

Special Issue on  
Healthcare Sector



# Journal of Management

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Dr. Sunil Kumar Saggar\*

## Critical Aspects in Patient Safety

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### Abstract

*Safety provided to patients is an important measure of the quality care provided by hospitals. This article describes various aspects of patient safety and how the hospital shifts affect the safety of care being delivered. It also mentions the measures for improving patient's safety in a hospital setting.*

### Definition of Patient Safety

The simplest definition of patient safety is, prevention of errors and adverse effects to patients associated with healthcare. Healthcare has become more complex with greater use of new technologies, medicines and treatments. Health services treat older and sicker patients who often present with significant co-morbidities requiring more and more difficult decisions as to healthcare priorities. Increasing economic pressure on health systems often leads to overloaded healthcare environments.

Unexpected and unwanted events can take place in any setting where healthcare is delivered at various levels— primary, secondary and tertiary care, community care, social and private care, acute and chronic care. Every 10th patient in Europe experiences preventable harm or adverse events in hospital, causing suffering and loss for the patient, families and healthcare providers, and taking a high financial toll on health care systems. Safety is part of the quality agenda and therefore a dimension of the quality culture, requiring broad commitment from both the organization and the community. The need of ensuring patients safety and responsibility in the case of handicapped and differently-able patients further throws a challenge for the healthcare providers. Patient's safety is not limited to radiation safety and taking informed consents.

World Health Organisation/Europe is committed to enhancing the quality of healthcare, and patient safety is a crucial element of that quality. This encompasses:

- Developing active networks of patients and providers
- Sharing experiences

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\* CEO, Jaipur Golden Hospital, Delhi (email: ceo@jghdelhi.net)

- Learning from failure and pro-active risk assessment
- Facilitating effective evidence-based care
- Monitoring improvement
- Empowering and educating patients and the public, as partners in the process of care
- Installing process to improve patients radiation safety, avoiding medication errors
- Taking informed consents.

The diversity in the WHO European Region's 53 member States is reflected in wide disparities in health systems' development, funding mechanisms and resources. Varying paces of socioeconomic growth and changes in demography and lifestyle practices have resulted in widening gaps in life expectancy between groups of countries, and sometimes within countries. At the same time, expectations of health system performance are mounting, challenging its readiness to change and adjust to technological development and emerging health threats.

Evidence has shown that to maintain and increase the health status of their populations, countries in the European region must strengthen their health systems in terms of addressing patient safety and quality of care. The '2008 Tallinn Charter: Health Systems for Health and Wealth' renewed the concerted political commitment of its Member States to strengthen the quality agenda.

### **Making Improvements in Radiation Safety to increase Patients safety including that of the other users.**

There are numerous ways healthcare facilities can make radiation safety improvements. An excellent first step is to require that all who work with or around radiation, including physicians, equipment operators, technologists, nurses, anesthesiologists, and any others, take a radiation safety course. Although some may argue there is no time in the work day for this, it must be made a priority. Training can't help but it results in improvement in safer use of radiation. California, for instance, requires anyone who works with fluoroscopy, including technologists, physician assistants, nurses and physicians, to attend a fluoroscopy class and be issued a permit.

It is also important to foster good communication among the healthcare team, and ensure that everyone understands radiation safety is his or her job. Nurses and technologists must be encouraged to speak up if they are concerned about safety practices. Physicians must be made to know that their support staff is required to speak up, and that they need to take those concerns under consideration and not ignore them. The U.S. military has created a system of openness and communication,

where all team members are expected to speak up and make suggestions. Unfortunately, this isn't part of the culture at many hospitals.

Dose reduction also is important because radiation scatter from the patient causes the most exposure to workers. Controlling patient dose, therefore, benefits workers as well as patients. That includes minimizing fluoroscopy time as well as the number of fluoroscopic images.

Shielding is another important safety mechanism, and there are many types in existence. It is important to not only use all that are available (requesting additional shielding, if appropriate), but to use them effectively. Shielding includes: 1) Personal: aprons with thyroid shields, leaded glasses; 2) Equipment-mounted: protective drapes (particularly important for eye protection during interventional procedures); 3) Rolling and stationary shields; and 4) Disposable patient drapes to prevent scatter radiation. Architectural shielding is also required, in that any room where radiation is used must have a predetermined thickness of lead in the walls, doors, windows, etc.

Additionally, there are numerous positional and equipment-related radiation safety features that require full knowledge not only of the equipment, but of the properties of radiation. Again, those who do not have a radiation background are at a disadvantage because they don't fully grasp how radiation works and, therefore, how to work with it more safely.

