OMB Clearance Application

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

June 2007

Agency of Healthcare Research and Quality (AHRQ)

Table of contents

A. Justification

A.1. Circumstances of Information Collection

Medication errors are among the most common medical errors, harming at least 1.5 million Americans and costing billions of dollars annually.[1] Adverse drug events (ADEs), defined as any untoward event related to mediation (about 30 percent of which are thought to be preventable) also occur frequently. Studies indicate that 400,000 preventable drug-related mistakes occur each year in hospitals, and 6.5 percent of hospitalized patients have an adverse drug event.[2] [3] However, there is a dearth of information about medication errors and adverse drug events that occur in the ambulatory setting, where most prescribing occurs. Manufacturers are required by regulation to report to the U.S. Food and Drug Administration (FDA) all adverse drug reactions. Reporting of such events by health care professionals through the FDA's MedWatch program is however voluntary, and the relatively small number of such reports filed annually by clinicians indicates that this paper-based system is significantly underutilized. Anecdotal information suggests that busy clinicians in the ambulatory setting find the filing of a paper report to MedWatch time-consuming and thus burdensome to the practice. Clincians may also be concerned about the confidentiality and security of the data being reported.

Chart review is the most commonly used method to ascertain medication-related events among inpatients,[4] but inadequate documentation of outpatient care limits the usefulness of this approach in ambulatory settings.[5] For this reason, attention is being focused on prospective collection of data describing outpatient medication-related events.[6] [7] Prospective data about the frequency, type, severity, and consequences of drug-related events among outpatients could not only increase our understanding of the epidemiology and causes of such events, but could also directly assist clinical practices in identifying strategies to keep them from occurring or to ameliorate any consequences.

Through a contractor (Indiana University), and with the collaboration of the FDA, AHRQ has developed and refined (based on beta-testing in three primary care practices) a new internet-based reporting system called Medication Error and Adverse Drug Event Reporting System (MEADERS) designed for use in ambulatory practices. The system enables clinicians and staff within any practice having high-speed internet access to report information on medication errors and ADEs electronically. It has been designed to be simple to use and to require a minimal amount of time for reporting, thereby imposing little or no burden on the primary care practice. The new reporting tool is accessible for viewing at www.pcrxevents.org, (or see Attachment 1).

A.2. Purpose and Use of Information

AHRQ is requesting Office of Management and Budget approval to conduct a pilot test of MEADERS to determine the ability and willingness of physicians and staff in primary care practices to use the new system to report self-identified medication errors and adverse drug events. The test is to be conducted in a convenience sample of twenty primary care practices (including up to a maximum of 100 physicians). The practices

have been recruited from those that are active in four practice-based research networks (PBRNs) under contract to AHRQ. PBRNs are organizations of community-based practices, directed by clinician researchers and typically affiliated with an academic medical center, that work together to study issues related to primary health care.

To be eligible for the study, a practice must actively provide primary medical care (defined as general pediatrics, general internal medicine or family medicine), have high-speed access to the internet, and be willing to participate in the study. PBRNs from which practices are recruited will be responsible for providing the practices with training and on-going technical assistance on the use of MEADERS and for assuring that the project is reviewed and approved by an IRB with oversight for practice research. Physicians and staff within these practices will be asked to note during the testing period any event that they perceive to be a medication error or an adverse drug event, as categorized in the MEADERS reporting tool (see page 3 of Attachment 1), and to enter information describing these events into the electronic system.

The focus of the study is the ability and willingness of physicians and staff to report voluntarily information into MEADERS. The study is not intended to be a validation of the reported information compared to what actually happened, either through observation or medical record documentation. On-going direct observation of practices would be prohibitively expensive, and comparison of reported events to data recorded in the medical record is not planned given the known inadequacy of outpatient chart documentation. The study will assess the number of reports filed by each practice (in relation to the number of patients seen in the practice) and the completeness of the data reported in terms of (1) whether all questions asked about the observed event were reported (were all electronic fields completed?) and (2) whether the data provided are complete enough to understand the probable causes(s) of the event and possible solutions. We also intend to use a brief questionnaire to collect follow-up information from participating providers to identify practice- or clinician-specific barriers, or characteristics of MEADERS, that limit reporting of medication errors/ADEs by primary care practices. Please see Attachment 2 for the proposed questionnaire.

