Disclosure of Medical Errors

Use in Public Reporting

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Contents

Introduction:

Betsy Lehman, a health reporter from the *Boston Globe,"* died from an overdose during chemotherapy. Willie King had the wrong leg amputated. Ben Kolb was eight years old when he died during "minor" surgery due to a drug mix-up. (Kohn, 2000)

These are true stories and just a few of many that lead to the report entitled *To Err Is Human.* This report is based on two studies that looked at medical errors occurring in hospitals in Colorado and Utah. The findings were startling summarizing that over fifty percent of medical errors were preventable and further brought to light the need to evaluate healthcare in the United States. Attention to these study results could not only save lives and improve patient safety and quality of care; it could result in tremendous cost savings. (Kohn, 2000)

While healthcare organizations were being criticized and questioning what would be required to remedy the concerns, the internet was growing, and the public began demanding improved healthcare. This evolved into the requirement for public reporting of defined quality measure sets by hospitals. Unfortunately, to date, medical errors are not one of the publically reported measures and more importantly incorporated into hospital "report cards" that make hospitals winners of distinguished awards in patient quality and safety. In this paper, discloser of medical errors, the idea of publically reporting medical errors along with legal ramifications, hindrances to reporting, and if and how these errors should influence who are high quality healthcare organizations will be discussed.

The Studies: Background Information

To ERR Is Human was based on two studies of inpatient hospital admissions that occurred in 1997 in Colorado, Utah, and New York. Based on the findings, applied to the

estimated 33.6 million hospital admissions that year, it was estimated that between 44,000 and 98,000 Americans die each year from medical errors making it the eighth leading cause of death. The estimated cost resulting from these errors, which is inclusive of lost wages, disability, and health care costs, was estimated between $17 billion and $29 billion. (IOM, 1999)

Medication areas are a specific area of concern with preventable deaths occurring in both inpatients and outpatients. Results of a more recent study of inpatients at two prestigious teaching hospitals provided data used to extrapolate cost for medication errors alone to be approximately two billion dollars annually. (Kohn, 2000)

In addition to physical harm that medical errors can cause, there are monetary losses and other intangible affects that result from medical errors to the patient and/or family, health professionals and the healthcare organization. Depending on the extent of the error, intangible benefits may include psychological harm as well as a lack of trust in the healthcare providers or the healthcare organization. Healthcare providers may also experience a psychological impact when an error is made because as mentioned earlier errors are usually unintentional and opens the door for potential lawsuits and licensing reviews. (Kohn, 2000)

The intended outcome of these studies was to bring attention to the severity of poor and unsafe care being provided and force healthcare systems to set in motion plans for improvement. Recommendations were provided with the intent of financially impacting organizations to ensure action plans are taken seriously. (Kohn, 2000)

In June 1998, The Institute of Medicine (IOM) Quality of Health Care in America Committee, whose focus was to address patient safety, which is defined as a subset of quality

concerns, was established. Their goal was to develop a national framework that would force states to enact legislation focused on improvement of healthcare. Recommendations for improvement included bringing awareness to the public and health care providers followed by realigning reimbursement to providers and aligning the liability system. Some approaches included attention to education and change in culture within healthcare organizations bringing safety to the forefront. (Kohn, 2000)

To Err Is Human, instigated the movement of patient safety in healthcare by drawing public interest through publication of the study results. It was successful gaining the support of the public as well as support from legislative and regulatory groups. An aspect lacking in the report was acknowledging the fact that the American Medical Association (AMA) had recognized its ethical responsibility to disclose "harm-causing errors" twenty years prior to the study. (Banja, www.ncbi.nlm.nih.gov)

> "Section 8.12 of the AMA's Code of Medical Ethics: Current Opinions clearly states, it is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients. Patients have a right to know their past and present medical status and to be free of any mistaken beliefs concerning their conditions. Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred. Only through full disclosure is a patient able to make informed decisions regarding future medical care." (Banja, www.ncbi.nlm.nih.gov)

Defining Medical Error

One issue encountered with disclosure of medical errors is terminology. The term medical error is often interchanged with serious event or adverse event. Each of these terms has been defined separately while at the same time can be interpreted to fit the case at hand. These terms are defined as follows:

Adverse event: “unintentional definable injury.” (Weiss, 2007)

Medical error: “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.” (Weiss, 2007)

Serious event: “an event, occurrence or situation involving the clinical care of a Patient in a medical facility that results in death or compromises patient safety and results in unanticipated injury requiring the delivery of additional healthcare services to the patient.” (Weiss, 2007)

When applying these definitions to a case, although the facts are the same, the definition chosen affects the clinician’s perspective in determining an event requiring disclosure. Take into account the well-publicized case of Dennis Quaid’s twins at 12 days of age given a dose of Heparin (anticoagulant used in the prevention or treatment of blood clots) 1000 times the normal dose. This involved not one patient, but the Quaid’s newborns and only two children. The hospital did not call and notify the parents of the incident but waited until the next day when they arrived to visit and found the twins bruised and bleeding. (Kroft, 2008) Additional blood draws were required to monitor clotting times and the discharge delayed until blood levels had stabilized. Fortunately, no permanent physical injury resulted from the error. Applying the definition of adverse event, since it was an unintentional error and no injury resulted, assumption would likely be that it was not an adverse event and therefore why report. Based on the definition of medical error, one could argue that in fact this was an error because while the medication was given not as intended the outcome was the same. Applying the definition of serious event, one may argue that this does not apply because although it did involve medical care in a medical facility, no injury resulted disregarding the need for additional care (blood draws and additional hospital days. (Weiss, 2007) The fact this case involved a

popular actor, lead to discloser beyond the patients' family becoming a public example and learning experience for the hospital.

