

Estimated Annual Costs to the Federal Government

The total cost to the Government for developing this survey is approximately \$319,000, and is being funded solely by AHRQ. This estimate includes the costs of a background literature review, survey development, cognitive testing, pilot data collection, data analysis, and preparation of final deliverables and reports.

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 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.

Dated: December 1, 2006.

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, Department of Health and Human Services.

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) allow the proposed

information collection project: "Development of an Electronic System for Reporting Medication Errors and Adverse Drug Events in Primary Care Practice (MEADERS)." In accordance with the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by February 12, 2007.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, 540 Gaither Road, Room #5036, Rockville, MD 20850.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from AHRQ's Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ, Reports Clearance Officer, (301) 427-1477.

SUPPLEMENTARY INFORMATION:

Proposed Project

"Development of an Electronic System for Reporting Medication Errors and Adverse Drug Events in Primary Care Practice (MEADERS)"

The project is being conducted in response to an AHRQ RFP entitled "Resource Center for Primary Care Practice-Based Research Networks (PBRNs)" (issued under Contract 290-88-0008).

In response to a proposed modification to AHRQ contract no. 290.02.0008, the PBRN Resource Center is proposing to assist AHRQ in its continued commitment to assessing the status and capabilities of its funded PBRNs and making available to them the tools and resources necessary to improve the quality of care they provide. Through the modification of this contract, the PBRN Resource Center will develop and make available an electronic system for reporting medication errors and adverse drug events that occur in outpatient physician practices of selected PBRNs to their own practices for quality improvement purposes and to the Food and Drug Administration (FDA).

The landmark Harvard Medical Practice Study was published in 1991 and stated that 98,000 Americans die each year from medical errors.¹ Although the exact figure has been disputed, no one disputes the fact that too many Americans are injured unnecessarily by medical mistakes that could be avoided.^{2,3} Another study performed by the Department of

Veterans Affairs suggests that in one out of every 10,000 hospitalizations, a patient dies due directly to a medical error.⁴

In response to the growing concern over medical errors, the Agency for Healthcare Research and Quality (AHRQ) has published three important monographs outlining the problem of errors,⁵ their effects on the quality of care,⁶ and offering suggestions on improving patient safety.⁷ The first recommendation of this third monograph was to "capture information on patient safety—including both adverse events and near misses—as a byproduct of care, and use this information to design even safer care delivery systems." One central theme to each of these monographs is that there simply is too much chaotic information flowing in the medical environment for a single provider to handle effectively. Therefore, solutions to the problem of medical errors should include some combination of health information technology and redesign of health care systems to enhance the prevalence of appropriate decisions (*i.e.*, avoiding errors of omission) and reduce the occurrence of avoidable mistakes (*i.e.*, avoiding errors of commission).

A recent conference sponsored by AHRQ highlighted interventions to improve medical decision-making and reduce medical errors.⁸ Most of the interventions presented were based in hospitals, where the most intensive and immediately life-threatening events occur. Yet the majority of medical decisions are made in outpatient practices and offices where there has been little error-reduction research performed. Further, most outpatient studies have been performed in academic medical centers which have capabilities, providers, and patients that may not typify the average U.S. medical practice.⁹

With the recent passing of the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21-b-26, now is an opportune time to evaluate a primary care error reporting system, and PBRNs are an ideally suited place to study interventions aimed at reporting and reducing medical errors. In most primary care practices there is no mechanism in place to report medical errors as they occur. We propose to develop, implement, and study an outpatient error reporting system to better understand the ability of physicians to identify their own errors and their willingness to report them to their own practices and the FDA and AHRQ. We will focus on the most common invasive intervention invoked in outpatient practice—drug treatment

of acute and chronic conditions—and will create and test a paper- and computer-based system for both capturing medication errors and reporting adverse drug events, which are also under-reported.¹⁰

The fundamental objective is to utilize the Resource Center’s expertise in health information technology and its working relationships with PBRNs to support AHRQ’s objectives in developing and evaluating systems for reporting medication errors and adverse drug events in primary care. We will accomplish this objective through (1) Developing and implementing an electronic and paper-based outpatient medication error and adverse event reporting system, (2) evaluating the usefulness, ease of use, and actual use of the system in everyday clinical practices, and (3) identifying patient, provider, and practice characteristics that predict uptake and use of this system in participating primary care practices.

