Final Report to Agency for Healthcare Research and Quality

Title of Project: Multicenter Medication Reconciliation Quality Improvement Study (MARQUIS)

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Structured Abstract

Purpose: The goals of the Multi-Center Medication Reconciliation Quality Improvement Study (MARQUIS) were to operationalize best practices for inpatient medication reconciliation, test their effect on potentially harmful unintentional medication discrepancies, and understand barriers and facilitators of successful implementation.

Scope: Unresolved medication discrepancies during hospitalization can contribute to adverse drug events, resulting in patient harm. Discrepancies can be reduced by performing medication reconciliation; however, effective implementation of medication reconciliation has proven to be challenging. This pragmatic quality improvement study was conducted on medical-surgical services at five US hospitals that varied in terms of size, location, academic affiliation, and use of health information technology (HIT).

Methods: The study was conducted between September 2011 and July 2014. With the guidance of trained mentors and using standard quality improvement (QI) principles, each site implemented at least one of 11 intervention components consistent with best practices in medication reconciliation. A toolkit and supplementary materials, such as instructional videos and slide presentations, described the design and implementation of these intervention components in detail. Mentors conducted monthly phone calls and two site visits during the intervention period.

The primary outcome was the number of potentially harmful unintentional medication discrepancies per patient. This was determined in approximately 22 randomly selected patients per month at each site during a 6-month baseline period and throughout the intervention. Trained on-site pharmacists took “gold-standard” medication histories on these patients, compared these histories to admission and discharge medication orders, and identified and categorized all discrepancies. Trained physician adjudicators at each site determined the potential for harm of all unintentional discrepancies. We also collected demographic and billing data from computerized administrative data sources for each patient.

To analyze the effect of the entire intervention on the primary outcome, we conducted a time series analysis using multivariable Poisson regression to detect both sudden improvement with initiation of the intervention and change in the temporal trend after initiation, adjusted for patient characteristics, baseline temporal trends, and baseline differences between intervention and any control units.

To determine the most effective components of the intervention, we also categorized all QI activities conducted by any site by component, including date(s) of implementation. We analyzed the data using Poisson regression to detect sudden reductions in potentially harmful discrepancy rates temporally associated with each implementation of each intervention component across all sites.

To understand barriers and facilitators of implementation, we performed mixed-methods program evaluation, including surveys, interviews, and focus groups of frontline staff and hospital leaders. This led to a separate analysis of the effect of health information technology (HIT) on outcomes.

Results: Across the five participating sites, 1479 patients were enrolled, including 548 patients during the baseline period and 931 patients during the intervention period. Implementation of the intervention as a whole was associated with a reduction in the number of potentially harmful discrepancies over time beyond any baseline temporal trends: incidence rate ratio, 0.89 per month (95% CI, 0.80 to 0.99; p=0.03). Of the four sites that implemented anywhere from four to seven different intervention components during the study period, three sites saw reductions in their potentially harmful discrepancy rate. The site that saw an increase in their discrepancy rate implemented a new electronic medical record shortly after beginning the intervention.

In on-treatment analyses, one intervention component was associated with significant reductions in potentially harmful discrepancies: hiring new staff (usually pharmacists) to assist with both medication reconciliation and patient counseling at discharge (incidence rate ratio, 0.16; 95% CI, 0.08 to 0.33). Two components were

associated with increases in discrepancy rates: training existing staff to take medication histories (IRR, 1.27; 1.01 to 1.59) and implementing a new electronic medical record (IRR, 3.38; 1.65 to 6.93).
In mixed-methods analyses, a number of barriers to implementation were identified, including lack of institutional support, competing initiatives, and (most notably) the use of vendor electronic medical systems that were poorly designed, locally implemented, and/or suboptimally used in practice.

In conclusion, adoption of a multi-faceted medication reconciliation quality improvement initiative using a mentored implementation model was associated with a reduction in potentially harmful medication discrepancies over time. We found that hiring additional pharmacy staff to assist with discharge reconciliation and patient counseling was the most effective component of a medication reconciliation QI program. We also identified several barriers to implementation. Next steps include a larger round of mentored implementation, using an enhanced version of the toolkit, with rigorous recruitment of sites committed and able to improve their medication reconciliation process, and incorporating lessons learned regarding the most effective ways to implement this intervention and improve medication safety during transitions of care.

Key Words:
Medication errors/prevention & control
*Medication reconciliation
Organizational culture
Pharmacists/standards
*Quality improvement

Purpose (Objectives of Study)

The specific aims of MARQUIS were to:

1. Develop a toolkit consolidating the best practices for medication reconciliation based on the strongest evidence available.
2. Conduct a multisite, mentored quality improvement (QI) study in which each site adapts the tools for its own environment and implements them.
3. Assess the effects of medication reconciliation QI interventions on unintentional medication discrepancies with potential for patient harm.
4. Conduct rigorous program evaluation to determine the most important components of a medication reconciliation program and how best to implement them.

Scope (Background, Context, Settings, Participants, Incidence, Prevalence)

One of the most prevalent hazards facing hospitalized patients is unintentional medication discrepancies (i.e., unexplained differences in documented medication regimens across different sites of care). Unresolved medication discrepancies can contribute to adverse drug events (ADEs), resulting in patient harm. Nearly two thirds of inpatients have at least one unexplained discrepancy in their admission medication history, and some studies found up to three medication discrepancies per patient. Such medication discrepancies are caused by either history errors (i.e., errors in determining a patient's preadmission medication list) or reconciliation errors (i.e., errors in orders despite accurate medication histories, such as the failure to restart at discharge a medication that was held on admission).

One way to minimize medication discrepancies is to perform high-quality medication reconciliation, defined as the process of identifying the most accurate list of all medications a patient is taking and using this list to provide correct medications for patients anywhere within the healthcare system. Since 2005, The Joint Commission (TJC) has required US hospitals to conduct medication reconciliation on admission, upon transfer, and at discharge. When tested, hospital-based medication reconciliation interventions have consistently demonstrated reductions in medication discrepancies, though effects on more distal outcomes such as readmission have been less consistent and limited by study size. Yet, one study at two large urban academic hospitals found that general medical inpatients averaged more than one potentially harmful discrepancy in medication orders despite documented completion of medication reconciliation.

Though medication reconciliation practices are required at care transitions throughout hospitalization, implementation has been challenging for many hospitals, because it often involves a dramatic change in work processes and additional tasks for busy clinicians. Furthermore, hospitals need clearer guidance on which interventions are more likely to be successful in their local environment. Last, it has been relatively easy for hospitals to document compliance with medication reconciliation processes to meet national regulatory requirements without demonstrating that medication safety has actually improved. To identify and address the barriers to implementing medication reconciliation, an Agency for Healthcare Research and Quality (AHRQ)-funded conference organized by the Society of Hospital Medicine (SHM) in 2009 brought together 36 key stakeholders from 20 organizations representing healthcare policy, patient safety, regulatory, technology, and consumer and medical professional groups. The conference yielded a White Paper with recommendations, including a call for further research. To address the latter, SHM subsequently received funding from AHRQ to conduct the Multi-Center Medication Reconciliation Quality Improvement Study (MARQUIS).

