# Evidence-based Practice Center Technical Brief Protocol

## Project Title: *Environmental, Clinical and Economic Outcomes of Hospital Resources to Prevent Hospital-Acquired Infections*

# I. Background and Objectives for the Technical Brief

Hospitals have long prioritized infection prevention while also aiming to limit operational expenses. More recently, environmental responsibility has emerged as an important value in healthcare.[1,2] Balancing these often-competing interests of patient safety, cost minimization, and sustainability is a substantial challenge. One key issue at the nexus of these concerns is the choice hospitals routinely face between medical devices and patient care items that are approved as reusable or are authorized for single-use reprocessing (i.e., a validated process for cleaning, disinfecting, and/or sterilizing a given device or item before reuse), and products that are discarded after one use. While devices and items used only once are often promoted as a means to reduce the risk of hospital-acquired infections (HAI), they may increase hospital costs and lead to greater environmental impact.[3] Conversely, reprocessed devices and items may be environmentally friendlier but incur direct and indirect costs associated with reprocessing, and potentially increase patient exposure to infectious pathogens.[4-6]

The Agency for Healthcare Research and Quality (AHRQ) is interested in the state of the science in respect to these issues, and determined that a review of the evidence would inform programmatic planning. However, the evidence is broadly dispersed across research on infection prevention, device utilization, and environmental impact, and studies rarely focus simultaneously on clinical, economic, and environmental outcomes, which makes it difficult to synthesize findings. Additionally, the published literature consists primarily of non-randomized studies, life cycle assessments, modeling studies, and case reports, yielding results that cannot easily be compared. Moreover, many single-use products and reprocessing procedures have been developed relatively recently, and research is still emerging. Given these challenges, a traditional systematic review with meta-analyses and strength of evidence ratings might not be a feasible or appropriate approach to evaluating the evidence. Therefore, we will develop a Technical Brief that aims to summarize the current landscape of evidence and identify key knowledge gaps, to inform and facilitate future research and programming.

For devices and items that are used more than once, we will include products that are approved as reusable by the U.S. Food and Drug Administration (FDA), as well as those designated as single-use which are authorized for reprocessing. These products will be compared with single-use devices and items that are discarded after one use. Our primary focus will be on 1) devices and items whose inherent purpose is infection prevention and 2) devices and items commonly used in bedside care. Our secondary interest will be on surgical devices, scopes, and other products that are available to hospitals in both reprocessed and disposable form.

# II. Guiding Questions

GQ 1. What healthcare research examines the health, economic, and environmental outcomes of reprocessed reusable devices and items or reprocessed single-use devices and items compared with non-reprocessed single-use devices and items in hospital settings?

GQ 2. What are key evidence gaps and opportunities for future research?

# III. Methods

## 1. Data Collection:

### A. Discussions with Key Informants

We interviewed 10 Key Informants (KIs), including representatives of federal agencies, with expertise in one or more of the following areas: hospital-acquired infections, infection prevention, healthcare sustainability, environmental engineering, environmental impact research, device manufacturing and reprocessing, health system leadership, health system costs associated with infection prevention and/or sustainability, and healthcare worker safety. KIs were queried about the types of items and devices to include and how to categorize and prioritize them, the settings to include, the health, economic, and environmental outcomes that are most relevant, databases and other resources that may provide helpful data, contextual issues (e.g., operations, implementation, regulation), and the research landscape.

KI input informed GQ 1 and 2, and was also used to refine the systematic literature search, identify grey literature resources, provide information about ongoing research, confirm evidence limitations, and recommend approaches to help fill these gaps.

### B. Gray Literature Search

Gray literature sources and retrieval may include the Agency for Healthcare Research and Quality (AHRQ), Canada's Drug and Health Technology Agency (CADTH), the Center for the Evaluation of Value and Risk in Health (CEVR), the Centers for Disease Control and Prevention (CDC), Google Scholar, Health Systems Evidence database (McMaster University), International Network of Agencies for Health Technology Assessment, National Academy of Medicine, OPENGREY.EU, Practice Greenhealth, Prospero (for similar registered trials), and the FDA.

