AHRQ Final Report

Improving Laboratory Monitoring in Community Practices: A Randomized Trial

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Dates of Project: 9/1/2007 – 2/29/2012

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Acknowledgement of Agency Support: This work was supported by a grant from the Agency of Healthcare Research and Quality (Grant Number: R18HS017201).

Structured Abstract

Purpose: To evaluate in a randomized controlled trial the effects of point-of-care alerts on laboratory monitoring for commonly used medications in ambulatory care; and to evaluate the use of a web-based patient portal to communicate laboratory results.

Scope: The use of laboratory testing to ensure the safety and effectiveness of drug therapy and the management of abnormal results of laboratory and diagnostic testing have been increasingly recognized as an important area for improving patient safety in ambulatory care.

Methods: We designed and implemented computerized point-of-care laboratory monitoring alerts in a commercial EHR for use in New York community-based practices. Use of the patient portal was evaluated in practices in Massachusetts and Maryland. Data on medications, laboratory tests, and patient portal use were collected through the EHR vendor system to measure adherence to laboratory monitoring recommendations and time to test result notification.

Results: Preliminary data analysis showed that, for intervention practices, appropriate monitoring of drug therapy decreased from 66.9% in the baseline period to 41.6% in the intervention period, compared to 57.6% and 36.9%, respectively, for control practices. As this result is unexpected, we are currently conducting additional data quality checks to ensure that these results are valid before proceeding with additional analyses. In the patient portal study, data suggest that, over time, the proportion of results posted to a portal drops (56% to 50%), proportion of patients logging in drops (40% to 31%), but patients log in more quickly following the posting of a result (7.6 to 3.0 days).

Key Words: Laboratory Monitoring, Results Management, Patient Portal, Alert Development

Purpose

Objectives of Study

Medication errors and preventable adverse drug events occur commonly among elderly patients in the ambulatory setting and constitute an important target for patient safety and quality improvement. Laboratory monitoring – the use of laboratory testing to ensure the safety and effectiveness of drug therapy – and the management of abnormal results of laboratory and diagnostic testing have been increasingly recognized as an important area for improving patient safety in ambulatory care. In addition, the management of abnormal laboratory test results has emerged as an important issue for physicians caring for the growing population of older patients. Recent attention has turned to the use of health information technology (HIT) to improve laboratory monitoring and results management. Systems for improving results management have been developed and implemented in large delivery systems, but most electronic health records (EHRs) in community-based office practices do not yet have this functionality.

The Primary Care Information Project (PCIP) of New York under the umbrella of Take Care New York provided an important opportunity to study HIT implementation in a community setting. In this group of small-to-medium sized office practices in both urban and suburban regions of New York, we conducted a randomized controlled trial (RCT) of computerized point-of-care alerts in the EHR to prevent errors related to laboratory monitoring at the initiation and continuation of drug therapy. In addition, we evaluated in three community-based practices in Massachusetts and Washington, D.C. delays associated with communicating laboratory test results and the use of patient portals to communicate test results. The study had the following specific aims:

Aim 1. The identification of barriers to and facilitators of laboratory monitoring and the timely follow-up of abnormal results. This aim was achieved through focus group sessions with clinicians.

Aim 2. The design, implementation and evaluation of clinical decision support (point-of-care alerts) for laboratory monitoring in a widely used, commercially available EHR that addresses the barriers to and facilitators of laboratory monitoring.

- **Aim 2a.** Measured baseline rates of laboratory monitoring and determined the correlates of inadequate monitoring for a variety of medications.
- **Aim 2b.** Developed alerts to improve laboratory monitoring at the initiation of drug therapy.
- **Aim 2c.** Developed alerts to improve laboratory monitoring for ongoing drug therapy.
- **Aim 2d.** Evaluated the effects of point-of-care alerts on laboratory monitoring at the initiation of therapy and for ongoing drug therapy in ambulatory care in a randomized controlled trial.

Aim 3. Evaluated a patient portal results management system for the timely handling of laboratory test results in ambulatory care.

- **Aim 3a.** Measured at baseline the delays associated with managing laboratory test results in ambulatory care and the factors that correlate with delays.
- **Aim 3b**. Evaluated in a quasi-experimental study the effects of a patient portal-based results management system on the timely management of test results in community-based ambulatory care practices.

Aim 4. Developed a detailed dissemination guide that will be made widely available to other practices and communities interested in implementing the same or similar interventions.