This study was targeted at US hospitals regardless of size, location, academic affiliation, or use of health information technology (HIT). We requested that sites target their QI efforts at medical-surgical non-critical-care inpatient services and units, although final decisions of scope were up to each site.

Methods (Study Design, Data Sources/Collection, Intervention, Measures, Limitations)

Study Design

This study was designed as a pragmatic clinical trial using an interrupted time series to measure the incremental effect of the intervention over baseline temporal trends. Each toolkit component (described below) was framed as a standardized functional goal (e.g., “Improve access to preadmission medication sources”). This approach is ideal for complex QI interventions, allowing sites to 1) integrate intervention components with their baseline medication reconciliation efforts, information system capabilities, and organizational structures and 2) add, customize, and iteratively refine the toolkit components and their implementation over time. This approach also improves generalizability, allowing other organizations to apply the lessons learned regardless of their culture or unique circumstances.

While recognizing the importance of flexibility, it was nevertheless important to have some common elements across sites. Thus, each site prioritized the implementation of certain toolkit components based on their potential for improvement and effort required. These included provider hiring and/or training on medication history taking, provider hiring and/or training to conduct discharge medication reconciliation and patient education, and patient risk stratification and delivery of more intensive medication reconciliation efforts in high-risk patients.

Study sites
Six US sites originally chose to participate in this study: three academic medical centers, two community hospitals, and one Veterans Affairs hospital. We purposely chose sites that varied in size, academic affiliation, geographic location, and use of health information technology. However, all sites had several common features: 1) medication reconciliation was a priority; 2) hospital leadership was committed to making further improvements in the process; 3) an active hospitalist group was engaged in QI; 4) a suitable hospitalist and/or pharmacist clinical champion was at each site; and 5) each site planned to use primarily its own resources to pursue this effort.

Unfortunately, one site (one of the academic medical centers) had to withdraw from the study for a variety of reasons: change in hospital leadership between the time of original statement of commitment (as part of the AHRQ grant proposal) and the start of the intervention (more than 1 year later); a decision by hospital leadership to deny funds to their pharmacy department necessary to conduct the study; and new commitments by the designated mentee, making participation in the study difficult. Thus, after the period of baseline data collection, the site stopped participation in the study, leaving us with five sites.

Patients
Patient subjects were drawn from the medical and surgical inpatient, non-critical-care units of each site and were included if hospitalized long enough for a “gold-standard” medication history to be obtained by a study pharmacist (i.e., generally more than 24 hours). Each site’s Institutional Review Board (IRB) reviewed the study: four considered it an exempt QI project, and two sites required informed consent of patients prior to participation. Informed consent was thus incorporated into the data collection process at these sites. Each site chose the initial and eventual scope of the intervention, generally at least one and often several medical or surgical units. At some of the smaller hospitals, scope tended to involve all medical/surgical inpatients. Once sites started interventions, they were instructed to choose approximately three fourths of selected patients to be observed from intervention units to track iterative refinement of the intervention over time while still allowing for concurrent controls, if feasible.

Data Sources/Collection

Study outcomes were assessed from 6 months pre-intervention through 21 months post-intervention. The main source of data collection was a trained onsite pharmacist taking a “gold-standard” medication history on a random sample of patients (approximately 22 patients per month) using a standard protocol. This history was then compared with the primary team’s medication history and with admission and discharge orders. Discrepancies in admission or discharge orders due to errors in the primary team’s medication history were categorized as “history errors.” For discrepancies in orders not caused by history errors, the pharmacist then reviewed the medical record for a clinical explanation and, if necessary, talked with the medical team. This allowed sites to distinguish unintentional medication discrepancies (i.e., due to “reconciliation errors”) from intentional medication changes. Pharmacists then categorized each unintentional discrepancy by timing

(admission vs. discharge orders), type (e.g., omission, additional medication, discrepancy in dose or frequency), and reason (history error vs. reconciliation error).

In an effort to ensure consistency of onsite pharmacist data collection, the research team 1) conducted monthly phone meetings with onsite pharmacists in which a patient case was reviewed for consistency and all discrepancies were discussed; 2) provided onsite pharmacists with an updated 'frequently asked questions' (FAQ) document for managing new situations; and 3) conducted site visits with the research team's pharmacist to observe data collection processes and provide feedback, including how to improve process efficiency.

In addition, each site collected de-identified data on each study patient using demographic and billing data from available computerized administrative data sources. Based on the medical literature on risk factors for post-discharge medication discrepancies, the following variables were collected: 1) patient age, 2) sex, 3) insurance, 4) marital status, 5) median income by zip code of residence, 6) hospital length of stay, 7) admission source, 8) service, 9) unit, 10) admitting and discharging providers, 11) any major procedures, 12) number of emergency department and hospitalizations in the prior year, 13) DRG weight (case mix index) of the principal diagnosis (using MS-DRG weights from the year of admission), 14) Elixhauser comorbidity score, and 15) number and classes of "gold-standard" preadmission medications.

The study sites utilized a web-based data collection and reporting system built specifically for this study. The system created HIPAA-compliant, de-identified data sets for the coordinating data center and all investigators. The system allowed for identification, classification, and adjudication of all discrepancies. Unintentional discrepancies identified by the onsite pharmacist were flagged in the system for physician adjudication. The data center provided detailed reports to trend discrepancies, facilitated uploads of patient-specific administrative data, tracked implementation of intervention components, and provided tools to support mentored implementation. It also provided tracking for patient enrollment compared with monthly targets.

Interventions

Tool Development
From October 2010 through January 2011, the MARQUIS research team members performed a collaborative review of the previously determined medication reconciliation recommendations from the white paper and transformed each item into draft components of the intervention toolkit. Concurrently, a systematic review of the literature on most effective practices of inpatient medication reconciliation was performed. Following these initial steps, the research team and steering committee members further developed the content for each draft intervention component, synthesizing evidence from the literature, expert opinion, and any available examples of best practices, including results from the Medications at Transitions and Clinical Handoffs (MATCH) study. A 2-day steering committee conference was held in January 2011, during which the content for each intervention component was presented and discussed by the group to foster consensus.

Following the conference, investigators participated in weekly phone meetings with quarterly input from steering committee members to further refine the components and create specific tools and measurements that comprised the MARQUIS toolkit.

Tool Description
The original toolkit was composed of the following three major sections:

- Section A. First steps a hospital should undertake before beginning any interventions, including preparation and site assessment, to allow for maximum likelihood of successful implementation
- Section B. MARQUIS intervention components
- Section C. Appendix material, which supplemented the narrative components of the implementation guide with ready-to-use tools

Unlike many intervention projects, several components of this toolkit were intended to be customized as needed at each site on the basis of existing personnel and work flow structures and previous medication reconciliation QI efforts, thus enhancing applicability, generalizability, and "shelf life."

