

# Re-engineering the medication error-reporting process: Removing the blame and improving the system

LISA S. STUMP

The safe and appropriate use of medications is a central tenet of the profession of pharmacy, and it is reflected in the credo to “first do no harm” shared by all medical professionals. The issue of medication error and improvement efforts have been in the pharmacy professional literature since at least the early 1960s.<sup>1</sup> Over the last decade, medication errors have become an increasingly newsworthy topic, covered in the lay press and television media. With heightened public and political attention on patient safety and medical error, hospitals and medical professionals have been thrust into the spotlight and face increasing pressure to safeguard the medication-use process. Clearly the Institute of Medicine report “To Err Is Human”<sup>2</sup> spurred unprecedented government and media attention to the need to improve the safety of medication use in hospitals and in the community. Key to an organization’s ability to improve this process is its understanding of the vulnerabilities and weaknesses inherent in the design of its own medication-use process.

**Abstract:** A hospital’s change from a traditional, multitiered incident-reporting system for medication errors to a standardized, nonpunitive medication-use variance process is described.

After weaknesses were identified in the hospital’s system for reporting and evaluating medication errors, a multidisciplinary task force was formed to redesign the hospital’s medication error-reporting system. Its guiding principles were as follows: anonymity and freedom from punitive action are essential for increasing the number of reports, rating medication errors facilitates identification of areas for system improvement, potential errors provide valuable insight into the system’s vulnerabilities, and timely review of reports enables rapid systematic correction. To support the intended nonpunitive culture, the term medication-use variance was used in lieu of medication error for any unplanned event that deviates from the intended course of prescribing, dispensing, administering, or monitoring medications. A one-page medication-use variance report was developed that prompted the reporter for key data elements, including root causes, patient outcomes, and possible ways to prevent similar incidents. The most difficult decision for the task force was deciding whether the process should be anonymous. After getting the support

of the medical-legal counsel and the quality improvement department for an anonymous reporting process, the task force agreed to test it in the department of pharmacy and in three patient units in September 1998. A paper-driven reporting process was selected initially because an electronic system would not be truly anonymous. The number of reports from these units increased compared with historical trends, and for the first time potential errors were reported. The report form was easy to use and improved the interpretation of reports. Despite these positive results, task force members remained divided on the issue of anonymity but ultimately embraced the nonpunitive culture. In the first six months following hospitalwide implementation, the number of events captured increased more than fivefold; it continues to increase. The resulting database serves as a trigger for quality improvement efforts and a measure of their effectiveness.

The redesign of the medication error-reporting process served as the impetus for a change in the organizational culture surrounding medication errors.

**Index terms:** Administration; Errors, medication; Hospitals; Pharmacy, institutional, hospital; Quality assurance; Reports  
**Am J Health-Syst Pharm.** 2000; 57(Suppl 4):S10-7

LISA S. STUMP, M.S., is Associate Director, Department of Pharmacy, Yale-New Haven Hospital, New Haven, CT. At the time this paper was written, she was Clinical Coordinator, Drug Use Policy. Address reprint requests to Ms. Stump at 20 York Street, New Haven, CT 06504 (stumps@ynhh.com).

The assistance of members of the Medication Use Variance Task Force at Yale-New Haven Hospital is acknowledged: Sandra Alfano, Pharm.D., FASHP, Tracy Carafeno, Sarah Cohn, J.D., William Crede, M.D., Barbara Few, Elaine Holman, Sharon Klein, Richard Lisitano, M.S., Andrea Wilson, and Gail Wojtyna.

Based on the proceedings of the ASHP Best Practices in Health-System Pharmacy Management Award Symposium held June 6, 2000, during the ASHP Annual Meeting in Philadelphia, PA, and supported by an educational grant from Pfizer Inc. Ms. Stump received a monetary award from Pfizer, as well as an honorarium for preparing the manuscript.

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Medication errors occurring in hospitals have traditionally been reported via spontaneous, voluntary reports often linked with the organization's incident-reporting process. The effectiveness of an error-reporting process is dependent on many factors, including the presence of incentives or disincentives for reporting and the accuracy and completeness of the reports received. More often than not, hospital employees face disincentives like disciplinary action, shame, termination, and legal repercussions when errors are reported. As a result, employees are reluctant to participate in error-reporting efforts. Further, the reporting mechanism is often designed from a medical-legal perspective and lacks the specific details that enable root-cause analysis of medication errors.