### C. Published Literature Search

Published literature will be used to answer GQ 1. Literature searches will be performed by a Senior Medical Research Librarian and will follow established systematic review protocols. We will search the following databases using controlled vocabulary and text words: Embase (including the MEDLINE database), PubMed (unprocessed records only), CINAHL, Cochrane Library, Agricultural and Environmental Science Collection, Healthcare LCA, Compendex, and Econlit. Searches will cover the literature published since January 1, 2010. Search dates may be adjusted based on the quantity and quality of the available literature. Appendix 1 presents a sample search strategy.

Literature screening will be performed using the database Distiller SR (Evidence Partners, Ottawa, Canada). Abstracts will initially be screened for potential inclusion by one or two screeners, and two screeners will be required for exclusion. Studies that could meet inclusion criteria will be retrieved in full and screened in duplicate. All disagreements will be resolved by consensus discussion among the two full-text screeners. The literature searches will be updated during public comment, before finalization of the review.

## D. Inclusion of Published Literature

Table 2 summarizes the criteria for including and excluding studies based on the Population, Interventions, Comparators, Outcomes, Timing, and Setting (PICOTS) framework.

**Table 1. Inclusion and Exclusion Criteria**

| Category | Inclusion Criteria | Exclusion Criteria |
|---|---|---|
| **Population** | Primary: Individuals receiving acute medical care<br>Secondary: Healthcare workers using or caring for devices used in patient care | Individuals receiving ambulatory care |
| **Interventions** | Primary interest: Devices/items that are intended to prevent infection or are used for general bedside care, including but not limited to PPE, drapes, linens, laryngoscopes, blood pressure cuffs, pulse oximeters<br>Secondary interest: Other devices/items used during hospital care, including but not limited to: surgical devices, other scopes<br>Regulatory status: All devices/items must be either<br>• FDA approved as reusable, and reprocessed per specifications<br>OR<br>• Designated as single-use, FDA authorized for reprocessing, and reprocessed per specifications | Devices/items with minimal or no pathogen transmission risk<br>Devices/items primarily used in an ambulatory or non-acute-care setting<br>Devices/items that have been reprocessed under emergency use authorization only<br>Implantable devices other than catheters |
| **Comparators** | Devices/items that are approved as single-use and are discarded after one use | Single-use devices/items for which no reusable or authorized reprocessed alternatives are available in the US |
| **Outcomes** | <u>Health outcomes</u><br>(Patient-level or aggregated patient data)<br>Outcomes include but are not limited to: HAI, SSI, or pathogen transmission (including MDRO; Sepsis; ICU stay related to HAI; Length of stay; Mortality; Adverse effects; Healthcare worker infection or injury<br><br><u>Economic outcomes</u><br>(Hospital/health system perspective)<br>Outcomes include but are not limited to: Procurement cost; Cost per procedure/use; Costs | Quality of reprocessing<br>Usability by healthcare workers or patients<br>Device/item preferences of healthcare workers or patients<br>Device/item availability<br>Bacterial colonization of device/item |

| Category | Inclusion Criteria | Exclusion Criteria |
|---|---|---|
| | for: reprocessing, transportation, storage, functionality testing, maintenance, repair, disposal, replacement; Supply chain implications<br><br>Environmental outcomes<br>*a. Environmental impact*<br>(Global, national, or regional perspective)<br>Outcomes include but are not limited to: Greenhouse gas emissions; Air pollution; Water use; Water contamination; Energy use; Chemical use and toxicity; Recycling volume; Landfill use; Carcinogenic exposure; Climate change; Raw material extraction and processing<br>*b. Environmental health*<br>(Population health perspective)<br>Outcomes include but are not limited to: Respiratory illness; Cardiovascular disease; Cancer risk; Infectious disease outbreaks | |
| **Timing** | Any | NA |
| **Setting** | Acute care hospitals in countries rated "very high" on the 2021 Human Development Index (as defined by the United Nations Development Programme)* | Non-hospital settings<br>Other countries |
| **Publication type** | English language<br>For primary interest interventions (devices/items used to prevent infections or for general bedside care): SRs, randomized controlled trials, nonrandomized controlled studies<br>For secondary interest interventions (other devices/items used for hospital care): SRs | Non-English-language, abstracts, case reports, non-comparative studies, narrative reviews, commentaries, guidelines |

