DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting Standards Subcommittee

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards.

Time and Date: February 27, 2013 9:30 a.m.–5:00 p.m. EST

Place: U.S. Department of Health and Human Services, HHS, 200 Independence Ave, SW., Room 705–A, Washington, DC 20201, (202) 690–7100.

Status: Open

Purpose: The purpose of the meeting is to learn about the current state of standards and operating rules for electronic claims attachments. In accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Affordable Care Act of 2010 (ACA), the Department of Health and Human Services (HHS) must adopt a standard and operating rules for electronic claims attachments. The National Committee on Vital Health Statistics is the public advisory body to the Secretary of HHS and will make recommendations based on information gleaned at the hearing. The Sub-Committee is interested in evaluating the innovations underway in industry as the convergence occurs between the clinical and administrative information exchanges, and industry moves from a claim-centric, transaction-based administrative information infrastructure to quality-oriented and outcomes-based reporting.

Contact Person for More Information: Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4245 or Lorraine Doo, lead staff for the Standards Subcommittee, NCVHS, Centers for Medicare and Medicaid Services, Office of E-Health Standards and Services, 7500 Security Boulevard, Baltimore, Maryland, 21244, telephone (410) 786–6597. Program information as well as summaries of meetings and a roster of committee members are available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/*, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: December 21, 2012.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2013–00011 Filed 1–4–13; 8:45 am]

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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 Health Information Technology in Practice Redesign: Impact of Health Information Technology on Workflow.'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on October 31st, 2012 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by February 6, 2013.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

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 email at *dorislefkowitz@AHRO.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Using Health Information Technology in Practice Redesign: Impact of Health Information Technology on Workflow

The Agency for Healthcare Research and Quality (AHRQ) is a lead Federal agency in developing and disseminating evidence and evidence-based tools on how health information technology (IT) can improve health care quality, safety, efficiency, and effectiveness.

Health IT has the potential to improve the quality, safety, efficiency, and effectiveness of care. In particular, health IT can aid health care professionals in improving care delivery by redesigning care processes to be more effective and efficient (e.g., engaging care settings in practice redesign). The use of health IT to support practice redesign requires a deep understanding of the interaction between health IT and workflow, ideally through a human factors and socio-technical framework. Unfortunately, these health IT-workflow interactions are poorly understood and the research to date has largely focused on large academic medical centers and large health maintenance organizations, while the impact of health IT on workflow in smaller, ambulatory care practices is not well studied.

To that end, AHRQ conducted an in-depth study of existing research and evidence in the area of the impact of health IT on workflow, its linkage to clinician adoption, and its links to the safety, quality, efficiency, and effectiveness of care delivery. However, most of the articles found were not focused directly on workflow, so the quality of evidence related to workflow change varied substantially. The majority of studies described research completed in large clinics affiliated with academic medical centers, health maintenance organizations or national health systems outside the U.S., limiting applicability to other settings, particularly small and medium-sized primary care and other ambulatory care settings. Also, most of the studies did not use a scientifically rigorous design. Finally, most of the literature did not include descriptions of the socio-technical context of health IT implementations and use, making it difficult to understand the role of potentially conflating or mediating factors such as training, technical support, and organizational culture.

These gaps and limitations of existing research study designs and findings related to health IT and workflow limit the relevance and quality of the available evidence for health care organizations wishing to effectively implement health IT systems to support

current work without negatively affecting existing workflow processes. The existing evidence is of equally limited utility to those organizations seeking to use health IT systems to support redesign of their ambulatory care settings.

The goal of the project is to understand the impact of implementing health IT-enabled care coordination on workflow within small community-based primary care clinics in various stages of practice redesign. The focus of this study is the interaction of health IT and care coordination workflow in the context of practice redesign. This study will focus on clinic staff caring for patients with diabetes within small primary care clinics to understand enablers and barriers to care coordination workflow through the use of health IT.