In 1994 and 1995, the work of Leape<sup>3</sup> and Bates<sup>4</sup> together with their colleagues radically changed the way people think about the causes of medication error. Both reports demonstrated that error is often the end result of a complex chain of events that either contribute to the error or render it difficult to detect. Their work demonstrated the need for a systems approach to the medication error problem. Coupled with mounting public concern and awareness of the medication error problem, the physician and pharmacy leaders at Yale-New Haven Hospital were sensitized to the vulnerabilities inherent in our process for medication error identification, reporting, and prevention. Correcting this deficit was believed to be vital to the future quality improvement efforts of the institution and compelled us to engage in a comprehensive re-engineering of that process.

#### Previous medication error-reporting process

Yale-New Haven Hospital is a 944-bed, tertiary-care teaching hospital affiliated with the Yale Univer-

sity School of Medicine. It is one of three independent vertical networks within the Yale-New Haven Health System.

Historically, the medication error-reporting process at Yale-New Haven Hospital was incorporated into the hospital's incident-reporting process and overseen by the hospital's medical-legal department. Incidents, including medication errors, were reported using the organization's incident-report form. Employees discovering or committing an incident completed a free-text description of the incident, including an assessment of the patient by a physician. The individual, the examining physician, and the employee's immediate supervisor then signed the form. The report was forwarded to the department head or administrative director, who in turn forwarded it to the medical-legal department. A hospital attorney reviewed the reports and was responsible for forwarding reports related to medications to the department of pharmacy. Under this process, only errors that reached the patient were reported.

A second reporting process was used to track potential chemotherapy errors that were intercepted and corrected by a pharmacist before the error reached the patient. The reports generated from these two mechanisms were then tabulated and summarized for the pharmacy and therapeutics (P&T) committee. Concurrently, the hospital's quality improvement department tabulated the medication errors generated via the incident-reporting process.

Yet a third process was maintained internally by the department of pharmacy for errors that occurred within the pharmacy but were discovered before the medication left the pharmacist's control. These potential dispensing errors were not reported outside of the department.

Table 1 summarizes the many limitations of this reporting process.

All of these factors together created a deficiency in our ability to understand our weaknesses, masked opportunities for systems enhancement, and delayed performance improvement. Therefore, our ability to safeguard the medication-use process was crippled.

#### Development of new medication error-reporting process

In 1997, the P&T committee charged me as the pharmacy clinical coordinator for drug-use policy with leading an interdisciplinary task force to carry out the redesign process. Based on a review of the literature on medication errors,<sup>5-10</sup> including recommendations from expert panels<sup>11,12</sup> and a thorough assessment of our current process, the following founding principles were adopted:

- An error is created through a series of events set in motion by faulty system design,
- Anonymity and freedom from punitive action are essential for increasing the number of reports,
- Categorizing and rating medication errors facilitates the identification of areas for system improvement,
- Potential errors or "near misses" provide valuable insight into the system's vulnerabilities, and
- Timely review of reports enables rapid systematic correction.

With these guiding principles in mind, task force members representing the medical staff, nursing leadership, pharmacy leadership, the medical-legal department, and the quality improvement department were selected. Our goals were as follows: increase the number of voluntary reports that would generate a rich data source capable of uncovering system weaknesses; increase the quality of reports such that key data elements are captured, root causes are identified, and the severity is rated; shorten the turn-

Table 1.  
Comparison of the Historical Reporting Process with the Medication-Use Variance Process

Historical Process	Medication-Use Variance Process
Culture was punitive with corrective action focused on individual employee counseling, remedial training, and disciplinary action.	Culture is nonpunitive with improvement efforts focused on the medication-use system, competency assessment, and reporting incentives.
Multitiered administrative reporting process delayed receipt of report in department of pharmacy until 2–3 months after incident.	Using centralized reporting to the department of pharmacy, reports are received within 48 hours of event occurrence.
Fragmented reporting processes made quantifying errors and trends difficult; summary reports by department of pharmacy and quality improvement department often had discrepancies.	A unified database for all medication errors has enabled identification of several quality improvement targets.
Data on “near misses” or potential errors were limited to the dispensing process and reviewed only by the department of pharmacy.	“Near misses” in every stage of the medication-use process are captured and analyzed in conjunction with events that reach the patient; these data have uncovered previously unidentified areas for improvement.
Handwritten, free-text reports were difficult to read and interpret, and they lacked key data elements.	Structured, “check-box” reports prompt the user for key data elements and afford ease of interpretation.
Reporting rate was consistently lower than external benchmarks <sup>1-4</sup> and moving in a downward trend.	Event capture increased fivefold over historical data and is moving in an upward trend.
Data on medication errors were generated only through internal, voluntary reports.	Internal as well as external sources are used as triggers for systems improvement.
Data were reviewed by individuals far from the frontline of medication use.	Staff at the grassroots level are involved in reviewing data and planning improvements.

