
Invited commentaries

Patient safety is an important problem in the USA today. The 1999 Institute of Medicine (IOM) report, *To Err Is Human*, brought the issue into the public eye (1). This report suggested that 44,000 to 98,000 patients die annually in the USA as a result of medical errors and that approximately a million patients are injured. These figures seemed implausible to many and have been the object of considerable controversy (2–4), but most agree that whatever the true figures are they are higher than would be desirable.

Before the IOM report, the problem of patient safety was not visible on the radar screen of most of the nation's health care leaders or providers; in a 1999 Advisory Board survey, hospital chief executive officers ranked "reducing clinical errors and adverse events" 133rd on their priority list. A major reason for this lack of visibility is that health care organizations use primarily spontaneous reporting to detect errors and adverse events, and spontaneous reporting detects only a minority of adverse events. The proportion is about 1 in 20 for adverse drug events (5), and for medication errors the figure is much lower (6). At Brigham and Women's Hospital, we have estimated that we have about 300,000 medication errors annually (many of these have little or no potential for harm), yet only a few hundred are reported. For patient safety to improve, this issue has to be higher on the leadership's list. Clearly, Baylor's leadership has become engaged, as demonstrated by Mr. Hood's commentary in this issue of *BUMC Proceedings*.

For adverse events, a number of promising approaches are being used and refined that should make detection easier (7, 8). Typically, these rely on using computerized data to identify "signals" that suggest that an adverse event may have occurred. Such tools may allow routine assessment of the frequency of adverse events and could even provide sufficiently robust information to allow benchmarking. In contrast, benchmarking with spontaneous reporting is probably not meaningful, except internally, since higher rates are probably actually better, and the reporting rate depends so much on the safety climate. Spontaneous reporting will remain useful for error detection, since computerized moni-

toring so far does not appear especially effective for detecting errors (8).

One issue is whether to focus on errors or adverse events. I believe that both are useful. Errors and near misses are important because they occur many times as often as adverse events (6). Thus, after a process change, it is easier to detect a change in the error rate than the adverse event rate. Aviation has dramatically improved safety largely by focusing on near misses. However, most errors have little or no potential for harm, though they may be costly to the system because of the extra work they cause. It is also important to track adverse events, because at the end of the day it is the adverse event rate that we seek to reduce to improve patient safety. Among errors that have the potential to hurt patients, errors that actually result in injuries appear to be different from those that do not (9). In particular, the errors that hurt patients tend to be subtler than those that could but get intercepted (for example, a 5-fold overdose may slip through when a 50-fold overdose would not).

Spontaneous reporting of errors and adverse events has yielded many useful lessons, especially at the national level. For anesthesia, neonatal intensive care units, and medication errors and adverse drug events, databases have been built, which have revealed important ways that care could be improved. For example, associations between Norplant (a contraceptive that can be implanted in the forearm) and a variety of complications including infections at the insertion site, hospitalizations because of difficulty removing the capsule, stroke, thrombotic thrombocytopenic purpura, thrombocytopenia, and pseudotumor cerebri were identified through the Food and Drug Administration's Medwatch program (10). Also, a number of deaths associated with concentrated potassium have been identified through the Medication Errors Reporting Program, and a series of warnings regarding these risks by the Institute for Safe Medication Practices (11) and others have resulted in removal of the medication from most units in the nation's hospitals.

Reporting is also important within organizations because it provides local information about problems, and leadership is

often skeptical regarding whether problems that present one place are actually occurring at another.

Yet getting clinicians to report has been challenging. Rates are often low—a third of organizations report having no medication errors. Strategies to increase reporting rates have often had little or no effect (5). Some groups of providers do most of the reporting (nurses and pharmacists)—and some groups, like physicians, almost never report. Clearly, new strategies to increase reporting rates are needed.

In this issue of the *BUMC Proceedings*, 2 articles describe the impact of novel Web-based reporting systems (see articles by J. F. Dixon et al and T. Atherton). Both applications resulted in a substantial increase in the number of reports of errors and adverse events. Compared with paper reporting, such tools have a number of important advantages: data can be coded as they are collected, anonymous reporting is facilitated, greater security can be achieved, data are more immediately available, analysis is vastly easier, and rates and types of reports can be compared with those of other organizations.

