proper application of a chlorohexidine gluconate-impregnated sponge at the insertion site; performance of hand hygiene before handling the intravenous system; and application of an alcohol scrub to the infusion hub for 15 seconds before each entry. A 4-hour hands-on training class in techniques for accessing and caring for all IV catheters was mandatory for all nursing staff. This training was followed by a competency evaluation, in which each nurse was required to demonstrate competence in catheter insertion site and hub care.		The hands-on training was followed by a competency evaluation, in which each nurse was required to demonstrate competence in catheter insertion site and hub care.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	Patient-based NI surveillance protocol adapted from the Hospitals in Europe Link for Infection Control through Surveillance (HELICS) was used. Patients in the units were assessed by physicians on duty, and standard data collection form was filled out. The multimodal intervention (i.e. an infection control program) was designed depending on the NI surveillance data analysis in the control group and the data gathered from the evaluation form of NI prevention methods. The intervention included education of the ICU staff (6 hours) about NI prevention and implementation or correction of daily routine procedures, according to the evidence-based recommendations. Prevention of bloodstream infection •Emphasize hand washing for ICU staff, consultants, and parents •Use only single use towels in the ICU •Educate health-care workers regarding the indications for intravascular catheter use, proper procedures for the insertion and maintenance of intravascular catheters, and appropriate infection control measures to prevent intravascular catheter-related infections •Use of gloves does not obviate the need for hand hygiene •Record the operator, date, and time of catheter insertion and removal, and dressing changes on a standardized form •Observe hand hygiene before and after palpating catheter insertion sites, as well as before and after inserting, replacing, accessing, repairing, or dressing an intravascular catheter •Encourage patients to report to their health care provider any changes in their catheter site or any new discomfort •Maintain aseptic technique for the insertion and care of intravascular catheters •Wearing clean gloves rather than sterile gloves is acceptable for the insertion of peripheral intravascular catheters if the access site is not touched after the application of skin antiseptics. Sterile gloves should be worn for the insertion of arterial and central catheters •Wear clean or sterile gloves when changing the dressing on intravascular catheters •Do not routinely use arterial or venous cutdown procedures as a method to insert catheters •Leave peripheral venous catheters in place in children until IV therapy is completed, unless complications (e.g. phlebitis and infiltration) occur •When adherence to aseptic technique cannot be ensured (i.e. when catheters are inserted during a medical emergency), replace all catheters as soon as possible and after no longer than 48 hours •Replace catheter-site dressing if the dressing becomes damp, loosened,		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
		or visibly soiled •Consider reduction of CV catheter utilization		
Jain, United States - 2006	CAUTI; CLABSI; VAP	Physician led multidisciplinary rounds were initiated in October 2002. The team included in these rounds consisted of the patient's nurse, ICU charge nurse, pharmacist, dietician, respiratory therapist, case manager, social worker, physical therapist, and palliative care nurse. This team would set daily goals and use trigger tools to define adverse ICU events. Daily bed flow meetings were also implemented which happened twice daily. They were 20 minutes long and discussed facility status, intervention priorities, historical data, and daily goal setting. The meeting was led by the administrative house supervisor. After October 2002 bundles for VAP, CLABSI, and CAUTI were implemented. The bundles were developed using published guidelines, CDC recommendations, and local staff recommendations. Feedback was provided to the physicians.	Intensivists were reimbursed for doing rounds.	Feedback was provided to physicians.
Jeffries, United States - 2009	CLABSI	Based on Associates in Process Improvement model. Included recommendation from CDC guidelines, published studies, and IHI save 100,000 lives campaign. Baseline data was collected and shared with the teams at each hospital. Qualitative feedback on hospital-specific improvements were distributed monthly. 9 month improvement project followed by 12 month follow up. 2 bundles insertion and maintenance each composed of 5 categories of improvement. Insertion: Hand hygiene Hand hygiene consistent with local guidelines and/or policies, Dressings Apply transparent semipermeable dressing (use gauze only with bleeding and/or oozing), Sterile barrier Maximum sterile barrier (large sterile drape, sterile gloves, sterile gown, cap, and mask), Sterile technique throughout, Prepare skin with antiseptic and/or detergent chlorhexidine gluconate 2% except for patients with a contraindication. Maintenance: Hand hygiene consistent with local guidelines and/or policies, Replace dressing if it becomes damp, loosened, or visibly soiled; apply transparent semipermeable dressing (use gauze only with bleeding and/or oozing), Aseptic gloves and sterile dressing, Aseptic technique throughout, Prepare skin with antiseptic and/or detergent chlorhexidine gluconate 2% except for patients with contraindication.		Feedback was given to teams with monthly qualitative reports including: self-assessment, barriers, success, lessons learned, next steps and hospital-specific feedback providing information on next steps.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Koll, United States - 2008	CLABSI	Needs assessment identified need for regional, systematic improvement in central line practices. Buy-in from hospital leadership was a requirement for participation in this intervention. A real-time question and answer web portal for study participants and staff was created to share information and technical resources. On-call technical experts were available to provide clinical guidance and inform practitioners why these central line procedures were being adopted. Site-visits were conducted to monitor compliance with the bundle. Interdisciplinary teams met weekly initially and then monthly to discuss implementation of CLABSI bundle and to reassess strategies (or in place of meetings some hospitals had monthly or weekly goals posted). HICPAC CLAB central line bundle (hand hygiene, maximal barrier precautions, chlorhexidine skin antisepsis, optimal catheter site selection, daily review of line necessity). Data were reported to hospital CEOs quarterly and to the CLABSI teams monthly.		Data were reported to hospital CEOs quarterly and to the CLABSI teams monthly.
Lobo, Brazil - 2010	CLABSI	3 study periods: baseline, pre-intervention and intervention. Survey was administered to ICU staff covering hand hygiene, cvc insertion, dressing, handing and replacement. Observation of hand hygiene practices was conducted by nurses with a checklist. ICUs were assigned to one of two groups, an individual lecture or continuous lectures on the infection control practices observed to be lacking in each ICU.		Feedback was given monthly during the intervention period and provided staff with information on BSI rates; during the pre-intervention period staff were informed about problems found during the nurses' direct observation
Marra, Brazil - 2010	CLABSI	Study consisted of two phases, the first phase included insertion of catheters through a new venipuncture into the subclavian, jugular, or femoral vein using full sterile-barrier precautions and 2% chlorhexidine preparation for antisepsis. The next phase continued the processes in phase one and randomly audited a small sample of patients monthly undergoing central line insertion. A central catheter insertion cart, hand hygiene intervention, maximal barrier precautions, chlorhexidine skin antisepsis, optimal catheter site selection with avoidance of the femoral vein for central venous access in adults and a daily review of line necessity. This bundle was monitored by nurses and doctors and nurses had the opportunity to stop any procedure deviating from the bundle guidelines.		Phase 1: Each year, a convenience sample of patients was chosen for whom catheter insertion and catheter dressings were directly observed by assigned nurses. Feedback was provided via e-mail on compliance with these processes for the ICU team (doctors and nurses). Phase 2: Interventions were audited once monthly at random intervals in a small sample of patients undergoing central line insertion and the IHI bundle and feedback was provided via email. In addition, posters were provided in the ICU and SDU with bar graphs displaying compliance with process of care measures.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Render, United States - 2006	CLABSI	The process change-oriented intervention included a CVC insertion checklist that offered binary choices (yes/no) for hand washing, chlorhexidine use, bed sized sterile drape, and use by the operator of a cap/mask/sterile gown/sterile gloves during insertion, as well as date and site of catheter. The checklist was completed by nurses as the physician prepares for the procedure, acting as both a teaching and a measurement tool. The team leaders also modified the prepackaged insertion trays, removing betadine and small drape and replacing them with an "accessory pack" with a large drape, a sterile gown, gap and mask. The pack was accessed with the checklist on a central line cart, making it easy to do it right. To promote sustained practice change, hospital committees at the senior leadership level (clinical executive board) also approved written policies that matched the best practices to codify the practice change. Certain communication strategies were used to enforce the practice changes (but the paper does not state the specifics) such as a reminder poster on CVC insertion used by 5 of the 10 hospitals that were participating in the 2-year CLABSI-SSI prevention project. Project leadership reported outcomes of the project to the GCHC infection control and patient safety committees. Twice a year, project leadership informed the hospital CEOs of the results of the project, which compared local process adherence and outcomes to the mean of the group. The project leaders organized the work-learning-reporting cycles at each site which included at minimum one test of change every month and met monthly with project leadership and reported their experience using presentation slides in small groups to share effective strategies, solve problems together, etc. Then each project leader reported processes and outcomes to the unit staff, posting monthly project presentation slides on a bulletin board throughout the unit. Results were also reported in the hospital newsletter.		Then each project leader reported processes and outcomes to the unit staff, posting monthly project presentation slides on a bulletin board throughout the unit. Results were also reported in the hospital newsletter. Feedback reports also included other hospitals.
Rogers, Ireland - 2010	CLABSI; VAP	A multidisciplinary team designed an educational package to promote hand hygiene in addition to current infection control measures. A 3 month education intervention included a presentation of evidence-based hand hygiene guidelines, new infection related posters, and demonstration of a six step hand hygiene technique using Glo Germ. Questionnaires were also sent out to ICU staff before and after the intervention to compare attitudes, knowledge and personal practices associated with hand hygiene.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Sannoh, United States - 2010	CLABSI	Neonatal ICU central venous catheter database created, new catheter hub policy including: the surface area of the needleless port and the outer surface of the stop cork or Luer-lock threads of the catheter hub were scrubbed in a circular motion with friction using2%chlorhexidine in 70%isopropyl alcohol (ChloraPrep Sepp, CareFusion, Leawood, KS) for 10 seconds and allowed to dry for 30 seconds. The catheter hub care protocol also mandated standard hand hygiene, the use of clean gloves, and the establishment of sterile fields with 4'' 3 4'' gauze under the catheter port and the syringes used to access the hub with medications and flushing solution. The new catheter dressing change policy was to change dressings only when soiled, instead of routine weekly changes. A DVD containing 15-minute lectures demonstrating catheter hub care was viewed in multiple sessions by staff and made available on the hospital NICU website. Catheter hub care checklists were present at every bedside to remind the healthcare team of the protocol, and a CVC cart was placed with hygiene materials in each room. Hand hygiene campaigns were reinforced at this time.		
Santana, Brazil - 2008	CLABSI	Healthcare personnel were evaluated with a pre-test first. Next fact sheets and posters were distributed to healthcare personnel. Performance of 1-hour lectures by an expert infection control nurse regarding CLABSI were given to hospital staff.	Audit and feedback of infection rates	

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Shannon, United States - 2006	CLABSI	The AGH working group drew on a local community resource, the Pittsburgh Regional Health Initiative (PRHI) to learn about process improvement techniques rooted in the Toyota Production System (Lean thinking). AGH physicians, nurses, and infection control practitioners received five days of intensive training at PRHI in the improvement system called Perfecting Patient Care (PPC) and then applied those principles in clinical practice. The team, headed by the chairman of the department of medicine, also included unit directors, infection control nurses, ICU nurses, and staff from PRHI. The team began by looking at individual infections, case by case, reviewing charts of the 1,753 persons admitted to the MICU and CCU between July 2002 and June 2003, during which conventional approaches were employed. With a clearer sense of the frequency, types, and consequences of CLABs in its MICU and CCU, the team began observing staff to determine how lines were actually placed and maintained. Each occurrence was examined to its root cause as close as possible to receipt of a positive lab culture (range, 3–24 hours; average, 6 hours, including weekends). The root cause team investigating each occurrence included the infection control nurse, the physician of record, and the residents, fellows, and nurses caring for the patient. The team was headed by the chairman of the department of medicine. The team developed a countermeasure that required new trainees (nurses and doctors) to be educated in a multidisciplinary training exercise using patient simulators with the guidance of physician mentors and nursing staff.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Venkatram, United States - 2010	CAUTI; CLABSI; VAP	The HHC collaborative was comprised of participating institution's medical directors, nursing directors, chiefs of medical and surgical departments, directors of critical care units, and respiratory therapy and nursing supervisors. The directors of critical care met monthly and emphasized the use of the bundle strategies. Data from the participating hospitals was shared both on the critical care collaborative website as well as during learning sessions. Focused learning sessions were conducted by intensivists periodically. The MICU director served as the champion and held monthly sessions for all ICU staff to reinforce the procedures involved in the bundled approach. Nurses collected compliance data and shared it with the MICU team at the performance improvement committee meetings. Data was also shared with other HHC hospitals. 'Zero Infection Rate' certificates were given by the infection control staff monthly as positive feedback. A CAUTI bundle was implemented in January 2005. It included daily assessment of need, sterile technique when inserting, and use of silver-coated catheters. In addition nurses monitored for breaches in infection control. The MICU nurse was also empowered to stop a procedure if there was a deviation from the recommendations. Evaluation of the necessity of the urinary catheter was integrated into the daily goals and discussed at bedside rounds daily.		The ICU was awarded monthly 'Zero Infection Rate' certificates based on outcomes by the infection control staff. Nurses collected compliance data and shared it at the MICU performance improvement committee meetings.
Warren, United States - 2006	CLABSI	The intervention took place in two-folds: 1) updating existing CVC insertion and care policies, and 2) educating staff (didactic lectures for physicians and nurses using a slideshow, self-study module with accompanying 24-question pretest and posttest, and fact sheets and posters highlighting proper techniques for CVC insertion and care placed in the units). The primary messages of the intervention material were as follows: (1) the subclavian vein is the preferred insertion site for a non-tunneled CVC, and the femoral vein is the least desirable site; (2) catheters should be inserted using maximal sterile barrier precautions; (3) catheter insertion site dressings should be kept clean, dry, and intact; and (4) catheter dressings should be properly dated, to ensure regular dressing changes.		Before and after the 9-page self-study module, the physicians and nurses were required to take a 24-question pretest and posttest.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Wicker, United States - 2011	CLABSI	NICU staff held an infection control meeting, which consisted of various disciplines within the hospital, and formed an infection control task force. The NICU infection control task force consisted of neonatologists, pediatric infectious disease specialists, respiratory therapists, the NICU clinical director, NICU staff nurses, the NICU educator, and a pediatric surgeon. The task force reviewed the current practice guidelines and the literature for infection control in the neonatal population and, based on best practices, formulated comprehensive infection control measures. Comprehensive control measures included hand hygiene, prevention of catheter-related infections, education, and environmental infection control measures. The hand hygiene portion included: 1. a hand-washing campaign, 2. prohibiting wearing jewelry (except wedding band) or artificial nails. Prevention of catheter related infections included: 1. IV practice guidelines and education program for all NICU staff, 2. dedicated central line management team, 3. limited blood draws through the catheters, 4. daily assessment of Catheter site, 5. reinforce early removal of central lines, 6. limited the number of vascular puncture and heel sticks by clustering laboratory tests. Education included: 1. focused education for new residents, 2. mandatory infectious disease education to all registered nurses in NICU, 3. mandatory learning packets for all pool and agency nurses, 4. reinforce judicious use of antibiotics, 5. early feeding with breast milk. Environmental included1. Applied keyboard covers on all computers 2. Replaced counter-mounted Corian (DuPont, Wilmington, DE) sinks (attached aprons collected standing water) with freestanding ceramic sinks 3. Instituted daily bleaching of all sinks 4. Obtained individual stethoscopes, bandage scissors, and hemostats 5. Removed all stuffed animals from beds 6. Instructed unit secretary/nurse associates on protocol for bedside use and sterilization of instruments between infants 7. Eliminated all food and drink from direct patient care areas 8. Implemented use of Styrofoam containers to warm formula/breast milk with infant's name identified on container		
Yilmaz, Turkey - 2007	CLABSI	The study involved the following 3 periods: pre-education, education, and post-education. In pre-education, patients were monitored daily. During the education period physicians, interns and RNs were trained to prevent catheter-related infection. And during the post-education period, patients were again monitored. Monitoring followed CDC criteria.	HCWs who scored <80 on the post-education test had to be retrained and retested;	Catheter insertion and follow-up activities were observed and corrections were made on the spot. Monthly CLABSI rates were also provided to the healthcare staff;

Appendix Table C3-LQ-c. Intervention characteristics for SSI which do not control for secular trend or confounding

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Acklin, Switzerland - 2011	SSI	When a spike in SSI following hip fracture surgery occurred, the hospital began a bundle intervention. Using evidence from international guidelines, an independent hospital epidemiology team developed internal guidelines, provided continuing education of staff, limited traffic in OR, standardized disinfection of surgical site, observed standard perioperative procedures and provided feedback to staff. An expert in quality improvement was hired to implement the interventions. Infection rate were regularly reported at internal grand rounds.		Infection rates were reported at internal grand rounds. A feedback session for all staff was organized. When one OR nurse had an increased association with SSIs, he/she was instructed separately about the intervention measures.
Awad, United States - 2009	SSI	A MRSA bundle was initiated, which involved: 1) nasal screening of pts at admission, transfer, discharge, 2) contact isolation of positive pts, 3) standardized hand hygiene, 4) cultural transformation campaign with staff and leadership engagement thru positive deviance, and 5) ongoing monitoring of process and outcome measures. To implement this bundle, clinical staff were educated. Outcome measures were tracked on each unit, and data updated monthly. meetings with all staff were held to discuss unit data, including swab rates on admission, transfer, and discharge, # positive pts, and hand hygiene compliance.	The authors cite CMS's consideration of adding MRSA to the list of conditions for nonpayment.	Monthly meetings in each unit were held to discuss swab rates, # positive pts, and hand hygiene compliance.
Berenguer, United States - 2010	SSI	The hospital decided to enroll in the National Surgical Quality Improvement Program (NSQIP). The NSQIP receives the following data from trained nurses of enrolled hospitals: pre-operative risk factors, post-operative occurrences, mortality reports, SSI, and pt statistics. The NSQIP then generates a 12-mon biyearly report in which enrolled hospitals can compare their statistics with each other. When this hospital received their report, they were in the 4th quartile compared to other hospitals. They began using SCIP as a means to improve their outcomes. Nurses and physicians were trained on appropriate antibiotic choice, timing, and duration. Razors were removed from ORs and replaced with clippers. Anesthesiologists and surgeons were educated on post-operative normothermia and body warming devices were made available. Surgeons were alerted to the hospital's high SSI rate and were encouraged to take the lead and become active participants in the quality safety team.	The hospital wanted to improve their statistics in the NSQIP reports, in comparison to the other hospitals.	

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Berry, United States - 2009	SSI	ProvenCare's goal is to deliver evidence-based recommended care to elective CABG pts. A steering committee was formed composed of senior leaders and a process improvement specialist. A cardiac surgeon was assigned within the clinical effectiveness division as the clinical improvement specialist whose role was to facilitate and coordinate the initiative. The initiative had 3 phases: review and validate best practice evidence, redesign processes, and implement new processes. CABG guidelines class I and IIa from American College of Cardiology/American Heart Association were reviewed in a series of consensus-building meetings of all Geisinger cardiac surgeons. This resulted in 19 clinically applicable recommendations and 40 measurable process elements. Those relating to SSI are preoperative antibiotics and tight perioperative glucose control. A multidisciplinary team was formed in each hospital, consisting of a physician, a cardiac physician asst, critical care nurse, OR nurse, cardiac rehabilitation tech, electronic health record programmer, and clinical process improvement specialist. The team assessed current process flows for CABG pts, determined which best practices were already in place, and redesigned the process to incorporate best practices not already in place. The Study-Act-Plan-Do process was used to standardize intra-operative glycemic control. Cardiac surgeons chose 110 mg/dl or greater as the trigger to start insulin infusion. Certified registered nurse anesthetists (CRNA) posted insulin protocol in OR and a daily feedback mechanism was put in place to alert CRNA of adherence. Director of anesthesia reviewed protocol with all anesthesia personnel. Details on system for preoperative antibiotics were not provided. The electronic health record was adopted to include: clinical decision support, care flow maps, and history and physical templates. Performance data on all 40 process measures were continually monitored so that any process defect was quickly identified and immediately redesigned. Within 3 months, 100% reliability of process measures was achieved.	As a part of the existing hospital setting policy physician compensation was tied to physician performance and compliance. Also, all HCW's were made aware that compliance with each of the process elements (as a team and as individuals)would be followed and that real-time feedback would be given so this would affect their performance;	When a lapse in adhering to new process measures occurred, the clinical improvement specialist worked with staff responsible for lapse and reinforced the new process measure.; Real-time feedback was able to be done due to the robust measurement strategy (A standardized abstraction tool that graphically depicts the sequential delivery of care and highlights defects) so any variation or ''failure'' was fed back to the responsible care provider and the improvement team on the day it occurred (as the clinical improvement specialist was notified for each new patient entering the process and the abstracted data tool was in use at a time in parallel to the care being provided);
Carles, France - 2006	SSI	Weekly, the anesthesiologists created lists with pt name, type of surgery, and date of surgery and sent the list to the hospital pharmacy. Pharmacists prepared personalized surgical antibiotic prophylaxis kits (SAPK) with pt name, antibiotic to be given, and instruction sheet specifying dose, times of administration, and duration of antibiotic. SAPKs were delivered to the operating room on the morning of the planned surgery.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Forbes, Canada - 2008	SSI	Three multidisciplinary working groups, one for each bundle, met to design new practice protocols. Members of the depts. of surgery, anesthesia, and perioperative nursing tested the new protocols prior to implementation. The new plans were introduced thru academic rounds and in-services. An OR nurse and a nurse from same-day surgery were study champions, acting as resources to other staff. The antibiotic bundle included: location of antibiotic administration was changed from the admissions unit to the OR. Preprinted, preoperative order forms were designed to standardize the choice of antibiotic. The plan was introduced to attending and house staff during rounds, and to nurses through a series of in-services. Before implementing the previously mentioned interventions, each working group conducted independent tests of change.		Monthly performance figures were posted in the OR.
Gomez, Argentina - 2006	SSI	A multidisciplinary team of pharmacists and infection control personnel developed an automatic stop prophylaxis form which included pt info, surgery info, level of bacterial contamination of surgery, and surgeon name. The form had a checklist for antibiotic recommendations so the physician can check which antibiotic was to be administered. The forms were then sent to pharmacy and every morning, pharmacy checked the forms and stopped the antibiotic prophylaxis if the surgery had been completed. If physician wanted to extend antibiotics, he/she could call pharmacy for extension. Educational programs were presented to different surgical teams, nursing, and pharmacy staff on guidelines and how to use form. Each physician also received a 1 hr one-on-one instruction on antibiotic guidelines so that consensus was reached.		
Graf, Germany - 2009	SSI	When a rising incidence of deep sternal surgical site infections occurred, an infection control team was formed, including cardiac surgeons and nurses, anesthesiologists, technicians, ward physicians and nurses, and members of the infection control dept. The team developed a bundle of prevention strategies to be implemented. The bundle of prevention strategies included using hair clippers instead of shaving, administering antibiotic prophylaxis after 1st venous puncture during operation preparation, use of antiseptic body scrub, and bacterial decolonization measures. A pt-specific information sheet was created describing appropriate infection control measures before cardiac surgery, a standard operation protocol for infection control measures was implemented, and successful application of the infection control measures was documented using a rubber stamp in the pts' files. Frequent education of physicians and residents from participating departments was conducted together, allowing for discussions on the practicality of prevention measures, optimizing the working process. Continuous feedback of SSI rates were provided to staff.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Hermsen, United States - 2008	SSI	An order form for surgical antimicrobial prophylaxis was developed according to published guidelines, the hospital formulary and local prevalence of antimicrobial resistance. It was designed to assist in the choice, dose and duration of use of antibiotics. It also included guidelines for weight-based dosing and alternatives for patients with allergies. The form was made mandatory for all adult, elective, inpatient surgical procedures. Physicians, pharmacists and nurses were educated about the form and the Surgical Infection Prevention (SIP) program via written communication, posters, and presentations. Feedback was given to medical staff throughout the study.		
Ichikawa, Japan - 2007	SSI	Study staff created antibiotic protocols for the management of infections in children. The protocol includes the type of antibiotic, timing of antibiotics and dosing of Antibiotics for different disease/operations for different wound types. The infection control team (ICT) determined the choice of Antibiotics, its route of administration, and duration of use. The pre and intra-operative Antibiotics were administered exclusively by anesthesiologists at tracheal intubation or soon after intubation just before final positioning on the table. This was confirmed by the operating room nursing staff or attending surgeons. If an infection was detected, the ICT advised other staff about the protocols, adequate wound care management, and treatment.		If an infection was identified, a meeting was arranged for the ICT to advise other staff about protocols, wound care, and treatment.
Kable, Australia - 2008	SSI	An interdisciplinary approach was taken to implementing antibiotic prophylaxis measures. Protocols for each surgery type were designed using guidelines, and approved by the Director of Microbiology and Infectious Diseases and the Director of Pharmacy. The protocols were inserted in the medical records of the corresponding pts by the pre-op staff. Staff were educated on the study and the protocols during training sessions.		
Kramer, United States - 2008	SSI	A continuous insulin infusion (CII) order set, was developed in 2004, but nurses found it cumbersome and difficult to use. The form was designed to avoid hypoglycemia. The cardiac team, led by a multidisciplinary quality improvement group, worked with graduate students to devise a new CII. The team focused on the clinical microsystem and nursing workflow. A color-coded nomogram for CII orders which fit on one page, was developed. The group also coordinated weekly intensive in-service sessions that stressed the dangers of hyperglycemia and the lesser dangers of hypoglycemia, and the nomogram was explained and feedback from the frontline users (nurses) was obtained. There was widespread acceptance of the new form by all nurses (OR, cardiothoracic ICU, general ICU), all of which would use the nomogram.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Liau, Singapore - 2010	SSI	A project team was assembled consisting of surgeons, anesthesiologists, OR attendants, OR nurses, post-anesthesia care unit nurses (PACU), ward nurses, and ward physicians. The team identified factors causing SSI and voted for the following factors to work on: antibiotic prophylaxis, hypoglycemia, hair removal, and normothermia. Hair removal: shavers replaced clippers, reminder signs were posted, pts instructed not to shave preoperatively, OR attendants trained to use clippers, and the team worked with the purchasing dept to ensure a continuous supply of clippers. Antibiotic prophylaxis: The Department of Surgery Prophylactic Antibiotic Guideline was developed based on international guidelines, agreed upon by surgeons, pharmacists, and infection control, and distributed to all staff for reference and compliance. Signs and posters on the guideline were posted, and drugs were stocked accordingly. Glucose control: PACU and ward nursing officers were tasked to monitor and control blood glucose concentrations postoperatively. Normothermia: Warmed intravenous fluids, higher temp in OR, and use of warming blankets throughout entire operation were strategies employed. A pilot study was conducted and upon positive results, the full study was implemented. The operation workflow was modified to embed all of these changes.		Following the successful pilot study, hospital leadership spread the news to the rest of the surgical disciplines. Within 2 yrs, other subspecialties (breast, urology, vascular, endocrine, and orthopedics) adopted similar practices.
Martin, United States - 2010	SSI	The following changes in surgical wear were implemented: 1) during stages and reconstruction, staff wore surgical caps to contain hair and no jewelry except smooth wedding rings were allowed, 2) during removal, staff scrubbed with CHG and alcohol and wore sterile gloves and pts draped with sterile towels and sterile dressing applied, and 3) during reconstruction, staff scrubbed with CHG and alcohol and wore sterile gloves and gowns.		
Nemeth, United States - 2010	SSI	One month of education of the anesthesia, nursing and surgical staffs, and the inclusion of the question "Has the antibiotic been administered within the correct time frame?" added to the verification of patient identity, operative procedure, and surgical site during the pre-operative 'time out'.		
Ozgun, Turkey - 2010	SSI	Pre-intervention data was collected on antibiotic prophylaxis use. This data was analyzed and shared with physicians and residents. General and branch meetings were held to educate the surgeons, residents, and nurses on antibiotic prophylaxis. Topics discussed included choice of antibiotic, timing of administration, and duration. Specific problems and misuses that were detected in the pre-intervention data were discussed separately within each branch. If surgeons could not attend meetings, they were caught up to the study individually. Guideline documents were distributed to staff and posters were hung around the hospital.		Misuses of antibiotics detected in the pre-intervention data were discussed separately within each surgery branch.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Parker, United States - 2007	SSI	The Six Sigma approach is a data-driven, quality improvement methodology developed by Motorola and improved by GE. It is used to improve outcomes by reducing process variability. A 10-member multidisciplinary team consisting of physician process champions, nurses, a hospital epidemiologist, and an outcome administrator were assigned a 3M "black belt" mentor responsible for team building and overall project management. All team members participated in a two month Six Sigma "green belt" training to learn the tools and concepts necessary to begin this quality improvement project. A process map was made to help outline the critical steps involved in increasing compliance with antibiotic prophylaxis. The intervention aimed to reinforce use of standardized preoperative order forms, eliminate administration of antibiotic prophylaxis in the surgical admissions preoperative area, and send antibiotics and IV tubing to the OR. A 1 week education program preceded the beginning of the project. The education program targeted all clinicians that might interact with the patient. In 2005, an electronic anesthesia record keeping system (ARKS) was instituted in the main ORs. ARKS acts as a decision support tool to remind the anesthesia provider to administer the antibiotics at an optimal time. ARKS also displays a reminder to give a second dose if the first dose was given >60 min prior to incision.		
Pastor, United States - 2010	SSI	A multidisciplinary task force was convened to implement changes and monitor compliance with SCIP process measures. The task force consisted of surgeons, anesthesiologists, infection control personnel, and intra-operative nurses. The committee identified and assisted in overcoming the following obstacles: obtaining certain antibiotics inside operating room, availability of warming blankets in preoperative area, tracking of temp and glucose readings in nursing and recovery room flow sheets. The task force also provided in-service education for all staff on the SCIP process measures.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Paull, United States - 2010	SSI	The NCPS initiated a Medical Team Training (MTT) Program in VHA hospitals. In each facility, a nurse educator from NCPS worked with a hospital leader (chief of surgery, nurse manager) to develop a plan for preoperative briefing and postoperative debriefing. Instructors from NCPS then held learning sessions for physicians, nurses, residents, and allied health care personnel working in the OR, post-anesthesia care unit, ICU, and surgery clinics. In addition to providing instruction on pre-operative briefings and post-operative debriefings, the sessions also gave examples of checklists. Over 12.000 providers underwent training. Each facility developed their own checklist, using either paper, slider board, poster, whiteboard, electronic, or other. One item on the checklist was a reminder to administer antibiotic prophylaxis within 60 min of incision. Prophylactic antibiotic use was then reviewed retrospectively in 45 +/- 7 charts/facility pre checklist and in 33 +/- 6 charts/facility post checklist.		
Potenza, United States - 2009	SSI	In response to SCIP guidelines, a team consisting of members from each specialty, as well as nursing and pharmacy, convened. A lead performance improvement nurse and a data analyst were designated for technical and logistical organization, data abstraction, and analysis. The team core met monthly to review data and the whole team met quarterly. Charts were reviewed for compliance with 9 SCIP guidelines. The team identified barriers to compliance with antibiotic prophylaxis, normothermia, appropriate hair removal, and glucose control. First, they educated all staff on the project and the goals and emphasized the need to standardize their approaches to basic surgical issues. Next, methods to address the 9 SCIP guidelines were developed. The methods covered 3 main areas: people, process, and systems. To improve antibiotic prophylaxis compliance, there was a gradual agreement among key surgical personnel on antibiotic selection and a standard policy for timing of administration was set. The pharmacy created a system to deliver approved antibiotics and anesthesia stocked them on carts. Surgical house staff and faculty were given laminated cards with SCIP guidelines including antibiotic choices. ORs also have antibiotic listings for quick reference. Anesthesiologists, responsible for administering antibiotics, were empowered to question antibiotic choice, and the anesthetic worksheet was revised to include SCIP guidelines, which improved documentation.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Rauk, United States - 2010	SSI	A team consisting of administrators, staff, physicians, and infection control personnel met to identify potential causes of SSI after cesarean deliveries. Next the team developed a preoperative skin preparation protocol. The new protocol included using 2% CHG clothes preoperatively on all pts undergoing c-section as well as all pts with prolonged labor or other risk for c-section. The clothes were no-rinse. Staff were instructed on use of the clothes, proper attire, room setup, skin coverage, and sterile technique. A video was made to demonstrate these techniques and a knowledge assessment tool was developed. The team also developed a quick reference sheet on the clothes. Flash sterilization of instruments was eliminated. All sterilization was done at central surgical supply and availability of enough surgical instruments was provided so that flash sterilization was no longer necessary.		Following educational instruction, a knowledge base assessment tool ensured the staff understood the instructions.
Shimoni, Israel - 2009	SSI	The epidemiology nurse and hospital's infections disease consultant persuaded heads of obstetrics and anesthesia departments to empower 6 operating room nurses to ensure that the 13 anesthesiologists give 1g or 2g of cefazolin (1 g if under 80 kg weight and 2 g if 80 kg or more) after cord clamping of caesarean births.		
Suchitra, India - 2009	CAUTI;SSI	An education program was conducted at the respective hospitals by a trained microbiologist. Small groups comprising of 10-15 staff were allowed to attend the education program, which extended for 2.5 to 3 h and was conducted as two sessions for the sake of convenience. It was conducted during the duty hours of the staff. The topics covered were hand washing, waste disposal, skin disinfection, universal precautions, hospital-acquired infections and prevention of infections. The sessions were interactive and the HCW were encouraged to ask questions.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Takahashi, Japan - 2010	SSI	An antimicrobial stewardship team from the department of Infection Control and Prevention consisting of an infection control doctor and certified pharmacist prepared manuals with a physician from each department and chief surgeons in each department on the appropriate use of antimicrobial prophylaxis. The appropriateness of AMP was determined by the "Guideline for prevention of SSI, 1999" established by HICPAC and "Guidelines for implementation of clinical studies on surgical antimicrobial prophylaxis (2007)". A manual was created for each of the 15 surgical departments outlining the correct use of antimicrobial prophylaxis (AMP). Nurses administered AMP in the pre-intervention period under the direction of a surgeon while an anesthesiologist administered AMP in the operating suite during the post intervention period. After the post-intervention period, each department received feedback of its AMP data discussed with surgeons, anesthetists, pharmacists, microbiologists and nurses. Educational meetings were organized for medical staff. Persons implementing feedback and educational meeting were not specified.		Study staff provided feedback of AMP data to departments surgeons, anesthetists, pharmacists, microbiologists, and nurses
Wax, United States - 2007	SSI	an interactive visual reminder for prophylactic antibiotic administration was activated in the anesthesia information management system (AIMS) in nearly all anesthetizing locations. An event icon with the wording "Prophylactic Antibiotics Given" would appear between the "Position/Prep Start" and "Procedure/Surgery Start" icons. The event icon could then be acknowledged or ignored.	The surgical Care Improvement project mandate to publicly report surgical antibiotic selection/timeliness and pay-for-performance initiatives by payers as well as accrediting organizations and competitive forces in the market place were noted as motivating factors to increase compliance.	Practitioners with low compliance rates were interviewed. It was found that some had custom AIMS configurations that suppressed the antibiotic reminder and some felt that it was redundant to have to document seeing the reminder as well as document the actual administration of the antibiotic.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Whitman, United States - 2008	SSI	The hospital-wide Performance Improvement Committee reviewed hospital-specific data and challenged the university surgical faculty to improve compliance with antibiotic prophylaxis guidelines. In spring 2005, surgical chairs began developing a protocol for antibiotic selection for operations performed in their respective departments. In January 1, 2006 they then implemented a surgical scheduling order form in which specialty-specific antibiotic prophylaxis was listed on the physician form to aid in the appropriate selection of antibiotics. In July 2006, the Temple University Hospital (TUH) adopted a policy mandating physician admission orders be available to the preadmission testing area (PAT) a the time of preadmission appointment to ensure orders for antibiotics were on the chart the day of admission. From Sept. 2006 through November 2006 TUH required administration of prophylactic antibiotics before the patient could leave the preparation and hold area. From December 2006 to June 2007, the Department of Anesthesia assumed responsibility for administering ordered antibiotic prophylaxis in the operating suite at the time of "universal timeout". In order to promote timely cessation of antibiotic prophylaxis, the hospital's associate director for perioperative services (first author) educated residents and faculty at each of the department's routinely scheduled monthly resident educational meetings. In September 2006, a separate pathway for ordering "prophylactic antibiotics" was added to the electronic medical record, although the pathway could be bypassed. Hospital reports were reviewed monthly by the TUH SCIP committee and also presented at the operating room executive committee meeting.	Surgical Care Improvement Project requiring all Medicare participating hospitals to report specific data about antibiotic prophylaxis	Data acquisition was overseen by the medical record abstractors' director (coauthor) and reports reviewed by the TUH SCIP committee
Willemsen, Netherlands - 2007	SSI	This hospital was founded after a merger of 3 hospitals, and different antibiotic guidelines from before the merger were used by different staff. A multidisciplinary team of microbiologists and pharmacists created a standardized guideline which was approved by all surgeons and anesthetists. The guideline included information on antibiotic choice, dosage, and timing. The project coordinator educated all staff involved in perioperative antibiotic prophylaxis, which included nurses, pharmacy assistants, and anesthesia technicians. All antimicrobials in supply closets were switched in the ORs and on the wards, to only those recommended in the guideline.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Zvonar, Canada - 2008	SSI	Following the baseline audit a multidisciplinary team was formed. The team recommended that antibiotics be given at time of anesthesia administration. To facilitate delivery, in June 2003, pre-mixed pre-op doses of antibiotics were sent to the OR with the patient's chart and were also made available in the OR suites. Also patients with BMI>30 or weight>90kg, received a larger dose of antibiotics. The surgeon was to confirm that antibiotic prophylaxis was administered prior to incision. Antibiotics were also to be given intra-operatively for surgeries >3-4 hours. The second audit in 2004 showed some barriers so changes to the protocol were made. Nurses and pharmacists were allowed to automatically substitute larger doses for patients with BMI>30 or weight>90kg. Antibiotic prophylaxis was also added to the pre-op checklist. A list of surgeries requiring prophylaxis and recommended agents was created. Allergy and cross-allergy education also took place. In March 2005, a pre-op time out was implemented. This was used to verify that the patient, procedure, and surgical site were all correct as well as to ensure antibiotic prophylaxis was administered.		The data from the audit was used to make changes to the protocol.

