SUPPORTING STATEMENT

Part A

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

Version: October 4th, 2012

Agency for Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that make the collection of information necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see http://www.ahrq.gov/hrqa99.pdf), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. research that develops and presents scientific evidence regarding all aspects of health care; and

2. the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

3. initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

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)[1]. 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.[2]

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.[3]

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 EHR, 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.

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 (Attachment A). 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 (Attachment B). This data collection

will not burden the clinic staff and is not included in the burden estimates in Section 12.

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 (see Attachment C).

   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 Section 12.

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 interview guide is provided as Attachment D. 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. The TAM survey is included as Attachment E.

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 interview guide is provided as Attachment F**.** 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 PAM and SDSCA are included as Attachments G and H**.**

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).

2. Purpose and Use of Information

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.[3,4] 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 Website, e-mail alerts, and conference presentations.

3. Use of Improved Information Technology

In this mixed methods study, direct observations by researchers will be captured electronically whenever possible, or transcribed immediately into an electronic format. Hour-long individual interviews with clinic staff or patients will be audio-recorded with the respondent's consent and transcribed. Staff or patient survey responses will be captured online directly or, if chosen by respondents, captured on paper and entered into a database by researchers.

4. Efforts to Identify Duplication

AHRQ has conducted a systematic review of the literature and conferred with internal and external experts on current and planned research on the topic of workflow and has found that rigorous research focused on evaluations of workflow in ambulatory care settings is lacking. From this work, AHRQ has concluded that data does not exist that specifically addresses the interaction of workflow and health IT in small and medium-sized ambulatory practices establishing care coordination programs. Furthermore, this study will use a rigorous data collection approach that has been described in the literature[5] but has not been systematically used to understand health IT and workflow in a socio-technical context.

5. Involvement of Small Entities

This study is designed to examine the interactions of health IT and workflow in six small primary care clinics that are independently operated. To minimize burden, any information that does not require a direct response from a clinic staff member or can be obtained from another source (e.g., clinic website or publicly available documents) will be collected before or after interactions with respondents.

Study participation is voluntary, and AHRQ has designed a participation schedule that is intended to minimize the impact of the study on the clinics. In observing general clinic activities, the observer will position him or herself in a location that is unobtrusive, yet in sight of a range of activities (e.g., against a wall with a view of both the check-in desk and the nurses' work area). When observing specific individuals, care will be taken to avoid interrupting the individual when he or she is cognitively engaged in work. Observations and individual interviews will be scheduled at times convenient for clinic staff.

The interview protocols consist of the minimum questions required for the study purposes. The one-hour interview duration for each participant will not be exceeded. The validated surveys used for this study are brief and may be declined by participants if they choose. The TAM consists of 24 items, the PAM consists of 13 items, and the SDSCA consists of 14 items.

The information requested from participants has been held to the minimum required for understanding workflow in small primary care settings.

6. Consequences if Information Collected Less Frequently

This is a one-time collection.

7. Special Circumstances

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

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on October 31st, 2012 for 60 days and again on January 7th, 2013 for 30 days (see Attachment I). One comment was received (see Attachment J for the comment and Attachment K for AHRQ's response).

8.b. Outside Consultations

AHRQ consulted with its research contractor, RTI, in developing the study protocol. Supporting Statements Parts A and B along with all the attachments were also shared with David Hunt from the Office of the National Coordinator for Health IT for review.

9. Payments/Gifts to Respondents

AHRQ will offer eligible clinic staff a gift of $25 to participate in individual semi-structured interviews and surveys. This amount is appropriate and necessary to gain cooperation from physicians and medical personnel who have demanding work schedules and significant competing demands. Furthermore, physicians are frequently approached to participate in research projects, making them more reluctant to participate. Response rates among physicians average about 10% lower than studies with the general population[6]. This gift amount is consistent with the gifts provided to clinicians under the project *Barriers to Meaningful Use in Medicaid*, OMB No. 0935-0186, Expiration Date 10/31/2013.

AHRQ will offer eligible patients a gift of $25 to participate in individual semi-structured interviews and surveys. This amount is appropriate to secure adequate participation of patients, as there are a limited number of patients who will be approached to participate in this study.

10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their replies under Section 944(c) of the Public Health Service Act. 42 U.S.C. 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied.