Section A. First Steps for Success: Preparation and Site Assessment

This section of the guide reviewed key QI principles necessary for successful implementation, including the importance of pre-implementation planning, identifying key stakeholders, obtaining institutional support, and assembling an effective multidisciplinary QI team. Because implementation of this type of intervention requires hospital-level commitment, resources, and time, we emphasized the talking points necessary to obtain institutional support, including ongoing benefits to patient safety and the return on investment (ROI) in terms of decreased inpatient adverse drug events and hospital readmissions. In the appendix (Section C), we also included links to a spreadsheet so that sites could customize their own ROI calculations. The implementation guide also highlighted the importance of understanding the institution's current practices of medication reconciliation and ongoing QI efforts in this area. Recommendations to achieve this understanding included performing process mapping and a gap analysis between current and ideal processes.

The ideal medication reconciliation process, as proposed by the MARQUIS team, was provided in this section of the toolkit to assist with these efforts. For example, on the basis of the literature, the guide recommended robust involvement of pharmacists in medication reconciliation processes, communicating with postdischarge providers, and focusing efforts on patients at highest risk for adverse drug events. Descriptions of each step of medication reconciliation and the skills required helped sites match individual tasks to the personnel and roles best able to complete those tasks at their site. The toolkit also included a site assessment, adapted from another AHRQ-funded toolkit, to be used before implementation to help the QI teams assess their current environment and readiness.

Section B. Intervention Components

Individual intervention components in the toolkit addressed all aspects of the proposed ideal medication reconciliation process, including methods, tools, and guidance for implementation as well as specific metrics for measuring its effectiveness. Certain intervention components (i.e., those that are the most evidence based) were grouped together to comprise a core set of interventions, whereas other components were designated as optional, to be chosen on the basis of the institution's self-assessment, process mapping, and gap analysis. The individual components included methods of obtaining an accurate medication history from the patient or other sources (including how to perform a "best possible medication history" [BPMH]), methods of empowering patients or their caregivers to take ownership of the medication list, discharge counseling techniques, and patient risk stratification for intensification of resources for high-risk patients. The intervention components also emphasized basic QI principles, including the importance of assigning roles and responsibilities to clinical care team members and stressing the importance of phased implementation.

Additional intervention components highlighted various high-risk/high-reward features of the medication reconciliation process, including incorporation of effective health information technology (HIT) components and social marketing techniques. These components likely required substantial resources, planning, and institutional commitment. Therefore, sites were encouraged to decide early whether or not they wished to pursue these efforts and include these decisions when obtaining institutional support for this intervention.

Intervention components believed to be high yield by the MARQUIS team and most likely to achieve rapid and substantial improvements in medication safety were highlighted throughout the implementation guide, including (1) training clinical personnel in taking a BPMH and in performing health literacy-sensitive discharge medication education, (2) risk-stratifying patients, and (3) providing high-risk patients with an intensive medication reconciliation bundle. It was emphasized in the guide that having adequate time and personnel dedicated to performing these tasks was essential.

Section C. Appendix, Supplemental Material

To supplement the narrative components of the intervention toolkit, we also included an appendix with ready-to-use tools that assisted with various intervention components, including instructional material on how to obtain senior leadership buy-in (with ROI calculations), perform a site assessment, and train personnel on taking a BPMH. Examples were also provided for patient-friendly discharge instructions, patient-owned medication lists, paper and electronic medication reconciliation forms, vendors of products that can enhance the medication reconciliation and discharge process, and social marketing materials.

Finally, this toolkit section included links to several additional useful references, including the following:

1. An instructional video on how to perform high-quality discharge education, which emphasized approaches for effective patient communication, including use of the “teach-back” technique. This video also provided examples performed by actors of both inadequate medication education and effective medication education, allowing for reflection on both examples.
2. Materials on how to take a BPMH, including an instructional video that modeled the process, didactic slide deck, a case study for role playing, and pocket cards for clinicians.

Mentored Implementation

MARQUIS utilized SHM’s mentored implementation approach, providing each site with a hospitalist mentor to facilitate toolkit implementation. Each mentor had QI expertise and performed distance mentoring through monthly calls with the study site’s mentee/clinical champion, based upon the MARQUIS Implementation Guide. Each study site also received two visits from the mentor, important from a QI standpoint (e.g., to maintain institutional support and enthusiasm among the local QI team and to better understand local practices) and from a research standpoint (e.g., to assess intervention fidelity and other barriers and facilitators of implementation). Additionally, SHM provided sites with an assigned lead project manager and research assistants located at SHM headquarters to assist with monitoring progress and collecting and analyzing data.

At each study site, a local QI team, led by the mentee/clinical champion, conducted regular meetings to oversee intervention implementation and data collection as well as to address protocol questions and determine the effectiveness of the interventions. Sites could access a central website with additional resources and a listserv. The monthly conference calls with their mentor and ad lib email communications promoted a consistent approach across sites.

Measures

Outcome assessment

The primary outcome of the study was unintentional medical discrepancies in admission and discharge orders with potential for patient harm. Physician adjudicators, blinded to the status of intervention implementation, recorded and categorized unintentional medication discrepancies with respect to 1) timing (admission vs. discharge); 2) type (omission, additional medication, change in dose, route, frequency, or formulation, or other); 3) reason (history vs. reconciliation error); 4) potential for harm; and, 5) potential severity. For the first three items above, which were previously documented by the study pharmacist, the main role of the adjudicator was to confirm or modify the decisions of the pharmacist.

Adjudicators received standardized training by the principal investigator, including a primer on medication safety, a guide on how to perform adjudication, and standardized cases to review. In addition, to ensure the consistency of the adjudication process, the principal investigator conducted a quarterly conference call with the sites’ physician adjudicators to discuss cases from each site on a rotating basis. In addition, the PI and a co-investigator reviewed six cases from each site quarterly and reviewed the results individually with each site’s adjudicators. An FAQ document for adjudicators was updated and redistributed as needed based on decisions made on how to manage certain cases.

Secondary outcomes included the total number of medication discrepancies per patient (regardless of potential for harm), discrepancies in admission orders and discharge orders, and discrepancies due to history versus reconciliation errors.

Contextual factors were measured using surveys of providers directly involved in the medication reconciliation process. Questions included satisfaction with medication reconciliation, perceived effects on patient care, degree of training and feedback received, and time available to conduct medication reconciliation tasks as well as baseline questions on patient safety culture, teamwork, and burnout using standard instruments. Respondents were purposefully sampled to be representative of every role and location responsible for the medication reconciliation process. After interventions that had major effects on providers were implemented (e.g., education on taking medication histories), surveys were re-administered to quantify the effects.

To determine the most effective components of the intervention, we categorized all QI activities conducted by any site by component, including date(s) of implementation, based on input from each site's mentee and mentor.

