2020 will reflect assessments of major risks to health and wellness, changing public health priorities, and emerging issues related to our nation's health preparedness and prevention.

Public Participation at Meeting: Members of the public are invited to listen to the online Committee meeting. There will be no opportunity for oral public comments during the online Committee meeting. Written comments, however, are welcome throughout the development process of the national health promotion and disease prevention objectives for 2020. They can be submitted through the Healthy People Web site at: *http://www.healthypeople.gov/hp2020/comments/* or they can be e-mailed to *HP2020@hhs.gov*.

To listen to the Committee meeting, individuals must pre-register to attend at the Healthy People Web site located at *http://www.healthypeople.gov.* Participation in the meeting is limited. Registrations will be accepted until maximum WebEx capacity is reached and must be completed by 9 a.m. EST on December 11, 2009. A waiting list will be maintained should registrations exceed WebEx capacity. Individuals on the waiting list will be contacted as additional space for the meeting becomes available.

Registration questions may be directed to Hilary Scherer at *HP2020@norc.org* (e-mail), (301) 634–9374 (phone) or (301) 634–9301 (fax).

Dated: November 18, 2009.

Penelope Slade-Sawyer,

RADM, USPHS, Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion).

[FR Doc. E9–28320 Filed 11–24–09; 8:45 am]

BILLING CODE 4150–32–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: ''Spreading Techniques to Radically Reduce Antibiotic Resistant Bacteria (Methicillin Resistant Staphylococcus aureus, or MRSA).'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 350 1–3520, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by January 25, 2010.

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

Spreading Techniques To Radically Reduce Antibiotic Resistant Bacteria (Methicillin Resistant Staphylococcus aureus, or MRSA)

Healthcare Acquired Infections (HAIs) caused almost 100,000 deaths among the 2.1 million people who acquired infections while hospitalized in 2000, and HAI rates have risen relentlessly since then. Alarmingly, 70% of HATs are due to bacteria that are resistant to commonly used antibiotics, with Methicillin Resistant Staphylococcus aureus (MRSA) being the most rapidly growing, and among the most virulent, pathogens. Resistance is increasing rapidly in all types of hospitals (Huang 2007). Despite evidence that routinely applied, simple interventions do work, most hospitals have failed to make notable progress in reducing MRSA infections. Hospitals in some European countries and select U.S. hospitals, however, have succeeded with impressive results.

Sites that have already achieved dramatic decreases in their MRSA infection rates have done so by implementing precautions to prevent transmission, using system redesign approaches. Further, many hospitals have successfully instituted isolation procedures for patients suspected to be MRSA carriers. In doing so, these hospitals have followed the broadly disseminated guidelines for hand hygiene and contact isolation precautions. This study is a follow up to a recent study implemented in 6 hospital systems in the Indianapolis metropolitan area that used a ''MRSA intervention bundle'' composed of active surveillance screening, contact isolation precautions, and increased hand hygiene. Preliminary data from that initial study suggest a 60% decrease in MRSA rates in participating intensive care units (ICUs) (Doebbeling, B. Redesigning Hospital Care for Quality and Efficiency Applications of Positive Deviance and Lean in Reducing MRSA. Presentation at AHRQ Annual Meeting, Rockville, MD, Sept 2009).

This study is designed to further test this intervention bundle in non-ICU settings in hospitals currently using the intervention bundle in their ICUs, as well as in additional ICUs in newly recruited hospital systems. This project will utilize the same guidelines and precautions that were applied in the original study, and will add an innovative feature that will use electronic medical record systems to improve identifying, communicating and tracking MRSA infections among healthcare systems. More specifically, this study has five aims:

(1) Further test the ''MRSA intervention bundle'' from the original Indianapolis MRSA study, and test the intervention in additional units in the 4 original Indianapolis hospital systems and an additional 3 hospital systems beyond Indianapolis;

(2) Identify and monitor healthcare associated community onset (HACO) MRSA cases and controls who receive care in participating hospitals and affiliated settings, identify strategies to reduce HACO MRSA and demonstrate reduction of HACO MRSA;

(3) Assess the relative effectiveness of various antibiotics in abatement or eradication of MRSA carriage in hospital patients;

(4) Evaluate the effectiveness of the tested implementation strategies and innovations by applying information technology to enable consistent collection, sharing, analysis and reporting of data;

(5) Disseminate findings and promote outreach to target audiences and other stakeholders.

While many secondary data are available for this study, Aims 1 and 2 involve primary data collection. Use of the intervention bundle requires that opinion leaders and front line workers be equipped with techniques used in the reorganization of healthcare delivery to improve health outcomes (Singhal and Greiner, 2007; IHI, 2005). These techniques will assist in identifying goals, implementing the interventions to meet local needs and measuring and feeding back progress on key processes and outcomes to staff and others.

The study also incorporates an additional informatics surveillance system to allow participating hospitals to more efficiently communicate, share and track MRSA infections. This system will save infection control and clinicians' time—for example, by electronically identifying patients with a known history of drug-resistant infections when they first contact a new institution.

This study is being conducted by AHRQ through its contractor, Indiana University and the Regenstrief Institute, 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 and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(l) and (2).

