



## Evidence-based Practice Center

### Project Title: Critical Analysis of the Evidence for Patient Safety Practices in Nursing Home Settings

#### I. Background and Objectives for the Technical Brief Nursing Home Safety

An estimated 1,383,700 individuals live in nursing homes (NH) and 713,300 in residential care communities in the United States.<sup>1</sup> In 2012, 55% of “health deficiencies” in self-reported surveys of Medicare and Medicaid-certified NH in the U.S. were considered to be at the greater than minimal harm level, and 2% were considered to be an actual harm.<sup>2</sup> An estimated mean 1.5 falls/bed/year occur in long-term care facilities, with 4% of these resulting in fracture and 11% resulting in serious injuries such as lacerations and head trauma.<sup>3,4</sup> The Agency for Healthcare Research & Quality (AHRQ) defines safety as “*a type of process or structure whose application reduces the probability of an adverse event...*” Consistent with this definition, the NH clinical literature contains many studies that have measured poor outcomes thought to be preventable if specific care processes were consistently implemented for all residents in need.

Key safety issues identified in multiple sources, and of particular interest in this Technical Brief, include falls, pressure ulcers, infection, including hospital acquired infection (HAI) and urinary tract infection, excessive weight loss, medication error and adverse drug events, help with activities of daily living, fecal/urinary incontinence, depressive symptoms, overuse or inappropriate use of antipsychotic medication, moderate to severe pain, influenza vaccine, pneumococcal vaccine, physical restraints, and catheter left in bladder<sup>5-8</sup> These outcomes align with the most common reasons for NH litigation (falls, pressure ulcers, weight loss, medication errors).<sup>9</sup> The NH safety issues identified above are captured in the Patient Safety Organization Privacy Protection Center (PSOPPC) Common Formats for Event reporting on Nursing Home Safety version 0.1 Beta.<sup>10</sup> These include: falls, healthcare-associated infection, medication or Other Substance, and pressure ulcers. These NH safety issues are also represented in the Centers for Medicare & Medicaid Services (CMS) Nursing Home Compare Quality Indicators.<sup>10</sup> These include: falls, pressure ulcers, infection, including hospital acquired infection (HAI) and urinary tract infection, excessive weight loss, medication error and adverse drug events, help with activities of daily living, fecal/urinary incontinence, depressive symptoms, overuse or inappropriate use of antipsychotic medication, moderate to severe pain, influenza vaccine, pneumococcal vaccine, physical restraints, and catheter left in bladder. The Quality Measures are derived from the Minimum Data Set (MDS) of regularly collected assessment information from NHs to evaluate aspects of NH care and compare one NH to another.<sup>11</sup>

#### Approaches to Studying NH Safety

The literature relevant to NH safety and the challenges with moving forward to improve safety can be, at least partially, categorized by the approaches and data sources used to study safety problems. Early and ongoing research has focused in large part on the use of secondary data analyses, rather than direct intervention evaluation. This secondary analysis typically includes data from across a large number of NHs and largely reflects self-reported data by the indigenous NH staff. The most commonly used and cited data set has been the CMS MDS because the MDS is intended to assess comprehensively multiple aspects of a resident’s

functional status based on NH staff self-report and must be completed for all residents routinely. In many studies, MDS data are compared to other publicly-available data such as: NH self-reported staffing levels (licensed nurses and nurse aides), deficiencies or citations for quality problems issued by state or federal surveyors, and/or claims data to reflect health care utilization. Use of these data has revealed key NH structural factors (e.g., staffing levels, for-profit status) to be significantly correlated with many safety outcomes including, but not limited to, pressure ulcers, falls and high health care utilization.<sup>12, 13</sup> However, a major limitation to this approach is that it is difficult to identify specific care processes that may provide a causal link or explanation for the relationship of structural factors and outcomes, though approaches to drawing inferences from such data have included interrupted time series, difference-in-differences analyses, and instrumental variable approaches. Moreover, serious deficiencies in the accuracy of NH self-reported outcome and process data have been identified by a number of researchers.<sup>14</sup>

The second category of studies comprises prospective, uncontrolled evaluations of safety interventions. Examples include efforts to provide incentives for NH to improve care quality, to NH staff training efforts to improve care processes and prevent safety problems, and other staff training approaches to improve both NH care processes and outcomes in the areas of unintentional weight loss, urinary incontinence, and hospital readmissions.<sup>15-17</sup> Studies using this second approach suffer several limitations including lack of long-term data and small sample sizes. Furthermore, the concern about inaccuracies in self-reported data remains as most outcomes are collected via report by the NH.