around time from event occurrence to data analysis and ultimately to implementation of corrective action; and create a system for centralized data analysis and report generation.

The task force met every two to four weeks and developed several recommendations. First, we wanted to create an anonymous, nonpunitive environment for reporting actual and potential medication errors that is distinct from the hospital incident-reporting process. Note that the term nonpunitive applies to the reporting process and does not absolve individuals who willfully disregard established policies, procedures, and standards of practice or who act with malicious intent.

Second, the three existing processes (for incident reports, prevented chemotherapy errors, and potential dispensing errors in the pharmacy department) should be consolidated and replaced with the new reporting process.

Third, to support the nonpunitive culture, the term “medication-use variance,” which is free of negative connotations, should be used in lieu of “medication error.” The term

“variance” was understood by staff and had been used historically to describe departure from clinical pathways. This familiarity and analogy to another nonpunitive quality improvement process helped convey that we were truly viewing medication error data in a new light—as a quality improvement tool, rather than a disciplinary one. We defined a medication-use variance as any unplanned event that deviates from the intended course of prescribing, dispensing, administering, or monitoring medications. These are preventable events that may cause or lead to inappropriate medication use or patient harm.

Fourth, the task force also recommended creation of a standardized report form that minimizes free text and prompts the reporter for key data elements, including root causes and patient outcomes. In addition, to facilitate more timely review of data, all variance reports should be submitted directly to the department of pharmacy’s drug information center.

Fifth, the task force recommended that we invoke staff level support and

review of data in the identification of systems solutions. Finally, data from external sources, including but not limited to the Institute for Safe Medication Practices, American Society of Health-System Pharmacists, and the Joint Commission on the Accreditation of Health Care Organizations, should be incorporated into our quality improvement efforts.

Our first decision point was to define medication-use variance and the key elements of data that we wanted to capture about each variance. The team agreed that capturing potential errors was invaluable. We also agreed that prompting the reporter to identify root causes and potential solutions would both streamline data analysis and encourage systems analysis rather than individual blame. For severity rating, we adopted the scale of the National Coordinating Council for Medication Error Reporting and Prevention.<sup>12</sup> The decision about whether or not to include reporter and patient identifiers was tabled for later discussion, as group consensus around anonymity of reporting was not yet achieved.

Our next decision point was whether to use a traditional paper-driven reporting process, a hot line, or an electronic report form. The sophistication of our medical information system gives us many unique opportunities to capture information surrounding medication errors and provide feedback to practitioners. Yale-New Haven Hospital is equipped with a fully computerized physician order-entry system, which is complemented by the availability of clinical workstations throughout the medical campus. The clinical workstations, jointly managed by the university and the hospital, offers Internet capability and access to the hospital's intranet functions. Linked to the Yale University School of Medicine Library, the clinical workstation contains internal information resources, online medical textbooks, journals, and Medline access.

Both of these systems offered the potential to automate reporting via a computerized reporting process and to disseminate information electronically to the medical and hospital staffs. This was a very attractive option in terms of generating timely reports in a standardized format that could be easily downloaded for analysis and uploaded for distribution. However, the task force was very cognizant of employees' perception that electronic transactions are traceable, which in fact they are. This factor would jeopardize our ability to create a truly anonymous reporting process. Since the decision had not yet been made to pursue an anonymous system, a computerized template was developed and tested. In addition, a paper form containing the same data elements was concurrently drafted. To distinguish this form from the many others used throughout the hospital, the medication-use variance report was designed to be pocket-sized and brightly colored (Figure 1).

With that work completed, the task force arrived at a critical junc-

ture requiring a decision on the issue of anonymity for the project to proceed. This was our most daunting obstacle, since individual blame was deeply rooted in our culture. There was strong concern among members over the perceived loss of managerial control and the perceived inability to detect staff competency issues. Since employee discipline as a quality improvement tool was entrenched in people's minds, it was difficult to overcome.

