

Multifaceted approach to reducing preventable adverse drug events

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Management Case Studies describe approaches to real-life management problems in health systems. Each installment is a brief description of a problem and how it was dealt with. The cases are intended to help readers deal with similar experiences in their own work sites. Problem solving, not hypothesis testing, is emphasized. Successful resolution of the management issue is not a criterion for publication—important lessons can be learned from failures, too.

Problem

Patient safety has become a leading topic at the national level. The overall rate of adverse drug events (ADEs) is estimated to be 6.5 per 100 admissions; 28% of these ADEs are preventable.^{1,2} One meta-analysis found an adverse-drug-reaction (ADR) rate of 6.7% among hospitalized patients.³ Another study found that ADEs cost \$2595 each, with each preventable ADE being almost twice as costly as nonpreventable ones.² The same study concluded that a large tertiary care hospital would incur annual costs of \$5.6 million and \$2.8 million for ADEs and preventable ADEs, respectively. The human and monetary costs of ADEs have necessitated a commitment to reduce the rate of preventable ADEs.

Background

Brigham and Women's Hospital (BWH) is a 726-bed tertiary care teaching facility that offers a wide range of services, including thoracic care, general medicine, infectious diseases care, cardiology, cardiac surgery, obstetrics and gynecology, newborn medicine, neurology, hematology and oncology, bone marrow

transplantation, orthopedic surgery, renal care, immunology, and emergency services. There are 10 intensive care units. BWH has computerized physician order entry (CPOE) as part of the Brigham Integrated Computer System, a MUMPS-based system. BWH received 500 reported incident reports and 575 reported ADRs in the calendar year 2000.

At BWH, the drug safety committee, a subcommittee of the pharmacy & therapeutics (P&T) committee, has primary responsibility for ensuring safe drug delivery and reducing preventable ADEs. Initially, the drug safety committee focused on medication error reports, pharmacist-reported ADRs, departmental computerized physician order sets, maintenance and approval of the list of drugs for which orders are considered "overrideable"

or available for emergent use from the point-of-care distribution system, and other issues pertaining to drug or patient safety that were requested for the group to discuss. While these were laudable goals, in practice the committee was not functioning as well as pharmacy and nursing leadership had hoped.

In an effort to improve the medication-use process, a multidisciplinary team was established to identify weaknesses in our current ADE-reduction activities. Three main deficiencies pertaining to the drug safety committee were identified: (1) incomplete analysis and follow-up of incident reports or medication errors, (2) low reporting of ADRs, and (3) lack of an automated system for detecting ADEs. These deficiencies were the result of several functional limitations. First, our tracking databases did not offer the means for effectively reporting and identifying trends in medication errors and voluntarily reported ADRs. Second, recommendations for process improvement were difficult to implement because of lack of proper membership on the drug safety committee. Excessively long agendas kept the committee from addressing all of the issues that warranted its time. Finally, there were no resources dedicated to monitoring and evaluating ADEs and promoting ADR reporting. Therefore, the drug

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safety committee had to be restructured to meet the institutional needs for improving medication safety and for creating an effective program of ADR reduction and prevention.

Any injury due to a medication error or an ADR is defined here as an ADE. ADEs are categorized as preventable and nonpreventable. Preventable ADEs are usually the result of errors in the medication-use process, including prescribing, dispensing, transcribing, administering, and monitoring errors. If a medication error does occur and there is no resulting injury, the event would be a medication error but not an ADE. Nonpreventable ADEs are known as ADRs because of the often unpredictable response to the effects of a medication; these are not associated with errors.⁴

Analysis and resolution

An action plan was created focusing on (1) reconfiguration of the drug safety committee, (2) improving medication error review and follow-up, (3) reenergizing the reporting and evaluation of ADRs, and (4) proactive prevention of ADEs via an online ADE-monitoring system.

Reconfiguring the drug safety committee. The existing drug safety committee did not have the required decision-makers as formal members, so action frequently could not be taken without long delays in obtaining management approvals. The committee's extensive agenda was hampering the ability to implement changes. And the committee lacked formal mechanisms for tracking progress.

Pharmacy and nursing leadership requested permission to restructure the committee to address its membership and processes. At the same time, a patient safety team was created with the goal of improving safety for all medication and non-medication-related adverse events. The revised drug safety committee is cochaired by the director of pharmacy services

and the director of patient safety, who is a physician. Physician involvement allows the integration of medication safety efforts with non-medication-related safety initiatives. The drug safety committee also includes senior nurses, quality managers, risk managers, the patient safety manager, information systems people, the drug safety pharmacist, pharmacy and nursing managers, and staff physicians. One of the pharmacy supervisors was appointed to serve as secretary. This committee makeup ensured that each of the major disciplines was represented and that decisions would be prompt.

