Title: Multi-Method Proactive Risk Assessment

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Abstract:

Purpose: To evaluate the ability of a multi-method risk assessment - a combination of a safety culture survey, a readiness to change survey, error reports, and an error visualization process - to guide the development of a risk-informed safety improvement action plan.

Scope: Developing safe medical delivery systems requires the creation of a culture of safety, a review of error-prone processes, and the risk of harm associated with given errors coupled with the creation of an organization that supports change. These areas were assessed within one academic ambulatory system and used to guide the development of an Action Plan focused on either medication management, lab test management, or imaging management.

Methods: Data from the Medical Office Safety Culture Survey, the Office Vital Signs Survey, two error reporting systems, the Medical Group Management Association Office Procedures Survey, and an error visualization process were combined to create an Action Plan designed to decrease patient harm caused by errors in the ambulatory system of the University of Colorado Hospital.

Result: The overall safety culture of the system requires reinforcement. The Safety Culture Survey may not accurately identify high- and low-safety cultures. The Medical Group Management Association Office Procedures Survey, error reporting system, and visualization process resulted in a negotiated Action Plan focused on medication management.

Key Words: ambulatory safety culture, readiness to change, error reporting, error visualization

Purpose:

1. Collect practice-level data using the instruments listed below from 12 University of Colorado Hospital (UCH) ambulatory clinics to help inform a proactive risk analysis:
   a. AHRQ Medical Office Survey on Healthcare Quality and Patient Safety;
   b. AHRQ-supported Office Vital Signs instrument;
   c. Medical Group Management Association's office risk assessment instrument;
   d. Proactive risk assessment through a visual process map and group reflection.

2. Analyze data from two UCH-specific ambulatory error databases to corroborate specific ambulatory high-risk areas identified in Aim 1.

3. Develop a data-driven risk reduction plan for one of three areas (laboratory management, imaging management, or medication management) using participatory methods within the UCH ambulatory system using a Strengths, Weaknesses, Opportunities, Threats analysis.

The inpatient component of the healthcare system has received the most attention related to understanding the source of errors and developing interventions to improve care. This is appropriate given the intensity of service in the inpatient environment and the potential for immediately catastrophic failures. Nonetheless, in any given month, approximately one-quarter of the American public is seen in an ambulatory care facility, and approximately 1% will be cared for in the inpatient setting. Furthermore, errors in ambulatory care have been well documented. Thus, the need for a safer ambulatory system is clear. Published data on ambulatory errors can help guide the overall ambulatory care areas that deserve attention. But developing interventions to reduce errors and harm requires local information concerning not only system failures but also local care processes, practice-level readiness to change, and a commitment to the provision of safe care at all levels of an institution.

This proactive risk assessment of the University of Colorado Hospital's ambulatory care system encompassed all these components. Notably, we collected and analyzed the "culture of safety" using an instrument developed with AHRQ support, the Medical Office Survey on Healthcare Quality and Patient Safety. We assessed practice's "readiness to change" using another instrument developed with AHRQ support, the Office Vital Signs Survey. We assessed care processes through an instrument developed by the Medical Group Management Association (MGMA) as well as through a visualization process developed with AHRQ support. Finally, we assessed failures in our care system using error reports collected during an AHRQ-funded error reporting demonstration project as well as using local error reporting data. This combination of information provided a robust foundation of information on which we developed an Action Plan to improve the safety of our ambulatory care system.

Scope:

The Institute of Medicine (IOM) identified six core qualities in a well-functioning healthcare system, the first of which was safety.[1] The ecology of medical care, as originally depicted by White[2] and updated by Green,[3] highlights the importance of the ambulatory environment in healthcare. In any given month, almost a quarter of us visit a physician in the ambulatory setting compared to less than 1% who spend time in the hospital.

Research indicates that ambulatory care is far from safe,[4-8] and the sheer number of people at risk highlights the need to address ambulatory patient safety.

