Medication Safety: One Organization's Approach to the Challenge

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The Institute of Medicine report *To Err Is Human* has led to increased recognition of the problem of safety in the U.S. health system [1]. Subsequent studies have continued to document the need for improvement [2]. The next step in the process of improving safety in health care is to move from theoretical recognition of problems to implementation of practical initiatives that decrease adverse clinical outcomes.

Medication error is 1 facet of the clinical safety problem in the U.S. health system. A study cited in the executive summary of *To Err* estimated that up to 7000 deaths are caused each year by medication errors [3]. However, studies have shown that most errors do not pose a significant threat to patient safety [4–6]**.** In 1997, Luther Midelfort, a community hospital located in Wisconsin, sought to improve clinical safety by implementing a series of initiatives that focused on adverse drug events (ADEs). An ADE is defined as an injury resulting from medical intervention related to a drug [4]. ADEs have been shown to be a better measure of clinical safety than medication errors because by definition ADEs are linked to clinical outcomes [7–9]. The following report discusses the rationale for differentiating ADEs from the broader spectrum of medication errors and describes a practical, resource-friendly approach to enhancing patient safety.

Background

Luther Midelfort is a physician-led, vertically integrated health care system serving west-central Wisconsin. It is staffed by more than 180 physicians and 2500 employees and has a 310-bed inpatient facility with 10,000 annual admissions. Luther Midelfort also offers its own insurance products through Valley Health Plan, a health maintenance organization with 35,000 enrollees.

In January 1997, hospital leadership participated in a seminar on reducing ADEs sponsored by the Institute for Healthcare Improvement (Boston, MA). The following month, Luther Midelfort staff members met to discuss how to improve medication safety, and a 6-member pilot team consisting of nurses, physicians, and administrators was organized. At this time, the primary focus of efforts was a global reduction in all medication errors.

Assessing Medication Errors

Methods

Between February and April 1997, the pilot team comprehensively reviewed at least 20 charts per week over 6 consecutive weeks and documented the number and types of errors (**Table 1**) and when the errors occurred. Each page in every chart was examined by at least 2 team members and cross-referenced with separate pharmacy records. The information was summarized at the end of each week and compiled into a hospital database for medication errors.

Initial efforts to identify and track medication errors also included interviews with nurses, physicians, pharmacists, and ward secretaries. Interviews were conducted by an individual not well known outside of administration to minimize the chance that staff would feel intimidated. We asked the staff to respond to the following: (1) "Tell us about the last clinically significant medication event that occurred on your unit"; and (2) "Describe the clinically significant medication event that is just waiting to occur." Over a period of 2 weeks effective communication regarding the 2 questions was established. At this point, administration recognized that the success of the hospital efforts to improve safety depended on establishing "buy in" from the staff. The pilot team's efforts were changing the culture of the hospital as they challenged traditional patterns of patient care in an attempt to improve safety. Acceptance of the cultural changes was predicated on nurses, physicians, and ward personnel understanding and acknowledging the need for change.

Time studies were conducted to quantify the amount of time nurses and pharmacists were spending in reconciling the medications of each patient. In these studies, a nurse administrator monitored nurses on a general medical floor for up to 50% of a typical shift. Different intervals of 2 to 6 hours throughout a 24-hour period were examined to avoid artificially repetitive patterns (eg, monitoring only AM shifts). In a similar fashion, pharmacists tracked the amount of time spent and reported this on a weekly basis.

From Luther Midelfort Clinic, Mayo Health System, Eau Claire, WI.

