

SUPPORTING STATEMENT

Part A

Hospital Survey on Patient Safety Culture Database

January 11, 2019

Agency of Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that make the collection of information necessary

AHRQ's mission. As described in its 1999 reauthorizing legislation, Congress directed the Agency for Healthcare Research and Quality (AHRQ) to enhance the quality, appropriateness, and effectiveness of health services, as well as access to such services, by establishing a broad base of scientific research and promoting clinical and health systems practice improvements.¹ The legislation also directed AHRQ to “conduct and support research, evaluations, and training, support demonstration projects, research networks, and multidisciplinary centers, provide technical assistance, and disseminate information on health care and on systems for the delivery of such care, including activities with respect to health statistics, surveys, database development, and epidemiology.”²

Furthermore, AHRQ shall conduct and support research “to provide objective clinical information to health care practitioners and other providers of health care goods or services; identify the causes of preventable health care errors and patient injury in health care delivery; develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and disseminate such effective strategies throughout the health care industry”.³

Background on the Hospital Survey on Patient Safety Culture (Hospital SOPS). In 1999, the Institute of Medicine called for health care 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 System*). To respond to the need for tools to assess patient safety culture in health care, AHRQ developed and pilot tested the Hospital Survey on Patient Safety Culture with OMB approval (OMB NO. 0935-0115; Approved 2/4/2003).

The survey is designed to enable hospitals to assess provider and staff perspectives about patient safety issues, medical error, and error reporting. The survey includes 42 items that measure 12 composites of patient safety culture. AHRQ made the survey publicly available along with a Survey User's Guide and other toolkit materials in November 2004 on the AHRQ web site⁴.

The Hospital SOPS Database consists of data from the AHRQ Hospital Survey on Patient Safety Culture and may include reportable, non-required supplemental items⁵. Hospitals in the U.S. can voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The Hospital SOPS Database (OMB NO. 0935-0162, last approved on September 30, 2016) was developed by AHRQ in 2006 in response to requests from hospitals interested in tracking their own survey results. Those organizations submitting data receive a feedback report, as well as a report of the aggregated de-identified findings of the other hospitals submitting data. These reports are used to assist hospital staff in their efforts to improve patient safety culture in their organizations.

Rationale for the information collection. The Hospital SOPS and the Hospital SOPS Database support AHRQ's goals of promoting improvements in the quality and safety of health care in hospital settings. The survey, toolkit materials, and database results are all made publicly available on AHRQ's web site. Technical assistance is provided by AHRQ through its contractor at no charge to hospitals, to facilitate the use of these materials for hospital patient safety and quality improvement.

Request for information collection approval. The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) reapprove, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for the AHRQ Hospital Survey on Patient Safety Culture (Hospital SOPS) Database; OMB NO. 0935-0162, last approved on September 30, 2016.

This database will:

- 1) present results from hospitals that voluntarily submit their data,
- 2) provide data to hospitals to facilitate internal assessment and learning in the patient safety improvement process, and
- 3) provide supplemental information to help hospitals identify their strengths and areas with potential for improvement in patient safety culture.

To achieve the goal of this project the following activities and data collections will be implemented:

- 1) **Eligibility and Registration Form** – The hospital point-of-contact (POC) completes a number of data submission steps and forms, beginning with the completion of an online Eligibility and Registration Form (see Attachment A). The purpose of this form is to collect basic demographic information about the hospital and initiate the registration process.
- 2) **Data Use Agreement** – The purpose of the data use agreement, completed by the hospital POC, is to state how data submitted by hospitals will be used and provides privacy assurances (see Attachment B).
- 3) **Hospital Site Information Form** – The purpose of the site information form (see Attachment C), also completed by the hospital POC, is to collect background characteristics of the hospital. This information will be used to analyze data collected with the Hospital SOPS survey.
- 4) **Data Files Submission** – POCs upload their data file(s), using hospital data file specifications (see Attachment E), to ensure that users submit standardized and consistent data in the way variables are named, coded, and formatted. The number of submissions to the database is likely to vary each year because hospitals do not administer the survey and submit data every year. Data submission is typically handled by one POC who is either a patient safety manager in the hospital or a survey vendor who contracts with a hospital to collect and submit their data. POCs submit data on behalf of 3 hospitals, on average, because many hospitals are part of a health system that includes many hospitals, or the POC is a vendor that is submitting data for multiple hospitals.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to: the quality, effectiveness, efficiency, appropriateness and value of healthcare services; quality measurement and improvement; and database development.⁶

2. Purpose and Use of Information

Survey data from the AHRQ Hospital Survey on Patient Safety Culture is used to produce three types of products:

- 1) A Hospital SOPS Database Report that is made publicly available on the AHRQ web site (see [Hospital User Database Report](#))⁷;
- 2) Individual Hospital Survey Feedback Reports that are customized for each hospital that submits data to the database; and
- 3) Research data sets of individual-level and hospital-level de-identified data to enable researchers to conduct analyses. All data released in a data set are de-identified at the individual-level and the hospital-level.