To further assess the utility and impact of MEADERS on participating clinicians and practices, we will conduct a separate "debriefing" focus group session with representatives from the practices of each of the four PBRNs involved in the pilot testing. Each PBRN will recruit 8-10 individuals from the participating practices to dial into a toll free access number at a scheduled time in order to discuss their experiences using MEADERS. We have found that moderated group discussions via conference call are not only a more efficient way of gathering information but are also a very effective method of drawing out issues that might not be identified in a more structured individual interview process or from the follow-up survey. We will work with each PBRN to determine a time for the call that is most convenient for the busy clinicians. Each of the four calls should take no more than 45 minutes of the participants' time (see modification of estimate of cost burden to respondents). See attachment (FOCUS GROUPS) for a description of the proposed process and a preliminary group discussion guide.

AHRQ has collaborated with the FDA to create within MEADERS the capacity for a reporter to opt to have a report forwarded to MedWatch with a single computer click. Practices will be fully aware (through the training program and through a built-in computer alert) that, by clicking to send a report to MedWatch, the identity of the practice will no longer be confidential and that FDA may follow up with the practice in order to obtain more detailed information about the event. As part of this follow-up, FDA would request the identity of both the reporter and the patient involved. An outcome of interest to both AHRQ and FDA is the number and type of events reported to the FDA from MEADERS compared to the total number of events recorded in MEADERS through the reporting period, and the apparent reasons practices chose to forward (or not forward) reports to MedWatch.

Another important feature of MEADERS is the ability of the system manager to generate a summary of the events reported by a single practice, including a comparison of these events to the events reported by the aggregate of all reporting practices. Practices participating in the pilot testing will be provided such feedback regularly throughout the study. The analyses are intended to inform locally-tailored practice efforts to improve the quality of care and patient safety by reducing medication errors and ADEs. A number of interventions available to primary care practices have been reported in the literature.[8] This feedback may also be a significant incentive encouraging repeated use of the system.

We recognize that the data collected from 20 practices during this pilot testing will likely be insufficient to characterize all ambulatory medication errors/ADEs in the U.S. If we determine that outpatient practices are able and willing to use the new electronic reporting system, the results of this test can be leveraged for larger future studies that will be sufficiently powered to allow investigators to draw conclusions about the types and rates of medication errors and adverse drug events observed in ambulatory practice settings across the country.

A.3. Use of Improved Information Technology

Data will be collected using a computer-based system for capturing perceived medication errors and adverse drug events in primary care practices. Practices participating in the test must have at least one computer with high speed internet connectivity and will be provided a link to the HIPAA compliant, secure website on which MEADERS resides. The PBRNs under contract to AHRQ have reported that nearly 100% of practices within their networks currently have high-speed access to the internet. The major objective of this pilot test is to determine the extent to which primary care practices will use this website for reporting purposes.

A.4. Efforts to Identify Duplication

While electronic systems to facilitate the reporting of medication errors or adverse drug events are in use in hospital settings, we are unaware of any internet-based system similar to MEADERS that has been designed specifically for the ambulatory setting and tested in practices. As noted previously, the FDA has developed a computerized information database for storing and analyzing medication safety reports, but reports sent voluntarily by health care professionals and consumers through the MedWatch program are paper-

based. Since information collected electronically through MEADERS is compatible with that requested for MedWatch reports, MEADERS is intended to augment rather than duplicate the reporting of medication-related events.

A.5. Involvement of Small Entities

MEADERS will be tested in smaller primary care practices composed of 2-5 physicians as well as nursing and other non-clinical staff. Reports of perceived medication errors or adverse drug events may be filed by any member of the practice staff, although we anticipate that around 70% of the reports will be filed by physicians. Since MEADERS was designed to facilitate reporting and to require only minutes to complete, the burden to the practice will be kept to a minimum. Further, completion of the practice survey (Attachment 2) is a one time occurrence which will require minimal time out of respondents' work day to complete (approximately 10-15 minutes).