Identifying Quality Healthcare Organizations

As attention has turned to improving quality and safety in healthcare comes an attempt at recognizing "high performing" health care organizations that are providing exceptional care. Data is shared in the form of report cards and awards and recognition. Recognition can be self-defined by comparing hospitals of your choice by selecting hospitals on the Hospital Compare website or recognition may come in the form awards based on organizations such as Healthgrades Distinguished Hospital Award or Thomson Reuters 100 Top Hospital or Everest award. Additional recognitions frequently seen in organizations includes American Heart Association/American Stroke Association's Get with the Guideline Stroke Gold Performance Achievement Award, Blue Distinction offered by Blue Cross Blue Shield for high quality cardiac care as well the Center for Excellence Recognitions for Joint Replacement, Stroke Care and Breast Care. Despite all the awards and recognitions, none of them account for medical errors. Below is a table summarizing some of the recognitions and the data they consider in determining "high performers":

Report/Study	Initial Start Date	Sponsoring Organization	Contents
Top 50 Hospitals	1998	U.S. News and World Report	● Top 50 Hospitals in 17 specialties ● Score based on reputation from surveys of physicians **Outcome:** Bigger Hospitals = Higher ratings
Leapfrog Group		Large Employer Groups	● 30 Safety Practices reported by Hospitals (patient volumes, CPOE, etc) ●Participation Voluntary

Consumer Checkbook	Center for the Study of Services	● "desirability" ratings based on surveys of physicians ●risk-adjusted mortality figures ●adverse outcome rates on select surgical procedures ●Mortality and outcome data outdated (1996–99 Medicare data)
Distinguished Hospital Clinical Excellence	Health Grades	●Five-star grading system ●Rated highly on mortality data from Medicare. ●No overall scoring ●Mortality adjusted using formula that is not shared for validation
Select Quality Care	HealthShare Technology	●Site not accessible to the public ●Ranking of Hospital based personal importance of patient volume, mortality rates, and other factors. ●Revising preferences alters outcomes
100 Top Hospitals	Thompson Reuters	●Aggregated results based on public data ●Outcomes includes Core measure, Select patient safety measure, mortality rates, readmission rates, financial performance, length of stay, Select HCAHPS question
Hospital Compare Website	U.S. Department of Health and Human Services	●Outcomes includes Core measure, Select patient safety measure, mortality rates, readmission rates, medicare payment and volumes

As healthcare consumers become more technology savvy and opt to select their health providers based on information that is publically reported, they need to be educated in regards to what the data represents. The data that is available for reporting is "old" data. It lags behind, therefore does not illustrate current results, and because it lags it frequently does not

reflect best practice enacted to address concerns recognized as a result of studies and reporting. In addition, measures such as mortality rates require adjustment for the severity of the patients, which is completed inconsistently. Recognition that assigns overall scores is frequently subject to personal bias as to level of importance. (Harvard Medical Review, 2006)

The concept of hospital report cards introduced resulting from the IOM study in 1999 fall short for the reasons previously stated. Current reports and awards fail to incorporate medical error disclosures as a measure of hospital quality and safety. (Harvard Medical Review, 2006)

In 2010, ten years after the initial IOM report, the IOM reports there continues to be ten or possibly hundreds of thousands of errors occurring on a daily basis. This does not account for the "nearmisses" not reported. On a positive note, because of the IOM report, development of patient safety reporting systems began to flourish, however, not without flaw. The error reporting systems are incomplete, nonstandardized, pricey, and they do not address the issue of enforcing consistent reporting. (IOM, 2010) The problem, systems do not solve the errors occurring in healthcare. Implementation of information systems provides the means for capturing error information for the sole purpose of learning and using the learnings to improve processes in the healthcare system for improvement in quality and safety.

Ethical Responsibility to Disclose

As discussed earlier, providers have an ethical responsibility to their patients that should not be influenced by liability that may result. Included in the code of ethics is the responsibility to inform patients of findings resulting from retrospective review of tests, procedures and any additional information. Regardless of the impact, the findings may have on a patient's medical

treatment or diagnosis, the ethical responsibility holds precedent much imparts due to a patient's right to know. (Banja, www.ncbi.nlm.nih.gov)

In 2002, a study was conducted to determine disclosure practices when presented an actual case scenario. The study included over 200 hospitals. The study concluded there was a decreased likelihood of reporting preventable errors as opposed to non-preventable errors. These results were further compounded by the hospitals concern for malpractice resulting from disclosure. Surprisingly, the report indicates more than half of those responding to the study would disclose a death or serious injury, a statistic most people would like to believe would be much higher. (Banja, www.ncbi.nlm.nih.gov)

Cultural Challenges to Medical Errors and Disclosure

When thinking about medical errors and the potential to be the victim of one, most people want to know why and how such errors occur. One factor that plays into the equation is best stated by the title of the study leading up to the movement to disclose medical errors, *To Err is Human.* Keeping in mind the human factor, healthcare will continue to experience a degree of error but medical errors must be used to learn and put in place best practices to reduce the current error rate and minimize future errors.