Table 1. Types of Medication Errors

Drug
Wrong drug ordered; drug given
Wrong drug in PYXIS (medication dispensing system)
Wrong strength/concentration
Dose
Improper dose ordered; dose given
Dose missed
Extra dose given
Wrong dosage form used
Administration of drug
Wrong route of administration
Wrong rate of administration
Wrong duration of therapy
Wrong time scheduled
Wrong time given
Wrong patient
MAR errors
Medication not on MAR
Medication discontinued, still on MAR
Duplicate order on MAR
Wrong drug on MAR
Wrong dose on MAR
Allergy or interaction
Drug-drug interaction
Drug-food interaction
Patient allergic to medication and medication ordered; medication given
Allergic reaction in patient with unknown drug allergy
Other
Therapeutic duplication
Medication found on dietary tray
Illegible order, physician contacted
Expired drug dispensed
Reconciliation error
Other

MAR = medication administration record.

Findings

Most medication errors posed no threat to patients. The initial review of patient hospital charts over the 6-week interval revealed that more than 98% of errors being detected were minor, to the point that there were discussions among the team members as to the relevance of reporting some of them. The chart review found 283 medication errors, but only 5 (1.7%) posed significant risk to patient safety. For example, administering digoxin an hour after it was supposed to be administered may constitute an error, but it poses minimal, if any, clinical risk to a patient. Furthermore, pharmacist intervention, defined as pharmacy personnel changing an order, occurred at a rate of 14 events per 100 admissions. However, less than 3 of these events per 100 had potential for clinical harm. Incident reports, another traditional mechanism for identifying medication errors or events, were filed in only 7 instances, and only 1 of these concerned a medication event. Thus, although chart reviews found 5 instances of medication errors that posed potential harm, and pharmacy noted fewer than 3 per 100, the traditional incident reporting contained only a single entry. These data not only support the finding that most medication errors do not represent a threat to clinical safety, but they also suggest that traditional mechanisms for reporting potentially harmful errors may be inadequate.

Most medication errors occurred at the interfaces of care. Chart audits revealed that approximately 60% of the errors found in more than 250 charts occurred when patients were discharged from, admitted to, or transferred within the institution (ie, the "interfaces" of care). In addition, feedback from nurses and ward personnel during interviews indicated that they were spending tremendous amounts of time trying to define and validate the accuracy of patient medications at admission, discharge, and intrahospital transfer. The time study data corroborated the anecdotal accounts obtained through interviews. Hospital staff were spending between 60 and 90 minutes reconciling medications for a single patient being transferred from the coronary care unit. Pharmacists were spending between 45 to 60 minutes for each patient at the time of discharge, and nurses were spending another 30 minutes on average per patient at time of admission. These data confirmed that tremendous amounts of time were being invested in ensuring that medications were properly and correctly processed. Moreover, nurses were frustrated with the time and the effort needed to accomplish these tasks. Based on these data, the pilot team examined specific steps to reduce the time invested, to simplify the process, and to increase the accuracy of documentation and processing.

Lack of standardization resulted in error. Data gathered during the 6-week initial pilot project revealed that 14 different protocols for sliding scale insulin were being used to treat diabetic patients in the hospital. Data collected from these initial chart reviews and then confirmed by laboratory records showed that up to 20 separate hypoglycemic episodes (defined as blood glucose level below 70 mg/dL) occurred in a given week. Examination of the hypoglycemic events suggested that frequent and potentially serious safety issues were related to the inherent difficulty that nurses experienced in trying to use vastly different protocols.

Similarly, there were multiple dosing protocols for coumadin/warfarin. Standard clinical guidelines recommend therapeutic anticoagulation INRs between 2.0 and

3.0 (unless clinically specified for a given situation). Chart reviews noted frequent deviations in INRs greater than 0.5 ratio units from the desired range (ie, 3.5 or greater, or 1.5 or less); this was occurring in 1 out of every 4 INRs documented in the medical record. These deviations were not related to concomitant use of other anticoagulants, but were considered to be secondary to multiple different dosing protocols for coumadin/warfarin.