Appendix Table C3-LQ-d. Intervention characteristics for CAUTI which do not control for secular trend or confounding

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	Patient-based NI surveillance protocol adapted from the Hospitals in Europe Link for Infection Control through Surveillance (HELICS) was used. Patients in the units were assessed by physicians on duty, and standard data collection form was filled out. The multimodal intervention (i.e. an infection control program) was designed depending on the NI surveillance data analysis in the control group and the data gathered from the evaluation form of NI prevention methods. The intervention included education of the ICU staff (6 hours) about NI prevention and implementation or correction of daily routine procedures, according to the evidence-based recommendations. Prevention of bloodstream infection •Emphasize hand washing for ICU staff, consultants, and parents •Use only single use towels in the ICU •Educate health-care workers regarding the indications for intravascular catheter use, proper procedures for the insertion and maintenance of intravascular catheters, and appropriate infection control measures to prevent intravascular catheter-related infections •Use of gloves does not obviate the need for hand hygiene •Record the operator, date, and time of catheter insertion and removal, and dressing changes on a standardized form •Observe hand hygiene before and after palpating catheter insertion sites, as well as before and after inserting, replacing, accessing, repairing, or dressing an intravascular catheter •Encourage patients to report to their health care provider any changes in their catheter site or any new discomfort •Maintain aseptic technique for the insertion and care of intravascular catheters •Wearing clean gloves rather than sterile gloves is acceptable for the insertion of peripheral intravascular catheters if the access site is not touched after the application of skin antiseptics. Sterile gloves should be worn for the insertion of arterial and central catheters •Wear clean or sterile gloves when changing the dressing on intravascular catheters •Do not routinely use arterial or venous cutdown procedures as a method to insert catheters		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
		•Leave peripheral venous catheters in place in children until IV therapy is completed, unless complications (e.g. phlebitis and infiltration) occur •When adherence to aseptic technique cannot be ensured (i.e. when catheters are inserted during a medical emergency), replace all catheters as soon as possible and after no longer than 48 hours •Replace catheter-site dressing if the dressing becomes damp, loosened, or visibly soiled •Consider reduction of CV catheter utilization		
Gokula, United States - 2007	CAUTI	6 educational sessions were held by the PI for all the ED staff. These focused on baseline rates, appropriate use of indwelling catheters, and the problems associated to overuse. The nursing director also held weekly sessions to educate and remind the nurses about appropriate use during this time period. A urinary catheter indication sheet (UCIS) was created and attached to the catheter trays. It was a list of the acceptable indications for catheter use and nurses were asked to fill it out before inserting catheters. ED staff was also reminded at weekly department meetings about the UCIS. The sheets were collected weekly by the PI.		The educational sessions began with a presentation of the baseline rates.
Jain, United States - 2006	CAUTI; CLABSI; VAP	Physician led multidisciplinary rounds were initiated in October 2002. The team included in these rounds consisted of the patient's nurse, ICU charge nurse, pharmacist, dietician, respiratory therapist, case manager, social worker, physical therapist, and palliative care nurse. This team would set daily goals and use trigger tools to define adverse ICU events. Daily bed flow meetings were also implemented which happened twice daily. They were 20 minutes long and discussed facility status, intervention priorities, historical data, and daily goal setting. The meeting was led by the administrative house supervisor. After October 2002 bundles for VAP, CLABSI, and CAUTI were implemented. The bundles were developed using published guidelines, CDC recommendations, and local staff recommendations. Feedback was provided to the physicians.	Intensivists were reimbursed for doing rounds.	Feedback was provided to physicians.

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Rothfeld, United States - 2010	CAUTI	Nurses were educated on the use of superabsorbent adult diapers and pads. A wound care nurse was conferred with for patients with decubitus ulcers. This nurse had the authority to advise physicians to replace the urinary catheter. Indications for catheter use were made clear and if a patient had none of these indications then a request was submitted to the physician to discontinue the catheter use.		
Stephan, Switzerland - 2006	CAUTI	Multifaceted, multidisciplinary intervention that combined tailored, locally developed guidelines, education sessions and posters with a visual display of the guidelines. The guidelines outlined criteria for the placement and management of urinary catheters in the operating room, post-anesthesia care unit and surgical ward. These guidelines were approved by the orthopedic department chair, senior nurses, and senior anesthetists of our institution. Rotating resident anesthetists were individually instructed. After an educational presentation on the epidemiology and prevention of UTI, guidelines were endorsed by nursing staff. Additional information was also given individually to nurses and physicians upon request. A4-format posters illustrating the guidelines and endorsed by the orthopedic department senior staff (department chair, senior nurse, and chief anesthetist) and the hospital infection control program director were displayed in all operating rooms dedicated to orthopedic procedures, the post-anesthesia care unit and orthopedic nursing staff offices.		
Suchitra, India - 2009	CAUTI;SSI	An education program was conducted at the respective hospitals by a trained microbiologist. Small groups comprising of 10-15 staff were allowed to attend the education program, which extended for 2.5 to 3 h and was conducted as two sessions for the sake of convenience. It was conducted during the duty hours of the staff. The topics covered were hand washing, waste disposal, skin disinfection, universal precautions, hospital-acquired infections and prevention of infections. The sessions were interactive and the HCW were encouraged to ask questions.		

Study	Infection	Intervention Specifics	Positive or Negative Incentives	Feedback or consequences given to interveners/intervenees
Venkatram, United States - 2010	CAUTI;CLABSI;VAP	The HHC collaborative was comprised of participating institution's medical directors, nursing directors, chiefs of medical and surgical departments, directors of critical care units, and respiratory therapy and nursing supervisors. The directors of critical care met monthly and emphasized the use of the bundle strategies. Data from the participating hospitals was shared both on the critical care collaborative website as well as during learning sessions. Focused learning sessions were conducted by intensivists periodically. The MICU director served as the champion and held monthly sessions for all ICU staff to reinforce the procedures involved in the bundled approach. Nurses collected compliance data and shared it with the MICU team at the performance improvement committee meetings. Data was also shared with other HHC hospitals. 'Zero Infection Rate' certificates were given by the infection control staff monthly as positive feedback. A CAUTI bundle was implemented in January 2005. It included daily assessment of need, sterile technique when inserting, and use of silver-coated catheters. In addition nurses monitored for breaches in infection control. The MICU nurse was also empowered to stop a procedure if there was a deviation from the recommendations. Evaluation of the necessity of the urinary catheter was integrated into the daily goals and discussed at bedside rounds daily.		The ICU was awarded monthly 'Zero Infection Rate' certificates based on outcomes by the infection control staff. Nurses collected compliance data and shared it at the MICU performance improvement committee meetings.
Wald, United States - 2011	CAUTI	An educational program was developed for and delivered by the principal investigator to the nursing staff (1/2 hour CE credit, a brain-storming session, and brief evaluation of the session followed). Following an audit of postoperative urinary catheter duration, feedback was given to each unit's nursing staff.	1/2 hour CE credit for nurses attending the educational program	Following an audit of postoperative urinary catheter duration, feedback was given to each unit's nursing staff

Appendix Table C4-LQ-a. Study context for VAP which do not control for secular trend or confounding

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Abbott, United States - 2006	VAP	Southwestern United States/	Hospital 2 had added a dentist and dental hygienist to their team and may have contributed to the significant increase in oral care adoption while Hospital 1 did not see much of a change.	The researchers used the ACE star model, PRECEDE-PROCEED model, and diffusion of innovation model to develop the protocol in this study.			A multidisciplinary education team was developed and consisted of clinical nurse specialists, staff physicians, infection control officers, staff nurse team "champions," critical care educators, respiratory therapists, and unit clinical staff as process facilitators.	
Assanasen, - 2008	CLABSI;VAP	Richmond, VA/820 bed hospital		Literature suggests that medical practitioners are more likely to change their behavior if they have received feedback			Infection control professionals were responsible for observing compliance and providing feedback. Nurses were responsible for HOB elevation while nursing directors oversaw compliance of this. CVCs were done by house staff and monitored by the attending physician.	
Berriel-Cass, United States - 2006	CLABSI;VAP	Detroit, Michigan/607 bed hospital	Physician support was greater for the CLABSI center than the VAP center.			Ascension Health issued a call to action for decreasing preventable injuries among patients of their hospitals. Hospital participated in the IHI Critical Care Collaborative.	ICPs helped with educating the ICU staff. Nursing champion was defined as a nurse well known in the ICU who was involved in training nurses on his or her unit on using the checklist to document the correct placement of central	Physician champions are available if problems occur between operator (physician) and nursing. The hospitals used a system wide website to share their

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
							catheters and was responsible for compliance with the checklist on all lines placed. The unit nurse manager acted as the nurse champion and supported the nurses' stopping of the procedure at any time if the physician was not complying with the established protocol. The physician champion was chosen based on being well known in the ICU, being involved in training residents for catheter placement, directing in-services for resident physicians (medical and surgical) on appropriate line placement and the use of the tool, and serving as a contact person if problems occur between operator (physician) and nursing.	experiences, educational materials, and tools they developed with other Ascension Health hospitals.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Berriel-Cass, United States - 2006	CLABSI;VAP	Birmingham, Alabama/338 bed hospital	VAP hospital does not have an intensivist program, most patients on mechanical ventilation are managed by pulmonary physicians. VAP hospital had less physician support.			Hospital participated in the IHI Critical Care Collaborative.	Multidisciplinary rounds team consisted of nursing staff, pharmacy, infection control, case management, social workers, dietary, respiratory, chaplain, transporters, quality managers, and a representative from CVICU, who would eventually spread the process changes to that unit. Charge nurses educated the staff on their various shifts. Nurses were asked to document compliance and discuss at the MDR daily meetings.	Complete oral care kits for every two hours of care were placed in the patients room each morning. The hospitals used a system wide website to share their experiences, educational materials, and tools they developed with other Ascension Health hospitals.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Bigham, United States - 2009	VAP	Cincinnati, OH/475 bed hospital		The respiratory therapists and nurses used rapid cycle tests of change (Plan-Do-Study-Act) to establish the best methods to achieve high reliability compliance for each bundle component. This cycle promoted ownership and buy-in to the project by the bedside practitioners.		Authors mention HAIs as a means of disqualifying providers from receiving Medicaid or Medicare reimbursements.	A VAP Prevention Collaborative was established to oversee the changes to decrease VAP rates. The collaborative included physicians, nurses, respiratory therapists, infection control staff, and quality improvement consultants.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Bird, United States - 2010	VAP	Boston, MA/626 bed hospital	TICU had a higher VAP rate than the SICU before the intervention. The authors attribute this to the higher risk of VAP in trauma patients. The TICU had a higher rate of compliance the SICU. The authors say this may be due to the fact that the TICU staff initiated the VAP bundle project.		A handwashing campaign, blood glucose control protocols, a chlorhexidine gluconate mouthwash protocol, and continuous aspiration of subglottic secretions were also being implemented.	CMS is no longer reimbursing HAI-related costs.	Respiratory care service was responsible for measuring compliance to the bundle. The infection control team was in charge of diagnosing VAP. Daily assessment of bundle goals and order entry took place by the multidisciplinary team which was comprised of physicians, NPs, SICU nurses, and pharmacists. SICU nurses were responsible for HOB elevation and sedation breaks.	
Blamoun, United States - 2009	VAP	Paterson, New Jersey/750 bed hospital, 18-beds in MICU.			Existing infrastructure (see intervention specifics for full list) was maintained at baseline and enforced in study	Institute for Healthcare Improvement's "100,000 Lives Campaign"	The laboratory technician provides a prompt verbal alert to the nurse caring for the patient on the detection of any pathogens; Respiratory therapists maintained a specialized protocol for procedures. Nurses were involved in procedures however it is not clear as to specific duties.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Bloos, Germany - 2009	VAP	Jena, Germany/50 bed surgical ICU			Handwashing before dealing with patients, daily oral care, and sterile tracheal suctioning were already in place in critical care areas of the hospital.		The change team was made up of the ICU manager, ICU consultants (physicians), and interested ICU residents and nurses. Change team designed educational program, conducted the audits, and supplied feedback.	
Cocanour, United States - 2006	VAP	Houston, TX/690 bed hospital	The STICU nursing staff turnover decreased from 22% in the baseline period to 4% in the follow-up period.		Infection control practitioner (ICP) monitored HAIs in the unit a few times a week.	The hospital had joined the IHI and Voluntary Hospital Association (VHA) efforts to improve ICU care.	The multidisciplinary team included the hospital's director of performance improvement, STICU medical director, infection control practitioner assigned to the STICU, the STICU PharmD, the STICU respiratory supervisor, the STICU nursing director, the STICU nursing manager, and senior nursing leaders from all shifts. After the start of the study the ICP began monitoring infections daily. A tight glucose control project was also taking place in the STICU during this study.	Infection control practitioner, nursing manager or senior nursing leaders were in the ICU on a daily basis and available for clarification of expectations and positive reinforcement. The STICU Infection Control Guidelines were published and made available to the STICU staff.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Garcia, United States - 2009	VAP	Brookdale, New York/427 bed hospital			Existing standard QI procedures included: Changes in the ventilator circuit every 7 days, replacement of the heat moisture exchange filter every 24 hours, closed suction catheter changes every 24 hours (suctioning performed every 2 hours or as needed), use of a 30º semi-recumbent positioning protocol when medically feasible, administration of stress ulcer prophylaxis, and use of an active weaning protocol. Compliance with these interventions for the full study period ranged from 90% to 100%.		The VAP Prevention Task Force was a multidisciplinary team comprised of nursing and physician staffs of the MICU, nurse educators, anesthesiologists, and staff from the emergency, materials management, and performance improvement departments. Nurses were responsible for carrying out the oral care protocol. Infection control professionals conducted staff interviews and observations of practice to identify barriers as well as conducted the education programs.	
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	Kuanas, Lithuania						

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Heimes, United States - 2011	VAP	Kansas City, KN/				The authors discuss that the reduction in Medicare reimbursement made the study worthwhile.	The study reappropriated responsibilities to existing staff members. The IC officer and ICU case manager were used to track compliance and diagnose VAP. The physicians were not allowed to contest the VAP diagnosis.	
Jain, United States - 2006	CAUTI;CLABSI;VAP	DeSoto, MS/28 ICU beds			Hospital administration and nursing leadership pushed for quality improvement initiatives in 2003. No specifics are given.	The hospital joined the IHI project to improve patient safety and outcomes	The house supervisor was relieved of some of her duties with bed flow through the bed flow meetings. Physicians took a more active role in daily patient care through leading the multidisciplinary rounds.	
Jimenez, United States - 2009	VAP	San Juan, Puerto Rico/232 bed hospital					Deep vein thrombosis prophylaxis was already a high priority in the NSICU.	
Landrum, Afghanistan - 2008	VAP	Air Force Theater Hospital in Iraq/					The infectious disease physician inspected the facility and provided education and reinforcement when needed.	Forms tracking compliance with new practices were added to the patient charts.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Quenot, France - 2007	VAP	Dijon, France/11 bed medical ICU			VAP bundle was already being used (Oral care, HOB elevation, hand hygiene)		The multidisciplinary team consisted of physicians and nurses and were in charge of developing the protocol and training the staff. Nurses were now given more responsibility and control over managing patients' sedation level.	
Rogers, Ireland - 2010	CLABSI;VAP	Northern Ireland/53 ICU beds in total	There was a very wide range in staffing (3 units were under-staffed) and bed occupancy (58%-132%). The authors note that these are both associated with increased infection rates and these differences may have led to the non-significant changes in infections rates.				The authors note partnering with lead medical staff, nurse managers, Advanced Neonatal Nurse Practitioners, infection control teams, lab staff, and the regional Neonatal Nursing Benchmarking Group was key to the success of this project.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Rosenthal, Argentina - 2006	VAP	Buenos Aires, Argentina/330 bed hospital			Infection Control Department already existed. A vigorous campaign for hand hygiene was also in place during the study.			
Ross, United States - 2007	VAP	Winston Salem, NC/854 bed hospital			Oral care products were already being stocked in the hospital, but not being utilized by the staff.		Critical care nurse specialists trained the educators and also provided the education program in some of the units. They were also in charge of providing feedback to the nurses and CNAs.	The storyboards were posted on the hospital's intranet to increase accessibility.
Sona, United States - 2009	VAP	St. Louis, MO/1344 bed hospital			During both the control and intervention period the hospital had implemented the CDC Guidelines for Preventing Healthcare-Associated Pneumonia.		CNSs were given the ability to audit oral care orders and make sure nurses were implementing the protocol on eligible patients.	The pictorial of the oral care technique was laminated and posted at every patient's bedside.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Venkatram, United States - 2010	CAUTI;CLABSI;VAP	New York, New York/20 ICU beds		Their model was based on the SMART (Specific, Measurable, Achievable, Relevant, and Time-bound) approach. Authors note this theory may have contributed to the consistent and sustained change and decline in HAIs.		The hospital was a part of the Health and Hospital Corporation network.	The HHC collaborative was comprised of participating institution's medical directors, nursing directors, chiefs of medical and surgical departments, directors of critical care units, and respiratory therapy and nursing supervisors. The MICU director served as the champion and held monthly sessions about the importance of bundles. MICU nurses were given the following responsibilities: collecting compliance data, completing the CLABSI bundle checklist, stopping a procedure if there was a deviation from the recommendations, and monitoring for any breaches in infection control.	Data from all participating hospitals was available on the critical care collaborative website.

Appendix Table C4-LQ-b. Study context for CLABSI which do not control for secular trend or confounding

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Assanasen, - 2008	CLABSI;VAP	Richmond, VA/820 bed hospital		Literature suggests that medical practitioners are more likely to change their behavior if they have received feedback			Infection control professionals were responsible for observing compliance and providing feedback. Nurses were responsible for HOB elevation while nursing directors oversaw compliance of this. CVCs were done by house staff and monitored by the attending physician.	
Berriel-Cass, United States - 2006	CLABSI;VAP	Detroit, Michigan/607 bed hospital	Physician support was greater for the CLABSI center than the VAP center.			Ascension Health issued a call to action for decreasing preventable injuries among patients of their hospitals. Hospital participated in the IHI Critical Care Collaborative.	ICPs helped with educating the ICU staff. Nursing champion was defined as a nurse well known in the ICU who was involved in training nurses on his or her unit on using the checklist to document the correct placement of central catheters and was responsible for compliance with the checklist on all lines placed. The unit nurse manager acted as the nurse champion and supported the nurses' stopping of the procedure at any	Physician champions are available if problems occur between operator (physician) and nursing. The hospitals used a system wide website to share their experiences, educational materials, and tools they developed with other Ascension Health hospitals.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
							time if the physician was not complying with the established protocol. The physician champion was chosen based on being well known in the ICU, being involved in training residents for catheter placement, directing in-services for resident physicians (medical and surgical) on appropriate line placement and the use of the tool, and serving as a contact person if problems occur between operator (physician) and nursing.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Berriel-Cass, United States - 2006	CLABSI;VAP	Birmingham, Alabama/338 bed hospital	VAP hospital does not have an intensivist program, most patients on mechanical ventilation are managed by pulmonary physicians. VAP hospital had less physician support.			Hospital participated in the IHI Critical Care Collaborative.	Multidisciplinary rounds team consisted of nursing staff, pharmacy, infection control, case management, social workers, dietary, respiratory, chaplain, transporters, quality managers, and a representative from CVICU, who would eventually spread the process changes to that unit. Charge nurses educated the staff on their various shifts. Nurses were asked to document compliance and discuss at the MDR daily meetings.	Complete oral care kits for every two hours of care were placed in the patients room each morning. The hospitals used a system wide website to share their experiences, educational materials, and tools they developed with other Ascension Health hospitals.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Bhutta, United States - 2007	CLABSI	Arkansas Children's Medical/292 bed children's tertiary hospital					Multidisciplinary team consisted of a group of pediatric clinicians including the director of infection control, critical care nurses, infectious diseases specialists, and critical care medicine physicians. The hospital's medical director served as a senior leader and advocate for this project. The multidisciplinary group identified the problem, created a data collection system to measure baseline performance and ongoing improvement, and created a data reporting system that allowed all stakeholders to understand the extent of the problem and gauge the effects of changes in practice. Infection control staff reported quarterly data to the nursing and medical directors of the unit.	Trolleys with supplies for insertion or other invasive procedures were available at patients bedsides and restocked by technicians.
Bizzarro, United States -	CLABSI	Yale, New Haven/54 Bed Level IIIc NICU			Participation in the National Healthcare Safety	Participation in the National Healthcare Safety	Multidisciplinary team comprised of 20 representatives	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
2010					Network.	Network (They were required to report rates at certain times and compare them with benchmarks and once they reviewed the comparisons they formed a committee to start intervention).	(physicians, neonatal nurse practitioners, physician assistants, registered nurses, and a hospital infection control practitioner) was formed for the training of fellows. Multidisciplinary team representatives inspected dressings and addressed deviations from protocol with individual staff members. A physician and 2 nurses, who would be present in the NBSCU during both daytime and nighttime hours, were identified to lead the effort. During patient rounds daily discussions were undertaken concerning the duration of time a CVC had been in place and whether its use was still vital.; Fellows who are formally trained may independently perform and assist in the training of incoming personnel.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Galpern, United States - 2008	CLABSI	Brooklyn, New York/628 bed hospital				The hospital was a part of the Greater New York Hospital Association Quality Improvement Collaborative.	The multidisciplinary team included the Head of the Surgical ICU as the team leader, nurse managers from the ICU, and 2 infection-control nurses. Data were collected by a trained, hospital based infection-control practitioner. Nurses were now asked to help with placement of CVCs.	
Guerin, United States - 2010	CLABSI	Denver, CO/10-bed MICU; 13-bed SICU			The CVC insertion bundle (without the post-insertion care bundle) had already been implemented since 2006. There were also other standard infection control practices ongoing at the time of the study intervention implementation.		An IV team was assembled to provide insertion and site care of PICCs as well as monitoring of site care and dwell time of all IV catheters throughout the hospital.	
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	Kuanas, Lithuania						

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Jain, United States - 2006	CAUTI;CLABSI;VAP	DeSoto, MS/28 ICU beds			Hospital administration and nursing leadership pushed for quality improvement initiatives in 2003. No specifics are given.	The hospital joined the IHI project to improve patient safety and outcomes	The house supervisor was relieved of some of her duties with bed flow through the bed flow meetings. Physicians took a more active role in daily patient care through leading the multidisciplinary rounds.	
Jeffries, United States - 2009	CLABSI	>10 locations in the United States/26 hospitals						
Koll, United States - 2008	CLABSI	New York/36 hospitals; 56% had 400 beds, 22% had 300-399 beds, 19% had 200-299 beds, 3% had < 200 beds.	Compliance with CLAB bundle;			In 2005 the Greater New York Hospital Association board of governors became industry leaders in supporting the public reporting of HAI's.	Materials management staff played a pivotal role in implementing the hospitals' all-inclusive central-line insertion kits. In this sense, the collaborative broke new ground by including materials managers as an essential part of the quality improvement team. Hospital leadership committed to and played an active role in trying to achieve the theoretical limit of "zero" tolerance for CLABs.; Change from individual 'infection practitioner'	Hospital teams encountering resistance from physicians and other clinicians relied on the "expert-on-call," (an infectious disease physician consultant) to provide guidance and customized solutions, as well as to educate clinicians about reasons for practice changes and CLABs bundle adoption. Within the first year this

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
							to multidisciplinary team containing ICU physicians, nursing staff, ICPs, representatives where central-lines were placed.	“expert-on-call” also made site visits at 3/4 of the hospitals to help out and be available. ; Collaborative web-site with interactive forum available to share information, ask question, share technical resources, and retrieve immediate responses from peers on central-line best practices.
Lobo, Brazil - 2010	CLABSI	Sao Paulo, Brazil/1 hospital with 2 ICUs participating		Increased education on catheter infection control practices will reduce the rate of CLABSI infection and increase adherence to these practices.				
Marra, Brazil - 2010	CLABSI	Sao Paulo, Brazil/One 38-bed med-surg ICU and two 20-bed SDU’s			CDC Guidelines for adhering to skin antisepsis and sterile barrier precautions when inserting CVC		In phase 1 and 2, attending physicians (eg, surgery doctors), ICU doctors, or ICU medical residents	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
							inserted the catheters through a new venipuncture, into the subclavian, jugular, or femoral vein using full sterile barrier precautions and 2% chlorhexidine preparation for skin antisepsis per CDC guidelines. Decision to remove catheter was made solely by the patient's physician. Phase 2: central line bundle was monitored everyday by ICU and SDU nurses and doctors. The ICU and SDU nurses intervened in this process at the same time that performance monitoring was occurring at the bedside if noncompliance with an element of the bundle was detected. Implementation of an ICU doctor's group to remove the unnecessary catheters every day. Once a day, an ICU doctor (not on clinical duty) checked all the ICU patients with	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
							central lines and asked the ICU doctors (on duty) if each central line was necessary. The same strategy was performed in the SDUs, except in these units there were nurses who questioned SDU doctors (on duty) about central line necessity.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Render, United States - 2006	CLABSI	Metropolitan area of Cincinnati/9 hospitals with 21 ICUs		Team used work-learning-reporting cycles to problem solve and find effective strategies.	The Greater Cincinnati Health Council (GCHC) represented 35 hospital members and members of the council's patient safety and pharmacy work groups standardized implementation of surgical site marking and abbreviation use in medical orders and records.	The Greater Cincinnati Health Council (GCHC) asked for commitment from 9 healthcare systems to fund a project to reduce HAIs.	The project leaders organized the work-learning-reporting cycles at each site which included at minimum one test of change every month and met monthly with project leadership and reported their experience using presentation slides in small groups to share effective strategies, solve problems together, etc. The nursing manager of the intervention ICU was part of the project team at each hospital. The hospital committees at the senior leadership level also approved written policies to promote sustained practice change. The infection control practitioner was often times the project lead within the hospital.	CVC insertion checklist and the "accessory pack" (large drape, cap, mask, sterile gown and glove) - both placed within the central line cart - were available.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Rogers, Ireland - 2010	CLABSI;VAP	Northern Ireland/53 ICU beds in total	There was a very wide range in staffing (3 units were under-staffed) and bed occupancy (58%-132%). The authors note that these are both associated with increased infection rates and these differences may have led to the non-significant changes in infections rates.				The authors note partnering with lead medical staff, nurse managers, Advanced Neonatal Nurse Practitioners, infection control teams, lab staff, and the regional Neonatal Nursing Benchmarking Group was key to the success of this project.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Sannoh, United States - 2010	CLABSI	Westchester Medical Center, New York Medical College/50-bed NICU		CVC hub infections occur at the insertion site and disinfection of all vascular hubs, needleless connectors, injection ports before access, and adherence to sterile technique will reduce the incidence of CLABSI infection.			Hand hygiene campaign	Educational DVD made available on the NICU Web site for the health care team to view at any time. A CVC care cart was placed in each room to facilitate ready access to cleaning materials. Catheter hub care checklists were at every bedside to remind the health care team of the steps of the protocol.
Santana, Brazil - 2008	CLABSI	Sao Paulo, Brazil/26 beds between 2 ICUs						

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Shannon, United States - 2006	CLABSI	Pittsburgh, PA/778 bed hospital		They used the Toyota Production System adapted to health care - Perfecting Patient Care. They find this method employed in organizations such as Toyota and Alcoa have helped achieve superior levels of quality, productivity, efficiency, flexibility and safety.	It was noted that traditional QI approaches based on CDC guidelines were previously employed		Multidisciplinary teams of infection control nurses, physicians, residents, fellows and nurses were created and led by the chairman of the department of medicine	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Venkatram, United States - 2010	CAUTI;CLABSI;VAP	New York, New York/20 ICU beds		Their model was based on the SMART (Specific, Measurable, Achievable, Relevant, and Time-bound) approach. Authors note this theory may have contributed to the consistent and sustained change and decline in HAIs.		The hospital was a part of the Health and Hospital Corporation network.	The HHC collaborative was comprised of participating institution's medical directors, nursing directors, chiefs of medical and surgical departments, directors of critical care units, and respiratory therapy and nursing supervisors. The MICU director served as the champion and held monthly sessions about the importance of bundles. MICU nurses were given the following responsibilities: collecting compliance data, completing the CLABSI bundle checklist, stopping a procedure if there was a deviation from the recommendations, and monitoring for any breaches in infection control.	Data from all participating hospitals was available on the critical care collaborative website.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Warren, United States – 2006	CLABSI	St. Louis, MO; Baltimore, MD; Iowa City, IA; New York, NY; Richmond, VA; Chicago, IL; Atlanta, GA/mean # of bed hospital: 775 (range: 427-1385)	Among individual units, there was variability in the impact of the intervention among the various units, possibly yielding the variable effects. Change in CVC insertion and care practice that best correlated with a reduction in the infection rate was the degree to which an individual unit reduced the proportion of non-tunneled catheters inserted in the femoral vein.		Several of the 6 participating hospitals had implemented other interventions (i.e., bundling of supplies and/or procedure carts or hand-on training of staff). One ICU instituted an education-based intervention at the start of the pre-intervention period of this study. 5 units were using antimicrobial-impregnated catheters at the start of the study.	HICPAC/CDC's recommendation for hospitals to implement education programs that teach proper CVC insertion and maintenance techniques		Fact sheets on proper CVC insertion techniques were placed in the units in places that staff were likely to see and read them.
Wicker, United States - 2011	CLABSI	Camden, NJ/35-bed NICU			mentions in discussion that improvement in technology and other unidentified factors may have contributed to the reduction of late onset blood infections in the unit		The NICU infection control task force consisted of neonatologists, pediatric infectious disease specialists, respiratory therapists, the NICU clinical director, NICU staff nurses, the NICU educator, and a pediatric surgeon.	mandatory learning packets were given to all pool and agency nurses

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Yilmaz, Turkey - 2007	CLABSI	Trabzon, Turkey/495 bed hospital	Increase HCWs understanding of CLABSI risk factors;					Educational information was put in a 20-page booklet and given to all of the HCWs; Information and training were made available to all 113 involved clinical staff.

