

Patient safety risk assessment and risk management: A review on Indian hospitals

Abstract

This paper is intended to discuss a critical need expressed by present healthcare system of India, and how to provide a better health facility and diluting the medication errors caused by inappropriate management of the hospitals. Adverse events related to medication occur due to pathetic infrastructures, corporal punishment by the patient if unsatisfied, doctors on strike and working only for riches, trivial financial aid, and lack of basic amenities in the government-run hospitals of India. Government should reduce the barriers of awareness, accountability, ability, and action into accelerators of patient safety in the government organizations. Physicians, nurses, and pharmacists are truly the critical ingredient to rapid safety practice adoption. Various approaches like Technological Iatrogenesis, Computerized Provider Order Entry, and Electronic Health Record should be used. Although patient safety is recognized as a serious issue in health system, there is an urgent need for development and implementation of strategies for prevention and early detection of errors.

Key words:

Adverse events, medication errors, technological iatrogenesis

Introduction

How often does a patient ask his doctor on the possible “side-effects” of a medicine he has been prescribed? Hardly ever, which point out the significant role that patient play in the chain of reporting “adverse drug reactions” (ADRs).

Patient safety is a new healthcare discipline that emphasizes the reporting, analysis, and prevention of medical error that often lead to adverse healthcare events. Risk assessment is a qualitative or quantitative estimation of the likelihood of adverse effects that may result from exposure to specified health hazards or from the absence of beneficial influences. Risk management is the term for the systematic analysis and control of risk.

The prevention of serious errors in medical care has long been of concern to health professionals, as well as courts and legislatures.^[1] Risks are caused by exposure to hazards.

In the present era, the safety of patient is very necessary. Whenever a patient goes to a doctor, the patient is treated in several conditions, due to this, the chances of medical error increases. Thousands of patients die due to medical error and improper treatment every year. The main cause is human factor, medication error, and system failure. This type of problem needed to be sort out and need an initiation.

However, the recent report by the Institute of Medicine (IOM), To Err Is Human, found out that the number of death from medical errors in hospitals is more than that by automobile accidents.^[2,3] As soon as the report was released, a survey showed that half of the American public followed the media coverage of it.^[4] Since then, there have been many new efforts to reduce the incidence of medical errors.^[5-10] However, some people disagree with the report’s conclusions, arguing that the report overstated the magnitude of the problem.^[11-14] Dr. Barbara Starfield, MD, MPH, of the Johns Hopkins School of Hygiene and Public

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Health, shows that medical errors may be the third leading cause of death in the United States.^[15]

Patient Safety

Recent advancement in the technology has created an immensely complex healthcare system. This complexity brings many challenges for healthcare staff in continuing to keep the patient safe. Every day, more than a million people are treated safely and successfully in the hospitals, but there are times when things can go wrong.

In any given typical surgery, estimated 250 to 300 surgical tools are used.^[16] The number significantly increases to 600 when a larger surgery is performed, thus increasing the chance of the surgeon losing an instrument.^[16] Common instruments are needles, knife blades, safety pins, scalpels, clamps, scissors, sponges, towels, and electrosurgical adapters. Also retained are tweezers, forceps, suction tips and tubes, scopes, ultrasound tissue disruptors, asepto bulbs,^[17] cryotomes and cutting laser guides, and measuring devices. The single most common left behind object is a sponge.^[18]

Patient safety includes a gamut of initiatives which includes empowering consumers, engaging patient (and their families) in their own care; healthcare professionals training; health services improvement; and bolstering the health system. When a doctor has to go for hundreds of patients a day, due to overburden, he can go wrong in providing the health services to the patient. This gives birth to medication error, where patient safety becomes an obligatory discipline to be followed.