FDA: Food and Drug Administration; HAI: Healthcare-associated infection; ICU: Intensive care unit; MDRO: Multi-drug resistant organism; NA: Not applicable; PPE: Personal protective equipment; SR: Systematic review; SSI: Surgical site infection; US: United States

*Human development index. United Nations Development Programme. Accessed April 16, 2024. https://hdr.undp.org/data-center/human-development-index#/indicies/HDI

# 2. Data Organization and Presentation:

## A. Information Management

Descriptive characteristics will be abstracted from published SRs and tabled. Data will be abstracted by a single reviewer, with ten percent of studies checked by a second reviewer to ensure accuracy. Factors to be abstracted will include:

- Patient population (age; sex; primary diagnosis; time since diagnosis)
- Specifics of the acute care hospital(s) in the study (urban/rural; academic/non-academic, type of unit, number of beds)

- Item/device characteristics (manufacturers; model names/numbers; number of times reprocessed; risk category: High/Intermediate/Low using the system outlined by MacNeil et al. (2020),[2] which is based on the Spaulding classification;[7] complexity category)
- Health outcomes (as specified in Table 2)
- Economic outcomes (as specified in Table 2)
- Environmental outcomes (as specified in Table 2)

### B. Data Presentation

Abstracted data will be presented in searchable evidence tables. To optimize usability of the findings we will design evidence map(s) that broadly summarize the volume and quality of existing research for each device category, and describe their effects on health, cost, and the environment.

## IV. References


1. Sampath B, Jensen M, Lenoci-Edwards J, et al. Reducing healthcare carbon emissions: A primer on measures and actions for healthcare organizations to mitigate climate change. (Prepared by Institute for Healthcare Improvement under Contract No. 75Q80122P00007.) AHRQ Publication No. 22-M011. Rockville (MD): Agency for Healthcare Research and Quality; 2022 Sep. https://www.ahrq.gov/healthsystemsresearch/decarbonization/index.html. Accessed on February 1, 2024.
2. MacNeill AJ, Hopf H, Khanuja A, et al. Transforming the medical device industry: Road map to a circular economy. Health Aff (Millwood). 2020 Dec;39(Millwood):2088-97. doi: 10.1377/hlthaff.2020.01118. PMID: 33284689.
3. Soto E. Advantages of single-use instruments for infection prevention and control. North Miami (FL): EDM Medical Solutions; 2020 Jun. https://us.edm-imaging.com/blogs/blog/advantages-of-single-use-instruments-for-infection-prevention-and-control. Accessed on Februar 20, 2024.
4. McGrath N, Farragher A, Waldron C, et al. Cost, safety, and environmental impact of reprocessing single-use medical devices: A systematic review and meta-analysis. Dublin (Ireland): Health Research Board; 2023 Sep. https://www.hrb.ie/publications/publication/cost-safety-and-environmental-impact-of-reprocessing-single-use-medical-devices-a-systematic-revi/returnPage/1/
5. Keil M, Viere T, Helms K, Rogowski W. The impact of switching from single-use to reusable healthcare products: A transparency checklist and systematic review of life-cycle assessments. Eur J Public Health. 2023 Feb;33(1):56-63. doi: 10.1093/eurpub/ckac174. PMID: 36433787.
6. Mansur JM. Reuse of single-use devices: Understanding risks and strategies for decision-making for health care organizations. Oakbrook Terrace (IL): Joint Commission International; 2017. http://www.jointcommissioninternational.org/
7. Spaulding EH. Chemical disinfection of medical and surgical materials. In: Lawrence C, Block SS, eds. Disinfection, sterilization, and preservation. Philadelphia, PA: Lea & Febiger; 1968:517-31.


## V. 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.

## VI. 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 of 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 will not review 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 $5,000 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.

## VII. 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 draft report are considered by the EPC in preparation of the final 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 may be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $5,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

## VIII. 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.

## IX. Role of the Funder

This project is funded under Contract No. 75Q80120D00002 from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The AHRQ Task Order Officer will review 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.