The committee was designed to assess the impact and severity of identified ADEs, recommend resource allocation, and facilitate any planned interventions. The drug safety pharmacist was funded on the basis of cost data from the study by Bates et al.² and the potential saving or cost avoidance that could be achieved. This pharmacist is responsible for ensuring that all initiatives encompassing medication errors, spontaneously reported ADRs, and the online ADE-detection system are implemented. The pharmacy director can facilitate the drug safety efforts, since he cochairs the drug safety committee and is a voting member of the P&T committee.

Many issues and recommendations involving patient and drug safety are raised during meetings, and these are all tracked on a drug safety worksheet. The worksheet records specific initiatives, the date an issue was identified, a brief description of the action plan, the contact person on the committee, and the anticipated closing date, if possible. The purpose of the worksheet is to ensure that all initiatives are documented and addressed and that a single person is responsible for bringing the initiative to completion. The drug safety pharmacist attends the monthly P&T committee meeting and provides a brief update on the

activities of the drug safety committee and any matters that need P&T committee approval. The drug safety committee is considered a subcommittee of the P&T committee, and the drug safety committee cochairpersons, as members of the P&T committee, decide what needs approval. A close working relationship between the pharmacy department and the patient safety team ensures full collaboration and minimal duplication of effort. Implementation of the major changes occurred over a four- to six-month period.

Improving the review of medication errors. To improve the hospital's review and analysis of medication errors, the drug safety committee focused on improving the timeliness and quality of follow-up. This was partially achieved through a new standardized process for evaluation, classification, and reporting. Incident reports are reported via the Brigham Integrated Computer System, and they had been manually entered into a Microsoft Excel spreadsheet (Microsoft, Redmond, WA). Under the new system the reports are downloaded directly into Microsoft Access, saving time on data entry and enhancing the ability to generate reports and track trends. The committee established a goal of obtaining follow-up within 24–48 hours of a reported medication error. The drug safety pharmacist is an essential resource for initiating follow-up. The pharmacist works closely with a nursing representative responsible for medication error follow-up to ensure a collaborative approach to the review. The severity, the step or steps in the drug-use process involved, the medication error reporting and prevention (MERP) categories (e.g., wrong dose, wrong time), and other details of the incident are all reviewed. Severity is assessed with a medication error index system developed by the insurance company hired by our risk management foundation, which evaluates severity on a

scale from 1 to 4, with 1 being the lowest severity rating and 4 the highest. The process involved refers to the step or steps in the medication-use process. After this initial assessment, the medication errors are then reviewed by the drug safety committee leadership, the secretary, and the drug safety pharmacist. A plan is set to obtain additional follow-up, initiate any action, and decide whether the medication error report should go to the full committee.

Each quarter, the committee reviews trends in medication errors and designs interventions to prevent events from recurring. For example, when an increase in errors involving heparin infusion rates was identified, the committee changed the standard concentration of heparin from 25,000 units per 500 mL (50 units/mL) to 25,000 units per 250 mL (100 units/mL). This change would theoretically allow easier drip-rate calculations because nurses could use 100 units/mL as the denominator rather than 50 units/mL. The committee also requested that our CPOE system attach instructions indicating the correct infusion rate on each heparin infusion order. The CPOE system would make this calculation by using

the new standard heparin concentration. Thus, an order for a continuous intravenous infusion of heparin at 800 units/hr would include instructions indicating a rate of 8 mL/hr based on the standard 100-unit/mL bag. All 50-unit/mL bags were removed from the institution. Figure 1 shows the resulting decrease in the number of reported heparin infusion-rate errors.

Other results of our new process include follow-up that is performed in real time; reductions in errors involving selected interventions; the development of recommendations involving computerized physician orders for insulin, acetylcysteine, and potassium; and increased awareness of medication safety.

Reenergizing ADR reporting.