For this project, we hypothesized that there are three domains that must be addressed to successfully transform care in a sustainable approach. These three domains track with what others have considered the key components necessary for an organization to recognize the need for change, implement a given change, and then sustain it.[9] The first domain is a ***culture of safety.*** Recently, efforts at improving safety have focused on technical solutions.[10-13] Despite the heavy attention on informatics solutions to the safety challenge, several IOM committees and others have identified the creation of a "culture of safety" as ***the key institutional requirement to achieve safe medical care***.[1,14-15] The variability of the safety culture within individual practices and across the entire UCH ambulatory system was measured in preparation for interventions. The second domain that was assessed was the ***organizational readiness to change***. When a risky system is identified, a culture of safety will create pressure to consider improving that system, and the organization's readiness to change provides the substrate on which successful and sustainable change can occur. Various organizational characteristics have been associated with particular failed attempts to change. An understanding of the strengths and weaknesses of particular practices and the readiness to change of the UCH organization, as a whole, was incorporated into the final recommendations for improvement. The final domain was an ***understanding of the relative importance of the risks within the organization***. Resources are always limited – whether considering the financial costs required to support change or the human ability to adapt to change – and so it is important to spend these resources wisely. This project reviewed the confluence of frequency, risk of harm, extent of harm, and potential for improvement to arrive at a final Action Plan.[16] We implemented high-quality data collection methods and used the information from all three domains to triangulate our proactive risk assessment process.

The UCH ambulatory care system includes 77 distinct clinics that cover the gamut of ambulatory medical care. Each year, the system delivers over 500,000 ambulatory visits and over 55,000 emergency room visits and performs over 6,700 ambulatory surgical cases. For this project, we focused on the scheduled ambulatory visits and excluded the emergency room and ambulatory surgical areas. The UCH system as a whole has declared that the provision of safe, high-quality care is its primary focus.

Methods:

Overview

The project involved primary data collection via the three surveys (Medical Office Survey on Healthcare Quality and Patient Safety, Office Vital Signs Survey, and MGMA Office Safety Procedures Survey) from 12 UCH ambulatory practices ranging from primary care to transplant surgery to radiation oncology. The two staff-clinician surveys (Culture of Safety and Office Vital Signs) were supplemented with an on-site review of safety-related systems. This information was further supplemented with reports of ambulatory errors submitted to the Applied Strategies for Improving Patient Safety (ASIPS) reporting system along with error reports submitted to UCH's error reporting system from UCH ambulatory practices. Finally, three practices participated in a visualization process using a graphic depiction of the medication and laboratory ambulatory systems associated with errors related to each step in each process.

Participating Practices

The clinics were chosen to present both medical and surgical specialties, primary care and sub-specialty clinics, and large (>10 providers) versus small (<10 providers) clinics.

Based on these criteria, the clinics were chosen as a purposeful sample from the total complement of 77 clinics. The 12 participating practices included three primary care and nine sub-specialty clinics.

The three primary care practices were one family medicine clinic and two general internal medicine clinics (all clinics included residents and faculty in the office). All primary care clinics had been previously involved in several externally funded safety projects, including error reporting, learning community development from error events, and previous use of the Culture of Safety Survey. The nine sub-specialty clinics were neurology, radiation oncology, solid organ transplant, gastroenterology, hepatology, general surgery, OB-GYN, a breast clinic, a pain clinic, and Ophthalmology. None of the specialty clinics had been involved in a previous externally supported ambulatory safety project. All 12 clinics had been involved in internal safety projects focused on laboratory specimen labeling and handling and medication reconciliation.

Data Collection

The Culture of Safety and Office Vital Signs surveys were completed by all staff members and clinicians working in each practice, with high overall response rates. For most of these clinics, this was the first time both office staff and physicians had completed the same survey related to clinic operations. All the primary care clinics and three of the sub-specialty clinics were able to complete the two surveys that required direct staff and clinician input at a single, clinic-wide meeting. Six of the sub-specialty clinics never held clinic-wide meetings, and staff and clinician surveys were completed at separate meetings – a telling piece of information. All data from the Culture of Safety and Office Vital Signs surveys were double entered and verified. The surveys were then analyzed at the clinic level, role level (clinician, back office clinical staff, other staff) for both surveys, and individual level for the Culture of Safety Survey.

