*Grant Final Report*

**Grant ID: 5R18 HS017020-02**

# A Systems Engineering Approach: Improving Medication Safety with Clinician Use of Health IT

**Inclusive dates: 09/07/07 - 11/30/10**


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**Submitted to:**
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# Abstract

**Purpose:** To develop and pilot-test a web-based implementation of a Team Resource Management (TRM) intervention aimed at improving medication safety in primary care.

**Scope:** Medication safety is known to be a major problem in ambulatory primary care. Existing methodologies have had limited success. The project utilized an approach based on failure modes and effects analysis, adapted for primary care. Practices with pre-existing EMR's were recruited from within a local practice-based research network. Safety net practices were included.

**Methods:** 8 Practices were randomized to either the web-based TRM or usual practice (4 practices in each group). Primary outcome was adverse drug events (ADE's) in older adults, ascertained using a trigger tool chart review methodology at two 12-month periods (pre- and – post-intervention).

**Results:** The rate of ADE's showed a downward trend from 25.8 to 18.3 ADE's per 100 patients per year in the intervention (not statistically significant). The rate was unchanged in the control group (24.3 vs. 24.8). This pilot study was limited by small size and short follow-up period, and by weaknesses of the trigger tool methodology for measuring ADE's. Nevertheless it achieved its aim of demonstrating successful implementation of a web-based TRM in busy primary care practices.

**Key Words:** Medication safety, adverse drug events, primary care, older adults, team resource management

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# Final Report

## Purpose

The objectives of this study were to develop and pilot-test an IT-based Team Resource Management system for primary care to address medication safety. The specific aims were to:

1. Examine the impact of an IT-based Team Resource Management (TRM) intervention on reducing selected adverse drug events (ADEs) among geriatric patients in primary care;

2. Examine the impact of an IT-based TRM intervention on improving monitoring for geriatric patients taking selected chronic medications in primary care;

3. Evaluate office staff use and application of the IT-based TRM Tool for improving geriatric medication safety in primary care settings.

## Scope

### Background and Context

Medication use is recognized to be a high risk activity across all settings. A recent IOM report on this subject acknowledges that the rates and impact of medication errors are huge but are poorly understood.[1] In ambulatory settings, medication errors and adverse drug events (ADE's) are one of the most important safety issues. Gurwitz and colleagues have estimated (by extrapolation) that Medicare enrollees alone suffer approximately 500,000 preventable ADE's per year.[2]

Lack of awareness of the type, incidence and consequences of errors in any setting is one of the most important barriers to reducing these errors and improving safety quality of care. The most commonly used method for estimating vulnerabilities in healthcare is to *retrospectively* collect and count errors through voluntary reporting systems (often referred to as 'incident reports'). These are fraught with difficulty due to various issues including under-reporting; according to IOM's 1999 report, only 5% of known errors are typically reported.[3] Error reporting often does not promote understanding of the organizational structure and processes of care. Instead it tends to be associated with blame and shame, and frequently results in antagonism between team members undermining mutual respect, trust and cooperation. Bates and colleagues have described difficulties involved in defining and quantifying errors; they report that even direct observational studies, which are highly labor intensive, often miss errors.[4]

An alternative approach that is *prospective*, rather than retrospective, and encourages involvement of all team-members for identifying and prioritizing safety and quality problems invokes Failure Modes and Effects Analysis (FMEA). This has been widely used in other high-risk industries and has been advocated by the IOM as a means of analyzing a system to identify

its weaknesses ('Failure Modes'), possible consequences of failure ('Effects'), and to prioritize areas for improvement.[3] We have adapted and tailored this methodology to allow for the levels of resources and expertise available in ambulatory settings, and developed an instrument that has been well received by staff in a variety of settings. The details of the rationale and processes behind this instrument termed 'Safety Enhancement and Monitoring Instrument that is Patient Centered' (SEMI-P) are described elsewhere.[5-7]

## Settings

The study took place in ambulatory primary care practices. Table 1 shows the characteristics of the practice sites in both the intervention and control groups. All practices were part of the Upstate New York Practice Based Research Network (UNYNET) and had EMR's in place for at least 12 months prior to the start of the study. Both groups contain a variety of practice types including safety net practices. Urban, suburban, and rural practices are represented, of various sizes and ownership structures.