# Appendix 1. Sample Search Strategy
# Embase and MEDLINE in Embase.com Syntax

| Line # | Description | Search String |
|---|---|---|
| #1 | Reuse terms | 'instrument sterilization'/mj OR (decontaminat* OR desinfect* OR disinfect* OR recertif* OR 're certif*' OR recycl* OR refurbish* OR remanufact* OR 're manufactut*' OR reprocess* OR 're process' OR resterilis* OR 're sterilis*' OR resteriliz* OR 're steriliz*' OR reusable OR reuse* OR 're use*' OR reusing OR sterilis* OR steriliz*):ti,ab,kw |
| #2 | Single use terms | (disposable OR new OR nonreus* OR 'non reus*' OR 'single use'):ti,ab,kw |
| #3 | Contact precaution devices - controlled terms | 'apron'/de OR 'gown'/de OR 'linen'/de OR 'mask'/exp OR 'protective equipment'/exp OR 'surgical glove'/exp |
| #4 | Contact precaution devices - keywords | (apron OR aprons OR bedding OR cap OR caps OR ((eye OR eyeglass* OR eyewear OR 'eye wear' OR glasses OR ocular OR optic) NEAR/2 (protection OR protective OR protector* OR shield*)) OR facemask* OR glove* OR goggle* OR gown* OR 'hair cover*' OR hat OR hats OR linen* OR mask OR masks OR ppe OR (protect* NEAR/2 (clothing OR equipment* OR device* OR garment* OR product* OR suit OR suits)) OR respirator* OR shield* OR 'shoe cover*' OR splashshield* OR 'splash shield*' OR 'surgical hood*'):ti,ab,kw |
| #5 | Laryngeal scopes, etc | 'laryngeal tube'/de OR 'laryngoscope'/exp OR (((endotrachea* OR laryng* OR trachea*) NEAR/3 (blade* OR scope* OR tube*)) OR laryngoscope*):ti,ab,kw |
| #6 | Blood pressure cuffs | 'blood pressure cuff'/de OR 'sphygmomanometer'/exp OR (cuff OR cuffs OR oximet* OR sphygmomanomet*):ti,ab,kw |
| #7 | Pulse oximeters | 'pulse oximeter'/exp OR oximet*:ti,ab,kw |
| #8 | Additional device terms (of interest to AHRQ) | (((bag OR 'bag valve') NEAR/3 (mask* OR resuscitat* OR ventilator*)) OR 'bronchial telescope*' OR bougie* OR bronchoscope* OR catheter* OR (compression NEAR/3 sleeve*) OR curtain OR curtains OR dialyser* OR dialyzer* OR diatherm* OR drape OR drapes OR duodenoscope* OR ((ecg OR electrocardio*) NEAR/3 (adaptor* OR electrode* OR lead* OR patch* OR wire*)) OR endoscope* OR fiberscope* OR gastroduodenoscope* OR haemodialyzer* OR hemodialyzer* OR haemofilter* OR hemofilter* OR 'hemofiltration filter*' OR ((hover OR transfer) NEAR/3 (mat OR mats OR mattress*)) OR (inhalation* NEAR/3 (adapter* OR adaptor*)) OR inhalator* OR inhaler* OR ((intermittent OR sequential) NEAR/3 (compression OR pneumatic)) OR 'lead wire*' OR leadwire* OR (oxygen NEAR/3 humidifier*) OR (pneumatic NEAR/3 tourniquet*) OR (room* NEAR/3 |