The Office Safety Procedures Surveys were completed through one to three on-site visits to each clinic along with interviews of key clinical staff, including the office administrator, medical records staff, and head nurse. The surveys then were entered into the online MGMA data collection and analysis system. This system returned practice-specific results and comparisons to the entire national universe of practices that have completed the survey. MGMA further compared as a group our project's 12 submitted surveys against the national data as well as against other academic practices.

The results from the Office Safety Procedures Survey were reviewed extensively by the research team. The survey results were extensive, and many questions showed no variation within the UCH sample and little variation from the national analysis. These survey items were considered suspect. Of note, the entire survey was developed through primarily expert opinion and never fully validated. The research team, therefore, went through these reports in detail and selected items that demonstrated both positive and negative findings at the system level that were reasonably under the control of the local clinic. The results from all three surveys were combined into a single report and presented to each clinic. The overall results were used to guide the focus of the visualization process. Imaging result management was dropped from consideration, given the lack of identified problems in this area within the system.

The visualization process was conducted with a small group of practice staff and clinicians for each practice – generally five to six individuals instead of the entire practice. These sessions were conducted by Mr. Fernald without either the practice manager or medical director present in an attempt to create an open environment to discuss practice-level errors. The three groups included one primary care and two sub-specialty practices.

The data from the large ambulatory error reporting system had been previously analyzed extensively, and these analyses were reviewed for frequency versus harm. Eighteen months of error reports were pulled for the entire UCH ambulatory system, and the report classifications were reviewed for 100% of the reports. From this group, all actual errors or potential errors were manually reviewed in detail.

The top reason personnel made a report was *falls* – similar to inpatient reports. A quick review of these reports indicated they were primarily environmental in nature without any detail that would indicate a medical reason, if one was present; thus, all falls were removed from the analysis.

Information from the various data sources above were combined to create an initial Action Plan. This Action Plan was reviewed and amended by the practices that were involved in visualization process. This amended Action Plan was then reviewed by the UCH ambulatory administration and further modified to its final form.

The planning process was designed to test the various data collection approaches and to determine what, if anything, they added to the overall development of a risk-informed intervention. The limitations of the project include the purposeful sampling of practices across the UCH ambulatory system, so the findings may not reflect the entire system. Another limitation is the extensive use of self-reported measures, including the Office Safety Culture Survey, the Office Vital Signs Survey, and the self-reported errors to two different collection systems. This high reliance on self-reported data is at least somewhat offset by the collection of the MGMA Office Procedures Survey through on-site observational data collection. Even so, this survey still relies moderately on self-reported behavior by members of the office staff. This planning process was also limited by the very small number of meaningful ambulatory error reports submitted to the UCH reporting system.

Results:

Office Vital Signs and Office Safety Culture

The clinic-level results of the Office Safety Culture and Office Vital Signs surveys demonstrated a fair range from clinic to clinic as well as variability across the domains of each survey (see Table 1). The two domains with significant overlap between the two surveys were Leadership and Communication. The questions in each survey were fairly different within these domains, so the team elected to leave both sets in the final questionnaire. Other domains with high overlap in the questions' wording were removed from the Office Vital Signs Survey. Nonetheless, the scores for the Leadership domains between the two surveys did not always correlate well, indicating that they were likely to be measuring different components of leadership. For instance, one clinic demonstrated a leadership score of 3.2 on the Office Vital Signs Survey, which was exactly the same as the system average, while the Leadership domain in the Safety Culture survey was a 4.1, the highest of any clinic in the system. The two Communication domains tracked much more closely between the two surveys. With only 12 clinics in the data set, statistical analysis of the results between practices was not possible (nor the purpose of the exercise) and will not be reported.

