

To err is human. Building a safer health system

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Human beings, make errors

Healthcare Services is a complex industry prone to accidents. The IOM Report [1] points out that some systems are more prone to accidents than others. When a system fails there are often multiple faults. In healthcare, human errors are the greatest contributors to accidents, however when human error is to blame it often depends upon failures within the system. These failures exist in the system before the error occurs, the same as with latent errors which are difficult to identify since they may be hidden in computers or within the various managerial layers. Most of the errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing. In healthcare, this means designing processes that are able to ensure that patients are safe from accidental injury.

As healthcare and the system that delivers it become more complex, the opportunities for errors abound. The IOM report *"To Err is Human"* proposes an approach for reducing medical errors and improving patient safety. The environment within which this occurs has a critical influence on quality. This influence may contain two dimensions; the first consists of the domain of quality which includes the practice that is consistent with current medical knowledge. The second dimension consists of forces in the external environment that can drive quality improvement in the delivery system. Although the risk of dying as a result of a medical error, far surpasses the risk of dying in an airline accident, public attention has been more focused on improving safety in the airline industry than in healthcare systems.

Because of the absence of standardized nomenclature, it is important to define what an error is and what is an adverse event, the IOM Report defines them in the following way:

"An error is the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim."

An adverse event is an injury caused by medical management rather than the underlying condition of the patient.

An adverse event attributable to error is a "preventable adverse event".

Apart from the two definitions above, there are many studies that address medication related errors. This kind of error is more common and also has methodological issues. Prescription drugs are widely used and, for this reason, it is easier to identify a sample of patients who experience adverse drug events; medication errors also frequently occur in hospitals.

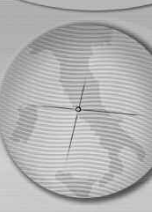
Using data from the Medical Practice Study, The IOM reports that 70 percent of the adverse events it found were preventable.

The Report goes further to say that patient safety problems occur during the course of providing health care. In addition to the unfortunate health consequences suffered by many as result of medical errors, there also are direct and indirect costs resulting from medical errors. Direct costs refer to higher health care expenditure; indirect costs include factors such as lost productivity, disability, and personal costs of care.

The authors of *"To Err is Human"* propose the development of the Center for Patient Safety within the Agency for Healthcare Research and Quality (AHRQ), to keep attention focused on patient safety. They suggest that AHRQ is the best choice because of its goals of quality measurement, quality improvement and the identification of best practices.

In aviation and occupational health there was a growing awareness of safety concerns and the need to improve performances which resulted in the creation of government agencies with regulatory responsibility for safety. Both areas recognized the need to expand the knowledge base on safety and substantial resources were devoted to these initiatives. In healthcare there is no cohesive effort to improve safety in healthcare.

The Center for Patient Safety should provide visibility to safety concerns and it should provide a limited number of high priority goals. The Center should establish a formal process to gather input on priorities, methodologies, and approaches for research. The deliverables include the development of tools and methods for educating consumers about patient safety, but also focus on health professionals and



managers, hospitals policy makers and pharmaceutical companies, viewing them as an important audience.

In terms of funding the Center for Patient Safety, the committee considered three major factors: research investments made to address healthcare issues of a similar magnitude, investments in safety research in other industries, and operating budgets for research initiatives with similar programs.

To learn from errors it is necessary to utilize a reporting system. This has two main functions:

1. Holding providers accountable for performance;
2. Providing information to improve safety.

In theory it is very difficult to meet these two conditions simultaneously, with the same kind of report. In fact the IOM's Report underlines the importance of achieving these results through an error reporting system.

There are two kinds of Error Reporting Systems, one is "mandatory" and the other is "voluntary".

The first is ordered by state regulatory programmes that investigate errors, so it is an external entity. Its focus is on the detection of errors which result in patient harm or death (preventable adverse events).

The main purpose of mandatory reporting is accountability and as an incentive to healthcare organizations, thus checking standards and enhancing investments in patient safety.

There are different kinds of mandatory reporting systems; some programs receive reports from individuals, others from organizations. There are mandatory systems which report to an external body, this approach is employed by states. The other reporting system is internally associated with audit, for example as seen with the Occupational Safety and Health Administration (OASHA), which could be required to make the data available during an inspection, or to keep data according to an internal format.

The second kind of error reporting system is voluntary. It may be confidential, reporting to an external group whose main purpose is quality improvement. The focus of this system is on errors that resulted in no harm, near misses, or very minimal patient harm.

Voluntary reporting is useful for identifying errors that occur too infrequently for an individual health care organization to react promptly to the data, and patterns of errors that indicate systemic issues affecting all healthcare organizations.

Many healthcare organizations use voluntary systems for accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). However, there is a problem with providing information as the information may be used against the physicians and other healthcare providers. In fact, the prominence of litigation can be a strong deterrent to the development of reporting systems. Even though the committee recommendations differ on these issues; alternative views are recognized.

Congress should approve legislation to extend peer review protection of data on patient safety that are reported by healthcare organizations.