**Table 1. Characteristics of the study sites**

| Site Char-acteristic | Intervention Site 1 | Intervention Site 2 | Intervention Site 3 | Intervention Site 4 | Control Site 1 | Control Site 2 | Control Site 3 | Control Site 4 |
|---|---|---|---|---|---|---|---|---|
| Ownership | Hospital (satellite) | Private | Private | Private | FQHC | Private | Private | Private |
| Geographic Location | Urban | Suburban | Suburban | Rural | Urban | Urban | Suburban | Urban |
| Safety Net | Y | N | N | Y | Y | Y | N | Y |
| Residency practice site?(Y/N) | Y | N | N | Y | N | N | N | Y |
| Approximate visits/year | 9,300 | 14,000 | 6,000 | 36,000 | 30,000 | 23,000 | 10,000 | 13,000 |
| Total Staff | 45 | 13 | 8 | 42 | 74 | 42 | 20 | 47 |

## Participants

All staff at the above sites were invited to participate in surveys and team discussions.

There is interest in enabling patients to access reports of ambulatory care quality and safety for their providers, and in having patients report experience with their care. These are important areas that require research but were beyond the scope of this study.

## IOM Priority Areas

The project addressed the following IOM priority areas:

- Frailty associated with old age
- Medication management

# Methods

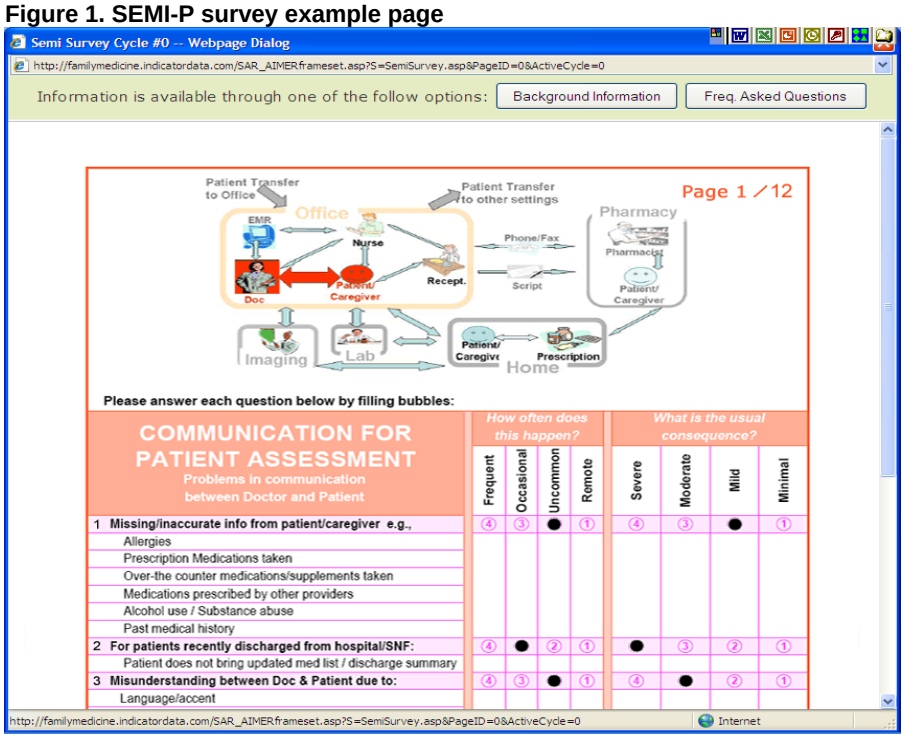
This study was a randomized controlled trial of a TRM intervention to reduce ADE's in primary care. Randomization was at the site level; 4 sites were assigned to the intervention and 4 to a control state (usual practice). In all 8 sites, ADE's were ascertained using a previously published trigger tool methodology[2,8].

