

or provide usual care (which could include no access to specific services).

Outcomes for Each Key Question

Key Question 1: Clinical and Economic Outcomes

- Clinical outcomes such as mortality, morbidity, function, recovery, infection, and access to services.
- Economic outcomes such as return on investment, cost, volume of visits, and resource use.

Key Question 2: Intermediate Outcomes

- Patient satisfaction, behavior, and decisions such as completion of treatment, or satisfaction with less travel to access health care.
- Provider satisfaction, behavior, and decisions such as choice of treatment or antibiotic stewardship.

- Time to diagnosis and time to treatment.

- Diagnostic concordance or other measures of agreement between in-person and telehealth consultations.

Key Question 3: Adverse Effects or Unintended Consequences

- Loss of privacy or breach of data security.
- Misdiagnosis or delayed diagnosis.
- Inappropriate treatment.
- Increase in resource costs, negative return on investment.

Key Question 4: Not Applicable (This is a Descriptive Question)

Key Question 5: Clinical and Economic Outcomes (see Key Question 1), Intermediate Outcomes (see Key Question 2), and Adverse Effects or Unintended Consequences (see Key Question 3).

Timing

- Telehealth consultations can be used at any point in the diagnosis, treatment, or management of a patient.
- Outcome measurement needs to occur after the telehealth consultation.

Setting

The consultation can involve providers and patients in any location. These could include inpatient, outpatient, or long-term care, and could be in civilian, Veterans Administration, or military facilities.

Study Designs

- Comparative studies, including trials and observational studies.
- Descriptive studies may be used to inform the decision model as needed

but will not be included in the systematic review.

Sharon B. Arnold,

Acting Director.

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BILLING CODE 4160-90-P

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 proposed information collection project “*Generic Clearance for the Collection of Data Through ACTION III Field-Based Investigations To Improve Health Care Delivery.*” In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on December 20, 2016 and allowed 60 days for public comment. AHRQ did not receive any substantive comments during this period. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by April 24, 2017.

ADDRESSES: Written comments should be submitted to: AHRQ’s OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ’s desk officer) or by email at OIRA_submission@omb.eop.gov (attention: AHRQ’s desk officer).

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov

SUPPLEMENTARY INFORMATION:

Proposed Project

Generic Clearance for the Collection of Data Through ACTION III Field-Based Investigations To Improve Health Care Delivery

The Agency for Healthcare Research and Quality (AHRQ) is requesting OMB approval of a generic clearance for purposes of conducting field-based

research to improve care delivery in diverse health care settings. More specifically, AHRQ seeks this clearance to support timely and meaningful answers to research questions investigated through AHRQ’s ACTION Program. ACTION III research produces field-based, stakeholder-informed knowledge about ways to improve care delivery, and real-world-driven implementation and dissemination of evidence across diverse care settings. A generic clearance to support expedited performance of ACTION III research activities would enable AHRQ to more efficiently meet agency goals while fully meeting the intent and requirements of the Paperwork Reduction Act in a timely manner.

Collection of the information described in this request is essential to supporting AHRQ’s mission, which is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within HHS and with other partners to make sure that the evidence is understood and used. More specifically, in support of this mission, AHRQ initiates and oversees projects with the following overarching aims:

- Expand knowledge about how specific changes to processes or structures of care delivery might improve care quality;
- Develop and test interventions, strategies, tools, trainings and guidance for putting that knowledge into practice;
- Disseminate and implement evidence-based practices across diverse care settings.