Finally, the third category, interventions conducted in randomized controlled trials (RCTs), is the gold standard for intervention evaluations. These studies typically use dedicated research staff to implement specific, standardized protocols to improve care and independently measure both care process implementation and clinical outcomes, again using specific standardized protocols. Studies may also be conducted with NH staff, and randomization may occur at the patient or unit or facility level (cluster RCT). These studies document safety outcomes that are achievable under ideal implementation conditions (e.g., consistent, optimal care) and, hence, can serve as an important standard for what may be possible to achieve under usual care conditions, given a frail population. RCTs in the nursing home setting have examined interventions including staff training and multicomponent interventions for applying dressings and positioning for pressure ulcers,<sup>18-24</sup> exercise and other modalities for falls prevention,<sup>8, 25-33</sup> and mealtime and feeding approaches to promote adequate intake.<sup>5, 34, 35</sup> Findings from RCTs, which generally include highly selected participants, may have limited applicability to the larger population of individuals in nursing homes. RCTs may also be limited in their ability to inform our understanding of which interventions may work in which participants, and which components of multifaceted interventions are responsible for effects.

### **Hospital Safety Interventions Potentially Relevant to NH**

Hospitals serve many patients who are at risk for the same safety problems as residents of NHs. Thus, the outcomes targeted for prevention are often the same: falls, pressure ulcers, delirium and adverse drug events all have been the subject of hospital quality improvement efforts and each of these conditions are also prevalent in the NH population. Engineering methods to reduce errors and accidents previously developed and refined in other high-consequence industries including commercial and military aviation have been applied in hospital care.<sup>36, 37</sup> Hospital safety practices of obvious relevance to non-acute settings include the literature about fall and pressure ulcer prevention noted above as well as studies identifying

cultural and staffing factors influencing safety (e.g., staffing levels, work hours/burnout).<sup>3, 38-40</sup> Thus, an important consideration is also whether hospital-based interventions may also be applicable in the nursing home setting. Differences in setting (acute vs. long-term care), staffing, resources, including health information technology, and other factors may limit applicability of hospital-based interventions to the NH setting. Guiding Question (GQ) 1c will address literature related to relevant hospital safety practices and their potential applicability to the NH setting.

## Scope and Format

As noted above, methods used to assess patient safety have ranged from database analyses to comparative studies without controls and finally include more than 100 RCTs. An overview of the existing literature and an assessment of gaps in systematic reviews and primary research will help to inform ongoing and future research in this area.

To that end, this technical brief will focus on the following patient safety outcomes in the nursing home environment (Table 1). We selected these criteria as they represent the four AHRQ Common Formats elements for reporting NH safety events as well as the 14 Quality Indicators specified in the CMS Nursing Home Compare dataset. These outcomes broadly represent key NH safety issues and encompass multiple related issues.

**Table 1. Patient safety outcomes to be addressed in technical brief**

Safety Outcome Area	Source of Outcome Area	Sample Potential Interventions
Falls	Common Format/ Nursing Home Compare QI	Exercise, environmental modification, staffing level changes, vitamin D supplementation, systems-level culture change
Pressure ulcers	Common Format/ Nursing Home Compare QI	Positioning, environmental modifications (beds, cushions, etc.), dressings, cleansing agents, nutritional support
Infection, including healthcare-associated infection (HAI) and urinary tract infection	Common Format/ Nursing Home Compare QI	Cleansing agents, staff education and training, infection controls (hand washing, vaccines, etc.)
Medication error and adverse drug events	Common Format/ Nursing Home Compare QI	Medication management, staff education and training, health information technology
Excessive weight loss	Nursing Home Compare QI	Diet (high protein, etc.), environmental changes, enteral feeding
Help with Activities of Daily Living	Nursing Home Compare QI	Mobility
Fecal/Urinary Incontinence		Physical training, toileting skills
Depressive symptoms	Nursing Home Compare QI	Psychosocial interventions, medication, environmental changes, exercise/activity programs
Overuse or inappropriate use of antipsychotic medication	Nursing Home Compare QI	Medication management, staff education and training
Moderate to severe pain	Nursing Home Compare QI	Staffing changes, staff education, medication management
Influenza Vaccine	Nursing Home Compare QI	Immunization programs, infection control
Pneumococcal Vaccine	Nursing Home Compare QI	Immunization programs, infection control
Physical Restraints	Nursing Home Compare QI	Staff education and training
Catheter Left in Bladder	Nursing Home Compare QI	Cleansing solutions, Hygiene, Staff training

