A Policy of System Safety: Shifting the Medical and Legal Paradigms to Effectively Address Error in Medicine

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Medical error causes the vast majority of patient injuries both in the U.S. and around the world.\textsuperscript{1} With the publication of the Institute of Medicine’s report, To Err is Human, the scope of this problem was defined and publicized broadly in both the academic and lay presses.\textsuperscript{1,4} Various statistics and studies abound as to the specific frequency of errors and their consequences.\textsuperscript{2,5-7} The overall message of these studies is clear: patients enter into the healthcare delivery system with a significant risk of being subject to medical error.

Yet the picture is not entirely bleak. Some systems within medicine, as well as other complex industries such as aviation and nuclear power, have been successful in reducing error and improving performance and safety through the use of a systems analysis approach.\textsuperscript{8-11} Despite these success stories, systems analysis has not been implemented to the extent that it warrants. Instead, law, medicine and health policy continue to focus on other means of reducing medical error that have in some ways brought about the opposite results. These antithetical methods rely on the “shame and blame” of individuals; the exactly wrong approach to improve complex system safety and performance. As a result, a new policy and ethical paradigm must be implemented in order to move the healthcare delivery system forward and to improve patient safety by reducing medical error and its attendant effects.

The Basics of Error

Medical error can be defined as a mistake, inadvertent occurrence or unintended event in healthcare delivery which may, or may not, result in patient injury.\textsuperscript{12} It is important to note, however, that this definition does not include purposeful or reckless actions that are intended to harm, directly or indirectly, the patient. These latter actions, which are malicious and volitional rather than erroneous, represent only a tiny
fraction of patient injuries associated with the healthcare system. Instead of focusing on “bad actors,” we must address the much more pervasive problem of error by those who are well-intentioned, but are working in complex systems with weaknesses that may contribute to its occurrence.13

Human error in social systems is ubiquitous and inevitable.14 It bears emphasizing that “no matter how professional they might be, no matter their care and concern, humans can never outperform the system which bounds and constrains them.”15

Errors arise from two major sources: 1) unintentional actions in the performance of routine tasks and 2) mistakes in judgment or inadequate plans of action. These sources correspond to active failures – errors and violations of rules – and managerial or latent failures – weaknesses in the organizational/systemic processes in which the human operates. Latent failures, particularly within the design and structure of complex systems, are the most dangerous because they often go unrecognized. In this way, they often remain in the system, increasing the potential for future adverse events because they predispose the system to failure. Hence, these system failures have been appropriately represented as “accidents waiting to happen” with the human operator acting in good faith but “set up to fail” under these conditions.13

Systems in which humans operate usually have several layers of defenses against the adverse consequences of error, each representing both a source and a barrier against errors and their effects. In a “Swiss-cheese” model of error developed by Professor James Reason, each layer of activity within the system has holes and solid areas. The holes represent active and particularly latent failures within the system, and solid areas represent barriers against potential adverse events associated with error. When holes of failure between all layers align, an error penetrates through the entire system resulting in an accident or adverse event.14 This model also indicates that there is the possibility that an error may penetrate all but the last barrier of the system; these situations, which happen much more frequently than total penetration, are considered “near misses.” Near misses are success stories not only because at some point the error’s effect was blocked, but also because they identify potential system failures for corrective action.16 Importantly, in the current litigation climate, near misses are also valuable because they are legally less risky and hence more amenable for reporting and discussion.34

Complex systems such as healthcare delivery have a high potential for error. Generally, these errors occur in environments that require high level technical expertise, quick reaction times, team coordination, long hours, and tradeoffs between service and safety. Furthermore, it is important to note that in this environment only a small fraction of errors leads to adverse consequences and that one individual is not responsible for the outcome of the entire system.10,14,15 This last point is worth emphasizing – using aviation as an example, it is not the pilot alone who is responsible for transporting passengers to their intended destination without injury. The pilot, stewards, ground staff, maintenance crew, air traffic controllers, airport tower personnel as well as many other aviation system members contribute to the outcome, whether positive or negative. Thus, it is not the last person who touches the controls or the patient who is solely
responsible for the final outcome; instead it is the system as a whole that is the necessary and appropriate focus.\textsuperscript{12,13,17,18}

Successful error reduction has taken advantage of the systems nature of error. Interventions target preexisting weaknesses and seek to prevent new errors from occurring. For example, in both the aviation and nuclear power industries, after instituting systems analysis and corrective action efforts, not only did errors and accidents dramatically decrease, but safety and productivity increased as well.\textsuperscript{10} This successful systems approach can be seen as a continuous cyclical process involving several important stages working to identify and prevent errors and to block any potential negative effects. Error reduction stages include process detection, process change/design and process reassessment. These stages loop continuously for each detected error and intervention.