Technologists should make full use of radiation-reduction features built into the equipment. Manufacturers should be requested to regularly provide training for new workers, who may be unaware of the equipment's safety features. Operators should learn how to use and position the system around the patient to ensure the lowest radiation dose to the patient and workers. Positioning can be done effectively or poorly, and again, physicians and healthcare workers must learn about the benefits and trade-offs.

In particular, one area that is often overlooked is the positioning of the tube that produces the x-ray, which passes through the patient to the detector. The detector should be as close to the patient as possible, in order to block scatter radiation, improve image quality, and require less radiation. During procedures such as cardiac angioplasty and stenting, many operators consider it a convenience to have the detector further away from the patient so it is more easily moved around the patient. Unfortunately, this results in 50 to 60 percent more radiation to the patient if it's done incorrectly.

Radiation is an important diagnostic tool, but it must be treated with respect. It has become apparent that there is significant room for improvement in radiation

safety practices, which can vary widely from institution to institution, and from clinician to clinician. All who work in hospital radiation environments, including technologists, nurses, physicians and others, must make a commitment to the safer use of radiation, for the good of everyone.

### **What Is Informed Consent and its Role in Improving Patients Safety?**

The document a patient signs to verify that he has engaged in a dialog with a health care practitioner about a proposed medical treatment is commonly referred to as an “informed consent.” However, it is the dialog itself that constitutes the actual informed consent process.<sup>3</sup> Informed consent is used in both clinical and research settings; this review focuses primarily on informed consent in the clinical setting.

Although no evidence currently links informed consent with improved adherence to medication or other self-care procedures, to prevention of medical errors, or to improved overall health outcomes, some evidence links increased patient-physician communication with more realistic expectations, increased patient satisfaction, and fewer medical malpractice claims.

### **How is Informed Consent to be implemented?**

A complete informed consent process consists of seven elements: (1) Discussing the patient’s role in the decision-making process; (2) Describing the clinical issue and suggested treatment; (3) Discussing alternatives to the suggested treatment (including the option of no treatment); (4) Discussing risks and benefits of the suggested treatment (and comparing them to the risks and benefits of alternatives); (5) Discussing related uncertainties; (6) Assessing the patient’s understanding of the information provided; and (7) Eliciting the patient’s preference (and thereby consent).<sup>10</sup> Not every detail needs to be discussed, but all details needed for a “reasonable person” to make a decision must be provided. Therefore, all risks of serious complications, even if they occur very rarely, need to be discussed. Less serious risks need to be discussed if they occur more commonly. This process of informed consent may occur within one encounter, or across multiple encounters.

Although informed consent is often used prior to invasive procedures, designated radiologic examinations, and other high-risk medical treatments (e.g., chemotherapy), the process of informed consent, or informed decision-making, is applicable to all medical care decisions where one or more alternatives exist (including the alternative of no treatment or procedure). Recently, there has also been increased attention to the importance of informed consent in screening procedures and genetic testing. As such, the informed consent process has considerable overlap with the principles of “shared decision making.”

## How Hospital Shift Changes Puts A Strain On Patient Safety?

Shift changes of both physicians and nursing staff are always inevitable in a hospital setting. This can be a precarious time for patients as effective communication between medical staff going off duty and staff coming on duty is crucial for maximum patient safety. It is important for doctors and nurses to have a plan for quickly yet efficiently communicating the most vital aspects of each patient's condition to the next shift for the benefit of both patients and staff.

### A. Severity of Condition Supersedes Bed Number

Research conducted by Kaiser Health, indicates that one big problem in American hospitals is doctors and nurses communicating with the incoming shift in bed number order instead of in the order of severity of case. Medical errors have been shown to be reduced when doctors and nurses discussing patient cases with the next shift begin with the most serious cases first. This helps to better insure hospital patient safety as shift change time is limited and more time is typically needed to discuss necessary treatment for the sickest patients on the floor.

### B. Patient Privacy

Doctors and nurses usually have to clear the floor of patients' family members prior to discussing care plans with the next shift. This is due to patient privacy regulations outlined in the Federal Health Information Portability and Accountability Act (HIPAA). Hospital staff cannot take the chance of having anyone overhear the private health information (PHI) of any patient; therefore, all visitors generally have to leave the floor during shift change. It is best if hospital staff begins moving visitors off the floor a little before shift change to allow maximum time of outgoing shifts and incoming shifts to review patient cases. This tends to help improve patient safety during shift change challenges.