Methods of Collection

The value of MEADERS to practicing primary care clinicians will be illustrated by performing demonstration implementations in two PBRNs. A PBRN is a group of clinicians working together, either locally or nationally, to conduct research and implement research findings into practice settings. A total of 45 physicians and their practice staff will participate in the field test in addition to completing baseline surveys of their practice.

A request for proposals will be sent to all PBRNs that have registered with the

PBRN Resource Center. A review committee consisting of a selection of four expert panel members, one or two PBRN representatives, and some members of the PBRN Resource Center will evaluate the applications. The AHRQ Project Officer will chair the review committee and, together with PBRN Resource Center staff, develop a set of review criteria. The review committee will make recommendations to the PBRN Resource Center who will make the final determination of participating PBRNs. Once the PBRNs are selected, each PBRN will choose up to three of its affiliated practices to participate in this trial. Although initial participation by a practice is voluntary, once selected the practice must provide assurances that at least three to five clinicians will agree to use the system and that the practice will support the project.

The PBRN Resource Center will develop a series of surveys to capture data describing the practice and the patients it serves, the extent of the error reporting system’s use, and an assessment of the users’ overall satisfaction with the system. practice and provider information will be collected at baseline along with characteristics that could be facilitators (such as an electronic medical record system) or barriers (such as lack of time and resources needed to report information) to implementation of the MEADER system. Data collected on the system’s use will include the number of clinicians who have used MEADERS at least once, the number of times used

overall, the time it takes to enter data into the electronic MEADERS, and the types of medication errors and adverse drug events that are being reported. Both the paper and electronic versions of the system will be assessed at the conclusion of the evaluation period. The follow-up assessment will include clinicians’ and managers’ satisfaction with the system (e.g., ease of use, usefulness of the generated reports and individual feedback) and whether they intend to continue its use after the initial study period has concluded. Finally, semi-structured interviews and conference call discussions will be used to collect additional comments and suggestions for future implementation of MEADERS.

Although any clinician in the practice will be able to use the system, physicians are likely to be the primary users of the system. The Resource Center is estimating that physicians will account for about 80% of MEADERS use and Nurse Practitioners, Physician Assistants and Medical Assistants will make up the remainder (See Exhibit 1). The time for entering an event into the system is estimated to require no more than 8 minutes of a clinician’s time.

Wherever possible, existing validated measures will be used. Where validated measures do not exist, new measures will be developed and assessed. The final instruments will be field tested within selected practices in the PBRNs chosen to participate in the implementation study.

Estimated Annual Respondent Burden

EXHIBIT 1.—ESTIMATE OF COST BURDEN TO RESPONDENTS

| Data collection effort | Number of responses* | Estimated time per respondent in hours | Estimated total burden hours | Average hourly wage rate** | Estimated annual cost burden to respondents |
|---|----------------------|--|------------------------------|----------------------------|---|
| Office Manager baseline survey | 45 | 0.25 | 11.25 | \$34.67 | \$390.04 |
| Physician baseline survey | 45 | 0.25 | 11.25 | 57.90 | 651.38 |
| Physician opinion survey of system | 45 | 0.25 | 11.25 | 57.90 | 651.83 |
| Physician entry of medication error | 216 | 0.134 | 28.94 | 57.90 | 1675.63 |
| Nurse opinion survey of system | 45 | 0.25 | 11.25 | 27.35 | 307.69 |
| Nurse entry of medication error | 18 | 0.134 | 2.4 | 27.35 | 65.64 |
| PA/NP opinion survey of system | 45 | 0.25 | 11.25 | 34.17 | 384.41 |
| PA/NP entry of medication error | 18 | 0.134 | 2.4 | 34.17 | 82.00 |
| Medical assistant survey of system | 45 | 0.25 | 11.25 | 12.58 | 141.53 |
| Medical assistant entry of medication error | 18 | 0.134 | 2.4 | 12.58 | 30.19 |
| Officer Manager opinion-survey of system | 45 | 0.25 | 11.25 | 34.67 | 390.04 |
| Total | 585 | | 114.89 | | 4769.93 |

*Based on a six month trial period of MEADER reporting system.

**Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States 2004, “U.S. Department of Labor, Bureau of Labor Statistics.”