Another issue is whether organizations should build their own tool or use one that is externally developed. I believe that organizations using tools that have been developed elsewhere have substantial advantages. Specifically, using an externally developed tool promotes use of standardized definitions, allows comparisons within a network, facilitates building branching algorithms that can be done electronically but not with paper, and makes it easier to maintain and update the application. Furthermore, incident tracking works well as a stand-alone application that need not be closely integrated with the organization's underlying information system.

Getting more reports represents a key step in building a culture of safety, since being willing to report and having taken the risk of reporting may make individuals more invested. Growing a culture of safety in health care is challenging, especially since the traditional approach to dealing with errors is to find the responsible individuals and punish them. However, good people make most errors. A more productive approach may be to identify bad behavior and deal with that, instead of castigating those who make or report errors.

However, getting more reports is not an end in itself. Simply having the reports does not tell you what to do with them. They must be analyzed, which is not trivial. Assessing frequency and root causes using a human factors approach is essential, and the tools of failure mode and effects analysis are important. New techniques like data mining may be valuable for assessing previously unrecognized associations within databases. Organizations

With the publication of the Institute of Medicine report *To Err Is Human* in 1999 (1), health care organizations throughout the country were challenged to improve patient safety and reduce medical errors. Reporting systems are one part of the patient safety equation.

In this issue of *BUMC Proceedings*, hospitals in the Baylor Health Care System describe their experiences with incident reporting systems, one developed internally (2) and one developed by a national vendor (DoctorQuality) (3). While sometimes

need infrastructure to successfully perform these analyses and to make the changes that the analyses suggest. That requires having a director of patient safety within the organization, with a staff and budget. Too often, such work is delegated to someone with no dedicated time for it.

Thus, increased reporting represents the beginning on the road to a safer health care system, not the end. The key steps will be developing tools to analyze reports and other types of patient safety data, building the infrastructure within organizations to make processes safer, testing that these steps have made a difference, and monitoring them.

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1. Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human. Building a Safer Health System*. Washington, DC: National Academy Press, 1999.
2. Brennan TA. The Institute of Medicine report on medical errors—could it do harm? *N Engl J Med* 2000;342:1123–1125.
3. Leape LL. Institute of Medicine medical error figures are not exaggerated. *JAMA* 2000;284:95–97.
4. McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in Institute of Medicine report. *JAMA* 2000;284:93–95.
5. Cullen DJ, Bates DW, Small SD, Cooper JB, Nemeskal AR, Leape LL. The incident reporting system does not detect adverse drug events: a problem for quality improvement. *Jt Comm J Qual Improv* 1995;21:541–548.
6. Bates DW, Boyle DL, Vander Vliet MB, Schneider J, Leape L. Relationship between medication errors and adverse drug events. *J Gen Intern Med* 1995;10:199–205.
7. Hripcsak G, Friedman C, Alderson PO, DuMouchel W, Johnson SB, Clayton PD. Unlocking clinical data from narrative reports: a study of natural language processing. *Ann Intern Med* 1995;122:681–688.
8. Honigman B, Lee J, Rothschild J, Light P, Pulling RM, Yu T, Bates DW. Using computerized data to identify adverse drug events in outpatients. *J Am Med Inform Assoc* 2001;8:254–266.
9. Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, Laffel G, Sweitzer BJ, Shea BF, Hallisey R, Vander Vliet M, Nemeskal R, Leape LL. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. *JAMA* 1995;274:29–34.
10. Wysowski DK, Green L. Serious adverse events in Norplant users reported to the Food and Drug Administration's MedWatch Spontaneous Reporting System. *Obstet Gynecol* 1995;85:538–542.
11. Institute for Safe Medication Practices. Despite knowledge of accidents, opportunities for potassium ADEs persist in some US hospitals. *ISMP Medication Safety Alert* 1996 (August 28). Available at <http://www.ismp.org/msaarticles/potassium.html>. Accessed February 12, 2002.

described as error reporting systems, they are both truly incident or event reporting systems, with only some of the reports involving a true medical error. For example, such systems capture medication incidents, of which some are purely undesirable patient reactions to proper medication use, some are due to errors in ordering or giving medication, and some are of unclear cause.

Despite the different development sources, the 2 reporting systems are actually quite similar. They share a common approach to capturing incidents regardless of the presence of error. Their

scope is also similar, as they are not a module of a larger existing hospital information system. Also, as systems developed in essentially the same time frame, they are at the current Web-based state of the art, available online on computer workstations across the hospital. It is also likely that the thinking of the 2 development teams affected each other, given the role of Baylor as an “alpha” site for the DoctorQuality system. They each are in active development, reducing the usual difference in flexibility, where the “homegrown” product adapts rapidly to the organization’s needs, while the external vendor’s product tends to be fixed and driven by the differing priorities of groups of customers.