### C. Vicious Cycle

Severe medical errors caused by inadequate time spent on the most severe cases threaten patient safety and may result in injuries and even deaths in patient populations. These kinds of tragedies often lead to malpractice lawsuits which in turn result in higher malpractice premiums for the hospital. When the higher malpractice premiums increase hospital costs, budget cuts have to be made in other areas to offset the added malpractice costs. Many times, layoffs in nursing staff and other staff result. Less staff puts the hospital at a greater risk for medical errors, and so continues the vicious cycle. The best way to stop the cycle is for hospital staff to address patient cases according to severity during shift changes.

The research conducted by Kaiser Health shows conclusively that shift change is the most dangerous time for patients as this is when miscommunications regarding patient medications and treatment tend to take place. This inadequate communication is what leads to medical errors which have been proven to be the number one cause of preventable patient deaths in a hospital setting. This is why it is vital that medical staff properly communicate during shift changes.

### **Improve Patient Safety: 6 Tips for Hospitals**

The complexity of the health care system requires the need for quality and safety standards to minimize preventable medical errors. Following evidence-based practices to reduce errors is a critical component in maintaining patient safety in hospital settings.

### **Patient Safety Assessment**

To improve the efficacy of the organization's safety plan, it is important to first evaluate current hospital patient safety culture. The Agency for Healthcare Research and Quality (AHRQ) provides a staff survey tool that can be utilized to measure the effectiveness of current interventions utilized. The impact of hospital practices on safety outcomes can be tracked over time using this data. Methods for ensuring continued safety for patients can be implemented and reassessed using this helpful standardized tool.

### **Medication Safety**

Hospitals can utilize digital drug information made available at the point of care to effectively reduce potential medication errors. Implementing a computerized provider order entry system allows medication orders to be entered directly into the system and sent electronically to the patient's pharmacy. This standardized method ensures legible, complete orders and can help to significantly reduce errors from the onset. For pharmacists, work spaces should be conducive to filling prescriptions without environmental distractions.

### **Bar Coded Wristbands**

Implementing a positive patient identification system is a significant way to improve patient safety in hospital settings. Bar coded wristbands provide a comprehensive way to improve accuracy of patient identification, and therefore accurate administration of medication and appropriate treatment for patients. The system not only identifies patients before any treatment is provided, but stores relevant patient information to allow clinicians to efficiently and effectively administer patient care. Bar coding can include all critical individual information including patient allergies, fall alerts and DNR orders.

## Limited Shift Durations

Fatigue among physicians is an important consideration in regard to patient safety. Sleep deprivation impairs cognitive function and performance, and medical errors are more likely to occur when medical personnel are not well rested. Hospital systems can strive to eliminate consecutive 30-hour shifts, and establish appropriate work schedules for physicians and nurses. Call schedule policies and practices should reflect both continuity of care for patients and medical team wellness to support optimal patient care.

## Fall Prevention

Falls are the most common safety incident occurring in hospitals. Decreasing the number of falls and reducing the risk of injury related to falls for patients requires a risk-prediction and management plan. Identifying patient risk for falls, as well as educating patients, family members and staff about falls is an important part of a prevention program. Hospitals can strive to prevent patient falls by implementing standard safety measures. Providing well-designed rooms and bathrooms for patients, along with nurses' stations that allow easy access to patients are important considerations in minimizing patient risk for falls.

## Avoiding Hospital -Acquired Infections

Health care-associated infections are a common complication for hospital patients. Simple measures can be taken to prevent the majority of infections patients acquire during their hospital stay and to reduce resulting readmission rates. Hand hygiene, appropriate insertion site selection and prompt removal of catheters are just a few of the important identified clinical practices that can reduce the rate of hospital-acquired infections. Additionally, offering single bed rooms for patients, improving air filtration systems, and providing convenient hand washing stations throughout the facility can support a reduced infection rate within the hospital setting.

Utilizing a systems-approach to address safety within hospitals can greatly improve outcomes. A trained staff that communicates well, provides rapid-response care, and functions as an integrative team is an important part of reducing medical errors and improving patient safety.

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Rajeev Chourey\*

## Risk Management in Hospitals

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### Abstract

*All human beings and organizations are exposed to risk at every stage of their lives. Hospitals also face various types of risks and even pose serious risks to the staff, patients and community. Most of these risks can be eliminated or minimized by either having a proactive approach of identification and analysis or a reactive approach by conducting a proper root cause analysis after the event has occurred. Risk Management has become a very important aspect of operations management in hospitals now. The top management, operations managers and quality managers need to accord top priority to risk management activities and encourage open and blame-free incident reporting and analysis system in order to minimize the risks to staff, patients and community at large.*

### Introduction

The Oxford dictionary defines risk as “a situation involving exposure to danger”. Merriam-Webster’s dictionary defines risk as “the possibility that something bad or unpleasant (such as injury or loss) will happen”. Thus, risk may be defined as the probability of something bad or wrong happening to a person or an organization. It is the chance of being potentially harmed. It could also mean a chance of making a good or bad choice. The ISO 31000 (2009) / ISO Guide 73:2002 definition of risk is the “effect of uncertainty on objectives”. In this definition, uncertainties include events (which may or may not happen) and uncertainties caused by ambiguity or a lack of information (Wikipedia). Risk always goes hand in hand with life. Anyone who is born faces risk. This is true for organizations too. Hospitals, the people working there and those utilizing the services of the hospital are always at risk.

