

SUPPORTING STATEMENT

Part B

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

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Agency for Healthcare Research and Quality (AHRQ)

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B. Collections of Information Employing Statistical Methods

1. Respondent universe and sampling methods

For this study, a purposive sampling strategy will be used to identify six primary care clinics that use the same electronic health record (EHR) system, and that are in specific stages of introducing the same health IT care coordination (CC) module as part of a care coordination practice redesign program called My Health Team (MHT). The six clinics will be selected from the ten Vanderbilt University Medical Center (VUMC) affiliated, community-based clinics that have implemented, or are implementing the MHT program. These clinics are located in the state of Tennessee, within a 40 mile radius of VUMC. Clinics will be sampled to generate a detailed understanding of changes in health IT-workflow interaction for each clinic over time, for clinics that are at different stages of implementing practice redesign. Therefore, two clinics (pre-MHT) will not have the MHT program adopted during the study period; two clinics (mature-MHT) will have already adopted the MHT program when the study begins; and two clinics (early-MHT) will be in the process of adopting the MHT program during the 12-month observation period for each clinic.

Study findings cannot be statistically generalized to the respondent universe (e.g. all clinics, or all clinic staff, or all patients with diabetes). However, findings will be relevant to other settings in which health IT is used to support care coordination activities for diabetes and other chronic conditions. In considering the multiple avenues of analysis (clinic, health IT system, workflows, and interactions between individuals and technology) certain aspects may be relevant to other settings and technologies based on similarities in health IT tool function, overall workflow patterns, and interactions. The study design allows for comparisons within clinics (multiple time points) and comparisons between clinics (multiple clinics). This design provides in-depth information at different points in time, an advantage over a cross-sectional study (frozen in time), or a simple before-after study (where the stability of findings could not be assessed).¹ The primary unit of analysis is the clinic—specifically, the usefulness of health IT in supporting care coordination workflow. Data collection and analysis span multiple data types to create a rich picture of similarities and differences among clinic sites at various implementation times.

Each clinic site includes two to four physicians working with nurses (registered or licensed practical nurses), clinical assistants, office staff, and for MHT-implemented clinics, a registered nurse care coordinator.

Once clinics are selected to participate, care teams and patients of those care teams will also be invited to participate. Each clinic has two to four physician-led care teams. Of these, one care team will be selected to participate in each clinic. The selection will be based on convenience to align with the observation schedule. For example, if a physician

is on vacation during the observation period, he/she would not be included in the study. Since this study focuses on workflows, health IT usage, and interactions between and among people and technology, studying a single, complete care team will yield the richest information about these factors. The composition of the care team will likely vary from site to site based on how each clinic is staffed. Patients with diabetes who are enrolled in MHT and cared for by the care team will be eligible to participate in the study. A conservative estimate is that a care team would see two such eligible patients a day. The 60 hour observation period will be conducted over a period of eight to ten days; during this time, the care team will likely see at least 16-20 eligible patients. These individuals will be approached to participate; the first eight eligible patients to enroll will be included in the sample. Across the clinics, care teams, and patients, it is anticipated that saturation will be reached with regard to the knowledge needed to understand and describe workflow interactions.