While internal incident and error reporting systems are required elements in all hospitals, what are some of the key purposes of promoting their development and use today?

First, such systems provide a way to change and nurture a “safety culture.” In such a culture, staff take every opportunity to communicate the occurrence of patient events as much as time permits. With easy access and data entry, these reporting systems minimize the time conflict between reporting and patient care. It is then for management to meaningfully screen events for important safety lessons, put in place solutions, and “close the loop” by communicating back to staff how reports lead to improvements in care and safety.

Second, they support communication between frontline staff and leadership around safety. Staff can communicate the occurrence of events with or without error, ranging from near misses with no patient effect up to unexpected severe patient outcomes including death. By personally emphasizing the importance of these reporting systems, senior leadership is emphasizing to staff its focus on patient outcomes and their precursors, whether there is an overt error or not. While many events can be and are handled by direct supervisors and managers of local areas, it is important for staff to have a communication route to organization-wide systems and senior leaders.

Third, automated reporting systems achieve their obvious goal of making it easier to gather various incidents and errors so the organization can analyze their nature, patterns, and frequency to identify improvements. Just as only some of the incidents involve error, some of the improvements relate directly to error reduction and others to making care better in the absence of error. For example, a diabetic patient may have severe, unexpected hypoglycemia while receiving insulin therapy in the hospital. On review, the complication may have been due to an error in timing, type, or dosage of insulin or to lack of knowledge of newer insulins or insulin pumps, with improvements focused on ways to prevent such errors in the future. Alternatively, the hypoglycemia may have been due to a routine or sliding-scale dose of insulin not well matched to the patient’s insulin needs or food intake, with improvements focused on better insulin regimens tailored to key diabetic patient characteristics. The next patient who does not experience hypoglycemia in the same circumstances is unaware of the improvements that prevented the event, and staff who see hypoglycemia events reduced don’t particularly care if the changes would be classified as “error reduction” or “quality improvement.”

Even if the systems of care in hospitals were to move from their current high rates of both minor and serious errors reaching the patient to being one of the “ultra-safe” systems with very

low rates of serious patient harm, there is still an important role for incident reporting systems. Best studied outside of health care in safe systems such as the European rail system or the air traffic control system, reporting systems still help staff and managers understand the type and patterns of minor flaws and events so existing protections can be maintained and new potential serious errors systemically identified and prevented before serious events occur for the first time (4).

What are internal incident and error reporting systems unable to do?

First, such systems are unlikely to accurately and completely find all events or errors. Both events and errors are underidentified and underreported. As a result, especially since the Institute of Medicine report, enlightened leaders within and outside organizations applaud increases in reporting numbers. They take on the difficult task of communicating within their organization and to the public that hearing about more errors is good, not bad, and is part of the system of making health care safer.

Second, like externally mandated systems, with rare exceptions they do not get true rates of events with accurate numerators and denominators. The exceptions may be situations in which automated data systems in the hospital contain both accurate information on the events of interest and the population at risk, such as the records for medications ordered and administered (5). Those accurate rates will get into the hospital’s reporting system only if there is a direct, routine handoff of the information between the systems.

Third, reporting systems are imperfect in parts of all key phases of error management: prevention, detection, and mitigation. While reports of near misses can help guide redesigns to prevent events and errors from happening in the first place, most often reports are of incidents that have already reached the patient with varying degrees of harm. Also, by their nature as reports of events after they are over, they are not part of the detection and mitigation of the effects of errors during real-time patient care. Only people themselves and online systems such as those that support direct provider order entry can detect, avert, or reduce the harm of individual potential events.

So, what decision should these Baylor Health Care System hospitals make? The benefits and limitations of both the homegrown and DoctorQuality systems are similar in essentially all the parameters discussed in earlier sections of this commentary. The decision will likely depend on a few choices and projections. Does the hospital value more its ability to directly guide features and customizations of its system? Or does it value more the larger base of reports, development guidance, and programming resources of the DoctorQuality system with its developing customer base? In terms of being able to maintain and continue to develop the reporting system, does it have more confidence over the long term in its own software programming resources or in this external vendor?