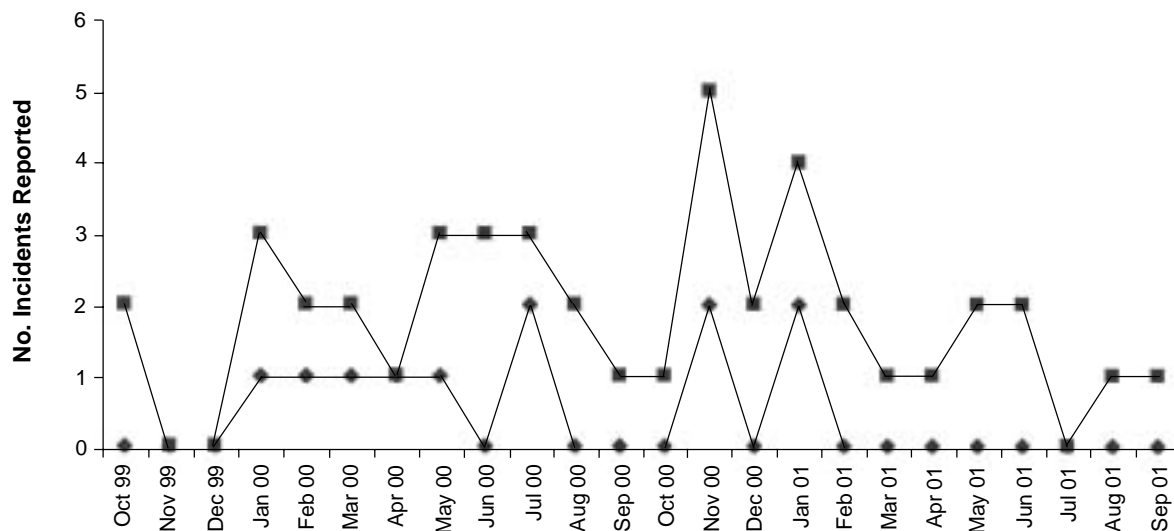
From 1997 through 1999, voluntary reporting of ADRs was low (167, 275, and 334 events reported annually). Also, review and follow-up were minimal. Events were being analyzed on a case-by-case basis, without examination of data for trends or prioritization of cases on the basis of severity or safety concerns. There was also limited or inadequate follow-up. Our plan focused on increasing reporting and improving assessment,

especially improving our ability to identify trends.

Senior pharmacy management decided that voluntary reporting of ADRs must be increased. It was decided to make ADR reporting a formal part of the pharmacist's job description and performance appraisal. Scoring criteria were designed to monitor the frequency and effectiveness of reporting for each pharmacist. The department established two reported ADRs per month per pharmacist as the minimum baseline reporting requirement. Higher levels of reporting are rewarded with a higher score. The performance appraisal score is directly linked to salary increases. This arrangement was communicated to the staff during 1999 and implemented in 2000. The pharmacy department conducts educational sessions for its staff to emphasize the importance of reporting ADRs so that the drug safety committee can in turn identify trends and better develop a system for preventing ADRs. The number of ADRs reported is communicated quarterly to the staff.

As ADRs are reported, the drug safety pharmacist reviews them to determine their preventability and any trends. Data are entered manual-

Figure 1. Number of reported errors in heparin infusion rates (diamonds) and total number of reported errors involving heparin (squares). Steps to enhance the safety of heparin administration were initiated in April 2001.



ly and are maintained with Microsoft Access. Reporting increased a total of 404% between 1997 and 2000, with 575 ADRs reported in the final year.

Once a month, the drug safety committee reviews any ADRs that are deemed preventable in order to determine if any standard recommendation can be developed to prevent the ADR in the future. For example, warfarin was the drug with the highest frequency of ADRs. The committee analyzed each report and planned a response. First, the committee ensured that the information was communicated to the new anticoagulation clinic and the two services that care for patients who commonly receive warfarin. Second, the committee created two new rules within the computer system that tracks ADEs. The new rules lead pharmacists to patients who may potentially have a problem with their International Normalized Ratio (INR) while receiving warfarin as inpatients. The pharmacists receive the alert to initiate a deeper investigation of the situation when a patient's INR increases above 4 or when it increases by more than 2 points within a 24-hour period.

On a quarterly basis, the committee assesses trends in a report. The report provides data on the number of reactions reported each month, the medications most frequently involved, the severity and types of reactions (i.e., the body system involved), and preventability. If warranted, a deeper analysis is performed that looks at the number of adverse reactions for a specific medication by month, by severity, and by type of reaction. Also, the full explanations of the reported ADRs for a particular medication are reviewed to determine if a standard recommendation can be implemented. This quarterly report is presented to and shared with nursing leadership and the medical director of each inpatient care service to ensure their awareness and to promote improvements.

Implementing a computerized ADE-detection system. A search engine was implemented to identify ADEs and potential ADEs, with a focus on prevention. This search engine operates independently of the CPOE and pharmacy systems. It screens computerized physician orders for medications and clinical laboratory data for real-time actual or potential ADEs by using a set of criteria called rules.