Hospitals will be invited to voluntarily submit their Hospital SOPS survey data to the database. AHRQ's contractor, Westat, then cleans and aggregates the data to produce a PDF-formatted Database Report displaying averages, standard deviations, and percentile scores on the survey's 42 items and 12 composites of patient safety culture. The report also displays these results by hospital characteristics (bed size, teaching status, ownership) and respondent characteristics (hospital work area, staff position, and those with direct interaction with patients). In addition, trend data, showing changes in scores over time, are presented from hospitals that have submitted to the database more than once.

The Database Report includes a section on data limitations, emphasizing that the report does not reflect a representative sampling of the U.S. hospital population. Because participating hospitals will choose to voluntarily submit their data into the database and therefore are not a random or national sample of hospitals, estimates based on this self-selected group might be biased estimates. We recommend that users review the database results with these caveats in mind.

Each hospital that submits its data receives a customized survey feedback report that presents their results alongside the aggregated results from other participating hospitals.

Hospitals use the Hospital SOPS, Database Reports, and Individual Hospital Survey Feedback Reports for a number of purposes, to:

- Raise staff awareness about patient safety;
- Elucidate and assess the current status of patient safety culture in their hospital;
- Identify strengths and areas for improvement in patient safety culture;
- Evaluate trends in patient safety culture change over time;
- Evaluate the cultural impact of patient safety initiatives and interventions.

3. Use of Improved Information Technology

All information collection for the Hospital SOPS Database is done electronically, except the Data Use Agreement (DUA) that hospitals print, sign, and return (either via fax, by scanning and emailing or uploading to a secure web site, or by mailing back). Registration, submission of hospital information, and data upload is handled online through a secure web site. Customized hospital survey feedback reports are delivered electronically (the person submitting the data will enter a username and password for access to a secure web site from which to download their reports).

4. Efforts to Identify Duplication

While survey vendors and hospital systems that administer the AHRQ Hospital Survey on Patient Safety Culture and hospital systems may maintain a database of survey responses for their particular clients (survey vendors) or their individual facility (hospitals), AHRQ is the only entity that serves as a central U.S. repository for data on the Hospital SOPS survey and houses the largest database of the survey's results.

5. Involvement of Small Entities

AHRQ designed the data collection instruments and procedures to minimize burden on individual hospital respondents. The data request of hospitals represents the absolute minimum information required for the intended uses and the data submission process does not unduly burden small hospitals or other businesses.

6. Consequences if Information Collected Less Frequently

Because hospitals administer the survey voluntarily, on their own schedule, most hospitals would only submit their data once every two years (depending on their survey administration schedule), and greater frequency may not be immediately feasible. Less frequent data collection would inhibit timely response to developing interventions designed to enhance patient safety culture. Hospital data submission will be available in June 2020.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d) (2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on March 19, 2019 on Page 10077 for 60 days (see Attachment H). AHRQ did not receive substantive comments.

8.b. Outside Consultations

AHRQ periodically convenes an external Technical Expert Panel (TEP) to provide expertise and guidance to the development, functioning, and expansion of the SOPS Databases. The most recent TEP was comprised of 18 individuals with expertise for each of seven difference settings: hospital, medical office, nursing home, community pharmacy, ambulatory surgery center, international, and U.S. Department of Defense (see Attachment F). With representation from hospital experts, the TEP will provide guidance as needed on the administration of the hospital SOPS database.

9. Payments/Gifts to Respondents

No payment or remuneration is provided to hospitals for submitting data to the database.

10. Assurance of Confidentiality

Individuals and organizations will be assured limitation on use of certain information under Section 944(c) of the Public Health Service Act, 42 USC 299c-3(c). That law requires that

information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied.

Privacy of the Point of Contact for a Hospital. The hospital point-of-contact, who submits data on behalf of a hospital, is asked to provide his/her name, phone number, and email address during the data submission process to ensure that the hospital’s individual survey feedback report is delivered to that person. Such contact information is critical if any clarifications or corrections of the submitted data set are necessary. However, the name of the hospital POC and name of the hospital is kept private and not reported. Only aggregated, de-identified results are displayed in any reports.

