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International Journal of Current Research
Vol. 10, Issue, 08, pp.72926-72932, August, 2018

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

ISSN: 0975-833X

RESEARCH ARTICLE

BASIC CONCEPT OF PATIENT SAFETY IN HEALTHCARE DELIVERY

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ARTICLE INFO

Article History:
Received 14th May, 2018
Received in revised form
24th June, 2018
Accepted 27th July, 2018
Published online 31st August, 2018

Key Words:
Patient Safety,
Healthcare Delivery,
Medical error, Harm to the Patient.

ABSTRACT

Realising the impact of medical errors and the importance of patient safety in healthcare delivery has been an astonishing journey with surprising findings at each step. With very few rules and laws for safety of patients, it has been an undermined subject but, at the same time, has been associated with huge amounts of emotions and costs involved. It is said that, risk and safety are flip sides of the therapeutic coin. Patient safety must be an attribute of the healthcare system. An assertive action is needed to safeguard the interests of the patient in their healing process. But the action and progress on patient safety is frustratingly slow and inadequate. Robust plans of action should be created with the help of all levels of staff members and advancing technologies. Patient safety and error management may be inculcated in the undergraduate curriculum of medical students.

Citation: ***Aashita, Sah, A., Khan, Z. H. and Khokhar, A.*** **2018.** "Basic Concept of Patient Safety in Healthcare delivery", *International Journal of Current Research*, 10, (08), 72926-72932.

INTRODUCTION

The discussion on safety of patients came in light when Institute of Medicine published its report "To Err is Human: Building a Safer Health System" in 1999. This report brought awareness to the world that, at least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented, in the United States (Institute of Medicine, 2000). World Health Organisation states that, there is a one in 1,000,000 chance of a traveller being harmed while in an aircraft. In comparison, there is a one in 300 chance of a patient being harmed while being given healthcare (http://www.who.int/features/ factfiles/ patient_safety/en/) The inference is that, our healthcare system is in a bad state, with the pace of improvements and the importance of safety being much higher in other industries like aviation, automobile, food packaging, nuclear industry etc. than healthcare.

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DOI: https://doi.org/10.24941/ijcr.30612.08.2018

Institute of Medicine has mentioned that healthcare is a decade or more behind many other high-risk industries in its attention to ensuring basic safety (Institute of Medicine, 2000). WHO reports approximately 1 in 10 patients entering the hospital will suffer harm from an adverse event (http://www.who.int/ patientsafety/en/). Stating a quote by Dr. Don Berwick, President Emeritus, Institute for Healthcare Improvement, 'Every system is perfectly designed to get the results it gets.'; so the need of the hour is to work on the designing and safety in healthcare system. Johns Hopkins study suggests medical errors are third-leading cause of death in U.S., reporting from a study in which they analyzed medical death rate data over an eight-year period, and have calculated that more than 250,000 deaths per year are due to medical error in the U.S. Their figure surpasses the U.S. Centers for Disease Control and Prevention's third leading cause of death—respiratory disease, which kills close to 150,000 people per year (Makary *et al*., 2016; https://hub.jhu.edu/2016/05/03/medical-errors-third-leading-cause-of-death/6. Second study says medical errors third-leading cause of death in U.S. (Internet). USA Today. 2016 (cited 30 April 2018).

Denmark and Italy are the only countries to have a comprehensive law on patient safety, bringing together patients' rights to safe care, transparency of processes and outcomes, and fair compensation in case of harm, with the protection of health professionals' liability when they comply with guidelines and safe practices, as well as a safe space for reporting and learning from adverse events. Other countries, such as the US, have separate acts for adverse events reporting and liability protection, while in most countries patient safety is simply part of national programmes or policies and not covered by a specific, comprehensive law (for example Australia, Brazil, Canada, France, Germany, Spain, and the United Kingdom) (Bellandi, 2017) India lags behind with not even a medication error reporting system (MERS) (https://www.fip.org/files/fip/Patient%20Safety/Medication%20Error%20Reporting%20; Patel, 2010). A Harvard study by Prof Jha shows that 5.2 million medical errors are happening in India annually. Similarly the British Medical Journal quoted that India like any other developing country is recording a lot of medical errors. The reason behind this is that we have not trained doctors and nurses to measure the clinical outcomes (http://ahpi.in/Vol-4-Ceo.html).