The human factor is not unique to healthcare but the perceived fragmentation of the health system is a real factor believed to be a major contributing factor to the error rates. Patients often seek specialized healthcare providers to address different aspects of their medical needs. (IOM, 2000) For example, a woman in childbearing years would likely prefer to see an obstetrician as opposed to a physician specializing in family practice or internal medicine. If a complication ensues during a pregnancy that is resolved upon delivery of the

baby, the patient may forget or opt not to share this information with her regular physician. Without integrated and interoperable means of communications such as in the case of health information exchanges or regional health information organizations, care is fragmented which could result in error. Further complicating matters is if the patient opts to see providers that are members of nonaffiliated organizations leading to the potential for fragmented care.

Regardless of the outcome of the error or the disclosure, a culture has been created that has an impact on reporting. The culture is the act of blaming leaving healthcare providers fearful of reporting. In organizations with implemented electronic reporting systems, support of anonymous reporting occurs in less than one third of hospitals and does not support privacy for those that do report. A survey of 1,652 risk managers throughout the country reported that over 80% of them have not or do not receive reported errors from the physicians. Additional findings in the study included: (O'Reilly, 2009)

- One in five hospitals issued adverse-event reports
- One in five hospitals shared the reports with key personnel/departments
- One in three hospitals report they do not disseminate analyses of the adverse events and near misses reported. (O'Reilly, 2009)

The Patient Safety and Quality Improvement Act, supported by the American Medical Association, were implemented in 2005 with the hope that confidential error reporting would be supported. Twenty organizations focusing on patient-safety were certified by the U.S. Agency for Healthcare Research and Quality as result of this rule. Regardless if an error results in harm, every error offers a learning experience. It is the act of blaming that prevented the reporting of medical errors making it challenging to develop processes of improvement. With the public focus on healthcare and improving quality and

safety, while still holding individuals accountable, standards for reporting have been developed and supported with the intent of improving process and implementation of best practice for overall safety of patients. (O'Reilly, 2009)

Another common theme among physicians impacting disclosure and reporting of medical errors is the potential for punitive consequences. There is an expressed fear of being blamed themselves for poor performance and outcomes that is reflected to the public, the press and to the patient in the form of trust. Some providers have gone as far as referring to disclosing errors as a "witch hunt". (Waring, 2005) With the promotion of a "just culture", there is still skepticism by providers about how reporting errors will be used against them. With the 'patient safety' movement, providers are beginning to recognize the need for reporting as a means of quality improvement. There is now an understanding of the impact on reporting and indentifying failures in other areas of the organization that support staffing and equipment needs. As more providers recognize the shift in blame, there is decrease apprehension to report. (Waring, 2005)

. Finally, there is the fear of litigation leading to investigation of credentials and competency. These concerns lead to fear of the physicians for their reputation questioning the impact on future career opportunities as well as providing documentation that could be used in future litigation. (Waring, 2005)

Beyond the larger cultural concerns discussed so far, other common themes among physicians include the concept that medicine is not an exact science but rather an art. Errors will always be part of the process since "trial and error" is a characteristic in the practice of medicine. In addition to the complexities medicine brings are the complexities of the

healthcare organization. It is for these reasons that reporting is perceived as “big brother” watching, contributing to a growing fear that providers will be strapped by rules, and not be able to practice medicine as they see fit. (Waring, 2005)

Apologizing for Errors

Recognizing that medical errors are a critical concern in meeting high standards of healthcare quality and safety, consideration should be given to another aspect of publically reported information, disclosure of medical errors. Finding out you or a family member are the victim of a medical error stirs many emotions. In addition to the emotions stirred from the patient perspective comes the fear of medical malpractice that can affect the provider as well as the healthcare organization. (perfectapology.com)

The debate that has lead to the continued inconsistencies in how medical errors are disclosed to patients stems from the fear an apology has the potential of being confused with an admission of guilt. Admitting guilt was believed to result in increased and more costly lawsuits. This in fact is not the case. A study conducted at the University of Michigan and published in the New England Journal of Medicine in 2006 demonstrated a two million dollar reduction in litigation cost with a greater than 50% reduction in claims resulting from apologizing for errors. (www.perfectapology.com) It was this evidence that was cited by Senators Hillary Rodham Clinton and Barrack Obama to promote support of medical liability reform emphasizing "I'm Sorry" legislation and sponsorship of the National Medical Error Disclosure and Compensation Bill (S. 1784, the MEDiC bill) bill. The objective of this bill is to provide protection to physicians participating in national error reporting protecting them from

legal liability. The MEDiC bill is an extension of the Patient Safety and Quality Improvement Act of 2005 established by former President George W. Bush. (Becker, 2005)

In Denver, Colorado, Hartford Courant (medical malpractice insurance) initiated a program in support of apologies and quick settlements. The results supported the University of Michigan findings showing "payments to aggrieved patients were under $6,000, compared with about $284,000 for doctors not in the program." (www.perfectapology.com)

