

52.204–10(d)(3) is estimated to average 1 hour per response for a prime contractor. The information on a first-tier subcontract covered by paragraph (d)(3) is reported when the subcontract is awarded and annually thereafter if needed. The aggregate of twelve hours per contractor per year covers the reporting variation that firms may experience.

**Obtaining Copies:** Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing [GSARegSec@gsa.gov](mailto:GSARegSec@gsa.gov). Please cite OMB Control No. 9000–0177, Reporting Executive Compensation and First-tier Subcontract Awards.

**Janet Fry,**

*Director, Federal Acquisition Policy Division,  
Office of Governmentwide Acquisition Policy,  
Office of Acquisition Policy, Office of  
Governmentwide Policy.*

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**BILLING CODE 6820–EP–P**

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Agency for Healthcare Research and  
Quality**

**Supplemental Evidence and Data  
Request on Environmental, Clinical  
and Economic Outcomes of Hospital  
Resources To Prevent Hospital-  
Acquired Infections**

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.

**ACTION:** Request for supplemental evidence and data submission.

**SUMMARY:** The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Environmental, Clinical and Economic Outcomes of Hospital Resources to Prevent Hospital-Acquired Infections*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

**DATES:** *Submission Deadline* on or before September 12, 2024.

**ADDRESSES:**

*Email submissions:* [epc@ahrq.hhs.gov](mailto:epc@ahrq.hhs.gov).

*Print submissions:*

*Mailing Address:* Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

*Shipping Address (FedEx, UPS, etc.):* Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Kelly Carper, Telephone: 301–427–1656 or Email: [epc@ahrq.hhs.gov](mailto:epc@ahrq.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Environmental, Clinical and Economic Outcomes of Hospital Resources to Prevent Hospital-Acquired Infections*. AHRQ is conducting this review pursuant to section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Environmental, Clinical and Economic Outcomes of Hospital Resources to Prevent Hospital-Acquired Infections*. The entire research protocol is available online at: <https://effectivehealthcare.ahrq.gov/products/prevent-hai/protocol>.

This is to notify the public that the EPC Program would find the following information on *Environmental, Clinical and Economic Outcomes of Hospital Resources to Prevent Hospital-Acquired Infections* helpful:

- A list of completed studies that your organization has sponsored for this topic. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov, a summary, including the following elements, if relevant: study number,*

study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

- *A list of ongoing studies that your organization has sponsored for this topic.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including, if relevant, a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this topic and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on topics not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <https://effectivehealthcare.ahrq.gov/email-updates>.

The review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

**Guiding Questions (GQ)**

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?

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING) INCLUSION AND EXCLUSION CRITERIA

Category	Inclusion criteria	Exclusion criteria
Population	<p><i>Primary:</i> Individuals receiving acute medical care</p> <p><i>Secondary:</i> Healthcare workers using or caring for devices used in patient care</p>	Individuals receiving ambulatory care.
Interventions	<p><i>Primary interest:</i> 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.</p> <p><i>Secondary interest:</i> Other devices/items used during hospital care, including but not limited to: surgical devices, other scopes.</p> <p>Regulatory status: All devices/items must be either</p> <ul style="list-style-type: none"> <li>FDA approved as reusable, and reprocessed per specifications.</li> <li>OR</li> <li>Designated as single-use, FDA authorized for reprocessing, and reprocessed per specifications.</li> </ul>	<p>Devices/items with minimal or no pathogen transmission risk.</p> <p>Devices/items primarily used in an ambulatory or non-acute-care setting.</p> <p>Devices/items that have been reprocessed under emergency use authorization only.</p> <p>Implantable devices other than catheters.</p>
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	<p><i>Health outcomes</i> (Patient-level or aggregated patient data)</p> <p>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.</p> <p><i>Economic outcomes</i> (Hospital/health system perspective)</p> <p>Outcomes include but are not limited to: Procurement cost; Cost per procedure/use; Costs for: reprocessing, transportation, storage, functionality testing, maintenance, repair, disposal, replacement; Supply chain implications.</p> <p><i>Environmental outcomes</i></p> <p><i>a. Environmental impact</i> (Global, national, or regional perspective).</p> <p>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.</p> <p><i>b. Environmental health</i> (Population health perspective).</p> <p>Outcomes include but are not limited to: Respiratory illness; Cardiovascular disease; Cancer risk; Infectious disease outbreaks.</p>	<p>Quality of reprocessing.</p> <p>Usability by healthcare workers or patients.</p> <p>Device/item preferences of healthcare workers or patients.</p> <p>Device/item availability.</p> <p>Bacterial colonization of device/item.</p>
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. Other countries.
Publication type	<p>English language</p> <p>For primary interest interventions (devices/items used to prevent infections or for general bedside care): SRs, randomized controlled trials, nonrandomized controlled studies.</p> <p>For secondary interest interventions (other devices/items used for hospital care): SRs.</p>	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>.

**Mamatha Pancholi,**  
 Deputy Director.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Healthcare Research and Quality**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Agency for Healthcare Research and Quality, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the intention of the Agency for Healthcare

Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the extension without change of the currently approved information collection “Surveys on Patient Safety Culture (SOPS) Ambulatory Surgery Center (ASC) Survey Database, (OMB No. 0935-0242).”

**DATES:** Comments on this notice must be received by October 15, 2024.

**ADDRESSES:** Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at [REPORTSCLEARANCEOFFICER@ahrq.hhs.gov](mailto:REPORTSCLEARANCEOFFICER@ahrq.hhs.gov).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden

can be obtained from the AHRQ Reports Clearance Officer.

**FOR FURTHER INFORMATION CONTACT:** Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at [REPORTSCLEARANCEOFFICER@ahrq.hhs.gov](mailto:REPORTSCLEARANCEOFFICER@ahrq.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Proposed Project**

*Surveys on Patient Safety Culture® (SOPS®) Ambulatory Surgery Center (ASC) Survey Database*

In 1999, the Institute of Medicine called for healthcare organizations to develop a “culture of safety” such that their workforce and processes focus on improving the reliability and safety of care for patients (IOM, 1999; *To Err is Human: Building a Safer Health*