The study will be conducted over a 14-month period in six Vanderbilt University Medical Center (VUMC) affiliated-clinics that each have an electronic health record (EHR) but are in different phases of introducing the health IT component of a care coordination redesign program called My Health Team (MHT). MHT was launched at Vanderbilt University Medical Center to redesign ambulatory care delivery for patients with three chronic conditions (diabetes, hypertension, and congestive heart failure) through intensified patient engagement, dedicated care coordinators, and specific health IT tools to facilitate scalable chronic disease management. The health IT component of MHT, layered on a mature ERR, enables (1) diabetes, hypertension and congestive heart failure registries, (2) a shared view of the care plan for the patient among clinical staff, (3) alerts and reminders to track patients' acute care episodes, (4) closed-loop feedback of patient self-management through at-home physiological monitoring and two-way electronic clinical messaging (via the patient portal), and (5) frequent patient contact with coordinators in between physician visits by telephone and using a secure patient portal.

This study is intended to address existing gaps and generate findings of particular relevance to health IT and workflow by employing a mixed-methods, theoretically-grounded research design that focuses on the socio-technical factors in smaller, ambulatory care settings.

Combining this formal approach with iterative observations and analysis across six clinics for 14 months will generate a detailed understanding of changes in health IT-workflow interaction for each clinic over time, and across clinics in various implementation phases (pre-MHT, early-MHT, or mature-MHT). Each clinic will be observed at two time points: the first (time = 0 months) to capture baseline interactions, and the second (time = 12 months) to capture interactions later in adoption. Although each clinic will be observed over a period of 12 months, the total study period will span 14 months to allow for staggered observation windows for the clinics. All clinics are anticipated to exhibit changes to health IT-workflow interactions over time given that learning and efforts to streamline workflow at each practice are ongoing. The early-MHT clinics, engaged actively in practice redesign, will be observed at a third time point—midway between the first and second observation period—since more changes, and possibly more rapid changes in workflow and the use of health IT could occur. The 6-month interval between observation periods was chosen based on prior experience with MHT implementation in which many adoption changes occur during a 3–5 month period during practice redesign. Thus, in clinics anticipated to experience slower change, an observation period of one year is anticipated to allow capture of workflow patterns that have occurred; in fast-changing clinics, a 6-month observation interval will improve capture of key interactions.

This study is being conducted by AHRQ through its contractor, RTI International, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve the goals of this project the following activities will be carried out:

(1) Project orientation meeting—Researchers will hold an orientation meeting for clinic staff to introduce them to the study. Up to ten staff members at each clinic will be asked to participate in the orientation meetings. During the orientation meeting, research staff will explain the purpose of the study, provide an overview of the study schedule, explain processes for recruiting individual clinic staff to participate, and answer any questions that clinic staff might have.

(2) Direct observation by researchers of clinic staff performing care coordination activities with patients, caregivers, and providers to capture their workflow, health IT usage, and work processes. A total of 14 observation periods will take place across the six clinics. Each site will have an initial observation period that occurs over several weeks, with an estimated 60 hours of observation time per site. The two sites in the early MHT phase of implementation will also have a middle observation period (at 6 months), and all six sites will have a final observation period (at 12 months). The middle and final observation periods, which build on data gathered during the initial observation period, are shorter—approximately 30 hours of observation per site, because observations will be more targeted as a result of the previously collected contextual data. Observations will be recorded on the Direct Observation Field Notes Form. This data collection will not burden the clinic staff and is not included in the burden estimates in Exhibit 1.

(3) Artifact and spatial data collection—Artifacts such as paper notes or forms, or reminder postcards identified by researchers during direct observations as relevant to understanding workflow and health IT, will be collected.