Scope

Background

Medication errors and preventable adverse drug events are an important target for patient safety and quality improvement. Studies by Gandhi et al have shown that as many as 25% of patients in the ambulatory care setting experience adverse drug events (ADEs) annually. In one Gandhi study, out of 661 patients who received care at one of four ambulatory practices in the Boston, there were a total of 181 ADEs, 39% of which were determined to be preventable or ameliorable. The Institute of Medicine report "Prevention of Medication Errors," highlights the problem of medication errors and adverse drug events in the outpatient setting and estimates that at least 1.5 million preventable ADEs occur across care settings in the United States each year. The report recommends further development of HIT to improve health care quality and safety by preventing ADEs. In addition to errors in medication ordering, dispensing, or administration, patients may be at risk for ADEs as a result of inadequate laboratory monitoring of medications requiring periodic laboratory tests to assess efficacy or toxicity.

Many medications require laboratory measurement at initial prescription and during ongoing monitoring of a patient's drug therapy. However, though an identified need for monitoring has been acknowledged, few empirical data exist regarding the specific frequency with which many medications should be monitored. Furthermore, while monitoring is recommended, only modest evidence exists to demonstrate that monitoring is associated with a decrease in the adverse drug event rate. This may be due, in part, to alert design. Alerts are more effective when they occur only when the action is needed and if they require some acknowledgement by the clinician. Therefore, there has been increasing interest in using HIT to improve laboratory monitoring.

Interventions to improve the follow-up of laboratory results are also urgently needed, as research has revealed high levels of variability and limited standardization in test result management systems both among and within physician practices. HIT to assist in results management may help ameliorate the failure to follow up on abnormal diagnostic test results in outpatient medicine. When test results are not acted on in a timely and appropriate manner, patients' safety and satisfaction may be jeopardized. Prior research indicates that many physicians employ largely deficient systems to manage test results: 36% of clinicians do not routinely inform their patients about test results, and only 23% of primary care physicians have a reliable method to ensure that abnormal test results receive the appropriate follow-up.

An important issue related to clinical decision support (CDS) is the fact that use of these tools has not been adequately tested in community settings. Most studies of their effectiveness have been concentrated in hospital-affiliated practices and integrated delivery systems, which are much more centralized and better resourced for quality improvement activities than most primary care practices in the United States. Systems for improving results management have also been developed and implemented in large delivery systems, but most electronic health records in community-based office practices do not yet have this functionality. There is an urgent need to implement and evaluate CDS systems in the practices of physicians in the community, outside the extensive HIT infrastructure of academic medical centers. In addition, few studies have tested the effectiveness of CDS within multifunctional, commercially developed systems. Developing and implementing computerized CDS for community-based ambulatory care offices to improve laboratory monitoring and to evaluate the use of a patient portal in results management will address important gaps in the existing literature of HIT implementation.

Our investigative team from Boston VA Healthcare and Harvard Medical School, led by Dr. Simon, and Brigham and Women's Hospital (BWH), led by Dr. Bates, has considerable expertise in the areas of ambulatory quality of care and patient safety, especially as they relate to the safe and effective use of medications and specifically the role of laboratory monitoring. They also have expertise in evaluating HIT, particularly the use of EHRs, computerized order entry and computerized clinical decision support; and the development, implementation and evaluation of interventions to improve quality of ambulatory care, including multiple community-based cluster-randomized controlled trials of educational and HIT interventions. This broad range of experience and expertise has allowed the team to conduct a large, cluster-RCT to improve the use of laboratory monitoring and to evaluate patient portal use in results management to improve safety and quality in ambulatory care.

Settings

Laboratory Monitoring: This evaluation was performed in small to medium sized primary care office practices associated with the demonstration project of the Primary Care Information Project (PCIP) of New York, under the umbrella of Take Care New York (TCNY). TCNY has successfully recruited over 2,500 providers from numerous private medical practices, community health centers, and hospitals to use the prevention-oriented Take Care New York version of eClinicalWorks, a commercially available EHR.

Patient Portal Results Management: This evaluation was performed in clinicians' office practices that had adopted the Patient Portal feature of eClinicalWorks. We worked with eClinicalWorks to identify community-based primary care practices meeting eligibility criteria both within and beyond Massachusetts.

Study Population and Participants

*Laboratory Monitoring***:** We recruited practices from those participating in the Primary Care Information Project (PCIP) of New York, under the umbrella of Take Care New York (TCNY). Our sample was restricted to primary care practices who had adopted eClinicalWorks version 8.0100 which has clinical decision support alert capability. This was done because implementing the laboratory monitoring decision support required new development by the vendor and because primary care clinicians prescribe the most medications and order the most tests. Practices also had to have electronic laboratory data exchange in which the practice both ordered and received labs electronically.

We identified approximately 100 medical practices participating in TCNY that reported using the specified system of eClinicalWorks and invited them via e-mail, fax and telephone to consider participation in the research study. We contacted physicians and/or practice managers from approximately 40 practices and identified 11 eligible practices meeting study criteria and willing to participate. We provided study information by telephone, fax and e-mail, and, the Principal Investigator visited each practice to obtain informed consent for participation. Practices were randomly assigned to control or intervention groups. Out of the 11 practices, 6 practices were randomly assigned as intervention practices, while 5 practices were assigned as control practices. These practices represented 17 clinicians (see Table 1).

