

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.

Dated: March 15, 2011.

Carolyn M. Clancy,
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 proposed information collection project: "Using Nursing Home Antibiotics to Improve Antibiotic Prescribing and 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.

DATES: Comments on this notice must be received by May 24, 2011.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at doris.lefkowitz@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

e-mail at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Using Nursing Home Antibiotics To Improve Antibiotic Prescribing and Delivery

Overuse and inappropriate use of antibiotics, particularly broad-spectrum antibiotics, is recognized as a serious problem in nursing homes (NHs). The adverse consequences of inappropriate prescribing practices including drug reactions/interactions, secondary complications, and the emergence of multi-drug resistant organisms, have become more common. For example, in one point-prevalence survey of 117 NH residents, 43 percent were culture-positive for one or more antimicrobial-resistant pathogens, including methicillin-resistant staphylococcus aureus (24 percent), extended-spectrum β -lactamase-producing klebsiella pneumoniae (18 percent) or Escherichia coli (15 percent), and vancomycin-resistant enterococci. Inappropriate overprescribing and overuse of broad-spectrum antibiotics, when narrower spectrum drugs would suffice, are believed to be important contributors to this problem.

Physicians typically begin antibiotics for suspected infections in NH residents without waiting for bacteriology laboratory culture results. If there is a clinical failure (e.g., patient does not improve), the physician may request a bacteriology laboratory test, but will often try a second antibiotic without waiting for culture confirmation. If a NH resident is deteriorating, many NHs do not try a second antibiotic but will instead transfer the patient to a hospital emergency department (ED). In the ED, physicians must make quick decisions about whether to continue the first antibiotic prescribed in the NH or start another, again often without culture results.

NH patients are transferred to EDs for all sorts of medical reasons, including but not limited to infections. When NH patients arrive at an ED, physicians may identify a urinary tract, respiratory, or other infection that was not the primary reason for the ED visit. Thus, patients may not leave the NH with a suspected bacterial infection or taking any antibiotics, but an infection is suspected in the ED and the first antibiotic is prescribed there.

As a result of the above complexities, NHs are increasingly recognized as reservoirs of antibiotic-resistant bacteria. Antibiotics aggregate information for an entire institution

over a period of several months or a year. They display the organisms present in clinical specimens sent for laboratory testing, and the susceptibility of each organisms to an array of antibiotics. Antibiotics are routinely prepared by hospital laboratories but are not routine in the NH setting. The culmination of this project will be a NH Antibiotic toolkit so that NHs can create facility-specific antibiotics that are cost-effective and helpful to physicians who must make antibiotic prescription decisions without bacteriology laboratory test results, for patients in NHs, and for patients who are transferred from the NH to the ED. Outcomes of interest for antibiotics include reduced reliance on broad-spectrum antibiotics as initial therapy, and fewer clinical failures of antibiotics that are first prescribed. The development of a toolkit will be the first step in this process; future studies are required to test the toolkit and, subsequently, the effectiveness of NH antibiotics.

The objectives of the study are to:

1. Develop a standardized method for determining antibiotic susceptibility patterns and developing NH-specific antibiotics;

2. Extract preliminary data from NH facilities of various sizes and types to guide the development of the draft toolkit; and

3. Develop a draft toolkit to guide a wide variety of sizes and types of NHs in developing and sharing antibiotic information with prescribing providers (i.e., physicians and physician extenders) and EDs.

Three NHs and one ED will participate in this study, which will be conducted in two phases. The first phase will include one small NH and one ED and is intended to test the data collection instruments and to draft the initial toolkit, including the creation of a NH specific antibiotic. The second phase will expand the study by adding two larger NHs, while retaining the same NH and ED as in the first phase and is intended to further test the data collection instruments and refine the draft toolkit. Each phase will use the same methods and data collections.

This study is being conducted by the Agency for Healthcare Research and Quality through its contractors, Abt Associates and the Brigham and Women's Hospital ED, pursuant to the Agency for Healthcare Research and Quality'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 and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

The following data collection activities will be implemented to achieve the objectives of this project:

(1) Medical Records Extraction. Medical record data related to antibiotic use will be extracted by the research team at the three participating NHs and one ED. The team will extract the necessary data from the infection control log and request access to additional records (e.g., medication log and/or patient medical record) as needed to collect relevant data. Two months of retrospective NH and ED medical records will be reviewed prior to the implementation period, on a monthly basis during implementation, and for one month post-implementation. In the ED medical records will be extracted for only those NH residents who have been transferred to the ED from one of the participating NHs. The pre-implementation data will be compared to the data collected during implementation and post-implementation to see if the use of the antibiotic report had an effect on antibiotic use at the participating facilities. It is unlikely, but possible, that NH staff may be asked to assist the research team with this task in the two larger, Expansion Phase Two sites; however, ED staff will not. Medical record extraction during Phase One will occur prior to OMB clearance and will be limited to 9 or fewer records.

(2) Provider Pre-Implementation and Post-Implementation Questionnaires. These questionnaires will be completed by providers at both the NHs and ED one month prior to implementation and again in the final month of implementation. NH and ED questions differ somewhat, as do pre- and post-

implementation surveys. In addition to basic background questions such as the providers' title, type of residency and length of practice, questions related to their use and opinion of antibiograms are included. The post-implementation questionnaire contains three additional questions related to the use of antibiograms as well as a series of vignettes administered before and after the presentation of an antibiogram report. These questionnaires will assess change in the providers' use and opinion of antibiograms.