Our medical-legal counsel firmly supported the recommendation for anonymity on the basis that serious errors are quickly promulgated to an appropriate level of authority out of staff concern for the patient's well-being, as well as the inherent tendency to protect one's own liability. This concept was also supported by the quality improvement department, which recognized that the perceived risks of anonymity were far outweighed by the benefits of identifying system weaknesses. Believing this point to be critical to our success, we began a pilot of the anonymous reporting process to test its impact on the volume of reports and gauge its influence on the perceptions of pharmacy managers, nurse managers, and staff. The information elucidated in this step would prove invaluable to the future success of our redesign process.

#### **Pilot test followed by program implementation**

A pilot test of the new medication error-reporting program was conducted from May through September 1998 in the department of pharmacy and in three patient-care areas whose nurse managers were members of the task force. The paper form was used during this pilot phase because of its ease of implementation and use. Nurse managers and I conducted inservice education programs on the pilot units.

The number of reports from these units increased compared with historical trends. We recognized,

however, that this increase could be attributed to the increased emphasis on these units and the staff's knowledge that reporting behavior was being observed (the Hawthorne effect). More important, the pilot demonstrated that the medication-use variance report form was easy to use and dramatically improved the interpretation of reports. Staff members were able to identify potential root causes of the variance by using the prompts built into the report form, and they offered reasonable potential solutions to the variances that they reported. In addition, staff members did continue to communicate serious errors to their managers while using the anonymous report form to capture data on the event. Finally, for the first time in our institution, "near misses" were reported.

Upon first review of these results, the task force remained divided on the issue of anonymity and had difficulty justifying this complete overhaul of the reporting process and the large amount of work it would entail. This hesitation on the part of task force members clearly demonstrated the need to ignite a change in organizational culture and that anything short of a complete change in philosophy and practice would fail to change our ability to manage the risk of medication error. It took convincing, but finally task force members supported the anonymous reporting process and recommended its expansion to other patient-care areas.

The debate over anonymity versus accountability recurred at almost every level of the organization—from staff to administrators. By pointing out the benefits of a richer database on medication error and consistently emphasizing the "no-fault" philosophy of the medication-use variance process, the task force gained support for this initiative.

Once the decision to implement anonymous reporting was made, the paper form was selected because

■ **SYMPOSIUM Improving the system**

**Figure 1.** Front (top) and back sides of the medication-use variance report. It is printed on 8½ by 5½-inch white cardstock with a neon orange and black border. (CCSS stands for clinical care support system, which is the computerized physician order-entry system.)