Table 1. Eleven control and intervention practices using eClinicalWorks version 8.0100				
	Control or Intervention	State	Practice Type	No. of Physicians
Practice 1	Intervention	NY	Primary Care	5
Practice 2	Intervention	NY	Primary Care	1
Practice 3	Control	NY	Primary Care	1
Practice 4	Control	NY	Primary Care	1
Practice 5	Control	NY	Primary Care	1
Practice 6	Control	NY	Primary Care	1
Practice 7	Intervention	NY	Primary Care	1
Practice 8	Intervention	NY	Primary Care	1
Practice 9	Control	NY	Primary Care	1
Practice 10	Intervention	NY	Primary Care	2
Practice 11	Intervention	NY	Primary Care	2

Results Management: This evaluation was performed in primary care clinicians' office practices that had adopted the Patient Portal feature of eClinicalWorks and had been using it for at least 6 months. Three practices were enrolled that were using Patient Portal to provide laboratory results to patients. For practices selected, we recruited individual clinicians to participate by mail and/or in person to obtain a signed informed consent.

The characteristics of the three patient portal study practices are shown in Table 2.

Table 2. Three primary care practices using Patient Portal in eClinicalWorks			
	State	Practice Type	No. of Physicians
Practice A	MA	Primary Care	6
Practice B	Washington, DC	Primary Care	5
Practice C	MA	Primary Care	2

Methods

Study Design

Our laboratory monitoring intervention detects potential omissions of recommended laboratory monitoring and intervenes to prevent the errors at the time of medication prescribing. The results management intervention evaluated a comprehensive patient-portal based result management system in the study practices, measuring the effects of the system on timely receipt of laboratory test results and on ensuring adequate and timely follow-up of abnormal results.

Aim 1: Barriers to, and facilitators of, laboratory monitoring and results management

In understanding the barriers to and facilitators of laboratory monitoring and results management among community-based primary care clinicians, we used qualitative methods to inform the evaluation and shape the clinical decision support tool that we implemented as an intervention. Qualitative research is particularly appropriate for the development of interventions to improve quality of care and patient safety in the ambulatory care setting, because multiple barriers often co-exist and interventions must be tailored to the needs of the practicing clinicians to maximize effectiveness.

We conducted a focus group to characterize the barriers to and facilitators of laboratory monitoring and of timely results management. A secondary goal was to solicit physicians' guidance on prioritizing the medications for which laboratory monitoring alerts were generated and the laboratory tests for which the results management program will provide decision support. Six focus group interviews and one individual interview with primary care physicians and specialists were conducted from three different communities in Massachusetts who were all using an EHR from the same vendor and were participating in a pilot project of EHR implementation in the state. The focus groups and interview were held in community health care settings convenient to the participants, were moderated by a physician-researcher (PI, Dr. Simon), and lasted approximately 2 hours. Each session was audio recorded, and the recordings were professionally transcribed. The study protocol was approved by the Harvard Pilgrim Health Care Human Studies Committee. Participants received a $150 gift card and a meal.

Investigators developed a Focus Group Discussion (FGD) Moderator's Guide and a member of our research team, a trained anthropologist, conducted the focus groups. Our Advisory Panel, consisting of experienced researchers in our study areas, assisted the investigators in choosing the final set of topics to be included in the FGD Moderator's Guide. The content of the FGDs helped to build upon on our prior experience in conducting qualitative research studies in health care. The FGD Moderator's Guide and the FGDs themselves began with a series of warm-up questions to explore physicians' current practices regarding laboratory monitoring and management of laboratory test results. Physicians were asked to characterize the importance they attribute to laboratory monitoring and timely follow up of abnormal laboratory results, and the moderator encouraged them to describe their workflow for these activities and, particularly, to articulate the ease or difficulty involved in carrying out necessary steps. Additionally, the moderator shared with FGD participants a list of proposed medications that generated point-of-care alerts regarding laboratory monitoring and helped seek participants' input on which alerts have the greatest significance to their practice and which alerts, if any, should not be included in the study because of clinical irrelevance or inappropriateness. Similarly, the moderator provided participants with a list of laboratory tests and ranges of normal and abnormal results that will

trigger varying degrees of notification in the results management system, seeking physicians' input on which tests and results should have highest priority and which, if any, should be excluded from decision support. As for the laboratory monitoring alerts, any laboratory tests considered for exclusion were vetted by the Advisory Panel.