| Line # | Description | Search String |
|---|---|---|
| | | (barrier* OR divider*)) OR ((scalp OR electroencephalograph*) NEAR/3 (cup OR electrode*)) OR (sharp* NEAR/3 contain*) OR scope* OR ((needle* OR syringe*) NEAR/3 (cap OR caps OR tip OR tips)) OR trocar* OR underpad* OR 'under pad*' OR ureteroscope* OR ventilator*):de,ti,ab,kw |
| #9 | Primary interest devices | (#1 AND #2) AND (#3 OR #4 OR #5 OR #6 OR #7 OR #8) |
| #10 | Device terms (general) | 'medical device'/exp OR (device* OR equipment* OR instrument* OR kit OR kits OR unit OR units):ti,ab,kw |
| #11 | Reuse of any item tagged as a medical device | (#1 AND #2) AND #10 |
| #12 | Cost hedge | ((cost OR costs OR economic*):ti,ab OR 'device economics':lnk) |
| #13 | Environmental impacts | 'carbon dioxide'/de OR 'chemical toxicity'/de OR 'climate change'/exp OR 'environmental aspects and related phenomena'/mj OR 'environmental change'/mj OR 'environmental decision making'/mj OR 'environmental economics'/mj OR 'environmental factor'/mj OR 'environmental impact'/exp/mj OR 'environmental impact assessment'/mj OR 'environmental protection'/exp/mj OR 'life cycle assessment'/de OR 'pollution'/exp/mj OR 'greenhouse gas emission'/exp/mj OR 'greenhouse gas'/mj OR 'solid waste management'/exp/mj OR 'waste disposal'/exp OR 'water footprint'/mj OR (burn OR burning OR (chemical NEAR/2 toxicit*) OR (climate NEAR/5 chang*) OR environment* OR footprint OR 'foot print' OR ((garbage OR refuse OR trash OR waste) NEXT/2 (collection OR dispos* OR manag*)) OR ((greenhouse OR 'green house') AND gas*) OR incinerat* OR landfill OR 'land fill' OR 'life cycle assessment*' OR pollut* OR sustainabl*):ti |
| #14 | Systematic Reviews | ('meta analysis'/exp OR 'systematic review'/de OR cochrane:jt OR [cochrane review]/lim OR systematic*:ti OR (cochrane* OR metaanaly* OR 'meta analy*' OR (search* AND (cinahl* OR databases OR ebsco* OR embase* OR psychinfo* OR psycinfo* OR 'science direct*' OR sciencedirect* OR scopus* OR systematic* OR 'web of knowledge*' OR 'web of science')) OR (systematic* NEAR/3 review*)):ti,ab) |
| #15 | RCTs | ('random sample'/de OR 'randomization'/de OR 'randomized controlled trial'/exp OR 'phase 3':ti,ab OR 'phase iii':ti,ab OR random*:ti,ab OR RCT:ti,ab) |
| #16 | Observational/ Cohort Studies/ Non-randomized Controlled Trials | 'controlled clinical trial'/de OR 'cohort analysis'/de OR 'experimental study'/de OR 'observational study'/de OR 'controlled clinical trial*':ti OR (('non randomized' OR nonrandomized) NEXT/1 control*):ti OR ((cohort* OR experimental OR observational) NEAR/2 (stud* OR trial)):ti |

| Line # | Description | Search String |
|---|---|---|
| #17 | Devices of primary interest (SRs, RCTs, Non-randomized controlled studies) | #9 AND (#14 OR #15 OR #16) |
| #18 | Devices of secondary interest - SRs only | #11 AND #14 |
| #19 | Devices of primary interest - economic studies (no study type limitations) | #9 AND #12 |
| #20 | Devices of primary interest - environmental studies (no study type limitations) | #9 AND #13 |
| #21 | Combine result sets | #17 OR #18 OR #19 OR #20 |
| #22 | Exclude undesired study types | #21 NOT ('book'/de OR 'case report'/de OR 'conference paper'/exp OR 'editorial'/de OR 'letter'/de OR (book OR chapter OR conference OR editorial OR letter):it OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR (abstract OR annual OR conference OR congress OR meeting OR proceedings OR sessions OR symposium):nc OR ((book NOT series) OR 'conference proceeding'):pt OR ('case report' OR comment* OR editorial OR letter OR news):ti) |
| #23 | Exclude animal studies | #22 NOT (([animals]/lim NOT [humans]/lim) OR ((animal OR animals OR canine* OR dog OR dogs OR feline OR hamster* OR lamb OR lambs OR mice OR monkey OR monkeys OR mouse OR murine OR pig OR piglet* OR pigs OR porcine OR primate* OR rabbit* OR rat OR rats OR rodent* OR sheep* OR swine OR veterinar* OR (vitro NOT vivo)) NOT (human* OR patient*)):ti) |
| #24 | Limit to English language | #23 AND [english]/lim |
| #25 | Limit to items published 2010-2024 | #24 AND [2010-2024]/py |
| #26 | Studies identified by SMEs | l2000780172 OR l2004551774 OR l2011488391 OR l615631097 OR l639098371 |
| #27 | Combine result sets | #25 OR #26 |