Request for Approval under AHRQ's Generic Clearance "Questionnaire and Data Collection Testing, Evaluation, and Research for the AHRQ" (OMB Control Number: 0935-0124)

TITLE OF INFORMATION COLLECTION: Identifying, Assessing, and Balancing Competing Risks of Multiple Hospital-Acquired Conditions (HACs)

PURPOSE:

Section 5001(c) of the Deficit Reduction Act of 2005 requires the Secretary of Health and Human Services to identify hospital acquired conditions (HACs) that: (a) are high cost or high volume or both, (b) result in the assignment of a case to a diagnosis related group (DRG) that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines. The Centers for Medicare and Medicaid Services identified 11 categories of HACs that include hospital acquired pressure ulcers (HAPUs), patient falls during a hospital stay, and catheter associated urinary tract infections (CAUTIs). HACs often result in longer hospital stays and increased health care costs. For example, AHRQ has estimated that on average a CAUTI increases hospitalization costs by $1,000, a fall increases costs by $7,234 and a HAPU increases cost by $17,000.[1]

Although overall rates of HACs are estimated to have decreased by 21% from 2010 to 2015, improvements have plateaued since 2013.[2] In addition, whereas CAUTIs is one of the three HACs with the largest improvement (33% reduction), falls and HAPUs are two of the three HACs with the smallest improvement (15% and 10%, respectively) from 2010 to 2015.[2]

These three HACs – CAUTIs, falls, and HAPUs – are interrelated, nursing-sensitive conditions and interventions to prevent each individual HAC may have potential inter-actions and trade-offs such that an intervention designed to reduce the risk of one HAC (e.g., in-dwelling urinary catheter [IUC] removal to reduce CAUTIs) may increase the risk of others (e.g., falls and/or HAPU through impacts on mobility and skin moisture). As a result, patients at risk for CAUTI, falls, and HAPU are subject to multiple, often conflicting prevention strategies, leaving frontline clinicians with challenging clinical decisions to make to promote overall patient safety. To date, there are no tools that clinicians can use in managing these competing risks in an inpatient setting despite the need for such a tool to improve patient safety and its relevance to health care costs from the perspective of health systems and payers.

This project is an aggregate of three information collection requests to develop a toolkit to meet this need using an iterative participatory toolkit design framework. The data collection activity has the following goals:

1. Engage clinicians and hospital/health system administrators to identify informative and practical ways to communicate information to these users of a tool that takes patient-specific information, calculates predicted values of the likelihood of each HAC based on a clinical decision, and displays these values in a way that communicates competing risks of each HAC; and

2. Pilot test the tool through a series of on-site usability tests of multiple visual display prototypes for two to four patient care delivery scenarios that depict likely outcomes using examples of high risk patients to validate and refine the tool's risk dashboard information and visual designs.

This project is being conducted by AHRQ through its contractor, Board of Regents of the University of Colorado, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2). The information collected will be used solely for toolkit development and does not extend to the collection of data for public release or policy formation.

To achieve these goals, AHRQ's contractor, the Board of Regents of the University of Colorado, will conduct two rounds of focus groups with health care providers and administrators and a series of one-on-one key informant interviews (KIIs) with target audiences of the competing risk HAC dashboard tool being developed.

Focus Groups of Clinicians and Administrators to Develop and Refine HAC Risk Dashboard Tool

Two rounds of focus groups with nurses, physicians, nurse practitioners, physician assistants and nurse managers will be convened to identify informative ways to communicate information on competing risks of multiple HACs to these target audiences through a simple to use competing risk dashboard tool. Focus group topics will cover: contextual work factors related to care delivery for patients with multiple competing risk factors, barriers and facilitators to informational support, the role of technology in patient care, and visual display preferences. The Focus Groups will be held in the Denver, Colorado metro area and using the Focus Group Discussion Guides provided in Attachments A and B. All focus groups will last 60-90 minutes and will be audio-recorded, transcribed and analyzed applying a general inductive framework to identify information needs and visual display preferences that will be used as requirements for the HAC Risk Dashboard Tool.