We performed a content analysis of the transcribed physician FGDs, incorporating the principles of the immersion-crystallization method. This qualitative approach consists of repeated cycles of immersion into the collected data with subsequent emergence, after reflection, of an intuitive crystallization of the dominant themes. We looked for themes and issues common to physicians across communities and identified areas of concordance and discordance in their views. Through iterative discussions among the study team, these qualitative findings were used to enrich and modify the alerts for laboratory monitoring and inform the evaluation of the patient portal results management system.

Aim 2: Design, implement and evaluate clinical decision support for laboratory monitoring

The laboratory monitoring point-of-care alerts were designed in eClinicalWorks to be adaptable to other EHRs certified by the Certification Commission for Healthcare Information Technology (CCHIT). In the development of eClinicalWorks laboratory monitoring alerts all standards set by the American National Standards Institute (ANSI) and the Healthcare Information Technology Standards Panel (HITSP) where they applied were followed.

To design the alerts, we first derived a starter list of medications requiring laboratory testing at initiation of therapy and for ongoing treatment from review of the literature and consultation with experts. They were reviewed during the focus group discussions and vetted by the Advisory Panel. The design and development process was iterative and involved input from the focus groups, research team, EHR vendor staff, and the Advisory Panel. Through this iterative process, we met with a dedicated clinical team to define the clinical parameters for each of the alerts. We used both the existing literature, expert opinions, and information obtained on our focus groups to compile our final list of intervention medications and laboratory monitoring alerts. Appropriate functioning of the system as designed was carefully tested from both the technical and clinical side during development. Pilot testing allowed testing of the system in the real world before rolling it out for the randomized controlled trial. Adequate time was provided to make programming changes as were needed after the pilot.

To roll out the HIT intervention, we met with clinicians in each practice. For practices with more than one clinician, we identified a peer leader and targeted our roll out to that clinician, though all clinicians were invited to participate. We demonstrated the functionality of the laboratory monitoring alert using paper-based representations (i.e., "wireframes") and text descriptions. We highlighted the features of the new alert that were in common with the existing system. We allowed clinicians to ask questions. Following the in-person meetings, Dr. Simon developed and moderated an online video webinar to demonstrate the use of the actual intervention alerts. Dr. Simon demonstrated how the alerts are triggered, how they are "satisfied", and multiple ways of navigating to and through them.

After completing the training with each of the practices, the system for laboratory monitoring alerts was implemented via a combination of remote and on-site processes. Because the laboratory monitoring alerts would only function in the EHR if a practice's lab test names were linked to laboratory LOINC codes, Dr. Simon visited each practice to do this backend mapping. In addition, Dr. Simon checked back with the practice 2-4 weeks following deployment of the

new program to ensure it was functioning as intended and to answer any questions the clinicians may have.

Aim 3. Evaluate a patient portal results management system

To evaluate the patient-portal based results management system, we conducted a retrospective pre- and post-intervention patient notification of test results in three practices that had been using the patient portal at least 6 months, focusing on the effects of the results management system on ensuring adequate and timely follow-up of abnormal laboratory test results. As these practices were already using the patient portal and data could be extracted from eClinicalWorks, the practices involvement was limited to consenting for their data to be reviewed, a brief practice demographic survey, and having a research staff member onsite to conduct a chart review. This chart review was done on a sample of records at each practice to assess the validity of the automated data collection. For each practice, we defined 3 time periods: 1) 6 months immediately prior to portal adoption ("pre-adoption"); 2) 6 months beginning four months after portal activation ("early post-adoption"); and 3) 6 months from 6/1/10 to 12/1/11 ("late post-adoption").

Aim 4: Develop a detailed Dissemination Guide

To create the Dissemination Guide, products developed for the Focus Groups and in support of designing, implementing, and evaluating laboratory monitoring alerts, and in the evaluation of the patient-portal results management have been compiled. In addition, lessons learned through the process and advice for applying the processes and products to other settings and other software rollouts will be included.

Data Sources/Collection

The principal data source for this project is the electronic health records and the patient portals of the participating practices. Automated data extracts will be obtained from eClinicalWorks for participating physicians. In addition, for patient portal results management, a sample of electronic records was reviewed onsite using a chart abstraction form. Paper-based demographic and laboratory monitoring system experience surveys were also collected from the participating practices.

In addition to system medication and laboratory data, we collected patient demographic characteristics (age, sex, and socioeconomic status, based on the geo-coding) and clinical characteristics, including co-morbid conditions (based on diagnoses and medication use), prescription medication use, and number of office visits.

For the laboratory monitoring analysis, we extracted automated data related to medication and date prescribed, laboratory tests and the date ordered, and alert audit data to determine if alerts were snoozed and why. For patient portal results management analysis, we extracted automated data related to laboratory test results: date result delivered to the EHR; date result reviewed by physician; whether result was posted to the portal; date of posting; and patient log-in date. We also extracted variables to indicate patient notification of test results via other routes (e.g., telephone encounter or letter).