We will not limit the technical brief to specific interventions, but will identify empirical literature assessing any interventions to reduce the patient safety events noted above.

## Issues and Challenges in the Evidence Base

The evidence base for NH safety interventions is not insubstantial, with more than 100 RCTs anticipated across the span of patient safety issues. We will focus the description of the evidence

base in this Technical Brief (GQ3) on RCTs and prospective cohort studies that report on direct NH safety interventions (including system-level interventions) targeting any of the outcome areas outlined in Table 1. As the focus of the brief is on understanding the state of the intervention literature, we will not include secondary data analyses to address this GQ.

Challenges exist in the intervention literature on several planes. Characterization of the participant population may be inadequate, for example, mixing short- and long-term populations, who have different risk profiles but live within the same facility and are served by the same staff. Outcomes are frequently self-reported and may lack both validity and reliability. Interventions themselves may be inadequately described such that replication would be impossible. Many interventions have multiple components, with varied levels of description of how the components are intended to work, either individually or in concert. In documenting what evidence is available, what form it takes, what outcomes are studied and whether they are valid, this technical brief can inform our understanding of the evolution of work in the area, future research, and policy questions related to the care of this growing population.

## II. Guiding Questions (GQs)

The following GQs will provide the structure for this technical brief.

### **Guiding Question 1: Describe the Intervention for Patient Safety Practices in Nursing Home Settings**

- GQ1a. What are the patient safety issues of particular concern in the nursing home setting and how are they best measured?
- GQ1b. Are there important differences in patient safety issues for short-stay versus long-stay residents?
- GQ1c. Are there specific patient safety interventions that have improved patient safety in the hospital setting that could transfer to the nursing home setting, but have yet to be tested as such?

### **Guiding Question 2: Describe the Context in which the Intervention Is Used for Patient Safety Practices in Nursing Home Settings**

- GQ2a. What characteristics and qualities of nursing homes and nursing home residents create unique settings for assessing patient safety and may affect choice of intervention and success rates? Considerations include:
  - a. Staffing – type, education, numbers, turnover
  - b. For-profit versus not-for-profit
  - c. Bed size
  - d. Small versus large institutions
  - e. Particular vulnerability of the residents
  - f. Resident mix, including short and long stay

### **Guiding Question 3: Describe the Current Evidence of the Intervention for Patient Safety Practices in Nursing Home Settings**

- GQ3a. What is the state of the current research based on the following criteria:
  - a. Indication/patient inclusion criteria
  - b. Type of intervention
  - c. Study design/size
  - d. Comparator

- e. Length of follow up
- g. Outcomes
- h. Sources of outcome data (i.e., facility self-report versus resident/family self-report versus objective, independent assessments)

#### **Guiding Question 4: Identify the Important Issues raised by the Intervention for Patient Safety Practices in Nursing Home Settings**

GQ4a. What is the uptake of evidence-based nursing home interventions beyond individual test sites? What are the most important barriers to / facilitators to uptake of successful interventions?

GQ4b: What major areas for future research remain regarding patient safety in nursing homes?

GQ4c: In what ways is the field of long-term care changing such that patient safety interventions may need to adapt to a new environment, and what additional challenges do these changing conditions bring to increasing long-term care patient safety?

Examples include: expansion of and increasing acuity in the assisted living environment, increasing acuity of nursing home population, addition of palliative/hospice care resources, increasing need to address adverse drug events and polypharmacy, behavioral health needs of residents including dementia care and substance abuse, complex conditions including multiple comorbidities in nursing home residents, and growing number of HIV patients in long-term care.