The current, traditional approach in contrast to a systems-based one uses an individually-oriented, “shame and blame” conception. This mechanism has proven to be highly ineffective and even antithetical to error reduction.\textsuperscript{13,14,18} Since the last person who touches the controls or patient is not responsible for the entire system’s outcome, the shame and blame of the individual run contrary to improving safety and serve only to drive error information underground. This results in suboptimal individual and system performance fueled by fear of punishment.\textsuperscript{12,13} Thus, cooperative, non-threatening and blame-free approaches that hold the entire system responsible are more effective methods for reducing medical error.\textsuperscript{19}

The Legal Paradigm: Shame and Blame I

The legal system attempts to provide incentives for safe healthcare delivery by utilizing tort law – specifically, medical malpractice under the negligence rule. This legal approach is the longest standing social incentive structure that attempts to promote safety in healthcare delivery and represents an ethic of individual behavioral control.\textsuperscript{20} Consequently, it focuses on attaching liability and blame to single individuals or entities rather than assessing the system itself.

Such an effort, at least in theory, could have been seen as appropriate for past generations of medical care, when physicians had unfettered access to diagnostic efforts and treatment and the blank check approach for care reimbursement was standard.\textsuperscript{21,22} During these times, the physician guided all decisions on treatment without modern complexities such as managed care and cost containment. Thus, the physician controlled all aspects of how, when and what care was administered to the patient.\textsuperscript{22}

Modern medical care is vastly different from the picture painted above. Physicians no longer have unfettered access to diagnostic and treatment modalities, and cost concerns are ubiquitous. More importantly, modern healthcare delivery is carried out by a complex web of participants including physicians, nurses, technicians, administrators, counselors, managed care organizations and patients. All of these participants contribute to the way in which care is delivered. In particular, the patient is no longer a mere passive recipient of health care; instead, he or she is now a partner in this endeavor.\textsuperscript{23}
Of course, with the highly complex nature of healthcare delivery today, it is appropriate to invoke a systems focus in order to mitigate human error and its associated potential injuries. Nevertheless, the legal system’s approach to promoting safety has not changed alongside the evolution of the medical care system.

Malpractice litigation is a strong example of the shame and blame approach. Heavily focused on the individual, this approach assigns blame to the “last person to touch the patient.” Not only does this process inhibit discussions about error, it fails to unearth important systems information and lessons that could be gleaned from an analysis of the systems issues surrounding it. Instead, it creates an environment of distrust – distrust amongst the patient, the provider and the legal system. This situation is deadly for the patient because communication among the patient and providers breaks down due to fears of litigation. Information is often withheld from the patient because providers fear that if released, it could be used against them in litigation. Additionally, litigation is harmful to systems analysis and improvement because it does not always result in an accurate determination of facts – zealous advocates often twist and tweak facts in support of their particular client. Finally, the delays associated with litigation, which can last up to a decade before cases are resolved, may make the “facts” obsolete. For these reasons, the current legal system represents a significant impediment to ensuring and promoting patient safety.

The legal system also fails in its compensatory function. Although a great many patients are injured in the health delivery system due to medical error, the legal system provides compensation for only a small number of them. Indeed, even under the individually-oriented shame and blame approach, those who do receive compensation are not the “negligently” injured. Finally, the injured have needs other than a simple monetary award (of which approximately 50% is deducted when or if any award is forthcoming). These include an explanation or apology, the chance to vent and the opportunity to tell their story or have their suffering acknowledged. Litigation does not address these important needs.

The Medical Paradigm: Shame and Blame II

The traditional medical ethic for physicians in healthcare delivery has been aptly described as the “gentlemanly honor” paradigm, where physician professionals take individual responsibility for any and all diagnostic and treatment results. This paradigm is familiar to virtually all who have attended medical school over the past thirty years: simply put, it dictates that if treatment affects the patient poorly, you as the individual provider are at fault, should be blamed and should be reprimanded. This culture places tremendous pressure on providers not to make any errors, or, more realistically, not to admit to any errors made.

Although medicine has changed with new systems of delivery, increasing complexity of care and a heightened patient focus, the medical ethic regarding the individual provider has not. Indeed, like the
law, medicine continues to adhere to traditional, individually-oriented shame and blame using the “gentlemanly honor” paradigm. As this paper has noted, this creates barriers to systems assessment and error analysis that could improve healthcare delivery and patient safety.\(^{31,32}\) Predictably, such an ethic creates an incentive to hide error so as to avoid the unpleasantness of public humiliation – easily done due to the complexity of the medical care system – and to maintain the fallacy of perfection as medical professionalism.\(^{13}\) Under this paradigm, system failures represented by error go unaddressed, and approaches that could have mitigated the occurrence and effects of error are ignored, predisposing the system to future failure – an “accident waiting to happen.” This situation fates future providers and patients to the same faults, errors and outcomes that could have been avoided had they been openly reported, discussed and assessed when they were first identified.\(^{14,25}\)

**A New Paradigm**

To reflect the significant changes in the complexity of healthcare delivery over the past several decades, a new paradigm must be adopted. Because systems are the appropriate focus for improvement of outcomes and reduction of error, they must be the focus of this paradigm to promote patient safety.

Both law and medicine must move to an ideal of system accountability. Each must create incentives to facilitate communication about error and system weaknesses, rather than dampen these discussions using an unrealistic expectation of error-free human action.

