CHAPTER 115

Medical Errors – Aiming to Improve the Art and Science of Healthcare

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Introduction

Medicine is not mathematics. Hence seldom is 2 and 2 equal to 4. If such was, in fact, the case, doctors could easily be replaced by supercomputers that would cure every patient. Obviously, such is not the case. The prime reason is that the biology of the human body, the myriads of diseases and the various ways of managing them (both diagnosis and treatment) have infinite variations and permutations. Therefore, medicine is as much an Art as it is a Science.

Nevertheless, the primary aim of the medical profession is to ensure, first and always, patient safety. For this reason, there is a need to evaluate the magnitude of medical errors existing today, find out which of these are preventable ones and focus on devising a system that would eliminate (or at least minimize) them.

Alleged Magnitude of Medical Errors

Medical Errors are not new. They have been reported in English literature at least since 1964 (Schimmel EM: The hazards of hospitalization. Ann Int Med 1964; 60: 100 pp10).

Of late, there has been a lot of focus and debate on its magnitude and implications. For instance in 2000, in their executive summary, the presidential committee in US quoted the 1999 the Institute of Medicine (IOM), USA reported that upto 98,000 Americans die each year as a result of preventable medical errors, nearly half of the adverse events that occur in US patients are due to avoidable medical errors and that they cost 17 to 29 billion US dollars (Doing what counts for patient safety: Federal actions to reduce medical errors and their impact, February 2000 by Donna Shalala and Alexis Herman). It also stated that there could be as many as two errors in the ICU every day. (Institute of Medicine Report – To err is human: building a safer health system Nov 1999 http://www.nap.edu/books/0309068371/html/ accessed on 1st Dec 2007)

This was quickly picked up by the lay press and dramatized all over the electronic and print media globally. In India as well, the fourth estate highlights bad news about patient outcomes and attribute them to medical errors from time to time.

What is Medical Error?

IOMs (IOMs report "To Err is Human: Building a Safer Health System" on November 30th 1999) definition of Medical Error is as follows: An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures and systems (added by QuIC)

It is critical to recognize that not all bad outcomes for patients are due to medical errors. Also not all adverse events are due to medical errors. Medical errors are adverse events that are preventable with our current state of medical knowledge. They can be broadly categorized in those due to Overuse, Underuse and misuse (Chassin M: is health care ready for six sigma quality? Milbank Quarterly 1998; 76(4): 565-1).

Another way of classifying medical errors is as shown in Table 1.

Table I : Types of Errors

Preventive

    Prophylactic treatment

    Advise

    Follow up

Diagnosis

    Delay

    Error

    Wrong tests

    Outdated tests

    Failure to act on results

Treatment

    Error in execution (procedure/ surgery/test)

    Error in administration medication

    Delay in Rx

    Inappropriate management

Others

    Equipment malfunction

    System error

    Communication lapse

True picture of Medical Error

The US presidential committee report o February 2000 choose to dramatize the facts stated in the IOM report. If one takes the trouble to go through the details of the said IOM report, it is clear that the report was indeed misquoted. The full report states that this is only an estimate. Also the figures for preventable deaths due to medication errors are 7,000 per year and its cost is estimated to be 2 billion US$.

In another report, from the British authorities, it was estimated that 40,000 hospitalized patients die annually as a result of errors, giving a 3.7 % overall rate of errors. Similarly the report from Australia does conclude that errors are a serious cause of morbidity and mortality – but at a much lower level than quoted in the US.

The Harward Medical Practices Study (Leape LL: Errors in medicine JAMA 1994; 272: 1851-57 and Leape LL, Nrennan TA Laird N et al: The nature of adverse events in hospitalizes patients:Results of the Harward Medical Practice Study II N Engl J Med 1991; 324: 377-84) involved 30,195 random indoor case records from 51 New Your Hospitals. Medication complications were identified in 19.4 % of adverse events. Of these 45 % were due to medication errors; of which 58 % were potentially preventable and 27.6 % could be considered as due to negligence. These included

1. mistakes in writing prescriptions

2. mistakes in dispensing drugs

3. mistakes in administering drugs

The outpatient study of 1000 patients showed that (Burnam JF: Preventability of adverse drug reactions Ann Intern Med 1976; 85: 80-1) side effects occurred in 4.2% of patients. A total of 23 instances could potentially have been prevented.

