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# Errors in medicine

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ABSTRACT

Modern awareness of the problem of medical injury – complications of treatment – can be fairly dated to the publication in 1991 of the results of the Harvard Medical Practice Study, but it was not until the publication of the 2000 Institute of Medicine (IOM) report, *To Err is Human* that patient safety really came to medical and public attention. Medical injury is a serious problem, affecting, as multiple studies have now shown, approximately 10% of hospitalized patients, and causing hundreds of thousands of preventable deaths each year. The organizing principle is that the cause is not bad people, it is bad systems. This concept is transforming; it replaces the previous exclusive focus on individual error with a focus on defective systems. Although the major focus on patient safety has been on implementing safe practices, it has become increasingly apparent that achieving a high level of safety in our health care organizations requires much more: several streams have emerged. One of these is the recognition of the importance of engaging patients more fully in their care. Another is the need for transparency. In the current health care organizational environment in most hospitals, at least six major changes are required to begin the journey to a culture of safety: 1. We need to move from looking at errors as individual failures to realizing they are caused by system failures; 2. We must move from a punitive environment to a just culture; 3. We move from secrecy to transparency; 4. Care changes from being provider (doctors) centered to being patient-centered; 5. We move our models of care from reliance on independent, individual performance excellence to *inter*dependent, collaborative, interprofessional teamwork; 6. Accountability is universal and reciprocal, not top-down.



## 1. History

Modern awareness of the problem of medical injury – complications of treatment – can be fairly dated to the publication in 1991 of the results of the Harvard Medical Practice Study [1,2]. This review of 30,000 medical records of patients hospitalized in New York state showed that 4% of patients had complications of their treatment, which we call *adverse events*. Even more shocking was the finding that two-thirds of these iatrogenic injuries were due to mistakes and therefore were preventable. Surprisingly, there was almost no public or professional outcry at this time.

These findings led health care leaders to discover the substantial literature concerning error prevention in other industries that had been developed by cognitive psychologists and human factors engineers over the preceding decades. A few investigators began to apply these principles to the analysis and redesign of medical systems [3]. The US study was replicated in other countries with even more alarming results (Australia: 13% of patients with AE; UK: 10%) [4,5].

But it was not until the publication of the 2000 Institute of Medicine (IOM) report, *To Err is Human* that patient safety really came to medical and public attention. Extrapolating from the earlier New York study, the IOM proclaimed that nationwide as many as 98,000 Americans died yearly from medical mistakes [6]. Although policymakers and some physicians had been disturbed by concerns about overuse and underuse of health care services for a decade or more, most doctors and the public had little interest in quality issues. The revelation that thousands were dying from medical mistakes, however, grabbed the attention of both the public and our profession. The field of patient safety was born.

Fortunately, the other major message from the IOM report, that the cause of those 98,000 preventable deaths was not careless or incompetent people, but bad systems, was also heard. Quit blaming people for making errors and change your systems, the IOM said. Errors are signs of sick systems, not bad people. It makes no sense to punish individuals for errors.

"Systems" includes almost all of the processes and methods we use to organize and carry out virtually everything we do — whether simple or complicated. For example: It is well known that nurses make frequent mistakes in measuring out medications from multiple use vials. Thirty years ago it was discovered that having the pharmacist provide every medication to the nurse in the dose and form in which it is to be given – which we call *unit-dosing* – nearly completely eliminates dosing errors.

And so, the underpinnings of patient safety are a fact and an extremely simple organizing principle. The fact is that medical injury is a serious problem, affecting, as multiple studies have now shown, approximately 10% of hospitalized patients, and causing hundreds of thousands of preventable deaths each year.

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The organizing principle is that the cause is not bad people, it is bad systems. This concept is transforming; it replaces the previous exclusive focus on individual error with a focus on defective systems. The question is not, Who did it?, but Why did it happen? In a very real sense, the quest for patient safety is the effort to figure out how to implement this simple idea.

At about the same time as the IOM report, in 2000, Liam Donaldson, chief medical officer of the UK, issued a report: *An Organization with a Memory*, calling on health care to be more accountable and focus on error prevention. Progress since then has been impressive. Safety agencies were established in the UK, Canada, Australia, and Denmark. In 2004, the World Health Organization (WHO) established the World Alliance for Patient Safety to promote safe practices worldwide.

Meanwhile, at the clinical level, a massive voluntary effort was undertaken by doctors, nurses, and pharmacists on the "front line", to develop new safe practices, such as protocols for communicating critical test results and reconciling medications. In a fairly short period of time, a substantial number of these new practices were developed and tested for validity. In 2005–06, the Institute for Healthcare Improvement (IHI) in America carried out a nationwide campaign, in which >3000 hospitals tried to implement 6 new safe practices. The results: over 122,000 lives were saved in a 2-year period [7].