Steps Taken to Improve Safety

Focus on ADEs, Not Errors

The pilot team found a high number of medication errors but few clinically significant events. Based on this observation, they realized that a reduction in medication errors would not necessarily result in improved patient safety. The team decided that efforts to improve clinical safety should center on identifying, tracking, and reducing the occurrence of ADEs. Several team members who were new to medication safety questioned the change in strategy, arguing that in order to eliminate serious errors, even minor errors that cause no harm would have to be addressed to "clean up" the system. However, this strategy of addressing errors in isolation is flawed because the number of medication errors impacting clinical outcomes has been repeatedly demonstrated to be a small minority of the total [4,5]. Thus, in April 1997 ADEs supplanted medication errors as the focal point of efforts to improve clinical safety.

Development of Trigger Tool

To identify and track ADEs, the team used the Idealized Design of the Medication System (Institute for Healthcare Improvement; Premier, Inc., San Diego, CA) "trigger tool." The tool is a data-gathering device that consists of a list of key words, or "triggers," that connote clinical importance and signal the presence of information in a patient's chart that is likely to represent actions that impact safety or outcomes (**Figure 1**). The concept of a trigger tool has been reported previously, often within the context of computerized examination of pharmacy or hospital patient records [6,10–12]. The team at Luther Midelfort modified this strategy, enabling the tool to be used by hand and avoiding the costs associated with the purchase of new technology.

The trigger tool greatly simplifies the chart review process by allowing systematic, rapid examination of charts to extract relevant data. In addition, the tool links unfavorable medication events (ADEs) with patient outcomes. For example, triggers such as an elevated prothrombin time or elevated INR are sought within the medical record. If the trigger is found, the chart is examined to determine if an ADE occurred. If an ADE is present, then drug use and clinical outcome are linked, causality is implied, and relevance to safety is established. Thus, the tool provided a mechanism for the team to rapidly assess ADEs and longitudinally monitor the effectiveness of subsequent initiatives to improve clinical safety.

Medication Reconciliation Program

The findings that the majority of medication errors were occurring at the "interfaces" of care and that nurses were expending excessive amounts of time corroborating medication orders led to the implementation of the reconciliation of medications program in spring 1998. With this program, a detailed list of current medications is placed in every patient's chart at the time of admission and is used for "downstream" reconciliation of medications. As the patient moves through the health care system, providers must account for any changes in medications. Medications prescribed in physician orders, during transfers within the hospital, and for home use at time of discharge must be accurately listed. The chart was reconstructed so that the reconciliation lists could be located prominently at the front, eliminating complaints by staff that the important medication records were often "buried" in the chart.

Reconciliation of medications begins at admission, when both the hospital unit pharmacist and the patient's nurse conduct a rigorous review of the medications the patient is taking, including dosing schedules and quantities. This information is updated at discharge or patient transfer. An integral component of this process is verbal confirmation of exactly what medications are being taken by the patient. Published reports have shown that errors occur because patients do not understand dosing schedules and dosing quantities [8,9,13]. Informal surveys of nursing staff support these published reports and also suggest that there is often a striking disparity between what is entered in the medical record and what is in the patient's actual pharmaceutical regimen. Therefore, at the time of admission a nurse sits with the patient and the family and discusses what medications the patient is taking and the schedule being used. If the information is not available from the patient and/or family, it is gathered from medical records, pharmacy records, or, ultimately, physicians. At the time of discharge, physician, nurse, and pharmacist repeat this process, explaining the discharge medications and the dosing schedule. The program also attempts to simplify the dosing regimens to ensure better compliance.

