SPECIAL PAPER

A system of medical error disclosure

B A Liang

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External mandates for medical error disclosure are often justified by potential cost savings, the belief in individual moral obligations in health care, and the concept that patients have rights and providers have responsibilities. Such an approach does not recognise the systems nature of error and outcomes and the important quality role disclosure can play in a system of medical error disclosure. Systems concepts, the patient-provider partnership, and overall quality of care can be enhanced using a system of disclosure that provides for education about the systems nature of error, fulfils the delivery system philosophy of mutual respect, and integrates the patient and his/her family as a partner in the error reduction enterprise. Such a system can result using clear disclosure policies and procedures sensitive to patient and family needs, open communications with concerned, committed, and compassionate system representatives, and use of mediation methods that foster communication, allow for venting, and are flexible in their approach to resolving conflict, including using apology. Although a system may also result in conflict resolution costs, more importantly it may foster and solidify a team approach to reducing errors and promoting patient safety.

Medical errors—defined here as the failure of a planned action to be completed as intended or the use of the wrong plan to achieve an aim[1] but not including intentional or reckless actions that harm the patient[2]—have been established as the main cause of patient injury around the world. This finding has provided a significant basis for optimism in improving the quality of health care, for a centre of focus has been identified and successful experiences from other industries may be applied which have reduced the incidence of error and its associated negative consequences.[2] These negative consequences, or "adverse events", are defined for health care as an injury caused by the medical management rather than the underlying condition of the patient.[1]

However, the difficulty associated with this recognition remains the "shame and blame" concept of error that continues to persist within medicine, law, and the polity.[3–5] Exacerbating this difficulty are mandates and calls for full and unqualified disclosure of errors by accreditors[6] and others[7–11] without attention to the underlying misunderstanding of the genesis of error by the medical and legal professions, the public, and policy makers.

Instead of a simple requirement of disclosure of medical errors laid over the traditional healthcare delivery system, a *system* of disclosure would provide much greater benefit to those involved and would also have the potential to improve quality through education and integration of all relevant parties in health care. This paper outlines such an approach.

BEGINNING AT THE BEGINNING

The medical profession has traditionally relied upon that method found most unhelpful in reducing errors and improving quality—namely, shame and blame of individuals with accusations of incompetence, unprofessionalism, and unworthiness to treat patients. In what Sharpe calls the "gentlemanly honour"[12] model of medicine, individual error is deemed a moral failure on the part of the practitioner. Unfortunately, in this model of health care, quality is focused upon single individuals performing individually and does not recognise the systems nature of error and system outcomes. Such a traditional blame model has led to decades of ignoring the systems nature of health care and an epidemic of deaths due to medical error.[13]

The first step in a system of disclosure is therefore to educate physicians and other providers regarding the appropriate focus of quality improvement—systems. Physicians cannot claim full credit for a positive patient outcome; rather, it is a team effort involving a minimum of physicians, nurses, administrators, and the patient. Although a physician may be instrumental in providing care to a patient, the patient must be involved in recognising the need for care, obtaining it, and following instructions to obtain an acceptable clinical result. Other staff are needed to support that physician and patient as well as providing other organisational tools to ensure that the correct patient is seen by the appropriate provider in the most appropriate forum.[14] Indeed, it would be the height of arrogance for a provider to presume that a particular positive clinical outcome was the result of his or her actions alone.

Similarly, when a negative patient outcome occurs, physicians or other providers cannot and should not assume full responsibility for the entire team. In aviation it is not merely the pilot who is responsible for the outcome of a flight; it is the pilot, the air traffic controllers, the maintenance crew, the stewards, and the ground staff—in other words, the aviation system.[3] Thus, neither the last person to touch the controls nor the last person to touch the patient is fully and solely responsible for the outcome, good or bad.

Correspondence to:
Professor B A Liang, Arthur W Grayson Distinguished Professor of Law and Medicine, Southern Illinois University School of Law and School of Medicine, 1150 Douglas Drive, Carbondale, IL 62901-6804, USA;
baliang@alum.mit.edu

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This fundamental understanding must be transferred to medical providers so that they are open to systems based error reduction methods and system focused disclosure efforts.