A.6. Consequences if Information Collected Less Frequently

The design of this study requires practices to enter data as medication-related events occur or shortly thereafter. The frequency of reporting is entirely dependent upon the frequency of events occurring. As noted previously, data entered after the fact into ambulatory medical records about medication errors/ADEs have been found to be insufficient to use in characterizing such events. The purpose of this study is to determine if ambulatory practices will use an internet-based system for prospective data collection at the point of care.

A.7. Special Circumstances

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

A.8. Consultation outside the Agency

In April, 2006, prior to the development of MEADERS, AHRQ and its contractor (Indiana University) consulted with a panel of experts for advice on the design of the system, including identification and classification of medication errors and adverse drug events, and best methods of collecting data. The consulted individuals, listed in Attachment 3, included nationally recognized leaders and researchers in error-reporting systems, industrial engineering, clinical pharmacy, primary care, behavioral science, medical information technology. Representatives of AHRQ, U.S. Pharmacopeia and the FDA also participated in the meeting.

A.9. Payments/Gifts to Respondents

Neither physicians nor practice staff will receive direct payment for participation in the study. AHRQ will fund the four practice-based research networks from which the primary care practices enrolled in the study will be recruited (see attachment 4). In addition to recruiting practices for the study, these research networks will be responsible for (1) applying for project approval by the IRB(s) that oversee research efforts of the practices; (2) providing in-office training for the physician(s) and staff in each practice on recognition of medication errors/ADEs, access and use of MEADERS, and required security measures; (3) providing on-going technical assistance in the use of MEADERS,

as needed, to practices over the course of the pilot test; and (4) administering the follow-up practice questionnaires; and (5) analyzing the data collected. Each PBRN will receive financial support of up to $160,000 in total costs for this project, which will include funding of investigators, research support staff, equipment, supplies, and an honorarium to practices that participate in the pilot.

A.10. Assurance of Confidentiality

All personally identifiable information related to respondents or patients will be encrypted at the practice site. Each practice will be provided a sitename and password to access MEADERS. Respondents within each practice will be assigned a unique practice identifier, the key to which will not be available to anyone outside the practice. No patient names or medical record numbers will be entered into MEADERS although each practice will have the ability to create its own confidential system for linking individual reports to individual patients. Practices will be trained in physical security measures that are specifically designed to ensure that access to all confidential data is restricted to only those employees in the practice that possess both the need as well as the proper authorization to review the documentation.

This encryption system will allow individual practices the opportunity to follow up on events reported at their site, but will assure that all data entered into MEADERS is de-identified. System managers can access de-identified reports submitted by each practice through the sitenames and prepare practice-specific summaries of observed events which will be periodically fed back to the practices for use in quality improvement/patient safety activities.

The follow-up practice surveys will request no explicit information (e.g., name, address, zip code) that could be used to identify respondents. Survey results will be reported as aggregates that will not allow the identification of any specific practice.

AHRQ is acutely aware of the legal issues surrounding the reporting of medication-related events, especially those that involve clinician or staff error, related patient harm, or "near misses." As noted, MEADERS is a completely confidential system in that the information in the database will not contain personal identifiers from either the individual physician/staff reporting the incident, or the patient involved. While this safeguard should encourage frank reporting of medication errors and ADEs, persons seeking information about a particular event will be unable to identify any participant from the MEADERS database. In addition, the personally identifiable data encrypted and held confidential at the practice level is protected since AHRQ's authorizing language includes a provision declaring data collected as part of any agency-supported research project to be non-disclosable.

A.11. Questions of a Sensitive Nature

Questions included in MEADERS address actual or potential errors committed in the prescribing of medications for patients, which may not only be embarrassing to the clinician but may also raise liability concerns. As noted above, the MEADERS database

will not contain personal identifiers of patients or respondents and information encrypted at the practice level is legally protected from disclosure.