2. Information Collection Procedures

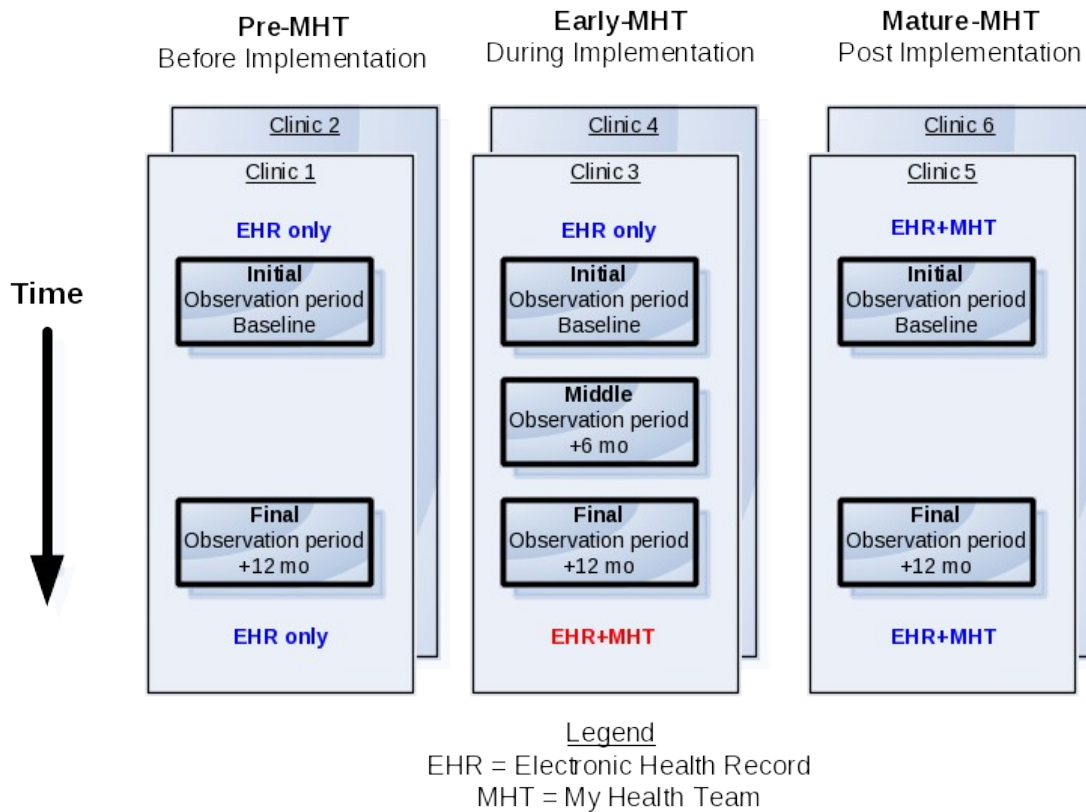
Participant Recruitment. This study will recruit six clinics to participate in the study. To enroll each participating clinic, a research investigator will contact the clinic leader at each clinic site to confirm interest in participating and the site's MHT implementation status (e.g., pre-MHT, early-MHT, or mature-MHT). The first data collection activity will include observations of workflows and health IT use in each clinic. Clinic leaders will be provided with detailed information about the project that can be shared with clinic staff prior to the scheduling of observation periods. Research staff will then work with each clinic's leader(s) to schedule observation periods and an orientation meeting, which will last up to 30 minutes, for clinic staff to introduce them to the study. 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.

The recruitment and enrollment of clinic staff will take place at the start of each observation period. Clinic staff will be identified by noting the physician, clinical assistant, nurse (RN or LPN), and office staff work with patients who are enrolled in the MHT program for the site. In non-MHT sites, the research team will identify a representative care team. Additional staff such as a nurse practitioner, physician assistant, or care coordinator will be interviewed if they participate in care coordination activities (as identified by the clinic manager). Some staff variability is expected (e.g., a job may be split between two individuals, requiring an additional interview). Once care teams have been identified, research staff will approach the clinic staff directly and ask them to participate in the study. In order to be included in the study, all members of the care team must agree to participate. After the care team has agreed to participate, research staff will schedule interviews with each care team member at a convenient time. To the greatest extent possible, these interviews will be conducted on the same day, or within as narrow a time window as possible. Prior to each interview, the research team will review the consent form (**Attachment L**) with clinic staff before they agree to participate, and, if they consent, enroll them in the study.

Patients with diabetes who are scheduled to be seen by the care teams during the study period and are identified for inclusion will be approached to participate in the study. In order to be eligible, patients must be undergoing treatment for diabetes at the clinic, and be eligible to participate in (pre-MHT sites) or be enrolled in MHT (early or mature-MHT sites). Enrollment in MHT requires referral and approval by the patient's physician. Patients will first receive a letter (**Attachment N**) informing them of the study and alerting them that they may be asked to participate. During the observation periods, research staff will approach patients cared for by each care team and ask them to participate. Research staff will explain the purpose of the study and invite the patient to participate. If the patient accepts the invitation, the research team will review the consent form with them (**Attachment M**) and, if consent is received, the patient will be enrolled in the study.