The first round of focus groups will engage stakeholders that are the target audience for the tool, which includes nurses, physicians, nurse practitioners, physician assistants and nurse managers from medical and surgical units of hospitals, to identify their information needs when providing care for patients with an indwelling urinary catheter (IUC) that are at risk for one or more HACs. Focus group participants will be provided with a series of sketches and digital mockups developed by the University of Colorado project team's clinical experts (Wald, Makic, Stevens). Results from the first round of focus groups will be used to develop a low-fidelity risk dashboard tool that includes rudimentary digital mockups of alternative visual displays and tool interfaces. These low-fidelity examples will be member-checked via e-mail with a subset of participants from the first round of focus groups to ensure their clinical relevance.

The second round of focus groups will a different group of representatives from the same stakeholder participant roles as the first round. The second round participants will also be drawn from the medical and surgical units of the same two hospitals. These focus groups will evaluate the benefits and tradeoffs of the different low fidelity prototypes resulting from the first round of focus groups. The results from the second round of focus groups will inform the development of high-fidelity displays of the identified information needs of the tool's target audience. The resulting high-fidelity visual displays will be incorporated in an Excel-based tool that will be used in the usability tests of the usefulness of this tool.

Key Informant Interviews with Clinicians to Assess Usability:

One-on-one key informant interviews (KIIs) will be conducted with nurses, physicians, nurse practitioners, physician assistants and nurse managers from medical and surgical units to assess the usability of an Excel-based HAC Risk Dashboard tool. Usability test using think-aloud and cognitive walk-through methodologies will engage these targeted users to evaluate perceived ease of use and perceived usefulness of alternative dashboards that include high-fidelity visual displays. The KIIs will occur in four metropolitan areas (Long Beach, CA; New Orleans, LA; Omaha, NE and Galveston, TX) using the Key Informant Interview Guides provided in Attachment C. Usability test KIIs will last for approximately 60 minutes each and be audio-recorded and transcribed verbatim.

Our high-fidelity visual display prototypes will be developed for two to four patient care delivery scenarios that depict likely outcomes using examples of high risk patients. High fidelity prototypes will entail scripted, limited interactivity patient care delivery scenarios and developed in conjunction with our Excel-based tool that calculates patient-specific HAC predictive values under alternative clinical decisions. Usability tests will occur at five hospitals over a two-day period at each hospital and involve six to eight one-on-one test sessions with at least one nurse, one physician, one nurse practitioner or physician assistant, and one nurse manager from medical and surgical units. Usability tests will be audio-recorded and transcribed verbatim.

These findings from these KIIs will be used to make refinements to the information content and visual displays

needed for decision-making around IUC removal related to competing risks of CAUTI, HAPU and falls that clinical providers find acceptable with regard to perceived ease of use and perceived usefulness. These refinements will be incorporated into the Excel-based tool that can be used to implement the HAC Risk Dashboard in actual clinical workflows.

DESCRIPTION OF RESPONDENTS:
Respondents will be a mix of healthcare professionals working in acute care hospitals that have medical and/or surgical units. The participating hospital will identify and recruit the healthcare professionals that work in their medical and surgical units and are nurses, physicians, nurse practitioners, physician assistants and nurse managers that care for patients likely to have an indwelling urinary catheter and at risk for hospital acquired conditions.

Table 1 displays the expected number of respondents from each profession for each round of focus groups and key informant interviews.

Table 1: Expected Number of Respondents for Focus Groups and Key Information Interviews

Respondent Type	Information Needs Identification Focus Groups	Low-Fidelity Prototype Evaluation Focus Groups	Key Informant Interviews
Nurse	8	8	8
Physician	6	6	8
Nurse Practitioner/ Physician Assistant	6	6	8
Nurse Manager	4	4	4

Respondents will be asked to provide demographic information include their age, gender, educational attainment, profession, and number of years working in their profession. Personal identifying information will only be collected for the purpose of paying incentives as described below and will not be associated with any information obtained during the focus group discussions or interview.