Another study by Hayward and Hofer involved 383 reviews of 111 hospital departments in a Veterans Medical Center. They identified 22.7 % of active care deaths ad at least possibly preventable. But only 0.5% of patients who died would have lived 3 months or more if the care had been optimal (Hayward RA, Hofer TP: Estimating hospital deaths due to medical errors JAMA 2001; 286: 415-420).

Problems related to use of pharma drugs have been shown to account for almost 10% of all hospital admissions (Bates DW, Cullen DJ, Laird N et al: Incidence of adverse drug events and potential adverse druge events: Implications for prevention. ADE Prevention Study Group JAMA 1995; 274: 29-34) – but this does not mean that it was a Medical

Error. Even when an event is termed as medical error, it is as a consequence of the healthcare team having weighted the options (including the drug reaction possibility) and the patients condition still required that particular drug to be administered. Even under such circumstances, most errors do not result in serious consequences for the patient.

One study tried to find out the cause of medication errors. It evaluated the understanding of 5 drug prescription labels among outpatients. The results indicated that only 34.7% of patients understood how many tablets are to be taken daily when the label read "take two tablets by mouth twice daily". The more the no. of medications the patient was required to take, the greater was the risk of misunderstanding. (Davis TC, Wold MS et al: Literacy and misunderstanding prescription drug labels Ann Int Med 2006; 145: 887- 895)

Medical Errors – patient versus physician perceptions

Upto 95 % of physicians have reported being witness to a medical error. And 61% of health care professionals actually believe that errors are a routine part of medical practice. (Rajendran PR: Ethical issues involved in disclosing medical errors JAMA 2001; 286: 1078) (Medical errors: The scope of the problem. Publication No AHRQ 00-PO37 [Karen.migdail@ahrq.hhs.gov] Feb 2000)

Another study showed that when faced with such a medical mistake, about 46 % of US doctors fail to inform the institution about any incompetent or unethical practice of their colleagues. The reasons cited include not knowing what really happened, fear of reprisal and the feeling that a lawsuit would not bring back the dead person. Reasons for actually reporting include the duty of being truthful, believing in the principle of reparations and the need to protect future patients. (Forst N: Ethical Issues in Whistleblowing JAMA 2001; 286: 1079-1083).

Often the debate is between opinion about the best way to manage a patient versus actual medical error. Such ethical dilemmas in day to day life are particularly difficult for medical students, since neither do they have insight into the medical problem nor the experience of how to choose the best treatment option (Forst N: Ethical Issues in Whistleblowing JAMA 2001; 286: 1079-1083).

Most doctors (93%) agreed that they should treat patients irrespective of their ability to pay. However, only 69 % did accept uninsured patients for treatment. (Gallagher TH, Waterman AD et al: Patients and physicians attitudes regarding the disclosure of medical errors JAMA 2003; 289: 1001-1007)

Most patients and family members want to know immediately (76%) and completely (88%) if a medical error has taken place. They also are happy to recommend that such errors also be reported to government agencies (92%) and hospital committees (99%). (Hobgood C, Peck CR, Gilbert B, Chappell K: Medical errors – what and when: what do patients want to know? Acad Emerg Med 2002; 9: 1156-1161) Another study confirmed that 98.8% wanted full disclosure, 83% favoured financial compensation and even then, upto 47% of patients would still seek legal advise with a view of filing a lawsuit (Mazor KM, Simon SR et al: Health plan members view about disclosure of medical errors Ann Int Med 2004; 140: 409-418).