A key driver for change has been the World Alliance for Patient Safety. Its seven programs – solutions, research, reporting and learning, taxonomy, Patients for Patient Safety, and implementing standard procedures – have stimulated progress worldwide. The first global campaign, to promote and facilitate effective hand hygiene, garnered commitments from 116 countries. The current campaign, Safe Surgery, in which all operating rooms in the world are encouraged to use a simple, standardized check list, might well save thousands of lives.

## 2. Achieving safe health care

Although the major focus has been on implementing safe practices, it has become increasingly apparent that achieving a high level of safety in our health care organizations requires much more. Several streams have emerged. One of these is the recognition of the importance of engaging patients more fully in their care. Another is the need for transparency. Safety experts and patient advocates agree that patients have a right to know all about their care, especially when things go wrong. Full explanation and complete honesty is the only way to deal with an error [8].

Patients also need to be full participants in the care process – a member of the team – if care is to be truly safe. For example, a patient who knows exactly what medications have been prescribed and also feels comfortable communicating with doctors and nurses might well notice when a wrong medication is about to be given, or when the dose is out of bounds, and intercept (prevent) the error.

Another stream is the need for monitoring, assessing, and improving physician performance [9]. The specialty boards in the U.S. are developing sophisticated measures of competence in multiple domains [10]. These will be used as part of an ongoing certification process to assure that physicians maintain their knowledge and skills, identify areas of weakness, and correct them promptly so that patients are not at risk. The time has passed when it is appropriate to assume that every physician is competent just because he or she was well trained and/or passed an examination at some time in the past. Maintaining competence is a cornerstone of safe care.

Yet another recent development has been the interest in requiring hospitals to report serious avoidable adverse events (sometimes called "sentinel" events). These are injuries, such as amputation of the wrong leg, that should never happen. If they do, it suggests that the hospital systems for assuring safe care are not working properly. This type of public accountability is growing rapidly among states in the U.S.

## 3. What have we learned?

From this relatively short experience, we have already learned a great deal. The most important lesson is that systems theory works. Errors and injuries can, in fact, be prevented by redesigning systems to make it difficult, and sometimes impossible, for caregivers to make mistakes. A classic example is the elimination of accidental (fatal) intravenous injections of concentrated potassium chloride by removing the medication from the nursing units and requiring it to be added to intravenous solutions when they are prepared in the pharmacy.

Another example is computerized physician order entry systems (CPOE), where the physician must enter all orders, including all prescriptions for medications, by computer. This ensures that the order is complete, it is not a medication the patient is allergic to, and that the dose is within usual limits. Studies show that CPOE can reduce serious medication errors by 60–80% [11,12].

A second lesson is that safety depends on the power of dedicated people – nurses and doctors – on the front line to make changes. This is where safety occurs; this is where change must occur. It has been local improvements, not national policies, that have made most of the difference.

But, we are finding, it is difficult to implement even simple practices. All change requires that people do their tasks differently. Many changes require additional work. Not surprisingly, people do not change old habits easily. A classic, and disturbing, example is hand hygiene. While the underlying science is indisputable, and the methods are well defined, in most hospitals most doctors still refuse to disinfect their hands before and after touching a patient.

Another habit that dies slowly is the tendency to blame and punish individuals when they make a mistake. Although again the science is irrefutable, that almost all errors are caused by system failures, not individual carelessness, it has proved difficult for doctors and nurses to really accept this concept and to create a nonblaming environment where it is safe to talk about your mistakes and where the response is to seek the underlying system failures and not blame the individual.

One of the most important lessons is that individuals cannot achieve safe care on their own. As the famed international error expert, James Reason, says, safety is about relationships — about working in teams. It is teams that have achieved the remarkable successes, such as total elimination of central line associated blood stream infections or ventilator associated pneumonia [13]. Unfortunately, until now our educational systems, both in medicine and in nursing and in other related professions, have emphasized individual performance. Doctors and nurses have been taught to believe if they do their own job right, there will be no problems. Changing that mindset requires a different type of educational experience, as well as reinforcement of this new model of professional behavior in the care situation.

Thinking in systems terms and working in teams requires a change in our culture. This is an international concern: the problem is similar in countries around the world. While national cultures vary considerably, and cultures even vary between hospitals, the practice of medicine almost everywhere follows the 19th century model of apprenticeship training and autonomous professionalism in a hierarchical model where the physician dictates care. We need to change to a culture of safety.