Spatial data, such as still photographs of the workplace and/or objects in the workplace, will be collected to augment observation data. These will enable the researcher to capture spatial relationships and other dimensions, such as the proximity of work stations, exam rooms, and technology. For example, a health IT tool may include the functionality to print information to give to the patient, but if the printer is not conveniently located for the user, busy clinic staff may choose not to use this function. An image or drawing of this spatial relationship can be included in the data and will be coded in the data analysis phase. The choice of using a photograph or a drawing will be dependent upon the type of information that is needed to better understand the context of the workflow. For example, to capture the overall configuration of the workspace, photographs will be taken. When other information such as process flows are being captured, the observer will draw a sketch of that process. This may include the steps that a nurse takes to retrieve a patient chart, call the patient from the waiting room, escort the patient to a station where vital signs are measured, and escort them to an exam room.

Artifacts and spatial data will be used to enrich the understanding of the environment in which care coordination activities and health IT interact and will

add information that is important for modeling workflow. This data collection will not burden the clinic staff and is not included in the burden estimates in Exhibit 1.

(4) Semi-structured individual interviews and surveys with clinic staff to further understand their use of health information technology and work routines. During each observation period, up to six staff members at each clinic will be asked to participate in semi-structured interviews and to complete the Technology Assessment Model (TAM) survey. The interview will address up to five key topic areas: demographics; general experience with technology; work routines; interactions with computers in the work context; and strategies for dealing with unanticipated health IT or workflow challenges. The survey will be used to consistently assess the staff attitudes that may impact their experience of using health IT and adapting workflow to their needs.

(5) Semi-structured interviews and surveys with patients with diabetes to gather information from patients as participant-observers of clinical workflow and health IT, to understand the impact of work processes on their experience of care, and to identify enablers and barriers in clinic work processes from their perspective. During the initial observation period in each clinic, and during the final observation period in two of the clinics (early-MHT), eight patients with diabetes will be invited to participate in semi-structured interviews and to complete the Patient Activation Measure and Summary of Diabetes Self-Care Activities surveys (64 patients total). Since fewer changes are anticipated in the pre-MHT and mature-MHT clinics, patients will be interviewed at baseline only in these four clinics. Since the pre-MHT and mature-MHT clinics will not undergo changes in technology during the study period, it is anticipated that saturation of patient experiences and observations of workflow, technology use and interactions will occur during the initial observation period. Greater changes are anticipated at the early-MHT clinics as they adopt MHT, therefore, patient interviews will be conducted at these two clinics twice. The purpose of the patient interviews is to gather information from patients as participant-observers of clinical workflow and health IT, to understand the impact on their experience of care, and to identify enablers and barriers in work processes from their perspective. The interviews will address six key areas related to care coordination, including (1) general care experience; (2) patient workflow; (3) information needs; (4) barriers; (5) strategies; (6) evaluation. The Patient Activation Measure (PAM) and Summary of Diabetes Self-Care Activities (SDSCA) surveys will be used to understand patient motivation for self-care and the potential impact on care processes and workflows.

The focus of this research is anticipated to be relevant to many other settings in which health IT is used to support care coordination activities for diabetes and other chronic conditions. This focus is especially important given the cost and illness burden of diabetes. Information collected by the study will help researchers and practitioners better understand the impact of workflow and health IT in ambulatory care practices.

The lessons learned from this research may be used in a variety of ways: (1) To identify additional workflow components that ambulatory practices should consider when implementing health IT systems; (2) to identify issues to address in best practice guidelines health IT implementation; and (3) to identify issues for consideration in the design and evaluation of other health IT tools.

The study findings will be widely disseminated to health IT researchers and implementers via AHRQ's National Resource Center for Health IT Web site, email alerts, and conference presentations.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annual burden hours for each respondent's time to participate in this study.

A total of up to 60 persons will participate in the project orientation meeting across the six clinics (up to 10 per clinic), which will last up to 30 minutes.