Table 1

Survey/Domain	**High Score**	**Low Score**	**Ave Score**
Office Vital Signs			
Leadership	3.6	2.8	3.2
Communication/Teamwork	4.2	3.0	3.6
Value Evidence	4.1	1.6	3.3
Information Management	4.1	1.0	2.8
Readiness to Change	4.4	2.4	3.4

Survey/Domain	High Score	Low Score	Ave Score
Office Safety Culture			
Leadership	4.1	2.7	3.6
Work Environment	3.5	2.7	3.1
Communication	3.9	3.2	3.4
Office processes and value of safety	3.8	2.8	3.4

An alternative analysis of the Safety Culture Survey was performed at the individual respondent level (without revealing the identity of the respondent). In this analysis, respondents were considered to be either positive or negative responders to a domain, based on the average score of their responses to the questions in that domain (>3.4 = positive; < 3.5 = negative, on 5-point scale). With this analysis, the variability between clinics was further highlighted, and relatively benign average scores (for instance, average work environment score of 2.7 with system average of 3.1) demonstrated greater levels of dissatisfaction: 22 of 23 respondents reported "negative" scores. This system helped to differentiate the effects of a small number of very negative or positive individuals versus a more widespread positive or negative set of responses.

Overall, the staff and clinicians within the UCH ambulatory system demonstrated only a moderate degree of confidence in their ability to effect practice change and, at best, a moderate degree of confidence in the safety of their office systems. Selected practices' self-perceived ability to change and provide safe care were distinctly lower than the average, but no clinic stood out in an overall positive sense.

MGMA Office Procedures Survey

The results of this survey were, overall, fairly positive at the system level. Scores were significantly higher than national averages for providing patients medication lists, medication indications on prescriptions, critical labs and imaging results, staff and clinician training and competency assessments, and error-reporting systems. On the other hand, high-risk medication monitoring, medication-pregnancy monitoring, lab and imaging test tracking, consultation tracking, and test result communication to patients all scored significantly lower than the national averages. Clinic-level variation was substantial, as expected, because many of the activities are either not performed at all or are performed at the system level, thus scoring at the two extremes of the scale.

Comparison of Self-reported Activities Versus Office Procedures Survey

For a set of practices, we observed an interesting dichotomy between the two self-reported surveys and the Office Procedures Survey, which was primarily collected via observation. The three primary care practices, which had all been involved in previous safety projects, had universally implemented office procedures to track potential errors, including tracking all lab, imaging, and consult requests; tracking individual clinician response times to returned results; tracking high-risk results (such as abnormal Pap smears); having standardized medication monitoring requirements for refills; and working actively on medication reconciliation. Two specialty clinics, meanwhile, had virtually none of these systems. Nonetheless, the two practices with no safety systems in place scored themselves much higher on the self-report surveys than the three practices with extensive systems in place. This was puzzling until the research team had opportunities for greater interactions with clinicians and staff from several of these clinics. The primary care practice staff and clinicians were very aware of the risks associated with medical care from their extensive error-reporting activities. They were also very aware of the ongoing failures in the system, which were picked up by their tracking systems.

Their heightened awareness of these issues, despite the efficient mitigation of errors through their tracking system, apparently caused them to score their practice and the overall UCH ambulatory system safety relatively low. On the other hand, two of the high-scoring clinics were still very much accepting of many of the "errors" as "expected" and "routine" and of essentially no consequence. Thus, it appears that, in the same way that the successful implementation of error-reporting systems will generate increased error reports, the perceived culture of safety may be lower in practices that are actively working to mitigate errors through tracking.

Error Reporting System Review

The analysis of the ASIPS ambulatory error reports has been extensively published. The most common errors involve lab testing errors. The highest-risk errors are associated with medication prescribing and fulfillment and patient referrals (ambulatory handoffs). Lab-related errors actually have a lower chance of causing harm than all errors combined, while medication errors have a relative risk of causing harm over five times greater than all errors combined. Medication errors overall were fairly common, accounting for over 20% of all error reports, while referral errors were relatively rare, accounting for less than 5% of all errors. Thus, from the ASIPS dataset, medication errors clearly have the highest overall risk when frequency is combined with risk of harm. These findings were previously published. In the present project, we sought to validate those findings or uncover site-specific errors related to the UCH ambulatory system. We reviewed 100% of the reports made to the UCH incident reporting system for a 24-month period. The overall number of error reports was surprisingly small, averaging fewer than 70 reports per year. The greatest number of reports related to falls and other environmental concerns with patients. No practice reported over 12 true medical errors during this time frame. The primary care clinics all reported between five and 12 errors during this time frame, while no specialty clinic reported more than three true medical errors. Again, all primary care practices had been previously involved in the ASIPS project. Overall, the information was very sparse from the internal reporting system and did not serve to identify any new areas of concern within the UCH ambulatory system. In fact, the data were so sparse that they do not really support or refute the ASIPS findings.