According to Jha A.K. *et al*, there are at least 43 million injuries each year due to medical care, and nearly 23 million DALYs are lost as a consequence. A large majority of these injuries and harm occur in developing and transitional countries and these numbers will likely grow (Jha *et al*., 2013). Errors are costly! They cost in human lives. They have been estimated to result in total costs of between $17 billion and $29 billion per year in hospitals nationwide (in US). Errors also are costly in terms of loss of trust in the health care system by patients and diminished satisfaction by both patients and health professionals. Patients who experience a long hospital stay or disability as a result of errors, pay with physical and psychological discomfort. Health professionals pay with loss of morale and frustration at not being able to provide the best care possible. Society bears the cost of errors as well, in terms of lost worker productivity, reduced school attendance by children, and lower levels of population health status (Institute of Medicine, 2000). So what is a medical error? "Medical errors can be defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" (Reason, 1990)

There are 3 types of Medical Error which include

Diagnostic: which could be due to error or delay in diagnosis; failure to employ indicated tests; use of outmoded tests or therapy, failure to act on results of monitoring or testing.

Treatment: error in the performance of an operation, procedure, or test; error in administering the treatment; error in the dose or method of using a drug; avoidable delay in treatment or in responding to an abnormal test.

Preventive: failure to provide prophylactic treatment, inadequate monitoring or follow-up of treatment.

Others: failure of communication; equipment failure; other system failure (Leape, 1993). Error can be a result of slip of action which are actions not carried out as intended or planned. Slips are observable. Eg. Injecting IV instead of ID. Or they could be a memory lapse which are missed actions and omissions. They are non-observable. Eg. Forgetting to monitor electrolytes level. Or they could be due to knowledge-based mistake which is brought about by faulty plan or incorrect intentions. The intended action is wrong. Eg. Extubating a patient pre-maturely based on misapplication of guidelines. Violations are deliberate actions where someone does something and knows it to be against the rules (Reason, 1990). The commonly occurring medical errors during the course of providing health care are adverse drug events, improper transfusions, surgical injuries, wrong-site surgery, suicides, restraint-related injuries, death, falls, burns, pressure ulcers, mistaken patient identities (Oliver, 2014). The cause of these adverse events is usually not 'Intentional injury'. Instead it is due to complexity of healthcare system along with human error. One of the greatest contributors to accidents in any industry including healthcare, is human error. However, saying that an accident is due to human error is not the same as assigning blame because most human errors are induced by system failures. Humans commit errors for a variety of known and complicated reasons (Institute of Medicine, 2000). The researchers from Johns Hopkins caution that most medical errors aren't due to inherently bad doctors, and that reporting these errors shouldn't be addressed by punishment or legal action. Rather, they say, most errors represent systemic problems, including poorly coordinated care, fragmented insurance networks, the absence or underuse of safety nets, and other protocols, in addition to unwarranted variation in physician practice patterns that lack accountability (Makary, 2016; https://hub.jhu.edu/2016/05/03/medical-errors-third-leading-cause-of-death; https://www.usatoday.com/ story/ news/politics/2016/05/03/second-study-says-medical-errors-third-leading-cause-death-us/83874022/).

According to Allen Frances, Professor Emeritus at Duke University and Chairman of the DSM-IV task force, "The basic problem is that modern medicine consistently violates the ancient advice of Hippocrates: "It is better to know the patient who has the disease than the disease the patient has." He continues, "but we can't trust doctors and hospitals to get it right. I am getting in the habit of joining my friend at his visits to make sure the doctors and nurses don't screw up. You shouldn't need to bring along a doctor to protect you from your doctors. Hippocrates must be spinning in his grave. We have lost track of what should be the most important dictum in medicine, his "First, do no harm." Too many doctors, too many tests, too many procedures, and no one keeping track. Its a prescription for disaster, and the disasters keep happening." (https:// www.huffingtonpost.com/allen-frances/why-are-medical- mistakes-_b_5888408.html)

The potential for human error is amplified by poor working conditions which include

- Poor workplace conditions
- Overworked staff
- Time pressures
- Lack of safety protocols
- Lack of appropriate supervision
- Poor individual conditions (fatigue, stress or illness)
- Communication and teamwork failures (Inconsistency in team membership, Lack of information sharing, Hierarchy, Defensiveness, Conventional thinking, Complacency, Varying communication styles, Conflict, Lack of coordination, Distractions, Misinterpretation of cues, Lack of role clarity) (Carrie, 2016).