Statistical analysis
The primary outcome, number of potentially harmful discrepancies per patient, was analyzed using multivariable Poisson regression, including clustering of patients by site and treating physician. To account for temporal trends and the varied introduction of interventions by site, we employed a longitudinal analysis on all patients across the five sites, evaluating outcomes monthly during the pre-intervention and post-implementation periods. The outcome was assessed as both a change from site-specific baseline temporal trends (i.e., change in slope) and a sudden improvement with implementation of the intervention as a whole (i.e., change in y-intercept). To adjust for concurrent controls, we also entered into the model any baseline differences in discrepancy rates and in temporal trends as well as sudden improvement in control units at the time the intervention happened to have started in the intervention units (i.e., to partially adjust for the effect of concurrent interventions). We also adjusted for patient covariates, as noted above in Data Sources/Collection, and then manually eliminated nonsignificant collinear variables. We repeated this process for the total number of discrepancies per patient. When administrative data were missing, we imputed mean values.

To determine the most effective components of the intervention, in a separate model, we analyzed the data among post-intervention patients in the intervention units only using Poisson regression to detect sudden reductions in potentially harmful (and total) discrepancy rates temporally associated with each implementation of each intervention component across all sites. All intervention components were added simultaneously, but we only modeled changes in y-intercept (and not slope), for simplicity.

Power and sample size
For a stable estimate of temporal trends, each site's data collection goal was approximately 22 patients per month, beginning 6 months pre-intervention through 21 months post-intervention. With our study design, it was impossible to know *a priori* the nature of our post-intervention data and, therefore, what our actual power would be to look at the effect of any specific intervention. However, based on prior research, we assumed that the number of medication discrepancies would follow a Poisson distribution and that, in the absence of an intervention, each hospitalized patient would have an average of 1.5 potentially harmful medication discrepancies in admission and discharge orders combined. We also conservatively assumed that an intervention would be implemented at only one of six sites with 12, not 21, months of follow-up due to delays in planning and phasing in the intervention widely. This would yield data from 133 patients pre-intervention and 266 patients post-intervention. With these estimates and alpha=0.05, we would have 90% power to detect a reduction in the mean number of medication discrepancies from 1.5 per patient to 1.1 per patient.

As sites began to implement the intervention, one methodological issue that arose was the extent to which sites should over-sample data from hospital areas receiving early versions of the intervention. We decided on a 3:1 ratio of intervention to control patients during the intervention period. This allowed for concurrent controls during the spread of the intervention while maintaining an adequate sample of intervention patients to evaluate iterative refinement of the intervention on patients outcomes. Two-sided p values were considered significant. SAS 9.2 (Cary, NC) was used for all quantitative analyses.

Program evaluation
We evaluated barriers and facilitators of implementation using a mixed-methods approach. Measures of context were gathered using frontline staff and site surveys, as noted above, as well as by direct observation, focus groups, and interviews.

Intervention fidelity was assessed by direct, semi-structured observation of the site's medication reconciliation process by their mentor during site visits at 3 and 12 months after implementation of the intervention. The observation protocol evaluated five steps of the medication reconciliation process: taking an admission medication history, identifying high-risk patients to receive a high-intensity medication reconciliation intervention, performing discharge medication reconciliation, performing discharge medication counseling

using the teach-back method, and forwarding the discharge medication list to the next provider of care after discharge. The mentor observed the actual process to identify if the intervention was being implemented as designed (content fidelity) and how well it was performed (process fidelity). The observation forms also allowed for documentation of systems issues that impacted the medication reconciliation process based on the Systems Engineering Initiative for Patient Safety (SEIPS) model's five domains: people, technology/tools, tasks, organization, and environment. Mentors received group training on how to assess fidelity, using a coding manual with standardized examples and training from a human factors expert. Mentors shared feedback about the direct observations during the site visit with the site leader and QI team.

Focus groups and interviews of clinicians, site leaders, and hospital leadership were conducted to better understand the role of organizational context in explaining why some interventions were more successful in some places than others (i.e., to understand variations in implementation of the MARQUIS intervention across sites) and to understand the role of frontline clinicians in the medication reconciliation process (e.g., who they perceive "owns" the process). We asked, *What are the precursors to implementing the MARQUIS medication reconciliation intervention? What are the facilitators/barriers to implementation and adaptation? What adaptations were made to organizational context?*

One investigator, an expert in qualitative research (KTH), conducted interviews with each site lead, project pharmacist or coordinator, and site mentor approximately 2 weeks before the first visit to each site. During the site visits, a purposeful sample of participants was selected that included each site lead, QI team members (n=43), hospital executive leadership (e.g., CMO, CNO, COO, CTO) (n=7), and a convenience sample of clinical staff (n=84) selected by role (e.g., pharmacists, admitting and discharge nurses, residents, attending physicians) and department to ensure broad representation. Under the original research design, the intent was to conduct focus groups by stakeholder group. These wound up being rapid-fire interviews with frontline staff based on their availability. The qualitative researcher (KTH) also led onsite focus groups (jointly conducted with the MARQUIS Project Manager [JR or JG]) with the QI team and individual interviews with hospital leadership. Approximately 10 months after the initial site visit, KTH conducted follow-up interviews with the site lead and project pharmacist or coordinator (and executive champions) by telephone.

To guide this process, we developed a series of semi-structured interview and focus group guides that provided clear aims and questions for data collection with provisions for following up on participant responses. The interview guides focused on the MARQUIS intervention components and followed an expanded version of the SEIPS framework.

Participants were asked about the standard approach prior to MARQUIS for taking the best possible medication history (BPMH), ordering and reconciling medications on admission, discharge ordering and reconciliation, patient education, and forwarding of the discharge medication list to the next provider; teamwork, workflow, risk stratification, the organizational context, institutional support and buy-in for medication reconciliation; and their experiences with implementing the MARQUIS intervention, including facilitators of and barriers to implementation, steps taken to overcome these barriers, and recommendations for improvement. Follow-up probes, both planned and spontaneous, were used to clarify responses.

Interviews and focus groups were audio recorded and transcribed. KTH, JR, and JG also took notes. Transcripts and notes were analyzed using NVivo, a qualitative data analysis software program. KTH developed a coding framework that mirrored the study conceptual framework and followed the structure of the interview guide. HH and KTH initially coded each transcript and then discussed and reconciled discrepant coding. HH wrote up thematic analyses assessing the range of perspectives on each coding theme and variations within the themes. KTH reviewed and revised each thematic summary and compared themes across the sites to gain deeper understanding of intervention implementation in each setting. KTH and HH culled illustrative quotes from the interview data to include in the thematic analyses. The thematic analyses were used to compile a summary document and executive summary of the findings from the fieldwork.

Limitations (See Discussion)

Results (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

Principal Findings

Across the five participating sites, 1481 patients were enrolled, including 574 patients during the baseline period and 907 patients during the intervention period. The characteristics of the sites are shown in **Table 1.** The characteristics of the patients are shown in **Table 2**. Characteristics differ between usual care and intervention arms and across time due to the nonrandom selection of intervention units by site and the relatively small sample size compared with all patients admitted to these hospitals.