Appendix Table C4-LQ-c. Study context for SSI which do not control for secular trend or confounding

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Acklin, Switzerland - 2011	SSI	Switzerland/		Once an adverse event has been identified, immediate rigorous analysis of the circumstances involved needs to be undertaken. This process is time-consuming, needs additional manpower and additional financial resources, and can be psychologically challenging for all involved.			When an increase in SSI occurred, an interdisciplinary team of surgeons, epidemiologists and infectious disease specialists initiated an emergency investigation, which then led to an independent epidemiology team to develop and implement the bundle.	An expert in quality improvement was hired to oversee the implementation of the preventive practices.
Awad, United States - 2009	SSI	Houston, TX/					One component of the MRSA bundle was a cultural transformation campaign with staff and leadership engagement thru positive deviance, and another component was an ongoing monitoring system of the process and outcome measures.	Nasal screening with rapid results (70 minutes for PCR assay) and contact isolation of pts is needed to implement this bundle.
Berenguer, United States - 2010	SSI	Savannah, GA/500 bed hospital			The hospital has a trained nurse to collect data for NSQIP reports.		Surgeons were alerted to the high SSI rates and were encouraged to take the lead and be active participants in following the SCIP guidelines.	The hospital was enrolled in the NSQIP.
Berry, United States -	SSI	rural central and northeastern PA/Geisinger	Geisinger uses clinical microsystem fundamentals as a	Approaches of quality improvement thru	Multiple efforts underway to improve pt	the cardiothoracic surgery	ProvenCare had the unwavering support from system executive leaders.	electronic health record, multidisciplinary

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
2009		system has 650 MDs (6 cardiac surgeons), 500 med students, residents, fellows	foundation of improvement work, so the staff was used to this type of system, making the implementation of the new processes easier.	process redesign and high reliability help address the gap between evidence-based medicine recommendations and actual clinical practice.	safety, guided by Joint Commission's national pt safety goals, and Healthcare Improvement's 100,000 lives initiative.	department had no systematic process for the evaluation and incorporation of evidence-based medicine (EBM) into acute episodic clinical practice. As a result, there was steadily increasing severity of comorbid conditions among patients referred for CABG surgery. Inconsistent clinical practice was present from the preoperative phase through the entire continuum of care (preoperative evaluation through postoperative rehabilitation)	Leadership was engaged from inception of idea thru allocation of necessary resources for implementation.; multidisciplinary improvement team comprised of a physician, cardiac surgery physician assistant, critical care registered nurse, operating theatre registered nurse, cardiac rehabilitation technician, electronic health record programmer, and clinical process improvement specialists	team cooperation

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
						and varying practice patterns increased the probability of error.		
Carles, France - 2006	SSI	Nice, France/	Despite the intervention, 12% still did not receive SAP appropriately. This could have been due to operating room organizational problems or equipment problems causing unexpected delays in either the induction of anesthesia or the time of surgical incision.				Daily SAPK use requires a change in the hospital routine. Anesthesiologists need to get the pt-specific information to the pharmacy in a timely manner so that the pharmacists can prepare the SAPK, and an organized drug-delivery system between the pharmacy and the operating room needs to be set up.	A new system requires coordinated efforts between the operating room and the pharmacy
Forbes, Canada - 2008	SSI	Ontario, Canada/365 bed hospital, >850 elective general surgery procedures/yr		The development of the interventions was through a transparent system, open to critique from all members of the pt care staff, to identify process issues that could prevent the successful delivery of care.			A multidisciplinary team of surgeons, anesthesiologists, nurses, and pharmacists developed interventions. An OR nurse and a same-day surgery nurse acted as study champions, resources to physicians and nurses, provided direction, and confirmed compliance.	staff education and training, OR nurse and same-day surgery nurse were study champions, monthly performance figures posted in OR

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Gomez, Argentina - 2006	SSI	Argentina/88 bed hospital	The gynecology and general surgery units had best attendance at the educational workshops and showed the most interest in the automatic stop form. Their adherence rates improved significantly.				A team consisting of infection control and pharmacy developed form, surgeons completed form and had to call pharmacy if they wanted to extend antibiotics	multidisciplinary team, automatic stop form
Graf, Germany - 2009	SSI	Hannover, Germany/					The infection control team had the following interdisciplinary members: cardiac surgeons and nurses, anesthesiologists, technicians, ward physicians and nurses, and colleagues from the infection control dept.	Reminders and documentation were in pt charts, and requires cooperation across departments.
Hermsen, United States - 2008	SSI	Nebraska/689 bed hospital			Previous educational efforts for the reduction in the rate of SSI			Education on the form and SIP were provided in written communication and displayed with posters
Ichikawa, Japan - 2007	SSI	Tokyo, Japan/	At this hospital, the Infection Control Team (ICT) is intimately involved in the prevention and management of surgical site infections. The team stresses the importance/necessity of accurate antibiotic administration and meets regularly with nursing and medical staff.				The ICT encourages cooperation between anesthesiologists, OR staff, junior medical staff, and surgeons.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Kable, Australia - 2008	SSI	Callaghan, Australia and Darlinghurst, Australia/2 teaching hospitals	Despite the high level of physician involvement in protocol development, and many indicating that they appreciated the advantages of using an agreed upon protocol, many surgeons still did not adopt the protocol, with dosages and timing differing from the recommendations. There were differences in the adoption of the protocols among the different surgeons. Surgeons who performed cholecystectomies and hysterectomies did not improve compliance as much as surgeons who performed TURP and herniorrhaphies. Surgeons who performed joint arthroplasties were highly compliant in the pre-intervention period and remained so in the post-intervention phase.				Physicians were involved from the beginning, in developing protocols along with pharmacy and microbiology. Pre-op staff were then responsible for inserting protocols into pts' charts.	Multidisciplinary team developed antibiotic protocols to be placed in pts' charts.
Kramer, United States - 2008	SSI	Portland, ME/600 bed hospital				A blood conservation program was initiated in the same time frame and may have contributed to the lower deep sternal wound infection rate.	Multidisciplinary team worked closely with the nurses who were responsible for the glycemic control of the cardiac pts.	color-coded one page nomogram

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Liau, Singapore - 2010	SSI	Singapore/1200 bed hospital	The authors noticed a fluctuation of compliance coincided with medical personnel rotation. This suggests that constant monitoring and publication of good results is necessary to motivate and educate the staff through the changes.		Since 2001, the hospital has been training physicians and nurses using the Clinical Practice Improvement Program (CPIP) as part of the Staff Learning Need and Clinical Quality Improvement Programs.		The multidisciplinary team developed the interventions and was responsible for implementing them. Constant monitoring of process measures and positive feedback were given to physicians.	Staff from all disciplines need to be involved. Other than manpower, little associated costs with this intervention.
Martin, United States - 2010	SSI	Galveston, TX/					This study took place in a single-surgeon academic Mohs practice and the physician decided to implement the surgical wear changes.	Sterility upgrades for gloves, gowns, and half sheets for draping.
Nemeth, United States - 2010	SSI	Minneapolis, MN/	In the previous yr, the operating team had been exposed to other quality improvement techniques such as signage, education, and informal feedback/encouragement, so they may have been more prepared to respond to this new set of procedural changes than other operating teams.				In the previous year, this group had implemented other quality improvement techniques, including signage, education and informal feedback/encouragement.	a simple form to be used during the “time out” period to indicate if the antibiotic was used in the correct timeframe

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Ozgun, Turkey - 2010	SSI	Aydin, Turkey/about 2000 surgical procedures performed each yr	The intervention did not take into account that junior surgeons consult with senior surgeons about antibiotic prescribing practices. Also, some junior surgeons left during the course of the study and new junior surgeons joined the staff and missed receiving the intervention. They would like to target junior surgeons in future interventions.				All staff underwent educational training, but surgeons ultimately made the antibiotic prescribing decisions.	educational meetings, guidelines distributed, posters
Parker, United States - 2007	SSI	Cleveland, OH/	The patients undergoing vascular surgery did not see a significant improvement in compliance. The authors note that antibiotics were being given either before or during placement of invasive hemodynamic monitors and patient positioning before incision. The cardiothoracic surgical teams had already developed standardized and defined protocols and may be why their compliance was so much higher at baseline.	The Six Sigma approach is a data-driven, quality improvement methodology developed by Motorola and improved by GE. It is used to improve outcomes by reducing process variability.			A 10-member multidisciplinary team consisting of physician process champions, nurses, a hospital epidemiologist, and an outcome administrator. The cardiothoracic surgical teams had already developed standardized and defined protocols.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Pastor, United States - 2010	SSI	Duarte, CA/				This intervention was implemented in response to the Surgical Care Improvement Project (SCIP), a national health initiative.	A multidisciplinary task force was convened and worked with all staff to identify problems and implement changes.	The task force ensured that supplies (antibiotics, warming blankets, flow sheets) were available to meet SCIP process measures.
Paull, United States - 2010	SSI	74 Veterans Administration Hospitals/130 facilities in Veterans Administration Hospitals		Communication breakdown and teamwork failure can cause human errors leading to patient harm. The use of pre-op briefings and post-op debriefings, guided by a checklist can improve communication among health care providers.		This study was a part of the Medical team training (MTT) program initiated by the VHA National Center for Patient Safety	A nurse educator from NCPS worked with a team leader as well as frontline providers at each VA hospital.	The team at each hospital developed their own surgical checklist, using any of the following: paper, slider board, poster, whiteboard, electronic, or other material.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Potenza, United States - 2009	SSI	San Diego, CA/325 bed hospital	Many surgeons had a strong sense of individuality with their surgical practice, and resisted the group practice model. These surgeons needed to be reassured that the practice changes would be as efficacious as their present practice behaviors. Over time, through educational venues such as morbidity and mortality conferences, an agreement among key surgical personnel developed.		When SCIP guidelines were published, the medical center had begun a perioperative safety initiative called "Crew resource management" which was a requirement of all surgeons and operating room personnel. The project centered on "team responsibility for pt safety, recognized individual fallibility, and promoted peer monitoring. There was an operating room philosophy of teamwork which included a preoperative briefing checklist and a postsurgical time-out.		There was a lead performance improvement nurse and data analyst who organized the technical and logistical components of the data abstraction and analysis. The committee worked with all staff and in particular, the anesthesiologists became the key staff to implement the antibiotic prophylaxis measures.	a multidisciplinary team, anesthetic worksheet, laminated cards with SCIP guidelines

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Rauk, United States - 2010	SSI	Minneapolis, MN/1868 bed hospital					Multidisciplinary team developed and implemented interventions and an experienced OR educator reviewed and observed surgical site preparation, sterile technique, and documentation.	an educational video was made and sufficient surgical instruments were made available
Shimoni, Israel - 2009	SSI	Netanya, Israel/	Because all medical staff were involved in the policy change, the implementation was accepted without resistance from physicians. Also, this set of nurses were of high quality	Because of nurses' direct contact with pt care activities, they are in the best position to detect and report medication errors. In some situations, nurses are more open to compliance measures than physicians, and nurses may be more likely to report medical errors.			Noted previous attempts in 2006 to get obstetricians to use antibiotic prophylaxis, empowered 6 nurses with the ability to remind anesthesiologists to administer prophylaxis	
Suchitra, India - 2009	CAUTI;SSI	Karnataka, India/site 1: 400 bed hospital; site 2 size not specified; site 3: 250 bed hospital	Although not statistically tested, the reductions in SSI and hospital UTI rates does not appear to differ much between the 3 sites. All had reductions.					

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Takahashi, Japan - 2010	SSI	Nishinomiya, Japan/1044 bed hospital	all departments, except cardiovascular, showed a significant reduction in the duration of AMP. Only 2 departments measured change in rate of SSIs - Incidence of SSIs significantly decreased in the Lower Gastrointestinal Department of Surgery (6 months pre-intervention rate of SSI: 18.4%; 6 months post-intervention: 8.1%; p=.002), but rate of SSI was not statistically different in the Hepatic-biliary Pancreatic Department of Surgery (6 months before: 13.1%; 6 months after intervention: 11.1%; p = 0.673)				The antimicrobial stewardship team was made up of an infection control doctor, certified pharmacist and a physician in each department	15 manuals were distributed to 15 departments - one per department
Wax, United States - 2007	SSI	New York, NY/	Significant increases in compliance were seen in the total anesthesiologist population, as well as among anesthesiologists who worked with assistants and those working without assistants. Compliance increased in 80%, declined in 9%, and remained unchanged in 11%.		The hospital's published antibiotic prophylaxis guidelines regarding choice and timing of preoperative antibiotics had been disseminated to the staff before the study period		The electronic reminder was implemented in all anesthetizing locations, so all anesthesiologists were exposed to the intervention.	The electronic prompt was programmed into a pre-existing anesthesia information management system (AIMS)

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Whitman, United States - 2008	SSI	Philadelphia, PA/					TUH SCIP committee was comprised of physicians, hospital administrators including representation from anesthesia, surgery, infectious disease, pharmacy, information technology, medical records, and hospital compliance; Department of Anesthesia assumed responsibility for administering ordered antibiotic prophylaxis in the operating suite at the time of "universal timeout".	standardized forms, electronic medical records
Willemsen, Netherlands - 2007	SSI	Breda, The Netherlands/1370 bed hospital; 3 operating complexes; 11,000 procedures performed annually	Hospital was under increased pressure to be efficient, so pts spent less time in pre-op area, so surgeon did not always have time to decide on antibiotic before pt was placed in OR. This caused delay in antibiotic administration. The new protocol and guideline forced antibiotic decisions before pt placed in OR.				multidisciplinary team got approval of guideline from all surgeons and anesthetists	multidisciplinary team, guideline developed

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Zvonar, Canada - 2008	SSI	Ottawa, Canada/1163 bed hospital					A multidisciplinary team consisting of antimicrobial pharmacist, clinical director, clinical managers and nurse educators for per-operative services, pharmacy operations manager, and physicians from surgery anesthesiology, and infection prevention/control. Nurses and pharmacists were allowed to automatic substitute larger doses for the larger patients. Anesthesiologists were asked to administer antibiotics when initial anesthesia was given.	

Appendix Table C4-LQ-d. Study context for CAUTI which do not control for secular trend or confounding

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	Kuanas, Lithuania						
Gokula, United States - 2007	CAUTI	Lansing, MI/550 bed hospital					The nursing director was asked to hold weekly educational meetings for the ED nurses.	The UCISs were placed on the catheter trays for increased visibility.
Jain, United States - 2006	CAUTI;CLABSI;VAP	DeSoto, MS/28 ICU beds			Hospital administration and nursing leadership pushed for quality improvement initiatives in 2003. No specifics are given.	The hospital joined the IHI project to improve patient safety and outcomes	The house supervisor was relieved of some of her duties with bed flow through the bed flow meetings. Physicians took a more active role in daily patient care through leading the multidisciplinary rounds.	
Rothfeld, United States - 2010	CAUTI	Los Angeles, CA/389 bed hospital			The use of silver coated catheters was already in place in this hospital	Center for Medicare and Medicaid labeled CAUTI as a “never event” and discontinued funding for CAUTI related hospital costs	Wound care nurse was given the authority to advise an attending physician to replace a urinary catheter.	

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Stephan, Switzerland - 2006	CAUTI	Geneva, Switzerland/					A multidisciplinary team of orthopedic department chair, senior nurse and senior anesthetists was assembled to approve guidelines	Posters with guidelines were displayed in all operating rooms dedicated to orthopedic procedures, post-anesthesia care unit, and orthopedic nursing staff offices
Suchitra, India - 2009	CAUTI;SSI	Karnataka, India/site 1: 400 bed hospital; site 2 size not specified; site 3: 250 bed hospital	Although not statistically tested, the reductions in SSI and hospital UTI rates does not appear to differ much between the 3 sites. All had reductions.					

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Venkatram, United States - 2010	CAUTI;CLABSI;VAP	New York, New York/20 ICU beds		Their model was based on the SMART (Specific, Measurable, Achievable, Relevant, and Time-bound) approach. Authors note this theory may have contributed to the consistent and sustained change and decline in HAIs.		The hospital was a part of the Health and Hospital Corporation network.	The HHC collaborative was comprised of participating institution's medical directors, nursing directors, chiefs of medical and surgical departments, directors of critical care units, and respiratory therapy and nursing supervisors. The MICU director served as the champion and held monthly sessions about the importance of bundles. MICU nurses were given the following responsibilities: collecting compliance data, completing the CLABSI bundle checklist, stopping a procedure if there was a deviation from the recommendations, and monitoring for any breaches in infection control.	Data from all participating hospitals was available on the critical care collaborative website.

Study	Infection	Location/Size	Influence of context on outcomes	Theory behind Patient Safety Practice	Existing Patient Safety Infrastructure	External Factors	Patient Safety Culture at Unit Level	Availability of Intervention materials
Wald, United States - 2011	CAUTI	Aurora, CO/425 bed hospital	CAUTI rate was only decreased in the orthopedic surgery unit which had much higher rates of postoperative catheter duration <3 days at baseline. Authors also noted that the two units had very different practice patterns associated with urinary catheters and that a “one-size-fits-all” approach is most likely not the best.			Recent change in CMS Inpatient Prospective Payment System whereby hospital-acquired conditions (including CAUTIs) would not be reimbursed for.		

Appendix Table C5a-LQ(1). Infection rate outcomes for VAP which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention infection rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Unit of Measure	Follow-up (months)
Abbott, United States - 2006	VAP	Academic Center of Evidence-based Practice (ACE) Star Model	Hospital 1 Medical ICU FY2001 Q4: 16.95; Hospital 1 Surgical ICU FY2001 Q4: 10.5; Hospital 1 Trauma ICU FY2001 Q4: 16.95; Hospital 2 Trauma ICU FY2001 Q4: 38	Hospital 1 Burn ICU FY2003 Q3: 25; Hospital 1 Burn ICU FY2004 Q3: 7; Hospital 1 Medical ICU FY2004 Q3: 0; Hospital 1 Surgical ICU FY2004 Q3: 4.5; Hospital 1 Trauma ICU FY2004 Q3: 7; Hospital 2 Trauma ICU FY2004 Q2: 20			
Assanasen, - 2008	CLABSI;VAP	Feedback Program					
Berriel-Cass, United States - 2006	CLABSI;VAP	VAP Bundle	mean: 8.2	mean: 3.3	t-test: p= 0.02	infections/1000 device-days	
Bigham, United States - 2009	VAP	VAP Bundle	5.6	post1: 8.8; post2: 0.3	<0.0001	infections/1000 device-days	
Bird, United States - 2010	VAP	VAP Bundle	overall: 10.2; TICU: 10.4; SICU: 10.0	post1 overall: 9.8; post1 TICU: 8.0; post1 SICU: 11.8; post2 overall: 5.8; post2 TICU: 6.1; post2 SICU: 5.0; post3 overall: 3.4; post3 TICU: 2.5; post3 SICU: 4.25	post2 overall p=0.01; post2 SICU p=0.06; post3 overall p=0.004; post3 TICU p=0.01	infections/1000 device-days	
Blamoun, United States - 2009	VAP	Expanded VAP bundle	Median: 14.1 (IQR 12.1-20.6)	Median: 0 (IQR 0-1.1)	95% CI: 10.9 to 20.3 95% CI: 0 to 2.4; p=0.006	infections/1000 device-days	
Bloos, Germany - 2009	VAP	Educational Program	33.1%	32.4%	Chi-square: p=0.68	(infections/Ventilated patients)*100	
Cocanour, United States - 2006	VAP	VAP Bundle	Pre-VAP bundle: 22.3-32.7; Pre-feedback program: 22.3-23.4	Post-feedback program: 0-12.8; May/June 2003: 10.7	p< 0.05	range of monthly Infections/1000 device-days	
Garcia, United States - 2009	VAP	VAP Education and Oral Care Protocol	12.0	8.0	p=0.06	infections/1000 device-days	
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	VAP Education	21.8	8.8	p=0.05	VAPs per 1,000 device days	12

Study	Infection	Intervention(s)	Pre-intervention infection rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Unit of Measure	Follow-up (months)
Heimes, United States - 2011	VAP	VAP Prevention Protocol (VAPP)	5.2	post1: 2.4; post2: 1.2	post1: p=0.172; post2: p=0.085	infections/1000 device-days	
Jain, United States - 2006	CAUTI;CLABSI;VAP	IMPACT initiative	CLABSI: 5.9; CAUTI: 3.8; VAP: 7.5	CLABSI: 3.1; CAUTI: 2.4; VAP: 3.2	CLABSI $\chi 2$: p=0.03; CAUTI $\chi 2$: p=0.17; VAP $\chi 2$: p=0.04	infections/1000 device-days	
Jimenez, United States - 2009	VAP	VAP Bundle					
Landrum, Afghanistan - 2008	VAP	Infection Control Protocol	60.6	post1: 31.6; post2: 21.3; post3: 11.1; post4: 11.6; post5: 9.7	trend p=0.029	infections/1000 device-days	
Quenot, France - 2007	VAP	Nurse-Implemented Sedation Protocol	19.3	14.5	p=0.45; Adjusted HR = 0.81 (95% CI 0.62-0.95, p = 0.03)	infections/1000 device-days	
Rogers, Ireland - 2010	CLABSI;VAP	Plan-Do-Study-Act (PDSA)cycle	overall CLABSI: 25.3; infants < 1000g CLABSI: 28.2; infants between 1001-1500g CLABSI: 17.8; overall VAP: 9.8; infants < 1000g VAP: 10.0; infants between 1001-1500g VAP: 8.3	overall CLABSI: 19.3; infants < 1000g CLABSI: 21.5; infants between 1001-1500g CLABSI: 12.5; overall VAP rate: 6.1; infants < 1000g VAP: 6.7; infants between 1001-1500g VAP: 0	Infants <1000g CLABSI, RR: 0.76, 95% CI:(0.43–1.25) p=0.28; RR for CLABSI infants between 1001-1500g: 0.70 (95% CI 0.14-2.07, p=0.58); RR for VAP all infants: 0.63 (95% CI 0.20-1.47), p=0.30	Infection/1000 device-days	
Rosenthal, Argentina - 2006	VAP	Multifaceted Infection Control Program	51.28	35.52	< 0.003; Rate ratio = 0.69 (95% CI 0.49-0.98)	infections/1000 device-days	
Ross, United States - 2007	VAP	Educational Program		VAP rates decrease by 50%			
Sona, United States - 2009	VAP	Oral Care Protocol	5.2	2.4	p=0.04	infections/1000 device-days	

Study	Infection	Intervention(s)	Pre-intervention infection rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Unit of Measure	Follow-up (months)
Venkatram, United States - 2010	CAUTI;CLABSI;VAP	VAP bundle	2.17	0.62	Unadjusted IRR specific stat for p value not specified: 0.29, 95% CI 0.21-0.38 (p<0.0001); IRR adjusted for device utilization specific stat for p value not specified: 0.33, 95% CI 0.08-1.1 (p=0.049)	infections/1000 device-days	

Appendix Table C5a-LQ(2). Infection rate outcomes for CLABSI which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention infection rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Unit of Measure	Follow-up (months)
Assanasen, - 2008	CLABSI;VAP	Feedback Program					
Berriel-Cass, United States - 2006	CLABSI;VAP	CLABSI Bundle	mean: 9.6	mean: 3.0	t-test: p=0.003	infections/1000 device-days	
Bhutta, United States - 2007	CLABSI	Bundle CLABSI	8.6	3	RR reduction of 75% no stat test mentioned; Incidence of BSI decreased no stat test mentioned (p<0.001; 95% CI: 35% to 126%)	infections/1000 device-days	
Bizzarro, United States - 2010	CLABSI	Bundle - CLABSI	8.44 (95% CI: 6.80-10.46)	1.71 (95% CI: 0.77-3.80)		infections/1000 device-days	
Galpern, United States - 2008	CLABSI	CLABSI Bundle	5.0	0.90	Statistical test not specified: p<0.001	infections/1000 device-days	
Guerin, United States - 2010	CLABSI	Post-insertion CVC care bundle	5.7	1.1	RR type of model not specified: 0.19 (95% CI: 0.06-0.63, p=0.004)	infections/1000 device-days	
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	CLABSI Education	9.3	2.7	p>0.05	number of CLABSIs per 1,000 device days	12
Jain, United States - 2006	CAUTI; CLABSI; VAP	IMPACT initiative	CLABSI: 5.9; CAUTI: 3.8; VAP: 7.5	CLABSI: 3.1; CAUTI: 2.4; VAP: 3.2	CLABSI χ^2: p=0.03; CAUTI χ^2: p=0.17; VAP χ^2: p=0.04	infections/1000 device-days	
Jeffries, United States - 2009	CLABSI	CVC Insertion and Maintenance Bundle	median: 6.3 (IQR 5.0-8.9)	median: 4.3 (IQR 2.6-7.6)	Wilcoxon rank sum test: p = .032	infections/1000 device-days	
Koll, United States - 2008	CLABSI	Central line bundle	mean CLABSI rate: 4.85	mean CLABSI rate: 2.24	statistical test not specified: p<0.001	infections/1000 device-days	
Lobo, Brazil - 2010	CLABSI	Continuous Education	12	post1: 10.6; post2: 0	χ^2/Fishers exact comparing pre-intervention and intervention period: P=.03	infections/1000 device-days	
Lobo, Brazil - 2010	CLABSI	Single lecture	16.2	post1: 12.9; post2: 13.7	χ^2/Fishers exact comparing pre-intervention and intervention period: p=0.41	infections/1000 device-days	
Marra, Brazil - 2010	CLABSI	IHI Bundle - CLABSI	mean ICU: 6.4 (2.9 SD); mean SDU 4.1 (3.3 SD)	mean ICU: 3.2 (2.5 SD); mean SDU 1.6 (2.4 SD)	ICU Student t-test: p<0.001; SDU Student t-test: p=0.005	infections/1000 device-days	
Render, United States - 2006	CLABSI	CLABSI bundle	1.7	0.4	t-test: p<0.05	infections/1000 device-days	

Study	Infection	Intervention(s)	Pre-intervention infection rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Unit of Measure	Follow-up (months)
Rogers, Ireland - 2010	CLABSI; VAP	Plan-Do-Study-Act (PDSA)cycle	overall CLABSI: 25.3; infants < 1000g CLABSI: 28.2; infants between 1001-1500g CLABSI: 17.8; overall VAP: 9.8; infants < 1000g VAP: 10.0; infants between 1001-1500g VAP: 8.3	overall CLABSI: 19.3; infants < 1000g CLABSI: 21.5; infants between 1001-1500g CLABSI: 12.5; overall VAP rate: 6.1; infants < 1000g VAP: 6.7; infants between 1001-1500g VAP: 0	Infants <1000g CLABSI, RR: 0.76, 95% CI:(0.43–1.25) p=0.28; RR for CLABSI infants between 1001-1500g: 0.70 (95% CI 0.14-2.07, p=0.58); RR for VAP all infants: 0.63 (95% CI 0.20-1.47), p=0.30	Infection/1000 device-days	
Sannoh, United States - 2010	CLABSI	Bundle - CLABSI	UVC: 7/1000; Brovac: 15/1000; PICC : 23/1000; UAC+UVC : 15/1000	UVC: 4/1000; Brovac: 10/1000; PICC : 12/1000; UAC+UVC : 5/1000	UVC OR=0.57 (95% CI 0.17-1.95); Brovac OR=0.60 (95% CI 0.26-1.40); PICC OR=0.47 (95% CI 0.17-0.91) ; UAC+UVC OR=0.33 (95% CI 0.12-0.91)	infections/1000 device-days	
Santana, Brazil - 2008	CLABSI	Education	mean: 9.5	mean: 5.4	OR 0.46 (95% CI 0.21-1.02); Fisher exact test, p=0.04	infections/1000 device-days	
Shannon, United States - 2006	CLABSI	Toyota Production System adaptation	10.5	post1: 1.2; post2: 1.6; post3: 0.39	all Chi-square/Fisher's exact test: p<0.05	infections/1000 device-days	
Venkatram, United States - 2010	CAUTI; CLABSI; VAP	CLABSI bundle	10.77	1.04	Unadjusted IRR specific stat for p value not specified: 0.155, 95% CI 0.13-0.18 (p<0.0001); IRR adjusted for device utilization specific stat for p value not specified: 0.09, 95% CI 0.09-0.23 (p<0.0001)	infections/1000 device-days	
Warren, United States - 2006	CLABSI	Multifaceted, education-based intervention	overall: 11.2	overall: 8.9	χ2 relative rate(95% CI): 0.79 (0.67-0.93)	infections/1000 device-days	
Wicker, United States - 2011	CLABSI	Comprehensive Infection Control Measures	late onset CLABSI: 30.8%; general BSI: 37.7%	late onset CLABSI: 19.4%; general BSI: 22.7%	CLABSI: p=.001; general BSI: p<.001	% late onset central line associated BSI of all central line infants	