The follow-up survey includes potentially sensitive questions related to the demographics of the survey respondent (age, race, ethnicity), but respondents will not be requested to provide their name or any other identifying information.

A.12. Estimates of Annualized Burden Hours and Costs

In Exhibit 1, we provide estimates of the collection burden on participants for this effort. The data is based on a six month reporting period, and anticipated reporting frequencies are based on previous studies of patient error reporting estimating that providers might observe between 2-3 medication errors or adverse drug events within a six-month period.[11, 18, 19] Additionally, these studies indicate a reporting frequency for each category of office personnel to be: 69% from physicians, 24% from nurses, and 7% from non-clinical staff.[18] These frequencies are consistent with observations from pre-testing of the instrument in 3 practices. We expect between 2 and 5 physicians from each of 20 practices will participate in this study. To provide an estimate of the largest burden anticipated in the study, Exhibit 1 assumes the maximum number of physicians will participate from each practice and report 3 medication errors or adverse events during the time period. Exhibit 1 also includes consideration for the time the respondents need to fill out a follow-up survey to assess the use of and satisfaction with the electronic reporting system. This survey is a one time effort that should require approximately 15 minutes of the respondent's time.

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
Physician entry	265	0.083	21.99	$57.90	$1273.22
Physician follow-up survey	100	0.25	25	$57.90	$1447.50
Post-Testing Focus Groups	40	0.75	30	$57.90	$1737.00
Subtotal			76.99		$4457.72
Nurse entry	93	0.083	7.72	$27.35	$211.14
Nurse follow-up survey	35	0.25	8.75	$27.35	$239.31
Subtotal			16.47		$450.45
Non-clinical staff electronic entry of error	27	0.083	2.24	$12.58	$28.18
Non-clinical staff follow-up survey	10	0.25	2.5	$12.58	$31.45
Subtotal			4.74		$59.63
Total			**98.20**		**$7688.52**

*Based on a six month trial period of MEADER reporting system and estimates of reporting rates from the literature [11, 18, 19]
**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."

Total burden (hours): 98.20
Total imputed costs: $7688.52

A.13. Estimates of Annualized Respondent Capital and Maintenance Costs

Data collection for this study will not result in any additional capital, start-up, maintenance, or purchase costs to respondents or record keepers. Therefore, there is no burden to respondents other than that discussed in the previous section (A.12).

A.14. Estimates of Annualized Cost to the Government

The total cost to the government for this activity is estimated to be $640,000. ($160,000 per PBRN under contract to AHRQ)

A.15. Changes in Hour Burden

The only changes in the burden discussed above would result from higher than expected numbers of responses from physicians or staff in the practices.

A.16. Time Schedule, Publication and Analysis Plans

This section contains a detailed analysis plan for this study. In order to present a coherent plan, this section presents an overview of the study purpose and main research questions, reviews the data sources, discusses the types of results the study will produce, the statistical analyses that will be conducted, and the time schedule for completing the project, including publication of the results.

A.16.a. Purpose and Main Research Questions

The main purpose of this study is to collect process indicators that will let us know if primary care physicians and practice staff are able and willing to use a new internet-based system to report perceived medication errors and adverse drug events that occur in ambulatory practice. Follow-up surveys will assess the usefulness of the system as well as other practice- or clinician-related factors that appear to facilitate or impede its use.

Research Objective 1: To pilot test the voluntary use of an outpatient medication error and adverse drug event reporting system (MEADERS) by clinicians and staff in primary care practices.

- What are the rates of submitting reports (number of reports submitted daily or weekly in relation to the number of patients seen)?
- How widely do reporting rates vary by practice?
- Do responders complete all or only some fields of information requested in MEADERS?

- Which elements are most frequently completed and which most frequently left blank or incomplete?
- How often is the information provided describing medication errors complete enough to determine a probable or possible cause of the error?

Research Objective 2: To examine physician/staff and practice characteristics that facilitate or impede the adoption and use of MEADERS in participating primary care practices.