The staff semi-structured interviews will be completed by a total of up to 36 persons across the six clinics (up to 6 per clinic) and requires one hour. Those same individuals will also be asked to complete Technology Acceptance Model surveys; each survey response is estimated to take 30 minutes. Clinic staff interviews and administration of surveys will take place at the clinics either two or three times. Staff interviews will be conducted twice at each of the pre-MHT and mature-MI–IT clinics, at the initial and final observation periods (eight total sets of interviews), for a total of up to 48 staff interviews. Staff interviews will be conducted three times at the two early-MHT clinics, during the initial, middle, and final observation periods, for up to 36 staff interviews across the two early-MHT clinics for all observation periods. In total, up to 84 interviews of clinic staff will be conducted with up to 36 individual staff for an average of 2.33 responses per staff member, as shown in Exhibit 1.

Up to 64 patients will be asked to participate in the patient-semi structured interview, which should take no longer than 1 hour. Those same patients will be asked to complete the Patient Activation Measures survey, which is estimated to take 12 minutes, and the Summary of Diabetes Self Care Activities survey, which should take no longer than 18 minutes. Patient interviews and surveys will take place at the clinics either once or twice. Up to eight patients will be interviewed during the initial observation period at each of the clinics for a total of 48 patient interviews across all six clinics. Up to 8 patients will be interviewed during the final observation period at each of the two early-MHT clinics, for a total of 16 patient interviews during the final observation period across the two early-MHT clinics. In total, up to 64 patient interviews and surveys will be conducted. The total annual burden is estimated to be 252 hours.

Exhibit 2 shows the estimated annual cost burden associated with the respondents' time to participate in this research. The total annual burden is estimated to be $6,670.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Maximum number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Project orientation meeting	60	1	30/60	30
Staff Semi-Structured Interviews	36	[a] 2.33	1	84
Technology Acceptance Model Survey	36	[a] 2.33	30/60	42
Patient Semi-Structured Interviews	64	1	1	64
Patient Activation Measures Survey	64	1	12/60	13

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Maximum number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Summary of Diabetes Self Care Activities Survey	64	1	18/60	19
Total	324	na	na	252

[a] This is an average based on the study design and the number of interviews that respondents will complete. Two thirds of respondents will participate in two interviews. One third will participate in three interviews.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Maximum number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Project orientation meeting	60	30	$34.80	$1,044
Staff Semi-Structured Interviews	36	84	32.03	2,691
Technology Acceptance Model Survey	36	42	32.03	1,345
Patient Semi-Structured Interviews	64	64	16.57	1,060
Patient Activation Measures Survey	64	13	16.57	215
Summary of Diabetes Self Care Activities Survey	64	19	16.57	315
	324	252	na	6,670

* Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States May 2011, ''U.S. Department of Labor, Bureau of Labor Statistics.'' For the project orientation meeting, the hourly rate is a weighted average of two physicians or surgeons, all other ($88.78), two registered nurses ($33.32), two licensed practical nurses ($19.79), two medical assistants ($13.99), one health care support worker other ($14.80), and one health care practitioners and technician other ($21.61). For the interviews and surveys with clinic staff, hourly wage is an average including one physician or surgeon, all other ($88.78), one registered nurse ($33.32), one licensed practical nurse ($19.79), one medical assistant ($13.99), one health care support worker other ($14.80), and one health care practitioners and technician other ($21.61). For patient interviews and surveys, median U.S. hourly wage was used.

Estimated Annual Costs to the Federal Government

The total cost of this study is $799,929 over a 36-month time period for an annualized cost of $266,643. Exhibit 3 provides a breakdown of the estimated total and average annual costs by category.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST *

Cost component	Total cost	Annualized cost
Development of Research Plan	$32,520	$10,840
Development of Analysis Plan	24,028	8,009
Compliance with PRA Requirements	21,252	7,084
Conduct Research Study	271,916	90,639
Conduct Data Analysis	279,009	93,003
Develop Final Report of Findings	62,237	20,746
Develop Presentation of Findings	28,670	9,557
Project Administration	58,976	19,659
Coordination with Other AHRQ Offices and Contractors	15,195	5,065
Ensure High Quality 508 Compliant Deliverables	6,125	2,042
Total	799,929	266,643

* Costs are fully loaded including overhead and G&A.

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 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 20, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–31591 Filed 1–4–13; 8:45 am]

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