Method of Collection

There will be 3 types of data collection to support the study Aims:

- Electronic medical record data on MRSA infections and rates will be collected from an existing and unique healthcare information exchange (Indiana Network for Patient Care or INPC) in the Indianapolis area, and the CDC's National Healthcare Safety Network (Aims 1–5).
- Data on hand washing, swabbing, and isolation rates will be collected by observation (Aims 1, 2, and 4).
- Four surveys will be conducted: A brief Social Network Analysis (SNA), a Cultural Survey, a Patient Healthcare Use survey, and an Implementation Assessment of key informants (Aims 1, 4, and 5).

The social network analysis questionnaire (SNA) (Wasserman *et al.*, 1994) will be administered to understand with whom hospital personnel work, how hospital networks mature over time and how information is shared. Additionally, cultural beliefs, attitudes, and knowledge will be captured by surveying staff on intervention units of participating hospitals using a cultural questionnaire. To compare changes in the network and cultural beliefs, both the SNA and the cultural questionnaire will be administered to staff at baseline and again one year later. These data will be collected from a sample of staff in the intervention units. Project team leaders will select relevant staff regularly working and providing patient care or direct patient services on the unit in a purposive sample. These staff will receive the paper-based questionnaires during staff meetings and will return them anonymously. A study ID will serve to determine which staff has responded and allow linkage of baseline and follow-up surveys.

The implementation assessment will be an interview obtained quarterly to key informants at each organization to assess the approaches to implementation of the program (*e.g.*, dose, intensity, leadership support, teamwork, etc). This assessment will be a short (10–12) item questionnaire.

Additionally, to better understand the healthcare associated community acquired aspect of MRSA transmission, 200 patients will be surveyed to gather risk factors and healthcare use statistics that we have found in preliminary studies are not otherwise available in electronic databases or medical records.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours associated with the hospital's time to participate in this research. Electronic medical record data will be collected weekly from 7 participating hospitals, however only two of these hospitals will use their staff to perform this data collection. Over the course of the project electronic medical record data will be extracted 52 times and each data extraction will take about 10 hours. Observational data will be collected weekly from all participating hospitals, however only 3 hospitals will use their staff to perform the observations. The project will require 52 observations per hospital and are estimated to take about 3 hours to perform.

Both the social network analysis questionnaire and the culture questionnaire will be administered twice, pretest and posttest, to about 75 personnel at each of the 7 hospitals. The social network analysis questionnaire will take about 15 minutes to complete while the culture questionnaire will take 30 minutes. The implementation assessment questionnaire will be administered quarterly to 3 key informants at each hospital and will take about one hour.

The patient healthcare use questionnaire will be completed by 200 patients sampled from the 7 participating hospitals. Each patient will respond once which will require about 15 minutes. The total annualized burden hours for all the associated data collections are estimated to be 2,430. Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this research. The total annual cost burden is estimated to be $76,118.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of hospitals	Numer of responses per hospital	Hours per response	Total burden hours
Electronic Medical Record Data Collection	2	52	10	1,040
Observational Data Collection	3	52	3	468
Social Network Analysis Questionnaire	7	150	15/60	263
Culture Questionnaire	7	150	30/60	525
Implementation Assessment Questionnaire	7	12	1	84
Patient Healthcare Use Questionnaire	200	1	15/60	50
Total	226	na	na	2,430

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of hospitals	Total burden hours	Average hourly wate rate*	Total cost burden
Electronic Medical Record Data Collection	2	1040	$30.03	$31,231
Observational Data Collection	3	468	$20.98	9,819
Social Network Analysis Questionnaire	7	263	$38.28	10,068

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of hospitals	Total burden hours	Average hourly wate rate*	Total cost burden
Culture Questionnaire	7	525	$38.28	$20,097
Implementation Assessment Questionnaire	7	84	$45.33	$3,808
Patient Healthcare Use Questionnaire	200	50	$21.90	$1,095
Total	226	2,430	na	$76,118

*Based upon the mean of the average wages for Nursing Care Providers ($30.03), Primary Care Physicians ($84.97), Allied Health Providers ($20.98), Administrators, Chief Executives ($76.23) and All Workers ($21.90); National Compensation Survey: Occupational wages in the United States May 2008, ''U.S. Department of Labor, Bureau of Labor Statistics.''

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the total and annualized cost of this project to the Federal Government over a two-year period. The total cost of this project is $1.8 million dollars which includes $785,000 for project development, $70,000 for data collection activities, $235,000 for data analysis, $125,000 for publication of the results, $170,000 for project management and $415,000 for overhead costs.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	$785,000	$262,000
Data Collection Activities	$70,000	$35,000
Data Processing and Analysis	$235,000	$78,000
Publication of Results	$125,000	$125,000
Project Management	$170,000	$57,000
Overhead	$415,000	$138,000
Total	$1,800,000	$900,000

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, 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: November 16, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–28211 Filed 11–24–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0413]

Guidance for Industry on Residual Solvents in Drug Products Marketed in the United States; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Residual Solvents in Drug Products Marketed in the United States.'' On July 1, 2008, the United States Pharmacopeia (USP) published a new test requirement for the control of residual solvents, General Chapter <467> ''Residual Solvents,'' which replaced USP General Chapter <467> ''Organic Volatile Impurities.'' The change affects all compendial drug products marketed in the United States. This guidance reflects FDA's recommendations on how to comply with those USP changes.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov* . See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Chris Watts, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4142 Silver Spring, MD 20993–0002, 301–796–1625.

SUPPLEMENTARY INFORMATION: