ABSTRACT

Problem considered: State and federal initiatives to develop medical error reporting systems are being proposed. For these to lead to an effective error reporting system to improve primary care, the needs of primary care professionals must be understood.

Methods: This study was based on the answers to key questions directed at primary care physicians and clinical assistants. A series of focus groups was held to determine what elements need to be included in the design of a medical error reporting system for ambulatory care.

Results: Participants addressed the purposes of an error reporting system, the barriers and motivators to the use of a system, the types of events that should be reported, how the reporting should be done, and how the data should be analyzed and used. During the sessions, 87 different themes emerged that were distilled down to the general principles and operating design elements deemed most important.

Conclusions: The participating physicians and clinical assistants supported a primary care medical error reporting system designed to provide useful information to improve health care. The system should not be punitive.

INTRODUCTION

To reduce the frequency of medical errors it is necessary to understand their causes and design methods to prevent or discover them before they do harm. One way to accomplish this is to have a system that can collect “real world” examples of errors and hazards, with suggestions for reducing their impact or eliminating them. To this end, several states and the federal government have proposed medical error reporting systems. In Wisconsin, preliminary steps are being taken towards legislation supporting such a system. Generally speaking, however, front-line health care professionals have not been asked to participate in designing such a system, raising the possibility that any system implemented would not be effective in improving patient safety.

Most of the medical error research to date has focused on errors in hospitals, and progress is being made in this area. However, it is likely that more hazards exist and more errors actually occur in outpatient settings, particularly in primary care, due to the rapid pace of practice, the multiple problems that patients have, and the complexity of the process of care. Medical errors that occur in primary care are different from those that occur in hospital settings, as are the potential means for preventing them. Thus, any valid error reporting system must be effective at collecting data from ambulatory care settings.

Recent literature has pointed toward what are believed to be the characteristics of successful reporting systems. One study found these systems to be:

- nonpunitive
- confidential
- independent of any authority with power to punish
- analyzed by experts who understand clinical care and systems causes of errors
- timely in reporting
- focused on systems, processes, or products, rather than individuals
- responsive to needs for information with agreement from participating organizations to implement recommendations when possible

Two others showed that physicians and other clinicians might differ from the general public in what they see as the best response to errors and the utility of a reporting system. In general, the public was more supportive of mandatory reporting and sanctions being
part of the system. Thus, it is still necessary to uncover specific user needs for an effective primary care error reporting system.

METHODS
To discover what type of error reporting system would be most useful to primary care clinicians, we held a series of focus groups with family physicians and their clinical assistants. While our attention was on ambulatory primary care, it seems likely that many of the results could be extrapolated to other care settings.

A series of telephone conference calls of 2 different focus groups was conducted over a 9-month period. One group of 8 family physicians met 9 times and 1 group of 6 clinical assistants (nurses and medical assistants) met 7 times. Both groups discussed the same topics, but the family physicians required more time to complete the discussion. Topics covered included potential purposes of a medical error reporting system, fears and concerns about reporting medical errors, what to report (e.g., chain of causality, mitigating factors, near misses), barriers and motivators for reporting to a system given the identified purposes, instructions for using the system, mechanisms of and medium for reporting, uses of the reported data, security, and ethical issues. All meetings were audi-taped and transcribed. The transcripts were analyzed using inductive content analysis, and data were displayed in a process/outcome matrix to facilitate interpretation. Subsequently, an external validation was conducted where the results and interpretations were provided back to the participants, who were then asked to assess their accuracy. No changes were suggested from the external validation.

RESULTS
During these sessions, 87 different themes emerged, which were distilled down to the general principles and operating design elements that seem most important. More complete reports on the process are available from the authors.

The groups were enthusiastic and generally very supportive of the development of a medical error reporting system. However, there were great concerns about the possibility of punishment or sanction arising from the use of a reporting system. Participants stated many times, in a variety of ways, that the system must have immunity from legal or other action resulting from its use. Our specific findings are presented below.

Why Should We Have A Medical Error Reporting System?
The participants clearly felt that the primary purposes of an error reporting system had to be to improve health care and to educate. This goal would be best served if, through reporting, a database of “solutions” was created, along with a database of errors so that clinicians could search for similar errors or hazards as well as potential solutions. Participants did not believe that an error reporting system designed for punishment or disciplinary action would succeed in improving health care.

What Type of Information Should Be Available?
There should be a focus on discovering and disseminating “best practices.” Aggregated data on errors should be disseminated to clinic administrators as well as caregivers so that they could implement useful error or hazard prevention strategies. Participants believed that information should be provided to patients so they understand their role in helping to prevent errors. For example, if errors are reported that, in part, resulted from a lack of information provided to clinicians from patients, such information could be used to develop patient education materials that explain the type of information they need to provide their caregivers during office visits. Focus group participants did not believe that the general public, that is patients, should be provided with anything other than educational material from the error reporting system. There was a concern that disseminating information about specific errors to patients could be detrimental to physician-patient interactions.