Table 1. Site Characteristics

Site	1	2	3	4	5
Hospital type	AMC	AMC[1]/ Community	Community	Community	VAMC[2]
Region	West Coast	Northeast	Southeast	Southeast	Midwest
Setting	Urban	Urban	Suburban	Suburban	Rural
Number of beds	450	653	535	110	45
Teaching status	Teaching	Teaching	Nonteaching	Teaching	Teaching
Inpatient CPOE[3]	No (moving to Epic)	Yes (Cerner)	No	No (moving to Cerner)	Yes
Medication reconciliation software	In progress (yes with Epic/Apex)	Yes, integrated with CPOE	Yes	No (but yes with Cerner)	Yes, not fully integrated
% patients for whom site has electronic access to ambulatory medication history	50%	50%	<10%	0%	95%
Clinicians primarily responsible for taking medication histories	Physicians	Jointly shared by physicians and nurses	Pharmacy and nursing	Nurses first, then physicians	Residents and PAs
Process of medication reconciliation at discharge	Physicians write orders, pharmacists available by request to reconcile medications	Physicians use electronic tool to reconcile medications	Physicians reconcile medications using paper form	Nurses fill out a reconciliation form, physicians reconcile medications	Physicians or pharmacists, depending on time of day

1 Academic medical center
2 Veterans Affairs medical center
3 Computerized physician order entry
4 Nurse practitioners/physician assistants

Table 2. Patient Characteristics

Characteristic	Control Units		Intervention Units	
	Pre-Intervention N=309	Post-Intervention N=239	Pre-Intervention N=265	Post-Intervention N=668
Age, mean (SD)	68.0 (13.6)	66.9 (18.1)	57.6 (17.6)	60.4 (17.6)
Female, N (%)	46.0%	58.0%	57.5%	59.7%
Service, N (%)				
Medicine	75.4%	64.8%	51.3%	58.4%
Surgery	24.6%	35.2%	48.7%	41.6%
Preadmission source				
Home	14.8%	4.4%	18.4%	19.8%
Clinic	1.6%	2.9%	36.8%	20.8%
Rehab	1.1%	1.4%	0	19.8%
Other hospital	5.3%	2.9%	2.3%	1.3%
Emergency dept.	77.3%	88.4%	42.5%	38.3%
Previous ED visits in past year, N (%)				
0	87.4%	94.1%	88.7%	84.6%
1-4	11.6%	5.9%	10.9%	13.5%
5 or more	1.0%	0	0.4%	1.9%
Previous admissions in past year, N (%)				
0	79.0%	92.1%	90.2%	83.8%
1-4	19.7%	7.1%	9.4%	15.0%
5 or more	1.3%	0.8%	0.4%	1.2%
Number of preadmission medications				
0-3	19.1%	13.8%	29.4%	25.2%
4-6	29.8%	28.0%	24.2%	25.6%
7-10	29.4%	26.8%	24.5%	24.7%
11 or more	21.7%	31.4%	21.9%	24.5%
DRG weight, mean (SD)	1.54 (0.82)	1.82 (1.23)	1.69 (0.61)	1.66 (0.83)
Elixhauser comorbidity score, N (%)				
<=0	18.6%	20.8%	32.6%	31.6%
1-5	25.0%	29.4%	32.6%	30.7%
6-10	24.4%	18.3%	23.9%	18.2%
>10	32.0%	31.5%	10.9%	19.5%
Marital status				
Married or living as if	48.7%	42.0%	56.9%	54.2%
Separated, widowed, divorced	25.9%	31.9%	24.1%	27.7%
Single, never married	25.4%	26.1%	17.2%	16.9%
Insurance				
Medicare	41.1%	18.8%	21.5%	42.5%
Medicaid	3.2%	2.1%	3.4%	5.4%
Private	12.6%	5.9%	32.1%	35.3%
Self-pay, other	43%	73.2%	43%	16.8%
Length of stay, N (%)				
0-4 days	75.1%	68.1%	89.1%	75.5%
5 or more days	24.9%	31.9%	10.9%	24.5%
Discharge destination				
Home	82.5%	69.6%	76.4%	80.7%
Rehab	12.2%	20.3%	9.2%	9.0%
Other hospital	4.8%	5.8%	13.2%	7.7%
Death	0.5%	4.3%	0.6%	0.3%

Of the four sites that implemented anywhere from four to seven different intervention components during the study period, three sites saw reductions in their potentially harmful discrepancy rate (**Table 3A**); the fifth site (Site 1) did not implement any interventions that directly impacted patients during the study period. The site that saw an increase in their discrepancy rate despite implementation of the intervention (Site 4) implemented a new electronic medical record (EMR) shortly after beginning the intervention. In addition, one site (Site 3) saw a large reduction in its total discrepancy rate (**Table 3B**). Results summed across all sites saw a net increase in discrepancies due to the dramatic increase at the site that implemented a new EMR (Site 4). When that site was excluded from analyses, the remaining sites combined saw a net reduction in potentially harmful and total discrepancies (**Tables 3A, 3B)** as well as in total discrepancies in admission orders, in discharge orders, and in reconciliation errors but not in history errors (**Table 3C**).

Table 3A. Pre-post Results by Site: Potentially Harmful Discrepancies

	Control floors		Intervention floors	
Potentially Harmful Discrepancies	**Pre-Intervention**	**Post-Intervention**	**Pre-Intervention**	**Post-Intervention**
Site 1	0.46	0.98	n/a	n/a
Site 2	0.98	1.64	1.00	0.88
Site 3	0.17	0.23	0.30	0.18
Site 4	n/a	n/a	0.19	0.79
Site 5	n/a	n/a	0.35	0.26
All sites	0.63	0.84	0.29	0.53
All sites except Site 4	0.63	0.84	0.34	0.29

Table 3B. Pre-post Results by Site: Total Discrepancies

	Control floors		Intervention floors	
Total Discrepancies	**Pre-Intervention**	**Post-Intervention**	**Pre-Intervention**	**Post-Intervention**
Site 1	2.36	3.37	n/a	n/a
Site 2	2.85	3.29	2.00	2.44
Site 3	3.42	4.07	4.10	3.11
Site 4	n/a	n/a	2.09	2.56
Site 5	n/a	n/a	3.45	4.10
All sites	2.77	3.53	3.07	2.99
All sites except Site 4	2.79	3.49	3.66	3.37

Table 3C. Discrepancies by Type, Excluding Site 4

	Control floors		Intervention floors	
All Sites Except EJCH	**Pre-Intervention**	**Post-Intervention**	**Pre-Intervention**	**Post-Intervention**
Total discrepancies	2.77	3.53	3.66	3.37
Potentially harmful discrepancies	0.63	0.84	0.34	0.29
Discrepancies on admission	1.33	1.81	1.89	1.63
Discrepancies at discharge	1.45	1.72	1.77	1.74
Discrepancies due to history errors	0.99	1.74	2.46	2.59
Discrepancies due to reconciliation errors	1.78	1.79	1.21	0.79

In the time series analysis, implementation of the intervention as a whole was associated with a reduction in the number of potentially harmful discrepancies over time, beyond any baseline temporal trends: incidence rate ratio, 0.89 per month (95% CI 0.80 to 0.99; p=0.03; **Table 4**). This effect was slightly attenuated after adjustment for patient factors (IRR, 0.92 per month; 0.82 to 1.02). A more robust effect was seen for the effect of the intervention on total discrepancies: adjusted IRR 0.91 per month (0.88 to 0.95; p<0.001; data not shown).