## TRM Intervention (4 Sites): Web-Based (Qaduceus.Com)

The intervention involved implementation of web-based Team Resource Management system (Qaducues.com) in the four practices that were randomly assigned to this group. The system uses a cyclical safety improvement process facilitated by use of 2 anonymous online staff surveys. The first survey instrument is the Safety Enhancement and Monitoring Instrument (SEMI-P) which is a Failure Modes and Effects Analysis tool designed for the ambulatory setting focusing on medication management processes.[5-7] The second instrument is the Safety Attitudes Questionnaire - Ambulatory version (SAQ-A) which provides measures of safety climate.[9,10] Among the published safety climate surveys available at the time of this study, the SAQ was determined by Colla and colleagues to have the best psychometric properties.[11] For each survey, online instructional clips and automated analysis with visual presentation of results were developed and implemented as part of the Qaduceus system.

Figure 1 is a screenshot of the first of 12 pages of the online SEMI-P survey. Each member of each intervention practice was invited to complete this survey anonymously as part of a staff meeting. The same procedure was followed for the SAQ-A.

**Figure 1. SEMI-P survey example page**



At each site, after administration of each survey, the practice teams immediately re-grouped and reviewed the results and commenced discussion. Figure 2 is a screenshot showing the compiled results of the SEMI-P, generated by the system in real time. Figure 3 shows example results from the SAQ-A, in a visual format that was developed especially for this project, to highlight strengths and weaknesses in the safety culture.

**Figure 2. Example SEMI-P results**

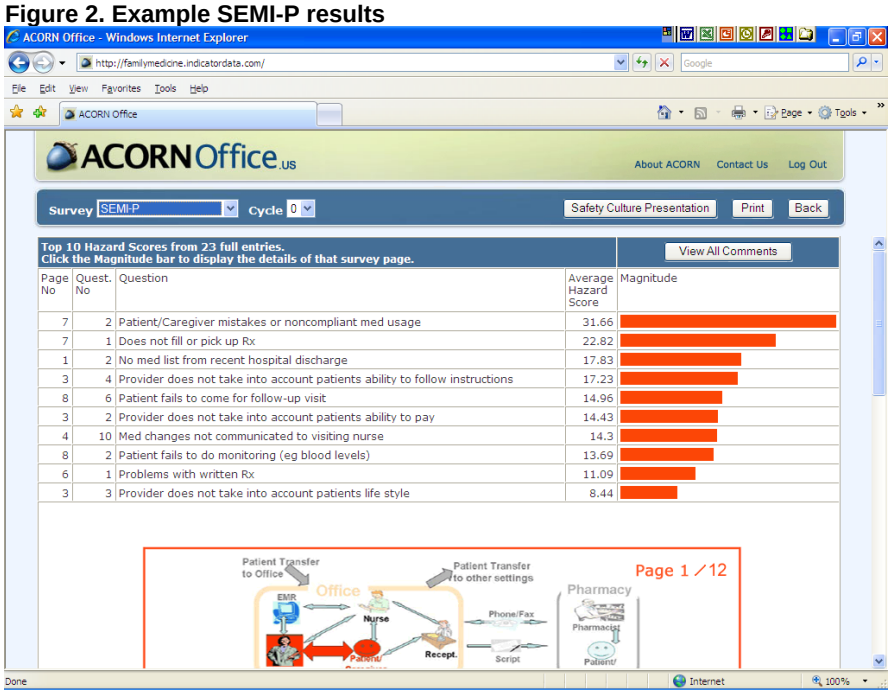
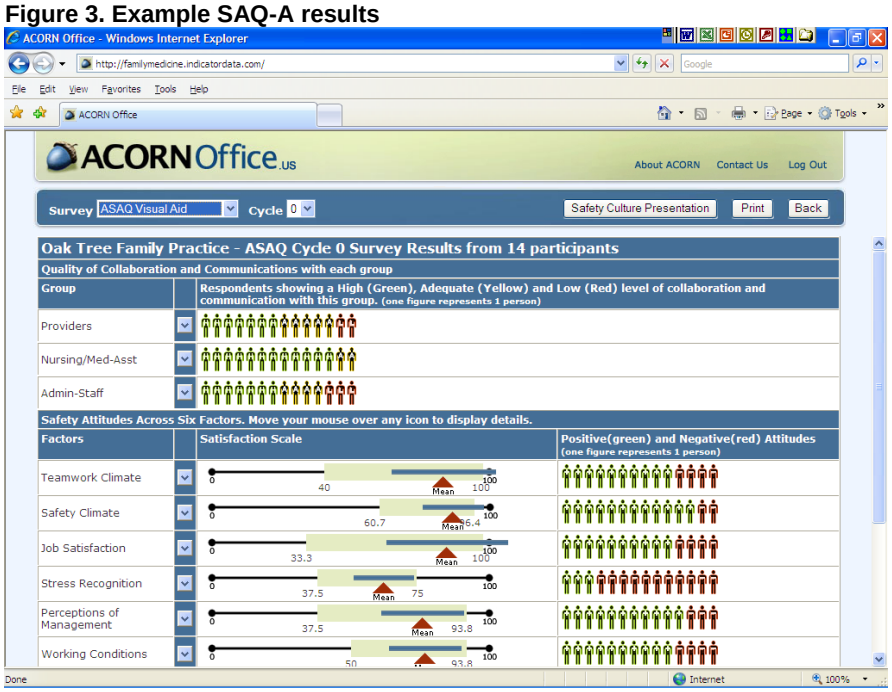