The systems basis does not mean, however, that providers abdicate their responsibilities for taking individual care. Indeed, because the system is now the focus of quality, all members of the healthcare team assume an even greater role: they must be vigilant of all aspects of care and note all actual or potential sources of error, going beyond their traditional activities and observations. A systems approach does not discern who acts to identify systems problems or the training he/she has, but simply that the problem is identified and that it provides an opportunity for corrective action. Like aviation, the corrective action may include activities focused upon individuals, but the difference is that such actions look to improving the system and its outcomes, occurs in an environment of cooperation and continuous improvement, and keeps a fixed eye towards system performance, not punishment of the individual even while that individual is maintaining his or her vigilance and personal accountability. It must be emphasised that both systems and individuals must be integrated in order to promote safer health care; any effort to promote safety without involving both individuals and systems will not succeed.

HEALTH DELIVERY SYSTEM PHILOSOPHY

Most hospitals and managed care organisations have an underlying philosophy and ethic regarding patient care: terms such as mutual respect, trust, responsibility, and partnership are used to describe the healthcare relationship. Consistent with these concepts and in concert with the systems nature of error and outcomes, when error occurs because of failures within the system, the system is accountable to those who are affected by the failure. If we are to take seriously our patient care obligations, we should disclose system errors to those who have been adversely affected as a matter of mutual respect, trust, responsibility, and partnership.

However, it should be emphasised that disclosure and accountability rest with both the system and the individual. Simply requiring the last person who touched the patient to take on a "shame and blame persona" of humiliation and forcing them to disclose is a retrograde shift back to the traditional harmful medical culture that represents an antithetical approach to reducing errors. Instead, an approach that combines the system, individual performance, and patient care philosophy represents a method by which quality may be enhanced. Both systems and individuals have important roles to play in the disclosure of errors to patients, and both must fulfil these roles to obtain the greatest amount of information for the system and to the patient.

METHOD

Integrating the patient

Much of the literature on error disclosure focuses only upon the rights of the patient.[7 8] Patients do indeed have rights, but with rights come responsibilities. A philosophy of partnership between providers and patients mandates that both engage in ensuring that the appropriate care is provided at the right place, at the right time, to the right person, in the safest and most efficacious manner possible.

Beyond educating physicians about the systems nature of error and outcomes, patients also must be informed about and understand what they can do to maintain a safe delivery environment. Indeed, there are many more patients than providers or administrators, so patients represent a potentially rich source of information due to their numbers and experience with the full spectrum of healthcare providers.[3] This requires a fundamental understanding between the provider and patient, perhaps best described as a "health care partnership agreement". Such an agreement should be provided at the outset of care, be discussed by the patient with his or her primary care provider, and signed by both. Such an action would signify the importance of the agreement and provide opportunities for patients to be educated in the processes of care. This agreement could state that:

"Medical care is complex and sometimes complicated. We believe that patients are an equal partner in the delivery of care and essential in improving the system. We will do everything we can to provide safe and effective care to you. As our partner, please ask any questions you have about your care, and in particular please let us know if you observe any mistakes in your care so we may use this important information as an opportunity to improve how we treat you and all patients. We want to work with you to make the best health delivery system for everyone! Thank you for your help and participation."

This agreement thus provides the patient with the impetus to be an active partner in safety and empowers him or her to have a direct and important role in the outcome of care. This approach also fosters mutual trust, respect for the patient, an ideal of responsibility shared, and an improved therapeutic relationship based on open communication between providers and patients.

Policies and procedures

Disclosure of errors at the present time is generally haphazard; ad hoc methods, varying published approaches and, in particular, vague standards by accreditors all represent a poor means from which to learn from errors in an uncertain legal environment. Instead, a clear approach that provides information to the patient but avoids the ever present risk of shame and blame is essential. This discussion will focus on disclosure of errors and adverse events that take place in hospitals, although the principles can be applied to other provider locations, errors that were unpreventable (such as drug allergies that arise on first administration), and near miss errors in an effort to obtain potentially useful system information from patients. Note that although errors are often difficult to define, errors here that are the focus of disclosure are those which a risk management committee, peer review/quality assurance committee, and/or incident report identify as an error that either did or had a great risk of resulting in the loss of a patient's function, earning capacity, or life that mirrors that used by the Lexington VA system.[15] Near miss errors are included to provide opportunities for systems learning that may be important for potentially serious adverse events[5 13 16–18] which may be discussed with patients as part of the normal quality improvement process indicated above.