Table 4. Time Series Analysis

Parameter	Crude Incident Rate Ratio (95% CI)	P Value	Adjusted Incident Rate (95% CI)*	P Value
Month (baseline temporal trend in control units)	0.95 (0.92 to 0.98)	0.002	0.96 (0.93 to 0.99)	0.007
Post-intervention time period (sudden improvement in control units when start intervention)	0.99 (0.63 to 1.55)	0.97	0.94 (0.60 to 1.48)	0.79
Month 2 (0 in pre-intervention period, then starts) (change in temporal trend in control units when start intervention)	1.09 (1.05 to 1.13)	<0.001	1.08 (1.03 to 1.12)	<0.001
Intervention unit (baseline difference between intervention and control units)	0.81 (0.46 to 1.43)	0.46	0.65 (0.37 to 1.16)	0.16
Month* intervention unit (difference in baseline temporal trend between control and intervention units)	1.10 (0.99 to 1.22)	0.08	1.08 (0.97 to 1.19)	0.16
Post* intervention unit (difference in sudden improvement between control and intervention units when intervention starts)	**1.49 (0.79 to 2.83)**	**0.22**	**1.51 (0.80 to 2.87)**	**0.20**
Month 2* intervention unit (difference in temporal trend in intervention units over baseline and over change in control units when start intervention)	**0.89 (0.80 to 0.99)**	**0.03**	**0.92 (0.82 to 1.02)**	**0.11**

***** Adjusted for DRG weight, Elixhauser comorbidity score, and medical service

Other Outcomes

Component Analysis

We identified 668 patients on intervention units during the post-implementation period.

In on-treatment analyses, one intervention component was associated with significant reductions in potentially harmful discrepancies: hiring new staff (usually pharmacists) to assist with both medication reconciliation and patient counseling at discharge (incidence rate ratio, 0.15; 95% CI, 0.07 to 0.31). Two components were associated with increases in discrepancy rates: training existing staff to take medication histories (IRR, 1.29; 1.03 to 1.61) and implementing a new electronic medical record (IRR, 3.90; 1.90 to 7.98; **Table 5A**). A greater number of components had an influence on the total number of medication discrepancies, likely owing to larger sample size: Hiring additional staff to perform discharge medication reconciliation and patient counseling, training existing staff to do the same, making improvements to existing HIT, and performing high-intensity interventions in high-risk patients all decreased discrepancies, but implementing a new EMR increased discrepancies (**Table 5B**).

Table 5A. Effects of Individual Intervention Components on Potentially Harmful Medication Discrepancies

Intervention Component	Adjusted Incidence Rate Ratio (95% CI)*	P value
Hiring additional staff to perform discharge medication reconciliation and patient counseling	0.15 (0.07 to 0.31)	<0.001
Training existing staff to perform discharge medication reconciliation and patient counseling	0.71 (0.43 to 1.18)	0.19
Hiring additional staff to take preadmission medication histories	1.23 (0.55 to 2.73)	0.61
Training existing staff to take preadmission medication histories	1.29 (1.03 to 1.61)	0.03
Making improvements to existing medication reconciliation health information technology	0.64 (0.07 to 5.80)	0.69
Performing high-intensity interventions on high-risk patients	0.89 (0.72 to 1.10)	0.28
Clearly defining roles and responsibilities and communicating this with clinical staff	0.56 (0.30 to 1.03)	0.06
Improving access to preadmission medication sources	1.14 (0.70 to 1.88)	0.59
Implementing a new electronic medical record	3.90 (1.90 to 7.98)	<0.001

* Adjusted for medical service, DRG weight, and Elixhauser comorbidity score

Table 5B. Effects of Individual Intervention Components on Total Medication Discrepancies

Intervention Component	Adjusted Incidence Rate Ratio (95% CI)*	P value
Hiring additional staff to perform discharge medication reconciliation and patient counseling	0.78 (0.64 to 0.95)	0.02
Training existing staff to perform discharge medication reconciliation and patient counseling	0.69 (0.56 to 0.86)	0.001
Hiring additional staff to take preadmission medication histories	1.16 (0.78 to 1.71)	0.47
Training existing staff to take preadmission medication histories	1.06 (0.97 to 1.16)	0.21
Making improvements to existing medication reconciliation health information technology	0.33 (0.11 to 0.96)	0.04
Performing high-intensity interventions on high-risk patients	0.85 (0.75 to 0.96)	0.01
Clearly defining roles and responsibilities and communicating this with clinical staff	0.80 (0.58 to 1.12)	0.19
Improving access to preadmission medication sources	1.11 (0.84 to 1.47)	0.46
Implementing a new electronic medical record	2.18 (1.58 to 3.01)	<0.001

* Adjusted for patient age, insurance, medical service, number of preadmission medications, and Elixhauser comorbidity score

Effects of HIT

Major HIT challenges were of several types, often interacting with each other (**Table 6**). For example, in some systems, due to design issues, preadmission medication lists (PAMLs) could not be modified without changing ambulatory orders from which the medications were derived; this often meant that nurses and pharmacists lacked EHR permission to make direct changes to PAMLs and instead left notes/comments. Physicians often did not see these comments (a combination of poor screen design, poor customization of screens, and issues of policy and workflow) and therefore did not make corresponding changes to the PAML or take appropriate action during admission reconciliation or medication ordering. In turn, this meant that discharge medication reconciliation did not account for changes that should have been made to the PAML but were not. Discharge patient instructions therefore lacked the ability to accurately document the changes in discharge medication regimens compared with the PAML (i.e., which medications were new, changed, and discontinued). Systems issues included lack of coordination with referring physicians and lack of documentation of reasons for medication changes, both leading to inappropriate discharge orders.