**Figure 3. Example SAQ-A results**



This was followed by a series of staff meetings in which the survey results were reviewed and discussed, leading to prioritization of medication safety issues. Examples of prioritized areas include: poor patient education about medications, high no-show rate, poor medication tracking, and poor co-ordination/teamwork with respect to handling of medication refill requests.

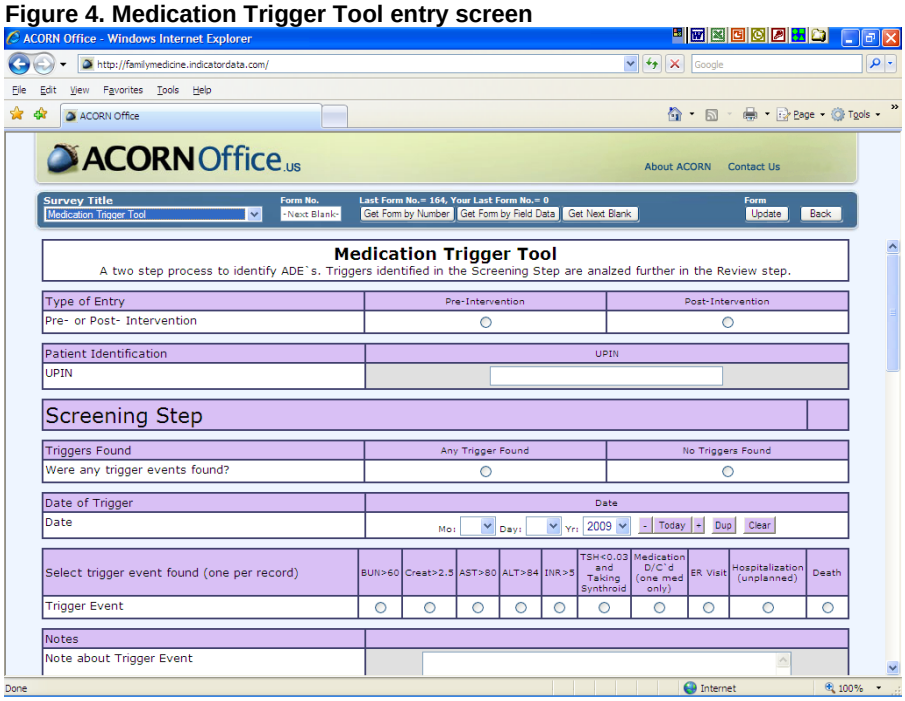
In subsequent staff meetings, teams worked together to address the chosen priorities by developing feasible system changes to improve medication safety. Examples include consistent use of patient education materials for high-risk medications, inclusion of diagnosis on prescriptions, patient reminders regarding follow-up, patient-carried medication lists, re-design of medication refill workflow, better training and follow-up for new personnel, and better employee performance feedback.