Study	Infection	Intervention(s)	Pre-intervention infection rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Unit of Measure	Follow-up (months)
Yilmaz, Turkey - 2007	CLABSI	Education	8.3	4.7	Chi-square p=0.018; relative risk of 0.57 (95% CI: 0.36-0.92)	infections/1000 device-days	

Appendix Table C5a-LQ(3). Infection rate outcomes for SSI which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention infection rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Unit of Measure	Follow-up (months)
Acklin, Switzerland - 2011	SSI	bundle - antibiotic prophylaxis, skin prep, sterile dressing	6.9%	2.0%	t test, p=0.029	infections/100 proximal femur fracture surgeries	
Awad, United States - 2009	SSI	MRSA bundle	MRSA transmissions: 5.8/1000 bed days; MRSA infections: 2.0/1000 BD	MRSA transmissions: 3.0/1000 bed days; MRSA infections: 1.0/1000 bed days	transmission, chi square: p=<.05; infections, chi square: p=.016		
Berenguer, United States - 2010	SSI	implementing SCIP measures	13.3%	8.3%	Fisher exact test, p=0.362	superficial infection/100 colorectal cases	
Berry, United States - 2009	SSI	ProvenCare	0.7%	0.9%	Fisher's exact test: p=1.0	# deep sternal wound infections/CABG	
Carles, France - 2006	SSI	surgical antibiotic prophylaxis kit (SAPK)					
Forbes, Canada - 2008	SSI	bundle - glucose control by screening all pts prior to surgery, administering weight-based regimen of insulin to diabetics, monthly performance figures posted in OR	superficial SSI: 14.3%; organ space infection: 7.6%	superficial SSI: 8.7%; organ space infection: 6.8%	superficial SSI: RR=0.61 (0.28-1.33) p=0.21 organ space infection: RR=0.89 (0.34-2.37) p=0.81		
Forbes, Canada - 2008	SSI	bundle - maintain normothermia by warming OR to 22 C, standardizing IV warmers and forced air devices, monthly performance figures posted in OR	superficial SSI: 14.3%; organ space infection: 7.6%	superficial SSI: 8.7%; organ space infection: 6.8%	superficial SSI: RR=0.61 (0.28-1.33) p=0.21 organ space infection: RR=0.89 (0.34-2.37) p=0.81	pre- and post-adherence rates were for the following time intervals from administration of antibiotic to incision (in minutes): <= 60, 61-120, 121-180, >180	
Forbes, Canada - 2008	SSI	bundle - antibiotic administration in OR, pre-printed order form to standardize choice of antibiotic, monthly performance figures posted in OR	superficial SSI: 14.3%; organ space infection: 7.6%	superficial SSI: 8.7%; organ space infection: 6.8%	superficial SSI: RR=0.61 (0.28-1.33) p=0.21; organ space infection: RR=0.89 (0.34-2.37) p=0.81		
Gomez, Argentina - 2006	SSI	automatic stop prophylaxis form	3.2%	1.9%	Relative risk: 0.59, 95% CI:(0.44-0.79), p<.01	infection/100 patients	
Graf, Germany - 2009	SSI	bundle - SSI	3.61%	1.83%	95% CI: 2.98-4.35 95% CI: 1.08-2.90	infection/100 cardiac surgical procedures	
Hermsen, United States - 2008	SSI	Standardized order form					

Study	Infection	Intervention(s)	Pre-intervention infection rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Unit of Measure	Follow-up (months)
Ichikawa, Japan - 2007	SSI	Implementation of Antibiotic Protocols	Clean wound: 0.5%; Clean-contaminated wound: 4.0%; Contaminated wound: 29.4%; Dirty-infected wound: 23.8%; total wounds: 3.7%	Clean wound: 0.2%; Clean-contaminated wound: 2.6%; Contaminated wound: 5.8%; Dirty-infected wound: 20.8%; Total wounds: 1.7%	Clean wound, chi square: p=NS; Clean-contaminated wound, chi square: p=NS; Contaminated wound, chi square: p<.01; Dirty-infected wound, chi square: p=NS; Total wounds, chi square: p<.05	percent of infection per wound type	
Kable, Australia - 2008	SSI	bundle - antibiotic prophylaxis	overall: 7.6%	overall: 8.1%; TURP: 5.8%; cholecystectomy: 6.1%; herniorrhaphy: 5.3%; hysterectomy: 18.5%; joint: 7.8%	difference=NS	infection/100 surgeries	
Kramer, United States - 2008	SSI	nomogram for glycemic control	2.6%	1.0%	test not specified, p<.001	infection/100 cardiac surgeries	
Liau, Singapore - 2010	SSI	bundle - antibiotic, glucose control, clippers, normothermia	overall: 3.1%	overall: 0.5%; 2006: 0.6%; 2007: 0.4%	Fisher exact test: p<.001	infection/100 operations	
Martin, United States - 2010	SSI	surgical wear changes in Mohs surgery	2.5%	0.9%	chi square, p=.04; Fisher exact, p=.05	infection/100 tumors	
Nemeth, United States - 2010	SSI	Education program					
Ozgun, Turkey - 2010	SSI	antibiotic prophylaxis education					
Parker, United States - 2007	SSI	Six Sigma methodology and antibiotic prophylaxis					
Pastor, United States - 2010	SSI	task force to meet SCIP process measures	19%	19%	Pearson, p=0.90	infection/100 operations	
Paull, United States - 2010	SSI	The Briefing Guide (BiG)					
Potenza, United States - 2009	SSI	bundle - glucose control					
Potenza, United States - 2009	SSI	bundle - appropriate hair removal					
Potenza, United States - 2009	SSI	bundle - antibiotic prophylaxis					

Study	Infection	Intervention(s)	Pre-intervention infection rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Unit of Measure	Follow-up (months)
Potenza, United States - 2009	SSI	bundle - normothermia					
Rauk, United States - 2010	SSI	bundle - skin prep and instrument sterilization	overall: 7.5%; endometritis SSI: 3%; incision SSI: 4.5%	overall: 1.2%; endometritis SSI: 1.2%; incisional SSI: 0%%	overall χ2: p<0.001; endometritis SSI χ2: p=0.06; incisional SSI χ2: p<0.001	infections/procedures	
Shimoni, Israel - 2009	SSI	Empowering surgical nurses	Infections: 16.8%; Positive cultures: 14.5%	Infections: 12.6%; Positive cultures: 7.3%	Chi-Square Infections: p=0.0048; Chi-Square Positive cultures: p=0.0055; infections Taylor series Relative Risk: 0.75 (95% CI 0.61-0.92); positive cultures Taylor series Relative Risk: 0.38 (95% CI 0.18-0.77)	% of infections among caesarean deliveries	
Suchitra, India - 2009	CAUTI;SSI	Education Program	SSI: 12.1%; Hospital UTI: 6.6%	SS1: 4.0%; Hospital UTI: 2.7%	SSI, chi square: p<.001; Hospital UTI, chi square: p<.001	Percent SSI and percent hospital acquired UTI	
Takahashi, Japan - 2010	SSI	Departmental Education	p. aeruginosa: 12.6%; MRSA: 11.5%; MRSA among S. aureus: 76%	p. aeruginosa: 7.3%; MRSA: 8.7%; MRSA among S. aureus: 60%	p. aeruginosa, t test: p=.004; MRSA, t test: p=.055; MRSA among S. aureus, t test: p=.006	isolation of p. aeruginosa/all gram-negative organisms; isolation of MRSA/all gram-positive organisms; isolation of MRSA/all S. aureus	
Wax, United States - 2007	SSI	Electronic reminder for provider					
Whitman, United States - 2008	SSI	Multiple 'forced functions'					
Willemsen, Netherlands - 2007	SSI	standardized antibiotic protocol					
Zvonar, Canada - 2008	SSI	Appropriate antibiotic prophylaxis administration					

Appendix Table C5a-LQ(4). Infection rate outcomes for CAUTI which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention infection rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Unit of Measure	Follow-up (months)
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	CAUTI Education	4.3	6.1	p>0.05	number of CAUTIs per 1,000 device days	12
Gokula, United States - 2007	CAUTI	Education and indications checklist					
Jain, United States - 2006	CAUTI;CLABSI;VAP	IMPACT initiative	CLABSI: 5.9; CAUTI: 3.8; VAP: 7.5	CLABSI: 3.1; CAUTI: 2.4; VAP: 3.2	CLABSI χ2: p=0.03; CAUTI χ2: p=0.17; VAP χ2: p=0.04	infections/1000 device-days	
Rothfeld, United States - 2010	CAUTI	Appropriate Catheter Use Protocol	3.2	2.4	statistical test not specified: p<0.10	infections/1000 device-days	
Stephan, Switzerland - 2006	CAUTI	CAUTI guidelines, education and posters	overall: 27.0; orthopedic: 45.8; abdominal: 9.0	post1 overall: 12.0; post1 orthopedic: 18.6; post1 abdominal: 5.6; post2 overall: 21.2	Incidence Density Ratio: overall; .44 (95% CI .24-.81); Orthopedic: .41 (95% CI .20-.70); abdominal: .62 (95% CI .14-2.50)	infections/1000 device-days	
Suchitra, India - 2009	CAUTI;SSI	Education Program	SSI: 12.1%; Hospital UTI: 6.6%	SS1: 4.0%; Hospital UTI: 2.7%	SSI, chi square: p<.001; Hospital UTI, chi square: p<.001	Percent SSI and percent hospital acquired UTI	
Venkatram, United States - 2010	CAUTI;CLABSI;VAP	CAUTI bundle	6.23	0.63	Unadjusted IRR specific stat for p value not specified: 0.10, 95% CI 0.08-0.19 (p<0.0001); IRR adjusted for device utilization specific stat for p value not specified: 0.09, 95% CI 0.02-0.23 (p<0.0001)	infections/1000 device-days	
Wald, United States - 2011	CAUTI	Audit and feedback on catheter duration	orthopedic: 8.6; general: 6.8	orthopedic: 0; general: 7.5	t test, p=NS	infections/1000 device-days	

Appendix Table C5b-LQ(1). Adherence outcomes for VAP which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Abbott, United States - 2006	VAP	Academic Center of Evidence-based Practice (ACE) Star Model	overall HOB: 77%; overall oral care: 22%; overall empty condensate: 94%; overall handwashing before pt contact: 8%; overall handwashing after pt contact: 36%; overall proper glove use: 74%	overall HOB: 69%; overall oral care: 30%; overall empty condensate: 93%; overall handwashing before pt contact: 14%; overall handwashing after pt contact: 36%; overall proper glove use: 90%	hand washing p<0.0001; glove use p<0.0001	3
Assanasen, - 2008	CLABSI;VAP	Feedback Program	overall HOB: 51%; overall HH: 40%; overall femoral catheter (FC): 13%	overall post1 HOB: 88%; overall post1 HH: 47%; overall post1 FC: 7%; overall post2 HOB: 93%; Overall post2 HH: 71%; overall post2 FC:7%		24
Berriel-Cass, United States - 2006	CLABSI;VAP	VAP Bundle				
Bigham, United States - 2009	VAP	VAP Bundle	post1 HOB: 57%; post1 mouth care: 60%; post1 oral suction: 60%; post1 in-line suction change: 60%; post1 condensate drained: 60%; post1 vent circuit inspected: 60%	post2 HOB: 85%; post2 mouth care: 85%; post2 oral suction: 78%; post2 in-line suction change: 100%; post2 condensate drained: 90%; post2 vent circuit inspected: 85%		24
Bird, United States - 2010	VAP	VAP Bundle		post1 SICU: 63% (95% CI 57-69%); post1 TICU: 53% (95% CI 46-60%); post2 SICU: 78% (95% CI 73-83%); post2 TICU: 85% (95% CI 82-89%); post3 SICU: 81% (95% CI 72-90%); post3 TICU: 91% (95% CI 85-97%)		31
Blamoun, United States - 2009	VAP	Expanded VAP bundle				
Bloos, Germany - 2009	VAP	Educational Program	all patients: 15.0%; patients without acute lung injury (ALI): 22.8%; patients with ALI: 9.9%	all patients: 33.8%; patients without ALI: 47%; patients with ALI: 18.2%	overall chi-square: p< 0.01; patients without ALI chi-square: p< 0.01; patients with ALI chi-square: p<0.01	6
Cocanour, United States - 2006	VAP	VAP Bundle				

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Garcia, United States - 2009	VAP	VAP Education and Oral Care Protocol		at least 80%		
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	VAP Education				12
Heimes, United States - 2011	VAP	VAP Prevention Protocol (VAPP)				
Jain, United States - 2006	CAUTI;CLABSI;VAP	IMPACT initiative				
Jimenez, United States - 2009	VAP	VAP Bundle	full compliance: 6%; HOB: 14%; sedation vacation: 67%; peptic ulcer prophylaxis: 93%; deep vein thrombosis prophylaxis: 87%	full compliance: 59%; HOB: 74%; sedation vacation: 72%; peptic ulcer prophylaxis: 95%; deep vein thrombosis prophylaxis: 92%	full compliance, RR: 0.43, OR: 0.04, Pearson: p<0.01; HOB, RR: 0.30, OR: 0.05, p<0.01; sedation vacation, RR: 0.84, OR: 0.77, p>0.05; peptic ulcer prophylaxis, RR: 0.68, OR: 0.66, p> 0.05; deep vein thrombosis prophylaxis, RR: 0.64, OR: 0.61, p> 0.05	4
Landrum, Afghanistan - 2008	VAP	Infection Control Protocol				
Quenot, France - 2007	VAP	Nurse-Implemented Sedation Protocol				
Rogers, Ireland - 2010	CLABSI;VAP	Plan-Do-Study-Act (PDSA)cycle	24%	53%	Cronbach's alpha: 0.71	6
Rosenthal, Argentina - 2006	VAP	Multifaceted Infection Control Program				
Ross, United States - 2007	VAP	Educational Program	median OAG score: 11	median OAG score: 9	p=0.0002	2
Sona, United States - 2009	VAP	Oral Care Protocol		81%		12
Venkatram, United States - 2010	CAUTI;CLABSI;VAP	VAP bundle				

Appendix Table C5b-LQ(2). Adherence outcomes for CLABSI which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Assanasen, - 2008	CLABSI;VAP	Feedback Program	overall HOB: 51%; overall HH: 40%; overall femoral catheter (FC): 13%	overall post1 HOB: 88%; overall post1 HH: 47%; overall post1 FC: 7%; overall post2 HOB: 93%; Overall post2 HH: 71%; overall post2 FC:7%		24
Berriel-Cass, United States - 2006	CLABSI;VAP	CLABSI Bundle				
Bhutta, United States - 2007	CLABSI	Bundle CLABSI	Hand Washing: 47%	Hand Washing: 82%		NR
Bizzarro, United States - 2010	CLABSI	Bundle - CLABSI				
Galpern, United States - 2008	CLABSI	CLABSI Bundle				
Guerin, United States - 2010	CLABSI	Post-insertion CVC care bundle				
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	CLABSI Education				12
Jain, United States - 2006	CAUTI;CLABSI;VAP	IMPACT initiative				
Jeffries, United States - 2009	CLABSI	CVC Insertion and Maintenance Bundle		insertion: Apr-Jun 82.1 (53.1-94.0), Jul-Sept 91.7 (78.0-98), Oct-Dec 93.8 (85.7-100.0); Maintenance: Apr-Jun 85.9 (78.3-100.0), Jul-Sep 98.2 (89.9-100), Oct-Dec 100.0 (94.5-100.0)	Fischer Exact Test: Insertion all P<.001 compared to first 3 months; Maintenance P=.206 for first 3 months compared to second: P=.023 for first 3 months compared to last 3 months	9
Koll, United States - 2008	CLABSI	Central line bundle				
Lobo, Brazil - 2010	CLABSI	Continuous Education	CVC insertion: Hand hygiene before procedure: 100%; Maximal barrier precautions: 100%; Skin antisepsis: 100%; hand hygiene after procedure: 58%	CVC insertion: Hand hygiene before procedure: 100%; Maximal barrier precautions: 100%; Skin antisepsis: 100%; hand hygiene after procedure: 83%	Relative Risk: 1.43 (95% CI .83-2.45) p=.37	

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Lobo, Brazil - 2010	CLABSI	Single lecture	CVC insertion: Hand hygiene before procedure: 100%; Maximal barrier precautions: 100%; Skin antisepsis: 100%; hand hygiene after procedure: 67%	CVC insertion: Hand hygiene before procedure: 100%; Maximal barrier precautions: 100%; Skin antisepsis: 100%; hand hygiene after procedure: 67%	Relative Risk: NA	
Marra, Brazil - 2010	CLABSI	IHI Bundle - CLABSI				
Render, United States - 2006	CLABSI	CLABSI bundle	sterile drapes: 0%; chlorhexidine: <50%	sterile drapes: 85-95%; chlorhexidine: 80-100%		12
Rogers, Ireland - 2010	CLABSI;VAP	Plan-Do-Study-Act (PDSA)cycle	24%	53%	Cronbach's alpha: 0.71	6
Sannoh, United States - 2010	CLABSI	Bundle - CLABSI	mean score: 14 (SD 4)	mean score: 23 (SD 0.7)	chi square: $p<0.05$	12
Santana, Brazil - 2008	CLABSI	Education				
Shannon, United States - 2006	CLABSI	Toyota Production System adaptation				
Venkatram, United States - 2010	CAUTI;CLABSI;VAP	CLABSI bundle				
Warren, United States - 2006	CLABSI	Multifaceted, education-based intervention	overall femoral vein insertion site: 12.9%; overall blood at dressing site: 24.6%; overall dated dressing: 26.6%	overall femoral vein insertion site: 9.4%; overall blood at dressing site: 22.2%; overall dated dressing: 34.3%	femoral vein insertion site χ^2 relative ratio: 0.73 (95% CI 0.61-0.88); blood at dressing site χ^2 relative ratio: 0.90 (95% CI 0.81-1.00); dated dressing χ^2 relative ratio: 1.29 (95% CI 1.17-1.42)	15-18
Wicker, United States - 2011	CLABSI	Comprehensive Infection Control Measures				
Yilmaz, Turkey - 2007	CLABSI	Education				

Appendix Table C5b-LQ(3). Adherence outcomes for SSI which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Acklin, Switzerland - 2011	SSI	bundle - antibiotic prophylaxis, skin prep, sterile dressing	antibiotic timing: 57.6%	antibiotic timing: 69.9%	chi square, p=0.016	12
Awad, United States - 2009	SSI	MRSA bundle	screening on admission: 94%; screening on discharge: 82%	screening on admission: 95%; screening on discharge: 86%	chi square: p=NS	24
Berenguer, United States - 2010	SSI	implementing SCIP measures	SCIP compliance: 38%	SCIP compliance: 92%		12
Berry, United States - 2009	SSI	ProvenCare		initial: 59%; 3 mos: 100%; 12 mos: 100%		12
Carles, France - 2006	SSI	surgical antibiotic prophylaxis kit (SAPK)	overall: 41%; antibiotic choice error: 28%; dose error: 0%; timing error: 24%; injection after incision: 1%; SAP duration error: 22%	overall: 82%; antibiotic choice error: 3%; dose error: 0.5%; timing error: 12%; injection after incision: 1.6%; SAP duration error: 1.5%	Overall, t test: p<0.001; antibiotic choice error, RR: 0.74, 95% CI: (0.6-0.88), t test: p<0.001; dose error, RR: 1.01 (0.99-1.02) t test: p=NS; timing error, RR: 0.86 95% CI: (0.78-0.98) t test: p=0.003; injection after incision, RR: 0.65 95% CI: (0.11-1	2
Forbes, Canada - 2008	SSI	bundle - glucose control by screening all pts prior to surgery, administering weight-based regimen of insulin to diabetics, monthly performance figures posted in OR	glucose <4 mmol/L: 4.8%; glucose >11 mmol?L: 17.7%	glucose <4 mmol/L: 0.4%; glucose >11 mmol/L: 14.2%	glucose <4 mmol/L, chi square: p<0.003 glucose >11 mmol/L, chi square: p=0.23	11
Forbes, Canada - 2008	SSI	bundle - maintain normothermia by warming OR to 22 C, standardizing IV warmers and forced air devices, monthly performance figures posted in OR	pts with temp >36 C: at start: 53.8%, at end: 60.5%, on arrival at ward: 90.1%	pts with temp >36 C: at start: 54.7%, at end: 97.6%, on arrival at ward: 100%	at start: RR=1.01 (0.77-1.34) p=0.90; at end: RR=1.61 (1.34-1.94) p<0.001; on arrival at ward, chi square: p=0.003	11
Forbes, Canada - 2008	SSI	bundle - antibiotic administration in OR, pre-printed order form to standardize choice of antibiotic, monthly performance figures posted in OR	antibiotic 1: <60min: 5.9%, 61-120min: 48.2%, 121-180min: 36.5%, >180min: 9.4%; antibiotic 2: <60min: 12.1%, 61-120 min: 50%, 121-180min: 29.3%, >180min: 8.6%	antibiotic 1: <60min: 92.6%, 61-120min: 3.2%, 121-180min: 2.1%, >180min: 0%; antibiotic 2: <60min: 93.8%, 61-120min: 1.5%, 121-180min: 0%, >180min: 0%	Only values 92.6% and 93.8% in <60min were significant for both antibiotic 1 and 2, chi square: p<0.001; all other p=NS	11

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Gomez, Argentina - 2006	SSI	automatic stop prophylaxis form	timing: 55%; choice: 74%; duration: 44%	timing: 88%; choice: 87%; duration: 55%	timing: RR 0.27 95% CI:(0.25-0.30) p<.01; choice: RR 0.50 (0.45-0.55) p<.01; duration: RR 0.80 (0.77-0.84) p<.01	36
Graf, Germany - 2009	SSI	bundle - SSI				
Hermsen, United States - 2008	SSI	Standardized order form	compliance with recommendations on form: 25%; appropriate antibiotic: 62.3%; appropriate duration: 77.8%	compliance with recommendations on form: 66%; appropriate antibiotic: 84.9%; appropriate duration: 89.1%	compliance with recommendations, Fisher: p<0.001; appropriate antibiotic, Fisher: p<.001; appropriate duration, Fisher: p<.001	9
Ichikawa, Japan - 2007	SSI	Implementation of Antibiotic Protocols	Correct admin of pre-operative Abs: 67%; post-operative Abs: 100%	Correct admin of pre-operative Abs: 100%; post-operative Abs: 100%		15
Kable, Australia - 2008	SSI	bundle - antibiotic prophylaxis	TURP: 46%; cholecystectomy: 15%; herniorrhaphy: 56%; hysterectomy: 1%; joint arthroplasty: 95%; overall: 46%	TURP: 73%; cholecystectomy: 17%; herniorrhaphy: 70%; hysterectomy: 25%; joint arthroplasty: 95%; overall: 64%	overall: 18%, 95% CI:(12%-23%)	6
Kramer, United States - 2008	SSI	nomogram for glycemic control				
Liau, Singapore - 2010	SSI	bundle - antibiotic, glucose control, clippers, normothermia		timing of antibiotic: 89%; clipper use: 91%; normoglycemia: 76%; normothermia: 44%		24
Martin, United States - 2010	SSI	surgical wear changes in Mohs surgery				
Nemeth, United States - 2010	SSI	Education program	Timely administration: 90%	Timely administration: 85%	p=.223	.16
Ozgun, Turkey - 2010	SSI	antibiotic prophylaxis education	total compliance: 34.3%; incorrect choice: 8%; inappropriate dose: 5%; prolonged use: 35%; appropriate choice, dose, duration: 52%	total compliance: 28.5%; incorrect choice: 6%; inappropriate dose: 0%; prolonged use: 52%; appropriate choice, dose, duration: 42%	total compliance χ^2/Fishers exact: p=0.59; incorrect choice χ^2/Fishers exact: p=0.51; inappropriate dose χ^2/Fishers exact: p<0.001; prolonged use χ^2/Fishers exact: p=0.01; appropriate choice, dose, duration χ^2/Fishers exact: p=0.09	3

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Parker, United States - 2007	SSI	Six Sigma methodology and antibiotic prophylaxis	overall: 38%	overall: 86%; orthopedic: 37-87%; colorectal: 31-89%; gynecologic: 43-92%; vascular: 67-61%	orthopedic p<0.01; colorectal p<0.01; gynecologic p<0.01; vascular p=0.6	
Pastor, United States - 2010	SSI	task force to meet SCIP process measures	global compliance with SCIP measures: 40%; global compliance with all measures: 30%	global compliance with SCIP measures: 68%; global compliance with all measures: 50%	for both measures, Pearson: p<0.001	14
Paull, United States - 2010	SSI	The Briefing Guide (BiG)	antibiotic prophylaxis: 92% +/- 1.5%	antibiotic prophylaxis: 97.0% +/- 0.1%	t test, p=0.01	12
Potenza, United States - 2009	SSI	bundle - glucose control	100%	91%	chi square, p=.19	27
Potenza, United States - 2009	SSI	bundle - appropriate hair removal	100%	100%	chi square, p=NA	27
Potenza, United States - 2009	SSI	bundle - antibiotic prophylaxis	timing: 81%; selection: 89%; discontinuation: 58%	timing: 98%; selection: 100%; discontinuation: 91%	timing, chi square: p=.02; selection, chi square: p=.01; discontinuation, chi square: p=.01	27
Potenza, United States - 2009	SSI	bundle - normothermia	91%	94%	chi square, p=.73	
Rauk, United States - 2010	SSI	bundle - skin prep and instrument sterilization				
Shimoni, Israel - 2009	SSI	Empowering surgical nurses	compliance: 25.2%	compliance: 100%	Chi-Square: p<0.001	12
Suchitra, India - 2009	CAUTI;SSI	Education Program				
Takahashi, Japan - 2010	SSI	Departmental Education	duration of AMP (days): mean 2.42 (SD 1.86); initial dose w/in 1 hr of incision (% of patients): 95%	duration of AMP (days): mean 1.56 (SD 1.53); initial dose w/in 1 hr of incision (% of patients): 100%	duration of AMP, t test: p<0.001; initial dose w/in 1 hr of incision, chi square: p<.001	3
Wax, United States - 2007	SSI	Electronic reminder for provider	82.4%	overall: 89.1%; acknowledged reminder: 93.4%; did not acknowledge reminder: 83.8%	overall, chi square: p<0.01; acknowledged reminder, chi square: p<0.01; did not acknowledge reminder, chi square: p<0.05	10

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Whitman, United States - 2008	SSI	Multiple ‘forced functions’	abx selection: 76% (95% CI 0.72-0.79); timing of abx admin: 55% (95% CI 0.52-0.58); abx cessation: 60% (95% CI 0.57-0.63)	post1 abx selection: 91% (95% CI 0.89-0.93); post1 timing of abx admin: 78% (95% CI 0.70-0.84); post2 timing of abx admin: 90% (95% CI 0.84-0.94); post3 timing of abx admin: 95% (95% CI 0.91-0.97); abx cessation: 86% (95% CI 0.82-0.89)	abx selection, no statistical tests specified, p<0.001; post1 vs. pre timing of abx admin p<0.001; post1 vs. post2 timing of abx admin: p=0.008; post2 vs. post 3 timing of abx admin p=0.07; abx cessation p<0.001	18
Willemsen, Netherlands - 2007	SSI	standardized antibiotic protocol	timing: 20% after incision	timing: 7% after incision	RR: 0.35 (95% CI: 0.18-0.68), p=.002	2
Zvonar, Canada - 2008	SSI	Appropriate antibiotic prophylaxis administration	appropriate agent: 93.4%; appropriate dose: 72.4%; appropriate administration: 36%	post1 appropriate agent: 92.3%; post1 appropriate dose: 83%; post1 appropriate administration: 67.7%; post2 appropriate agent: 92.5%; post2 appropriate dose: 89.7%; post2 appropriate administration: 78.5%	post1 agent: OR 0.8 (95% CI .4-1.8), p=.64; post1 dose: OR 1.9(95%CI 1.2-3.0), p=.007); post1 admin OR 3.7 (95%CI 2.5-5.5), p<.001; post2 agent OR 1.0 (95%CI .5-2.1), p=.9; post2 dose OR 1.8 (95%CI 0.9-3.2), p=.04; post2 admin OR 1.7 (95CI 1.2-2.6), p.00	

Appendix Table C5b-LQ(4). Adherence outcomes for CAUTI which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention Adherence rate	Post-Intervention Adherence Rate	Adherence Rate Statistical Analysis	Follow-up (months)
Gokula, United States - 2007	CAUTI	Education and indications checklist	appropriate use: 37%	appropriate use: 51%	OR (model not specified): 0.56 (95% CI 0.31, 1.03) p=0.06	12
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	CAUTI Education				12
Jain, United States - 2006	CAUTI;CLABSI;VAP	IMPACT initiative				
Rothfeld, United States - 2010	CAUTI	Appropriate Catheter Use Protocol				
Stephan, Switzerland - 2006	CAUTI	CAUTI guidelines, education and posters		post1: 82.2%; post2: 80.8%		post1: 4; post2: 27
Suchitra, India - 2009	CAUTI;SSI	Education Program				
Venkatram, United States - 2010	CAUTI;CLABSI;VAP	CAUTI bundle				
Wald, United States - 2011	CAUTI	Audit and feedback on catheter duration				

Appendix Table C5c-LQ(1). Cost/savings outcomes for VAP which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention cost	Post-Intervention cost	Cost Statistical Analysis	Savings from QI Intervention	Follow-up (months)
Abbott, United States - 2006	VAP	Academic Center of Evidence-based Practice (ACE) Star Model				Hospital 2: $23,000	
Assanasen, - 2008	CLABSI;VAP	Feedback Program					
Berriel-Cass, United States - 2006	CLABSI;VAP	VAP Bundle					
Bigham, United States - 2009	VAP	VAP Bundle					
Bird, United States - 2010	VAP	VAP Bundle				$1,080,000 ($360,000-1,800,000)	
Blamoun, United States - 2009	VAP	Expanded VAP bundle					
Bloos, Germany - 2009	VAP	Educational Program					
Cocanour, United States - 2006	VAP	VAP Bundle			p<.05		
Garcia, United States - 2009	VAP	VAP Education and Oral Care Protocol					
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	VAP Education					12
Heimes, United States - 2011	VAP	VAP Prevention Protocol (VAPP)					
Jain, United States - 2006	CAUTI;CLABSI;VAP	IMPACT initiative	$3406	$2973			
Jimenez, United States - 2009	VAP	VAP Bundle					
Landrum, Afghanistan - 2008	VAP	Infection Control Protocol					
Quenot, France - 2007	VAP	Nurse-Implemented Sedation Protocol					
Rogers, Ireland - 2010	CLABSI;VAP	Plan-Do-Study-Act (PDSA)cycle					
Rosenthal, Argentina - 2006	VAP	Multifaceted Infection Control Program					
Ross, United States - 2007	VAP	Educational Program					

Study	Infection	Intervention(s)	Pre-intervention cost	Post-Intervention cost	Cost Statistical Analysis	Savings from QI Intervention	Follow-up (months)
Sona, United States - 2009	VAP	Oral Care Protocol				$140,000-$560,000	
Venkatram, United States - 2010	CAUTI;CLABSI;VAP	VAP bundle					

Appendix Table C5c-LQ(2). Cost/savings outcomes for CLABSI which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention cost	Post-Intervention cost	Cost Statistical Analysis	Savings from QI Intervention	Follow-up (months)
Assanasen, - 2008	CLABSI;VAP	Feedback Program					
Berriel-Cass, United States - 2006	CLABSI;VAP	CLABSI Bundle					
Bhutta, United States - 2007	CLABSI	Bundle CLABSI					
Bizzarro, United States - 2010	CLABSI	Bundle - CLABSI					
Galpern, United States - 2008	CLABSI	CLABSI Bundle					
Guerin, United States - 2010	CLABSI	Post-insertion CVC care bundle					
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	VAP Education					12
Jain, United States - 2006	CAUTI;CLABSI; VAP	IMPACT initiative	$3406	$2973			
Jeffries, United States - 2009	CLABSI	CVC Insertion and Maintenance Bundle				Estimated 69 CVC-BSI prevented accounting for $2940000 estimated CVC associated savings across all teams	
Koll, United States - 2008	CLABSI	Central line bundle					
Lobo, Brazil - 2010	CLABSI	Continuous Education					
Lobo, Brazil - 2010	CLABSI	Single lecture					
Marra, Brazil - 2010	CLABSI	IHI Bundle - CLABSI					
Render, United States - 2006	CLABSI	CLABSI bundle					
Rogers, Ireland - 2010	CLABSI; VAP	Plan-Do-Study-Act (PDSA)cycle					
Sannoh, United States - 2010	CLABSI	Bundle - CLABSI				$75,920-$161,280	
Santana, Brazil - 2008	CLABSI	Education					
Shannon, United States - 2006	CLABSI	Toyota Production System adaptation					