- What are the experiences of the practices in using the MEADERS reporting system?
- Are specific characteristics of physicians/staff or of practices related to rates of event reporting and rates of submitting completed reports?
- What are the reasons for not using MEADERS or for infrequent use?
- Are there specific medication errors or types of errors that physicians/staff do not report because they feel uncomfortable reporting in MEADERS?
- To what extent does the use of MEADERS place a burden on the practice?
- To what extent are summaries of reported events useful to practices in instituting changes to improve patient safety?

Research Objective 3: To determine the extent to which physicians and practice staff who report medication errors/ADEs to MEADERS opt to have their reports forwarded to the FDA's MedWatch.

- What percentages of reports in MEADERS database are submitted to MedWatch?
- Are specific errors/ADEs, or types of errors/ADEs, entered in MEADERS more or less likely to be reported to MedWatch?
- Are there specific physician/staff or practice-related factors that influence the likelihood of reporting errors/ADEs to MedWatch?

A.16.b. Data Sources

Physicians and staff in 20 primary care practices recruited to participate in this study by four primary care practice-base research networks (PBRNs) will be the source of all data collected. Participants will be trained in the use of, and security measures required for, an internet-based medication errors and adverse drug event reporting system (MEADERS – see attachment 1). They will be encouraged to enter into the system a description of all drug-related events they perceive to occur within the practice during the testing period. Practices will also provide documentation of the number of patients seen by participating physicians and office staff during the testing period. At the end of the testing period, participants will be asked to complete a questionnaire (attachment 2) that assesses their experiences and satisfaction with using the system, as well as barriers or facilitators to its use.

The AHRQ contractor (Indiana University) responsible for developing and refining MEADERS will monitor and maintain the internet-based system throughout the testing period and will be responsible for generating site-specific analyses of reported events that will be provided to participating practices for use in improving quality/patient safety.

A.16.c. Tabulations and Statistical Analysis

Research objective 1: explores whether clinicians and staff from a primary care setting will voluntarily use an electronic system to report medication errors and adverse drug events. Simple descriptive analyses will be used to determine practice-specific rates of reporting medication errors/ADEs. Chi-square distributions and t-tests will allow testing of inter-practice rate differences and variability. Content analysis, univariate frequency and means testing will be used to assess item-specific rates of completion.

Research objective 2: will utilize data from the follow-up survey and the reported events to examine individual and practice characteristics that facilitate or impede utilization of the system. Descriptive analyses of responses to questionnaires as well as qualitative analysis and marginal distributions of responses to open-ended questions will be conducted to examine factors that enable or hinder use of MEADERS.

Research objective 3: will calculate the proportion of events each practice enters into MEADERS that are also reported to MedWatch. Univariate frequency and means testing, as well as logistic regression, will be used to determine the likelihood of reporting specific errors/ADEs or types of errors/ADEs to MedWatch.

Exhibit 2. Key Research Questions

	Research Domain	Key Data Points	Type of Analysis	Questions that will be pursued
Research Objective 1	What is the use of the MEADERS by clinicians and staff in primary care settings?	▪ Inputs to the electronic MEADER ▪ Patterns of system's use	▪ Content analysis ▪ Univariate frequency and means ▪ Chi-square distributions and t-tests comparing groups ▪ ANOVA or hierarchical modeling techniques	▪ What are the rates of submitted reports? ▪ What is the variation in reporting across practices? ▪ How complete are the data collected across participating practices? ▪ How complete are the data across the categories of reporters? ▪ Are certain types of events more likely to be reported? ▪ How well do primary care providers understand what events should be reported? ▪ Do the comment fields produce adequate data to explore causes of errors?