The 'Initiatives' tool within Qaduceus.com was used by staff to define their goals and objectives for safety improvement, identify and assign specific work steps to individual team members, track progress, coordinate meetings, and remind staff of their commitments. The 'Indicators' tool was used to define specific measurable outcomes related to each 'Initiative' and to track these over time in order to determine whether the stated objectives were being met.

## Outcome Ascertainment (4 Intervention and 4 Control Sites)

The primary outcome is the rate of ADE's (measured using a Trigger Tool methodology). A secondary outcome is compliance with HEDIS guidelines for laboratory monitoring for patients who are prescribed certain medications chronically (meaning that they are prescribed the medication for 6 or more months out of a 12 month period). Both of these outcomes are for older adults (aged 65 or above) since these patients are known to be at higher risk of adverse events. A web-based data capture tool was developed and implemented as part of the Qaduceus system for both the Trigger Tool (shown in Figure 4) and the HEDIS measure.

**Figure 4. Medication Trigger Tool entry screen**



These 2 outcomes were ascertained for a baseline period defined as 12 months prior to the start of the intervention, and an endpoint period defined as the 12 months following the start of the intervention. For each period (baseline and endpoint), research assistants reviewed an independent sample of 100 charts of patients aged 65 and above at each site. The HEDIS laboratory monitoring measurement was completed by these research assistants. For the Trigger Tool, the research assistants conducted the first of two steps, known as the 'Screening' step. Charts identified in this first step as having triggers underwent secondary review (the 'Review' step) by a physician or pharmacist who reviewed each trigger to determine whether an adverse drug event occurred, and if so, its severity and preventability.

# Results

## Patient Characteristics

Table 2 summarizes the demographic characteristics of the patients whose charts were reviewed for the outcome ascertainment described above. All patients were aged 65 and above. The vast majority had cardiovascular disease; about a third had Diabetes Mellitus. The average patient had 5 co-morbid conditions and was on 7 medications.

**Table 2. Patient characteristics in intervention and control groups, at Pre- and Post-intervention periods**

| | | Total pts | % in Age Range: 65-74 | % in Age Range: 75-84 | % in Age Range: 85+ | % female | % DM | % CVD | Mean no. of Co-morbities | Mean no. of chronic medications prescribed |
|---|---|---|---|---|---|---|---|---|---|---|
| Intervention | Pre | 400 | 51.5 | 37.5 | 11.0 | 61.8 | 26.3 | 85.3 | 5.6 | 6.8 |
| Intervention | Post | 400 | 53.8 | 34.5 | 11.8 | 63.0 | 31.3 | 85.8 | 5.2 | 7.1 |
| Control | Pre | 400 | 58.5 | 32.3 | 9.3 | 68.0 | 37.0 | 88.0 | 4.7 | 6.7 |
| Control | Post | 400 | 58.3 | 33.5 | 8.3 | 66.0 | 36.3 | 87.3 | 4.7 | 7.6 |