## 4. A culture of safety

What is a culture of safety? Various authors have defined it in different ways. James Reason emphasizes that a safe culture includes three characteristics. First and foremost it must be a *just* culture: people are not punished for making errors, but deliberate violations and misconduct are not tolerated. Second, it must be a *reporting* culture: the environment must be safe for people to talk about errors and report them. Only in that way can we discover our problems and

fix them. Finally, it must be a *learning* culture: one in which everyone is curious about why errors happen, investigates them, finds system failures, and fixes them [14].

Other writers have emphasized the need for an open culture, for transparency, where people work in teams, where safety is THE priority [15]. Roberts notes that a culture of safety is primarily a culture of *trust*, where people take responsibility and work collaboratively [16].

Changing our cultures is not easy, and cannot be done quickly. In the current health care organizational environment in most hospitals, at least six major changes are required to begin the journey to a culture of safety:

1. We need to move from looking at errors as individual failures to realizing they are caused by system failures. This is the driving principle. We all know it; many are trying to do it. But it is easy to slip into the blaming mode: "How could she possibly have done that?"
2. We must move from a punitive environment to a just culture [17]. We do not punish for errors, but we do not tolerate misconduct. The atmosphere must be truly non-punitive. People are never punished for errors. We may still not think of errors as "treasures", as the Japanese quality gurus claim, but we do see them as opportunities for learning. On the other hand, we do not tolerate people who deliberately break the rules and engage in unsafe acts. Everyone must feel responsible for implementing and following safe practices.
3. We move from secrecy to transparency. Instead of hiding errors, we discuss them and learn from them. Patients are honestly and completely informed of their care and when problems arise. We do not play games. We acknowledge our mistakes and inform patients of what we found in our investigations and what we are going to do to prevent recurrence.Similarly, we are open to the public. Health care is a public good. We have no right to hide what we do. In a safe culture, transparency and openness are part of everything we do.
4. Care changes from being provider (doctors) centered to being patient-centered. In a safe culture, the focus is on meeting the patients' needs, not the providers' needs. How can you tell if your organization is really patient-centered? Ask the simple question: Who waits?
5. We move our models of care from reliance on independent, individual performance excellence to *inter*dependent, collaborative, interprofessional teamwork [18,19]. We treat each other with respect and work well together in teams, because it is safer, and because it is more satisfying. Patients are part of those teams.
6. Accountability is universal and reciprocal, not top-down. At every level, we are accountable – we take responsibility for safety – for all aspects of safety, and we expect those above us to do so as well [20,21]. Just as the hospital administrator has a right to expect all doctors and nurses to follow a safe practice (such as disinfecting your hands), the caregivers have a right to expect the hospital to put in place the resources, rules, and practices to ensure safe practice (such as dispensers for hand hygiene, and unit-dosing for medications).

## 5. Making the changes: the importance of teamwork

Return to the problem of hand hygiene. Most hospitals have a policy requiring everyone, doctors, nurses, technicians, assistants, to disinfect their hands before and after touching a patient. But compliance in most hospitals is dismal. Why? The reason is that we do not work in teams. Compliance is, appropriately, an individual responsibility. But it is more likely to happen when caregivers work together in teams. And most doctors and other caregivers do not know much about working in teams.

It has become apparent that significant improvement in patient safety overall requires that caregivers work together in teams. It is not enough to have safety policies, or to require that personnel follow safe practices. To make them work requires a team effort. Effective teams have several important characteristics:

- *Clear focus*. Teams do not exist in the abstract, or as elements on an organization chart, they exist for a purpose. That is, teams are *functional* organizations that come together for a specific purpose. That purpose must be clearly defined and well understood by all who participate.
- *Multidisciplinary*. Perhaps the most important characteristic of health care teams for safety is that they include all stakeholders: everyone whose input is needed for the task at hand. Teams are not composed of just doctors and nurses, but include pharmacists, therapists, technicians, aides, clerks, and other support personnel, as needed for the job. And patients. Who has the greatest stake in the work of the team? The patient. Who suffers the most when the team fails? The patient. Should the patient be a member of the team? Of course.
- *Leveling of hierarchy*. Teams are not "command and control" organizations. They are not squads of people organized to do the leader's bidding. They are collaborative organizations where people come together to solve a problem and do a job well. The leader is the facilitator, not the dictator. While doctors are sometimes leaders of the team, at other times it is more appropriate for a nurse or a pharmacist or someone else to lead. All members of a team are essential; the doctor is no more important than anyone else.
- *Mutual respect*. Every member of the team brings an essential perspective, expertise and point of view that others do not have. Thus each deserves and must receive respect from all the other members of the team. In a well-functioning team, every voice is listened to, and every voice is heard. And everyone knows they have been heard. Mutual respect is what makes teamwork satisfying.
- *Leadership*. Strong leadership is essential for a team to function effectively. Although mutual respect is essential and no one should function in an authoritarian or dictatorial fashion, someone has to be in charge. Someone has to articulate the goals, facilitate the development of the plan, and support, encourage, and assist the group to achieve its mission [22]. As noted, this may or may not be a physician.