TYPE OF COLLECTION: (Check one)

[ ] Customer Comment Card/Complaint Form
[ ] Customer Satisfaction Survey
[x] Usability Testing (e.g., Website or Software
[ ] Small Discussion Group
[x] Focus Group
[ ] Other:_

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: Noel Eldridge

To assist review, please provide answers to the following question:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [x] Yes [ ] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [x] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [ ] No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants?
[x] Yes [ ] No

AHRQ will offer each individual a $50 honoraria to participate in the 90 minute focus groups and a $50 honoraria to participate in the 60 minute key informant interview (n=76 for a total of $3,800). Participants will be specialized healthcare professionals in clinical practice who will be attending the focus group or interview during normal business hours. Our experience in recruiting healthcare professionals for a recent study of catheter-associated urinary tract infections demonstrated the effectiveness of gift cards of this amount as a token of our appreciation for participants' time. A recent meta-analysis of alternative methods of increasing participation of healthcare professionals in these types of studies confirms our experiences.[3] specifically, the results of this meta-analysis indicated that monetary incentives increased participation rates of healthcare professionals by 12 percentage points. The team's experiences and the results of the meta-analysis both support the provision a $50 incentive to participants in the focus groups and key informant interviews will increase the likelihood of recruiting a diverse and cooperative set of respondents and reduce the time of team members needed to recruit participants with the desired clinical background, thus decreasing the overall project cost to the government.

Category of Respondent: *(the options here are Public Sector or Private Sector, or both)*
Both

Respondents will be from the private sector and healthcare professional from large hospitals that will not be small entities.

5. BURDEN HOURS:

Respondents will be identified by the participating hospital for both the focus groups and KIIs. Six focus groups (3 round 1 and 3 round 2) will involve 6 to 8 participants and in estimating burden hours each focus group is assumed to involve 8 participants. Each focus group will last 90 minutes and interviews will be 60 minutes each. Table 2 provides information on the estimated burden hours for the focus groups and interviews. This is a one-time data collection.

Table 2: Estimated Burden Hours

Data Collection Activity	Number of Respondents	Number of Responses per Respondent	Hours per Response	Total Burden Hours
Information Needs Identification Focus Groups	24	1	1.5	36
Low-Fidelity Prototype Evaluation Focus Groups	24	1	1.5	36
Key Informant Interviews	28	1	1	28
Total	76	NA	NA	100

FEDERAL COST: The estimated annual cost to the Federal government is $772 for this one-time data collection.

This includes 15 hours at the GS-13 level to provide project management and oversight to this project. The estimate is based on an annual salary OPM Pay Schedule for Washington/DC area. This task shall occur only once. The salary cost is estimated to be $722 to the Federal Government. The work conducted by AHRQ's contractor, Board of Regents of the University of Colorado, is already accounted. There will be no additional cost to the Federal Government under the contract at this time.

1. **If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:**
2. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?

[ ] Yes [X] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

Respondents will be identified and recruited for participation in the focus groups or KIIs by the participating hospitals. Each hospital will identify respondents from the facility database of healthcare providers who will voluntarily agree to participate in the focus group or interview. This will ensure that selected respondents will represent the target audience for the HAC Risk Dashboard tool being developed.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)

[ ] Web-based or other forms of Social Media

[ ] Telephone

[x] In-person

[ ] Mail

[ ] Other, Explain

2. Will interviewers or facilitators be used? [x] Yes [ ] No

Please make sure that all instruments, instructions, and scripts are submitted with the request.

Attachment A – HAC Risk Dashboard Tool Information Needs Identification Focus Group Guide

Attachment B – HAC Risk Dashboard Tool Low-Fidelity Prototype Evaluation Focus Group Guide

Attachment C – HAC Risk Dashboard Tool Key Informant Interview Guide

References

1. Efforts To Improve Patient Safety Result in 1.3 Million Fewer Patient Harms. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2013.html. Content last reviewed November 2015.

2. National Scorecard on Rates of Hospital-Acquired Conditions 2010 to 2015: Interim Data From National Efforts To Make Health Care Safer. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/professionals/quality-patient-safety/pfp/2015-interim.html. Content last reviewed December 2016.

3. Cho YI, Johnson TP, VanGeest JB. Enhancing surveys of health care professionals: a meta-analysis of techniques to improve response. Eval Health Prof. 2013;324:1183.