Public policy should establish incentives to collect, analyze and share error information among providers for greater system learning, without allowing its use for completely unintended purposes such as the support of lawsuits. This policy should reflect well-established bases of system improvements that have been recognized by some courts under state peer review/quality assurance privilege.\(^{33}\) However, such a policy must be established in national legislation in order to ameliorate the varying state laws and their uneven application to safety information.\(^{34-35}\) For example, Senate Bill 720 and House Resolution 663 of the 108th Congress protect safety communications, taking into account systems analyses and lesson sharing across providers, and their passage would be a positive step in this direction. It should also be emphasized, though, that providers must engage in such activities in order to avail themselves of these legal protections – simply collecting data and storing it in an administrator’s office does not promote safety for patients. Those who do not substantively participate should be subject to significant penalties and tort suits since they have not met their legal obligation to use this information to promote system safety.

Furthermore, a system that addresses the needs of injured patients (and their families) must be created. A system of medical error disclosure and administrative regimes such as “no fault” or strict liability for injury associated with the delivery system would provide compensation quickly, rather than requiring the patient to wait four to ten years before compensation (if any) is provided.\(^{25-26,36}\) Also, early intervention mediation would allow the patient and his/her family to have their
other important needs addressed, such as a forum to receive an apology and an explanation of the event, an opportunity to discuss the error and, importantly, the ability to participate in system assessment and improvement.\textsuperscript{26} Such a mediation system has been shown to be highly satisfactory to both patients and providers, and it consequently has great promise in promoting a partnership of provider and patient in improving system safety.\textsuperscript{37}

Medical ethics must also change. The "gentlemanly honor" system based on a single physician and a passive patient should give way to system accountability that acknowledges the more complex relationship between providers and the patient. To this end, providers and patients (as well as their families) should be equal members of the health delivery team, partnering to improve patient health and system function. The ethical rights and obligations that run between provider and patient should reflect a mutual respect, trust and responsibility that each has to the other in this joint endeavor.\textsuperscript{26}

Under this system, all members of the health delivery team should be able to identify and discuss system weaknesses openly without sanction. Also, all should be able to participate in corrective actions to address these issues. Providers should have the right to engage in error and system assessment in order to improve those medical processes of which they are a part. Patients (and their families) should have the right to vent, communicate their perspectives regarding error and system weaknesses, be kept informed of error occurrence, participate in corrective action and obtain compensation quickly for medical process accidents that affect them and their activities.\textsuperscript{26}

With these rights come responsibilities. All members of the team have a fundamental responsibility to assist in improving the healthcare system. Providers are obligated to have appropriate medical knowledge and experience, be a part of the systems process of care delivery and improve healthcare outcomes that result in an acceptable and optimal level of health. Patients (and their families) have the responsibility for maintaining and communicating accurate personal medical information and for being a part of the systems process of care delivery that results in an acceptable, optimal level of health.\textsuperscript{26}

This paradigm does not occur in a vacuum. Highly debilitated patients as well as others with significant disease should not be expected to play a leading role in system assessments due to their level of infirmity. Family members, however, can be highly valuable in providing insight and information regarding weaknesses in the healthcare system. Indeed, since patients and their families see the entire spectrum of health care while providers are limited to their more narrowly defined roles, the former may be the most valuable team members in identifying system issues that require attention in the ongoing effort to improve safety.

It should be emphasized that this policy paradigm does not mean that individual providers forego any individual responsibilities for patient care. The system under this paradigm is the focus of error reduction and quality improvement. Hence, all members of the healthcare enterprise, including providers, must be attentive to all actual and potential sources of error and system weakness. This approach necessarily results in the broadening of traditional activities and observations, and indeed
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leads to the overlapping of traditional provider “turf” in assessing where the delivery system can be improved. Also, providers must be educated in methods to identify and compensate for errors and system weaknesses. Thus, there is an expansion of ethical obligations for the individual, rather than a retraction, and such expansion is focused upon identifying methods to improve care outcomes and processes.

Finally, it should be noted that at times, system improvements might require corrective actions focusing on individuals. The difference under this policy paradigm, however, is that this corrective action has improvement of the system and its outcomes as its goal, not the delivery of individual punishment as a fear-based incentive.

Conclusion

Focusing on the systems nature of medical error, the need to encourage open communications regarding the weaknesses in the delivery system, the importance of a partnership model and the underlying goal of corrective action to improve system function, results in a policy that reflects the tremendous changes and important insights in healthcare delivery. By shifting away from an inappropriate and ineffective individual-based approach to a policy of system accountability in both medicine and law, the result may be a delivery system that continuously improves while also empowering the patient and ensuring that adverse events associated with system weakness will be less likely to recur. A shift to a systems-based public policy paradigm is not merely an academic solution, but rather a pressing reality that has the direct potential to save lives. As such, it demands attention so that we may leave a living legacy for our children: a safe, consistently improving system based on cooperation and empowerment of all partners in the healthcare enterprise.

Acknowledgements

The assistance of Shannon M. Biggs, JD, MA, MEd, is gratefully acknowledged. This work was supported in part by grant number 1 U18 HS11905-01 from the Agency for Healthcare Research and Quality, and is also gratefully acknowledged.

References