Leadership at the institutional level is also needed to enable the team to carry out its tasks. For safety, the major function of teams is to develop and implement new practices. This inevitably requires many changes in the way many people do their jobs. Not surprisingly, conflicts arise. The middle manager and the Chief Executive must be fully supportive of the changes and help resolve these conflicts.

Teamwork is the secret of success for every industry that has become truly safe: commercial aviation, chemical production, air traffic control, flight carrier operations, etc. Unfortunately, in health care we do not do teams very well. It is time to learn.

## 6. The safety challenge in laboratory medicine

In terms of quality control, and error rates specifically, laboratory medicine has a far better record than most other fields in health care. In the analytic phase, some studies indicate that the average error rate is as low as 0.002%. This is functioning at the 5 sigma level. For comparison, the rates of infections and medication errors are closer to 3 sigma, i.e., defect rates >3000 times those in the laboratory! (Fig. 1).

When the entire process of selecting, ordering, obtaining specimens, analyzing, reporting, and utilizing laboratory tests is considered, however, the results are less impressive. Reported results indicate failure rates of 12–18% in the pre-analytic phase and rates as high as 25% in the post-analytic phase [23]. While laboratory personnel do not have "control" over those phases comparable to

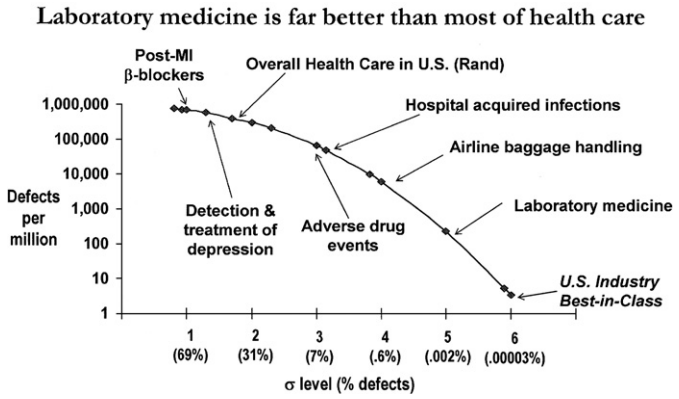


**Fig. 1.** Defect rates in laboratory medicine as compared to other sectors.

what happens in the laboratory itself, from the patient point of view it is the whole process that counts. And, to make the whole process work requires teamwork. Thus, in laboratory medicine as in all of health care, teamwork is the essence of safety. And the team must include all of the personnel involved from the initiation of the request to the use of the results. This is a larger team than is required to address most safety problems, spanning a large number of disciplines. All the more important to make it work!

A good example of the need – and the power – of teamwork in laboratory medicine is the challenge of communicating critical test results. These are test results that indicate conditions that are potential threats to life, and for which prompt action by the responsible physician is necessary.

For the team to develop an effective process to assure that these critical results are appropriately and promptly communicated to the responsible party, a number of questions must be addressed [24]. Here are some of them: What tests are "critical"? What are the thresholds for critical values? Who should receive the results? When do they need to have them — within an hour, a day, a week? How should results be transmitted: by computer, by telephone, by page, person-to-person? For the system to work smoothly, all of these and other questions must be considered, and agreement must be reached among all members of the team.

But even before these questions can be addressed and resolved, more fundamental issues must be dealt with. What is the mission of the team? Is it clear to all, and specified in enough detail that there are no misunderstandings about what the team is trying to accomplish? Who are the members of the team? All persons involved in the process must participate: doctors, nurses, lab technicians, technicians who draw the samples, aides and orderlies who transport specimens, etc. And a patient or two who could help the team understand some of their practical concerns.

Who should be the leader of the team? Should the tasks be divided with separate leaders and smaller teams to work on different phases of the process? How will we measure success? What kind of data do we need to know that the system is working properly? Who will collect those data? How will it be communicated? Does the team have full institutional support? Is there a commitment at the highest level to develop a process that achieves a goal of 100% success in communicating promptly every critical laboratory result? Will they provide the resources?

It is evident that teamwork is a complicated process, and that the challenges to make teams work effectively are significant. It is perhaps harder to make changes in health care than in any other industry, both because of the complexity of our processes and because of our deeply entrenched traditions of how we do things. It can only happen with firm and committed leadership by the heads of each department and by the leader of the organization. But the rewards can be great. Not just in the satisfaction of doing a difficult job well, but in the lives of our patients saved. Patient care can be made safe, if we are willing to do what it takes.

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