Table 6. Medication Reconciliation HIT Issues

Medication Reconciliation Step	HIT Design	HIT Local Implementation	HIT Use by Providers; Systems Issues
Taking a best-possible medication history (BPMH), documenting a preadmission medication list (PAML)	1. Systems do not consolidate medications from various ambulatory sources or sort them by class, making history taking difficult 2. When documenting a PAML, previously ordered medications cannot be modified without changing ambulatory orders: nonordering providers can only post comments 3. Comments are not displayed prominently enough to be seen by ordering providers 4. System allows incomplete medication information, does not facilitate complete data entry 5. No place to document quality of or sources used to create PAML 6. Can only see last person who changed PAML	1. Nurses and pharmacists do not have correct permissions to modify PAML 2. Local configuration of PAML screen for providers does not display comments except as a "hover" or only with scrolling	1. Ordering providers do not act upon comments written by nonordering providers regarding correct preadmission medications and/or do not update PAML 2. Nurses and pharmacists are not allowed to make changes to medication orders 3. Users not trained to use prescription refill information 4. PAML often documented in admission note rather than being updated in system to be used for reconciliation
Admission Medication Reconciliation	1. Difficulties directly ordering some PAML medications at admission, requires extra work 2. Lack of notification if changes made to PAML that require re-reconciliation		1. Ordering providers do not update medication orders based upon new PAML information 2. No requirement to document reasons for changes from PAML to admission orders (also leads to discrepancies at discharge)
Discharge Medication Reconciliation	1. Poor visual alignment of PAML and current inpatient medications makes discharge reconciliation difficult 2. Defaults set to continue preadmission medications at discharge	1. Discharge reconciliation does not account for changes that should have been made to PAML but were not 2. Ordering providers bypass discharge reconciliation that requires accurate PAMLs and instead order discharge medications from scratch, bypassing all decision support and creation of patient instructions that make medication changes clear	
Discharge Patient Education	1. Discharge medication lists for patients contain unusual abbreviations 2. Discharge medication lists don't make changes from PAML clear (e.g., regarding new, changed, and stopped medications)		
Forwarding Medication Information to Next Provider	1. Lack of place to document reasons for changes from PAML to discharge orders		1. No requirement to document changes from PAML to discharge orders 2. Poor communication with PCPs regarding medication changes
All Steps	1. Systems not designed for teams working together		1. Local IT staff slow to make necessary changes 2. Lack of consistency across HIT trainers

Qualitative Analysis: Barriers and Facilitators of Implementation

A full description of the qualitative findings is beyond the scope of this report. Numerous barriers and facilitators of implementation were identified through interviews and focus groups. The lessons learned can be summarized as follows:

- One of the biggest predictors of successful implementation was the degree of institutional support, which in turn was closely associated with the perceived alignment of medication reconciliation quality improvement efforts with individual and organizational priorities (e.g., readmission reduction) and with stakeholders' belief in the potential for these efforts to reduce costs, increase patient safety, promote beneficial patient-provider relationships, and increase patient satisfaction.
- It was critically important for project QI teams to identify the likely competing interventions and initiatives for resources, time, and attention (e.g., releasing an electronic medical record across the hospital), as they both directly and indirectly impacted the ability for a site to implement specific interventions from the MARQUIS bundle.
- Conversely, one of the biggest facilitators of implementation was the integration of MARQUIS intervention components with existing site initiatives (e.g., the use of "medication reconciliation assistants" and pre-existing post-discharge education programs for high-risk patients).
- The political process of getting clinicians and leadership on board for a substantive change in policies, processes, and procedures takes time, and this process often could not be rushed.
- Sometimes it takes a critical, tangible event (e.g., a case of severe patient harm due to a serious medication discrepancy) to overcome resistance and convert agnostics and adversaries into advocates.

Besides lessons learned for successful implementation, we also learned several lessons regarding the intervention components themselves:

- It is insufficient to teach providers how to take a Best Possible Medication History (BPMH) and assume competency. Rather, sites need to establish a certification process for BPMH taking in order to standardize the taking of high-quality medication histories throughout the hospital.
- BPMH training may be most effective if done in a peer-to-peer format so that the trainer can directly model the work the trainee should follow.
- Though some sites used decentralized pharmacists to assist with medication reconciliation, the presence of having clinical pharmacists on rounds brings with it many benefits, because care teams can identify problems that pharmacists can solve in real time and because pharmacists already know the patients.
- Some sites found that the generation of Public Safety Announcements (PSA) on computer screen savers was an effective campaign to change the culture of medication reconciliation from regulatory compliance to one that emphasizes the role of medication reconciliation to improve patient safety.
- Most successful efforts established workflow procedures around medication reconciliation that made roles explicit and held all stakeholders accountable.
- As noted above in HIT lessons learned, successful implementation of MARQUIS often required updates to and support from their EHR systems to help with workflow and ensure that accurate and complete information was being entered and seen by providers.

Discussion and Significance

Adoption of a multifaceted medication reconciliation quality improvement initiative using a mentored implementation model was associated with a reduction in potentially harmful medication discrepancies over time. Of the four sites that were able to implement interventions during the study period, three saw improvements in their potentially harmful medication discrepancy rate, but the fourth site was severely impeded by a new EMR that actually increased discrepancy rates.

We found that hiring additional pharmacy staff to assist with discharge reconciliation and patient counseling was the most effective component of a medication reconciliation QI program. Conversely, training existing staff to take medication histories was shown to increase potentially harmful discrepancies, perhaps because it led to diffusion of responsibility or delays in hiring new staff, which could potentially consolidate this role in a few well-trained personnel. A greater number of intervention components was shown to decrease total discrepancy rates, including training staff in discharge reconciliation/patient counseling and performing high-intensity interventions in high-risk patients.

Significant challenges exist with the design, implementation, and use of HIT during medication reconciliation processes that, together with systems issues, impacted patient safety. This was especially true for the implementation of new vendor EMR systems. These were found to be some of the biggest challenges to successful medication reconciliation QI efforts. In a few cases, improvements to existing HIT were possible that were somewhat able to reduce the total number of medication discrepancies.

We also discovered several factors that had major impacts on the extent to which MARQUIS was successfully implemented, including degree of institutional support, degree to which medication reconciliation was viewed as aligned with other institutional priorities, and the presence of competing (as opposed to complementary) QI projects. Last, we learned many lessons about how to optimize the intervention itself, such as the need to certify competency in medication history taking.

In response to our experience with MARQUIS, we subsequently created a second version of the toolkit, which is now available on the SHM website:
http://www.hospitalmedicine.org/Web/Quality___Innovation/Implementation_Toolkit/MARQUIS/Download_Manua_Medication_Reconciliation.aspx

The revised version includes a number of significant changes:

1. We streamlined the description of the intervention into three main categories:
    a. The medication reconciliation “bundle,” including risk assessment (and intensive efforts in high-risk patients), medication history taking, discharge reconciliation, and patient counseling. Also included in this section is provider training in the bundle and medication reconciliation forms and guidelines for patient-friendly educational materials.
    b. Improving access to preadmission sources of medication information, including pharmacies, outpatient providers, and other healthcare facilities as well as patient-owned medication lists.
    c. Other high-risk/high-cost but potentially high-reward interventions, including improvements in HIT, social marketing, and engagement of community resources
2. Other intervention components that are really about the process (e.g., phased implementation, assigning roles and responsibilities to clinical personnel) were moved to the first part of the implementation guide, which is focused on how to do inpatient quality improvement.
3. We revised many of the flow diagrams and other figures to more clearly illustrate best practices.
4. We emphasized the role of pharmacy technicians as “medication reconciliation assistants” trained to take best-possible medication histories.
5. We provided more details on design of HIT, including the hazards of poorly designed and implemented systems.
6. We expanded the appendix to include tools for BPMH certification, modifiable spreadsheets to calculate return on investment (to make the business case for medication reconciliation), a simplified survey tool for site leaders to track progress of the intervention components, and tools to train study pharmacists.
7. Throughout the implementation guide, we now provide links to other toolkit materials, including slide decks, educational videos, and BPMH pocket guides.