Regardless of their choice, moving forward with either of these reporting systems represents a “win” for the hospitals. Each will help move the hospitals toward a true safety culture, where each day leaders and staff work to design, deliver, and improve care that “gets it right the first time”—simultaneously giving the safety, quality, timeliness, and efficiency that is necessary for

hospitals to thrive and consistently improve the health of the population they serve.

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1. Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human. Building a Safer Health System*. Washington, DC: National Academy Press, 1999.

Many hospitals are sorting through difficult decisions regarding investments in systems to improve patient safety, including systems for error reporting. A common issue that has arisen among hospitals interested in the error reporting experience and success of Baylor Grapevine is the decision to use a “homegrown” product versus using a product from a national vendor. The purpose of this commentary is to articulate a framework for how hospitals might address such a decision.

In February 2000, Baylor Medical Center at Grapevine began working with DoctorQuality to improve the ease of incident/error reporting. The purpose of this effort was to increase the number of errors and incidents reported. It is generally accepted that incidents and errors are significantly underreported in hospitals. Underreporting occurs for a number of reasons—primarily, it is suspected, because of fear of punishment and the difficulty of reporting errors correctly. Improving error reporting is important for a number of reasons, the most important one being quality improvement. Through accurate error reporting, we can identify trends and target improvement opportunities.

Therefore, our management group felt that working with DoctorQuality on this project was meaningful work. A number of criteria should be considered when using an error-reporting tool; however, variables other than the tool must also be considered:

1. A very clear position of support from top management
2. Appropriate application of effective learning techniques
3. A well-planned communication effort
4. Ongoing feedback to users regarding data produced from the program
5. A meaningful reward and recognition program for users

The error reporting tool was implemented in August 2000. After over a year of experience with the product, several criteria have surfaced as being important. The most important criterion revolves around user satisfaction. Very simply, will employees use the system? It must be easy to use. For example, how difficult is the system to access? How many decisions must the user make along the way to correctly report? Also, does the user trust the system? Our system allows the report to be filed anonymously, if desired. This takes the punitive factor out of the picture. The user must trust that the reporting will be timely and, thus, relevant. These are all factors affecting user satisfaction.

2. Dixon JF, Wielgosz C, Pires ML. Description and outcomes of a custom Web-based patient occurrence reporting system developed for Baylor University Medical Center and other system entities. *BUMC Proceedings* 2002;15:199–202.
3. Atherton T. Description and outcomes of the DoctorQuality incident reporting system used at Baylor Medical Center at Grapevine. *BUMC Proceedings* 2002;15:203–208.
4. Amalberti R. The paradoxes of almost totally safe transportation systems. *Safety Science* 2001;37:109–126.
5. Classen DC, Pestotnik SL, Evans RS, Burke JP. Computerized surveillance of adverse drug events in hospital patients. *JAMA* 1991;266:2847–2851.

Second, tool adaptability is important. Each organization is different. Upon implementation, several changes were identified that would improve the tool for our situation. For example, we needed more specific information on patient falls, a high-risk activity. DoctorQuality was able to make this change to the system. The ability to make changes to the product increased its effectiveness.

Third, the production and use of data are important. The data must be easy to use and analyze. Improvement activities can be discovered only if the data are readily available. It is also important to benchmark your data with that from other organizations, both internal and external to the health care system. It will be meaningful to compare information among hospitals to identify best practices.

Fourth, cost must be considered when selecting a system. The initial cost of the system is only one of the factors. What resource utilization is required for implementation and ongoing use? Additional salary expense because of poor implementation or difficulty of use can far outweigh any initial cost advantage. Also, the cost of ongoing maintenance of the system must not be overlooked. Maintenance includes data maintenance as well as data access.

Finally, what type of ongoing relationship is established with the vendor? Does the vendor have a track record of support for its product? Baylor Medical Center at Grapevine has been very satisfied with the support and innovation provided by DoctorQuality. Recently, we have been approached about piloting a customer complaint tracking program, which will allow us to collect and trend customer complaints much as we track incidents. This will offer further improvement opportunities that we are excited about pursuing.

The criteria and other factors described above are all important when considering an error reporting system. Within Baylor Health Care System, a homegrown system is in use at Baylor University Medical Center, and the DoctorQuality system is in use at Baylor hospitals in Grapevine and Garland. The criteria I have detailed would be a good measuring stick to apply when evaluating the 2 systems. In addition, it would be important to look at outcomes from their use. The 2 most relevant outcomes are increases in error reporting at each facility and the sustainability of those increases.

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