After the search engine was created, we developed an Access database to store and produce daily alerts in a usable manner. Data from the search engine are downloaded directly into this database. The drug safety pharmacist was assigned to lead the development of the computer-based ADE-detection program. The pharmacist was to develop new or more defined rules, evaluate the effectiveness of each rule, follow up with staff pharmacists, and analyze the data. Initially, alerts were generated in the morning, investigated by the pharmacist throughout the day, and reported at the end of the day shift. After a few months, responsibility for alert review was assigned to clinical pharmacists, who report their findings to the drug safety pharmacist. Alerts are given to the pharmacists as they begin their shift and then collected by the drug safety pharmacist at the end of the day. The drug safety pharmacist went on rounds with individual pharmacists and helped them make and document clinical recommendations. The drug safety pharmacist also changed the procedure for the departmental change-of-shift report. The report is now conducted in the presence of all the clinical pharmacists so that experiences can be fully shared. In addition, the search rules are assessed and refined monthly, partly on the basis of feedback obtained during these meetings.

Through much of 2001, the number of alerts (or triggers) reviewed per month averaged more than 700. During the same period, the number of recommendations per month

ranged from 7 to 44; a large majority were accepted. Most of the recommendations have resulted in a change in dosage frequency or interval, discontinuation or withholding of a medication, dosage adjustment for renal impairment, adding or discontinuing a laboratory test, and elimination of therapeutic duplication. In a few instances, alerts led to a discussion on rounds that did not ultimately result in a recommendation. For example, pharmacists on rounds note that, if a patient's condition changes, then a recommendation may be necessary on the basis of the alert. Information tracked from June to September 2002 appears in Table 1. The alerts' low yield of recommendations was mainly due to a large number of duplicate alerts for the same clinical situations—a current limitation of the system.

Once a month, the drug safety leadership and the drug safety pharmacist meet to review the effectiveness of the search rules. The number of pharmacist reviews and the number of recommendations per rule are used to determine a positive predictive value (PPV) for each rule (the number of true positives divided by the number of alerts). Depending on the feedback from the pharmacists performing the reviews and the PPVs, the drug safety committee refines rules, deletes rules with low PPVs, or adds new ones.

Discussion

To initiate an ADE-prevention program, the ongoing commitment of senior staff is essential. An interdisciplinary drug safety committee helps enable the key stakeholders—who best know the policies and issues—to allocate the necessary resources. The drug safety pharmacist has been an invaluable resource at our institution and plays a key role in ensuring that all initiatives are brought to completion. This pharmacist is also the focal point for handling adverse events resulting from

Table 1.
Information on Adverse Drug Events (ADEs) Tracked by Computer

Routinely Tracked Variables ^a	No. ADEs					
	Jun 2001	Jul 2001	Aug 2001	Sep 2001	Monthly Average	Total
Triggers detected	2425	1821	1390	1690	1831.5	7326
Triggers received	1427	1372	947	1198	1236.0	4944
Triggers reviewed in detail	679	655	656	873	715.8	2863
ADEs	9	12	14	19	13.5	54
Potential ADEs	23	38	27	25	28.3	113
Not ADEs	647	616	580	763	651.5	2606
Laboratory value abnormalities	0	3	39	140	60.7	182
Recommendations made	22	44	29	25	30.0	120
Recommendations accepted or ADEs prevented (drug information not included)	16	31	26	20	23.3	93

^aTriggers detected = number of alerts generated by the detection engine. Triggers received = number of alerts given to clinical pharmacists for investigation. Triggers reviewed in detail = number of alerts for which an intensive investigation occurred and the pharmacist believed that prevention of an ADE was likely.

reported ADRs and medication errors, as well as for managing the search engine.

When assessing any potential ADE from any source, it is important to look at the preventability of the event and whether a standard intervention can be implemented. Obtaining follow-up within 24–48 hours facilitates the collection of necessary details before the people involved forget them. A standard process for evaluating events within an interdisciplinary group and identifying trends ensures that resources are prioritized. Once a decision is made to initiate a recommendation, it is necessary to assign responsibility to ensure its implementation.

Many future initiatives are planned at BWH, such as the implementation of an electronic medication administration record with bar-code scanning, increasing the reporter's involvement in the follow-up of medication errors, reducing the number of duplicate alerts, and increasing the ability of the alerts to identify potential ADEs. Perhaps the greatest challenge involving the computerized detection system will be rewriting the rules when the medication administration record goes online. It is anticipated that the system will have the ability to detect whether doses are given and when. The rules will need to become much more specific.

Conclusion

A multifaceted ADE-prevention program improved medication safety at a tertiary care teaching hospital.

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