Recently, Judith Graham, staff reporter of the Tribune in USA (*August 19, 2007 issue;* jegraham@tribune.com*)* reported about the changing response of physicians to medical errors. Dr. Divyesh Mehta, chief of oncology at the University of Illinois at Chicago Medical Center (and a well known name in India as well) walked up to a patient with breast cancer and admitted that she was administered double the dose of G-CSF by error and apologized for the same. He recommended increasing her hospital stay be a couple of days as a precaution. This action was applauded as a welcome change in the attitude of doctors and an ideal way of building relationships with patients. Not long ago, this encounter would have been almost unthinkable.

Medical foul-ups were rarely discussed among physicians and almost never acknowledged to patients. Doctors were too proud, too afraid of malpractice lawsuits, too worried about losing face.

The system needs improvement

IOM reported that majority of medical errors today are NOT produced by negligence, lack of education or lack of training. Rather errors occur in our health care system due to poor systems design and organizational factors - e.g. health care workers are expected to work 24 hour shifts, leading to overwork, fatigue and decreased mental concentration and alertness. Another important reason is the decentralized and fragmented nature of how health care is delivered. As a result, multiple providers at different locations may not know the full picture or have complete information regarding the patient's medical illness, current medication and past adverse events or allergies.

Errors occur everywhere the patient is looked after, including but not limited to,

- Hospitals
- Physicians office
- Nursing homes
- Pharmacies
- Casualty
- Home care
- Hospice

Knowhow already exists to prevent several medical errors. The value of Six Sigma Quality (greek letter use to represent standard deviation from the mean of any normally distributed curve) has already been well documented in other fields and industries. It is also important in healthcare delivery. Factors that need to be kept in mind include:

- Accountability
- Learning from errors

- Peer review protection – protect reporting systems from being used in litigation
- Raising the standard of health care organizations and professionals
- Building public awareness
- Using standardized procedures, checklists and results
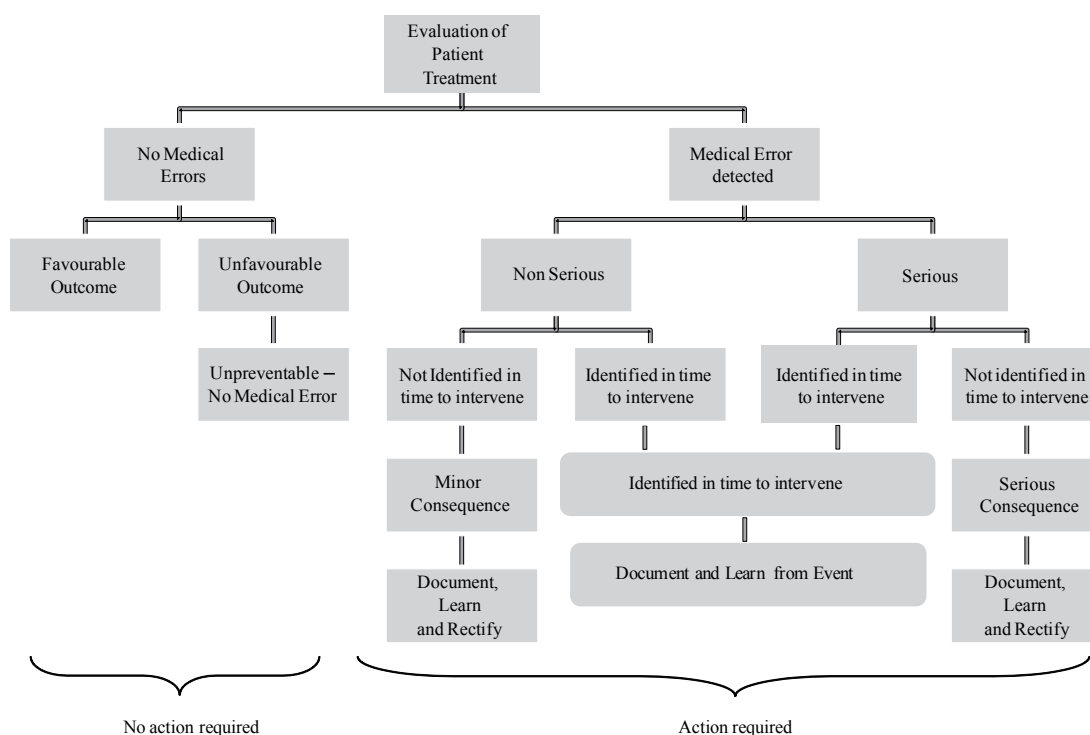- Data integration and integrity