In a recent survey, conducted by the JCAHO, one third of states were found to have an adverse event reporting system. The IOM interviewed some of these states with reporting systems to learn more about their scope and the running of their programs.

There are two main problems in studying these data: lack of resources and data limitation. Many states declare that the information they have received in reports is variable, incomplete and inadequate, which demonstrates the need for more standardized reporting formats.

The need for collaboration among states to identify best practices, create awareness of the problem of patient safety and errors amongst the general public and health profession was indicated.

Better instruments, tools, methods and protocols are necessary to constructively address the issue. Even though many states have an error reporting system, constraints on resources (money and people) often hinder improvements in patient safety.

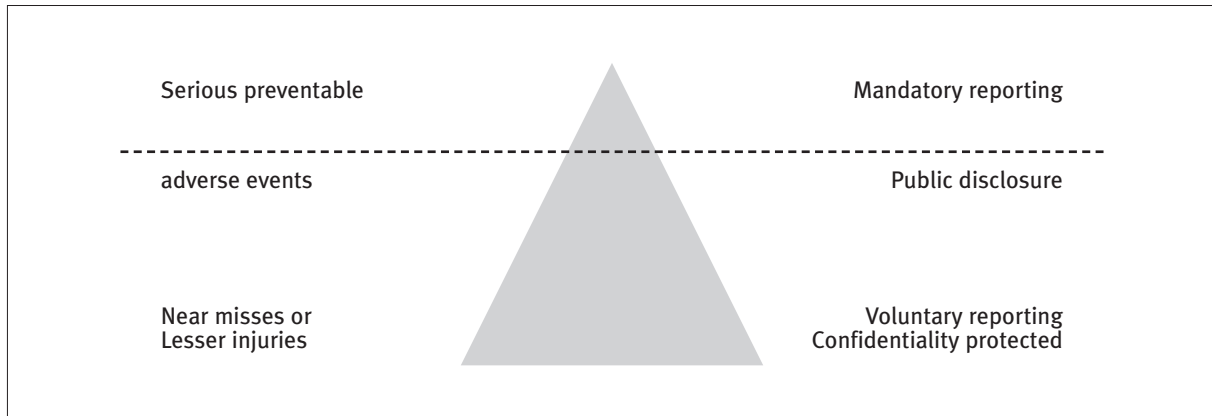
The Committee believes there is a hierarchy of reporting (Figure 1): there are two categories of errors, one is the result of serious injury or death and the other is lesser injuries or near misses. The first type of error is addressed by the mandatory reporting system (public disclosure); the second by a voluntary reporting system (Confidentiality protected).

Finally, the committee recommended having mandatory nationwide error reporting with state governments providing standardized information. Furthermore, Congress should nominate a national Forum for Health Care Quality Measurement and Reporting as being responsible for the diffusion and maintenance of a reporting standard as well as providing nomenclature (a list of adverse events). Then funds should be given to state governments targeted at training. In such ways the development of voluntary reporting could be encouraged.

The Committee suggests paying greater attention to patient safety issues in order to create a wider culture of safety.

Performance standards and expectations for health care organizations should therefore focus on developing a minimum standard for patient safety and developing patient safety programs within their structures.

Figure 1. Hierarchy of reporting



Source: *To err is human: building a safer health system.* (2000) [1].

The marketplace, through purchaser and consumer demands, also exerts influence on healthcare organizations. Considering safety issues in their contracting decisions, private and public purchasers could continuously improve patient safety.

Professional societies should establish a permanent committee devoted to safety improvement, working together both with the Center for Patient Safety, and with other professional societies and disciplines. They should collaborate in putting into practice guidelines and standards for the diffusion of new drugs and also by improving information on patient safety to doctors and other healthcare providers, for example, at annual conferences and through journal editorials, publications and websites.

The Committee identified a set of principles to improve patient safety:

1. Provide Leadership: making patient safety a priority corporate objective and an everyone's responsibility.
2. Respect Human Limits in Process Design: respects human beings as "problem solvers", but minimize reliance on their weaker traits by simplifying and standardizing work processes using constraints and forcing functions.
3. Promote Effective Team Functioning, recognizes the importance of training "team workers" by including the patient in safety design and the process of care.
4. Anticipate the Unexpected, adopting a proactive approach by examining processes of care for threats to safety and designing them before accidents occur, creating a reliable system for procedures, placing protocols in the patient's chart, using computerized lab data and reporting errors and near misses regularly. The need for electronic databases is very important.
5. Create a Learning Environment: "to fix the system" through the utilization of communication flows, ensuring feedback and learning from errors.

Another source of preventable errors in hospitals is medication error. Medication safety must be improved by selecting strategies such as implementing standard processes for medication doses, dose timing and scales within the health care unit.

The most important lesson of the past 5 years since the IOM spoke out on one of the major public health issues of our time is that we will not become safe until we choose to become safe.

(Lucian L. Leape, Donald M. Berwick - Boston)

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- 1) Kohn LT, Corrigan JM, Donaldson MS editors. *To err is human: building a safer health system.* Washington, D.C.: National Academy Press, 2000.