One study on physician performance found that being awake 24 hours was equivalent to having a blood alcohol level of 0.10 (legally intoxicated). (In India, BAC is set at 0.03 and in US, it is at 0.08.) (Dawson, ?). Errors can result into adverse events which are injuries that result directly from medical care, not from negative outcomes due to patient's disease (Institute of Medicine, 2000) or 'near misses' which are errors that occur but do not result in injury, harm to patient that was caught in time or simply because of luck (WHO, 2018). Of all the medical errors, diagnostic errors account for at least 17% of preventable errors in hospitalised patients. (Institute of Medicine, 2000; Leape *et al*., 1993) Diagnostic errors can be of 3 types. No fault errors - when there are masked or unusual symptoms of disease, or when a patient has not fully cooperated in care. System related - Technical failure, equipment problems and organizational flaws. Cognitive errors - Diagnosis that was wrong, missed or unintentionally delayed due to clinician error (Graber, 2005). The incidence of diagnostic error has been reported by Arthur Elstein, a cognitive psychologist interested in 'how doctors think', who studied clinical decision making for his entire career and concluded the diagnosis is wrong 10–15% of the time (Higgs, 1995). A diverse range of research approaches that have focused on this issue over the past several decades suggest that this estimate is very much on target (Berner, 2008).

Another study by Johns Hopkins University states that diagnostic errors are more common, costly and harmful than treatment mistakes. In reviewing 25 years of U.S. malpractice claim payouts, Johns Hopkins researchers found that diagnostic errors — not surgical mistakes or medication overdoses — accounted for the largest fraction of claims. The human toll of mistaken diagnoses is likely much greater than his team's review showed, Newman-Toker (Associate Professor of Neurology at the Johns Hopkins University School of Medicine) says, because the data they used covers only cases with the most severe consequences of diagnostic error. There are many others that occur daily that result in costly patient inconvenience and suffering, he says. One estimate suggests that when patients see a doctor for a new problem, the average diagnostic error rate may be as high as 15 percent. They also found that more diagnostic error claims were rooted in outpatient care than inpatient care, (68.8 percent vs. 31.2 percent) but inpatient diagnostic errors were more likely to be lethal (48.4 percent vs. 36.9 percent). The majority of diagnostic errors were missed diagnoses, rather than delayed or wrong ones (https://www.hopkinsmedicine.org/ news/media/releases/diagnostic_errors_more_common_costly_ and_harmful_than_treatment_mistakes). One of the most common causes of medical errors is medication error. 1.5 million deaths occur each year in the US due to medication error (Aspden, 2006). The IOM estimates that 1 medication error occurs per hospitalised patient each day (Aspden, 2007). The common causes are:

- Poor handwriting technique or abbreviation on prescription resulting in administering wrong drug.
- Dose or route of administration errors Failure to identify that given patient is allergic to a prescribed medication Look-alike or sound-alike drugs.
- Forgetting to specify a maximum daily dose for an 'as required' drug (Aronson, 2009)

Another cause of preventable patient harm is Healthcare Associated Infection that affects 5-15 % of hospitalised patients of which the most common is UTI affecting 40% of all cases; approximately 75% are associated with a urinary catheter (http://www.who.int/features/ factfiles/ patient_ safety/en/; Kalsi *et al*., 2003; https://www.cdc.gov /hai/ca_uti/uti.html; Septimus, 2016). Another HAI is CLABSI (Central Line Associated Bloodstream Infection) which is one of the most common infection seen in CCU. 70% of hospital acquired bloodstream infection occur due to central venous catheter leading to increased morbidity, hospital stay and cost (Septimus *et al*., 2016). HAP (Hospital Acquired Pneumonia) is the 2nd most common nosocomial infection (Antoni Torres, 2010; Rotstein *et al*., 2008). Pre-operative antibiotics have been effective in reducing the rate of SSIs, another type of HAI (Hawn *et al*., 2011). Patient falls is another major cause. Over 1/3rd of elderly people aged>65 years fall each year. (33 ?) Estimate is > 500,000 falls happen each year in US hospitals. (34 ?) About one in 10 falls result in serious injuries such as hip fracture, other fractures, subdural hematoma, or traumatic brain injury (Nevitt, 1991; Sattin, 1992).