Interventions

Laboratory Monitoring

The general principle of the laboratory monitoring alerts in this intervention was to inform the clinician when laboratory testing is indicated to monitor a medication that is being prescribed. Whenever one of the target medications was ordered, the computer checked the medication list to determine if it was a new prescription (defined as no evidence of prior active prescription in the preceding 12 months) or a renewal. If the medication order is a new prescription, the computer will look back in the laboratory results fields for evidence of completion of the indicated laboratory test(s) in the preceding 365 days. The alert will only occur if the indicated laboratory testing has not been completed in the preceding 365-day period. If the computer does identify an active prescription for the target medication, it will then look back for the presence of the indicated laboratory test as with the new prescriptions; the difference in the algorithm for ongoing therapy is that the look-back period for the presence of a laboratory result depends on the specific target medication in question. Alerts in this intervention arise at the time a target medication is ordered, whether upon initiation of therapy or upon renewing an existing prescription. The alert is presented in a list of clinical decision support items that require attention in the right panel of the screen. Any unaddressed alerts are also presented to the clinician when they complete the patient encounter and proceed through the steps of ordering, assigning diagnosis, and level of service codes.

The intervention included both real-time medication alerts, occurring at the time of e-prescribing during a visit, as well as 'proactive alerts" that are present and can be viewed when the clinician opens the record at the beginning of each encounter when a patient is receiving one of the study medications but does not have the recommended laboratory tests ordered or resulted in the record. Baseline alerts only occur one time at the point of the initial prescription. Ongoing alerts which arise once a medication requiring laboratory monitoring is in the record, occur on an ongoing basis until the alert is satisfied, suppressed by the physician, or "snoozed" for 30 days due to having an appropriate laboratory order in the record.

In addition, the clinical team developed a prioritization scheme for the alerts, such that a physician will not be alerted multiple times for the same laboratory test. Therefore, we prioritized all of the medications needing overlapping laboratory test so that the medication that is most important to monitor, determined by focus group interviews and our clinical advisory team, is listed as associated with the alert.

Patient Portal Results Management

Patient Portal is a feature of the eClinicalWorks' EHR that allows patients to view and manage their health data. Among other health information, laboratory results are organized and displayed to the patient through the Portal. After results are provided to the physicians' EHR, the physician must review results and, once reviewed, clicks a box that marks the results as reviewed and then clicks if the physician wishes the results to be released to the Patient Portal for the patient's review. At the same time result information is sent to the patient portal, the EHR generates a message to the patient's internet e-mail account, notifying him that there is new activity on the Portal that the patient can log-in and view. Physicians can request an electronic receipt indicating that a patient opened the Portal's "notification email". Furthermore, the patient can email the physician through the Portal regarding laboratory result data, follow-up appointments, and additional laboratory testing.

Measures

Laboratory Monitoring

For *medication baseline* laboratory monitoring, the **primary outcome measure** is the ratio of monitoring errors to the total number of target drug prescriptions. An error is defined as failure to perform indicated laboratory monitoring during the time period from 365 days prior to the index prescription of the drug of interest until 14 days afterwards. An index prescription will be defined as no active prescription for at least the previous 365 days.

For ongoing/follow-up laboratory monitoring, the **primary outcome measure** is the ratio of monitoring errors to the total number of prescriptions for the drug of interest. An error will be defined as failure to perform indicated ongoing laboratory monitoring during the recommended time period for the medication of interest. If a follow-up monitoring error occurs in the same patient for the same drug more than once during the study period, it will be counted as an error only once.

The **secondary outcome** measure for both the medication baseline and ongoing/follow-up laboratory is the number of days between prescription and monitoring when it is indicated.

Patient Portal Results Management

For each laboratory test, the **primary outcome measure** is the time to patient notification of a lab result. Time to notification was calculated for both normal and abnormal results. Operationally, we used the time-date-stamping function of the eClinicalWorks Patient Portal to indicate: the date/time the laboratory result was entered into the EHR system, the date/time a clinician has reviewed and "pushed" the laboratory result to the Patient Portal, the date/time that a patient receives an email notification of a new post on his/her Portal site, and the date/time that a patient opens the portal after receiving external email notification (although it was not possible to measure when they open the lab results page specifically).

Secondary outcome measures include 1) whether a patient was notified of an abnormal result within the assigned time frame and 2) whether clinician follow-up was performed within an appropriate time frame. These secondary outcome measures will be operationalized as follows:

1) Whether a patient was notified of an abnormal result within the assigned time frame: This time period was measured from the time the result enters the EHR to the time there was evidence of patient notification. This evidence will include receipt of email notification in the Portal, as well as other documentation of notification in the EHR itself.

2) Whether clinician follow-up was performed within an appropriate time frame: This time period was measured from the time the result enters the EHR to the time there was evidence of follow-up action.