The various types of risks faced by and in hospitals can be divided in two categories, those that can be eliminated completely and those that can only be minimized but not eliminated. Therefore, hospitals have to learn to manage the risk. The concept of risk management dates back to four thousand years ago to the Babylonian code of Hammurabi. According to this code physicians who caused death or harm through their own malpractice had to face severe punishment. (Florence Kavalier, 2014).

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\* Vice-president (Operations & Quality), CARE Group of Hospitals, Hyderabad (email: rajmeetu@gmail.com)

The reference to risk management after that is found during World War II (Dionne, 2013). It was mainly associated with financial markets.

The Economic Times, in its April 11, 2013 issue defined risk management in the world of finance as “the practice of identifying potential risks in advance, analyzing them and taking precautionary steps to reduce/curb the risk”. We can adapt this definition for risk management in hospitals too. Risk management in hospitals also comprises of identifying potential risks in advance, analyzing them and taking preventive steps to ensure that the risk is either eliminated or reduced. This management for hospitals can also be defined as an organized effort to identify, assess, and reduce, where appropriate, risks to patients, visitors, staff and organizational assets. (Florence Kavalier, 2014). It is evident from the above definitions that risk management is a proactive approach and not a reactive approach. However, in hospital settings, it is sometimes difficult to predict the risk of every nature and at times hospitals need to adopt a reactive approach too in order to ensure that the further harm is minimized.

Hospitals can face risks from their internal environment as well as external environment. The biggest risk from the internal environment is the ‘culture’ of the hospital. Culture of an organization describes the personality of the organization. The culture comprises of purpose, mission, values, assumptions and attitudes displayed by the staff. All these are derived from the vision of the hospital. It is essential for a hospital to have a strong vision statement that leads to an appropriate mission and set of values and directs the behavior of the staff. Hospitals function with the help of knowledge workers involving physicians, nurses, technicians, administrators and other paramedical staff. Each knowledge worker is an expert in his/her own field and it becomes challenging to establish a culture of adequate and effective communication amongst them. A communication gap can lead to various risks for a patient. JCI in its report titled “JC Root Causes and Percentages for Sentinel Events (All Categories)” January 1995-December 2005, stated that ineffective communication amongst healthcare workers was the root cause of nearly 66% of reported sentinel events (events that lead to patient harm).

Patient experience is one of the key measurable parameters that hospitals use in order to monitor the quality of services provided by them. The attitude of the staff plays a very important role in ensuring patient delight. The way the staff greet each other, how they receive and greet the patient, how much time a patient is made to wait for a consultation, how much attention is paid to the patient and relative’s counseling, etc. tells about the culture of the hospital. Hospitals fail to grow if the internal environment is not patient and staff friendly.

Hospitals need to manage this risk well in order to ensure patient delight and organizational growth. The top management of the hospital needs to define the

right vision for the organization and values that clearly spell out right and wrong behavior. This vision and the values need to be communicated well so that they become the DNA of the organization. Hospitals can minimize this risk by having a robust communication and staff training and reward programs on a regular basis and also by walking the talk.

The external environment of the hospital mainly comprises of regulatory framework, accreditation systems, competitors and suppliers. The external environment also poses various risks to the hospitals. Any change in the regulatory framework can affect its expenditure and may lead to a reduction in EBIDTA margins. It can also impact its revenue. For example when several drugs were brought under price control in India recently, it impacted the margins hospitals were deriving from the sale of drugs. Similarly, few years ago when CGHS revised its packages for certain procedures downwards, the revenue of CGHS empanelled hospitals was affected.

Practices adopted by competitors also pose a risk to hospitals, especially, practices related to marketing, referral fee, poaching of staff, and the HR policies of competitors. Accreditation systems can also be a risk from the external point of view in the sense that if hospital does not keep itself abreast with the country's accreditation system, it risks losing its staff and patients to other accredited hospitals.

Hospitals can mitigate this risk by having a robust costing methodology to price their services optimally and identify the empanelment and service mix that can give them better contribution margins. Hospitals can also develop a good market intelligence strategy to keep pace with the competition.