Method of Collection

Information collections conducted under this clearance will be collected via the following methods:

- Interviews—Interviews (telephone or in-person) will be conducted with clinical or management staff from diverse health care settings, patients, or other providers or recipients of care with the purposes of expanding knowledge about how specific changes to processes or structures of care delivery might improve care quality; obtaining stakeholder-informed input about how and why an intervention or strategy will or won’t work in a particular real world setting; identifying contextual factors that facilitate or impede implementation of complex system interventions or evidence-based practices; and identifying needs and challenges of intended users of tools and/or beneficiaries of trainings and other resources.
- Small discussion groups/focus groups—Small discussion groups/Focus

groups will be conducted with providers or recipients of care from diverse health care settings with the purposes of obtaining stakeholder-informed input about how and why an intervention or strategy is or is not working in a particular real world setting and identifying needs and gaining user/beneficiary feedback on value and limitations of prototype redesigned care processes, tools, resources or trainings.

- Implementation Logs will be used to track activities, time and resource use associated with use of tools, trainings or other resources and to monitor progress and identify needed revisions to implementation methods.
- Recruitment and Screening Calls will be used to identify and enroll individuals, groups, or organizations willing to participate in the broader research study.
- Questionnaires or brief surveys will be used to capture broad, high level staff or patient level feedback on experience with tools, redesigned care processes, trainings or other resources.
- Cognitive Testing of surveys, Web sites, or other resources will be used to support the development of materials

that resonate and can be understood by intended users.

- Collection of published and internal documents, performance assessments, and other data or information that could provide important contextual information about the specific settings of care into which new tools, resources, training or redesigned care processes will be introduced.

AHRQ will use the proposed generic clearance to obtain field-based, stakeholder-informed input and feedback about how and why interventions or strategies designed to improve care quality (*i.e.*, safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity) do or do not work in the real world. Information collected under this clearance would be expected to increase understanding of how contextual factors and other key variables might affect the implementation and effectiveness of specific strategies, interventions or tools when utilized in particular settings. This knowledge would help health care providers and other decision-makers consider whether, when and how to use and adapt such strategies, interventions

or tools to conform to their own needs and to the distinctive characteristics of the intended settings. Additionally, information collected under this clearance would be expected to increase AHRQ’s understanding of contextual variables and other factors that facilitate or impede dissemination and implementation of clinical guidelines, evidence-based practices, and other research-based findings from the Patient-Centered Outcomes Research Institute (PCORI), National Institutes of Health (NIH), and other partners.

Estimated Annual Respondent Burden

As described above a variety of instruments and platforms will be used to collect information from respondents, though few, if any, single projects would be expected to use all the methods listed.

The average number annual burden hours per year requested (2,189.5) are presented in Table 1 below, and is based on an assumed average of 5 projects per year (we rounded up the past average of 4.5 projects per year to 5). The maximum total burden across all three years is thus 6,568.5 hours.

TABLE 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection type	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Interviews	375	2	1	750
Focus Groups/Small Discussions	420	1.5	1.5	945
Implementation Logs	20	8	1	160
Recruitment and Screening	139	1	0.5	69.5
Cognitive Testing	40	1	1	40
Questionnaires/Brief Surveys	1000	1	0.2	200
Collection of Internal Documents	25	1	1	25
Total				2189.5

TABLE 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Interviews	250	500	^a \$95.05	\$47,525.00
(Clinicians—line 1; Patients—line 2)	125	250	^b 27.12	6,780.00
Focus Groups/Small Discussions	420	945	^c 27.12	25,628.40
Implementation Logs	20	160	^c 27.12	4,339.20
Recruitment and Screening	139	69.5	^a 95.05	6,605.98
Cognitive Testing	40	40	^c 27.12	1,084.80
Questionnaires/Brief Surveys	1000	200	^c 27.12	5,424.00
Collection of Internal Documents	25	25	^a 95.05	2,376.25
Total				99,763.63

* National Compensation Survey: Occupational wages in the United States May 2015 “U.S. Department of Labor, Bureau of Labor Statistics”: http://www.bls.gov/oes/current/oes_stru.htm.

^a Based on the mean wages for 29–1069 Physicians and Surgeons, All Other.

^b Based on the mean wages for 00–0000 All Occupations.

^c Based on the mean wages for 29–9099 Miscellaneous Health Practitioners and Technical Workers: Healthcare Practitioners and Technical Workers, All Other.