Study	Infection	Intervention(s)	Pre-intervention cost	Post-Intervention cost	Cost Statistical Analysis	Savings from QI Intervention	Follow-up (months)
Venkatram, United States - 2010	CAUTI;CLABSI; VAP	CLABSI bundle					
Warren, United States - 2006	CLABSI	Multifaceted, education-based intervention					
Wicker, United States - 2011	CLABSI	Comprehensive Infection Control Measures					
Yilmaz, Turkey - 2007	CLABSI	Education					

Appendix Table C5c-LQ(3). Cost/savings outcomes for SSI which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention cost	Post-Intervention cost	Cost Statistical Analysis	Savings from QI Intervention	Follow-up (months)
Acklin, Switzerland - 2011	SSI	bundle - antibiotic prophylaxis, skin prep, sterile dressing					
Awad, United States - 2009	SSI	MRSA bundle					
Berenguer, United States - 2010	SSI	implementing SCIP measures					
Berry, United States - 2009	SSI	ProvenCare					
Carles, France - 2006	SSI	surgical antibiotic prophylaxis kit (SAPK)					
Forbes, Canada - 2008	SSI	bundle - glucose control by screening all pts prior to surgery, administering weight-based regimen of insulin to diabetics, monthly performance figures posted in OR					
Forbes, Canada - 2008	SSI	bundle - maintain normothermia by warming OR to 22 C, standardizing IV warmers and forced air devices, monthly performance figures posted in OR					
Forbes, Canada - 2008	SSI	bundle - antibiotic administration in OR, pre-printed order form to standardize choice of antibiotic, monthly performance figures posted in OR					
Gomez, Argentina - 2006	SSI	automatic stop prophylaxis form	$10,679/1000 pt days	$7686/1000 pt days	RR 0.87 (0.86-0.89) p<.01		
Graf, Germany - 2009	SSI	bundle - SSI					

Study	Infection	Intervention(s)	Pre-intervention cost	Post-Intervention cost	Cost Statistical Analysis	Savings from QI Intervention	Follow-up (months)
Hermsen, United States - 2008	SSI	Standardized order form	mean cost of abx prophylaxis per pt: $46; mean cost of hospitalization per pt: $10,792	mean cost of abx prophylaxis per pt: $40; mean cost of hospitalization per pt: $11,892	cost of abx prophylaxis per pt, logistic regression: p=0.02; cost of hospitalization per pt, ANOVA: p=0.83	approximate annual savings: $30,000, adjusted for age, race, and diagnostic-related grouping	
Ichikawa, Japan - 2007	SSI	Implementation of Antibiotic Protocols					
Kable, Australia - 2008	SSI	bundle - antibiotic prophylaxis	Costs/pt: TURP: $0.68; cholecystectomy: $11.77; herniorrhaphy: $2.51; hysterectomy: $14.36; joint arthroplasty: $19.65; overall: $11.72	Costs/pt: TURP: $0.69; cholecystectomy: $4.14; herniorrhaphy: $1.08; hysterectomy: $6.83; joint arthroplasty: $19.77; overall: $10.53		$1.19/pt; if protocols routinely adopted, cost savings would have been $8.32/pt	
Kramer, United States - 2008	SSI	nomogram for glycemic control					
Liau, Singapore - 2010	SSI	bundle - antibiotic, glucose control, clippers, normothermia				mean cost of SSI estimated at US$1532, and estimating prevention of 63 pts from getting SSI, equals savings of US$97,200 during the 2 yr study period	
Martin, United States - 2010	SSI	surgical wear changes in Mohs surgery		Required costs of preventing an infection can be reduced from $672.50 to $250 per infection ($422.50 savings); sterility cost upgrades estimated at $10.76 per case			
Nemeth, United States - 2010	SSI	Education program					
Ozgun, Turkey - 2010	SSI	antibiotic prophylaxis education					
Parker, United States - 2007	SSI	Six Sigma methodology and antibiotic prophylaxis					

Study	Infection	Intervention(s)	Pre-intervention cost	Post-Intervention cost	Cost Statistical Analysis	Savings from QI Intervention	Follow-up (months)
Pastor, United States - 2010	SSI	task force to meet SCIP process measures					
Paull, United States - 2010	SSI	The Briefing Guide (BiG)					
Potenza, United States - 2009	SSI	bundle - glucose control					
Potenza, United States - 2009	SSI	bundle - appropriate hair removal					
Potenza, United States - 2009	SSI	bundle - antibiotic prophylaxis					
Potenza, United States - 2009	SSI	bundle - normothermia					
Rauk, United States - 2010	SSI	bundle - skin prep and instrument sterilization				estimated 4.5 infections less per month for 1 yr, for an estimated savings of $54,000 in case-related incremental costs	
Shimoni, Israel - 2009	SSI	Empowering surgical nurses					
Suchitra, India - 2009	CAUTI;SSI	Education Program					
Takahashi, Japan - 2010	SSI	Departmental Education	3 months preintervention: US $127,654	3 months postintervention: US $86,183		estimated annual savings: US $165,900	
Wax, United States - 2007	SSI	Electronic reminder for provider					
Whitman, United States - 2008	SSI	Multiple ‘forced functions’					

Study	Infection	Intervention(s)	Pre-intervention cost	Post-Intervention cost	Cost Statistical Analysis	Savings from QI Intervention	Follow-up (months)
Willemsen, Netherlands - 2007	SSI	standardized antibiotic protocol				Because less expensive antibiotics were in the recommended guidelines, the estimated savings in using the less expensive antibiotics was estimated at US$112,000 for one yr	
Zvonar, Canada - 2008	SSI	Appropriate antibiotic prophylaxis administration					

Appendix Table C5c-LQ(4). Cost/savings outcomes for CAUTI which do not control for secular trend or confounding

Study	Infection	Intervention(s)	Pre-intervention cost	Post-Intervention cost	Cost Statistical Analysis	Savings from QI Intervention	Follow-up (months)
Gurskis, Lithuania - 2009	CAUTI, CLABSI, VAP	VAP Education					12
Gokula, United States - 2007	CAUTI	Education and indications checklist					
Jain, United States - 2006	CAUTI;CLABSI;VAP	IMPACT initiative	$3406	$2973			
Rothfeld, United States - 2010	CAUTI	Appropriate Catheter Use Protocol					
Stephan, Switzerland - 2006	CAUTI	CAUTI guidelines, education and posters					
Suchitra, India - 2009	CAUTI;SSI	Education Program					
Venkatram, United States - 2010	CAUTI;CLABSI;VAP	CAUTI bundle					
Wald, United States - 2011	CAUTI	Audit and feedback on catheter duration					

Appendix Table C6-LQ-a. Quality ratings for VAP which do not control for secular trend or confounding

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	Infection CDC	Device Adju	Postsurveillance	QE_IndependentQI	QE_DataTimePoint	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Gurskis, Lithuania - 2009	VAP	No	No	Yes	Yes	Yes	No	No	Yes	Yes		Yes	Yes	TRUE	chi-square, Mann-Whitney U test, Kolmogorov-Smirnov tests, kaplan-meier survival with log-rank and Breslow tests	TRUE	binary logistic regression	not specified
Jimenez, Puerto Rico - 2009	VAP	Uncertain	Yes	Yes	No	Yes	No					Yes	No	TRUE	Pearson Chi-square test	FALSE		
Jain, United States - 2006	VAP	Uncertain	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes		No	No	TRUE	Chi-square test	FALSE		
Garcia, United States - 2009	VAP	Uncertain	Yes	Yes	Yes	Yes	No	Uncertain	Yes	Yes		No	Yes	TRUE	t-test, Mann-Whitney	FALSE		Adjusted for time
Ross, United States - 2007	VAP	Uncertain	Yes	Yes	No	Yes	No					Yes	No	TRUE	2 sample t-test	FALSE		
Assanasen, - 2008	VAP	Uncertain	Yes		Yes	Yes	No					Uncertain	No	TRUE	Chi-square test	FALSE		
Berriel-Cass, United States - 2006	VAP	Uncertain	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes		Uncertain	Yes	TRUE	independent 2-tailed t-test, assuming different variances	FALSE		

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	Infection CDC	Device Adju	Postsurveillance	QE_IndependentQI	QE_DataTimePoint	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Abbott, United States - 2006	VAP	No	Uncertain	Yes	No	Yes	Yes	Yes	Yes	Yes		Uncertain	No	TRUE	t-test	TRUE	MANCOVA	APACHE-II, years of respiratory disease, enteral tube feeding, in-hospital transfer events
Sona, United States - 2009	VAP	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes		No	No	TRUE	Mantel-Haenszel chi-square test and Mann-Whitney test	FALSE		
Rogers, Ireland - 2010	VAP	Uncertain	Yes	Yes	No	No	No	Yes	Yes	Yes		Yes	No	TRUE	Exact Poisson rate incidence test, paired t-test	FALSE		
Bigham, United States - 2009	VAP	Uncertain	Yes	Yes	Yes	No	No	Yes	Yes	Yes		Yes	No	TRUE	Chi-square test; Fisher exact test; One-way ANOVA	FALSE		
Bird, United States - 2010	VAP	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes		No	Yes	TRUE	Chi-square test	FALSE		
Bloos, Germany - 2009	VAP	Uncertain	Yes	Yes	Yes	Yes	No	Yes	No	No		No	No	TRUE	Mann-Whitney U-test; Chi-square test	TRUE	stepwise Cox regression	Cox regression had tracheostomy rates, angle of HOB elevation, number of patients receiving propofol, days with deep vein thrombosis prophylaxis (DVTP), and days where DVTP was contraindicated

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	Infection CDC	Device Adju	Postsurveillance	QE_IndependentQI	QE_DataTimePoint	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Cocanour, United States - 2006	VAP	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes		Yes	Yes	TRUE	Two sample t-test	FALSE		
Heimes, United States - 2011	VAP	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes		Yes	No	TRUE	Fisher Kruskal-Wallis two-tailed test; Satterthwaite test; chi-square test	FALSE		
Landrum, Afghanistan - 2008	VAP	No	No	Yes	No	Yes	No	No	Yes	Yes		Yes	No	TRUE	Mantel-Haenszel chi-square test	FALSE		
Blamoun, United States - 2009	VAP	Uncertain	Yes	Yes	Yes	Yes	No	No	Yes	Yes		No	Yes	TRUE	Mann-Whitney, Chi-Square	FALSE		
Quenot, France - 2007	VAP	No	No	Uncertain	Yes	Yes	No	No	Uncertain	Yes		No	No	TRUE	chi-square test, Fisher's exact test, Mann-Whitney test, Cox proportional hazard	FALSE		Cox was controlled for SAPS II score
Rosenthal, Argentina - 2006	VAP	No	No	Yes	Yes	Yes	No	No	Yes	Yes		No	No	TRUE	Student's t-test, Fisher exact test	FALSE		
Venkatram, United States - 2010	VAP	Uncertain	No	Yes	Yes	Yes	No	No	Yes	Yes		Yes	No	TRUE	Mann-Whitney U test	TRUE	incidence rate ratios	device utilization

All_Vary Did the execution of the study vary from the original protocol?
All_Valid Is the intervention assessed using valid and reliable measures, implemented consistently across all study participants?
All_Consist Are outcomes assessed using valid and reliable measures, implemented consistently across all study participants?
All_PrimOut Is the length of followup sufficient to support the evaluation of primary outcomes and harms?

All_ImpOut	Are any important primary outcomes missing from the results?
All_FundSource	Is the Source of funding Identified?
AdherenceReported	If infection rates reported, did study also report adherence rates?
InfectionCDC	If infection rates reported, was CDC/NNIS* methodology used?
DeviceAdju	For CLABSI, VAP, CAUTI: were infection rates adjusted for device utilization?
Postsurveillance	For SSI: was post-discharge surveillance for infections performed?
QE_IndependentQI	Was the intervention performed independent of other QI efforts or other changes?
QE_DataTimePoint	Did the study report data at more than one time point both before and after the intervention?
QE_InfectionRate	If the study reported infection rates, were process measurements also reported?
CON_Rand	Were study subjects randomized
CON_RandDesc	was randomization process described?
CON_NonRandRationale	For non-randomized studies, was rationale for comparison group selection explained?
CON_Assessor	Were outcome assessor blinded to treatment group assignment
CON_Unit	Was a unit of analysis error present?
CON_Corrected	Was a unit of analysis error present and corrected by appropriate statistical methods?
UnivarYN	Was Univariate Analysis Conducted?
UnivarModel	What model was used?
UnivarControl	What variables were controlled for?
MultivarYN	Was Multivariate Analysis Conducted?
MultivarModel	What model was used?

Appendix Table C6-LQ-b. Quality ratings for CLABSI which do not control for secular trend or confounding

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	Infection CDC	Device Adju	Postsurveillance	QE_IndependentQI	QE_DataTimePoint	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Warren, United States - 2006	CLABSI	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes		No	No	TRUE	chi-squared	FALSE		
Galpern, United States - 2008	CLABSI	Uncertain	Yes	Yes	Yes	Yes	No	No	Yes	Yes		Yes	No	TRUE		FALSE		
Bizzarro, United States - 2010	CLABSI	No	Yes	Yes	Yes	Yes	No	No	Uncertain	Yes		Uncertain	Yes	TRUE	student t-test, Wilcoxon-rank test, Chi-Square, Fischer exact test	FALSE		Birth weight, age, gender, CLABSI-related death, days of ventilation, days of hospital stay
Guerin, United States - 2010	CLABSI	No	No	Yes	Yes	Yes	No	No	Yes	Yes		No	No	TRUE	Fisher's exact test	FALSE		
Shannon, United States - 2006	CLABSI	No	No	Yes	Yes	No	No	No	Yes	Yes		No	No	TRUE	Chi-square, Fisher's exact test	FALSE		age, sex, frequency, rates, lines
Gurskis, Lithuania - 2009	CLABSI	No	No	Yes	Yes	Yes	No	No	Yes	Yes		Yes	Yes	TRUE	chi-square, Mann-Whitney U test, Kolmogorov-Smirnov tests, kaplan-meier survival with log-rank and Breslow tests	TRUE	binary logistic regression	not specified
Jain, United States - 2006	CLABSI	Uncertain	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes		No	No	TRUE	Chi-square test	FALSE		
Bhutta, United States - 2007	CLABSI	Uncertain	No	No	Yes	Yes	Yes	Yes	Yes	Yes		No	Yes	FALSE		FALSE		

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	Infection CDC	Device Adju	Postsurveillance	QE_IndependentQI	QE_DataTimePoint	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Yilmaz, Turkey - 2007	CLABSI	Uncertain	Yes	Yes	Uncertain	Yes	No	No	Yes	Yes		Yes	Yes	TRUE	student t-test, mann-whitney U test, chi-square	FALSE		
Santana, Brazil - 2008	CLABSI	Uncertain	Uncertain	Uncertain	Uncertain	Yes	No	No	Uncertain	Yes		Yes	No	TRUE	Fisher exact test, chi-square test, Wilcoxon rank-sum test, student t-test	FALSE		
Wicker, United States - 2011	CLABSI	No	No	Uncertain	Yes	Yes	No	No	Uncertain	Yes		No	No	TRUE	student t test, Mann-Whitney rank sum test, Chi-square, Fisher exact	FALSE		
Rogers, Ireland - 2010	CLABSI	Uncertain	Yes	Yes	No	No	No	Yes	Yes	Yes		Yes	No	TRUE	Exact Poisson rate incidence test, paired t-test	FALSE		
Berriel-Cass, United States - 2006	CLABSI	Uncertain	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes		Uncertain	Yes	TRUE	independent 2-tailed t-test, assuming different variances	FALSE		
Lobo, Brazil - 2010	CLABSI													FALSE		FALSE		
Assanasen, - 2008	CLABSI	Uncertain	Yes		Yes	Yes	No					Uncertain	No	TRUE	Chi-square test	FALSE		
Jeffries, United States - 2009	CLABSI	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes		Uncertain	No	TRUE	Wilcoxon rank sum test or Fisher exact test Wilcoxon rank sum test or the Fisher exact test sum test or the Fisher exact test	FALSE		

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	Infection CDC	Device Adju	Postsurveillance	QE_IndependentQI	QE_DataTimePoint	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Sannoh, United States - 2010	CLABSI	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes		No	Yes	TRUE	pearson's chi-square, student t-test, unpaired t-test	FALSE		
Marra, Brazil - 2010	CLABSI	No	Uncertain	Yes	Yes	Yes	Yes	No	Yes	Yes		No	Yes	TRUE	chi-square, Student T, Mann-Whitney U test	FALSE		
Koll, United States - 2008	CLABSI	Uncertain	Yes	Yes	Yes	Yes	Yes	No	Uncertain	Yes		Uncertain	No	TRUE		TRUE		
Venkatram, United States - 2010	CLABSI	Uncertain	No	Yes	Yes	Yes	No	No	Yes	Yes		Yes	No	TRUE	Mann-Whitney U test	TRUE	incidence rate ratios	device utilization

All_Vary	Did the execution of the study vary from the original protocol?
All_Valid	Is the intervention assessed using valid and reliable measures, implemented consistently across all study participants?
All_Consist	Are outcomes assessed using valid and reliable measures, implemented consistently across all study participants?
All_PrimOut	Is the length of followup sufficient to support the evaluation of primary outcomes and harms?
All_ImpOut	Are any important primary outcomes missing from the results?
All_FundSource	Is the Source of funding Identified?
AdherenceReported	If infection rates reported, did study also report adherence rates?
InfectionCDC	If infection rates reported, was CDC/NNIS* methodology used?
DeviceAdju	For CLABSI, VAP, CAUTI: were infection rates adjusted for device utilization?
Postsurveillance	For SSI: was post-discharge surveillance for infections performed?
QE_IndependentQI	Was the intervention performed independent of other QI efforts or other changes?
QE_DataTimePoint	Did the study report data at more than one time point both before and after the intervention?
QE_InfectionRate	If the study reported infection rates, were process measurements also reported?
CON_Rand	Were study subjects randomized
CON_RandDesc	was randomization process described?
CON_NonRandRationale	For non-randomized studies, was rationale for comparison group selection explained?
CON_Assessor	Were outcome assessor blinded to treatment group assignment?
CON_Unit	Was a unit of analysis error present?
CON_Corrected	Was a unit of analysis error present and corrected by appropriate statistical methods?
UnivarYN	Was Univariate Analysis Conducted?
UnivarModel	What model was used?

UnivarControl	What variables were controlled for?
MultivarYN	Was Multivariate Analysis Conducted?
MultivarModel	What model was used?

Appendix Table C6-LQ-c. Quality ratings for SSI which do not control for secular trend or confounding

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	Infection CDC	Device Adju	Postsurveillance	QE_IndependentQI	QE_DataTimePoint	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Carles, France - 2006	SSI	No	Yes	Yes	No	Yes	No				No	Uncertain	No	TRUE	student t-test, fisher exact test	FALSE		
Forbes, Canada - 2008	SSI	No	Yes	Yes	No	No	No	Yes	Uncertain		No	Uncertain	No	TRUE	Student t-test, Wilcoxon sum-rank test, chi-square	FALSE		
Takahashi, Japan - 2010	SSI	No	Yes	Uncertain	No	No	No	Yes	Uncertain		Uncertain	No	Yes	TRUE	Chi-square, student's t test, Mann-Whitney test	FALSE		
Wax, United States - 2007	SSI	No	Yes	Yes	No	Yes	No					No	No	TRUE	Chi-square, Wilcoxon's signed rank test	FALSE		
Whitman, United States - 2008	SSI	No	Yes	Yes	Yes	Yes	No					Uncertain	No	TRUE	z-test for independent proportions	FALSE		
Ichikawa, Japan - 2007	SSI	No	No	Yes	Yes	No	Yes	Yes	Uncertain		No	Uncertain	No	TRUE	Chi-square	FALSE		
Ozgun, Turkey - 2010	SSI	No	Yes	Yes	No	Yes	Yes					Yes	No	TRUE	t-test for continuous; chi-sq or Fisher exact for categorical	FALSE		demographics, wound type, surgery branch
Gomez, Argentina - 2006	SSI	No	Yes	Yes	Yes	No	No	Yes	Yes		Yes	Yes	No	TRUE	chi-sq, RR (95% CI)	FALSE		by surgery unit

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	Infection CDC	Device Adju	Postsurveillance	QE_IndependentQI	QE_DataTimePoint	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Willemsen, Netherlands - 2007	SSI	No	Yes	Yes	No	Yes	Yes					Yes	No	TRUE	Fisher’s Exact or chi-sq	FALSE		
Parker, United States - 2007	SSI	No	Yes	Yes	No	Yes	Yes					Yes	No	TRUE	chi-square test	FALSE		
Zvonar, Canada - 2008	SSI	Yes	Yes	Yes	Yes	Yes	No					Yes	No	TRUE		FALSE		
Graf, Germany - 2009	SSI	No	Yes	Yes	Yes	Yes	No	No	Yes		Uncertain	Yes	No	TRUE	Wilcoxon signed rank test, McNemar’s test	TRUE	conditional logistic regression	
Acklin, Switzerland - 2011	SSI	No	Yes	Yes	Yes	No	Yes	Yes	Yes		Yes	Yes	Yes	TRUE	chi-sq for categorical variables; t-test for continuous variables	TRUE	stepwise logistic regression	variables with p<.1 in univariate analysis (body weight, COPD, operation time, operation type, hematoma)
Awad, United States - 2009	SSI	No	Yes	Yes	Yes	No	No	Yes	Uncertain		Uncertain	Yes	Yes	TRUE	chi-sq	FALSE		
Berenguer, United States - 2010	SSI	No	Yes	Yes	Yes	No	No	Yes	No		Yes	Yes	No	TRUE	Fisher’s Exact test	FALSE		
Kable, Australia - 2008	SSI	No	Yes	Yes	No	No	No	Yes	No		Uncertain	Yes	No	TRUE	percentages and 95% CI	FALSE		

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	Infection CDC	Device Adju	Postsurveillance	QE_IndependentQI	QE_DataTimePoint	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Suchitra, India - 2009	SSI	No	No	Yes	Yes	Yes	No	No	Yes		Uncertain	Uncertain	No	TRUE	Chi-square, Fisher's exact	FALSE		
Liau, Singapore - 2010	SSI	No	Yes	Yes	Yes	No	Yes	Yes	Yes		Yes	Yes	Yes	TRUE	Fischer exact test	FALSE		
Berry, United States - 2009	SSI	No	Yes	Yes	Yes	No	No	Yes	Uncertain		Uncertain	Yes	No	TRUE	chi-sq, Fisher exact, Wilcoxon	FALSE		
Rauk, United States - 2010	SSI	No	Yes	Yes	No	Yes	No	No	Uncertain		Uncertain			TRUE	chi-sq	FALSE		
Shimoni, Israel - 2009	SSI	No	Yes	Uncertain	Yes	No	Yes	Yes	Uncertain		No	No	No	TRUE	Chi-square, Taylor's series used for Rel Risk confidence intervals	FALSE		
Nemeth, United States - 2010	SSI	No	Yes	Yes	No	Yes	No					No	No	TRUE	Chi-square	FALSE		
Kramer, United States - 2008	SSI	No	Yes	Yes	Yes	Yes	No	No	No		Yes	No	Yes	FALSE		FALSE		
Kim, United States - 2010	SSI	No	Yes	Yes	Yes	Yes	Yes	No	Yes		Yes	Yes	No	TRUE	chi-sq	FALSE		
Potenza, United States - 2009	SSI	No	Yes	Yes	Yes	Yes	No					No	No	TRUE	chi-sq	FALSE		

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	Infection CDC	Device Adju	Postsurveillance	QE_IndependentQI	QE_DataTimePoint	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Paull, United States - 2010	SSI	No	Yes	Yes	Yes	Yes	Yes					No	No	FALSE		FALSE		
Pastor, United States - 2010	SSI	No	Yes	Yes	Yes	No	No	Yes	Yes		Yes	Yes	No	TRUE	Student t-test for continuous variables; chi-sq for categorical variables	FALSE		

All_Vary	Did the execution of the study vary from the original protocol?
All_Valid	Is the intervention assessed using valid and reliable measures, implemented consistently across all study participants?
All_Consist	Are outcomes assessed using valid and reliable measures, implemented consistently across all study participants?
All_PrimOut	Is the length of followup sufficient to support the evaluation of primary outcomes and harms?
All_ImpOut	Are any important primary outcomes missing from the results?
All_FundSource	Is the Source of funding Identified?
AdherenceReported	If infection rates reported, did study also report adherence rates?
InfectionCDC	If infection rates reported, was CDC/NNIS* methodology used?
DeviceAdju	For CLABSI, VAP, CAUTI: were infection rates adjusted for device utilization?
Postsurveillance	For SSI: was post-discharge surveillance for infections performed?
QE_IndependentQI	Was the intervention performed independent of other QI efforts or other changes?
QE_DataTimePoint	Did the study report data at more than one time point both before and after the intervention?
QE_InfectionRate	If the study reported infection rates, were process measurements also reported?
CON_Rand	Were study subjects randomized
CON_RandDesc	was randomization process described?
CON_NonRandRationale	For non-randomized studies, was rationale for comparison group selection explained?
CON_Assessor	Were outcome assessor blinded to treatment group assignment?
CON_Unit	Was a unit of analysis error present?
CON_Corrected	Was a unit of analysis error present and corrected by appropriate statistical methods?
UnivarYN	Was Univariate Analysis Conducted?
UnivarModel	What model was used?
UnivarControl	What variables were controlled for?
MultivarYN	Was Multivariate Analysis Conducted?
MultivarModel	What model was used?

Appendix Table C6-LQ-d. Quality ratings for CAUTI which do not control for secular trend or confounding

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	Infection CDC	Device Adju	Postsurveillance	QE_IndependentQI	QE_DataTimePoint	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Stephan, Switzerland - 2006	CAUTI	No	Yes	Uncertain	No	No	Yes					Uncertain	No	TRUE	Chi-square, Fisher's exact, Student's t test, Mann-Whitney U test, ANOVA	FALSE		
Gurskis, Lithuania - 2009	CAUTI	No	No	Yes	Yes	Yes	No	No	Yes	Yes		Yes	Yes	TRUE	chi-square, Mann-Whitney U test, Kolmogorov-Smirnov tests, kaplan-meier survival with log-rank and Breslow tests	TRUE	binary logistic regression	not specified
Jain, United States - 2006	CAUTI	Uncertain	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes		No	No	TRUE	Chi-square test	FALSE		
Gokula, United States - 2007	CAUTI	No	Yes		Yes	Yes	No					Yes	No	FALSE		FALSE		
Venkatram, United States - 2010	CAUTI	Uncertain	No	Yes	Yes	Yes	No	No	Yes	Yes		Yes	No	TRUE	Mann-Whitney U test	TRUE	incidence rate ratios	device utilization
Rothfeld, United States - 2010	CAUTI	No	Uncertain	Uncertain	No	No	No	Uncertain	No	Yes		No	No	FALSE		FALSE		
Wald, United States - 2011	CAUTI	No	No	Yes	No	Yes	Yes	No	Yes	Yes		Yes	No	TRUE	t-test, chi-squared tests, Cochran-Mantel-Haenszel test for trend	FALSE		

Study	Infection	All_Vary	All_Valid	All_Consist	All_PrimOut	All_ImpOut	All_FundSource	Adherence Reported	Infection CDC	Device Adju	Postsurveillance	QE_IndependentQI	QE_DataTimePoint	UnivarYN	UnivarModel	MultivarYN	MultivarModel	MultivarControl
Suchitra, India - 2009	CAUTI	No	No	Yes	Yes	Yes	No	No	Yes		Uncertain	Uncertain	No	TRUE	Chi-square, Fisher's exact	FALSE		

All_Vary	Did the execution of the study vary from the original protocol?
All_Valid	Is the intervention assessed using valid and reliable measures, implemented consistently across all study participants?
All_Consist	Are outcomes assessed using valid and reliable measures, implemented consistently across all study participants?
All_PrimOut	Is the length of followup sufficient to support the evaluation of primary outcomes and harms?
All_ImpOut	Are any important primary outcomes missing from the results?
All_FundSource	Is the Source of funding Identified?
AdherenceReported	If infection rates reported, did study also report adherence rates?
InfectionCDC	If infection rates reported, was CDC/NNIS* methodology used?
DeviceAdju	For CLABSI, VAP, CAUTI: were infection rates adjusted for device utilization?
Postsurveillance	For SSI: was post-discharge surveillance for infections performed?
QE_IndependentQI	Was the intervention performed independent of other QI efforts or other changes?
QE_DataTimePoint	Did the study report data at more than one time point both before and after the intervention?
QE_InfectionRate	If the study reported infection rates, were process measurements also reported?
CON_Rand	Were study subjects randomized
CON_RandDesc	was randomization process described?
CON_NonRandRationale	For non-randomized studies, was rationale for comparison group selection explained?
CON_Assessor	Were outcome assessor blinded to treatment group assignment?
CON_Unit	Was a unit of analysis error present?
CON_Corrected	Was a unit of analysis error present and corrected by appropriate statistical methods?
UnivarYN	Was Univariate Analysis Conducted?
UnivarModel	What model was used?
UnivarControl	What variables were controlled for?
MultivarYN	Was Multivariate Analysis Conducted?
MultivarModel	What model was used?

AppendixTable C1a-Update. Study characteristics for VAP which control for secular trend or confounding from the update search

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up Months	Comment
Cheema, United States - 2011	Interrupted time series	VAP	Tertiary care or university hospital	Pediatric Intensive Care Unit	2007-2010	42	
Morris, Scotland - 2011	Simple before-after	VAP	Tertiary care or university hospital	Medical Intensive Care Unit	2008-2009	12	
Barrera, Colombia - 2011	Simple before-after	CAUTI, CLABSI, VAP	Tertiary care or university hospital	Medical Intensive Care Unit, Pediatric Intensive Care Unit, Surgical Intensive Care Unit	2002-2005	46	
Harris, United States - 2011	Simple before-after	CLABSI, VAP	Tertiary care or university hospital	Pediatric Intensive Care Unit	2008-2009	13	3 time periods: 1 yr baseline, 10 mon intervention, and 13 mon postintervention
Lilly, United States - 2011	non randomized Stepped wedge	CLABSI, VAP	Tertiary care or university hospital	Medical Intensive Care Unit, Surgical Intensive Care Unit	2006-2007	15	This is a nonrandomized stepped wedge design, in which the same intervention was implemented in 7 different ICUs at different times.
Speroff, United States - 2011	Cluster RCT	CLABSI, VAP	More than one hospital of different types	ICU setting not specified. Authors state either pediatric or adult ICU eligible for inclusion	2006-2007	18	

AppendixTable C1b-Update. Study characteristics for CLABSI which control for secular trend or confounding from the update search

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up Months	Comment
Burrell, Australia - 2011	Simple before-after	CLABSI	More than one hospital of different types	Medical Intensive Care Unit, Pediatric Intensive Care Unit	2007-2008	18	
Kim, United States – 2011	Simple before-after	CLABSI	Tertiary care or university hospital	Medical Intensive Care Unit, Surgical Intensive Care Unit, coronary care unit, cardiothoracic ICU	2008-2009	14	
Miller, United States – 2011	Interrupted time series	CLABSI	More than one hospital of different types	Pediatric Intensive Care Unit	2006-2009	36	
Render, United States – 2011	Simple before-after	CLABSI	VA Hospitals	Medical Intensive Care Unit, Surgical Intensive Care Unit, Cardiac ICU	2006-2009		
Taylor, United States – 2011	Simple before-after	CLABSI	Tertiary care or university hospital	neonatal ICU	2006-2007	12	
Barrera, Colombia – 2011	Simple before-after	CAUTI, CLABSI, VAP	Tertiary care or university hospital	Medical Intensive Care Unit, Pediatric Intensive Care Unit, Surgical Intensive Care Unit	2002-2005	46	
Harris, United States – 2011	Simple before-after	CLABSI, VAP	Tertiary care or university hospital	Pediatric Intensive Care Unit	2008-2009	13	3 time periods: 1 yr baseline, 10 mon intervention, and 13 mon postintervention
Lilly, United States – 2011	non randomized Stepped wedge	CLABSI, VAP	Tertiary care or university hospital	Medical Intensive Care Unit, Surgical Intensive Care Unit	2006-2007	15	This is a nonrandomized stepped wedge design, in which the same intervention was implemented in 7 different ICUs at different times.
Speroff, United States – 2011	Cluster RCT	CLABSI, VAP	More than one hospital of different types	ICU setting not specified. Authors state either pediatric or adult ICU eligible for inclusion	2006-2007	18	

Appendix Table C1c-Update. Study characteristics for SSI which control for secular trend or confounding from the update search

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up Months	Comment
Kestle, United States - 2011	Simple before-after	SSI	More than one hospital of different types	Pediatric Neurosurgical centers	2007-2009	21	
Lavu, United States - 2011	Simple before-after	SSI	Tertiary care or university hospital	Surgery Department	2008-2010	24	Baseline period was from October 2005 to April 2008.
Schwann, United States - 2011	Simple before-after	SSI	Tertiary care or university hospital	Operating Room	2007-2009	30	Baseline period was from June 2006 to November 2006. Calendar years 2008 and 2009 were considered the sustainability phase.
Salim, Israel - 2011	Simple before-after	CAUTI, SSI	Tertiary care or university hospital	Operating Room	2009-2010	12	Baseline period was from September 2006 to August 2007.