Standardization of Protocols for High-Risk Drugs

Multiple individual protocols for high-risk drugs such as insulin and warfarin added "system" complexity and created an environment favorable for clinical harm. The pilot team sought to standardize protocols for high-risk drugs and implemented other policies to improve safe use of these drugs (**Table 2**). To introduce standardization of insulin and coumadin, the team knew they needed "buy in" among the

Medical record number _____ Patient's name _____

Admission date _____ Patient's age _____

Discharge date _____
(Two days minimum required)

	Present in Review		ADE Found	
Trigger:	Yes	No	Yes	No
T_1 Diphenhydramine (Benadryl)				
T_2 Vitamin K (Aqua-mephyton)				
T_3 Flumazenil (Romazicon)				
T_4 Antiemetics (Inapsine, Zofran, Phenergan, Vistaril, Compazine, Reglan)				
T_5 Naloxone (Narcan)				
T_6 Antidiarrheals (diphenoxylate/Lomotil, loperamide/Imodium, kaopectate)				
T_7 Sodium polystyrene (Kayexalate)				
T_8 Serum glucose < 50				
T_9 *C. difficile* positive				
T_{10} PTT > 100 seconds				
T_{11} INR > 6				
T_{12} WBC < 3000				
T_{13} Platelet count < 50,000				
T_{14} Digoxin level > 2				
T_{15} Lidocaine level > 5				
T_{16} Rising serum creatinine				
T_{17} Gentamicin or tobramycin levels: peak > 10, trough > 2				
T_{18} Amikacin levels: peak > 30, trough > 10				
T_{19} Vancomycin trough > 15				
T_{20} Theophylline level > 20				
T_{21} Oversedation/lethargy/fall/hypotension				
T_{22} Rash				
T_{23} Abrupt medication stop				
T_{24} Transferred to a higher level of care				

Total medications for this patient (financial data) _____

Total doses of medications for this patient (financial data) _____

Total ADE's for this patient _____

Harm category for ADE _____

Figure 1. Adverse drug event (ADE) chart review tool. Charts are reviewed for the presence or absence of the 24 listed triggers. If a trigger is present in the chart, the reviewer examines the chart to determine if the trigger was a component of an ADE. Total medications for the patient are entered followed by the total doses of all of the medications. If harm was associated with the ADE, the "Harm category" for the event is also entered.

Table 2. Efforts to Reduce High-Risk Drug Errors

Sliding scale insulin protocol
Warfarin inpatient and outpatient protocols
Single weight-based heparin protocol
Premixed heparin solutions
Pharmacy drug-drug monitoring protocol
No verbal orders for chemotherapy
Dose limits for chemotherapy
Pharmacy adjusts all dosages for renal status
Aminoglycoside protocols
Elimination of concentrated electrolytes from the floor
Standard post-operation pain protocols
Conscious sedation protocol
All infusions mixed and dispensed in pharmacy

Table 3. Best Practice Recommendations (from Massachusetts Hospital Coalition)

Enteral and intravenous tubing not interchangeable
Educational program for dosage forms and route of administration
Color-coded label and special tubing for intrathecal medications
Special labeling for intramuscular medications
Use of oral syringes for oral medications
Pharmacy prepares all doses
Pharmacist available 24 hours
Alerts for dosage and drug interactions
Bar coding prior to patient administration
Computer-generated medication administration record

Table 4. Cultural Change Concepts

Nonpunitive report and response policy
Centralized error and event repository
Storytelling about local events
Leadership safety rounds
Safety reporting to the board of directors
Safety coaches on units
Integrated safety reporting structure

staff. They used the hypoglycemia and INR data to convince the hospital's physicians that the traditional acceptance of multiple drug regimens based on individual provider preferences was potentially harmful. Application of the trigger tool helped the team achieve buy-in by allowing rapid identification and extraction of rates of hypoglycemia from the medical record. Armed with accurate information from the medical record, members of the pilot project were able to successfully educate physicians and nurses and implement the standardized protocols.

An insulin protocol was developed as follows: A qualified physician chosen from among active staff developed a single protocol to dose insulin that accounted for factors commonly associated with errors in the prescribing process. These included the age of the patient, presence of impaired renal function or drug allergy, and the patient's daily caloric intake. After 2 weeks, the physician's protocol was introduced to 5 physicians who were asked to review the protocol and provide feedback. Based on the constructive feedback, the final protocol for sliding scale insulin was introduced to a select group of physicians. One month after these physicians had gained experience with the protocol, it was implemented throughout the hospital.