A hospital also faces risk from its suppliers. Hospitals require timely delivery of all drugs and consumables in the right quantity and of the right quality. We have had many instances in India where patients were harmed by spurious/substandard drugs supplied to the hospital and patients developed severe complications. A news report published by DNA in Dec 2013 said that substandard drugs were the biggest cause of worry in India. In 2014, around 11 women died in Chhattisgarh within hours of taking two post-surgery drugs that were suspected to be spurious. Recently, in a hospital in Kwai Chung in China, an elderly heart patient died as the stent deployed could not be expanded-(as reported in [thestandard.com.hk](http://thestandard.com.hk)).

Poor recovery of debts can pose a serious risk to hospitals. Many hospitals provide services on credit basis to various private and government organizations, insurance and government beneficiaries and the reimbursement period ranges anywhere between seven days to several years. Hospitals run a risk of piling bad debts and running out of cash when debt recovery is slow or delayed. Hence, they need to have robust internal processes for timely and accurate billing and regular follow-up in order to minimize this risk.

Another area of risks is occupational health hazard faced by the staff while working in various industries. According to the WHO, occupational health deals with all aspects of health and safety in the workplace and has a strong focus on primary prevention of hazards (Wikipedia). The staff working in hospitals face occupational health hazards and risk acquiring various communicable and infective diseases, while treating patients suffering from such diseases. Recently, when there was an outbreak of swine flu in Hyderabad, many doctors and nurses also acquired swine flu. Similarly, some doctors and nurses contracted EBOLA in the US and other countries. Other occupational health hazards that the staff face in hospitals are risk of needle prick injuries, accidental exposure to blood and body fluids, exposure to hazardous chemicals, stress, workplace violence, harassment by superiors and colleagues, risk of manhandling by patient's relatives, exposure to radiation etc. A study conducted in Turkish hospitals suggested that hospital workers experience more low back pain than many other groups. (Karahana A, 2009). The world health report 2002 stated that 2.5% of HIV, 40% of Hepatitis B (HBV) and Hepatitis C cases among healthcare workers worldwide were the result of occupational exposure. (WHO, 2002)

The staff and hospital management both have to share equal responsibility in minimizing this risk. The hospital management should provide adequate resources that reduce the chance of risk due to occupational health hazards. The hospital management has to ensure that PPEs (Personal Protective Equipment) like latex gloves, gowns, eye shields, etc. are adequately provided to all the staff working in direct patient care areas. The hospital management also needs to provide pre-exposure prophylaxis and educate the staff and make them aware of the risks and ways to minimize this risks by adhering to universal precautions, measures/guidelines as directed by government organizations like the Centre for disease control (CDC). The staff also have the responsibility of adhering to these guidelines scrupulously to avoid and minimize the risks.

Exposure to radiation and radioactive material is another risk that the staff faces in hospitals. Doctors, nurses, technicians and others who work in departments like Radiology, Cath lab, Nuclear medicine and Intensive Care Units, face a risk of over-exposure to radiation. For example, hospitals and staff in India need to ensure that all the guidelines defined by AERB are followed in all aspects, in order to reduce the harmful effects of radiation or radioactive materials.

Hospitals also face the risk of malpractice claims. In 2013, The Supreme Court asked AMRI hospital in Kolkata and three doctors to pay Rs 5.96 crore as compensation to a patient's relative for medical negligence. Such risks can be minimized if hospitals have a robust clinical audit in place. A clinical audit may be defined as peer review for evaluation of medical care through retrospective and concurrent analysis of

medical record(NABH, 2011). Hospitals can also reduce this risk by ensuring proper counseling of the patient and the patient's relatives as well as ensuring complete documentation in chronological order including informed consent. A study has shown that Risk management efforts may be associated with more positive malpractice claims experience.(Laura L.Morlock, 1991)

The most important part of risk management in hospitals is managing the risk to patients. Patients are exposed to risks related to structure and processes in the hospital. Poor facility management and inadequate infrastructure can be a serious factor. As recently as July 31, 2015, The Hindu reported that an 80 year old man, who had come as an attendant with his wife, died after sustaining head injuries when he fell into the elevator shaft at a private hospital in Bengaluru. The structure also includes the quality and training of staff employed in hospital. The staff can pose serious risk if their privileging is not as per their qualification and training. Also, inadequate training and lack of monitoring of the staff can lead to serious risks. In 2014 a patient died after a ward boy removed his oxygen mask, while in an inebriated state. Non-compliance to fire safety norms can also be a serious risk factor for patients. We are all aware of the incident that happened in a well-known hospital in Kolkata where many patients died in a fire.