Using average wage rates for relevant job categories from 2016 BLS data, the total annual costs associated with these data collections per year are \$116,746.13 as shown in Table 2 above, for a total cost for all three years of \$350,238.39.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,

Acting Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC-2017-0024, NIOSH-297]

Effect of Stockpiling Conditions on the Performance of Medical N95 Respirators and High-Level Protective Surgical Gowns

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention announces the request for information about facilities

that stockpile N95 respirators and high-level protective surgical gowns.

DATES: Electronic or written submissions must be received by [30 days from FRN posting].

ADDRESSES: You may submit responses, identified by CDC-2017-0024 and docket number NIOSH-297, by any of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, Ohio 45226-1998.

Instructions: All information received in response to this notice must include the agency name and docket number [CDC-2017-0024; NIOSH-297]. All relevant responses received will be posted without change to www.regulations.gov, including any personal information provided. For access to the docket to read background documents or information received, go to www.regulations.gov. All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226-1998.

FOR FURTHER INFORMATION CONTACT: Kerri Wizner, NIOSH, National Personal Protective Technology Laboratory, Research Branch, 626 Cochran Mill Road, Building 19A, Pittsburgh, PA 15236, (412) 386-5225, (not a toll free number).

SUPPLEMENTARY INFORMATION: NIOSH seeks information about personal protective equipment (PPE) environmental storage conditions and inventory for federal, state, municipal, county, and hospital system stockpiles. Maintaining PPE stockpiles for public health emergencies is a significant cost and time investment for these various entities, which may include purchasing new products, maintaining inventory records, and lease or purchase of environmentally controlled storage space away from contaminated areas, dust, sun light, extreme temperatures, excessive moisture, and damaging chemicals. The information provided by respondents to this Notice will be used to inform a research study design where N95 respirators and high-protection level surgical gowns are sampled from stockpiles and tested against established performance standards. The research study will be designed to obtain scientific data to assess (1) the potential to extend manufacturer-recommended shelf life and (2) the effect of common, albeit sometimes non-ideal, stockpile conditions on the protections provided

by respirators and surgical gowns. NIOSH seeks to sample N95 respirators and high-protection level surgical gowns from a variety of stockpiles representing contemporary storage conditions from across the nation. To that end, the information sought in this Notice is aimed at ensuring that study findings are broadly applicable to U.S. stockpiles.

Background: Various entities stockpile personal protective equipment (PPE) in preparation for public health responses to outbreaks of high consequence infectious diseases such as SARS, influenza, and Ebola, where PPE demand may outpace supply. Stockpiling PPE is a costly endeavor that includes PPE purchase, storage space, product rotation over time, and environmental controls for heat, humidity, dust, and sunlight. Resource limitations may lead facilities to stockpile PPE in environments that do not meet manufacturer storage recommendations or exceed shelf life, increasing the potential for PPE degradation. Even when resources exist to store PPE per manufacturer's environmental recommendations, the influence of long-term storage time alone on PPE performance has been questioned. Additionally, large quantities of stockpiled PPE obtained during previous nationwide responses may now be exceeding its shelf life and expected replacement costs will likely far exceed available budgets. Data is needed to better understand the potential impact upon worker health and safety.

Information Needs: Information is needed to assist NIOSH in identifying important factors to focus the research study design. Information is needed from facilities that stockpile N95 respirators and high-level protective surgical gowns for use during public health emergencies. Please ensure the type of stockpile you are affiliated with is included in the responses to any of the below questions.

1. Please describe the type of stockpile with which you are affiliated (e.g., federal, state, county). Please describe the end users of the stockpiled products (e.g., healthcare workers, public).

2. Please describe the extent to which environmental controls are implemented and maintained. For example, does the stockpile employ controls against humidity, temperature, sunlight, dust, or chemical exposure? Please describe how these controls are implemented, monitored, regularity of monitoring, and what optimal conditions are. Available guidance documents used for the stockpile would