DM = diabetes mellitus
CVD = cardiovascular disease
Pre = Pre-intervention period
Post = Post-intervention period

## Specific Aim 1: ADE's Ascertained Using Trigger Tool

Table 3 shows the rates of ADE's at each of the intervention and control sites, at pre-and post-intervention periods. As can be seen, in the intervention group as a whole, the total number of ADE's decreased from 25.8 per 100 patients per year to 18.3, while in the control group it began at about the same rate (24.3) and stayed about the same(24.8). 2-way ANOVA examining the interaction between Time (Pre vs.Post) and Group (Intervention vs. control) showed no significant interaction (p=.407) suggesting that there was no significant difference between the 2 practice groups with respect to change in ADE's over time.

**Table 3: ADE's , pADE's, and severity in intervention and control sites**

| | | Total charts screened | Total Triggers | # Trig-gers Re-viewed | ADE rate* | PPV% ** | pADE rate * | ADE Rates by Sev-erity*: None/ Min-imal | ADE Rates by Sev-erity*: Mild | ADE Rates by Sev-erity*: Mod-erate | ADE Rates by Sev-erity*: Severe | ADE Rates by Sev-erity*: Un-known |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Inter-vention Site 1 | Pre | 100 | 120 | 120 | 19 | 15.8 | 3 | 0 | 13 | 2 | 4 | 0 |
| Inter-vention Site 1 | Post | 100 | 147 | 147 | 24 | 16.3 | 4 | 2 | 14 | 1 | 6 | 1 |
| Inter-vention Site 2 | Pre | 100 | 90 | 89 | 16 | 18.0 | 2 | 4 | 6 | 6 | 0 | 0 |
| Inter-vention Site 2 | Post | 100 | 95 | 94 | 20 | 21.3 | 3 | 0 | 5 | 13 | 2 | 0 |
| Inter-vention Site 3 | Pre | 100 | 91 | 86 | 18 | 21.0 | 1 | 4 | 12 | 1 | 1 | 0 |
| Inter-vention Site 3 | Post | 100 | 42 | 41 | 13 | 31.7 | 0 | 0 | 13 | 0 | 0 | 0 |
| Inter-vention Site 4 | Pre | 100 | 210 | 209 | 50 | 23.9 | 9 | 6 | 29 | 5 | 7 | 3 |
| Inter-vention Site 4 | Post | 100 | 83 | 82 | 16 | 19.5 | 2 | 1 | 10 | 2 | 3 | 0 |
| **Inter-vention TOTAL** | **Pre** | **400** | **511** | **504** | **25.8** | **20.4** | **3.8** | **3.5** | **15.0** | **3.5** | **3.0** | **0.8** |
| **Inter-vention TOTAL** | **Post** | **400** | **367** | **364** | **18.3** | **20.1** | **2.3** | **0.8** | **10.5** | **4.0** | **2.8** | **0.3** |
| Control Site 1 | Pre | 100 | 119 | 119 | 24 | 20.2 | 4 | 3 | 14 | 4 | 3 | 0 |
| Control Site 1 | Post | 100 | 110 | 109 | 16 | 14.7 | 1 | 3 | 10 | 1 | 0 | 2 |
| Control Site 2 | Pre | 100 | 155 | 155 | 23 | 14.8 | 8 | 9 | 7 | 2 | 3 | 2 |
| Control Site 2 | Post | 100 | 133 | 133 | 21 | 15.8 | 4 | 1 | 4 | 12 | 3 | 1 |
| Control Site 3 | Pre | 100 | 136 | 136 | 26 | 19.1 | 1 | 5 | 19 | 1 | 0 | 1 |
| Control Site 3 | Post | 100 | 176 | 173 | 29 | 16.8 | 3 | 6 | 17 | 2 | 2 | 2 |
| Control Site 4 | Pre | 100 | 280 | 280 | 24 | 8.6 | 3 | 4 | 13 | 2 | 5 | 0 |
| Control Site 4 | Post | 100 | 285 | 285 | 33 | 11.6 | 4 | 7 | 24 | 2 | 0 | 0 |
| **Control TOTAL** | **Pre** | **400** | **690** | **690** | **24.3** | **14.1** | **4.0** | **5.3** | **13.3** | **2.3** | **2.8** | **0.8** |
| **Control TOTAL** | **Post** | **400** | **704** | **700** | **24.8** | **14.1** | **3.0** | **4.3** | **13.8** | **4.3** | **1.3** | **1.3** |