**YALE-NEW HAVEN HOSPITAL MEDICATION-USE VARIANCE REPORT**

<p>Section 1. Patient Age: _____</p>	<p>Section 3. Practitioner/Staff Involved</p>
<p>Section 2. Time and Location of Incident</p> <p>Day of the week: Sa Su Mon Tu Wed Th Fr</p> <p>Occurrence Time ____:____ (circle) AM or PM</p> <p>Unit/Location _____</p> <p>Was the patient a boarder on the unit? Yes No</p>	<p><i>Classification</i></p> <p><input type="checkbox"/> Nurse    <input type="checkbox"/> Pharmacist    <input type="checkbox"/> Regular staff    <input type="checkbox"/> Float</p> <p><input type="checkbox"/> Physician    <input type="checkbox"/> Technician    <input type="checkbox"/> Agency/contract    <input type="checkbox"/> Student</p> <p><input type="checkbox"/> Other _____    <input type="checkbox"/> Traveler    <input type="checkbox"/> Other</p>
<p>Section 4. Medication and Doses Involved</p> <p>Name each medication involved:</p> <p>1. drug <u>ordered</u> &amp; route: (circle one)    drug <u>given</u> &amp; route:</p> <p>IVpush IVdrip IM SC PO PR    IVpush IVdrip IM SC PO PR</p> <p>Number of DOSES affected: _____</p> <p>2. drug <u>ordered</u> &amp; route: (circle one)    drug <u>given</u> &amp; route:</p> <p>IVpush IVdrip IM SC PO PR    IVpush IVdrip IM SC PO PR</p> <p>Number of DOSES affected: _____</p>	<p>Section 5. What Happened? (Type of variance)</p> <p>INCORRECT...    <input type="checkbox"/> Given when criteria (e.g., BP, blood sugar, pain) not met</p> <p><input type="checkbox"/> patient    <input type="checkbox"/> Extra dose given (e.g., more than the scheduled doses, or dose given after stop date or after d/c)</p> <p><input type="checkbox"/> drug    <input type="checkbox"/> Given in the presence of documented allergy to drug</p> <p><input type="checkbox"/> dose    <input type="checkbox"/> Dose omitted</p> <p><input type="checkbox"/> route    <input type="checkbox"/> Other: _____</p> <p><input type="checkbox"/> formulation    <input type="checkbox"/> IV rate</p> <p><input type="checkbox"/> IV rate    <input type="checkbox"/> IV solution</p> <p><input type="checkbox"/> IV solution    <input type="checkbox"/> time</p>
<p>Section 6. Description of Incident (Causes of Variance)</p> <p>1. In your opinion, why did this incident occur? Please be specific and refer to the example descriptions below. Variance in:</p> <p><input type="checkbox"/> PRESCRIBING (e.g., incomplete or unclear order, excessive quantity prescribed, etc.)</p> <p><input type="checkbox"/> TRANSCRIBING (e.g., order entered on wrong patient, order content changed during schedule revision, verbal order incorrectly entered into CCSS, etc.)</p> <p><input type="checkbox"/> DISPENSING (e.g., medication mislabeled, wrong medication stocked in Pyxis, wrong medication withdrawn from Pyxis, inaccurate dose calculation, etc.)</p> <p><input type="checkbox"/> ADMINISTERING (e.g., medication label misread or not read, previous dose given but not charted or charted incorrectly, patient ID band not verified, patient not available on unit, etc.)</p> <p><input type="checkbox"/> MONITORING (e.g., inaccurate documentation of patient weight, necessary tests or procedures not ordered, test/procedures not ordered, test/procedure results misinterpreted, test/procedure results charted incorrectly or not charted, lapse in profile or new order review, etc.)</p> <p>Explain:</p>	
<p>Section 7. Contributing Factors</p> <p>In your opinion, were there factors that made this incident difficult to prevent or detect? Please be specific and refer to the descriptions below:</p> <p>Factors related to the:</p> <p><input type="checkbox"/> PRODUCT (e.g., unclear manufacturer labeling, "sound-alike" drug names, look-alike packaging, omission or misuse of a prefix or suffix such as "fos" phenytoin or diltiazem "CD", etc.)</p> <p><input type="checkbox"/> medication use SYSTEM (e.g., side-by-side storage of look-alike drugs, lack of standardization in practice, competing distractions, CCSS problems, etc.)</p> <p><input type="checkbox"/> OTHER _____</p> <p>Explain:</p>	
<p>Section 8. Severity of the Incident</p> <p>Using your best judgment, please rate the SEVERITY of this incident:</p> <ul style="list-style-type: none"> <li>◆ Circumstances or events that have the capacity to cause a medication-use variance</li> <li>◆ Variance occurred but was detected before it reached the patient</li> <li>◆ Variance occurred, reached the patient, but caused no harm or is unlikely to cause harm</li> <li>◆ Variance will require additional patient monitoring but is unlikely to result in a change in vital signs or patient harm</li> <li>◆ Variance requires intervention and caused or is likely to cause temporary patient harm</li> <li>◆ Variance caused or is likely to cause temporary patient harm and prolonged hospitalization</li> <li>◆ Variance caused or is likely to cause permanent patient harm</li> <li>◆ Variance resulted in a near death event (e.g., anaphylaxis, cardiac arrest)</li> <li>◆ Variance resulted in or contributed to patient death</li> </ul>	
<p>Section 9. Your Comments</p> <p>In your opinion, are there improvements or changes that can be made to help prevent a similar incident from occurring again?</p> <p>Explain:</p>	
<p><b>RETURN TO PHARMACY</b></p>	

electronic transactions are traceable. This decision also required that all staff and patient identifiers, as well as date of occurrence, be removed from the data collection form or noted as optional.

In March 1999, the anonymous medication-use variance reporting process was launched hospitalwide, with full implementation completed in June 1999. The forms were distributed to every patient-care area and clinic. Wherever possible, the report forms were stored in the immediate vicinity of automated drug dispensing devices to ensure that they were readily accessible to the nursing staff performing drug administration activities.