Results of the study produced from the IOM reporting a riveting number of avoidable medical errors and deaths and in response to the patient safety movement, Veteran's Administration Hospital in Lexington, Kentucky implemented a disclosure policy requiring the admission of error to families regardless if they were aware of the error. Pennsylvania followed suit in March 2002, enacting Act 13 mandating the disclosure of a "serious event" within seven days to the patient and/or family. (Weiss, 2007)

Outcome of the The Veterans Administration Hospital policy resulted in an increase in settlements, however, a marked reduction in monetary compensation with lawsuits becoming rare (three in 16 years). (www.perfectapology.com) (Weiss, 2007)

While there are results from organizations such as University of Michigan and Hartford Courant that support the positive outcomes of instituting "I'm Sorry" laws, others are not as clear and have studies with opposing results such as Harvard University. Harvard University reports that the claims reported resulted in increased payouts. This study brings about much controversy since the "experts" used to determine the outcomes were patients and families. (www.perfectapology.com)

Despite controversial studies such as the one conducted by Harvard University; disclosure provides an open means of communication and has resulted in new legislation and the Full Disclosure/Early Offer Movement. The Full Disclosure/Early Offer Movement sets the precedent for "full disclosure of medical errors with fair, upfront, and early compensation." (www.perfectapology.com) The three guiding principles for this movement are as follows:

> "1. Compensate quickly and fairly when appropriate medical care causes injury;
> 2. Defend medical appropriate care vigorously;
> 3. Reduce patient injuries (and therefore claims) by learning from mistakes."
> (www.perfectapology.com)

Through implementation of the guiding principles set forth as a result of the Full Disclosure/Early Offer Movement, state governments and healthcare organizations including insurance companies are jumping on board with the acceptance of "I'm Sorry" laws. (www.perfectaplogy.com) (Appendix 1) In addition to government support, Doug Wojcieszak, founded a coalition that supported full disclosure of medical errors to patients called *The Sorry Works.* The belief of this organization points to medical malpractice being the direct result of weakness in providing customer service taking the focus away from the legal arena. Objectives of the organization are to promote communications with patients and families through full disclosure of medical errors. Full disclosure is accomplished through a three-step process that includes initial Disclosure, investigation, and resolution. (http://www.sorryworks.net/home)

As seen through studies, legislative change and healthcare organizations are taking steps to institute internal policies and procedures supporting medical error disclosure. Medical Malpractice insurance companies such as Med Pro are taking steps by offering premium reductions to providers that participate in their "accredited risk management education

program." Robert J Walling and Shawna S. Ackerman (2006) summarize best the reasons to support change:

> *"Apology laws appear to have the potential to reduce overall medical malpractice liability costs by lowering the amount of lawsuits, attorney fees, and claim costs. Additionally, studies show that physician apology laws encourage open communication, reporting, and investigation of errors, thereby providing an opportunity to prevent future errors….The Bureau of Veterans Affairs (VA) hospital in Lexington, Ky., is often cited as an example of effective medical error communications policy….Besides encouraging expressions of sympathy and admissions of fault, the VA actively seeks to disclose medical errors and offers direction on how to file a claim…This policy of extreme honesty, practiced since the late 1980s, has reportedly reduced lawsuits and settlement and defense costs. Only three cases have gone to trial in 17 years, with the average settlement being $16,000, compared with the national VA average of $98,000."*

Legal Requirements and Implications of Disclosure

With activity around apologizing for medical errors, the first step is to disclose the error. Studies have shown that there is agreement between the public and healthcare providers that medical errors should be disclosed to the patients. One study or randomly selected patients supported that 98% of those in the study support the disclosure of even minor errors indicating they are more likely to seek legal if the error was not disclosed. (Quality Care Committee of the AAPA, 2010)

Included in the action plan of the Joint Commission to address issues around medical errors and their impact on paints and healthcare, accreditation standards were modified to include the reporting of "unanticipated outcomes" to patients. The National Quality Forum (NQF) followed suite in 2006 adding disclosure of "adverse events" to the safe practices manual. (Quality Care Committee of the AAPA, 2010) Agreeing that the action of the Joint Commission is a step forward, perception of "adverse event" remains open to interpretation supporting inconsistent reporting.

With the legal implications in mind, there has been serious concern regarding violation of medical malpractice insurance and if a medical error is disclosed, will a physician's coverage be placed in jeopardy. A "cooperation" clause is common in medical malpractice insurance policies. Simplified, this clause means that providers may not admit liability resulting in injury or harm. This is often interpreted to mean that disclosing a medical error would jeopardize any chance of coverage in case a malpractice claim is filed against the provider. Further, it causes moral and ethical conflict affecting the decision to disclose or not to disclose. Legal precedent has been set in some cases in which the cooperation clause resulted in the denial of coverage, however, disclosure of medical error were not the contributing factors. It did contribute to the question; is the cooperation clause enforceable? (Banja, www.ncbi.nlm.nih.gov,)

There is another clause contained in medical malpractice policies as well that prevents the provider from succumbing to the injured party (patient). Jack Schroder, a health attorney describes it as "more subtle yet potentially more damaging". *The clause usually states*, "The insured shall not, except at his own cost, make any payment, admit any liability, settle any claims, assume any obligations or incur any expense without the written consent of the company." Mr. Banja points out in this article that to date there are not cases setting precedent for denial due to this clause but precedent has been set for lack of cooperation with the insurer. Cases cited include *Pennsylvania Insurance Company* v. *Horner*, *Royston Moore* v. *General Accident Insurance Company and Donald Swofford* and *St. Paul Fire and Marine Insurance Company* v. *Albany Medical Emergency Center*. The lack of success in enforcing the cooperation clause for cases in which the provider does cooperate with the insurer ties back to

the physicians ethical obligation to the patient of honest disclosure.(Banja, www.ncbi.nlm.nih.gov)