Error Visualization Process

Even though the visualization process helped finalize the Action Plan developed from the planning process discussed above, the overall execution of the activity was spotty and difficult, at best. Based on the combined results above, with particular attention to the MGMA survey and the ASIPS data, the error visualization process was focused on medication management and lab management. The visualization activities were undertaken to focus the final Action Plan on either the medication management area OR the lab management area. Because virtually 100% of imaging studies are performed in-house, this area did not appear to have recurrent problems in the ambulatory system and had already been dropped from consideration.

The visualization process itself was reasonably successful in the primary care practice where it was conducted. The small group rapidly understood the process maps. They could identify which errors occurred in their office and quickly agreed that improving medication safety was of the highest priority. This is where the added-focus concept fell apart. The group was then quick to point out that the process map demonstrated that appropriate medication monitoring was an area that they felt needed the most attention. Often, medication monitoring involves lab testing, and, if this system was not working well, the push to improve medication monitoring would not result in any actual improvement in safety. Thus, they suggested that the Action Plan include both medication monitoring and lab test tracking, review, and reporting to patients. The two sub-specialty small groups were not able to effectively work through this process within the time allotted for the process.

These practices may have been able to work through this process successfully if they had been given several meetings to do so. But, in the time available for this planning process, they were not successful in reaching a conclusion on the focus of the Action Plan.

Ambulatory Administration Input

After the Action Plan was developed using the data collected above, it was presented to the Ambulatory Administration for review and input, as their support would be essential if the implementation grant were to be funded. This group was particularly worried about medication reconciliation processes, as there was concern that accreditation processes may focus on this particular step in the overall medication management process. Clinics had previously indicated that they were fairly tired of working on this area. The research team was concerned that a strong focus on medication reconciliation would alienate the clinic staff, but ignoring this area would alienate the ambulatory administration. Both groups were seen as critical to achieving long-term success, if the implementation grant were to be funded. Working between these two groups with a series of conversations, it was decided to allow clinics to work on one or more of three steps in the medication management process: 1) medication reconciliation – it is important to know what the patient is taking prior to initiating medication monitoring; 2) medication monitoring – the area of most interest to the clinics, as they were unclear as to the effectiveness of this area of care; and 3) lab tracking/results review – ordering the correct monitoring tests is not useful if the results are not reviewed.

Conclusions

The combination of error-reporting data supplemented with even a brief visualization process was successful in developing a risk-informed Action Plan for a multispecialty ambulatory group. The visualization process appeared very promising, but it will require considerable investment of time in practices that are still early in considering their overall safety activities. The Office Safety Culture Survey highlighted the spotty nature of the safety culture within the system. However, when direct observation was added to the survey results, the survey was not particularly successful at accurately identifying clinics with high versus low safety cultures. Thus, the overall usefulness of this survey is unclear. The Office Vital Signs survey was able to identify practices with variability in leadership and readiness to change, but whether this information is useful in a facilitated change process awaits the results of the implementation grant. The MGMA survey helped to guide direct observation activities, but, overall, it appeared to focus on fine details while not well delineating the important functions that most impact safety.

Publications and Products

No peer-reviewed publications have been submitted from this work.

The Office Safety Culture instrument is undergoing further analysis with Westat, the AAFP National Research Network, the University of Colorado, and others.

The facilitation process has been presented in a small group setting at the Practice Improvement Conference, Kansas City, Nov 2009.

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