Challenges and Limitations

Recruitment

Recruitment of community-based practices in this time of great change in healthcare and multiple demands relating to such things as new EHR implementations and pay-for-performance was particularly challenging. Initial efforts to recruit primary care practices participating in the Massachusetts eHealth Collaborative (MAeHC) were unsuccessful. There are multiple reasons for this failure, which can be enlightening and educational for future efforts to undertake HIT research and evaluation efforts in community-based practices. First, we note that there were three communities participating in the MAeHC. At the time of our grant submission, leaders of all three communities, as well as many physicians in many practices throughout the three communities, agreed to participate in our study if funded. Between the time the proposal was submitted and the time the project was funded and readied for implementation, one of the three communities underwent leadership changes and ultimately decided not to participate in the research study. In the second community, despite willingness from physicians and leadership of the community steering committee, the community's largest practice was unable to participate because of legal considerations. Specifically, the practice's attorneys noted that their HIPAA authorization included legacy language that informed their patients that they would notify each patient and obtain patient consent to use their data for any research activity. Because individual patient consent was not practicable for this study, we were forced to exclude this practice, and therefore the entire community, from participation. In the third community, we identified approximately 10 practices that had installed eClinicalWorks with the necessary technical specifications to support implementation of the study intervention alerts. However, because of delays in establishing interoperability between the hospital, practices and clinical laboratories in this community, none of these eligible and willing practices had electronic delivery of laboratory results at the time our study was prepared to launch. As a result, the alerts we had developed would have always "fired" and would not have been able to incorporate the information about presence or absence of laboratory testing, thus negating any potential benefit of the alert. Therefore, we excluded practices in this community from potential study participation, and were fortunate to identify the practices in New York City that ultimately comprised the study population.

Working with a Vendor

While we have a great working relationship with eClinicalWorks and they were in support of our study, there were many unexpected delays associated with implementing the alerts and extracting the data needed for the laboratory monitoring portion of the study. When we originally began developing the alerts, eClinicalWorks needed to delay their work with us due to operational demands and there continued to be delays in the adoption of version 8.0100, the version of this software necessary to support our project, in many of the practices. Therefore, while our alert intervention was originally planned to begin September of 2008, due to such delays, they were not turned on until June of 2009. Furthermore, though we hoped to obtain the baseline data after the baseline period ended in June 2011, we only received the complete and final baseline and intervention data together in February 2012.

Similar delays have occurred with the patient portal results management system. Given evolution of the EHR product independent of our research activities, as well as the delays experienced both in the software development and in the rollout of the necessary upgrade of the EHR system, we modified the nature of our original study. We also experienced delays associated with data extraction and formatting issues.

Turning on the Laboratory Monitoring Intervention

One of the problems we encountered with our laboratory monitoring intervention was "turning on" the alerts. While the alert data was collected for the six-month period June, 23, 2011 to December 23, 2011, we realized belatedly that one of the practices' alerts were not actually firing due to a misstep in the vendor's process. This practice did not have its alert system turned on until August 1, 2011 so will only have 5 months of data to contribute.

Alerting Interventions and Workflow

One of the most important considerations in developing and implementing any health care IT intervention is that the new technology must fit into the workflow and enhance clinical productivity. In this study, we relied on our experience with implementing similar interventions in other settings to ensure that the laboratory monitoring alerts suit the workflow needs of the end-users without unacceptable system slowing through usability testing during the focus group discussions and through pilot testing prior to launching the intervention.

One of the most important challenges to developing effective clinical decision support is the fact that every alert and reminder competes for the clinician's attention. Excessive alerting, often complicated by unnecessary alerting, contributes to this overall methodological challenge, often called "alert burden." We considered this potential limitation in developing the alerts for laboratory monitoring and results management. In order to combat this, our proposed alerts occurred only when action was required, thereby minimizing alert burden and likely leading to increased compliance.

We designed the trigger for laboratory monitoring alerts to be the prescription of a target medication, either at the initiation of therapy or upon renewal of continued therapy. This approach allows the alert to occur in the clinician's workflow at the time when consideration of laboratory monitoring is most relevant and when communication with the patient to complete monitoring is most likely to occur.

Challenges

<u>Will not know effects of intervention on ADEs</u>
The research study evaluated two important domains of patient safety: reduction of errors related to the monitoring of medication therapy and the reduction of errors related to delayed or inadequate follow-up of laboratory tests. Unfortunately, given the necessary time and resources for intervention development and implementation, it will not be feasible to assess the effects of the intervention on the outcome of ADEs.