The coumadin/warfarin protocol was completed in a similar fashion, but pharmacists were first asked to initiate the standard protocol. Physicians, nurses, and a pharmacist monitored the INR values, but the pharmacist regulated the dosing of the drug within the hospital. The successful effort was ultimately transferred from the pilot program to outpatient monitoring by nurses, who were trained by physicians and pharmacists to adjust coumadin/warfarin in patients. Nurses now perform all of the monitoring and adjustment of coumadin/warfarin in the outpatient clinics.

Standardization also resulted from the reconciliation initiative at time of discharge. Multiple prescriptions written on paper by numerous individual physicians were replaced with a uniform computer printout of current medications that is generated at discharge. The discharging physician now reviews each of the medications on the printed water-seal form, excluding medications that are not desired and checking off the doses, schedules, and amounts of those agents that are to be continued. Copies are given to the patient and sent to referring physicians and clinics. All commercial pharmacies within 150 miles accept these computer-generated documents. The physician saves time, and the potential for errors in transcription is reduced. Furthermore, by using the form, nurses and pharmacists are better able to instruct patients on their medications as they are working from a standardized document and a standardized process of discharge.

Cultural Changes

Underlying these targeted initiatives were organizational changes implemented to create a culture of safety, including best practice recommendations (**Table 3**) and cultural changes (**Table 4**). The hospital's leadership initiated and supported these efforts not only by providing funding for them, but also by acknowledging that physicians must place the goals of improving clinical safety in the same light as providing the correct diagnosis and therapy for each patient.

Improvements Documented

Since the implementation of the standardization and

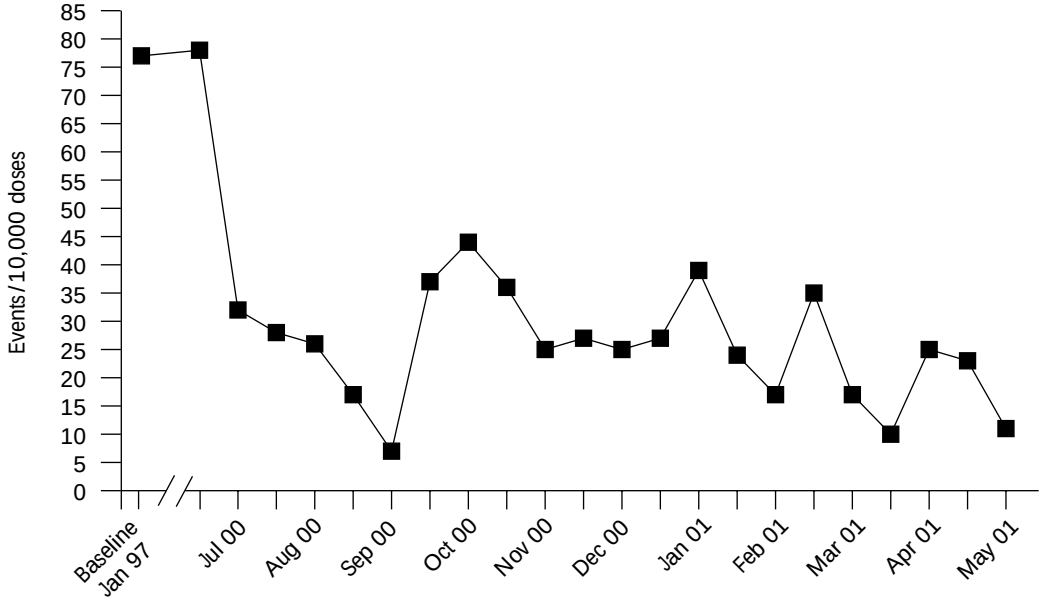

Figure 2. Adverse drug event rates at Luther Midelfort from July 2000 to May 2001 compared with baseline rate measured January 1997.