These efforts must begin with a set of policies and procedures surrounding error that reflects the systems nature of it. Firstly, the policies and procedures of the entity must provide for an "error investigation team", perhaps as part of the standard peer review/quality assurance body within the facility. This team should have the relevant expertise to investigate errors that result in adverse events and those that do not; the composition must therefore be adjusted for the error in question. The investigation team should include some "on call" members who can be called on to begin assessment as soon as an error is identified, particularly an error that causes an adverse event.

Secondly, these policies and procedures should provide for a "system disclosure team" comprising a high level representative of the administration, a patient care liaison, and a clinically trained individual in the relevant specialty relating to the potential error/adverse event, assuming disclosure will be to a patient or his/her family. The latter often ask clinically focused questions regarding the error so it is important to have a system representative present to answer such questions. The provider who last touched the patient should not be part of this disclosure, at least initially, since he/she is too close to the circumstance, may be experiencing tremendous emotional turmoil as a result of the error,[19–23] and will

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probably be ineffective in addressing it—at least in terms of the literature on communications effectiveness, medical education assessments on communication training, and the literature on breaking bad news to patients—if he/she has not been trained appropriately.[24–29] Other disclosure systems such as the VA system in Lexington, Kentucky also do not initially include the providers involved in the incident.[15] Furthermore, the presence of the provider may incite high levels of conflict and devolve the disclosure effort into a finger pointing and blame reaction. The provider should be part of the investigation of the event, however, including important face to face encounters with patients during mediation, and hopefully this activity will allow him/her to sublimate the difficult emotional issues experienced into positive corrective action efforts.

The potential conflict resulting from the presence of the provider leads to two relevant points. Firstly, some individuals affected by the error will be angry, will be strident and emotionally torn, and will generally be looking for culprits. It is essential that individuals who are part of the disclosure team understand that there will be significant emotional and at times hostile reactions by patients and their families to the error disclosure. Not all patients and/or their families will react in this manner, but the disclosure team must be prepared for this potential eventuality. Secondly, the individuals who represent the system in the error disclosure must be trained in communication and empathy; they must be concerned, committed, and compassionate; and, above all, they must not be defensive. It must be recognised that it is often not *what* is said but how one says it that predicts the listener's reaction. The relevant language, cultural values, and specific factors (such as communication aids for those with physical handicaps) should therefore be used to facilitate complete comprehension and discussion between the team and the patient/family. It is also essential that this team communication to the patient/family reflects a true sense of immediate and unceasing investigation of the event by all relevant parties until the situation is fully understood. Finally, the physician closest to the error may wish to participate in error disclosure; this should be encouraged, but, as noted, only if the provider is appropriately trained in the optimal sensitive methods of disclosing the error to the patient based on the appropriate literature.[24–29]

The policies and procedures should expressly indicate that the patient care liaison will communicate regularly (at least once every five days, for example) with the patient/family regarding the progress of the error investigation. The patient care liaison should be the point of contact for the patient/family for all information regarding the error and its investigation. This establishes a consistent and stable relationship between the patient/family and the provider entity and avoids anger at not being able to reach any representative of the entity to discuss the error or to obtain reports on its investigation. The patient care liaison should also be responsible for assisting the patient/family in obtaining any remedial care for the patient, regardless of whether the negative outcome was a result of the error or not, consistent with the philosophy of the organisation. This also includes any external needs such as temporary housing, contacts with relatives, and transportation.

There are well circumscribed circumstances that should be noted in the policies and procedures where disclosure is not appropriate—for example, when there is a suspicion or even actual knowledge of abuse or neglect by a member of the patient's family which may be exacerbated by the disclosure, police investigations, and psychological concerns for the patient. However, the first two are generally rare, and the latter should not be used as a "catch all" excuse to avoid disclosure.

A "disclosure record" of all actions should be described within the policies and procedures. The "when, where, who, what" of the disclosure meeting should be documented and a general description of the objective information discussed should be noted. All subsequent contacts between the disclosure team and the patient/family should be maintained in the same record. This record should include only objective descriptive information; no conclusions, accusations, and/or assessments of fault should be made.