Lessons about Error Reducing Efforts from Other Industries include:

- Make safety and error reduction a institution policy of importance
- Proactively identify error rate particularly in high risk populations
- Set high goals to reduce them
- Set us systems for reporting errors and close calls
- Promptly and thoroughly analyse errors to identify the root causes
- Call upon the services of experts as and when required (clinical, epidemiological and management experts)
- System should specifically be designed not to blame or find faults with individuals
- Earmark funds and human resources to support error prevention, remedy and develop safety culture
- Encourage out of the box thinking and solutions
- Make public, regulatory authorities, pharmaceutical and medical device companies as well as private purchasers involved in the process as important stakeholders

Obstacles to improving safety of healthcare services include:

- Lack of widespread awareness about the problem
- Incomplete data on the nature and magnitude of the problem

Figure 1 : Flowchart to address the problem of Medical Errors

- Disorganized system of providing healthcare services

- Mismatch between supply and demand

- Lack of complete information with each member of the healthcare team

- Tradition of blaming individuals physicians irrespective of root causes

- Physician administration disconnect

- Lack of protection from legal liability and litigation

- Lack of functional system for medical error reporting and remedy

- Unwillingness of the administration to accept their responsibility for system deficiency and allocation of resources to prevent errors

Figure 1 shows a flowchart framework to address the problem of Medical Errors in any location/ institution. Using such techniques medical errors have already been reduced significantly. For instance, presence of pharmacists on medical rounds, have reduced errors of medication by 66 %. In Surgical Anaesthesia, error were reduced from 25 to as little as 5.4 per million by using standard equipment, procedures and guidelines (Orkin FW: Patient monitoring during anesthesia as an exercise in technology assessment. In: Saidman LJ, Smith NT (eds). Monitoring in Asesthesia, 3rd ed. London, United Kingdom: Butterworth-Heineman 1993). A third example is that of the VA Hospital, which used hand held wireless computer and bar coding and found that medication errors reduced by 70 % (Medical errors: The scope of the problem. Publication No AHRQ 00-PO37 [Karen.migdail@ ahrq.hhs.gov] Feb 2000)

Healthcare professional and scientific bodies should implement periodic re-examination or relicensing dependent on participation on continuing medical education. MCI, National Board (DNB) and Health Universities should also develop a curriculum on patient safety. Information about medical errors should be disseminated on a regular basis to all healthcare professionals without letting it disappear in the existing information overload.

DCGI should revise the standards for drug packaging and labeling with a focus on drug safety. Pharmaceutical companies should proactively avoid the use of similar sounding brand names and similar appearance of logos. Post marketing surveillance should be taken seriously by all parties, including industry, hospitals, physicians, pharmacists, patients and family members. Participation in the drug adverse events surveillance of ICMR should be propagated and encouraged nationwide. Currently such an initiative is spearheaded by Dr Nilima Kshirsagar, Mumbai.

Medical Education should play emphasis on effective communication and medical empathy. Use of emotional labour (both deep acting and surface acting) can help in presenting the right image while displaying emotions. This can help improve patient physician communication by non verbal means as well. The advantages would be satisfaction with medical management for the patient and job satisfaction for the physician. (Larson WB, Yao X: Clinical empathy as emotional labor in the patient-physician relationship JAMA 2005; 293: 1100-1106)

Characteristics of a good reporting system for medical errors are:

- Goals are clearly stated and understood by all stake holders
- System is in place, easy and working
- Leadership plays a proactive role
- Support provided at all levels
- Reports are accepted from all parties and given equal importance
- Reports are kept confidential and used for prevention
- External peer experts are involved in the process at all stages
- Specifically individuals are not blamed or punished
- Reporters and community receives timely and constructive feedback