Information given to the clinicians and clinic administrators must go beyond statistics or it will not be very useful. The reports should present aggregated data to look at clusters and trends. Specifically, the hazards present that led up to the error should be shared so that these hazards can be identified and controlled by appropriate clinic personnel. The basic data should be reported anonymously and not be identifiable by health care organization or clinic. The error reporting system should help professionals and the public understand that procedures can be implemented to reduce error by identifying and controlling the associated hazards.

Should There Be Accountability For Errors Reported?
As a way to motivate system change, it was felt that there could be accountability for health by asking, “What programs has your organization instituted to prevent recurrence of errors?” That is, participants felt that organizations should be held accountable for implementing hazard control methods that have been found to reduce the likelihood of errors. On the other hand, focus group participants did not want an error
reporting system that could be used for comparing individuals or clinics on the number or severity of errors. They felt that the data would not be accurate, due to differences in reporting frequency between users. They were very clear that a punitive error reporting system would not only discourage clinicians and others from reporting but could even lead to false reports of errors in order to punish colleagues or clinics.

What Should the System Be Called?
The name of the system should be positive to encourage participation and to convey that its purpose is to improve health care. For example, it could be called the “Wisconsin Patient Care Improvement System.”

Who Should Govern the System and Control Data Use?
It was felt that the “ownership” of the error reporting system should be within the health care profession to assure that the information would be analyzed appropriately and to guard against its use for punitive purposes. The error and solution database should be reviewed by a professionally diverse entity with varied expertise including peers, systems experts, human factors engineers, patient representatives, risk management experts, safety professionals, and health care funders. Such a structure would engender trust among clinicians, which would further encourage reporting. On the other hand, respondents did not feel the government, specific managed care organizations, or any other specific health care delivery organization should manage the error reporting system. Participants did not trust the government because of fears that political pressures would compromise the data, and they did not trust specific managed care or other health care delivery organizations because of a fear that the data could then be used for competitive purposes. There has to be trust in the system’s integrity.

Should There Be Legal Protection for System Users?
The error reporting system will need to grant legal and administrative immunity to reporters so they and their peers and clinics are not at risk from reporting to it.

How Should Actual Reporting Occur?
The system’s logistics need to make it very easy to report. Data from existing clinic incident reporting systems should be fed into the statewide database to eliminate the need for duplicate reporting. Multiple media (internet, PDA-based, paper) should be available to suit user needs. Access to the reporting system must be constantly available to all people who might submit reports. Users should also have the option of reporting at the time of an event or at their leisure. The data entry forms should be designed so they can be completed quickly—preferably in 5 minutes or less. To accomplish that goal, the data entry form should be designed so that reporters can simply check boxes to complete the form. That, however, would require designing the reporting system so that currently known types, causes, and ways to reduce the impact of errors are present in the reporting form. Focus group participants also wanted the option of providing narrative information in addition to the check-box information.

What Would Encourage Error Reporting?
Several motivators to reporting emerged:

- A feedback system for submitters is necessary to maintain interest. One such mechanism could be that every time information was sent in, the submitter would get reminders, composite data, or a commentary to encourage a 2-way flow of information. Similarly, weekly or monthly newsletters that identify recent errors, their associated hazards, and hazard control strategies were suggested.
- Safe and secure access is necessary. The system will work only if reporters are anonymous or de-identified and no identifiable information is solicited regarding co-workers or patients. The potential of a leak about specifics to the press, legal, or regulatory agencies is a real concern.
- There needs to be easy access, as described in the previous section.
- What to report needs to be clearly defined. Any confusion will result in under-reporting of important information or over-reporting of unneeded information.
- The reporting forms must be simple. Algorithms that lead reporters through a series of check-box queries are preferred, as long as reporters may also provide narrative text when necessary.
- Error reporting must fit into the clinician’s current workflow. If reporting requires steps to be taken that do not fit naturally into existing work patterns, then, no matter how well the interface is designed, how easy the access, or how simple it is to complete, people may not report. A significant issue is that many ambulatory care clinics already have some form of incident or error reporting system. If reporters are required to report twice—one to a clinic-owned system and once to a statewide system, the statewide system will fail. A mechanism for allowing a single report must be developed.
- A non-punitive system is essential. If the possibility
exists that individuals or clinics could face legal action from reporting, the system will not be used.

**DISCUSSION**

State and federal proposals to develop medical error reporting systems need to take into account the needs of system users if they are to be successful. Because systems are being proposed now, there is some urgency for input from the potential users. This work provides some initial guidance to help assure that any legislative proposals meet the needs of practicing health professionals. The focus groups, albeit limited in size, provide very useful information to guide the design of any proposed system.

For a reporting system to be successful, it must provide useful information back to the professionals who are asked to submit information. The users must trust that the reporting will not be used in any punitive manner, and the reporting methods must be flexible, simple, and compatible with other “in-house” systems. Accountability should be at the system level and focus on implementation of error-reduction programs in problem areas as identified by the reporting system. Although not directly addressed by the focus groups, it is the opinion of the authors and others that it is critical that a medical error reporting system be distinct from any mandatory adverse event reporting system. Finally, it must be recognized that there are many factors that have impact on the use and effectiveness of an error reporting system, including many related to the analysis of the data submitted.

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**REFERENCES**

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