Privacy of the Survey Data Submitted by a Hospital. Hospitals are assured of the privacy of their Hospital SOPS survey data responses under the Data Use Agreement (DUA; see Attachment B). All respondents must sign the DUA. Reviewed by HHS’s general counsel, the DUA states that all submitted data will be handled in a secure manner using necessary administrative, technical, and physical safeguards to limit access to it and maintain its privacy. In addition, the DUA outlines that survey response data will be used for the purposes of the database, that only aggregated results will be reported, and that the hospital is not be identified by name.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours for the respondents’ time to participate in the database. An estimated 340 POCs, each representing an average of 3 individual hospitals each, will complete the database submission steps and forms annually. Each POC will submit the following:

- Eligibility and registration form (completion is estimated to take about 3 minutes).
- Data Use Agreement (completion is estimated to take about 3 minutes).
- Hospital Information Form (completion is estimated to take about 5 minutes).
- Survey data submission will take an average of one hour.

The total annual burden hours are estimated to be 459 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be \$26,572 annually.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility/Registration Form	340	1	3/60	17
Data Use Agreement	340	1	3/60	17
Hospital Information Form	340	3	5/60	85
Data Files Submission	340	1	1	340
Total	N/A	N/A	N/A	459

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Eligibility/Registration Form	340	17	\$57.89	\$984
Data Use Agreement	340	17	\$57.89	\$984
Hospital Information Form	340	85	\$57.89	\$4,921
Data Files Submission	340	340	\$57.89	\$19,683
Total	N/A	N/A	N/A	\$26,572

*Mean hourly wage of \$57.89 for Medical and Health Services Managers (SOC code 11-9111) was obtained from the May 2017 National Industry-Specific Occupational Employment and Wage Estimates NAICS 622000 – Hospitals, located at http://www.bls.gov/oes/current/naics3_622000.htm.

13. Estimates of Annualized Respondent Capital and Maintenance Costs

Capital and maintenance costs include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Annualized Cost to the Government

Exhibit 3 shows the estimated annualized cost to the government for developing, maintaining, and managing the database and analyzing the data and producing reports for each year in which data are collected. The cost is estimated to be \$200,000 each data submission year.

Exhibit 3. Estimated Annualized Cost

Cost Component	Annualized Cost
Database Development and Maintenance	\$40,000
Data Submission	\$50,000
Data Analysis & Reports	\$110,000
Total	\$200,000

Exhibit 4: Estimated Annual cost to AHRQ for project oversight

AHRQ Position	% Time	Annualized Cost
GS 15, Step-5	3%	\$4,686
GS-13, Step-5	3%	\$3,272
Total		\$7,958

<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2019/DCB.pdf>

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. Changes in Hour Burden

The estimated hour burden for each respondent participating in the Hospital SOPS database remains the same from the previous information collection request (ICR). However, due to increasing popularity with submission to the database, we are anticipating more respondents potentially participating and thus, estimate a greater overall annualized burden.

16. Time Schedule, Publication and Analysis Plans

Information for the Hospital SOPS database is collected by AHRQ through its contractor, Westat, beginning in 2006. Hospitals are invited voluntarily submit their Hospital SOPS survey data to the database approximately every other year in June. The data are then cleaned and aggregated and used to produce a Database Report that is posted on the AHRQ web site. Hospitals are also automatically provided with their own individual survey feedback report.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

- Attachment A: Hospital Eligibility and Registration Form
- Attachment B: Hospital Data Use Agreement
- Attachment C: Hospital Site Information Form
- Attachment D: Hospital Data Submission Emails
- Attachment E: Hospital Survey Data File Specifications
- Attachment F: SOPS Databases TEP List
- Attachment G: Example Screen Shots of Hospital SOPS Data Submission Web Site
- Attachment H: Federal Register Notice

¹ Healthcare Research and Quality Act of 1999. Available at <https://www.ahrq.gov/policymakers/hrqa99a.html>. Last accessed 12/3/2018.

² See Section 902, (a) (8) of the Healthcare Research and Quality Act of 1999. Available at <https://www.ahrq.gov/policymakers/hrqa99a.html>. Last accessed 12/3/2018.

³ See Section 912, (b) (2) (A) (ii) (I) and (iii) (II) and (c) (1) (2) and (3) of the Healthcare Research and Quality Act of 1999. Available at <http://www.ahrq.gov/policymakers/hrqa99b.html>. Last accessed 12/3/2018.

⁴ Hospital Survey on Patient Safety Culture. Content last reviewed August 2018. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/sops/quality-patient-safety/patientsafetyculture/hospital/index.html> Last accessed 12/3/2018.

⁵ Supplemental Items for the SOPS Hospital Survey. Content last reviewed March 2018. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/sops/quality-patient-safety/patientsafetyculture/hospitalsupplementalitems.html> Last accessed 12/3/2018.

⁶ See 42 U.S.C. 299a(a)(1) (2), and (8). Available at <http://uscode.house.gov/view.xhtml?req=Child+Support&f=treesort&fq=true&num=584>. Last accessed 12/3/2018.

⁷ Hospital User Database Reports. Content last reviewed May 2018. Agency for Healthcare Research and Quality, Rockville, MD. Available at <http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/hosp-reports.html> Last accessed 12/3/2018.