THINKING FORWARD: Where Do We Go From Here

Solutions to Disclosure and Reporting Medical Errors

Having identified multiple issues relating to the inconsistent reporting of medical error disclosures provides an understanding why disclosures are not incorporated in to quality measures and the bigger picture of the consideration be given to medical errors in naming high quality organizations. Thinking of this issue as if you were a healthcare consumer shopping for a provider or a hospital that you feel is competent in providing your healthcare, the hospital may rate extremely high in quality measures but is that enough information? Suppose this hospital does not go a day without a medical error or near miss, yet they have won numerous awards for quality and safety.

In February of 2009 the American Recovery and Reinvestment Act (ARRA), which includes the Health IT for Economic and Clinical Health Act (HITECH) was instituted to enforce the use of information technology to improve healthcare. There are millions of dollars at stake as incentive to encourage compliance with this legislation. A key to the success of implementing information systems solutions in healthcare organizations is to ensure that they meet the needs of clinicians but also offers opportunities to ensure systems output can accommodate the needs of payers, researchers, and other mandatory reporting requirements such as quality measures for *Center for Medicare & Medicaid Services* (CMS) and the *Joint Commission*. As Healthcare moves forward with its goals of improved quality and safety, an initiative should be pursued that incorporates real time reporting of all quality and safety

measures including attention to disclosing medical errors. In this section, we will look at what change is necessary to accomplish full disclosure of medical errors including incorporating them into public data. The areas that will be explored include:

- Culture Change
- System and Reporting Change and Development
- Recommendations for Regulatory and Legislative Change
- Re-writing medical malpractice policies setting guidelines for acceptable disclosure

Cultural Change

As discussed earlier, culture, both perceived and real, will require change in order to have a profound effect on the full disclosure of medical errors. In addition, until there is complete disclosure, public reporting of data would be inaccurate providing minimal benefit to the public, payers, and other organizations that may have an interest. Cultural areas that will require change include perceptions about reporting and the impact on litigation, anonymous reporting, and the "blame game."

The "blame game" is a means of shifting responsibility and sometimes viewed as "getting even", however, as Deane Waldman states in his article *The Blame Game –No Winners; "*Blaming gets you what you think you want right now, not what you really need or want long term." (Waldman, 2008) Waldman goes on to point out it is not who we need to address but what and why and most important, how do we fix it. This is especially true in healthcare, as we have seen the billions of dollars it is costing on unnecessary healthcare due to often-preventable errors. Waldman states, "The blame game in healthcare is the basis of the medical malpractice system (Med-mal) and in turn med-mal prevents error-reduction and suppresses quality improvement. In order to fix the problem, he suggests a reconnection between the

decision-maker and the consequences of the decision. (Waldman, 2008) In other words, we need to do a better job at root cause analysis, and everyone takes the good with the bad.

As culture begins to shift from one of blame to one of safety, expectation is for increased reporting of all medical errors including "nearmisses". As the culture shifts, organizational focus should shift as well focusing on key areas that minimize blame and focus on safety. These factors include; Feedback with an open line of communication about errors, handoffs, management focus on patient safety, continuous improvement through learning, attention to staffing, attention to team work within and across units and expectations set by management that promote safety. AHRQ conducted a survey to determine where hospitals are in the transition from blame to safety. Results of a survey of 622 hospitals found strength for the hospitals was teamwork while reporting was still a concern. Fifty two percent of the hospitals surveyed reported no errors in the organization in the past 12 months, which indicates underreporting. (Stakowski, 2009)

So, how do we minimize the "blame game" shifting the focus to reducing medical errors making healthcare safer? As discussed, there needs to be a shift away from the provider back to the institutional decision makers. In this case, the decision makers must include Quality Directors and administrative staff that have the ability to change and enforce policies and processes that will have a positive impact on the organization. These policies and process must support open and honest disclosure for all errors including "nearmisses" emphasizing that the information is a mere educational tool. Similar to taking an exam in school, questions are answered to the best of our abilities applying what we know but it is the ones we get wrong we

learn the most. We frequently go back and find the answers to prevent a similar error in the future.

One specific area that should be addressed as a cultural change through policy and procedure is the support for anonymous reporting. This will be discussed in more detail in the systems section but removing blame includes removing the ability to blame. If there are no names attached it would certainly eliminate the initial reaction of blaming forcing root cause analysis to determine what facts lead to the error as opposed to who caused the error.

Education is the key factor to enforcing the cultural changes necessary to make a true impact. All healthcare providers need a clear understanding of the impact errors have on patients and families and further the financial impact as an organization in whole resulting from lack of reporting. While recognizing we are all human and errors will happen, it should be emphasized the need to learn and grow from mistakes, not hide them.