Such risks related to structure can be minimized by having regular facility rounds by a designated team headed by a Safety Officer. Many hospitals in India, especially those that are NABH or JCI accredited, have adopted this system of facility or safety rounds on a weekly or monthly basis to identify structural risks and minimize their impact to the maximum extent possible, by taking appropriate steps within the stipulated time. This is in line with the executive walk-around concept in the US hospitals. Hazard Identification and Risk Assessment (HIRA) is another tool that hospitals use to manage risk.

Patients are also at risk in hospitals when either processes are not standardized or not adhered to. Medication errors, wrong site surgery, hospital acquired infections, patient falls, bed sores, etc. are some major risks that the patient is exposed to on account of improper processes or process failures. The IOM, in its report titled - "To err is human" estimated that between 44,000 and 98,000 deaths are caused by medical errors in US hospitals. These errors are preventable. A study found that medication errors caused 20% of all injuries, with 18% of these to be preventable (Reuben, 2002). These errors indicate a breakdown in the system or wrong decision making. Hospitals need to ensure that these errors are not ignored; they should be reported so that they can be analyzed and corrective and preventive actions can be taken.(Swaminath G., 2010).

Hospital acquired infections pose a constant threat to patients."In some studies hospital acquired infections have ranged from 1% in parts of Europe and North

America to more than 40% in parts of Asia, Latin America and sub-Saharan Africa".(Saxena P, 2014). Some of infections that patients can acquire in hospitals are Ventilator Associated Pneumonia (VAP), Catheter Associated Urinary Tract Infections, Blood stream infections etc. These not only add to mortality but also increase average length of stay in hospitals, adding substantially to hospital and patient costs.(Pramil Tiwari, 2013).Hospitals can minimize this risk to patients by adhering to good hand hygiene practice and implementing the guidelines defined by CDC. Many hospitals have adopted 'bundles'- a checklist of measures that can prevent and reduce infections- like the VAP. Some studies have shown that risk of HAI can be significantly reduced through proper training of the staff.(Saxena P, 2014)

Various tools are available which can be applied by hospitals to minimize these risks. Some of them are discussed here in brief.

Hospitals can use the well-tested PDCA tool for minimizing the risks. The planning phase could include formulation of a Risk Management committee with well-defined roles and responsibilities as well as the methodology to be adopted for identifying potential risks. The DO phase can include facility rounds by a multidisciplinary team on a regular basis- weekly or monthly- depending on the number of beds in the hospital. The risks identified can be recorded and the team can formulate a time bound plan to take corrective and preventive steps. The CHECK phase can consist of reviewing the minutes of the meeting and the status of corrective and preventive actions. The ACT phase could include review of the plan on a regular basis, mock drills to check the preparedness and readiness etc. National Accreditation Board for Hospitals and Healthcare Providers (NABH) standards require that mock drills for fire and non-fire emergencies are conducted at least twice a year.

Hazard Identification and Risk Assessment (HIRA) is another popular tool that hospitals can use as a risk management program. HIRA follows methodology similar to PDCA with little modification. It involves steps like identification of the hazard, assessing the risk associated with these hazards, controlling the risks implementing additional risk control measures and monitoring and reviewing. Risk assessment includes prioritization of the risks and dividing them into various risk categories, based on exposure factors. The risks are then rated as (critical, moderate, high, low and very low) based on a risk rating matrix, which is a combination of consequences (like catastrophic, major, minor, etc.) and the likelihood of their occurrence- (certain to occur, unlikely to occur or rare, etc.). The risks categorized as critical are to be attended to immediately and those categorized as very low can be attended to after all other risks have been either eliminated or minimized. Control measures involve eliminating the risk- if the risks cannot be eliminated then actions can be taken like substituting the hazard with something safer or isolating the hazard from

people, for example, restricting the entry of unwanted people in ICUs and reducing the exposure of people to risks or providing PPEs to the staff. These actions need to be monitored for their effectiveness and reviewed on periodical basis. (Sydney, 2012)

The Failure Mode and Effect Analysis (FMEA) is another effective tool that can be used for minimizing the risks that arise due to process failures. The methodology is similar to HIRA where the risk is accorded a Risk Priority Number (RPN) and priorities are assigned to risks with the highest RPN. The FMEA is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change. FMEA includes review of the steps in the process, failure modes (What could go wrong?), failure causes (Why would the failure happen?) and failure effects (What would be the consequences of each failure?). FMEA is particularly useful in evaluating a new process prior to implementation and in assessing the impact of a proposed change to an existing process. (improvement, 2012).