Each clinic will be engaged in data collection for 12 months, with observations, and interviews and surveys taking place on a mutually agreed upon schedule. Each site will have two rounds of data collection (initial and final observation periods); the two clinics undergoing MHT implementation will have a third round of data collection during the implementation (middle observation period). Researchers will stagger the initial observation period to occur during months 1, 2, or 3 of the study, and will schedule the final observation period to occur during months 12, 13, or 14 of the study. To the greatest extent possible, pairs of clinics will begin observation periods at the same time (e.g., both early-MHT clinics will be observed at months 2 and 13). The observation periods across the six clinics are illustrated in Figure 1.

Figure 1. Study Design Overview



3. Methods to Maximize Response Rates

Potential clinics have already expressed interest participating in the proposed study, which is expected to help maximize participation. Respondent organizations and individuals are not being selected via probability-based sampling methods. Data analysis is not being conducted using statistical methods based on specific sample size or power estimates, so a “response rate” discussion does not apply in the same way it would otherwise. However, the section below provides additional clarification of recruitment processes and strategies that will be employed to secure participation.

To conduct direct observations of care coordination, study staff will secure site agreement to participate in advance. In addition to scheduling observations in coordination with clinic leaders and holding an orientation session at each clinic as described under Section 2 (Information Collection Procedures: Participant Recruitment) above, clinic leaders will assist in promoting the study to their staff to help secure participation.

Since there will be multiple observation days, interviews will be scheduled at times convenient for clinic staff. Clinic staff will have the option of completing the TAM survey immediately after the interview or completing it at a convenient time afterwards. Clinic staff who choose to complete the survey electronically will receive e-mail

reminders seven days after the initial e-mail invitation, then every three days thereafter. For each observation period, the survey tool will remain open to complete unfinished surveys; non-responders identified at the end of the respective observation period will be approached one final time by the research team to complete a paper version of the survey.

Patients eligible to participate in the MHT program will be identified in advance of a scheduled appointment using software tools that examine problem lists, hypoglycemic medications, and previous visit diagnosis codes. Research staff will contact eligible patients by letter (**Attachment N**), in advance of their appointment, to alert them about the opportunity to participate in the study's semi-structured interviews and surveys, and then will recruit patients onsite and in person with the assent and introduction of their treating physicians.

For all components of the study, expectations (e.g., time limits and level of effort) will be clearly stated so that participants have a clear understanding of what their participation entails. Every effort will be made to ensure that interviews and surveys are scheduled at times convenient to participants.

4. Tests of Procedures

The surveys that will be used in this study (the Technology Acceptance Model [TAM], Patient Activation Measures [PAM], and Summary of Diabetes Self-Care Activities [SDSCA]) are all established, validated instruments and do not require pre-testing.

However, the TAM will be modified to include three additional questions tailored specifically to care coordination activities and staff experiences with the care coordination model, given research findings suggesting that tailoring of the TAM to work context is important.² The goal of collecting this data for clinic physicians and staff is to assess in a consistent way the staff attitudes that may impact their experience of using health IT and adapting workflow to their needs.

5. Statistical Consultants

This mixed-methods study will primarily employ qualitative methods for data collection and analysis. Project co-investigators Drs. Laurie Novak, Kim Unertl, and Richard Holden are experts on these methods.

Survey results will be summarized using descriptive statistics and, therefore, no statistical consultants were contacted.

AHRQ's contractor, RTI, and RTI's partner organization, Vanderbilt University, will be responsible for overseeing the recruitment of participants, conducting all of the data collection, and analyzing and reporting the findings. The project director is Jonathan Wald, MD. Dr. Wald can be reached by phone at 781-733-8116 or by email at

jwald@rti.org. Dr. Neeraja Peterson will oversee the data collection and analysis processes. Dr. Peterson can be reached by phone at 615-936-3214 and by email at neeraja.peterson@vanderbilt.edu.

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