<u>Intervention does not address delayed or incomplete follow-up of diagnostic imaging.</u>
The investigators recognize that delays in management of abnormal results of diagnostic imaging, such as abnormal chest x-rays or mammograms, carry at least as much clinical importance as delays in management of abnormal laboratory test results. We chose to focus on laboratory results management for this study because the laboratory monitoring intervention may reasonably be predicted to lead to an increase in laboratory testing and a potential corresponding increase in abnormal test results, which would require increased HIT support for their appropriate follow-up and management. Although technically feasible to implement diagnostic test result management concurrent with laboratory test result management, our prior experience suggests that overloading the users with excessive interventions at once may result in rejection of some or all of them.

Selection bias

Because the intervention practices that have eCW's Patient Portal are not randomly assigned this module, but instead have purchased this module in addition to the eCW electronic health record, it is conceivable that study practices will be systematically different on other variables that may be associated with the outcome of timely notification of test results. The threat of this potential selection bias will be minimized by the following approaches. First, the study design incorporates both pre- and post-intervention assessment of test result notification, allowing us to control for baseline differences in testing rates. Second, we will adjust for practice and physician variables in the analysis. These approaches should adequately mitigate the potential for selection bias to threaten the validity of the results.

Inability to evaluate effect of intervention across multiple EHR vendors

Specific Aim 3 examines a practice population invested in a single electronic health record vendor, eClinicalWorks. Since the time of the original grant submission, eCW has emerged as one of the preeminent providers of EHRs to small- and medium-sized office practices throughout the US. Because of this extended "install base" of eCW, the results of this study will have far-reaching implications for the more than 60,000 physicians, 180,000 providers, and 370,000 healthcare professionals across all 50 states who currently use eCW. More importantly, the intervention studied in this project – the provision of test results to patients via a web portal – is qualitatively similar to the systems currently in place in a large number of practices and health systems across the US. Because of the similarity of eCW's portal to other systems, such as those in Epic® (used widely by Kaiser and other systems) and Partners HealthCare's homegrown system, Patient Gateway, results from this study are likely to be generalizable to any existing EHR with a Patient Portal in which physicians are required to push lab test results out to the portal.

Results

Focus Groups

Six focus groups and one individual interview were conducted with 20 primary care physicians (PCPs) and 9 specialists from three Massachusetts communities. In the focus groups, participants reported viewing laboratory monitoring as a critical, time-consuming task integral to their practice of medicine. Most believed they commit few laboratory monitoring errors and were surprised at the error rates reported in the literature. They listed various barriers to monitoring, including: not knowing which physician was responsible for ensuring the completion of laboratory monitoring, uncertainty regarding the necessity of monitoring, lack of alerts/reminders, and patient non-adherence with recommended monitoring. The primary facilitator of monitoring was ordering laboratory tests while the patient is in the office. PCPs felt more strongly than specialists that computerized alert could improve laboratory monitoring. Participants wanted to individualize alerts for the practices, and warned that alerts must not interrupt workflow or require too many clicks. From the analysis of these focus groups, our research team concluded that physicians in community practice recognized the potential of computerized alerts to enhance their monitoring protocols for some medications. They viewed patient non-adherence as a barrier to optimal monitoring.

Laboratory Monitoring

We used both the existing literature, expert opinions, and information obtained on our focus groups to compile our final list of intervention medications and laboratory monitoring alerts shown in Table 3. In addition, this table presents the prioritization of the medications so as to prevent duplication of an alert for the same laboratory test.

Table 3. Medications, associated laboratory monitoring and priority for alert presentation

Lab Name	Med Name	Measure ID	Prioritization
ALT or AST	Methotrexate	LM-O15	1
	Amiodarone	LM-O28	2
	Azathioprine	LM-O57	3
	Cyclosporine	LM-O59	4
	Fibric Acid Derivatives	LM-O34	6
	Nefazodone	LM-O64	7
	Thiazolidinediones	LM-O8	8
	Statins	LM-O33	10
	Terbinafine (oral)	LM-O45	11
	Carbamazepine	LM-O17	12
	Phenytoin	LM-O22	13
	Valproic Acid	LM-O26	14
	Infliximab	LM-O55	16
	Ketoconazole (Oral)	LM-O43	17
CBC	Clozapine	LM-O62	1
	Warfarin	LM-O1	2
	Methotrexate	LM-O14	3
	Carbamazepine	LM-O20	4
	Valproic Acid	LM-O25	5
	Azathioprine	LM-O56	6
	Infliximab	LM-O54	7
	Etanercept	LM-O53	8
	Lithium	LM-O40	11
	Raloxifene	LM-O65	12
	Ticlopidine	LM-O63	13
Potassium	Potassium	LM-O11	1
	Digoxin	LM-O31	2
	ACE/ARB	LM-O6	3
	Potassium-sparing Diuretics	LM-O4	4
	Diuretic	LM-O13	5
	Lithium	LM-O42	6