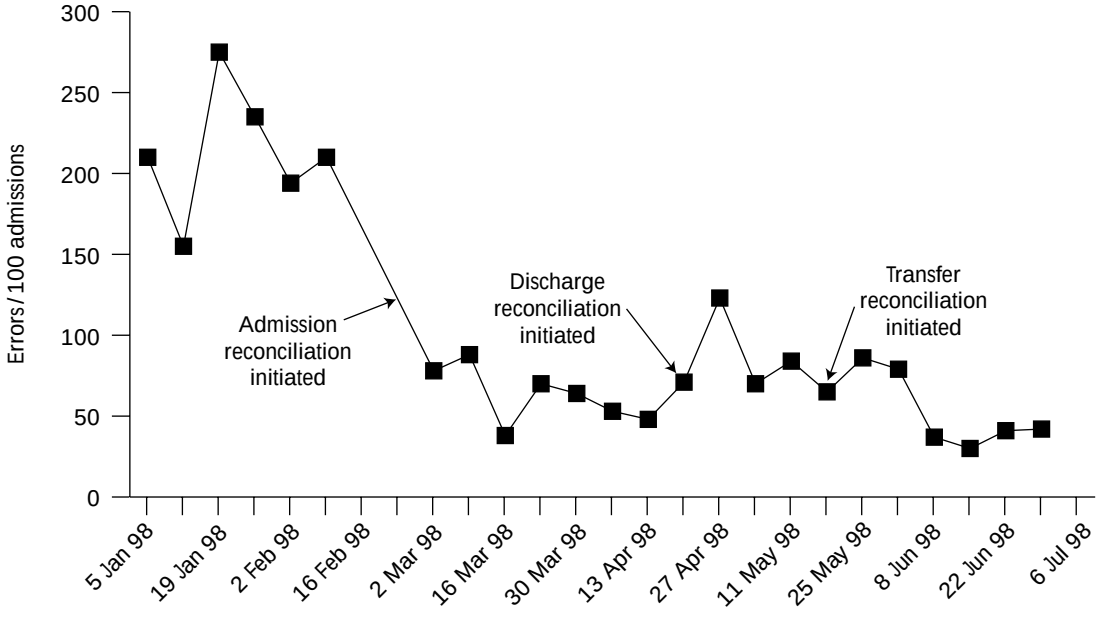

Figure 3. Rate of medical errors before and after implementation of medication reconciliation program.

reconciliation programs, the occurrence of ADEs has decreased from a baseline rate of 76 per 10,000 in January 1997 to 31 per 10,000 in May 2001 (**Figure 2**). As this figure shows, there was a "rebound" in the occurrence of ADEs after an initial period of rather pronounced success. As the continued variance in the rates suggests, a consistent effort was needed to maintain a downward trend. The rate of medication errors, the pilot team's original target, decreased from 213 per 100 admissions in January 1998 to 63 per 100 admissions in July 1998 (**Figure 3**). The efforts to develop standardized protocols for sliding scale