Systems and Reporting Change and Development

Based on the update by the IOM in 2010 indicating there continues to be significant numbers of medical errors, both reported and unreported, should give reason for concern. Added to the concern are information systems that have been developed that do not address problems of incomplete, nonstandardized, or inconsistent reporting. In addition, as we have seen, hospitals are currently selected for recognition as quality and safety leaders without consideration of their medical errors and more specifically their disclosure in the form of public reporting. With the implementation of health information systems, there should be a push to address the concerns that prevent consistent and complete reporting for the good of all consumers of healthcare.

The MEDiC Act of 2005 supports a proposal for a national database including the funding to develop and support the database to be overseen by a newly established organization known as Office of Patient Safety and Health Care Quality. The stated purpose for the national database is to allow national experts to use the data for the development of best practice as well as a means of accountability of the health systems. (Becker, 2005)

Several approaches could be developed to address the reporting issues. Solutions could include continuing development of current systems incorporating standardized reporting requirements and terminology with attention to tracking root cause analysis, and providing useable output or by developing modules integrated into existing vendor systems. Regardless the approach, systems should be able to support HL7 interfacing to EMR/EHR's as well as pharmacy systems and systems used for backend functions such as coding and billing. By integrating the systems, in the case of medication scanning used for administration of medications to patients, if a "nearmiss" occurs by the nurse scanning the incorrect medication or the nurse performs a system override during the medication administration process, it should not only log the event in the pharmacy system but trigger an event in the medical error disclosure system. This in turn could be sent to a queue that is pulled on a regular basis for investigation by the risk and/or quality management staff. One requirement would be a means of identifying a patient involved in the incident. As the root cause analysis is being completed, event updates would be provided in the system. In an effort to support the culture change of anonymity and encourage reporting of all medical errors, access to the system should be provided utilizing a generic password that is not linked to a particular user. This is one example of a situation I would encourage noncompliance with Federal Rules of Evidence (803(6)) and the

Uniform Business and Public Records Act that address authentication of records. The reasons for not abiding by these rules is by offering non-authenticated documentation in a system and ensure it is not tied to the medical record, the information provided would not be admissible in court, which supports anonymity and would provide reassurance to providers encouraging them to report.

Another area that we have not explored is incorporating coding as a means of reporting. Over the concern for quality in healthcare, one section of The Deficit Reduction Act of 2005 (DRA) mandates Medicare payments be adjusted to accommodate for hospital-acquired conditions. This provision was titled "Hospital-Acquired Conditions and Present on Admission Indicator Reporting" (HAC & POA) by CMS. The objective was to identify high volume and high cost diagnoses that increase reimbursement for conditions that could have been prevented through use of evidence-based medicine. There are currently 12 general categories identified as targets, such as post-operative infections for specific procedures such cardiac surgery, that when coded and were not a diagnosis when the patient had been admitted to the hospital, are flagged as HAC. A similar concept could be supported with disclosure of medical errors. By interfacing the Medical Error reporting system to the coding system or module, these events could be coded and subsequently reported at the patient case level or aggregated to the hospital level. (CMS)

Key to incorporating data supporting the disclosure of medical errors is to ensure they are truly errors. The HAC & POA system reports defined as patient safety indicators for specific codes currently have no correlation indicating an error occurred and was disclosed. This would

involve working with CMS to modify the Hospital Compare Data base and to ensure clarity in coding and reporting.

Incorporating public reporting of medical errors not only meets the needs and concerns of the consumer, but also provides a means of meeting the IOM's recommendation to acquire and share information that all health professionals can learn. (IOM, 2010) There may be errors in an organization resulting from new procedures/equipment your organization has not put in place to date but it will provide factors to consider with the goal of avoiding errors other organizations have experienced and maybe even felt a financial impact as a result of injury. It should be noted that anonymity has been maintained throughout the process ensuring the provider punitive outcomes are clearly not the result of reporting. This solution is best summarized by the IOM as follows:

> "…… access to and use of clinical data at the point of care is necessary to prevent, recognize and recover from events. The data also are essential to better understand the nature of patient safety events, how they occur, and how they can be prevented in the future. The ability to access useful data is directly dependent on a sound information infrastructure and data standards for representing the information." (IOM, 2010)

Systems will not resolve medical errors but aid in the process of reporting and aid in a timely and consistent manner among organizations allowing data sharing at a national level. With the open exchange of information, improvement in patient quality and safety is gained from shared learning among organizations with the objective of eliminating duplication of known preventable errors. In addition, with data aggregated at the hospital level, the consumer is afforded the opportunity and comfort in knowing they have selected a safe setting to receive health care.

Recommendations for Regulatory and Legislative Change

Based on the success of incident reporting in a prominent industry, NASA's Aviation Safety Reporting System, the IOM made the recommendation for two separate reporting systems. The two systems are divided into voluntary reporting for "accident" reporting, which means an actual death, or serious injury would have resulted from the event. The second type is involuntary reporting and involves incident-reporting meaning "nearmisses". (IOM, 2010) In the aviation industry, it is obvious determining accident versus incident, however, in healthcare there is a blurred line. An accident resulting in death is clear but in determining the less obvious damage an incident can cause in the form of emotional impact or possible physical complications in the future are unpredictable. It is for these reasons reporting can be inconsistent and therefore recommendation in the systems section was for reporting all events regardless of incident or accident. For the same reasons, recommendation for legislative and regulatory change should require mandatory reporting for all events in an effort to remove loose interpretation by healthcare organizations and providers.