This information collection will not impose a cost burden on the respondent beyond that associated with their time

to provide the required data. There will be no additional costs for capital

equipment, software, computer services, etc.

Estimated Costs to the Federal Government

The total cost to the government for this activity is estimated to be \$1,000,000.00.

Request for Comments

In accordance with the above-cited 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 health care research and information dissemination functions of AHRQ, 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 request for OMB approval of the proposed information collection. All comments will become a matter of public record.

References

¹ Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study. *N Engl J Med* 1991; 324:370–376.

² McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in the Institute of Medicine Report. *JAMA* 2000; 284:93–95.

³ Leape LL. Institute of Medicine medical error figures are not exaggerated. *JAMA*. 2000; 28:95–97.

⁴ Hayward RA, Hofer TP. Estimating hospital deaths due to medical errors: preventability is in the eye of the reviewer. *JAMA*. 2001; 286:415–420.

⁵ Institute of Medicine. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press, 2000.

⁶ Institute of Medicine. *Crossing the Quality Chasm: A New System for the 21st Century*. Washington, DC: National Academy Press, 2001.

⁷ Institute of Medicine. *Patient Safety: Achieving a New Standard for Care*. Washington, DC: National Academy Press, 2004.

⁸ <http://www.blsmeetings.net/PatientSafetyandHIT/> (Accessed August 11, 2005).

⁹ Green LA, Fryer GE, Yawn BP, Lanier D, Dovey SM: The ecology of medical care revisited. *N Engl J Med* 2001; 344:2021–2025.

¹⁰ Uribe CL, Schweikhart SB, Pathak DS, Dow M, Marsh GB. Perceived barriers to medical-error reporting: an exploratory

investigation. *J Healthcare Management*. 2002;47(4):263–79.

Dated: December 1, 2006.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–07–0008]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Emergency Epidemic Investigations (0920–0008)—Revision—Office of Workforce and Career Development (OWCD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

One of the objectives of CDC's epidemic services is to provide for the prevention and control of epidemics and protect the population from public health crises such as man made or natural biological disasters and chemical emergencies. This objective is carried out, in part, by training investigators, maintaining laboratory capabilities for identifying potential problems, collecting and analyzing data, and recommending appropriate actions to protect the public's health. When state, local, or foreign health authorities request help in controlling an epidemic or solving other health problems, CDC dispatches skilled epidemiologists from the Epidemiologist Intelligence Service (EIS) to investigate and resolve the problem.

The purpose of the Emergency Epidemic Investigation surveillance is to collect data on the conditions surrounding and preceding the onset of a problem. The data must be collected in a timely fashion so that information

can be used to develop prevention and control techniques, to interrupt disease transmission and to help identify the cause of an outbreak. Since the events necessitating the collections of information are of an emergency nature, most data collection is done by direct interview or written questionnaire and are one-time efforts related to a specific outbreak or circumstance. If during the emergency investigation, the need for further study is recognized, a project is designed and separate OMB clearance is required. Interviews are conducted to be as unobtrusive as possible and only the minimal information necessary is collected. The Emergency Epidemic Investigations is the principal source of data on outbreaks of infectious and noninfectious diseases, injuries, nutrition, environmental health and occupational problems.

Each investigation does contribute to the general knowledge about a particular type of problem or emergency, so that data collections are designed to take into account similar situations in the past. Some questionnaires are standardized, such as investigations of outbreaks aboard aircraft or cruise vessels.

The Emergency Epidemic Investigations provides a range of data on the characteristics of outbreaks and those affected by them. Data collected include demographic characteristics, exposure to the causative agent(s), transmission patterns and severity of the outbreak on the affected population. These data, together with trend data, may be used to monitor the effects of change in the health care system, planning of health services, improving the availability of medical services and assessing the health status of the population.

Users of the Emergency Epidemic Investigations data include, but are not limited to EIS Officers in investigating the patterns of disease or injury, investigating the level of risky behaviors, identifying the causative agent and identifying the transmission of the condition and the impact of interventions.

Epi Trip Reports are delivered to the state health agency official requesting assistance shortly after completion of the Emergency Epidemic Investigation. The official can comment on both the timeliness and the practical utility of the recommendations from the investigation. CDC is requesting that a new form be added to the current clearance. Upon completion of the Emergency Epidemic Investigation, requesting officials at the state or local health department will be asked to complete a brief questionnaire to assess