During implementation, task force members conducted inservice-education programs for nursing, pharmacy, and medical staffs, and the program was featured in hospital newsletters and on posters. Staff were educated about the reporting process, trained to use the new report form, and encouraged to participate in building a safer medication-use process. Presentations on our plan and progress were also made to the vice president of patient-care services and the administrative directors in that division, as well as to the chief of staff and clinical section chiefs.

Throughout this implementation phase, we offered examples of quality issues identified in the pilot test that were previously unidentified by the traditional reporting mechanism. We continually praised the pilot units for the increased number of reports, demonstrating our new philosophy about error reporting, and at every opportunity we asked staff members for their recommendations on improving the safety of medication use at Yale-New Haven Hospital. We emphasized that an upward trend in number of error reports was not evidence of poor practice, but rather evidence of improved event capture. Through all of these actions, we impressed upon

the staff the important role that each individual has in helping us to understand and safeguard our medication-use process.

#### Experience with the program

The anonymous medication-use variance reporting process achieved all four goals identified by the task force. As shown in Figure 2, the number of events captured in the program's first six months has increased more than fivefold and is still rising. Data are collected via a user-friendly report form that minimizes free text and prompts the user for key pieces of data, including root cause and patient outcome. In addition, reports are completed and submitted in a timely manner, often within 24 hours of event occurrence; because of the anonymous nature of the report, exact turnaround time cannot be calculated. Each report is reviewed as it is received, and timely improvements are implemented. As clinical coordinator for drug-use policy, I maintain the database on medication-use variances.

Many of the limitations inherent in the previous reporting structure have been overcome. Table 1 contrasts the previous reporting structure and the current medication-use variance process.

Since implementation of the new reporting process, we have observed a landmark change in the organizational culture related to medication error. The anonymity of the reporting process has resulted in a dramatic increase in the number of reports submitted. This has created a rich database on the occurrence of medication errors within the institution that, in turn, serves as a trigger for quality improvement efforts and a measure of their effectiveness. Several of the key areas identified for improvement in the last six months were previously unidentified by the incident-reporting process.

For example, we saw a number of errors in dose calculation and administration of intravenous heparin.

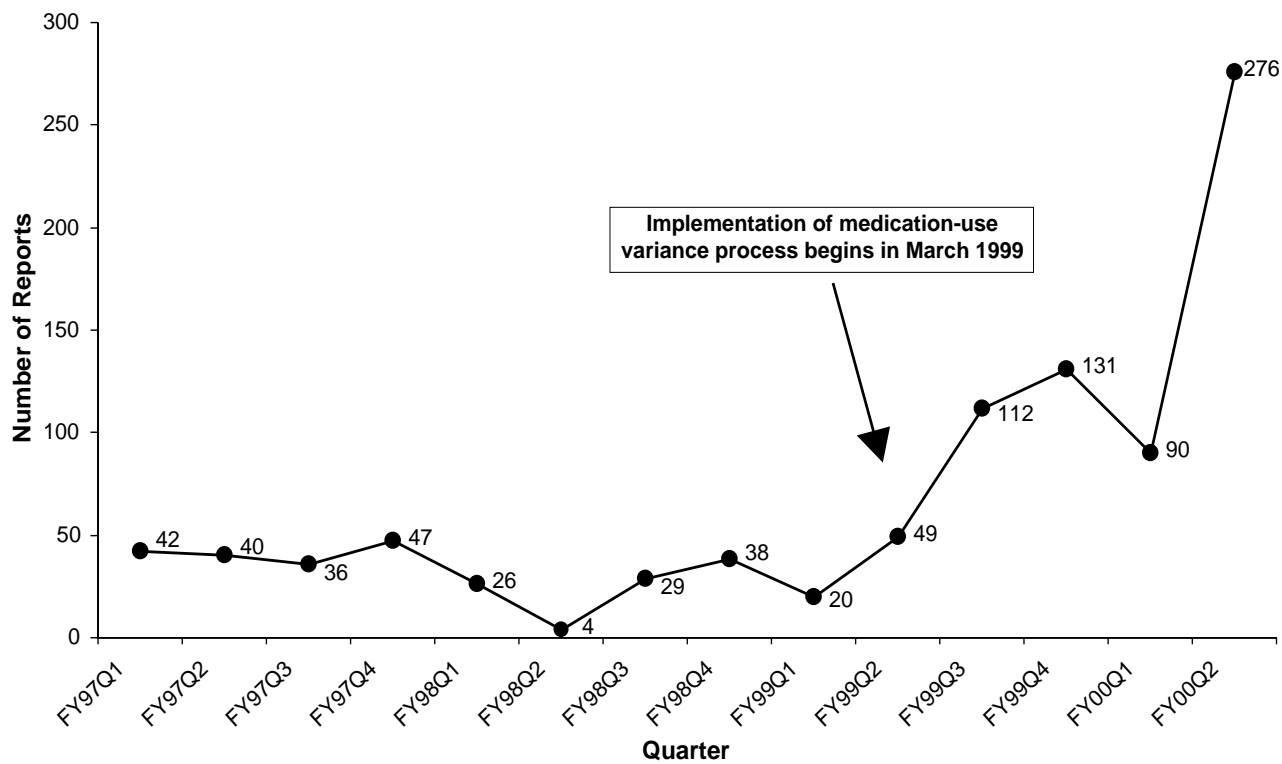
While such errors were occasionally reported in the former process, the magnitude and severity of the errors were unclear, and little was known about the root causes of these errors. The structured questions of the medication-use variance report form, coupled with discussion of these errors at staff forums, led to the discovery that these errors were caused by the inaccurate conversion by the nurse of the dose in units per hour to the infusion rate in milliliters per hour.