Indian Scenario of Patient Safety

Last year, nearly 45000 foreigners sought medical treatment in India as medical tourists.^[15] Indian healthcare industry is seen to be growing at a rapid pace and is expected to become a US\$280 billion industry by 2020.^[19] Recently, medical tourism has been a spur for select institutions to strive for the highest international standards.^[20]

But still, information relevant to drugs is not very common among Indian people. The health sector is severely affected by the increasing production and promotion of certain banned and fake drugs in all across the country. There are multitudes of drugs which are banned in many western countries, due to their side effects, but not in India.^[21]

There is a widening gap between doctors and patients due to asymmetry in knowledge, socioeconomic status, and educational levels. Increased reporting of medical errors in the media has also contributed to the polarization. Times of India stated medication error as a top ten causes of death in the world.^[22] Doctors stereotyped the patients as irresponsible for their own health, as they do not follow the

medical instruction, and do not consult a doctor until the disease reached to the advanced stage, and finally wants quick and cheap cures. Patients in turn found doctors intimidating and did not dare to express their concerns or ask questions. Doctors do not get the proper medical history they require for a proper diagnosis and to order appropriate tests. Patients did not understand the doctor's instructions regarding their medicines or follow-up.

This creates a huge communication gap between the doctor and the patient which in turn hampers care. Blame and frustration on both sides have resulted in a downward spiral with, in extreme cases, patients physically threatening doctors and of doctors going on strike. In the end, it is the patient who had to suffer. This results into a poor healthcare system in India.

Indian Hospitals

Common and main characteristics of Indian Government Hospitals are chronic overcrowding, pathetic infrastructures, underfunding, and facilities perpetually stretched to the limit.^[17] The major reason for this is our economy which spends less than 2% of its Gross Domestic Product on health. That turns out bright young doctors and looks after a workload of patients with a spectrum of diseases far broader than found in the private sector, yet are at times the unfair target of criticism during healthcare crises. Their circumstances seldom allow quality and safety to appear on their radar.

Today, two-thirds of the population seek the private sector for their health needs. There are burgeoning private hospitals and private teaching colleges in the past 30 years, showing the demand of students for a medical education, and of a public seeking more personal and patient friendly treatment at the time of sickness. Indian business also sees a profit from investing in healthcare. Recently, medical tourism has been a spur for select institutions to strive for the highest international standards.^[23]

Although there are scanty data on medical errors in India, a research detected 457 errors in pediatric practice at a single teaching hospital over a period of six months. The problem is compounded by the fact that the culture of reporting and recording medical errors is virtually absent in India.^[24] Pluralities of cases of medication error in Indian health system have been reported but still not come in limelight. In a civil hospital of Mohali, a lady doctor was carrying out the stitching for episiotomy, during which 40-mm needle broke. Lady Doctor said the patient had hard skin that led the needle to break and the patient's family has not given any complaint and are satisfied with their treatment.^[25] Kalsoom Rehman suffered a severe abdominal pain because of a towel which doctor forgot to take out while doing a delivery operation.^[26]

Many cases of these medication errors like a pair of surgical scissors in hysterectomy operation, a piece of medicated gauze in abdomen, a large surgical clamp in chest, a ten-inch steel retractor lodged in abdomen, pieces of plastic, sponges, and gauze in benign tumor operation, surgical scissor blade left in abdomen, surgeons left a laparotomy pad inside abdomen, and surgical sponge left behind the sternum have been reported.^[27]

When Things Go Wrong

When things go wrong, news spreads fast, and the search to find who is at fault is on. This is like a witch hunt, with the blame game shifting culpability from one person to another. The setting for this may vary from a departmental investigation, a peer review meeting, or a morbidity and mortality conference. Whichever one it is, it represents a retroactive response to an untoward incident. By reviewing and dissecting out the full sequence of events that led to the incident, one uses a process of Root Cause Analysis to identify how the error occurred and who or what could be responsible.^[28] The process is very effective, but it leaves casualties in its wake. Due to fear, people intentionally do not report errors, or adverse events in the future. This results into larger errors which are because of bad system and not bad people.^[29]

“Examine the systems” should be the motto as is the practice in industry and in the aviation sector. Be proactive and try to define the weak points in the system and take appropriate steps. It was not realized at the time that it required a dedicated person to clean the laparoscope of all organic matter before it could be sent for sterilization. The system was at fault. There was no question of negligence on the part of theatre staff, but patients suffered from institution’s lack of foresight.^[30]

Cause of Healthcare Errors

Healthcare error can be simply defined as a preventable adverse effect of care. A conservative average of both the IOM and Health Grades reports indicates that there have been between 400000 to 1.2 million error-induced deaths during 1996 to 2006 in the United States.^[31] These casualties have been attributed to the following.