Lab Name	Med Name	Measure ID	Prioritization
Creatinine	Digoxin	LM-O30	1
	ACE/ARB	LM-O5	2
	Diuretic	LM-O12	3
	Potassium-sparing Diuretics	LM-O3	4
	Potassium	LM-O10	5
	Amiodarone	LM-O27	6
	Metformin	LM-O7	7
	Exenatide	LM-O49	8
	Sitagliptin	LM-O48	9
	Lithium	LM-O38	10
	Cyclosporine	LM-O58	11
	NSAIDS	LM-O50	12
	Varenicline	LM-O52	13
	Allopurinol	LM-O16	14
Sodium	Lithium	LM-O41	1
	Tegretol	LM-O18	2
TSH	L-Thyroxine	LM-O36	1
	Amiodarone	LM-O29	2
	Lithium	LM-O37	3
	Tegretol	LM-O21	4

The specific data elements, definitions, and algorithms applied to create the laboratory monitoring alerts are presented in Appendix A. This information can be used by other EHR vendors to create similar functionality. Data analyses are still underway to evaluate the outcomes in this aim due to extensive delays in obtaining the data from eCW and some additional unforeseen data compilation challenges.

We received the data files from eClinicalWorks and filtered the data sets by date range and the medication classes of interest. The data sets were then restricted further to include only those labs of interest associated with monitoring medications. One of the limitations of our study is that if a clinician entered medication or lab information manually and the text field did not match the specific medication and lab names used by eCW, then these medications or labs would not be picked up by the algorithm and, as a result, were not included in our study.

After restricting the data sets, we compared the intervention period to the baseline period. Preliminary data analysis showed that, for intervention practices, appropriate monitoring of new or ongoing drug therapy decreased from 66.93% in the baseline period to 41.64% in the intervention period compared to 57.64% and 36.89%, respectively, in the control practices. As this result is unexpected, we are currently conducting additional data quality checks to ensure that these results are valid before proceeding with additional analyses.

Patient Portal

1840 laboratory results were reviewed in the early post-adoption period. To minimize autocorrelation, we included one randomly selected laboratory test per patient per period. A total of 56% of laboratory tests reviewed were sent to the portal. For test results posted to the portal, 40% of patients logged into the portal within 30 days of the posting, with an average of 7.6 days between posting and patient log-in. In the late post-adoption period, the percent of

results posted to portal dropped to 50%, with fewer patients (31%) logging into the portal within 30 days of posting. For those patients who logged in following result posting, the average time between posting and log-in dropped to 3.0 days. Understanding patient preferences for the use of a patient portal for test notification will help to improve timely results management. The data from a single practice, to be confirmed in the two other practices, suggest that, over time, patients using a portal log in more quickly following the posting of a test result. However, given the reduction in both the percentage of results posted to the portal and the proportion of patients with tests posted who logged in, this route may not be preferred by the majority of patients. Thus, when implementing a patient portal, physicians need to assess patient preferences to make informed decisions on the optimal use of the portal for test result notification. Additional analyses are underway to evaluate other outcome measures.

Study Products

Products that have been completed, to date, are the following. Work continues on data analysis for all aims and manuscripts will be prepared reporting on these results once completed.

1. A manuscript of the focus group findings was published in December 2010 at the Journal of Evaluation in Clinical Practice.

Goldman RE, Soran CS, Hayward GL, Simon SR. Doctors' Perceptions of Laboratory Monitoring in Office Practice. J Eval Clin Pract. 2010; 16(6):1136-41

2. An abstract and poster were presented at the Society of General Internal Medicine 2012 Conference and an abstract has been submitted for presentation at the American Medical Informatics Association annual 2012 meeting.

Collling CA, Volk LA, Jenter CJ, Dembowitz M, Maniam N, Bates DW, Simon SR. Using a Patient Portal to Communicate Laboratory Test Results in Community Practices. Poster presented at the Annual Meeting of the Society of General Internal Medicine, Orlando, FL, May 2012.

3. Design and architecture of clinical decision support tools for laboratory monitoring and results management that would be adaptable to other CCHIT-certified EHRs.

4. A main programming document detailing the timing of alerts, the look-back period, relevant LOINC codes, and Medispan/Multum drug classes and names for each alert. (Appendix A)

5. A Use Case document that details 19 specific scenarios that demonstrate the nuances of the laboratory monitoring alert logic

6. An Alert Prioritization scheme which prioritized all the medications needing overlapping laboratory tests, so that the medication that is the most important to monitor is listed. (Table 3)

7. Presentation and 10 minute training video to instruct providers on how to use the alerts, what they mean, and the medical conditions that prompt their appearance.

8. Lessons of implementing these types of functionality within the community setting and evaluation of correlates of successful implementation and use that will be presented in the Dissemination Guide that provides tool design information, training materials, and

implementation recommendations. The dissemination guide will be completed with all study products and information once final project analyses are completed.