Information that can directly identify the respondent, such as his or her social security number will not be collected. AHRQ will collect the respondent's name, organizational affiliation, organizational phone number, and role. This information will be used for respondent tracking purposes or for clarification call backs. All electronic files will be password protected and accessible only from within a secured network. When not in use by project staff, all printed information or materials that could be used to identify participants in the study will be stored in locked cabinets that are accessible only to project team members.

All respondent involvement will be voluntary. Informed consent will be obtained from each respondent from each organization prior to participation. Respondents will be informed that: (1) the project team will not share their name, their organization's name, or copies of the observation notes, interview notes, or survey responses with anyone outside of the team; and (2) respondent comments may be included in reports, but will not be attributed to specific individuals or organizations.

All project team members are required to complete human subjects training coursework through Institutional Review Boards.

11. Questions of a Sensitive Nature

No questions of a sensitive nature will be asked. Further, during the introduction to the observations or interviews, respondents will be informed that their participation is voluntary and that they can refuse to answer any question. Verbal consent will be obtained for the observational portions of the study and written consent will be obtained from all respondents who participate in the semi-structured interviews and surveys (see Attachments L and M).

12. Estimates of Annualized Burden Hours and Costs

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-MHT 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	2.33[a]	1	84
Technology Acceptance Model Survey	36	2.33[a]	30/60	42
Patient Semi-Structured Interviews	64	1	1	64
Patient Activation Measures Survey	64	1	12/60	13
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

Form Name	Maximum Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
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.

13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Annualized Cost to the 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.

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

The anticipated schedule for this project is shown in Exhibit 4. Once clearance from the Office of Management and Budget is obtained, AHRQ will begin identifying appropriate respondents and scheduling and conducting data collection.

Study findings will be made publicly available via a final report which will be provided in PDF format for easy download from the AHRQ National Resource Center for Health IT Web site.

Exhibit 4. Anticipated Schedule

Activity	Estimated timeline following OMB clearance
Clinic engagement and recruitment	Months 1-3
First observation period (six clinics)	Months 4-6
Interim analysis and planning	Months 7-10
Second observation period (two clinics)	Month 11
Interim analysis and planning	Months 12-14
Third observation period (six clinics)	Months 15-17
Cumulative analysis of all data	Months 18-20
Completion of analysis and reporting	Months 21-24
Develop final report and presentation	Months 25-27
Publication of findings	Month 28

Analysis plans. Qualitative and quantitative data will be analyzed and results will be synthesized. Qualitative data will be analyzed in three phases: (1) open coding, (2) axial coding, and (3) workflow modeling. The data analysis activities will be guided by the study's theoretical framework which combines two compatible models that have been applied to workflow research: the Systems Engineering Initiative for Patient Safety (SIEPS) model[6-8] and the Workflow Elements Model (WEM).[9,10] Dedoose software will be used to store, code, and search the interview data for analysis. Survey data will be entered into the Research Electronic Data Capture (REDCap) tool and analyzed using SPSS (version 19.0). The analysis will focus on specific findings such as workflow differences, interactions between health IT and workflow, and illustrative examples from the research to support the study findings. Data will be used to capture clinic workflows that comprise care coordination, and the health IT attributes that support, create barriers for, or do not appear to have an impact on the care coordination workflows.

Quantitative analysis will include scoring of staff and patient survey responses. Descriptive statistics (e.g., mean, standard deviation, and median) will be calculated

using SPSS for respondents at each practice, adding context in interpreting staff and patient perceptions related to health IT. These data will support the qualitative assessment of diabetes coordination from the respondents' perspective and help to reveal issues that might relate to the use of health IT by staff. Quantitative and qualitative data will reinforce one another to help identify complementary themes, resolve conflicting findings, and provide rich detail to support conclusions about health IT–workflow interactions.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

Attachments:

Attachment A: Introduction for Orientation Meeting
Attachment B: Direct Observations Field Notes Form
Attachment C: Directions for Artifact and Spatial Data Collection
Attachment D: Staff Interview Guide
Attachment E: Technology Acceptance Model Survey
Attachment F: Patient Interview Guide
Attachment G: Patient Activation Measures Survey
Attachment H: Summary of Diabetes Self-Care Activities Survey
Attachment I: Federal Register Notice
Attachment J: Public Comment from TMA
Attachment K: AHRQs response to Public Comments
Attachment L: Consent Form to Participate in Clinic Staff Interview
Attachment M: Consent Form to Participate in Patient Interview
Attachment N: Letter to Patient

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