Appendix Table C1d-Update. Study characteristics for CAUTI which control for secular trend or confounding from the update search

Study	Study Design	Infection	Healthcare Setting	Clinical Setting	Intervention Years	Follow-up Months	Comment
Fakih, United States - 2012	Simple before-after	CAUTI	More than one hospital of different types	163 units across 71 acute care hospitals, otherwise not specified	2007-2010	36	
Marra, Brazil – 2011	Interrupted time series	CAUTI	Tertiary care or university hospital	Medical Intensive Care Unit, Surgical Intensive Care Unit, Step down unit	2005-2010	61	
van den Broek, Netherlands – 2011	Cluster RCT	CAUTI	More than one hospital of different types	ICU, Internal medicine, Neurology, surgery		17	
Barrera, Colombia – 2011	Simple before-after	CAUTI, CLABSI, VAP	Tertiary care or university hospital	Medical Intensive Care Unit, Pediatric Intensive Care Unit, Surgical Intensive Care Unit	2002-2005	46	
Salim, Israel – 2011	Simple before-after	CAUTI, SSI	Tertiary care or university hospital	Operating Room	2009-2010	12	Baseline period was from September 2006 to August 2007.

Appendix Table C2a-Update. Patient characteristics for VAP which control for secular trend or confounding from the update search

Study	Infection	Intervention	Type of QI Strategies	Participants	Number of Hospitals	Number of Patients
Cheema, United States - 2011	VAP	Phase 3: VAP bundle with flowsheet	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	All Clinical Staff		
Morris, Scotland - 2011	VAP	VAP bundle - sedation holiday, elevated bed, oral care, with checklist and feedback	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	All Clinical Staff	1	pre: 1460 (216); post: 501 (43)
Barrera, Colombia - 2011	CAUTI, CLABSI, VAP	hand hygiene promotion	Audit and Feedback, Patient Education	All Clinical Staff	1	total: 14,516 (total # HAI: 2,398)
Harris, United States - 2011	CLABSI, VAP	hand hygiene, vap bundle, standardizing central line care	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	All Clinical Staff	1	pre: 817 (VAP: 16, CLABSI: 31; intervention: 601 (VAP: 16, CLABSI: 19); post: 961 (VAP: 7, CLABSI: 15)
Lilly, United States - 2011	CLABSI, VAP	tele-ICU, providing care from a remote location	Audit and Feedback, Organizational Change	All Clinical Staff	2	pre: 1529 (VAP: 76, CLABSI: 19); post: 4761 (VAP: 32, CLABSI: 29)
Speroff, United States - 2011	CLABSI, VAP	Virtual Collaborative Group	Organizational Change, Provider Education	Nurses, Physicians	Virtual Collaborative: 31; Toolkit: 29	

Appendix Table C2b-Update. Patient characteristics for CLABSI which control for secular trend or confounding from the update search

Study	Infection	Intervention	Type of QI Strategies	Participants	Number of Hospitals	Number of Patients
Burrell, Australia - 2011	CLABSI	CLABSI Physician + Patient Bundles	Audit and Feedback, Organizational Change, Provider Reminder Systems	Nurses, Physicians	37	
Kim, United States - 2011	CLABSI	CLABSI bundle	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	All Clinical Staff	1	no sample sizes given; pre # CLABSI: 275; post # CLABSI: 50
Miller, United States - 2011	CLABSI	Phase 3: Maintenance and Insertion CLABSI bundles with chlorhexidine impregnated sponge and/or scrub	Audit and Feedback, Organizational Change, Provider Reminder Systems	All Clinical Staff	27	
Render, United States - 2011	CLABSI	CLABSI Bundle collaboration among VA hospitals	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	Nurses, Physicians	123 VA ICUs	2006: (681); 2007: (683); 2008: (543); 2009: (404)
Taylor, United States - 2011	CLABSI	percutaneously inserted central catheters (PICC) team formed	Organizational Change, Provider Education	Nurses, Physicians	1	pre: 100 (23); post: 100 (24)
Barrera, Colombia - 2011	CAUTI, CLABSI, VAP	hand hygiene promotion	Audit and Feedback, Patient Education	All Clinical Staff	1	total: 14,516 (total # HAI: 2,398)
Harris, United States - 2011	CLABSI, VAP	hand hygiene, vap bundle, standardizing central line care	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	All Clinical Staff	1	pre: 817 (VAP: 16, CLABSI: 31; intervention: 601 (VAP: 16, CLABSI: 19); post: 961 (VAP: 7, CLABSI: 15)
Lilly, United States - 2011	CLABSI, VAP	tele-ICU, providing care from a remote location	Audit and Feedback, Organizational Change	All Clinical Staff	2	pre: 1529 (VAP: 76, CLABSI: 19); post: 4761 (VAP: 32, CLABSI: 29)
Speroff, United States - 2011	CLABSI, VAP	Virtual Collaborative Group	Organizational Change, Provider Education	Nurses, Physicians	Virtual Collaborative: 31; Toolkit: 29	

Appendix Table C2c-Update. Patient characteristics for SSI which control for secular trend or confounding from the update search

Study	Infection	Intervention	Type of QI Strategies	Participants	Number of Hospitals	Number of Patients
Kestle, United States - 2011	SSI	Operating room protocol with flow chart	Organizational Change, Provider Reminder Systems	All Clinical Staff	4	pre: 896 (79); post: 1571 (89)
Lavu, United States - 2011	SSI	Surgical care bundle	Organizational Change		1	pre: 233 (35); post: 233 (18)
Schwann, United States - 2011	SSI	Automatic antibiotic administration reminder incorporated into anesthesia information management system	Provider Reminder Systems		1	pre: 9,127 (101*); post: 10,617 (75*)
Salim, Israel - 2011	CAUTI, SSI	Refresher courses on infection control and catheter insertion	Audit and Feedback, Provider Education	Nurses, Physicians	1	pre: 751 (Overall SSI: 37; CAUTI: 9); post: 865 (Overall SSI: 18; CAUTI: 3)

Appendix Table C2d-Update. Patient characteristics for CAUTI which control for secular trend or confounding from the update search

Study	Infection	Intervention	Type of QI Strategies	Participants	Number of Hospitals	Number of Patients
Fakih, United States - 2012	CAUTI	CAUTI Bundle with education and feedback	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	Nurses, Physicians	71	
Marra, Brazil - 2011	CAUTI	CAUTI Bundle with nurse empowerment and daily check of UC necessity	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	Nurses, Physicians	1	
van den Broek, Netherlands - 2011	CAUTI	Revision of existing protocols, introduction of staff education and change to daily practice	Organizational Change, Provider Education, Provider Reminder Systems	Nurses, Physicians	5 hospitals in intervention group; 5 hospitals in baseline group	baseline: 1149 patients; intervention period: 1794 patients
Barrera, Colombia - 2011	CAUTI, CLABSI, VAP	hand hygiene promotion	Audit and Feedback, Patient Education	All Clinical Staff	1	total: 14,516 (total # HAI: 2,398)
Salim, Israel - 2011	CAUTI, SSI	Refresher courses on infection control and catheter insertion	Audit and Feedback, Provider Education	Nurses, Physicians	1	pre: 751 (Overall SSI: 37; CAUTI: 9); post: 865 (Overall SSI: 18; CAUTI: 3)

Appendix Table C3a-Update. Intervention characteristics for VAP which control for secular trend or confounding from the update search

Study	Infection	Intervention specifics	Comment
Cheema, United States - 2011	VAP	A unit based team was formed in 2007. They adapted and implemented a pediatric-specific VAP bundle. The team led provider education/reeducation, equipment procurement/modification, and conducted small cycles of change. Performance and compliance data was provided throughout the study period to both leadership and frontline staff. The checklist was used in the first study phase and was completed by the nurses and respiratory therapists everyday for each ventilated patient. A washout period occurred after the first phase because staff found the checklist to be too burdensome. A flowsheet was developed and implemented in the last phase of the study. It provided cues for key VAP prevention bundle practices.	
Morris, Scotland - 2011	VAP	Plan, Do, Study, Act cycles to implement the VAP bundle, included: nurse and medical champions, education, checklist bedside reminders, and compliance feedback thru e-mails and posters.	1) during baseline, tried head of bed elevation and nurse-led weaning protocol with variable results; no process measurements or feedback 2) median APACHE II score higher in post population compared to baseline (p=0.004)
Barrera, Colombia - 2011	CAUTI, CLABSI, VAP	alcohol-based hand rub (ABHR) dispensers placed by every ICU bed; education on hand hygiene; each unit given feedback on HAI rates	indirect measure of adherence - no observation of hand hygiene, only measurement of amt of ABHR used
Lilly, United States - 2011	CLABSI, VAP	Promoting adherence to critical care best practices by implementing tele-ICU tools to provide real time auditing and feedback to health care workers.	post population older and with higher mean APACHE II score
Harris, United States - 2011	CLABSI, VAP	Hand hygiene, VAP bundle, and catheter care standardization were developed by multidisciplinary team. Education fairs were held, followed up by daily goal form reminders. Dashboards visible to staff, pts, and families, tracked hand hygiene, oral care, bed elevation, # days since last VAP, and # days since last CLABSI.	Pts were similar in gender and race distribution, but age distribution, insurance coverage, and treating provider were statistically different.
Speroff, United States - 2011	CLABSI, VAP	Toolkit Group: hospitals who were in this arm received fact sheets and QI implementation guidelines as well as intranet training seminars and clinician QI tools. These ICUs were on their own to implement the QI strategies given in the toolkit; Virtual Collaborative: web site support and training, online meetings with facility leaders and project managers with individual coaching and activities designed to increase interaction among participating teams. ;CLABSI Bundle: Hand hygiene, use of chlorhexidine antisepsis, maximal barrier precautions, site selection and care, voidance of routine placement of catheters; VAP Bundle: elevation of head of bed, oral care, daily sedation vacation, daily assessment of readiness to wean, secretion cleaning, peptic ulcer disease prophylaxis, and DVT prophylaxis. Bundles were available to both groups.	Hospitals were similar

Appendix Table C3b-Update. Intervention characteristics for CLABSI which control for secular trend or confounding from the update search

Study	Infection	Intervention specifics	Comment
Burrell, Australia - 2011	CLABSI	A multidisciplinary team created a checklist for central venous line insertion including a patient and clinician bundle. The clinician bundle including scrubbing hands for at least 2 minutes, wearing a hat mask and eyewear, donning sterile gloves and gown, and maintaining sterile technique. The patient bundle included preparation with 2% alcoholic chlorhexidine, fully draping the patient in a sterile sheet, and checking the position of the CVL by imaging and or pressure transducer.	
Kim, United States - 2011	CLABSI	CLABSI prevention bundle included: nursing checklist with insertion instructions, all necessary equipment on CVL cart, education program, feedback from epi nurses on adherence and infection rates.	
Miller, United States - 2011	CLABSI	The maintenance and insertion bundles are described in 13550. The PICUs were divided up into 4 groups. All four groups continued doing what has previously been described. One group kept doing the same thing as was done in phase 2 (served as a control). One group used a chlorhexidine scrub on all CVC insertions. One group used a chlorhexidine impregnated sponge on all CVC insertions. One group used both the scrub and the sponge.	
Render, United States - 2011	CLABSI	Intervention is part of a national plan to recruit VA leadership and identify strong practices within the VA and spread their use. Provider education stressing five identified facilitors of CLABSI reduction: physician champion, use of a central line cart, checklist during line insertion as a forcing function, addition of a daily ICU goal sheet during physician rounds as a memory aid for central line removal, and feedback to front line nurses and doctors. A web-based dashboard relayed updates regarding the ICU's CLABSI rate to leadership. The intervention also introduced a web-based recording system for CALBSI infection. In addition, IPEC managers invited five to six ICUs with the highest CLABSI rates to be mentored which consisted of semi-structured interviews, physician champion, feedback, use of forcing functions, and availability of supplies.	
Taylor, United States - 2011	CLABSI	PICC team established to perform all catheter insertions; training and education based on National Association of Neonatal Nurses Guidelines for Practice.	intervention grp had more on respiratory support, higher average daily census, and longer central line days.
Barrera, Colombia - 2011	CAUTI, CLABSI, VAP	alcohol-based hand rub (ABHR) dispensers placed by every ICU bed; education on hand hygiene; each unit given feedback on HAI rates	indirect measure of adherence - no observation of hand hygiene, only measurement of amt of ABHR used
Harris, United States - 2011	CLABSI, VAP	Hand hygiene, VAP bundle, and catheter care standardization were developed by multidisciplinary team. Education fairs were held, followed up by daily goal form reminders. Dashboards visible to staff, pts, and families, tracked hand hygiene, oral care, bed elevation, # days since last VAP, and # days since last CLABSI.	Pts were similar in gender and race distribution, but age distribution, insurance coverage, and treating provider were statistically different.
Lilly, United States - 2011	CLABSI, VAP	Promoting adherence to critical care best practices by implementing tele-ICU tools to provide real time auditing and feedback to health care workers.	post population older and with higher mean APACHE II score

Study	Infection	Intervention specifics	Comment
Speroff, United States - 2011	CLABSI, VAP	Toolkit Group: hospitals who were in this arm received fact sheets and QI implementation guidelines as well as intranet training seminars and clinician QI tools. These ICUs were on their own to implement the QI strategies given in the toolkit; Virtual Collaborative: web site support and training, online meetings with facility leaders and project managers with individual coaching and activities designed to increase interaction among participating teams. ;CLABSI Bundle: Hand hygiene, use of chlorhexidine antisepsis, maximal barrier precautions, site selection and care, voidance of routine placement of catheters; VAP Bundle: elevation of head of bed, oral care, daily sedation vacation, daily assessment of readiness to wean, secretion cleaning, peptic ulcer disease prophylaxis, and DVT prophylaxis. Bundles were available to both groups.	Hospitals were similar

Appendix Table C3c-Update. Intervention characteristics for SSI which control for secular trend or confounding from the update search

Study	Infection	Intervention specifics	Comment
Kestle, United States - 2011	SSI	A protocol was developed iteratively by the Hydrocephalus Clinical Research Network (HCRN). It was discussed at the biweekly HCRN conference calls and biannual meetings. The protocol was agreed upon and reviewed by the infectious disease departments, pharmacy departments, and neurosurgical departments at each center.	
Lavu, United States - 2011	SSI	A new protocol was implemented to provide a more formal preoperative procedure. The bundle included: 1) assessment of existing infection, 2) preoperative smoking cessation (at least 2 weeks), 3) use of chlorhexidine-alcohol wipe night before surgery, 4) use of hair clippers, 5) use of chlorhexidine-alcohol immediately before surgery, 6) preoperative antibiotic administration, 7) intraoperative wound edge protection, 8) intraoperative glycemic control, 9) intraoperative normothermia, 10) gown and glove change prior to skin closure, 11) DVT prophylaxis and beta blocker administration, 12) pre- and postoperative briefings among OR team.	There were significant differences in hemoglobin A1c, albumin levels, and estimated blood loss.
Schwann, United States - 2011	SSI	A point-of-care electronic prompt was incorporated into the anesthesia information management system. The prompt instructed the provider to give a dose of antibiotics within one hour of surgery. It would appear within 5 minutes of operating room admission and further data entry was not allowed until this prompt was addressed. Prompts reappeared every 20 minutes after that unless an antibiotic dose and time of admin was entered manually into the patient record.	
Salim, Israel - 2011	CAUTI, SSI	All medical personnel underwent a refresher course in aseptic and scrub techniques led by the infection control nurse. The OR nursing staff underwent a refresher course in hand hygiene, urinary catheter insertion, patient preparation, and aseptic principles. Observation and feedback took place in the postintervention period. Also, all women undergoing cesarean were given prophylactic antibiotics after cord clamping. In the baseline period, only women undergoing nonelective cesarean were given antibiotic prophylaxis.	Patient populations were significantly different in the proportion of ruptured membranes (with the baseline period having more, p=0.01) and mean duration of operation (with the postintervention period being longer, p=0.001).

Appendix Table C3d-Update. Intervention characteristics for CAUTI which control for secular trend or confounding from the update search

Study	Infection	Intervention specifics	Comment
Fakih, United States - 2012	CAUTI	Multidisciplinary team garnered unit support from physicians and nurses to facilitate implementation of QI strategy. Strategy consisted of nurse education, evaluation of catheter placement, feedback to units [changes in catheter use, appropriateness of placed catheters], webinar education, and a 'bladder bundle' with educational information for the unit and healthcare workers.	
Marra, Brazil - 2011	CAUTI	A nurse group was created to remove unnecessary catheters daily. Study carried out in two phases. Phase I (2005-2007): adopt 2% chlorhexidine skin prep., insertion and maintenance according to CDC guidelines; Phase II (2008-2010): Audit of random sample of urinary catheters once per month, bladder bundle: catheter insertion cart, hand hygiene, chlorhexidine skin and meatal antisepsis, sterile field and gloves, adequate urinary catheter balloon inflation, daily review of catheter need, Nurse intervention if process was not following best practices, feedback provided monthly to ICU and SDU staff.	
van den Broek, Netherlands - 2011	CAUTI	Hospitals were randomized to group A or B. Group A implemented intervention at 4 months and discontinued at 9: group B then began their intervention at 9 months and discontinued at 14 months. A small multidisciplinary team at each hospital designed the intervention and introduced it to the participating wards. Because of this, each intervention varied by hospital, but the domains could be categorized as revision to existing protocols and materials (done in seven hospitals), education (done in ten hospitals), and change in daily practice (done in eight hospitals).	Interventions seemed to be inconsistent between hospitals with each hospital developing their own intervention implementation strategy for CAUTI prevention
Barrera, Colombia - 2011	CAUTI, CLABSI, VAP	alcohol-based hand rub (ABHR) dispensers placed by every ICU bed; education on hand hygiene; each unit given feedback on HAI rates	indirect measure of adherence - no observation of hand hygiene, only measurement of amt of ABHR used

Study	Infection	Intervention specifics	Comment
Salim, Israel - 2011	CAUTI, SSI	All medical personnel underwent a refresher course in aseptic and scrub techniques led by the infection control nurse. The OR nursing staff underwent a refresher course in hand hygiene, urinary catheter insertion, patient preparation, and aseptic principles. Observation and feedback took place in the postintervention period. Also, all women undergoing cesarean were given prophylactic antibiotics after cord clamping. In the baseline period, only women undergoing nonelective cesarean were given antibiotic prophylaxis.	Patient populations were significantly different in the proportion of ruptured membranes (with the baseline period having more, p=0.01) and mean duration of operation (with the postintervention period being longer, p=0.001).

Appendix Table C4a-Update. Study context for VAP which control for secular trend or confounding from the update search

Study	Infection	Organizational Characteristics Size	Organizational Characteristics Location	Theory Behind Patient Safety Practice was Present	Existing Patient Safety Infrastructure	External Factors were Present	Patient Safety Culture and Teamwork was Present	Management Tools were Present	Comment
Barrera, Colombia - 2011	VAP	715 bed	Cali, Columbia	FALSE			TRUE	TRUE	
Cheema, United States - 2011	VAP	200 bed academic quaternary care children's hospital	Ann Arbor, MI	FALSE			TRUE	TRUE	
Harris, United States - 2011	VAP	20 beds, 1000-1200 admissions/yr	Chapel Hill, NC	TRUE		Medicare's change in reimbursement policy	TRUE	TRUE	
Lilly, United States - 2011	VAP	834 beds among 2 campuses	Massachusetts	TRUE			TRUE	TRUE	
Morris, Scotland - 2011	VAP	18 bed ICU, >1000 pts/yr	Edinburgh, Scotland	FALSE	tried head of bed elevation and nurse-led weaning protocol with variable results; no process recording or feedback		TRUE	TRUE	
Speroff, United States - 2011	VAP	59 hospitals and 61 ICUs	United States, Hospital Corporation of America network	FALSE			TRUE	TRUE	

Appendix Table C4b-Update. Study context for CLABSI which control for secular trend or confounding from the update search

Study	Infection	Organizational Characteristics Size	Organizational Characteristics Location	Theory Behind Patient Safety Practice was Present	Existing Patient Safety Infrastructure	External Factors were Present	Patient Safety Culture and Teamwork was Present	Management Tools were Present	Comment
Barrera, Colombia - 2011	CLABSI	715 bed	Cali, Columbia	FALSE			TRUE	TRUE	
Burrell, Australia - 2011	CLABSI	37 ICUs: 10 tertiary, 12 metropolitan, 13 rural and 2 pediatric	New South Wales, Australia	FALSE			TRUE	TRUE	
Harris, United States - 2011	CLABSI	20 beds, 1000-1200 admissions/yr	Chapel Hill, NC	TRUE		Medicare’s change in reimbursement policy	TRUE	TRUE	
Kim, United States - 2011	CLABSI	600 bed	Los Angeles, CA	FALSE			TRUE	TRUE	
Lilly, United States - 2011	CLABSI	834 beds among 2 campuses	Massachusetts	TRUE			TRUE	TRUE	
Miller, United States - 2011	CLABSI	29 PICUs in 27 hospitals	United States	TRUE	All PICUs have been implementing a maintenance and insertion bundle for at least 2 years before the use of chlorhexidine started.	This study was a part of the QI collaborative of the National Association of Children’s Hospitals and Related Institutions (NACHRI).	FALSE	FALSE	

Study	Infection	Organizational Characteristics Size	Organizational Characteristics Location	Theory Behind Patient Safety Practice was Present	Existing Patient Safety Infrastructure	External Factors were Present	Patient Safety Culture and Teamwork was Present	Management Tools were Present	Comment
Render, United States - 2011	CLABSI	174 VA ICUs across 123 hospitals w/ 1744 beds	United States	FALSE		IHI 100,00 lives participant	TRUE	TRUE	This study sought to identify strong prevention practices within the VA system and thus some hospitals had strong practices at the onset of the study. However, no details are provided.
Speroff, United States - 2011	CLABSI	59 hospitals and 61 ICUs	United States, Hospital Corporation of America network	FALSE			TRUE	TRUE	
Taylor, United States - 2011	CLABSI		Washington, DC	FALSE	adopted closed medication system		TRUE	FALSE	

Appendix Table C4c-Update. Study context for SSI which control for secular trend or confounding from the update search

Study	Infection	Organizational Characteristics Size	Organizational Characteristics Location	Theory Behind Patient Safety Practice was Present	Existing Patient Safety Infrastructure	External Factors were Present	Patient Safety Culture and Teamwork was Present	Management Tools were Present	Comment
Kestle, United States - 2011	SSI	4 centers in North America	Utah, Alabama, Toronto, and Texas	FALSE		This was a collaborative's initiative. Centers that belonged to the HCRN were involved in the study.	FALSE	TRUE	
Lavu, United States - 2011	SSI		Philadelphia, PA	FALSE			FALSE	FALSE	
Salim, Israel - 2011	SSI		Afula, Israel	FALSE			FALSE	TRUE	
Schwann, United States - 2011	SSI		Allentown, PA	FALSE	Previous attempts to improve adherence to prophylactic antibiotic administration had been made in the past with little success.		FALSE	TRUE	

Appendix Table C4d-Update. Study context for CAUTI which control for secular trend or confounding from the update search

Study	Infection	Organizational Characteristics Size	Organizational Characteristics Location	Theory Behind Patient Safety Practice was Present	Existing Patient Safety Infrastructure	External Factors were Present	Patient Safety Culture and Teamwork was Present	Management Tools were Present	Comment
Barrera, Colombia - 2011	CAUTI	715 bed	Cali, Columbia	FALSE			TRUE	TRUE	
Fakih, United States - 2012	CAUTI	163 inpatient units across 71 hospitals	Michigan, United States	FALSE		Public reporting and financial incentives may have played a role	TRUE	TRUE	
Marra, Brazil - 2011	CAUTI	1 Medical-surgical ICU with 38 beds, and two 20-bed step down units	Sao Paulo, Brazil	FALSE	Patient safety practices were being changed to meet CDC Guidelines for urinary catheter insertion and maintenance in period I		TRUE	TRUE	
Salim, Israel - 2011	CAUTI		Afula, Israel	FALSE			FALSE	TRUE	
van den Broek, Netherlands - 2011	CAUTI	10 hospitals	Netherlands	FALSE		PREZIES nosocomial infection program participating hospitals	TRUE	TRUE	

Appendix Table C5a(1)-Update. Infection outcomes for VAP which control for secular trend or confounding from the update search

Study	Infection	Intervention	Pre-intervention Infection Rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Units of Measurement	Follow-up Months
Barrera, Colombia - 2011	CAUTI, CLABSI, VAP	hand hygiene promotion	2001*: CLABSI: 12; VAP:9; CAUTI: 1.7	2005*: CLABSI: 7; VAP: 14; CAUTI: 4.5	Poisson: CLABSI: decrease 12.7% yearly, p<0.001; VAP: no trend, p=0.87; CAUTI: increase 8.0% yearly, p=0.002	infections/ 1000 device-days	46
Cheema, United States - 2011	VAP	Phase 3: VAP bundle with flowsheet	4.2	Phase 2: 0.7; Washout Phase: 4.8; Phase 3: 0.8	t-test p=0.059, p=0.042, p=0.047, respectively compared to prior phase	infections/ 1000 device-days	42
Harris, United States - 2011	CLABSI, VAP	hand hygiene, vap bundle, standardizing central line care	baseline: VAP: 1.9, CLABSI: 3.8	intervention: VAP: 2.6 ; CLABSI: 3.1; post: VAP: 0.7; CLABSI: 1.6	regression: intervention VAP: OR 1.44 (0.71 to 2.92); intervention CLABSI: OR 0.86 (0.48 to 1.53); postintervention: VAP: OR 0.37 (0.15 to 0.97) p<0.01; postintervention CLABSI: OR 0.42 (0.22 to 0.80) p<0.001	infections/ 1000 device-days	13
Lilly, United States - 2011	CLABSI, VAP	tele-ICU, providing care from a remote location	VAP: 13%; CLABSI: 1%	VAP: 1.6%; CLABSI: 0.6%	VAP: OR 0.15 (95% CI: 0.09 to 0.23), p<0.001; CLABSI: OR 0.50 (95% CI:0.27 to 0.93), p=0.005		15
Morris, Scotland - 2011	VAP	VAP bundle - sedation holiday, elevated bed, oral care, with checklist and feedback	32 (95% CI: 27 to 35)	12 (95% CI: 9 to 15)	Poisson: p<0.001	infections/ 1000 device-days	12
Speroff, United States - 2011	CLABSI, VAP	Virtual Collaborative Group	Median CLABSI Baseline: Virtual Collaboration: 1.84 (IQR: 0.00-3.83); Toolkit:2.42 (IQR: 0.65-6.80); Median VAP Baseline: Virtual Collaboration: 2.14 (IQR:0.00-6.09) ; Toolkit: 3.49 (0.00-7.04)	Median CLABSI 18 month: Virtual Collaboration: 2.76 (IQR: 0.00-4.67); Toolkit:1.16 (IQR: 0.00-5.46); Median VAP 18 month: Virtual Collaboration: 2.93 (IQR:0.00-7.63) ; Toolkit: 2.06 (0.00-6.59)	t-test: No statistical differences at baseline; regression: collaborative CLABSI p=0.75, Toolkit CLABSI: p=0.83, Collaborative VAP: P=0.61; Toolkit VAP: p=0.37, CLABSI: p=0.71, VAP: p=0.80	infections/ 1000 device-days	18

Appendix Table C5a(2)-Update. Infection outcomes for CLABSI which control for secular trend or confounding from the update search

Study	Infection	Intervention	Pre-intervention Infection Rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Units of Measurement	Follow-up Months
Barrera, Colombia – 2011	CAUTI, CLABSI, VAP	hand hygiene promotion	2001*: CLABSI: 12; VAP:9; CAUTI: 1.7	2005*: CLABSI: 7; VAP: 14; CAUTI: 4.5	Poisson: CLABSI: decrease 12.7% yearly, p<0.001; VAP: no trend, p=0.87; CAUTI: increase 8.0% yearly, p=0.002	infections/ 1000 device	46
Burrell, Australia – 2011	CLABSI	CLABSI Physician + Patient Bundles	3.0 (95% CI 2.0 to 4.3)	1.2 (95% CI 0.6 to 2.2)	Chi-square: p=0.0006	infections/ 1000 device	18
Harris, United States – 2011	CLABSI, VAP	hand hygiene, vap bundle, standardizing central line care	baseline: VAP: 1.9, CLABSI: 3.8	intervention: VAP: 2.6 ; CLABSI: 3.1; post: VAP: 0.7; CLABSI: 1.6	regression: intervention VAP: OR 1.44 (0.71 to 2.92); intervention CLABSI: OR 0.86 (0.48 to 1.53); postintervention: VAP: OR 0.37 (0.15 to 0.97) p<0.01; postintervention CLABSI: OR 0.42 (0.22 to 0.80) p<0.001	infections/ 1000 device	13
Kim, United States – 2011	CLABSI	CLABSI bundle	total: 9.0; MICU: 13.9; SICU: 4.5; CTICU: 1.8; burn ICU: 5.2; neuro ICU: 7.0; CCU: 8.5	total: 2.7; MICU: 3.1; SICU: 1.9; CTICU: 1.4; burn ICU: 1.2; neuro ICU: 3.8; CCU: 5.4	total: RRR 0.70(0.59-0.77), p<0.00001; MICU: RRR 0.78(0.66-0.85) p<0.0001; SICU: RRR 0.59(0.11-0.81) p=0.01; CTICU: RRR 0.28(-3.3-0.88) p=0.36; burn ICU: RRR 0.76(-0.01-0.94) p=0.02; neuro ICU: 0.45(-0.30-0.77) p=0.08; CCU: RRR 0.36(-0.65-0.75) p=0.18	infections/ 1000 device	14
Lilly, United States – 2011	CLABSI, VAP	tele-ICU, providing care from a remote location	VAP: 13%; CLABSI: 1%	VAP: 1.6%; CLABSI: 0.6%	VAP: OR 0.15 (95% CI: 0.09 to 0.23), p<0.001; CLABSI: OR 0.50 (95% CI:0.27 to 0.93), p=0.005		15
Miller, United States – 2011	CLABSI	Phase 3: Maintenance and Insertion CLABSI bundles with chlorhexidine impregnated sponge and/or scrub	Mean: 5.2 (95% CI, 4.4 to 6.2)	Mean Ramp-up: 4.3 (95% CI, 3.2 to 5.7); Mean Phase 2+3: 2.3 (95% CI, 1.9 to 2.9)	GLM: Baseline RR=0.99 (95% CI, 0.98 to 1.01); Ramp-up RR=0.89 (95%CI, 0.81 to 0.97), p=0.006; Phase 2+3 RR=0.98 (95%CI, 0.96 to 1.01), p=0.08	infections/1000 device-days	36