In response, we invoked the support of the department of nursing education and the clinical nurse specialists. A self-study module and examination on medication use were incorporated into the annual competency assessment for nursing staff working in adult patient-care units. This module includes hospital policies and procedures on medication handling and storage, aseptic technique, medication misadventures, and pharmaceutical calculations. While originally stimulated in response to calculation errors, we took the opportunity to incorporate other key aspects of safe medication use. In addition, we created a heparin drip-chart label that is dispensed with the medication. Since implementation of these two action steps, we have seen a decline in the reported number of dose-calculation errors for heparin.

Another example is the previously unidentified prevalence of medications inaccurately stocked on patient-care units, such as the wrong drug or wrong dose present in a drug storage bin. This has prompted a quality improvement effort and more detailed audit of the dispensing and storage processes.

We supplement our internal data on medication-use variances with reports from external sources, and all are used as stimuli for the evaluation and improvement of our medication-use process. Table 2 shows some changes we have made in response to external data on potential errors.

**Figure 2.** Number of events reported at Yale-New Haven Hospital before and after implementation of the medication-use variance reporting process began in March 1999.



**Discussion**

Embracing the concept that medication errors are predominantly caused by system failures is difficult for many health system managers. Blaming individuals is a natural response when errors occur, and employee discipline often seems necessary to right the wrong and prevent its recurrence. The evidence continues to mount, however, that ensuring patient safety will depend, in part, on the design of a fail-safe medication-use process and the creation of a culture of safety.

Implementation of a nonpunitive reporting mechanism is becoming a widely recommended strategy for achieving that goal. Our experience has demonstrated the potential for such a process to improve reporting behavior.

Our quest for excellence is ongoing, and we have identified additional opportunities in our management of medication errors. First,

physician involvement in the identification and reporting of errors is minimal. We plan to engage representatives of the medical staff to identify their barriers to reporting. Second, the paper-driven process is labor intensive to manage. As staff experience and trust in the “no-fault” nature of the process grow, electronic data capture, even though it is not anonymous, bears exploring. This may simplify data compilation and analysis.

We also plan to expand this process across the health system under the guidance of the Yale-New Haven Health System quality council, enabling our member hospitals to share data and collaborate on quality improvement efforts. Finally, we recognize the need to encourage staff continually to identify and report actual and potential medication errors, engage them in the improvement process, and provide feedback on

the progress of these initiatives on a continuous basis.

**Conclusion**

The redesign of our medication error-reporting process served as the impetus for a change in the organizational culture surrounding medication errors. The reporting vehicle and hierarchy, while important for ensuring data integrity and timeliness, pale in importance to the organizational culture surrounding medication error reporting. The choice of reporting format, be it electronic, voice, or paper, is best determined by individual institutions on the basis of their resources, staff preferences, and work habits. We found that an organizational culture characterized by anonymity, rewards and recognition for staff members making reports, grassroots involvement in the review and interpretation of data, and use of external sources of error data is critical for

Table 2.