* rate of events per 100 patients per year

** PPV = positive predictive value. Calculated as number of ADE's per 100 triggers reviewed

## Specific Aim 2: HEDIS Lab Monitoring

The results of the HEDIS outcome measure regarding recommended laboratory monitoring for patients on certain chronic medications are summarized in Table 4. For each medication in the Table, the first column shows the number of patients in each practice who were found to be on the medication chronically. The second column shows the number (and percent of those prescribed the medication) who had an order for the relevant HEDIS-recommended laboratory test. The third column shows the number (and percent of those who had the test ordered) for whom the test result was found in the chart. As can be seen, ACE inhibitors, diuretics, and statins are used by a high proportion of patients (around 40% or more at most practices). In both the intervention and control groups, the majority of patients had appropriate lab monitoring for these medications. There was no significant change in these rates, from pre- to post-intervention periods.

**Table 4. Rates of HEDIS-recommended lab monitoring for patients on chronic medications**

**Table 4a. ACE**

| SITE | | Total Patients | Pts. Taking | Lab Ordered (%)* | Results in Chart (%)** |
|---|---|---|---|---|---|
| Intervention | Pre | 400 | 205 | 178 (86) | 163 (92) |
| Intervention | Post | 400 | 221 | 184 (83) | 165 (90) |
| Control | Pre | 400 | 189 | 167 (88) | 156 (93) |
| Control | Post | 400 | 210 | 188 (90) | 170 (90) |

**Table 4b. Diuretics**

| SITE | | Total Patients | Pts. Taking | Lab Ordered (%)* | Results in Chart (%)** |
|---|---|---|---|---|---|
| Intervention | Pre | 400 | 161 | 141 (88) | 128 (91) |
| Intervention | Post | 400 | 165 | 132 (80) | 116 (88) |
| Control | Pre | 400 | 174 | 153 (88) | 146 (95) |
| Control | Post | 400 | 201 | 182 (91) | 174 (96) |

**Table 4c. Digoxin**

| SITE | | Total Patients | Pts. Taking | Lab Ordered (%)* | Results in Chart (%)** |
|---|---|---|---|---|---|
| Intervention | Pre | 400 | 23 | 11 (48) | 10 (91) |
| Intervention | Post | 400 | 15 | 4 (27) | 3 (75) |
| Control | Pre | 400 | 9 | 6 (67) | 6 (100) |
| Control | Post | 400 | 11 | 6 (55) | 6 (100) |

**Table 4d. Statin**

| SITE | | Total Patients | Pts. Taking | Lab Ordered (%)* | Results in Chart (%)** |
|---|---|---|---|---|---|
| Intervention | Pre | 400 | 187 | 163 (87) | 142 (87) |
| Intervention | Post | 400 | 221 | 191 (86) | 169 (88) |
| Control | Pre | 400 | 187 | 159 (85) | 146 (92) |
| Control | Post | 400 | 181 | 155 (86) | 143 (92) |

**Table 4e. Anticonvulsant**

| SITE | | Total Patients | Pts. Taking | Lab Ordered (%)* | Results in Chart (%)** |
|---|---|---|---|---|---|
| Intervention | Pre | 400 | 6 | 3 (50) | 2 (67) |
| Intervention | Post | 400 | 7 | 3 (43) | 2 (67) |
| Control | Pre | 400 | 7 | 5 (71) | 5 (100) |
| Control | Post | 400 | 6 | 2 (33) | 2 (100) |