Study	Infection	Intervention	Pre-intervention Infection Rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Units of Measurement	Follow-up Months
Render, United States – 2011	CLABSI	CLABSI Bundle collaboration among VA hospitals	Mean CLABSI rate 2006: 3.85	Mean CLABSI rate 2007: 3.2; 2008: 2.5; 2009:1.8	All results compared to 2006 group. 2007: IRR 0.83 (95% CI 0.73 to 0.94) p=0.0033; 2008:IRR 0.65 (95% CI 0.56 to 0.76) p<0.0001; 2009: IRR 0.47 (95% CI 0.40 to 0.55) p<0.0001	infections/1000 device-days	
Speroff, United States – 2011	CLABSI, VAP	Virtual Collaborative Group	Median CLABSI Baseline: Virtual Collaboration: 1.84 (IQR: 0.00-3.83); Toolkit:2.42 (IQR: 0.65-6.80); Median VAP Baseline: Virtual Collaboration: 2.14 (IQR:0.00-6.09) ; Toolkit: 3.49 (0.00-7.04)	Median CLABSI 18 month: Virtual Collaboration: 2.76 (IQR: 0.00-4.67); Toolkit:1.16 (IQR: 0.00-5.46); Median VAP 18 month: Virtual Collaboration: 2.93 (IQR:0.00-7.63) ; Toolkit: 2.06 (0.00-6.59)	t-test: No statistical differences at baseline; regression: collaborative CLABSI p=0.75, Toolkit CLABSI: p=0.83, Collaborative VAP: P=0.61; Toolkit VAP: p=0.37, CLABSI: p=0.71, VAP: p=0.80	VAP And CLABSI Rate Per 1,000 days	18
Taylor, United States – 2011	CLABSI	percutaneously inserted central catheters (PICC) team formed			CLABSI risk: p>0.05 (no difference)	CLABSI risk	12

Appendix Table C5a(3)-Update. Infection outcomes for SSI which control for secular trend or confounding from the update search

Study	Infection	Intervention	Pre-intervention Infection Rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Units of Measurement	Follow-up Months
Kestle, United States – 2011	SSI	Operating room protocol with flow chart	8.8%	5.7%	chi-square p=0.003	proportion of patients	21
Lavu, United States – 2011	SSI	Surgical care bundle	15%	7.7%	chi-square p=0.01; Logistic regression p<0.001	percentage of patients with infection	24
Salim, Israel – 2011	CAUTI, SSI	Refresher courses on infection control and catheter insertion	Overall SSI: 4.9%; Incisional SSI: 3.5%; Organ SSI: 1.6%; CAUTI: 1.2%	Overall SSI: 2.1%; Incisional SSI: 0.9%; Organ SSI: 1.2%; CAUTI: 0.3%	Overall SSI OR=0.4, 95% CI, 0.23 to 0.72, p=0.002; Incisional SSI OR=0.27, 95% CI, 0.12 to 0.59, p=0.001; Organ SSI OR=0.67, 95% CI, 0.28 to 1.56, p=0.52; CAUTI OR=0.31, 95% CI, 0.08 to 1.17, p=0.08	Proportion of patients	12
Schwann, United States – 2011	SSI	Automatic antibiotic administration reminder incorporated into anesthesia information management system	1.1%	First 6 mos: 0.7%	RR=0.35, 95% CI, 0.13 to 0.52, p=0.003	Proportion of surgical procedures	30

Appendix Table C5a(4)-Update. Infection outcomes for CAUTI which control for secular trend or confounding from the update search

Study	Infection	Intervention	Pre-intervention Infection Rate	Post-Intervention Infection Rate	Infection Rate Statistical Analysis	Units of Measurement	Follow-up Months
Barrera, Colombia – 2011	CAUTI, CLABSI, VAP	hand hygiene promotion	2001*: CLABSI: 12; VAP:9; CAUTI: 1.7	2005*: CLABSI: 7; VAP: 14; CAUTI: 4.5	Poisson: CLABSI: decrease 12.7% yearly, p<0.001; VAP: no trend, p=0.87; CAUTI: increase 8.0% yearly, p=0.002	events/1000 device days	46
Fakih, United States – 2012	CAUTI	CAUTI Bundle with education and feedback					36
Marra, Brazil – 2011	CAUTI	CAUTI Bundle with nurse empowerment and daily check of UC necessity	ICU: 7.6 (95% CI 6.6 to 8.6); SDU: 15.3 (95% CI 13.9 to 16.6)	ICU: 5.0 (95% CI 4.2 to 5.8); SDU: 12.9 (95% CI 11.6 to 14.2)	Poisson regression ICU: p<0.001; Poisson regression SDU: p=0.014	Rate per 1,000 catheter-days	61
Salim, Israel – 2011	CAUTI, SSI	Refresher courses on infection control and catheter insertion	Overall SSI: 4.9%; Incisional SSI: 3.5%; Organ SSI: 1.6%; CAUTI: 1.2%	Overall SSI: 2.1%; Incisional SSI: 0.9%; Organ SSI: 1.2%; CAUTI: 0.3%	Overall SSI OR=0.4, 95% CI, 0.23 to 0.72, p=0.002; Incisional SSI OR=0.27, 95% CI, 0.12 to 0.59, p=0.001; Organ SSI OR=0.67, 95% CI, 0.28 to 1.56, p=0.52; CAUTI OR=0.31, 95% CI, 0.08 to 1.17, p=0.08	Proportion of patients	12
van den Broek, Netherlands – 2011	CAUTI	Revision of existing protocols, introduction of staff education and change to daily practice	Symptomatic CAUTI Rate: 12.6%; Asymptomatic CAUTI Rate: 37.4%	Symptomatic CAUTI Rate: 12.7%; Asymptomatic CAUTI Rate: 38.3%		Percentage of patients with urinary tract infections	17

Appendix Table C5b(1)-Update. Adherence outcomes for VAP which control for secular trend or confounding from the update search

Study	Infection	Intervention	Pre-Intervention rate of adherence	Post-intervention rate of adherence	Post-intervention rate of adherence Statistical Analysis	Follow-up Months
Barrera, Colombia – 2011	CAUTI, CLABSI, VAP	hand hygiene promotion			ABHR use: increase 9.2% monthly, p<0.001	46
Cheema, United States - 2011	VAP	Phase 3: VAP bundle with flowsheet		Phase 2: 48-78%		42
Harris, United States - 2011	CLABSI, VAP	hand hygiene, vap bundle, standardizing central line care				13
Lilly, United States – 2011	CLABSI, VAP	tele-ICU, providing care from a remote location	VAP: 33%	VAP: 52%	OR: 2.20 (95% CI: 1.79 to 2.70), p<0.001	15
Morris, Scotland – 2011	VAP	VAP bundle - sedation holiday, elevated bed, oral care, with checklist and feedback		for 2 parts of bundle (head tilt & oral care): >95%; for all 3 components in bundle: 70%		12
Speroff, United States - 2011	CLABSI, VAP	Virtual Collaborative Group		Virtual Collaborative: Clinical Tool Use: 61%; Data Tool Use: 56%; Prevention Strategy Use: 69%;Toolkit Group: Clinical Tool Use: 49%; Data Tool Use: 30%; Prevention Strategy Use: 54%	t-test: Clinical Tool Use: p=0.23; Data Tool Use: p=0.004; Prevention Strategy Use: p=0.017	18

Appendix Table C5b(2)-Update. Adherence outcomes for CLABSI which control for secular trend or confounding from the update search

Study	Infection	Intervention	Pre-Intervention rate of adherence	Post-intervention rate of adherence	Post-intervention rate of adherence Statistical Analysis	Follow-up Months
Barrera, Colombia – 2011	CAUTI, CLABSI, VAP	hand hygiene promotion			ABHR use: increase 9.2% monthly, p<0.001	46
Burrell, Australia – 2011	CLABSI	CLABSI Physician + Patient Bundles	Clinician Bundle: 74%; Patient Bundle: 81%	Clinician Bundle: 81%; Patient Bundle: 92%	Clinician Bundle: Chi-square p<0.0001 ; Patient Bundle: p<0.001 ; Both Bundles: Chi-square p=0.0001	18
Harris, United States – 2011	CLABSI, VAP	hand hygiene, vap bundle, standardizing central line care				13
Kim, United States – 2011	CLABSI	CLABSI bundle				14
Lilly, United States – 2011	CLABSI, VAP	tele-ICU, providing care from a remote location	VAP: 33%	VAP: 52%	OR: 2.20 (95% CI: 1.79 to 2.70), p<0.001	15
Miller, United States – 2011	CLABSI	Phase 3: Maintenance and Insertion CLABSI bundles with chlorhexidine impregnated sponge and/or scrub				36
Render, United States - 2011	CLABSI	CLABSI Bundle collaboration among VA hospitals	85%	98%	Strong inverse correlation with CLABSI rates (R=-0.81)	
Speroff, United States - 2011	CLABSI, VAP	Virtual Collaborative Group		Virtual Collaborative: Clinical Tool Use: 61%; Data Tool Use: 56%; Prevention Strategy Use: 69%;Toolkit Group: Clinical Tool Use: 49%; Data Tool Use: 30%; Prevention Strategy Use: 54%	t-test: Clinical Tool Use: p=0.23; Data Tool Use: p=0.004; Prevention Strategy Use: p=0.017	18
Taylor, United States - 2011	CLABSI	percutaneously inserted central catheters (PICC) team formed				12

Appendix Table C5b(3)-Update. Adherence outcomes for SSI which control for secular trend or confounding from the update search

Study	Infection	Intervention	Pre-Intervention rate of adherence	Post-intervention rate of adherence	Post-intervention rate of adherence Statistical Analysis	Follow-up Months
Kestle, United States - 2011	SSI	Operating room protocol with flow chart		Proper hand washing by all team members: 98.7%; Double gloving by all team members: 97.8%	Logistic regression p=0.025 and p=0.043 respectively	21
Lavu, United States – 2011	SSI	Automatic antibiotic administration reminder incorporated into anesthesia information management system	Antibiotic timing: 62%	Antibiotic timing first 6 mos: 92%	First 6 mos vs. baseline p=0.003	30
Salim, Israel – 2011	SSI	Surgical care bundle				24
Schwann, United States - 2011	CAUTI, SSI	Refresher courses on infection control and catheter insertion				12

Appendix Table C5b(4)-Update. Adherence outcomes for CAUTI which control for secular trend or confounding from the update search

Study	Infection	Intervention	Pre-Intervention rate of adherence	Post-intervention rate of adherence	Post-intervention rate of adherence Statistical Analysis	Follow-up Months
Barrera, Colombia - 2011	CAUTI, CLABSI, VAP	hand hygiene promotion			ABHR use: increase 9.2% monthly, p<0.001	46
Fakih, United States - 2012	CAUTI	CAUTI Bundle with education and feedback	Appropriate Catheterization: 44.3% (95% CI 40.3% to 48.4%)	Appropriate Catheterization at 2 years: 57.6% (95% CI 51.7% to 63.4%)	GEE model:P=0.005	36
Marra, Brazil – 2011	CAUTI	CAUTI Bundle with nurse empowerment and daily check of UC necessity		Compliance with all Catheter Insertion measures: ICU: 84.3%; SDU: 87.9; Appropriate Urinary Catheter Indication: ICU: 87.9%; SDU: 88.3%		61
Salim, Israel – 2011	CAUTI, SSI	Refresher courses on infection control and catheter insertion				12
van den Broek, Netherlands – 2011	CAUTI	Revision of existing protocols, introduction of staff education and change to daily practice	Correctly inserted catheters: 64%	Correctly inserted catheters: 74%	logistic regression: p<0.0001	17

Appendix Table C5c(1)-Update. Cost/savings outcomes for VAP which control for secular trend or confounding from the update search

Study	Infection	Intervention	Pre-Intervention Costs	Post-Intervention Costs	CostsStatistical Analysis	Estimated Savings from QI introduction	Follow-up Months
Barrera, Colombia - 2011	CAUTI, CLABSI, VAP	hand hygiene promotion					46
Cheema, United States - 2011	VAP	Phase 3: VAP bundle with flowsheet					42
Harris, United States - 2011	CLABSI, VAP	hand hygiene, vap bundle, standardizing central line care	avg PICU cost: baseline: $34,365 +/- $2,446; intervention: $30,175 +/- $2,139; adjusted intervention: -$3,948 (-$10,678, $2,782)	avg PICU cost: post: $25,938 +/- $1,146, adjusted post: -$8,826 (-$13,950, -$3,702)	baseline compared to post: p<0.01	avg cost per hospital stay in post period: $12,136. $1910 from reduced lab and pharm, remaining from shorter hosp stay. Projected annual cost savings study PICU $12 million.	13
Lilly, United States - 2011	CLABSI, VAP	tele-ICU, providing care from a remote location					15
Morris, Scotland - 2011	VAP	VAP bundle - sedation holiday, elevated bed, oral care, with checklist and feedback					12
Speroff, United States - 2011	CLABSI, VAP	Virtual Collaborative Group					18

Appendix Table C5c(2)-Update. Cost/savings outcomes for CLABSI which control for secular trend or confounding from the update search

Study	Infection	Intervention	Pre-Intervention Costs	Post-Intervention Costs	CostsStatistical Analysis	Estimated Savings from QI introduction	Follow-up Months
Barrera, Colombia – 2011	CAUTI, CLABSI, VAP	hand hygiene promotion					46
Burrell, Australia – 2011	CLABSI	CLABSI Physician + Patient Bundles					18
Harris, United States – 2011	CLABSI, VAP	hand hygiene, vap bundle, standardizing central line care	avg PICU cost: baseline: $34,365 +/- $2,446; intervention: $30,175 +/- $2,139; adjusted intervention: -$3,948 (-$10,678, $2,782)	avg PICU cost: post: $25,938 +/- $1,146, adjusted post: -$8,826 (-$13,950, -$3,702)	baseline compared to post: p<0.01	avg cost per hospital stay in post period: $12,136. $1910 from reduced lab and pharm, remaining from shorter hosp stay. Projected annual cost savings study PICU $12 million.	13
Kim, United States – 2011	CLABSI	CLABSI bundle				total excess cost of any given CLABSI estimated to be $32,254 (excess LOS + replacement CVL + drug admin cost + drug cost)	14
Lilly, United States – 2011	CLABSI, VAP	tele-ICU, providing care from a remote location					15
Miller, United States – 2011	CLABSI	Phase 3: Maintenance and Insertion CLABSI bundles with chlorhexidine impregnated sponge and/or scrub				$31 million in CLABSI attributable health care costs	36
Render, United States - 2011	CLABSI	CLABSI Bundle collaboration among VA hospitals					
Speroff, United States - 2011	CLABSI, VAP	Virtual Collaborative Group					18
Taylor, United States - 2011	CLABSI	percutaneously inserted central catheters (PICC) team formed					12

Appendix Table C5c(3)-Update. Cost/savings outcomes for SSI which control for secular trend or confounding from the update search

Study	Infection	Intervention	Pre-Intervention Costs	Post-Intervention Costs	CostsStatistical Analysis	Estimated Savings from QI introduction	Follow-up Months
Kestle, United States - 2011	SSI	Operating room protocol with flow chart					21
Lavu, United States – 2011	SSI	Surgical care bundle					24
Salim, Israel – 2011	CAUTI, SSI	Refresher courses on infection control and catheter insertion					12
Schwann, United States - 2011	SSI	Automatic antibiotic administration reminder incorporated into anesthesia information management system					30

Appendix Table C5c(4)-Update. Cost/savings outcomes for CAUTI which control for secular trend or confounding from the update search

Study	Infection	Intervention	Pre-Intervention Costs	Post-Intervention Costs	CostsStatistical Analysis	Estimated Savings from QI introduction	Follow-up Months
Barrera, Colombia – 2011	CAUTI, CLABSI, VAP	hand hygiene promotion					46
Fakih, United States – 2012	CAUTI	CAUTI Bundle with education and feedback					36
Marra, Brazil – 2011	CAUTI	CAUTI Bundle with nurse empowerment and daily check of UC necessity					61
Salim, Israel – 2011	CAUTI, SSI	Refresher courses on infection control and catheter insertion					12
van den Broek, Netherlands – 2011	CAUTI	Revision of existing protocols, introduction of staff education and change to daily practice		Cost of implementing program: 2,638 Euros (range: 1,023-3,763 Euros), cost of insertion of an indwelling catheter 28 Euros, removal of the catheter 3 Euros, and daily care 3 Euros.		Mean amount saved was 537 Euros per 100 patients	17

Appendix Table C6a-Update. Study quality for VAP which control for secular trend or confounding from the update search

Study	Infection	followup 1 year or longer	adequate statistical analysis	adherence rates analyzed	infection rates analyzed	independent of other QI efforts	Overall Quality	Univar YN	Univar Model	Multivar YN	Multivar Model	Multivar Control	Comment
Barrera, Colombia - 2011	CAUTI, CLABSI, VAP	Yes	Yes	Yes	Yes	Uncertain	Lower	FALSE		TRUE	Poisson regression	intragroup correlation specified each hospital unit as a cluster, to control for different pt populations in each unit, temporary workers and nurse-to-patient ratio	simple before-after study that controlled for potential confounders
Cheema, United States – 2011	VAP	Yes	No	No	Yes	Uncertain	Lower	TRUE	t-test	TRUE	u-chart, g-chart		Patient characteristics were not assessed.
Harris, United States - 2011	CLABSI, VAP	Yes	Yes	No	Yes	Uncertain	Lower	FALSE		TRUE	infection: time series, regression; cost: GLM	age, gender, race, comorbidity, insurance coverage, APR-DRG score, provider specialty	
Lilly, United States - 2011	CLABSI, VAP	No	Yes	Yes	Yes	Uncertain	Medium	TRUE	Fisher exact or chi-sq	TRUE	logistic regression	ICU, ICU type, admission time, acuity score, operative status	This is an unblinded nonrandomized stepped wedge design. They took the same intervention, and implemented it in 7 different ICUs at different times. There was no progression of changes to the intervention. Only 3 of the 7 ICUs had followup one or more yrs
Morris, Scotland - 2011	VAP	Yes	Yes	No	Yes	Uncertain	Lower	FALSE		TRUE	Poisson regression	gender, age, severity of illness	post-intervention adherence rates were reported, but no statistical analysis comparing pre and post measurements

Study	Infection	followup 1 year or longer	adequate statistical analysis	adherence rates analyzed	infection rates analyzed	independent of other QI efforts	Overall Quality	Univar YN	Univar Model	Multivar YN	Multivar Model	Multivar Control	Comment
Speroff, United States - 2011	CLABSI, VAP	Yes	Yes	No	Yes	N/A	Higher	FALSE		TRUE	Hierarchical negative binomial regression	hospital, baseline covariates	Adherence rates were calculated by follow-up survey, no baseline data. Statistical analysis did only chi-square or t-test to compare groups, but study had cluster randomized design. Did binomal negative regression analysis.

Was the followup period 1 year or longer?
Was the statistical analysis adequate?
Were the baseline and postintervention adherence rates reported and analyzed statistically?
Were the baseline and postintervention infection rates reported and analyzed statistically?
Was the intervention independent of other QI efforts implemented at the same time?

Appendix Table C6b-Update. Study quality for CLABSI which control for secular trend or confounding from the update search

Study	Infection	followup 1 year or longer	adequate statistical analysis	adherence rates analyzed	infection rates analyzed	independent of other QI efforts	Overall Quality	Univar YN	Univar Model	Multivar YN	Multivar Model	Multivar Control	Comment
Barrera, Colombia - 2011	CAUTI, CLABSI, VAP	Yes	Yes	Yes	Yes	Uncertain	Lower	FALSE		TRUE	Poisson regression	intragroup correlation specified each hospital unit as a cluster, to control for different pt populations in each unit, temporary workers and nurse-to-patient ratio	simple before-after study that controlled for potential confounders
Burrell, Australia - 2011	CLABSI	Yes	No	No	No	Uncertain	Lower	TRUE	chi-square	TRUE	multiple logistic regression	Patient Bundle, Physician Bundle, Line-days	Study uses a 'lead in period', 1 year from start of intervention, in place of baseline data. This data is compared to last 6 months of follow-up. Analysis did not control for pt. factors across the 37 ICUs.
Harris, United States - 2011	CLABSI, VAP	Yes	Yes	No	Yes	Uncertain	Lower	FALSE		TRUE	infection: time series, regression; cost: GLM	age, gender, race, comorbidity, insurance coverage, APR-DRG score, provider specialty	
Kim, United States - 2011	CLABSI	Yes	Yes	No	Yes	Uncertain	Lower	FALSE		TRUE	Poisson regression		

Study	Infection	followup 1 year or longer	adequate statistical analysis	adherence rates analyzed	infection rates analyzed	independent of other QI efforts	Overall Quality	Univar YN	Univar Model	Multivar YN	Multivar Model	Multivar Control	Comment
Lilly, United States - 2011	CLABSI, VAP	No	Yes	Yes	Yes	Uncertain	Medium	TRUE	Fisher exact or chi-sq	TRUE	logistic regression	ICU, ICU type, admission time, acuity score, operative status	This is an unblinded nonrandomized stepped wedge design. They took the same intervention, and implemented it in 7 different ICUs at different times. There was no progression of changes to the intervention. Only 3 of the 7 ICUs had followup one or more yrs
Miller, United States - 2011	CLABSI	Yes	No	Yes*	Yes	No	Lower	FALSE		TRUE	Generalized linear models	geographical region, average length of stay and bed capacity	Adherence to the insertion and maintenance bundles was included in the model for infections in the original analysis. Baseline patient characteristics were not assessed. Part way through the postintervention period a new chlorhexidine protocol was initiated
Render, United States - 2011	CLABSI	Yes	Yes	No	Yes	Uncertain	Lower	TRUE	Pearsons' correlation coefficient, standardized infection ratio, ANOVA	TRUE	Poisson GEE regression		Adherence rates were given by intervention year, however no analysis was presented save a single statistic about the inverse correlation of CLABSI rate and overall bundle compliance.
Speroff, United States - 2011	CLABSI, VAP	Yes	Yes	No	Yes	N/A	Higher	FALSE		TRUE	Hierarchical negative binomial regression	hospital, baseline covariates	Adherence rates were calculated by follow-up survey, no baseline data. Statistical analysis did only chi-square or t-test to compare groups, but study had cluster randomized design. Did binomal negative regression analysis.

Study	Infection	followup 1 year or longer	adequate statistical analysis	adherence rates analyzed	infection rates analyzed	independent of other QI efforts	Overall Quality	Univar YN	Univar Model	Multivar YN	Multivar Model	Multivar Control	Comment
Taylor, United States - 2011	CLABSI	Yes	Yes	No	Yes	Uncertain	Lower	FALSE		TRUE	Cox regression	gestational age, central line days, census, respiratory support days	No adherence rates reported. Infection risk was reported rather than infection rates.

Was the followup period 1 year or longer?
Was the statistical analysis adequate?
Were the baseline and postintervention adherence rates reported and analyzed statistically?
Were the baseline and postintervention infection rates reported and analyzed statistically?
Was the intervention independent of other QI efforts implemented at the same time?

Appendix Table C6c-Update. Study quality for SSI which control for secular trend or confounding from the update search

Study	Infection	followup 1 year or longer	adequate statistical analysis	adherence rates analyzed	infection rates analyzed	independent of other QI efforts	Overall Quality	Univar YN	Univar Model	Multivar YN	Multivar Model	Multivar Control	Comment
Kestle, United States - 2011	SSI	Yes	No	Yes	Yes	Uncertain	Lower	TRUE	chi-square test	TRUE	Logistic regression	protocol items, BioGlide catheters, antibiotic-impregnated sutures, antibiotic-impregnated shunts, no-touch surgical technique, use of chlorhexidine shampoo preoperatively	Association between each protocol item and infection rates was assessed, but change in adherence rates were not analyzed.
Lavu, United States - 2011	SSI	Yes	Yes	No	Yes	Uncertain	Lower	TRUE	chi-square test	TRUE	logistic regression	estimated blood loss, albumin, and hemoglobin A1c	Adherence measures were not reported.
Salim, Israel – 2011	CAUTI, SSI	Yes	Yes	No	Yes	Uncertain	Lower	FALSE		TRUE	Logistic and Poisson regression	membrane rupture and duration of operation	Adherence was not measured.
Schwann, United States – 2011	SSI	Yes	Yes	Yes	Yes	Uncertain	Lower	TRUE	hierarchical chi-square test	TRUE	logistic regression	inpatient vs outpatient surgery, location, surgical service, and individual surgeon	There was a JCHAO visit during the baseline period that may have affected provider behavior. Postdischarge surveillance was limited to positive cultures only.

Was the followup period 1 year or longer?
Was the statistical analysis adequate?
Were the baseline and postintervention adherence rates reported and analyzed statistically?
Were the baseline and postintervention infection rates reported and analyzed statistically?
Was the intervention independent of other QI efforts implemented at the same time?

Appendix Table C6d-Update. Study quality for CAUTI which control for secular trend or confounding from the update search

Study	Infection	followup 1 year or longer	adequate statistical analysis	adherence rates analyzed	infection rates analyzed	independent of other QI efforts	Overall Quality	Univar YN	Univar Model	Multivar YN	Multivar Model	Multivar Control	Comment
Barrera, Colombia - 2011	CAUTI, CLABSI, VAP	Yes	Yes	Yes	Yes	Uncertain	Lower	FALSE		TRUE	Poisson regression	intragroup correlation specified each hospital unit as a cluster, to control for different pt populations in each unit, temporary workers and nurse-to-patient ratio	simple before-after study that controlled for potential confounders
Fakih, United States - 2012	CAUTI	Yes	No	Yes	No	Uncertain	Lower	TRUE	GEE model	FALSE			Authors use GEE model for analysis of inappropriate catheter and time use at the patient-level. Additional covariate data were not collected or used.
Marra, Brazil – 2011	CAUTI	Yes	No	No	Yes	Uncertain	Lower	TRUE	GLM	FALSE			Patient characteristics were not compared
Salim, Israel – 2011	CAUTI, SSI	Yes	Yes	No	Yes	Uncertain	Lower	FALSE		TRUE	Logistic and Poisson regression	membrane rupture and duration of operation	Adherence was not measured.
van den Broek, Netherlands - 2011	CAUTI	No	Yes	Yes	No	Yes	Medium	FALSE		TRUE	Time-series analysis	ward type, and interaction of intervention and ward	Proportion of infected patients were reported but not analyzed and follow-up was only 5 months for each arm.

Was the followup period 1 year or longer?
Was the statistical analysis adequate?
Were the baseline and postintervention adherence rates reported and analyzed statistically?
Were the baseline and postintervention infection rates reported and analyzed statistically?
Was the intervention independent of other QI efforts implemented at the same time?

Appendix Table C1-Update LQ-a. Study characteristics for VAP which do not control for secular trend or confounding from the update search

Study	Infection	Intervention	Type of QI Strategies	Number of Hospitals	Number of Patients
Ban, Korea, (South) Republic of – 2011	VAP	multi-dimensional program for VAP prevention	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	1	
Kastrup, Germany - 2011	VAP	Visual feedback system of daily goals for ventilator weaning	Audit and Feedback, Provider Education		pre: 111; post: 94
Rosenthal, Colombia* - 2011	VAP	VAP bundle, education and feedback	Audit and Feedback, Organizational Change, Provider Education		pre: 1272 (61); post: 3067 (80)
Stone, United States - 2011	VAP	VAP bundle with daily goal rounds and checklist	Organizational Change, Provider Reminder Systems		pre: 85 (15); post: 89 (5)
Garcia-Vazquez, Spain - 2011	CAUTI, CLABSI, SSI, VAP	hand hygiene program	Provider Education	1	pre: 395; post: 411 (total: VAP: 35, CAUTI: 33, CLABSI: 6, SSI: 16)

Appendix Table C1-Update LQ-b. Study characteristics for CLABSI which do not control for secular trend or confounding from the update search

Study	Infection	Intervention	Type of QI Strategies	Number of Hospitals	Number of Patients
Cherry, United States - 2011	CLABSI	CVC insertion and maintenance training for nurses and residents	Organizational Change, Provider Education	1	pre: (202); post: (121)
Gozu, United States - 2011	CLABSI	CLABSI Audit and Feedback and Checklist	Audit and Feedback, Organizational Change, Provider Reminder Systems	2	ICU Pre: (10); NON-ICU Pre (9); ICU Post (6); Non-ICU Post (14)
Lopez, United States - 2011	CLABSI	CLABSI bundle	Audit and Feedback, Organizational Change, Provider Reminder Systems		
Garcia-Vazquez, Spain - 2011	CAUTI, CLABSI, SSI, VAP	hand hygiene program	Provider Education	1	pre: 395; post: 411 (total: VAP: 35, CAUTI: 33, CLABSI: 6, SSI: 16)
McHugh, Ireland - 2011	CLABSI, SSI	Web-based education program with podcasts, best practice videos, interactive cases, and tutorials	Audit and Feedback, Provider Education		
Bakke, United States - 2010	CLABSI	CLABSI Bundle	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems		Total: 385

Appendix Table C1-Update LQ-c. Study characteristics for SSI which do not control for secular trend or confounding from the update search

Study	Infection	Intervention	Type of QI Strategies	Number of Hospitals	Number of Patients
Barchitta, Italy – 2011	SSI	Infection control bundle and extensive dissemination of information	Audit and Feedback, Organizational Change, Provider Education		pre: 134 (22); post1: 160 (18); post2: 159 (9); post3: 147 (12)
Bull, Australia – 2011	SSI	Surgical care bundle with checklist and regular focus groups	Organizational Change, Provider Reminder Systems		post1: 133 (12); post2: 142 (10)
Lingard, Canada - 2011	SSI	pre-surgery team briefing	Organizational Change, Provider Reminder Systems	1	pre: 340; post: 340
Sewell, United Kingdom - 2011	SSI	Implementation of and training on use of WHO surgical checklist	Organizational Change, Provider Education, Provider Reminder Systems		pre: 480 (21*); post: 485 (17*)
Sun, Taiwan – 2011	SSI	PDSA cycles to improve antibiotic prophylaxis	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems		pre: 55 (0); post: 78 (0)
Garcia-Vazquez, Spain - 2011	CAUTI, CLABSI, SSI, VAP	hand hygiene program	Provider Education	1	pre: 395; post: 411 (total: VAP: 35, CAUTI: 33, CLABSI: 6, SSI: 16)
McHugh, Ireland - 2011	CLABSI, SSI	Web-based education program with podcasts, best practice videos, interactive cases, and tutorials	Audit and Feedback, Provider Education		

Appendix Table C1-Update LQ-d. Study characteristics for CAUTI which do not control for secular trend or confounding from the update search

Study	Infection	Intervention	Type of QI Strategies	Number of Hospitals	Number of Patients
Biese, United States - 2011	CAUTI	Geriatric specific curriculum with simulations for emergency medicine residents	Provider Education		
Dyc, United States - 2011	CAUTI	Peer-to-peer education and pocket card of proper urinary catheter indications	Provider Education, Provider Reminder Systems		
Fuchs, United States - 2011	CAUTI	Nurse driven checklist for catheter use	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems		
Knoll, United States - 2011	CAUTI	Phase 3: daily urinary catheter audit w discussion of necessity of nonindicated Ucs and pager reminders for expired orders.	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems	1	
Oman, United States - 2011	CAUTI	Nurse driven incorporation of evidence-based practice for urinary catheters	Audit and Feedback, Organizational Change, Patient Education, Provider Education, Provider Reminder Systems		pre: 219; post1: 238; post2: 238
Titsworth, United States - 2012	CAUTI	CAUTI bundle	Audit and Feedback, Organizational Change, Provider Education, Provider Reminder Systems		
Wright, United States - 2011	CAUTI	Use of physician order, daily nurse assessment of need, physician reminder every 48 hrs, and targeted education in high use areas to decrease urinary catheter use	Organizational Change, Provider Education, Provider Reminder Systems		pre: 12,172 (312); post: 9,366 (247)
Garcia-Vazquez, Spain - 2011	CAUTI, CLABSI, SSI, VAP	hand hygiene program	Provider Education	1	pre: 395; post: 411 (total: VAP: 35, CAUTI: 33, CLABSI: 6, SSI: 16)

*Only study characteristic data was extracted from studies that do not control for confounding or secular trend in the updated literature search. No synthesis of the evidence for these articles was presented in the comparative effectiveness review for reasons described in the Methods section.