Human factors

Variations in healthcare providers’ training and experience,^[32,33] fatigue,^[34-36] depression, and burnout;^[37] diverse patients, unfamiliar settings, and time pressures; moreover, failure to acknowledge the prevalence and seriousness of medical errors.^[38,39]

Poor communication

Unclear lines of authority of physicians, nurses, and other care providers.^[40]

Similar drugs names

Look alike and sound alike drugs.^[41] Inadequate system to share information about errors hampers analysis of contributory causes and improvement strategies.^[42]

Risk Management: In Search of a Solution

Medication error should not be considered as a total despair and if substantial measures are taken, the medication errors are decreased or finished. Following are the measures which have a potential to do this.

Ensuring patient identity

Use of wrist band worn to the patient having relevant information is an old procedure. New advancement should be added in this procedure like use of bar codes and chips instead of using written strips. This will help to prevent the loss of patient information and so decreases medication errors.^[43,44]

Use evidence-based medicine to save lives

Five years after the 1999 report of the IOM, the save 100 000 Lives Campaign^[45] was initiated to add momentum to the quality and safety campaign in healthcare. Common clinical situations were identified where simple clinical interventions including drug therapy were known to be effective.

Better communication between healthcare workers

In hospitals, caregivers might change according to their shifts, resulting into the chances of medication errors. Special consideration should be given in this field. For this, nurses and other staff should prefer verbal communication rather than telephone to avoid errors.^[46]

Hand hygiene to prevent nosocomial infection

There are pluralities of morbidity cases due to lack of hygiene in the hospitals.^[47] It is in a nature of doctors, nurses, and paramedical staff to do multiple works at a time. What makes the matter worse is distraction caused due to some devices like mobile phones, pagers, casualty calls, and emergencies superimposed upon patient work and meetings. Proper delivery of checklists and bundles in the Intensive Care Unit should be done to ensure that no component of care has been missed.^[48]

Due to recent advancement in technology, medicines are increasingly technology driven. The development of new technology gives birth to new errors and constant vigilance is required to tract this. One powerful tool that can be used is anonymous incident reporting by doctors, nurses, and technicians working in high-risk areas.^[49] Moreover, improving the working conditions of the nurses may also help in improving the patient safety.^[50]

Other strategic procedures like involvement of the media and nongovernment organizations for the prevention of patient rights will be beneficial. A more people-centered approach

to care which addresses the needs of consumers, healthcare workers, health institutions, and the healthcare system at large is required. Patient education, creating awareness, and healthcare provider's propensity toward the awareness programs of patient safety should be increased. When things go wrong, there should be a proper management which is done only by creating the partnerships between the providers and consumers to improve the quality of healthcare. In response, there is a need for improving how work is organized and services are delivered; including patient safety in medical and nursing curricula; strengthening the numbers, distribution, and skills of the workforce; and moving patient safety beyond the hospital to community-level care.

The nine solutions are now being made available in an accessible form for use and adaptation by WHO Member States to redesign patient care processes and make them safer. They are as follows: Look-alike, sound-alike medication names; patient identification; communication during patient handovers; performance of correct procedure at correct body site; control of concentrated electrolyte solutions; assuring medication accuracy at transitions in care; avoiding catheter and tubing misconnections; single use of injection devices; and improved hand hygiene to prevent healthcare-associated infection.^[51]

Moreover, in order to prevent some common errors, some hospitals do a counting of sponges and instruments before and after the operation are done.^[52]

Pharmacovigilance in India

Pharmacovigilance is the pharmacological science relating to the detection, assessment, understanding, and prevention of adverse effects, particularly long- and short-term side effects of medicines. The National Pharmacovigilance Program established in January 2005 was to be overseen by the National Pharmacovigilance Advisory Committee based in the Central Drugs Standard Control Organization, New Delhi. Two zonal centers—the South-West zonal center and the North-East zonal center—were to collate information from all over the country and send it to the Committee as well as to the Uppsala Monitoring centre in Sweden.^[53]

With the increasing number of high-profile drug recalls, the Pharmaceutical industry, regulatory agencies, and healthcare delivery systems (governmental and private) are more concerned with drug safety. The pharmaceutical industry in India is the third largest in the world. It is estimated to reach US \$50 billion by 2015, and with more and more clinical trials and other clinical research activities being conducted in India, there is an immense need to address all aspects of pharmacovigilance.