## Conclusion

Hospitals are complex and function in a risk-laden environment which expose the staff, patients and visitors to various risks. Risk management is the need of the hour to ensure that these risks are either eliminated or minimized. The most important step is to have a system of identification of risk factors and encourage the culture of reporting the minutest of risk factors, incidents and near misses by the staff and visitors. A root cause analysis should be done to identify the root cause of the risk and ensure they are either eliminated or exposure is minimized by timely corrective and preventive measures. Hospitals can use various tools available and also have a robust system of training and development of staff.

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Dr.Ravindra V.Karanjekar\* & Dr.Rudradatta J.Shrotriya\*\*

## Patient Safety: Impact of Medication Errors

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### Abstract

*Every error leads to a minor or a major impact. A medication error invariably harms patients. There is also evidence that the death rate from medication errors is increasing. Several factors contribute to this increase in medication errors and adverse drug events. This article makes a critical review of the role of medication errors in patients' safety.*

### Introduction

According to the Division of Medication Error Prevention and Analysis (DMEPA) under the Centre for Drug Evaluation and Research (CDER) of U.S. Food and Drug administration (FDA), a medication error is “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.”<sup>1</sup>

A medication error is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient.

Medication errors may occur in any environment, doctor's office, pharmacy, hospital wards or homes. Such errors may result from errors in prescribing, transcribing, communication, packaging and labelling, distribution and other practices.

Medication errors may arise due to -

- Choice of medication - irrational, inappropriate, and ineffective prescribing, under prescribing and overprescribing;
- Errors in prescription - form, dose, frequency, route of administration. This also includes illegibility of prescriptions.
- Manufacturing defects - contaminants or adulterants, misleading packaging and wrong strengths of medication.

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\* Corporate CEO, Jupitar Hospital, Thane, Maharashtra  
(e mail-rkaranjekar48@ gmail.com)

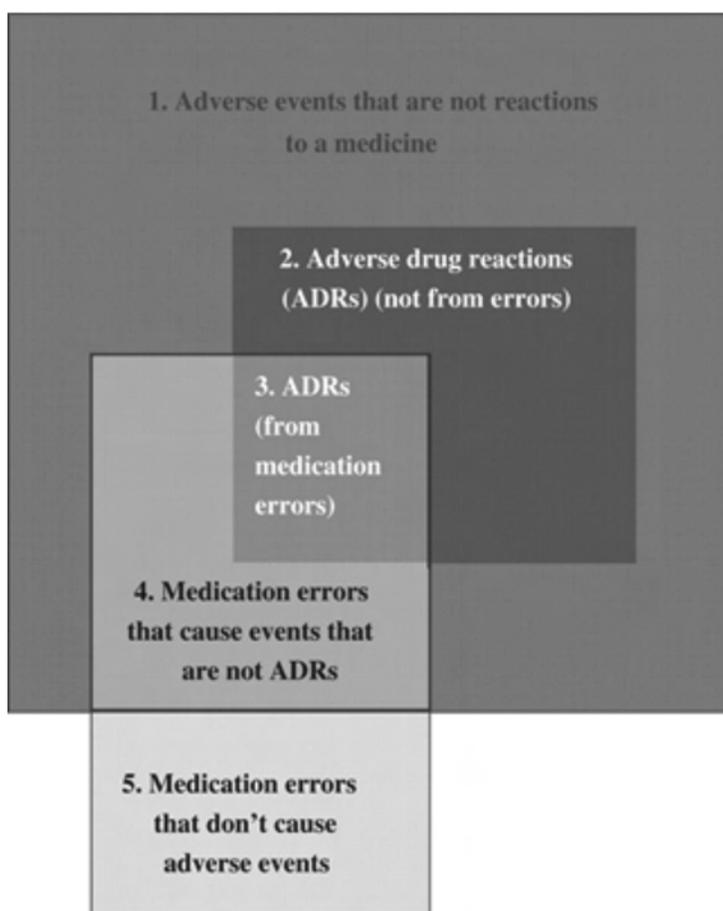
\*\* AGM-Operations, Jupitar Hospital, Thane, Maharashtra  
(e mail-shrotriya.r@ gmail.com)

- Dispensing errors - wrong drug, wrong formulation, wrong form of same formulation, wrong dose.
- Drug administration or consumption errors - wrong drug, wrong dose, wrong route, wrong frequency, wrong duration.
- Errors in monitoring - failing to alter therapy when required, erroneous alteration.<sup>2</sup>

### Adverse Drug Event

An adverse drug reaction (ADR) is ‘an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product.’<sup>3</sup>

Some medication errors result in ADRs but many do not; occasionally a medication error can result in an adverse event that is not an ADR for example, when a cannula penetrates a blood vessel and a haematoma results.



Detection of medication errors begins with reporting of such events. Reporting should start with trivial errors and it should be encouraged to detect system failures that result in minor errors which can later become serious. Medication errors are most often trivial errors. However occasionally they can be serious and it is important to detect them. Medication error reporting should be blame free and non-punitive.