Appendix D. Evidence-Based Preventive Interventions Used in Study Selection

The following evidence-based preventive interventions, identified from 2007 report (Ranji et al. 2007), HICPAC guidelines, IDSA/SHEA Compendium, and input from the Technical Expert Panel, were used for identifying studies from all settings for inclusion in this evidence review.

All HAIs: Hand hygiene

Surgical site infection:

- appropriate perioperative antibiotic prophylaxis (including appropriate antibiotic selection, timing, and duration) (2007 report)
- perioperative glucose control (2007 report)
- decreasing shaving [or hair removal] of the operative site (2007 report)
- specific technique for clinicians when washing hands prior to surgery (CDC/HICPAC IB)
- treat infections prior to surgery (CDC/HICPAC IA)
- encourage tobacco cessation (CDC/HICPAC IB)
- bathe and prepare skin with antiseptic agent (CDC/HICPAC IB)
- develop policies to manage infected surgical team (CDC/HICPAC IB)
- maintain positive pressure ventilation and minimal 15 air changes per hr during surgery (CDC/HICPAC IB)
- disinfect environmental surfaces (CDC/HICPAC IB)
- sterile instruments and surgical wear (CDC/HICPAC IB)
- after surgery, protect incision with sterile dressing (CDC/HICPAC IB)
- normothermia [recommended by Technical Expert Panel]
- intraoperative administration of oxygen (FIO2), for abdominal or colorectal cases [recommended by Technical Expert Panel]

Central line-associated bloodstream infection:

- adherence to maximal sterile barrier precautions (2007 report)
- use of chlorhexidine for skin antisepsis (2007 report); If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives. (CDC/HICPAC IA)
- avoidance of femoral catheterization (2007 report)
- decontaminate hands before donning sterile gloves when inserting a central intravascular catheter (CDC/HICPAC IB)
- do not use arterial or venous cutdown procedures during insertion (CDC/HICPAC IA)
- do not use organic solvents on skin (CDC/HICPAC IA)
- clean injection ports with 70% alcohol before accessing (CDC/HICPAC IA)
- prepare admixtures using sterile technique (CDC/HICPAC IB)
- do not use in-line filters for infection-control purposes (CDC/HICPAC IA)
- do not administer systemic antimicrobial prophylaxis routinely prior to catheter insertion (CDC/HICPAC IA)

- after insertion, remove nonessential catheters (SHEA/IDSA A-II); Promptly remove any intravascular catheter that is no longer essential (CDC/HICPAC IA)
- After insertion, change dressings and perform site care every 5-7 days and change gauze every 2 days (SHEA/IDSA A-I); Replace dressings used on short-term CVC sites at least every 7 days for transparent dressings, except in those pediatric patients in which the risk for dislodging the catheter may outweigh the benefit of changing the dressing. (CDC/HICPAC IB)
- after insertion, use antimicrobial ointments (SHEA/IDSA A-I); Do not use topical antibiotic ointment or creams on insertion sites, except for dialysis catheters, because of their potential to promote fungal infections and antimicrobial resistance. (CDC/HICPAC IB) (Need to resolve inconsistency based on TEP advice.)
- Weigh the risks and benefits of placing a central venous device at a recommended site to reduce infectious complications against the risk for mechanical complications (e.g., pneumothorax, subclavian artery puncture, subclavian vein laceration, subclavian vein stenosis, hemothorax, thrombosis, air embolism, and catheter misplacement) (CDC/HICPAC IA)
- Avoid the subclavian site in hemodialysis patients and patients with advanced kidney disease, to avoid subclavian vein stenosis (CDC/HICPAC IA)
- Use a fistula or graft in patients with chronic renal failure instead of a CVC for permanent access for dialysis (CDC/HICPAC IA)
- Use ultrasound guidance to place central venous catheters (if this technology is available) to reduce the number of cannulation attempts and mechanical complications. Ultrasound guidance should only be used by those fully trained in its technique. (CDC/HICPAC IB)
- Use a CVC with the minimum number of ports or lumens essential for the management of the patient. (CDC/HICPAC IB)
- When adherence to aseptic technique cannot be ensured (i.e. catheters inserted during a medical emergency), replace the catheter as soon as possible, that is, within 48 hours. (CDC/HICPAC IB)
- Maintain aseptic technique for the insertion and care of intravascular catheters. (CDC/HICPAC IB)
- Antiseptics should be allowed to dry according to the manufacturer's recommendation prior to placing the catheter. (CDC/HICPAC IB)
- Use either sterile gauze or sterile, transparent, semipermeable dressing to cover the catheter site. (CDC/HICPAC IA)
- Replace catheter site dressing if the dressing becomes damp, loosened, or visibly soiled. (CDC/HICPAC IB)
- Do not submerge the catheter or catheter site in water. Showering should be permitted if precautions can be taken to reduce the likelihood of introducing organisms into the catheter (e.g., if the catheter and connecting device are protected with an impermeable cover during the shower). (CDC/HICPAC IB)
- Ensure that catheter site care is compatible with the catheter material. (CDC/HICPAC IB)
- Monitor the catheter sites visually when changing the dressing or by palpation through an intact dressing on a regular basis, depending on the clinical situation of the individual patient. If patients have tenderness at the insertion site, fever without obvious source, or

other manifestations suggesting local or bloodstream infection, the dressing should be removed to allow thorough examination of the site. (CDC/HICPAC IB)

- Do not routinely replace CVCs, PICCs, hemodialysis catheters, or pulmonary artery catheters to prevent catheter-related infections. (CDC/HICPAC IB)
- Do not use guidewire exchanges routinely for non-tunneled catheters to prevent infection. (CDC/HICPAC IB)
- Do not use guidewire exchanges to replace a non-tunneled catheter suspected of infection. (CDC/HICPAC IB)
- Use a guidewire exchange to replace a malfunctioning non-tunneled catheter if no evidence of infection is present. (CDC/HICPAC IB)
- Ventilator-associated pneumonia:
- semirecumbent patient positioning (2007 report)
- daily assessment of readiness for ventilator weaning (2007 report)
- perform antiseptic oral care (CDC/HICPAC A-I)
- Catheter-associated urinary tract infection
- reduction in unnecessary catheter use (2007 report)
- adherence to aseptic catheter insertion and catheter care (2007 report)
- maintain a closed drainage system and maintain unobstructed urine flow (CDC/HICPAC IB); do not disconnect unless irrigation needed (SHEA/IDSA A-I)

CDC/HICPAC definitions for rating recommendations in above list:

Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
Category IB. Strongly recommended for implementation and supported by certain experimental, clinical, or epidemiologic studies and a strong theoretical rationale.

SHEA/IDSA definitions for rating recommendations in above list:
Strength of recommendation:

A good evidence to support recommendation

Quality of evidence:

I evidence from $\geq$ 1 properly randomized controlled trial

II evidence from $\geq$ 1 well-designed clinical trial w/out randomization; cohort or case-control analytic studies (preferably from > 1 center); multiple time series; or dramatic results from uncontrolled experiments

Appendix E. Items on Data Abstraction Forms

Study and Patient Characteristics Form

- Authors
- Country
- Year Published
- Infections
- Study Design
- Healthcare Setting
- Clinical Setting
- Intervention Start Year
- Intervention End Year
- Follow-up months
- Comments

Intervention Characteristics Form

- Intervention
- Comparator
- Number of Hospitals
- Number of Patients
- Number of Patients lost to follow-up
- Number of healthcare staff
- Type of QI strategy
- Clinical Characteristics
- Age
- Age distribution
- Percent Male
- Percent White
- Interventionists
- Participants
- Intervention Specifics
- Intervention expected influence on behavior
- Outcomes
- Comments

Intervention Context Form

- Were expectations made clear to interveners and intervenees?
- What positive and negative incentives were used?
- Describe feedback or consequences given to interveners and or intervenes?
- Description of theory behind patient safety practice
- Influence of context on processes and outcomes
    - Organizational characteristics

        - Size
        - Location
        - Financial Status
        - Existing patient safety infrastructure
        - External Factors
- Patient safety culture, teamwork, leadership at the unit level
- Availability of implementation and management tools
- Comments

Intervention Outcomes Form

- Outcome value (95% CI) and statistical results for all outcomes
- Rate of infection
    - Units of Measurement
    - Months since intervention
- Adherence
    - Months since intervention
- Costs
- Savings
- Type of univariate model used and variables controlled for
- Type of multivariate model used and variables controlled for
- Comments

Quality Form

- Did the execution of the study vary from the original protocol?
- Is the intervention assessed using valid and reliable measures, implemented consistently across all study participants?
- Are outcomes assessed using valid and reliable measures, implemented consistently across all study participants?
- Is the length of follow up sufficient to support the evaluation of primary outcomes and harms?
- Are any important primary outcomes missing from the results?
- Is the source of funding identified?
- If infection rates reported, did study also report adherence rates?
- If infection rate was reported, was CDC/NNIS methodology used?
- For CLABSI, VAP, CAUTI - were infection rates adjusted for device utilization?
- For SSI- was post-discharge surveillance for infections performed?
- Was the intervention performed independent of other QI efforts or other changes?
- Did the study report data at more than one time point both before and after the intervention?
- If the study reported infection rates, were process measurements also reported?
- Were study subjects randomized?
- Was the randomization process described?
- For non-randomized studies, was rationale for comparison group selection explained?
- Were outcome assessor blinded to treatment group assignment?

- Was a unit of analysis error present?
- Was it corrected by appropriate statistical methods?
- Comments

Appendix F. Overview Tables for Articles Not Included in Analysis

Appendix Table F1. VAP studies not included in analysis

Author, Location-Year	Sample Size (Infections)	Intervention	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Promotion of Self-Management	Provider Education	Provider Reminder Systems
Assanasen, United States - 2008	pre: 450 post: 2435	Feedback Program	•						
Bigham, United States - 2009	pre: 617 (77) post1: 447 (22) post2: 1782 (3)	VAP Bundle	•		•			•	•
Rogers, Ireland - 2010	pre: 8 (10) post: 5 (6)	Plan-Do-Study-Act (PDSA) cycle						•	
Venkatram, United States - 2010	pre: 549 (5) post: 1165 (3)	VAP bundle	•		•	•		•	
Sona, United States - 2009	pre: 777 (24) post: 871 (10)	Oral Care Protocol	•		•			•	
Garcia, United States - 2009	pre: 779 (67) post: 759 (31)	VAP Education and Oral Care Protocol			•			•	
Rosenthal, Argentina - 2006	pre: 435 (84) post: 366 (54)	Nurse-Implemented Sedation Protocol	•					•	
Gurskis, Lithuania - 2009	pre: 270 (15) post: 322 (6)	VAP Education						•	
Landrum, Afghanistan - 2008	total: 475 (25)	Infection Control Protocol	•		•			•	
Heimes, United States - 2011	pre: 215 (8) post1: 240 (4) post2 : 241 (3)	VAP Prevention Protocol (VAPP)	•		•			•	
Quenot, France - 2007	pre: 226 (34) post: 197 (12)	VAP Bundle			•				
Jain, United States - 2006	pre: (260) post: (70)	IMPACT initiative	•		•				
Bloos, Germany - 2009	pre: 133 (44) post: 141 (45)	Educational Program	•		•			•	

Author, Location-Year	Sample Size (Infections)	Intervention	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Promotion of Self-Management	Provider Education	Provider Reminder Systems
Jimenez, United States - 2009	pre: 102 post: 86	VAP Bundle	•					•	•
Ross, United States - 2007	pre: 55 post: 61	Multifaceted Infection Control Program	•					•	
Abbott, United States - 2006	pre: (9) post: (9) total: 106 (18)	Academic Center of Evidence-based Practice (ACE) Star Model	•		•			•	•
Berriel-Cass, United States - 2006		VAP bundle	•		•			•	
Bird, United States - 2010		VAP Bundle	•		•				•
Blamoun, United States - 2009		Expanded VAP bundle			•				
Cocanour, United States - 2006		VAP Bundle	•		•	•		•	
Ban, Korea, (South) Republic of - 2011		multi-dimensional program for VAP prevention	•		•			•	•
Kastrup, Germany - 2011	pre: 111 post: 94	Visual feedback system of daily goals for ventilator weaning	•					•	
Rosenthal, Colombia* - 2011	pre: 1272 (61) post: 3067 (80)	VAP bundle, education and feedback	•		•			•	
Stone, United States - 2011	pre: 85 (15) post: 89 (5)	VAP bundle with daily goal rounds and checklist			•				•
Garcia-Vazquez, Spain - 2011	pre: 395 post: 411 (Total: 35)	hand hygiene program						•	

Appendix Table F2. CLABSI articles not included in analysis

Author, Location-Year	Sample Size (Infections)	Intervention	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Promotion of Self-Management	Provider Education	Provider Reminder Systems
Lobo, Brazil - 2010	pre: 519 (41) post: 303 (12)	Continuous Education	•					•	•
Venkatram, United States - 2010	pre: 1096 (18) post: 3749 (8)	CLABSI bundle	•		•	•		•	
Shannon, United States - 2006	pre: 1067 (49) post: 1832 (3)	Toyota Production System adaptation			•			•	
Assanasen, United States - 2008	pre: 450 post: 2435	Feedback Program	•						
Warren, United States - 2006	pre: (229) post: (508)	Multifaceted, education-based intervention						•	
Koll, United States - 2008	pre: (364) post: (349)	Central line bundle	•		•			•	
Wicker, United States - 2011	pre: 334 (103) post: 303 (59)	Comprehensive Infection Control Measures	•		•			•	
Bizzarro, United States - 2010	pre: 417 (83) post: 159 (6)	Bundle - CLABSI	•		•		•	•	
Yilmaz, Turkey - 2007	pre: 241 (71) post: 193 (45)	Education	•		•			•	
Sannoh, United States - 2010	pre: 163 (45) post: 210 (35)	Bundle - CLABSI	•					•	•
Gurskis, Lithuania - 2009	pre: 95 (5) post: 108 (2)	CLABSI Education						•	
Marra, Brazil - 2010	pre: (134) post: (64)	IHI Bundle - CLABSI	•		•				•
Santana, Brazil - 2008	total: 186	Education						•	
Rogers, Ireland - 2010	pre: (31) post: (19)	Plan-Do-Study-Act (PDSA) cycle						•	
Guerin, United States - 2010	pre: (25) post: (3)	Post-insertion CVC care bundle						•	
Jeffries, United States - 2009		CVC Insertion and Maintenance Bundle	•		•			•	

Author, Location-Year	Sample Size (Infections)	Intervention	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Promotion of Self-Management	Provider Education	Provider Reminder Systems
Berriel-Cass, United States - 2006		CLABSI Bundle	•		•			•	
Bhutta, United States - 2007		Bundle CLABSI			•			•	•
Galpern, United States - 2008		CLABSI Bundle	•		•			•	
Jain, United States - 2006		IMPACT initiative	•		•				
Render, United States - 2006		CLABSI Bundle	•		•				•
Cherry, United States - 2011	pre: (202); post: (121)	CVC insertion and maintenance training for nurses and residents			•			•	
Gozu, United States - 2011	ICU Pre: (10); NON-ICU Pre (9); ICU Post (6); Non-ICU Post (14)	CLABSI Audit and Feedback and Checklist	•		•				•
Lopez, United States - 2011		CLABSI bundle	•		•				•
Garcia-Vazquez, Spain - 2011	pre: 395; post: 411 (total: VAP: 35, CAUTI: 33, CLABSI: 6, SSI: 16)	hand hygiene program						•	
McHugh, Ireland - 2011		Web-based education program with podcasts, best practice videos, interactive cases, and tutorials	•					•	
Bakke, United States - 2010	Total: 385	CLABSI Bundle	•		•			•	•

Appendix Table F3. SSI articles not included in analysis

Author, Location-Year	Sample Size (Infections)	Intervention	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Promotion of Self-Management	Provider Education	Provider Reminder Systems
Wax, United States - 2007	pre: 4987 post: 9478	Electronic reminder for provider							•
Gomez, Argentina - 2006	pre: 3496 (111) post: 3982 (75)	automatic stop prophylaxis form			•			•	•
Graf, Germany - 2009	pre: 3150 (114) post: 980 (80)	bundle - SSI	•					•	•
Takahashi, Japan - 2010	pre: 1627 post: 1627	Departmental Education	•		•			•	
Kramer, United States - 2008	pre: 1677 (44*) post: 1388 (14*)	nomogram for glycemic control			•			•	•
Liau, Singapore - 2010	post: 2408 (12*)	bundle - antibiotic, glucose control, clippers, normothermia			•			•	•
Parker, United States - 2007	pre: 615 post: 1716	Six Sigma methodology and antibiotic prophylaxis			•			•	
Suchitra, India - 2009	pre: 1125 (136) post: 1119 (45)	Education Program						•	
Shimoni, Israel - 2009	pre: 1104 (186) post: 1089 (137)	Empowering surgical nurses			•				
Ichikawa, Japan - 2007	pre: 721 (27) post: 1313 (22)	Implementation of Antibiotic Protocols	•					•	
Whitman, United States - 2008	total: 1622	Multiple 'forced functions'	•		•			•	•
Potenza, United States - 2009	total: 1359	bundle - antibiotic prophylaxis			•				•
Kable, Australia - 2008	pre: 659 (50) post: 518 (42)	bundle - antibiotic prophylaxis			•			•	•
Rauk, United States - 2010	pre: 441 (33) post: 436 (5)	bundle - skin prep and instrument sterilization			•			•	
Hermsen, United States - 2008	pre: 406 post: 396	Standardized order form	•		•			•	•
Ozgun, Turkey - 2010	pre: 312 post: 322	antibiotic prophylaxis education						•	

Author, Location-Year	Sample Size (Infections)	Intervention	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Promotion of Self-Management	Provider Education	Provider Reminder Systems
Pastor, United States - 2010	pre: 238 (45) post: 253 (49)	task force to meet SCIP process measures			•			•	
Carles, France - 2006	pre: 210 post: 210	surgical antibiotic prophylaxis kit (SAPK)			•				
Acklin, Switzerland - 2011	pre: 217 (15) post: 153 (3)	bundle - antibiotic prophylaxis, skin prep, sterile dressing	•					•	
Nemeth, United States - 2010	pre: 97 post: 193	Education program						•	•
Willemsen, Netherlands - 2007	pre: 153 post: 147	standardized antibiotic protocol			•			•	
Berry, United States - 2009	pre: 137 post: 117	ProvenCare	•		•			•	•
Forbes, Canada - 2008	pre: 105 (superficial: 15*, organ space: 8*) post: 103 (superficial: 9*, organ space: 7*)	bundle - antibiotic administration in OR, pre-printed order form to standardize choice of antibiotic, monthly performance figures posted in OR; bundle - maintain normothermia by warming OR to 22 C, standardizing IV warmers and forced air devices, monthly performance figures posted in OR; bundle - glucose control by screening all pts prior to surgery, administering weight-based regimen of insulin to diabetics, monthly performance figures posted in OR	•		•			•	
Berenguer, United States - 2010	pre: 113 (15) post: 84 (7)	implementing SCIP measures			•			•	
Awad, United States - 2009		MRSA bundle	•		•			•	
Paull, United States - 2010		The Briefing Guide (BiG)			•			•	•
Zvonar, Canada - 2008		Appropriate antibiotic prophylaxis administration	•		•			•	
Barchitta, Italy - 2011	pre: 134 (22); post1: 160 (18) post2: 159 (9) post3: 147 (12)	Infection control bundle and extensive dissemination of information	•		•			•	
Bull, Australia - 2011	post1: 133 (12); post2: 142 (10)	Surgical care bundle with checklist and regular focus groups			•				•

Author, Location-Year	Sample Size (Infections)	Intervention	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Promotion of Self-Management	Provider Education	Provider Reminder Systems
Lingard, Canada - 2011	pre: 340 post: 340	pre-surgery team briefing			•				•
Sewell, United Kingdom - 2011	pre: 480 (21*); post: 485 (17*)	Implementation of and training on use of WHO surgical checklist			•			•	•
Sun, Taiwan - 2011	pre: 55 (0) post: 78 (0)	PDSA cycles to improve antibiotic prophylaxis	•		•			•	•
Garcia-Vazquez, Spain - 2011	pre: 395 post: 411 (total: SSI: 16)	hand hygiene program						•	
McHugh, Ireland - 2011		Web-based education program with podcasts, best practice videos, interactive cases, and tutorials	•					•	

Appendix Table F4. CAUTI articles not included in analysis

Author, Location-Year	Sample Size (Infections)	Intervention	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Promotion of Self-Management	Provider Education	Provider Reminder Systems
Stephan, Switzerland - 2006	pre: 280 post: 300	CAUTI guidelines, education and posters	•					•	
Venkatram, United States - 2010	pre: 1096 (18) post: 2669 (5)	CAUTI bundle	•		•	•		•	
Suchitra, India - 2009	pre: 1125 (74) post: 1119 (30)	Education Program						•	
Wald, United States - 2011	pre orthopedic: 206 (3) post orthopedic: 290 (0) pre general: 167 (3) post general: 183 (3)	Audit and feedback on catheter duration	•					•	
Gurskis, Lithuania - 2009	pre: 270 (3) post: 322 (6)	CAUTI Education			•			•	•
Gokula, United States - 2007	pre: 100 post: 100	Education	•					•	•
Rothfeld, United States - 2010	pre: (51) post: (26)	Appropriate Catheter Use Protocol			•			•	
Jain, United States - 2006		IMPACT initiative	•		•				
Biese, United States - 2011		Geriatric specific curriculum with simulations for emergency medicine residents						•	
Dyc, United States - 2011		Peer-to-peer education and pocket card of proper urinary catheter indications						•	•
Fuchs, United States - 2011		Nurse driven checklist for catheter use	•		•			•	•
Knoll, United States - 2011		Phase 3: daily urinary catheter audit w discussion of necessity of nonindicated Ucs and pager reminders for expired orders.	•		•			•	•
Oman, United States - 2011	pre: 219; post1: 238; post2: 238	Nurse driven incorporation of evidence-based practice for urinary catheters	•		•	•		•	•
Titsworth, United States - 2012		CAUTI bundle	•		•			•	•

Author, Location-Year	Sample Size (Infections)	Intervention	Audit and Feedback	Financial Incentives	Organizational Change	Patient Education	Promotion of Self-Management	Provider Education	Provider Reminder Systems
Wright, United States - 2011	pre: 12,172 (312); post: 9,366 (247)	Use of physician order, daily nurse assessment of need, physician reminder every 48 hrs, and targeted education in high use areas to decrease urinary catheter use			•			•	•
Garcia-Vazquez, Spain - 2011	pre: 395; post: 411 (total: 33)	hand hygiene program						•	

Appendix G. Details of Interrupted Time Series Analysis

Appendix Table G1. Description of interrupted time series results for VAP studies

Author, Country-Year	Outcome	Test	Values	p-value	Comment
Zaydfudim, United States - 2009	Infection rates	t-test	Mean baseline: 15.2		
			Mean post-intervention: 9.3	0.01	
		piecewise linear regression		0.37	The trend during the baseline period is not significantly different than the trend during the post-intervention period.
Apisarnthanarak, Thailand - 2007	MICU Infection rates	t-test	Mean baseline: 20.6		p-values are comparing the subsequent period to baseline.
			Mean post-intervention: 8.5	0.001	
			Mean follow-up: 4.2	<0.001	
		segmented regression	Initial change from baseline to post-intervention: -2.291	0.6307	Difference between the last point in baseline is not significantly different than the first point in post-intervention.
			Initial change from post-intervention to follow-up: -1.594	0.7007	Difference between the last point in post-intervention is not significantly different than the first point in follow-up.
			Difference in trends from baseline and post-intervention: -1.171	0.0018	Trend during post-intervention is significantly different than the trend during baseline.
			Difference in trends from post-intervention and follow-up: -1.115	0.07	Trend during follow-up is marginally significantly different than the trend during post-intervention.
Bouadma, France - 2010	Infection rates	Wilcoxon rank sum test	Overall baseline: 22.6		
			Overall post-intervention: 13.1	<0.001	
		segmented regression	Trend during baseline	0.11	There was a non-significant change in trend during the baseline period.
			Trend during post-intervention	0.001	There was a significant decrease in trend during the post-intervention period.

Author, Country-Year	Outcome	Test	Values	p-value	Comment
Marra, Brazil - 2009	Infection rates	ANOVA	Mean baseline: 16.4		
			Mean post-intervention 1: 15.0		
			Mean post-intervention 2: 10.4	0.05	
		segmented regression	Trend part 1 of Phase 3: 2.59	0.001	There was a significant increase in the trend during the first part of Phase 3.
			Trend during part 2 of Phase 3: -2.30	0.27	There was a nonsignificant change in trend during the second part of Phase 3.
			Trend during part 3 of Phase 3: -0.76	0.18	There was a nonsignificant change in trend during the last part of Phase 3.
Papadimos, United States - 2008	Infection rates	2-tailed z-test/Wilcoxon rank sum test	Overall baseline: 19.3		
			Overall pre-FASTHUG: 16.6	0.62	
			Overall post-FASTHUG: 7.3	<0.01	
		ARIMA model	Baseline vs pre-FASTHUG period	0.5909	Authors combined baseline and pre-FASTHUG periods since they were non-significantly different.
			Combined pre-FASTHUG period vs post-FASTHUG period	0.0004	The mean monthly infection rates are significantly lower in the post-FASTHUG period

Appendix Table G2. Description of interrupted time series results for CLABSI studies

Author, Country-Year	Outcome	Test	Values	p-value	Comment
Apisarnthanarak, Thailand - 2007	Medical Ward Infection Rates	t-test	Mean baseline: 16		p-values are comparing subsequent period to baseline.
			Mean post-intervention: 6.8	<0.05	
			Mean follow-up: 1.5	<0.05	
		segmented regression	Initial change from baseline to post-intervention: -7.72	0.03	Difference between the last point in baseline is significantly different than the first point in post-intervention.
			Initial change from post-intervention to follow-up: -4.15	0.02	Difference between the last point in post-intervention is significantly different than the first point in follow-up.
			Difference in trends from baseline and post-intervention: -1.18	0.48	Trend during post-intervention is not significantly different than the trend during baseline.
			Difference in trends from post-intervention and follow-up: -1.15	0.07	Trend during follow-up is marginally significantly different than the trend during post-intervention.
	Surgical Ward Infection Rates	t-test	Mean baseline: 11		p-values are comparing subsequent period to baseline.
			Mean post-intervention: 5.5	<0.05	
			Mean follow-up: 0.8	<0.05	
		segmented regression	Initial change from baseline to post-intervention: -8.36	0.001	Difference between the last point in baseline is significantly different than the first point in post-intervention.
			Initial change from post-intervention to follow-up: -4.04	0.05	Difference between the last point in post-intervention is significantly different than the first point in follow-up.
			Difference in trends from baseline and post-intervention: 0.08	0.45	Trend during post-intervention is not significantly different than the trend during baseline.
			Difference in trends from post-intervention and follow-up: -0.22	0.40	Trend during follow-up is not significantly different than the trend during post-intervention.
	ICU Infection Rates	t-test	Mean baseline: 17		p-values are comparing subsequent period to baseline.
			Mean post-intervention: 7.1	<0.05	
			Mean follow-up: 2.1	<0.05	

Author, Country-Year	Outcome	Test	Values	p-value	Comment
		segmented regression	Initial change from baseline to post-intervention: -12.25	0.005	Difference between the last point in baseline is significantly different than the first point in post-intervention.
			Initial change from post-intervention to follow-up: -8.13	0.001	Difference between the last point in post-intervention is significantly different than the first point in follow-up.
			Difference in trends from baseline and post-intervention: 0.24	0.36	Trend during post-intervention is not significantly different than the trend during baseline.
			Difference in trends from post-intervention and follow-up: -1.54	0.06	Trend during follow-up is marginally significantly different than the trend during post-intervention.
	Other Units Infection Rates	t-test	Mean baseline: 9		p-values are comparing subsequent period to baseline.
			Mean post-intervention: 5.2	<0.05	
			Mean follow-up: 0.9	<0.05	
		segmented regression	Initial change from baseline to post-intervention: -3.36	0.04	Difference between the last point in baseline is significantly different than the first point in post-intervention.
			Initial change from post-intervention to follow-up: -1.45	0.14	Difference between the last point in post-intervention is not significantly different than the first point in follow-up.
			Difference in trends from baseline and post-intervention: 0.14	0.24	Trend during post-intervention is not significantly different than the trend during baseline.
			Difference in trends from post-intervention and follow-up: -0.04	0.2	Trend during follow-up is not significantly different than the trend during post-intervention.

Appendix Table G3. Description of interrupted time series results for SSI studies

Author, Country-Year	Outcome	Test	Values	p-value	Comment
Mannien, Netherlands - 2006	Overall Infection rates	t-test	Mean baseline: 21.5		
			Mean post-intervention 5.2	<0.001	
		segmented regression	Initial change from baseline to post-intervention: 13.71	<0.001	Difference between the last point in baseline is significantly different than the first point in post-intervention.
			Difference in trends from baseline and post-intervention: 0.27	0.5	Trend during post-intervention is not significantly different than the trend during baseline.
	Medical Ward Infection rates	t-test	Mean baseline: 21.5		
			Mean post-intervention 6.5	0.02	
		segmented regression	Initial change from baseline to post-intervention: 11.23	0.04	Difference between the last point in baseline is significantly different than the first point in post-intervention.
			Difference in trends from baseline and post-intervention: 0.67	0.24	Trend during post-intervention is not significantly different than the trend during baseline.
	Surgical Ward Infection rates	t-test	Mean baseline: 19.4		
			Mean post-intervention 7.8	0.03	
		segmented regression	Initial change from baseline to post-intervention: 7.61	0.03	Difference between the last point in baseline is significantly different than the first point in post-intervention.
			Difference in trends from baseline and post-intervention: 0.97	0.06	Trend during post-intervention is marginally significantly different than the trend during baseline.
	ICU Infection rates	t-test	Mean baseline: 23.4		
			Mean post-intervention 3.5	0.01	
		segmented regression	Initial change from baseline to post-intervention: 11.23	0.003	Difference between the last point in baseline is significantly different than the first point in post-intervention.
			Difference in trends from baseline and post-intervention: 0.67	0.5	Trend during post-intervention is not significantly different than the trend during baseline.

Appendix Table G4. Description of interrupted time series results for CAUTI studies

Author, Country-Year	Outcome	Test	Values	p-value	Comment
Apisarnthanarak, Thailand - 2007	Overall Infection rates	t-test	Mean baseline: 21.5		
			Mean post-intervention 5.2	<0.001	
		segmented regression	Initial change from baseline to post-intervention: 13.71	<0.001	Difference between the last point in baseline is significantly different than the first point in post-intervention.
			Difference in trends from baseline and post-intervention: 0.27	0.5	Trend during post-intervention is not significantly different than the trend during baseline.
	Medical Ward Infection rates	t-test	Mean baseline: 21.5		
			Mean post-intervention 6.5	0.02	
		segmented regression	Initial change from baseline to post-intervention: 11.23	0.04	Difference between the last point in baseline is significantly different than the first point in post-intervention.
			Difference in trends from baseline and post-intervention: 0.67	0.24	Trend during post-intervention is not significantly different than the trend during baseline.
	Surgical Ward Infection rates	t-test	Mean baseline: 19.4		
			Mean post-intervention 7.8	0.03	
		segmented regression	Initial change from baseline to post-intervention: 7.61	0.03	Difference between the last point in baseline is significantly different than the first point in post-intervention.
			Difference in trends from baseline and post-intervention: 0.97	0.06	Trend during post-intervention is marginally significantly different than the trend during baseline.
	ICU Infection rates	t-test	Mean baseline: 23.4		
			Mean post-intervention 3.5	0.01	
		segmented regression	Initial change from baseline to post-intervention: 11.23	0.003	Difference between the last point in baseline is significantly different than the first point in post-intervention.
			Difference in trends from baseline and post-intervention: 0.67	0.5	Trend during post-intervention is not significantly different than the trend during baseline.