Risk factors include

- Advanced age (age > 60)
- Muscle weakness
- Taking > 4 prescription medications (specially sedatives, hypnotics, antidepressants or benzodiazepines)
- Impaired memory
- Difficulty walking

A consequence of medical errors is unplanned readmissions, that is when patients unexpectantly return to the hospital < 30 days after being discharged (Hospital-Wide, 2018). According to a study in New England Journal of Medicine, nearly 20% of those discharged were readmitted within 30 days (Jencks, 2009)

Several factors result in this

- Poor quality of care
- Lack of guideline or polices for the standardized discharge process/care pathway
- Pressure on bed availability
- Issue of manpower shortage and management
- Breakdowns in communication during a transition of care
- Patient is discharged — prematurely from hospital or discharged to inappropriate settings
- Do not receive adequate information or resources to aid in recovery (Wong *et al*., 2018).

A wrong diagnosis can be a result of biases which may occur when the clinician holds on to a particular diagnosis (usually the initial one) and becomes dismissive to signs and symptoms pointing to another diagnosis. This is called Anchoring bias. (Redelmeier, 2005).

Availability bias is the tendency to assume a diagnosis based on recent patient encounters or memorable cases. Confirmation bias looks for evidence to support a pre-conceived opinion, rather than looking for evidence that refutes it or provides greater support to an alternate diagnosis (Redelmeier, 2005; Klein, 2005). Patient safety must be an attribute of the healthcare system. Patient safety seeks high reliability under conditions of risk.

Illness presents the first condition of risk in healthcare. Patient safety applies to the second condition: the therapeutic intervention. Sometimes the therapeutic risk is audacious, such as when a patient's heart is lifted, chilled, cut, and sewn during cardiac transplantation surgery. Risk and safety are flip sides of the therapeutic coin (Emanuel, 2008). A root cause analysis (RCA) is a retrospective systematic approach to understand the causes of an adverse event and identifying system flaws that can be corrected to prevent the error from happening again. (Patient Safety, 2018). Failure modes effects analysis (FMEA), a prospective method, is a step-by-step approach for identifying all possible failures in a design, a manufacturing or assembly process, or a product or service (Failure Mode Effects Analysis, 2018). The goal is to determine why an event happened and what can be done to prevent it from happening again; to redesign systems to be more fool-proof and able to compensate for human error.

Swiss Cheese Model of accident causation was proposed by James Reason for understanding the causes of system failures. According to this metaphor, in a complex system, hazards are prevented from causing human losses by a series of barriers. Each barrier has unintended weaknesses, or holes – hence the similarity with Swiss cheese. These weaknesses are inconstant – i.e., the holes open and close at random. When by chance all holes are aligned, the hazard reaches the patient and causes harm. This model draws attention to the healthcare system, as opposed to the individual, and to randomness, as opposed to deliberate action, in the occurrence of medical errors (Reason, 1990; Perneger, 2005). The micro system around the patient has to be improved in order to benefit from the treatment procedure. A very familiar event when a medical error occurs, is to identify who is responsible for the error and take punitive action against that individual. But this approach creates a culture of fear and doesn't address the root cause of the error. It does not improve safety. Unfortunately, health care has a long tradition of a blame culture. Blaming people who make errors doesn't get to underlying causes or help to prevent the error from happening to someone else in future (46, 47, 48?) Blame should not be put on a particular person who committed error or through whom error has been committed rather on the system that led to the mistake. Laboratory systems do not communicate directly with pharmacy systems. Even within medication systems, electronic links between parts of the system—prescribing, dispensing, and administering—typically do not exist today (David *et al*., 2009). It is essential to create and maintain effective communication amongst different departments involved in patient healthcare delivery. Concept of safety should be started as early as, in the medical curriculum that is being taught. Patient safety should be propagated as a culture. Safety should become an attitude in people. When patient safety becomes a culture the following should be invariably practiced:

- Safety should be considered the highest priority of the organization.
- There are strongly shared values and behavioural norms throughout the organization that are centered around safety.
- Resources and incentives are available for the organization to pursue and implement a safety commitment.
- There is non-hierarchical and open communication among workers—particularly in safety-related scenarios.
- There are rare occurrences of errors, but open recognition and reporting of them is accomplished without blame for individuals (Ulmer, 2009).