- Testing and validation takes place before final roll out

How to prevent Medical Error – Practical Tips

IOM report recommends reducing medical errors by 50 % over 5 years. The framework to achieve this was

- Establish a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety
- Identify and learn from medical errors by mandatory and voluntary reporting systems
- Raise standards for improvements in safety through oversight organizations, group purchasers and professional groups
- Implement safe practices at the delivery level

The program would be successful, provided there is a system in place, not only to do the right thing but also to be seen to do the right thing. One of the main reasons why mandatory reporting systems have failed is lack of clarity regarding the system as well as lack of timely and meaningful feedback.

The patients should remember that most errors result due to problems with the complex health care system. Physicians cannot do everything to make patients take informed decisions. The patient can help prevent medical error by becoming an active member of discussion with the health care team. This is the single most important factor identified to prevent errors. They can contribute in the following way:

- Select the hospital/ doctor that does the most procedures/ sees the most patients related to your specific condition
- Tell all the doctors about all the medication being taken – including prescription medicine, over the counter medicines, dietary supplements, alternate systems of medication and any recent change in the dietary habits

- Inform all the doctors about any allergy or past adverse reactions.

- If you have a test, find out what its report is

- Ask about the steps for each procedure/ surgery that you need to undergo

- Ask all healthcare workers whether they have washed their hands before being in contact with you

- Ask a family member or friend to be with you at times of important discussions

- Make notes about anything that you do not understand and ask them at the first opportunity

- At the time of discharge, ask them to describe to your satisfaction the treatment to be taken at home. Read and understand the prescriptions written by the doctor. Ask if you do not understand particularly about how many tablets, how many times and at what time of the day/ night.

- Confirm with the medical store that you have been provided the medicine exactly as specifically prescribed by the doctor without any substitution

- Buy and save the best devise to measure liquid medicines. Do not use your kitchen will provide you with a substitute measurement devise.

- Ask for written information/ resource regarding side effects of your medicine.

Unintended consequences of reporting Medical Error

Acknowledging medical errors with an apology is a noble intention to heal by neutralizing patients' anger and easing physicians' guilt. Some advocate it as a means to reduce potential malpractice lawsuits and payouts. However, though most doctors acknowledge their intention to be honest, majority are reluctant to reveal serious errors in practice. The main reason stated is the fear to their reputation as well as the risk of compromising their legal liability. In the US more than 30 states, have passed "apology laws" that prevent such statements from being admissible against physicians in court. The reality is that lawyers are skeptical that it would work. Insurance companies continue to insist that doctors do not acknowledge such errors and in fact, recommend termination of all communication with the patients or families. This is based on the premise that such admission of wrongdoing will strengthen the patient's case in the eyes of the courts. Such a thought process is backed by at least one Harvard University study that concluded that malpractice suits will increase as more patients become aware of errors.

Public reporting of information related to medical errors or competence has another downside. In the US, the courts would decide the level of the physician's competence based on his adverse event rate in the past. As a consequence, doctors would only take up standard risk patients and refer complicated cases elsewhere. They would also strive to get better rates of success by doing interventions even when the patients condition indicated it was of questionable need. (Werner RM, Asch DA: The unintended consequences of publicly reporting quality information JAMA 2005; 293: 1239-1244.)

In India as well, the consequence of laws related to medical negligence, medical error and consumer courts have led to the practice of defensive medicine.

Situation in India – Special Considerations

Dr Vasant Jaykar a prominent physician and cardiologist in Mumbai was shot dead in his own clinic. A disgruntled family member of a patient who died and threatened the doctor was arrested. Aparantly he had issued a "Supari" to have to doctor killed. Several years later, the accused were discharged by the court - due to lack of evidence. This is a very high price to pay by any physician, particularly a dedicated and sincere one of Dr Jaykar's stature.