How to disclose

Once providers are educated, the philosophy of the entity or institution results in acceptance of disclosure, and infrastructural policy and procedure components are put into place, disclosure as part of quality promotion can occur. Unfortunately, at this point legal risks come into play as well as the tendency to make conclusions and issue blame. These should be avoided because they are not consistent with the systems nature of error and may result in adverse legal consequences, including admission of liability.

The theme of disclosure and all resultant discussions with the patient and/or the family should be objectivity. A descriptive method is important substantively because a full systems assessment has generally not been completed by the healthcare entity. Any conclusions regarding the error are therefore premature at best and misleading at worst, and, again, they may have negative legal consequences as an admission of fault.

When an adverse event occurs, the error investigation policy should be put into action immediately and the on call investigator and investigation team (including all relevant providers) should begin assessment. The error disclosure team should meet with the patient or family when the adverse event is detected or as soon as practically possible. The team should indicate to the patient/family that there may have been a systems problem which may have adversely affected the patient/family member. The family should be told that the on call investigator, providers, and team are undertaking the investigation and will continue until the causes are determined. The team should then describe to the patient/family the steps that are being taken: whether the adverse event is a result of a medical error or complication associated with the patient's clinical condition and the specific investigation methods that will be or are being used to investigate the event (generally a description of systems assessments and root cause analyses as relevant to the clinical and administrative circumstance). The patient care liaison should indicate to the patient/family that he/she will be communicating with the family on a regular basis (as defined in the policies and procedures) regarding the error investigation, and that the patient/family should feel free to contact the patient care liaison at any time. The patient care liaison should also assist the patient/family in any additional care access that might be needed, even if the negative patient outcome is a result of underlying disease rather than medical error.

The patient/family should be asked to assist in the error investigation by the error disclosure team during the initial contact, if appropriate, or by the patient care liaison at a later time. This could range from discussion of any factor, problem, and/or witnessed error that may or may not have contributed to the negative outcome to a full debriefing on all stages of care from before entry into the facility to the event itself (and after, if appropriate). Such involvement of the patient is consistent with the systems nature of error and outcomes, the philosophy of partnership between provider and patient, and gives the patient/family a vested interest in corrective action at the facility.

Certain actions which may be seen as insensitive or inappropriate should not be performed—for example, sending the patient or the family a bill for services at least before a resolution of the investigation (or even after, if appropriate), putting the patient/family on hold during telephone conversations, and delays in communicating with the patient/family after they have requested it.

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Apology

Apology is an important signal of empathy, yet it is fraught with legal risks associated with the potential interpretation by the legal system as an admission of liability.[30] Apology, in the context of the systems nature of error and outcomes, should be provided as an expression of empathy from the representatives of the system, and worded as such. For example, rather than "I'm sorry that I made a mistake that injured you", which is inconsistent with the systems basis of outcomes and therefore should be avoided, a sincere expression of empathy such as "We are so sorry that this event has occurred to you" is a more appropriate expression of empathy and reflects system accountability. However, practically speaking, this statement should only be made after a thorough review of the relevant law in the provider's locality. In the US there are some jurisdictions where such an expression of empathy or offer of assistance after an injury will not generally be taken as an admission of liability.[31–36] These laws and, in their absence, general laws on the legal treatment of apology and their relation to party admissions should be scrutinised closely to determine the practical ability, extent, and form that apology should take. It should be noted that these legal considerations do not indicate that patients do not deserve an apology; indeed, if injury occurs, disclosure and apology should occur. However, if the apology is treated substantively differently by the legal system in court—such as an admission of guilt—practically speaking, the provider and the legal counsel must take this into account when assessing the optimal manner of disclosure and communicating empathy.

LAWSUITS AND THEIR ALTERNATIVES

The law presents tremendous legal barriers to provider efforts to discuss medical errors—for example, contractor law generally limits liability to individual providers; provider service contracts are easily terminated; gag clauses even in the context of prohibitions still have effect; broad discovery of medical information occurs to support lawsuits, limited peer review/quality assurance and attorney-client privilege exists for error information; and other means of using error information for unintended use to support lawsuits all deter disclosure and discussion of errors.[2 3 13 37–39] In the absence of legal reforms, it is likely that disclosure will result in lawsuits. Even with intellectual acceptance of the systems nature of error and outcomes by the patient/family, there will be a tendency to blame, at least in the short term. There is anecdotal evidence to suggest that full disclosure and honest admission may result in smaller damages settlements and suits[15 40]; however, significant limitations of the type of provider, patient, and law make these findings difficult to apply to the broader healthcare community. Yet, it has also been suggested that patients and their families are much less likely to engage in lawsuits if they have a positive open and honest relationship with their healthcare providers.[41] A disclosure system as advocated here may represent such a relationship and thus promote an avoidance of the harmful effects of litigation.