Recommendations by the IOM support voluntary reporting, however, they did not go to the extreme of recommending public reporting. The reason for this shortcoming was they believed that through the implementation of federal legislative protections and financial support reporting systems would thrive on their own. The IOM further recognizes the importance of obtaining error information in an effort to be proactive in preventing minor injuries from becoming major ones. (Richardson, IOM) While it seems the IOM understands the necessity for reporting by mandating reporting of reprehensible errors they are slow in taking the next steps. Acknowledging the need for public awareness, steps have not been

taken to ensure mandatory public reporting of all errors and for that reason I recommend modifications to the IOM's recommendations enforcing mandatory public reporting

Throughout this paper, several legislative and regulatory rules specific to the disclosure of medical errors have been discussed. Below is a table summarizing these rules along with their current intent along with recommendations for additions, deletions or modifications.

REGUALTION/LEGISLATION	DESCRIPTION	PROPOSED MODIFICATION
Patient Safety and Quality Improvement Act (2005)	Supported certification of organizations focusing on Patient Safety and Quality	
ACT 12 (2002)	Pennsylvania law mandating disclosure of "serious event"	Propose Federal Legislation to enforce in all states.
"I'm Sorry" Legislation	Law enacted in 17 states requiring apology for errors	Propose Federal Legislation to enforce in all states.
National Medical Error Disclosure and Compensation Bill (S. 1784, the MEDiC bill)	Bill amending Public Health Service Act promoting culture of safety in healthcare system through the National Medical Error Disclosure and Compensation Program.	Modify Bill to include additional regulations such "I'm Sorry", mandatory disclosure or all errors and near miss',
"Extreme Honesty" Policy	Kentucky law enforcing medical error disclosure to patients	Propose Federal Legislation to enforce in all states.
American Recovery and Reinvestment Act (ARRA) or Health IT for Economic and Clinical Health Act (2009)	Div. A,Title XIII: ONC for Health Information Technology established for electronic use and exchange of information protecting and securing PHI, improvement of healthcare quality, decrease medical errors and health disparities, costs savings from inefficiency, medical errors, inappropriate incomplete or duplicate care and improvement of coordination of care between health care entities	
Deficit Reduction Act (2005)	CMS ruling requiring adjustment to MS-DRG payments for hospital-acquired conditions.	
MEDiC Act of 2005	National bill protecting physicians from legal liability for disclosure of medical errors. Supports development of a national database.	Propose the bill is modified from supporting voluntary reporting to Mandatory with a financial penalty for non-reporting.

In addition, the push to expand the MEDiC bill incorporating requirements for apology in keeping with physician's ethical responsibility and ensuring compliance at a national level, the involvement of agencies such as CMS will be required. CMS in conjunction with Joint Commission would act as the regulating agencies mandating public reporting and setting precedent for organizations that are noncompliant. To ensure systems can accommodate the mandates, organizations with direct involvement in systems certification should ensure compliance with Medical Error Reporting. As part of system certification, certification should assure use of standard terminology, support anonymous reporting and interface capabilities. Internal to the organization is the responsibility to enforce use of the system coupled with mandated compliance and regulations by organizations such as JCAHO and the AOA as part of the certification process.

The objective of complete and thorough system evaluation is to ensure systems do not become a contributing factor to additional medical errors such as in the case described in the Journal *of the American Academy of Physician Assistants* in which a mammogram was misread due the system error allowing films to be reviewed in reverse chronological order. (Quality Care Committee of the AAPA, 2010)

Conclusion

The focus on the quality of healthcare and safety of patients became of great concern following the publication of the IOM report. Since publication of the report, there continues to be a growing concern over the safety in healthcare due to the continued number of errors. This comes in conjunction with the growing use of the internet, social media and growth in the area of public reporting of quality and safety data on healthcare organizations. While progress is

being made on the public awareness, there continues to be a gap in incorporating medical error reporting that could and should be used for the purposes of fixing our healthcare system and identification of high quality organizations. The mandatory disclosure and reporting of all medical errors whether a reprehensible error or a nearmiss, need to be used as the foundation of learning to address the problem. This can only be accomplished through modification of current legislation and regulations that will support public reporting. In addition, clauses contained in medical malpractice policies will require clarification to ensure a physician is not penalized for maintaining moral ethics. The current issues are best stated as follows:

> "What contributes to better reporting, culturally, is the fact there's pay dirt at the end of all that reporting," Loeb said. "Are systems and processes being changed as a result of what's being learned? That's been the failure of so much reporting so far. It's just been an information-gathering exercise." (O'Reilly, 2009)

To reach the objectives of disclosure and public reporting of medical errors will require the support of organizations such as CMS, Joint Commission, quality organizations such as the AHRQ, and the cooperation of healthcare organizations. Attention will need to focus on cultural acceptance of disclosure as well as certified information systems that will support tracking and reporting.

Finally, the reason most people enter the health care profession is with the intent of curing or helping to heal the sick not harm them. In making decisions that affect what and if we are going to disclose errors, it is important to keep in mind the ethical obligations to our patients of honesty, disclosure and apology.