* = percent among patients taking this medication
** = percent among patients who had the lab ordered

## Specific Aim 3: Use of the TRM tool

Table 5 summarizes the interventions that were carried out at one of the practices. Each practice prioritized different areas of concern based on their own discussion of SEMI-P and SAQ-A results, and made decisions based on available resources and feasibility. Table 5 shows a variety of interventions that were implemented at one site, together with the barriers that were faced, and strategies that were used to overcome them. All four intervention practices had some successful interventions as well as some with limited or no success. All used the Qaduceus system to record and track identified priorities and planned interventions.

**Table 5. Example of interventions, barriers, and solutions at one site**

| **Problem identified*** | **Intervention planned*** | **Barriers faced*: Description** | **Barriers faced*: Class** | **Solutions & Strategies tried*: Description** | **Solutions & Strategies tried*: Class** | **Was the inter-vention effective?**** | **What made it work?**** |
|---|---|---|---|---|---|---|---|
| High volume of refill requests, and Inefficient process for handling them | Change in workflow for handling medication refills requests | Lack of cooperation by one front office staff member | **INDIVIDUAL TEAM MEMBER** | 1) Work with this person to help them understand the benefits of the change to the office<br>2) Change in responsibility for this task | **COMMUN-ICATION**<br><br>**TEAM** | Yes | Change in responsibility for this task |
| Poor patient follow-up | Try to improve patient compliance with follow up visits | Low patient compliance with follow up visits | **PATIENT** | 1) Limited the number of med refills<br>2) used E-script notes to pharmacist about needed F/U<br>3) phone call reminders to pts<br>4) standardized F/U schedules for pts. with specific chronic diseases | **1) PROVIDER**<br><br>**2) TECHNICAL**<br><br>**3) COMMUN-ICATION**<br><br>**4) TEAM** | Yes | Combination of multiple strategies |
| Poor medication compliance | Try to improve medication compliance by writing indication for medication on prescription | Perceived extra time required Uncertain benefit | **TIME**<br><br>**UNCER-TAINTY** | Trial by one provider, realized that little effort was required. Staff perceived that the information was useful to patients | **PILOT** | Yes | Successful pilot |
| Inconsistent lab monitoring for patients on high-risk medications | Create registry for patients on statins to improve monitoring | Competing time demands on staff | **TIME** | Reminder to staff | **COMMUN-ICATION** | Limited | Still working to incorporate this into the workflow |

## Discussion, Conclusions, Significance and Implications

The TRM intervention using the online Qaduceus system was successfully implemented in all 4 intervention sites. Staff in each practice participated in designing and implementing interventions to improve medication safety, tailoring their interventions to their own unique circumstances.

The main outcome was a trend toward a decrease in the rate of ADE's in the intervention group over time, in contrast to the control group which showed no such trend. This suggests that the web-based TRM may be effective in improving medication safety but this pilot study was not able to prove this conclusively.

The study was a pilot study, and as such, is limited by the small number of practices and the small number of patients included in the outcome measures. The outcome measure used for ADE's was based on chart review and therefore is limited. The sensitivity of the trigger tool method for detecting ADE's is not known but is certainly less than 100%. Therefore ADE rates determined using this tool should not be seen as complete but only as a subset of the total ADEs. For comparability over time, the ascertainment methodology was made consistent from pre- to post-intervention periods. However, it should be noted that changes in physician charting behaviors may have occurred over time (even though EMR's did not change) which may have affected measured ADE rates. Furthermore, the time period for follow-up was limited and therefore there was limited time to observe the impact of the intervention.

The study achieved its main aims of developing and implementing a web-based TRM in a variety of ambulatory settings. Future studies should test the intervention on a larger scale, over a longer period of time, and should explore methods for overcoming common barriers faced.

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