In a survey report, 90% of doctors said that they are aware of ADR of drugs, of which 56% said they have not done its

reporting at reporting centers. 89% are aware of existence of ADR reporting and monitoring system, but only 64% did the reporting.^[54] The common causes of not reporting to the centers are they are time consuming, tedious, well-known reactions, mild adverse reactions, and immediate management of ADRs.^[54]

Technology to Reduce Medication Errors

Various methods have been developed which will help in diluting the medication errors and bolster the healthcare system.

Electronic health record

More advancement in Electronic Health Record includes automated drug-drug/drug-food interaction checks and allergies checks, standard drug dosages, and patient education information. Moreover, clinical guidance for disease management has demonstrated benefits when accessible within the electronic record during the process of treating the patient.^[55]

Computerized provider order entry

Errors in prescription are the largest identified source of preventable errors in hospitals.^[55] Computerized provider order entry (CPOE), also known as Computer Physician Order Entry, reduces the medication error by 80% overall as well as dilute harm to the patient by 55%.^[56]

Technological iatrogenesis

This includes errors related to errors caused in care delivery system.^[57,58] It can only be improved by bolstering the networks and connections working simultaneously to produce certain outcomes. Moreover, stress of multiple works at a time should also be decreased.

Evidence-based medicine

It includes experience of the doctor in developing dose regimen and drugs to be used. The clinician uses pertinent clinical research on the accuracy of diagnostic tests and the efficacy and safety of therapy, rehabilitation, and prevention to develop an individual plan of care.^[59] This have following advantages like ADR events decreases, errors caused by changing shifts, and multiple specialists also decreases and improves communication between physicians, patients, and nonmedical purchasers of healthcare.^[60]

Health literacy

It is one of the most common and serious safety concerns. Patient's inability to understand the physician and pharmacist counseling also develops patient medication errors.

In particular, these patients have a higher risk of hospitalization and longer hospital stays, are less likely to comply with treatment, are more likely to make errors with medication,^[61] and are more ill when they seek medical care.^[62]

Pay for performance

This technique seems to be the most promising approach in reducing the errors, but cases have been reported as avoidance of high-risk patients when payment was linked to outcome improvements.^[63]

Conclusion

The healthcare system has only recently begun to approach patient safety in a more systematic way. There is a clear need to improve the quality of care in the medical system that permits an alarmingly high annual rate of medical errors that harm tens of thousands of patients and drives up cost. Help desk at healthcare facilities should be created; telephones hotlines for major diseases should be created; audiovisual and printed education materials in waiting rooms; forums for open dialogue between doctors and patients should be encouraged; and the changing relationship between healthcare provider and consumer; doctors no longer perceived as “gods.” An estimated 60 million Americans use some form of complementary and alternative medicine, though approximately 70% do not tell their physicians about this use. Open communication between conventional medical providers and patients in this area is therefore lacking.^[64] Communication gap between doctor and patient should be decreased as healthcare becomes more complex. Physicians should not overestimate the extent to which they discussed patients’ ability to follow the treatment plan. A survey conducted in the Emergency Department at Kern Medical Center in Bakersfield, California, revealed that only 59% of the patient follows the doctor’s instructions. This was because of the Spanish-speaking patients who did not understand English very clearly. This implies that the doctor should be well-versed with the local dialect and vernacular language.^[65]

The direction which is to be highlighted in recent reports on medical errors is the need to move away from a search for individual culprits to blame for medical errors. This judgmental approach has sometimes been called the “name, shame, and blame game.” It is characterized by the belief that medical errors result from inadequate training or from a few “bad apples” in the system. It is then assumed that medical errors can be reduced or eliminated by identifying the individuals, and firing or disciplining them. The major drawback of this judgmental attitude is that it makes healthcare workers hesitate to report errors for fear of losing their own jobs or fear of some other form of reprisal. As a result of underreporting, hospital managers and others concerned with patient safety often do not have an accurate picture of the frequency of occurrence of some types of medical errors.

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