Strategies to reduce or prevent medication errors are the 5 R's that help to confirm several key points before administration of any medication - Right drug, Right patient, Right dose, Right route, Right time (Tyreman, 2010). Computerised Physician Order Entry (CPOE) should be brought to practice which involves entering medication orders directly into a computer system rather than on paper or verbally. Using a POE system prevented more than half of the serious medication errors. Reduction in errors was noted for all stages of the process. These results suggest that implementing even a modest POE system can result in important error reduction, if the system includes a dose selection menu, simple drug-allergy and drug-drug checking, and the requirement that clinicians indicate the route and frequency of drug doses. Furthermore, a computer system resolves the difficulty of translating illegible orders and greatly reduces the need for transcription (Bates *et al*., 1998). In 1998, Bates *et al*. found in a controlled trial that CPOE systems resulted in a 55 percent reduction in serious medication errors (Macklis *et al*., 1998). We should reduce the risk of infections by strict indications for adherence, hand hygiene, proper use of gloves, gown and mask; maintaining a sterile technique, exercising prompt removal of the catheter when no longer required and specially elevation of head end of bed in ventilated patient, measures to reduce the risk of aspiration for hospital acquired pneumonia (Septimus, 2016; Passaro *et al*., 2016). Interventions required to reduce readmissions include improving communication, patient education and providing appropriate support to patients at risk for readmissions (Kripalani *et al*., 2014). Academic medical centers (AMCs) should now work to develop a new workforce of technically-trained, yet clinically-focused, staff required to create, what the IOM refers to as a "Learning Health System" (Institute of Medicine, 2011). Team work training, effective communication skills, supportive working environment and a comfortable environment to speak when team members are in problem would lead to less errors. Also, interventions like increased observation and making the environment safe is required. Presence of pharmacists on medical rounds, have reduced errors of medication by 66% (Brown *et al*., 2008). In Surgical Anaesthesia, error were reduced from 25 to as little as 5.4 per million by using standard equipment, procedures and guidelines (http://www.ahrq.gov/qual/errback.htm). 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% (http://www.ahrq.gov/qual/errback.htm). Mnemonic to help assess the fitness of a health care professional to attend to patient care

IMSAFE

I: Illness (Are you suffering from any illness that is regarding your performance?).

M: Medications (Are you taking medications that may impair your judgement?).

S: Stress (Are you adequately managing the stressors in your life?).

A: Alcohol (Are you using alcohol in excess with negative consequences?).

F: Fatigue (Are you getting enough rest?) E: Eating (Are you maintaining a healthy diet?) (59)

According to James, John T., there was much debate after the IOM report about the accuracy of its estimates. In a sense, it does not matter whether the deaths of 100,000, 200,000 or 400,000 Americans each year are associated with Preventable Adverse Events (PAEs) in hospitals. Any of the estimates demands assertive action on the part of providers, legislators, and people who will one day become patients. Yet, the action and progress on patient safety is frustratingly slow; however, one must hope that the present, evidence-based estimate of 400,000+ deaths per year will foster an outcry for overdue changes and increased vigilance in medical care to address the problem of harm to patients who come to a hospital seeking only to be healed (James, 2013). The problem is huge and we should not wait till the time we or our near and dear ones become patients and suffer harm because of medical error. Ensuring patient safety is the responsibility of every member of the healthcare team. Patients, providers, payers and employers are all stakeholders in improving patient safety. Applying these principles can help healthcare professionals learn from past errors and develop systems that prevent future errors from harming subsequent patients. Medical errors aren't listed as an option for cause of death on death certificates. Errors aren't counted in national statistics (Makary, 2016). Introduction of these in the system will help to find the exact burden of medical errors that occur while treating a patient.

IBM Watson is being trained as a diagnosis tool, to which best medical journals and textbooks have been fed. Watson read all of Medline, PubMed, dozens of textbooks and asked and answered every question on board exams. "It's all the information you'd need to be as good as the smartest second year med student," says Siegel. The next, more difficult phase of the project is to load Watson up with anonymized patient records so it can marry what it knows about diagnostics with the procedures, treatments and outcomes that follow. Then doctors can query Watson and get a big assist in figuring out what to do (and what NOT to do) next (https://www.forbes.com/sites/bruceupbin/2011/05/ 25/ibms-watson-now-a-second-year-med-student/#732d7baf300a). In 2009, 10 years after the *To Err is Human* IOM report, Leape and colleagues (2009) concluded that progress on patient safety had been insufficient; in fact, they said that "safety does not depend just on measurement, practices, and rules, nor does it depend on any specific improvement methods; it depends on achieving a culture of trust, reporting, transparency, and discipline (Leape, 2009)

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