Appendix A

Table 1 - I'm Sorry Legislation[3]

STATE	YEAR ENACTED	BILL	NOTES
Arizona	2005 Pending	SB 1036	
California	2001		
Colorado	2003	HB 1232	Allows not just words of sympathy but a full admission of fault
Florida	2001		
Georgia	2005	SB 3	
Illinois	2004 Pending	HB 4847	Allows any expression of grief, apology, or otherwise saying "I'm sorry" for adverse outcomes within 72 hours
Massachusetts	1986		
Michigan	2004	HB 5311	
Montana	2005	HB 24	
North Carolina	2004	HB 669	Also allows offers to undertake corrective or remedial treatment or actions, and gratuitous acts to assist affected persons
Ohio	2004	HB 215	
Oklahoma	2004	HB 2661	
Oregon	2003	HB 3361	
Tennessee	2003		
Texas	1999		
Washington	2004	SB 6645	
Wyoming	2004	HB 1004 SB 1004	

Table 2 [4]

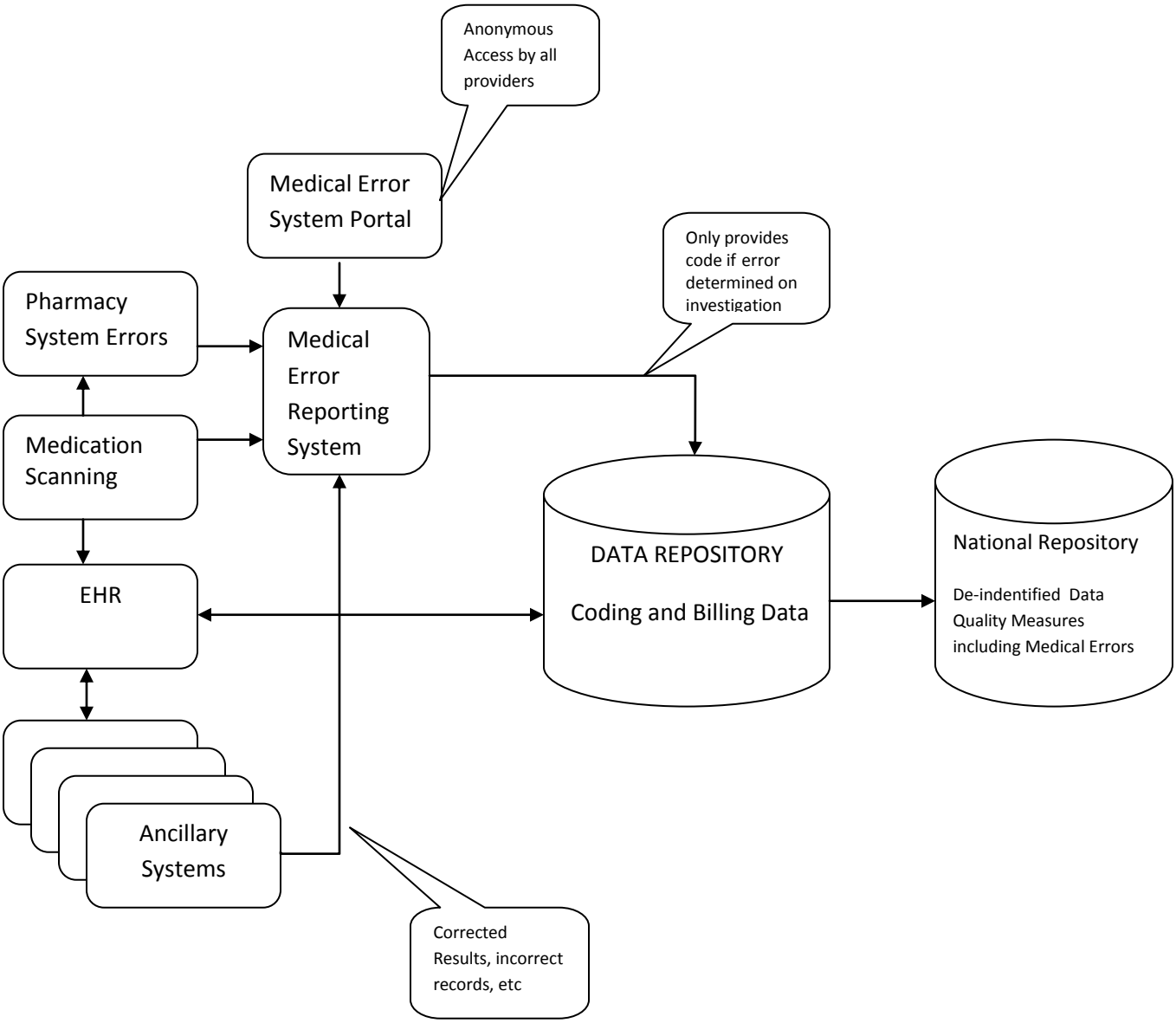
Twenty-nine states have enacted laws excluding expressions of sympathy after accidents as proof of liability.
They are:

- Arizona
- California
- Colorado
- Connecticut
- Delaware
- Florida
- Georgia
- Illinois
- Louisiana
- Hawaii
- Maine
- Maryland
- Massachusetts
- Missouri
- Montana
- New Hampshire
- North Carolina
- Ohio
- Oklahoma
- Oregon
- South Carolina
- South Dakota
- Tennessee
- Texas
- Vermont
- Virginia
- Washington
- West Virginia
- Wyoming

http://www.perfectapology.com/medical-errors.html

APPENDIX B

PROPOSED SYSTEM DIAGRAM



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