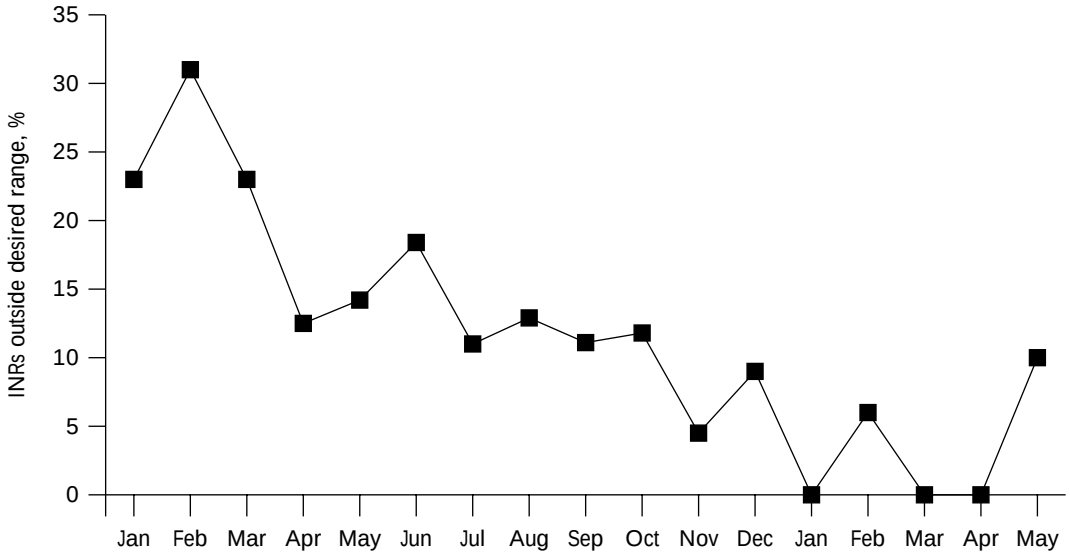

Figure 4. Percentage of all international normalized ratio (INR) measurements for coumadin/warfarin that were more than 0.5 above or below the desired range (2.0 to 3.0), January 1998 to May 1999.

insulin reduced both hypoglycemic events and insulin errors by 50%. Following the standardization of coumadin/warfarin dosing, the occurrence of unacceptable INRs decreased from an average rate of 25% of INRs recorded to 10% of INRs recorded (**Figure 4**). ADEs involving coumadin have been reduced by 50% for some practitioners.

Once the reconciliation programs were in place, additional time studies of nurses and pharmacists were conducted. The amount of time spent reconciling medications for a single patient being transferred from the coronary care unit decreased to between 30 to 45 minutes. Pharmacists spend approximately 10 minutes for each patient at the time of discharge. Nurses now require about 5 to 10 minutes on average per patient at time of admission.

Discussion

This report summarizes the development and implementation of a medication safety program that decreased clinically harmful drug events. Efforts to improve medication safety focused on reducing the occurrence of ADEs. These events are associated with increased morbidity and costs, with 1 report showing that ADEs increased the length of hospital stay by approximately 2 days at a cost of approximately $2600 per day [14]. Preventable ADEs increased costs by $4700 and added 4.5 days to hospitalization. Previous studies have suggested that expensive technological advancements such as computerized medication entry programs are needed to both accurately quantify ADEs [8,12] and reduce their occurrence [8,10–12]. However, the technology required to convert to a computerized medication order system may be prohibitive for smaller community hospitals facing competing fiscal priorities. At Luther Midelfort, the "trigger tool" provided an economically efficient means for quantifying the effect of error on patient safety and allowed us to longitudinally monitor the effectiveness of initiatives to improve safety. Luther Midelfort's adaptation of a trigger tool is inexpensive to implement and does not require an investment in new electronic equipment. Thus, it may have application in other community hospitals that wish to begin addressing safety concerns but that have limited resources.

Published reports continue to stress the need for dosage standardization [5,8,12]. These authors suggest that several easily identified factors are associated with a large proportion of medication prescribing errors/events and that mishaps can be avoided by standardization of dosing. The experience at Luther Midelfort supports these reports, suggesting that significant progress can be made in reducing inherent complexity within dosing regimens by adopting a single dosing schedule.

The role of hospital administrators in the creation of medication safety initiatives cannot be overemphasized. At Luther Midelfort, leadership made improved patient safety a priority, but, more importantly, they allocated sufficient resources to support initiatives designed to achieve this strategic goal. In addition, they sought expertise from outside the institution and combined it with advocates of medication safety from within. They encouraged true participation and facilitated involvement in safety initiatives. For example, they allowed a

senior physician to scale back clinical activities and redirect his energies to full-time efforts to decrease ADEs and explore improvements in medication safety. Perhaps most importantly, leadership created an environment with a tolerance for change.

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