As part of an effort to mitigate the emotionally damaging effects of litigation for all parties, the tendency of litigation to stifle communication between provider and patient, and the extensive pecuniary and non-pecuniary costs associated with lawsuits,[42–44] a system of alternative dispute resolution can be offered to the patient. This simply represents another aspect of patient advocacy, for those who are injured are those least able to confront the array of legal manoeuvres, time commitments, and uncomfortable personal scrutiny required to sustain a highly complex lawsuit. Mediation is a method that addresses patient concerns, including facilitation of communication (a critical issue for patients that is the basis of many conflicts and decisions for suits[45–47]), resolution of uncertainty,[48] allowance for venting and to be heard,[49] acknowledgment of suffering,[50] and creation of a dynamic that fosters a future relationship, healing, and flexibility in settlement.[51] It enables a wide variety of settlement solutions to be offered to the patient/family for consideration beyond simple monetary transfer, including a prominent and/or additional roles for the patient/family in corrective action efforts, naming a corrective action policy after the patient/family that was subject to the error, public thanks to the patient for assisting in improving the health delivery system if they participated in corrective action efforts, and/or apology and corrective action training.[52] Mediation is, of course, generally for crafting a desirable resolution to errors associated with patient injuries; the disclosure of near misses should be discussed during the normal disclosure process with patients.

The use of mediation is an important step for the patient as litigation may not be resolved for many years and the administrative costs will be deducted from any award.[44] Furthermore, litigation is a poor avenue for improvement for the system and for future patients because the very conditions that resulted in the error and injury remain undiscussed, latent, and unaddressed, setting up another provider and patient in the same system to experience the error and injury that could have been addressed through an appropriate systems analysis of relevant information that could have emerged through mediation.[13 52] Finally, in contrast to litigation, both providers and patients express high levels of satisfaction with mediation,[53] so the use of this dispute resolution tool benefits both.

Key messages

- Mandates for disclosure of medical errors have generally been ad hoc and based on notions of individual provider responsibility and potential cost savings which do not take into account the potential for quality promotion through appropriate disclosure.
- Quality promotion requires a system of disclosure that provides information to providers and patients on the systems nature of outcomes in health care.
- To empower patients, disclosure policies should be true to the philosophy of partnership with the patient, and should integrate patients from the outset to observe and report errors and to ask questions regarding their care.
- Because communication of difficult issues requires significant skill, trained error disclosure teams should be used. The last person to treat the patient should not participate in such a disclosure, at least initially.
- A patient care liaison should be available who is part of the error disclosure team.
- The theme for all disclosure communications is objectivity; a description of activities and events rather than conclusions and/or blame issuance is essential to reflect the systems nature of error and outcomes.
- Patients/families subject to an adverse event should be offered the opportunity to be part of the corrective action process.
- Patients/families should be offered mediation to avoid the high costs of litigation.

CONCLUSIONS

Disclosure should not simply be focused on a perspective that patients should only receive disclosures and providers should only give them in an effort to promote patient safety.[6–11] Furthermore, disclosure should not be justified simply by the potential for cost savings.[15 54] Such perspectives simply overlay what could be an important quality tool onto the traditional medical care and legal systems, which are predominantly still based on individually oriented shame and blame and punishment. By taking into account the systems nature of error and outcomes, a philosophy of mutual respect, trust, and partnership between provider and patient, and an open communications method of resolving issues between provider and patient

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subject to a medical error, a system of disclosure that brings important systems understandings and quality benefits to all relevant parties can be engaged. This is true even in the context of a legal system still focused on shame and blame and accreditation requirements that put providers at legal risk of safety information use to support lawsuits.[38 39] However, this approach can only work if the beliefs and philosophies so often stated regarding systems and mutual regard are truly accepted by all members of the healthcare enterprise. Otherwise, we are doomed simply to using the terms of safety to maintain the status quo and, worse, we leave another generation vulnerable to the errors that could have been corrected had we as a society been courageous enough to begin down the clearly identified road to safety.

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