## Quality Improvement Activities Initiated in Response to External Data Sources on Medication Errors

Misadventure	Improvement Activities
Several reports to the FDA of epidural hematoma resulting in paralysis in patients receiving low molecular weight heparin (LMWH) with an epidural or spinal catheter in place.	Prescriber warnings were added to the computerized physician order-entry pathways for LMWH and epidural therapy. Policy instituted prohibiting epidural or spinal catheter placement within 24 hours of a dose of LMWH.
Toxic overdoses of amphotericin B administered as a result of confusion between lipid-based products and the conventional amphotericin product. The recommended doses of the lipid and conventional products are 5 and 1.5 mg/kg/day, respectively.	The maximum dose function of the computerized physician order-entry system was activated to prohibit ordering of conventional amphotericin B at a dose exceeding 150 mg. For patients weighing more than 100 kg, the pharmacy can be contacted for ordering assistance.
National reports of problems with oral anticoagulation. Also several cases of overdosing and underdosing with warfarin at our hospital (administration of loading doses to elderly patients, patients with poor nutritional status, or those with disease states affecting coagulation; duplicate orders entered causing administration of excessive doses; and interaction of warfarin with enteral feedings containing large quantities of vitamin K).	Computer order-entry screens modified to eliminate large loading doses. Initial dose recommendations decreased to 5 mg. Entry of a warfarin order prompts review of all previous doses ordered. Information screens added to list the vitamin K content of enteral formulations.
National reports of anaphylaxis related to ipratropium-containing metered-dose inhalers (Atrovent, Combivent) in patients allergic to soya lecithin, soybean, or peanuts.	Warning screens added to the ordering pathways of implicated metered-dose inhalers noting the contraindication in patients with these allergies.
National reports of overdoses and improper administration of midazolam syrup. Doses incorrectly interpreted because of confusion between dose in milligrams and volume of liquid. Oral syrup measured in intravenous syringe and injected via i.v. site.	Maximum dose function activated to prohibit ordering of doses greater than 20 mg. Computer requires dose to be entered in milligrams. Midazolam syrup now prepackaged in unit-of-use oral syringes to prevent administration of large doses and to avoid intravenous injection (oral syringes do not fit any i.v. tubing port).
Reports of a drug interaction between trovafloxacin and morphine. The absorption of trovafloxacin is substantially reduced by the coadministration of morphine.	Warning screens added to the computerized physician order-entry pathways for trovafloxacin.
Alerts regarding intravenous administration of long-acting i.m. preparations of penicillin.	All "i.m.-only" medications identified, and order-entry pathways modified to prohibit selection of the i.v. route.

establishing a process truly capable of creating safety. This process for changing culture can be applied in any health care system desiring to improve the safety of the medication-use process.

## References

- Barker KN, McConnell WE. The problem of detecting medication errors in hospitals. *Am J Hosp Pharm.* 1962; 19:361-9.
- Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human: building a safer health system.* Washington, DC: National Academy Press; 1999.
- Leape LL, Bates DW, Cullen DJ et al. Systems analysis of adverse drug events. *JAMA.* 1995; 274:35-43.
- Bates DW, Cullen DJ, Laird N et al. Incidence of adverse drug events and potential adverse drug events: implications for prevention. *JAMA.* 1995; 274:29-34.
- Classen DC, Pestotnik SL, Evans RS. Computerized surveillance of adverse drug events in hospital patients. *JAMA.* 1991; 266:2847-51.
- Jha AK, Kuperman GJ, Teich JM et al. Identifying adverse drug events: development of a computer-based monitor and comparison with chart review and stimulated voluntary report. *J Am Med Inf Assoc.* 1998; 5:305-13.
- Leape LL. Error in medicine. *JAMA.* 1994; 272:1851-7.
- Leape LL, Brennan TA, Laird NM et al. The nature of adverse drug events in hospitalized patients: results of the Harvard Medical Practice Study II. *N Engl J Med.* 1991; 324:377-84.
- Bates DW, Spell N, Cullen DJ et al. The costs of adverse drug events in hospitalized patients. *JAMA.* 1997; 277:307-11.
- Belkin L. How can we save the next victim? *N Y Times Mag.* 1997; Jun 15:28-33.
- Cohen MR. Reducing adverse drug events and medical errors. Paper presented at Health Care Improvement Change Seminar. Boston; 1996 Jan 22-23.
- National Coordinating Council for Medication Error Reporting and Prevention. Taxonomy of medication errors. <http://www.nccmerp.orgtaxo1221.pdf>.