	Research Domain	Key Data Points	Type of Analysis	Questions that will be pursued
Research Objective 2	Physicians/staff characteristics that facilitate or impede utilization of MEADERS?	▪ Respondents' opinions about the system's implementation ▪ Respondents' opinions of the utility of the system ▪ Patterns of system's use	▪ Content analysis ▪ Univariate frequency and means ▪ Chi-square distributions and t-tests comparing groups ▪ Ordinary least squares regression of survey data.	▪ Does the system fit into the workflow of a primary care practice? ▪ Are the reporters' opinions of the system related to their utilization? ▪ Why don't reporters use the system? ▪ What do the error reporting figures suggest regarding system acceptance and use? ▪ Are the practices summaries useful to participating providers?
Research Objective 3	What is the proportion of events in MEADERS that are also submitted to MedWatch?	▪ Inputs to the electronic MEADER ▪ Patterns of system's use	▪ Univariate frequency and means ▪ Chi-square distributions and t-tests comparing groups ▪ Logistic regression	▪ What is the frequency of errors in MEADERS that are also reported to MedWatch? ▪ What kinds of errors are reported to both systems?

A.16.d. Time Schedule and Publication Plan

EXHIBIT 3. TIMETABLE FOR DATA COLLECTION, ANALYSIS, AND PUBLICATION

Activity	*Expected Date of Completion*
PBRNs recruit practices, obtain IRB approval for study	1-2 months following OMB approval
Data Collection Period	2-8 months following OMB approval
Analyze Findings	8-9 months following OMB approval
Prepare Draft Reports	9-10 months following OMB approval
Final Report	10 months following OMB approval

A.17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

A.18. Exceptions to Certification

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

B.1. Respondent universe and sampling methods

Since the purpose of the study is to pilot test the use of an internet-based system for recording medication errors/ADEs in ambulatory practices, the information being collected consists mainly of process measures. While respondents will be a convenience sample of 20 primary care practices, they have been selected from a diverse group of four practice research networks in order to maximize variation in terms of geographic spread, urban/suburban/rural distribution, and patient demographics. We expect the number of events reported by these practices to be robust enough to provide meaningful data on medication errors and ADEs even if they are not necessarily generalizable to the universe of primary care practice.

B.2. Information Collection Procedures

Practices will enter information directly into a central database using practice-owned computers with high-speed internet connectivity via a HIPAA compliant, password-protected web-entry network. The website and database will be housed on a secure server that will be managed and maintained by an AHRQ contractor. Reports entered into the system can be linked only to the practice site where the event occurred. The identity of individual respondents and related patients will be identifiable only through codes, and only the practice will have the key to the codes. Investigators and staff of the four PBRNs from which the practices are recruited will provide training in the use of MEADERS and will help the practices develop procedures to ensure that the system is secure within their practices. Follow-up questionnaires to evaluate factors affecting the use of the system will later be administered directly to physicians and practice staff.

B.3. Methods to Maximize Response Rates

The four practice-based research networks (PBRNs) who are recruiting practices to participate in the pilot test are composed of 30-75 primary care practices from distinct regions of the country. Each PBRN has assured us that nearly 100% of their network practices have high-speed access to the internet, and that many of their practices have already expressed enthusiasm about participating in the MEADERS pilot testing. We therefore do not anticipate problems recruiting 20 practices. Measuring the extent to which the practices actually use MEADERS is the purpose of this pilot test.

B.4. Tests of Procedures

The AHRQ contractor that designed and developed MEADERS (Indiana University) beta-tested the web-based system in three primary care practices affiliated with Indiana University and used the results of that testing to further refine the instrument.

B.5. Statistical Consultants

Dan Gaylin. MPP
Executive Vice President for Health Research, NORC

Caitlin Oppenheimer, MPH
Senior Research Scientist, NORC

Benjamin Hamlin, MPH
Senior Research Analyst, NORC

William Tierney, MD, FACP
Division of General Internal Medicine and Geriatrics
Indiana University School of Medicine

Brenda Hudson
Operations Director for AHRQ PBRN Resource Center
Indiana University

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[1]

[2]ATTACHMENTS:

#1 -- Screen shots of MEADERS

#2 -- Follow-up Questionnaire

#3 -- List of Expert Panel Members

#4 – List of 4 PBRNs under contract

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