We were not surprised that the intervention as a whole was successful, although we had expected a greater effect. One barrier was the long delay between sites signing up for the study (i.e., during the grant application

phase) and implementation of the intervention more than a year later. In the interval, several sites had turnover in leadership and/or changes in institutional priorities that impeded implementation (and in one extreme case led to a site dropping out of the study). We were also not surprised that hiring new pharmacy staff to help with discharge medication reconciliation and patient counseling was the most successful component of the intervention. Several prior studies have shown the impact of pharmacists on medication reconciliation quality. Because successful medication reconciliation efforts often require activities that are time consuming and historically have never been adequately resourced, it often requires new (or newly allocated) staff to ensure reliable and high-quality completion of those tasks (as opposed to education of existing staff, who are then expected to carve the time out of existing activities).

We were somewhat surprised by the potential for negative effects of EMR implementation. Several studies have shown the benefits of HIT in medication reconciliation, but most of those studies used proprietary systems for which medication reconciliation was the major (if not sole) HIT focus of the institution for that year. That is very different from wholesale adoption of a vendor EMR, for which the medication reconciliation component may not be particularly thoughtfully designed or locally customized and for which attention is divided among many other priorities, leading to inadequate attention to processes and use of the technology.

Barriers and facilitators of implementation were consistent with the broader implementation science literature and provide an important reminder about the need for institutional commitment to improve processes as complex and multidisciplinary as medication reconciliation.

To our knowledge, this is the largest multicenter medication reconciliation study conducted in the United States to date. Other studies have shown the benefits of interventions to improve medication reconciliation but very often occurred at single sites and often used one or two intervention components. Most of those studies did not offer an in-depth look at barriers and facilitators of implementation. Our study thus provides a very important contribution to the field. lso, by conducting it as a “real-world” study (e.g., not providing sites with resources or personnel other than a small stipend for data collection), it also provides a realistic assessment of the magnitude of likely benefit were this effort to be implemented more widely.

Limitations

There are several limitations to our study. The disadvantage of it being a real-world study is that we could not measure the potential impact of the intervention under ideal conditions. Sites had gaps in their monthly data collection that sometimes limited the power of the time series analysis. The choice of intervention and control units was not random, raising the possibility of confounding; however, we minimized this effect by comparing each unit to itself over time, adjusting for temporal trends, and robustly adjusting for patient case mix. Similarly, the choices of which intervention components to implement varied by site and were also not random, somewhat limiting our ability to determine the most effective components (e.g., is a certain component most effective or is it that the sites that chose to implement that component those most likely to be successful?). Our first site visit was sometimes too early to measure intervention fidelity but, nevertheless, was very important for obtaining institutional support and for observing the medication reconciliation process in real time, which often led to insights on how to design future interventions. Last, we cannot prove that personnel who participated in our interviews and focus groups were representative of all opinions at those sites or that their answers were completely forthcoming, but we made every effort to enlist a large, varied, and purposeful sample of respondents and to ensure them of the confidentiality of their responses.

Conclusions and Implications

MARQUIS demonstrates the potential of an evidence-based toolkit and mentored implementation to improve the medication reconciliation process across a wide variety of hospitals. With several improvements to our toolkit, our lessons learned regarding implementation, and our collective experience with MARQUIS, we hope our next effort will be even more successful. Specifically, we plan to a conduct a second round of mentored implementation with 18 additional sites. In this case, we plan to recruit sites using strict enrollment criteria to identify those most willing and able to successfully implement the intervention and plan to begin the study immediately after enrollment to avoid interim changes in personnel, leadership, and priorities.

Other implications and next steps include the following:

1. MARQUIS led to the National Quality Forum endorsing our measure of medication reconciliation quality (number of medication discrepancies per patient). Over the next 5 years, we plan to train pharmacists throughout the country to conduct this measure, and we hope that the measure will move from voluntary to mandatory reporting during that time. Once all sites are regularly measuring the quality of medication reconciliation, we anticipate this will increase the urgency (and decrease the barriers) to improve their processes.
2. We plan to engage medication safety experts, HIT experts, the national patient safety community (e.g., the National Patient Safety Foundation), and major EMR vendors in a roundtable conference to develop standards for the design of medication reconciliation software. We also hope to develop a consensus on the best ways to locally adopt and use this software.
3. During our study, it became apparent that trainees have never received adequate education on medication reconciliation. We are now working with professional schools (medical, nursing, and pharmacy) on the development of curricula around safe prescribing, including medication history taking, medication reconciliation, and patient counseling.
4. We are now working with the American Society of Health-System Pharmacists (ASHP) on a 1-day workshop for pharmacy technicians to become "medication reconciliation assistants" trained and certified in medication history taking. We also plan to train local pharmacists in how to supervise and certify competency of these personnel.

With these efforts, over the next few years, we hope to take the lessons learned from MARQUIS to greatly improve medication safety during transitions of care across the United States.

List of Publications and Products

1. Mueller SK, Kripalani S, Stein J, et al. A toolkit to disseminate best practices in inpatient medication reconciliation: multi-center medication reconciliation quality improvement study (MARQUIS). *Joint Commission journal on quality and patient safety / Joint Commission Resources.* Aug 2013;39(8):371-382.
2. Salanitro AH, Kripalani S, Resnic J, et al. Rationale and design of the Multicenter Medication Reconciliation Quality Improvement Study (MARQUIS). *BMC health services research.* 2013;13:230.
3. Society of Hospital Medicine. Medication Reconciliation Implementation Toolkit. 2014; http://www.hospitalmedicine.org/Web/Quality___Innovation/Implementation_Toolkit/MARQUIS/Download_Manua_Medication_Reconciliation.aspx. Accessed December 19, 2014.

Manuscripts in Preparation

1. Medication Reconciliation and Health Information Technology: HIT and Systems Challenges in the MARQUIS Study*
2. The Effects of a Multi-Faceted Medication Reconciliation Quality Improvement Intervention on Patient Safety: Final Results of the MARQUIS Study*
3. What are the best ways to improve medication reconciliation practices? An on-treatment analysis of the MARQUIS study*
4. Barriers and Facilitators to Implementation of Medication Reconciliation Interventions: Lessons Learned from Participants in the Multicenter Medication Reconciliation Quality Improvement Study (MARQUIS)
5. Case Studies in Medication Reconciliation Quality Improvement: lessons learned from the MARQUIS study
6. Are the Number of Medication Discrepancies Per Patient Associated with Patient Factors, the Quality of Medication Reconciliation Processes, Both, or Neither? Insights for Measurement from MARQUIS.

* Abstract submitted to Society of Hospital Medicine Annual Meeting