### **III. Methods**

#### **Data Collection**

##### **A. Discussions with Key Informants**

Key Informants in technical briefs provide critical insights into currently available research, unanswered questions, current practice, and the degree to which research and practice are aligned. We will engage stakeholders with multiple perspectives, including experts in safety research, nursing home research and individuals representing the policy perspective.

The key informants for this technical brief reflect key areas related to NH safety, including medical and nursing care, care for specialized populations such as individuals with dementia, quality improvement, design of care, and consumer/patient advocacy. Stakeholders also include representatives from relevant federal agencies including the Centers for Medicare and Medicaid Services, the Department of Health and Human Services Administration on Aging, and AHRQ's Center for Delivery, Organization, and Markets. As we complete stakeholder calls, we will assess the need to include additional relevant federal representatives to supplement the input we receive and address any gaps. We will consult with the TOO in identifying gaps and additional federal stakeholders.

Following approval by AHRQ of the completed Disclosure of Interest forms from Key Informants, we will schedule one-hour conference calls with up to nine Key Informants to hold conversations based on the GQs. Because the literature may not be optimally indexed on this subject, the Key Informants will also help to ensure that the search results capture the research landscape. We will record and transcribe the call discussion and distribute a call summary to call participants. Discussions with Key Informants may be used to refine the GQs and will inform the responses to all of the GQs.

## B. Grey Literature search

Technical briefs combine contextual information from Key Informants with targeted searches of the grey literature and the published literature. We will search for model programs and example approaches in relevant government websites, clinical trial databases, trade publications, and meeting abstracts from major conferences in geriatric/long-term care. The grey literature may be particularly useful for determining the degree of uptake of evidence-based practices in nursing homes. We anticipate that we will use grey literature sources to address GQs 1, 2, and 4 in particular. We do not anticipate identifying substantial reports of direct NH safety interventions (GQ 3) in the grey literature. We will include any grey literature reports of evaluations of interventions in our tabulation of new research.

## C. Published Literature search

A large number of systematic reviews have been published in this area. Therefore, we will begin by identifying rigorously conducted (low risk of bias) systematic reviews relevant to addressing the safety outcomes listed in Table 1. A single review by expert reviewers who have had a training session to promote consistency/shared understanding of the tool will assess each of the identified reviews for applicability and rigor, using the newly published ROBIS tool.<sup>41</sup> We will have all reviewers complete scoring of the same set of test reviews in order to compare ratings and discuss any areas of discrepancy. Existing reviews will be captured in tabular format to describe: population, definition of outcomes, inclusion criteria for interventions, number of RCTs, prospective cohort studies, and pre-post studies included, overall assessment of the literature, and ROBIS score.

The ROBIS tool is designed to assess relevance, potential for bias in the study eligibility criteria, identification and selection of studies, data collection and study appraisal, and synthesis and findings. Table 2 outlines criteria for determining the overall risk of bias of a review, based on these domains.

**Table 2. Risk of bias introduced by methods used to identify and/or select studies in systematic review<sup>41</sup>**

Low risk of bias	The findings of the review are likely to be reliable. Assessment of the fundamental domains of a systematic review did not raise any concerns with the review process or concerns were appropriately considered in the review conclusions. The conclusions were supported by the evidence and included consideration of the relevance of included studies.
High risk of bias	One or more of the concerns raised during the assessment of the fundamental domains of a systematic review was not addressed in the review conclusions, the review conclusions were not supported by the evidence, or the conclusions did not consider the relevance of the included studies to the review question.
Unclear risk of bias	There is insufficient information reported to make a judgement on risk of bias.

In addition to describing the available systematic reviews, we will catalogue the numbers and designs of newer studies that could potentially inform assessment of interventions for each of the patient safety outcomes identified in Table 1.

To search the primary literature for areas not covered by existing reviews and to update the reviews we do include, we will use indexing terms and keywords. An experienced library scientist who is familiar with all aspects of the technical brief protocol will examine the selection of databases and all search strategies. We will search at minimum MEDLINE, the Cochrane Database, and the Cumulative Index of Nursing and Allied Health Literature (CINAHL) and will investigate supplementing with other subject-specific resources as needed.