(3) Nurse Pre/Post-Implementation Questionnaire. This questionnaire will be administered one month prior to implementation and again in the final month of implementation. In addition to basic background questions such as the nurses' title, position at the NH and length of employment, questions related to their use and opinion of antibiograms are included. The same set of questions is asked at each time period. This questionnaire will measure any change in the nurses' use and opinion of antibiograms.

(4) NH Leadership Post-Implementation Questionnaire. This questionnaire will be completed by the NH administrator or the director of nursing in the final month of the implementation. In addition to basic background questions such as their title, position at the NH and length of employment, questions are asked about the impact the antibiograms had in terms of antibiotic use, the cost associated with their use and whether they intend to continue using them once the study has been completed.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this research. Although medical records extraction using the NH and ED Data

Extraction Tools will occur at the NHs and ED, the potential information collection burden will be limited to staff at each of the Expansion Phase 2 NHs. Medical record data extraction will occur monthly for 7 months at the two Expansion Phase Two NHs and may require 15 minutes assistance from the NH staff.

The NH Provider Pre-Implementation Questionnaire will be completed by 10 providers at each of the two Expansion Phase Two NHs and will take about 10 minutes to complete. The NH Provider Post-Implementation Questionnaire will be completed by three providers in the Initial Phase One NH and 10 providers at each of the two Expansion Phase Two NHs (23 total or an average of 7.67 providers per NH as shown in Exhibit 1) and takes 15 minutes to complete. The ED Provider Post-Implementation Questionnaire will be completed by 30 providers in the ED and requires 15 minutes to complete. The Nurse Pre/Post Implementation Questionnaire will be completed pre-implementation by approximately 25 nurses at each of the two Expansion Phase Two NHs and again post-implementation by 25 nurses at each of the 3 participating NHs (125 total or an average of 41.67 nurses per NH as shown in Exhibit 1). The Nurse Pre/Post-Implementation Questionnaire is estimated to take 5 minutes to complete. The NH Leadership Post-Implementation Questionnaire will be completed by one NH administrator or director of nursing at each of the three participating NHs and will require 10 minutes to complete.

The total annualized burden hours are estimated to be 32 hours.

Exhibit 2 shows the estimated annual cost burden to the respondent, based on their time to participate in this research. The annual cost burden is estimated to be \$1,921.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of facilities	Number of responses per facility	Hours per response	Total burden hours
Medical Records Extraction	2	7	15/60	4
NH Provider Pre-Implementation Questionnaire	2	10	10/60	3
NH Provider Post-Implementation Questionnaire	3	7.67	15/60	6
ED Physician Post-implementation Questionnaire	1	30	15/60	8
Nurse Pre/Post Implementation Questionnaire	3	41.67	5/60	10
NH Leadership Post-Implementation Questionnaire	3	1	10/60	1
Total	14	n/a	n/a	32

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of facilities	Total burden hours	Average hourly wage rate *	Total cost burden
Medical Records Extraction	2	4	\$31.99	\$128
NH Provider Pre-Implementation Questionnaire	2	3	83.59	251
NH Provider Post-Implementation Questionnaire	3	6	83.59	502
ED Physician Post-implementation Questionnaire	1	8	83.59	669
Nurse Pre/Post Implementation Questionnaire	5	10	31.99	320
NH Leadership Post-Implementation Questionnaire	3	1	51.45	511
Total	14	32	n/a	1,921

* Based upon the mean of the average wages, National Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics. May 2009. Hourly mean wage for registered nurse (\$31.99), physician (\$83.59), and NH administrator (\$51.45).

Estimated Annual Costs to the Federal Government

research. The total budget for this two year study is \$458,812.

Exhibit 3 shows the total and annualized cost for conducting this

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total	Annualized cost
Project Administration	\$60,511	\$30,256
Initial Antibioqram Development and Implementation	47,618	23,809
Expansion of Antibioqram Development and Implementation	36,948	18,474
Toolkit—Development and Refinement	92,688	46,344
Evaluation	153,978	76,989
Final Report and Dissemination	67,071	33,536
Total	458,812	229,406

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 healthcare research and healthcare 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.

Dated: March 15, 2011.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Agency for Healthcare Research and Quality****Meeting for Software Developers on the Technical Specifications for Common Formats for Patient Safety Data Collection and Event Reporting**

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

ACTION: Notice of public meeting.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to b-26, (Patient Safety Act) provides for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of healthcare delivery. The Patient Safety Act (at 42 U.S.C. 299b-23) authorizes the collection of this information in a

standardized manner, as explained in the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008: 73 FR 70731-70814. AHRQ coordinates the development of a set of common definitions and reporting formats (Common Formats) that allow healthcare providers to voluntarily collect and submit standardized information regarding patient safety events. In order to support the Common Formats, AHRQ has provided technical specifications to promote standardization by ensuring that data collected by PSOs and other entities are clinically and electronically comparable. More information on the Common Formats, including the technical specifications, can be obtained through AHRQ's PSO Web site: <http://www.PSO.AHRQ.GOV/index.html>.

The purpose of this notice is to announce a meeting to discuss the technical specifications, including the Hospital Common Formats technical specifications and the Skilled Nursing Facility Common Formats. This meeting is designed as an interactive forum where PSOs and software developers can provide input on these technical