Developing countries like India have a serious resource crunch in the healthcare sector. We have a dismal doctor to population ratio. This is also true for no of hospital beds per 1,00,000 of our population. Any government or teaching hospital will have hordes of patients flocking for medical management. When a doctor is faced with 300 to 500 patients every day, the time available for each patient is limited. This highlights the problem with the system. In spite of being well documented, the resource allocation for healthcare remains one of the lowest in any country. Under such circumstances, it is impossible to prevent medical errors.

On top of that, we have faced with frivolous lawsuits on several instances. One such example is about a lady who was suspected to have lung cancer. After cytological examination, which documented presence of lung cancer cells, she was advised admission for treatment. She chooses to go elsewhere, where a doubt was raised about the diagnosis. Tuberculosis was suspected and she was started on empirical anti-tubercular therapy. The patient's condition continued to deteriorate. After a couple of years, she filed a complaint that she was wrongly diagnosed as having lung cancer, subject to mental stress and that she could have faced the consequences of wrongly given chemotherapy. In another instance, a patient was given chemotherapy elsewhere and died of progressive disease. His father then filed a case against Tata Hospital stating that the chemotherapy advise (given six months before the actual chemotherapy was administered at native place) was wrong and this caused the death of the patient.

The outcome of lawsuits in the court is also a cause of concern. In one instance a patient with headache was subsequently found to have a brain tumor. He went to court against the delay in diagnosis. The plea of the neurologist was that all patients with headache do not need a CT Scan especially when the neurological examination was normal. Besides the patient could not afford the CT Scan. The hon'ble court made a remark that the patient's life was more important than Rs 5,000 for the CT Scan. In another instance, a pediatrician was jailed and fined for prescribing medication that was licensed for marketing in India. The court decision was based on the fact that the medicine was banned in USA and hence considered dangerous.

Patients and their families often make it difficult for healthcare professionals to impart proper medical management. When faced with an unfavourable prognosis, they will often shop from doctor to doctor. They will then focus only on the information that they like – often from different sources and without proper reference to the context. Subsequently they will then expect the treating team to deliver the outcome apparently promised by someone else. Another common occurrence is not revealing the full history to the doctors. In fact some patients will attribute their opinions to one doctor while talking to another member of the healthcare team – creating miscommunication and confusion. Patients are even given (sometimes without their knowledge) various sorts of medicines and nutraceuticals on the sly, deliberately withholding this information from their doctors. And this happens irrespective of literacy or socioeconomic background. This is particularly applicable when indigenous systems of medicine are being used. Thereafter, when any adverse reaction occurs, they are quick to blame the treating allopathic doctors.

Hospital administrators, particularly in India, often forget their pivotal responsibility in mitigating medical errors. Do they accept and acknowledge their role and responsibility in medical errors? Unfortunately, they are the first to pass the buck and look for a "bakra" to blame and cover their deficiencies. Senior and internationally renowned Head & Neck OncoSurgeon was recently put in the dock by the biased administration of his own hospital. He was accused of ethical misconduct for something that happened when he was not even present. In fact, the sequences of events clearly indicate that it was a known complication that had occurred in spite of comprehensive medical management. The way this was blown out of proportion and action intended to be initiated

against him for dereliction of duty in reporting the event could probably be explained by someone in the administration mounting a personal vendetta against him for "other" considerations. Fortunately there were enough sensible and ethical persons to ascertain the true picture and clearing him from allegations.

- Incidence of medical errors in India is not documented but they probably occur frequently

- Medical errors are usually underreported, overlooked and remain a controversial area.

- Most errors are due to system related problems and failures, not due to individual faults.

- Efforts to reduce and eliminate medical error are needed in a systematic and proactive manner

- Experience from other industries/ fields have the potential to teach us a lot how this can be done effectively

- Public opinion, legislation, voluntary reporting and a system of reporting with legal protection needs to be mobilized.

- SOP should specifically be designed to

  a. Find root causes

  b. Avoid tendency to blame individuals

  c. Allocate sufficient resources for all objectives

  d. Provide timely feedback in a manner that it is useful

  e. Including this topic in the medical curriculum

  f. Look at unique Indian environment to design "out-of-the-box" solutions