The search will be updated while the draft report is being reviewed to identify newly published relevant information. We will incorporate the results from the literature update into the technical brief prior to submission of the final report.

#### D. Inclusion and Exclusion

For GQ 1, 2, and 4 we will conduct targeted literature searches to address the questions posed and will integrate information from our Key Informants; we will use systematic reviews, narrative reviews, meta-analyses, and primary and secondary research studies to address these questions.

For GQ3, we will identify existing systematic reviews as noted above and supplement the studies presented in each selected review with a tabulation of new prospective comparative studies published since the review. We will use criteria outlined in Table 3 to screen the full text of the search results for inclusion for GQ3. We will develop a simple categorization scheme for coding the reasons for exclusion from the report (GQ3). We will use EndNote® to record and track the disposition of references. We will focus on mapping existing evidence for safety outcomes and identifying gaps.

**Table 3. Inclusion and Exclusion Criteria for Evaluation Studies of NH Safety Interventions**

Category	Criteria
Study population	Patients in nursing home facilities (short stay and long stay)
Publication languages	English only
Timeframe	2005 to the present
Admissible evidence	<p><b>Study design</b> Systematic Reviews, Meta-analyses, Randomized controlled trials, Prospective intervention studies, including cohorts with comparison groups and pre-post studies</p> <p><b>Outcomes</b> Falls Pressure ulcers Infection, including hospital acquired infection (HAI) and Urinary tract infection Medication error and adverse drug events Excessive weight loss Help with Activities of Daily Living Fecal/Urinary Incontinence Depressive symptoms Overuse or inappropriate use of antipsychotic medication Moderate to severe pain Influenza Vaccine Pneumococcal Vaccine Physical Restraints Catheter Left in Bladder</p>

### Data Organization and Presentation

#### A. Information Management

Key informant interviews will be transcribed, reviewed for themes and woven into the text of the technical brief. Our approach is to compile the literature-based information for each GQ, then to review the degree to which key informant data can add to, support, refute, or supplement that information.

The data from the published literature will be extracted into data collection forms, presented in an evidence map in the report and summarized. Data will be extracted by staff scientists and

verified by investigators on the team. For data collection, we will collect the following information for systematic reviews determined to be applicable:

- Focus of the review
- Search dates
- Inclusion criteria (including population and setting where available)
- Numbers of studies by study type included
- Overall conclusions
- Quality assessment

## **B. Data Presentation**

We will qualitatively summarize the Key Informant interviews and compile information extracted from the published and grey literature search results into a cohesive report. Tables necessary for the report are not yet specified, as the available data will determine them to some degree. At a minimum, we expect to have overview tables of the available systematic reviews included, as well as tables of the additional primary data to supplement the reviews.



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## **V. Definition of Terms**

N/A

## **VI. Summary of Protocol Amendments**

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

## **VII. Key Informants**

Within the Technical Brief process, Key Informants serve as a resource to offer insight into the clinical context of the technology/intervention, how it works, how it is currently used or might be used, and which features may be important from a patient or policy standpoint. They may include clinical experts, patients, manufacturers, researchers, payers, or other perspectives, depending on the technology/intervention in question. Differing viewpoints are expected, and all statements are crosschecked against available literature and statements from other Key Informants. Information gained from Key Informant interviews is identified as such in the report. Key Informants do not do analysis of any kind nor contribute to the writing of the report and have not reviewed the report, except as given the opportunity to do so through the public review mechanism.

Key Informants must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Key Informants and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

## **VIII. Peer Reviewers**

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodologic expertise. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than \$10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

## **IX. EPC Team Disclosures**

EPC core team members must disclose any financial conflicts of interest greater than \$1,000 and any other relevant business or professional conflicts of interest. Related financial conflicts of interest that cumulatively total greater than \$1,000 will usually disqualify EPC core team investigators.

## **X. Role of the Funder**

This project was funded under Contract No. 290-2015-00003I from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The Task Order Officer reviewed contract deliverables for adherence to contract requirements and quality. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.