In the US, The DMEPA has a medication error prevention program staffed with healthcare professionals whose main duties include reviewing medication error reports sent to Med-Watch, evaluate causality, and analyze the data to provide solutions to reduce the risk of medication errors to industry and others at FDA.

In UK, the Medicines and Healthcare products Regulatory Agency (MHRA) operates a pharmacovigilance system to monitor the use of medicines in everyday practice. The National Reporting and Learning System (NRLS) is being developed as an integrated reporting route for medication error incidents in England by National Health Service (NHS) England and the MHRA.

The estimated frequency of occurrence of medication errors depends on the method of detection used.<sup>4</sup> Most medication errors go unnoticed (the error iceberg).<sup>5</sup> Among the errors that are detected, a minority actually result in ADRs, or are serious errors.

In a UK hospital study of 36,200 medication orders, a prescribing error was identified in 1.5% and most (54%) were associated with the choice of dose; errors were potentially serious in 0.4%.<sup>6</sup>

In a survey of 40 000 medication errors in 173 hospital trusts in England and Wales in the 12 months to July 2006, collected by the National Patient Safety Agency, <“15% caused slight harm and 5% moderate or severe harm.”<sup>7</sup>

In a US study, 1.7% of prescriptions dispensed from community pharmacies contained errors.<sup>8</sup> Since <“3 billion prescriptions are dispensed each year in the USA, <“50 million would contain errors. Of those, only <“0.1% were thought to be clinically important, giving an annual incidence of such errors of about 50 000. Wrong label information and instructions were the most common types of errors.

Most litigations in the UK medical defence organizations according to a 2000 report<sup>9</sup> were due to medication errors. 25% of all litigation claims in general medical practice involved the following errors:

- Errors in prescribing and dispensing (including a wrong drug, wrong dosage, or wrong route of administration)
- Overprescribing without proper checks;

- Lack of adequate monitoring and
- Lack of education regarding adverse effects.

There is also evidence that the death rate from medication errors is increasing. In US, between 1983 and 1993 the number of deaths from medication errors and adverse reactions to medicines in hospitals increased from 2876 to 7391<sup>10</sup>. In the UK from 1990 to 2000 the annual number of deaths from medication errors increased from about 20 to just under 200<sup>11</sup>. Several factors contribute to this increase in medication errors and adverse drug events. Increasing patient volumes, newer drugs and narrower safety margins, complex treatment protocols and advanced age of population tends to increase the risk of medication errors.<sup>12</sup>

In a study<sup>13</sup> conducted in two large hospitals in Merseyside to determine the burden of ADRs in the NHS, it was found that in a period of six months out of 18,820 patients aged over 16 years admitted to hospital, 1,225 admissions were related to an ADR. Giving a prevalence of 6.5%. In 80% of these cases ADR was judged to be directly responsible for leading to admission. 72% of ADR-related admissions were judged as avoidable, average length of stay was 8 days and the projected annual cost of such admissions to the NHS was £466 million.

### **Types of Medication Errors**

Medication errors are classified into contextual, modal and psychological. Contextual refers to the context in which the error occurs. It refers to the time, place, person and other factors in a given situation. Modal refers to the mode of occurrence of error. It can be either commission or omission. Psychological classification explains the error with respect to human error rather than system error or failure<sup>14</sup>.

Medication errors can be further divided into four types based on psychological classification. These are also referred to as “active failures”.

1. Knowledge based errors. These occur because of lack of knowledge or failure to acquire the required information, eg. Failure to elicit history of hypersensitivity to a drug prior to its administration and having a reaction. These errors are due to lacunae in communication and failure to acquire or access to adequate information.
2. Rule based errors. These errors occur due to failure to follow established rules or due to wrong rules set. Hypersensitivity testing prior to administration of parenteral antibiotics being taken for the first time by the patient. Following this rule can avoid hypersensitivity reactions in many patients.
3. Action based errors. Errors resulting from faulty actions. Wrong drug, wrong dose, wrong route, wrong time, and wrong patient. Mostly occur due to lapses in attention.

4. Memory based errors. Occur due to lapses in memory. Forgetting that a particular drug has been withheld till the relevant investigation reports arrive.

Psychological classification brings out the human based errors. There are several system based factors which contribute to errors. These factors are referred to as latent factors. Several examples of latent factors can directly and indirectly contribute to the occurrence of errors. Short staffing, extended shifts and working overtime, distractions at work place, exhaustion and depression are all very relevant factors.

Errors in prescription may be due to irrational prescribing, ineffective or inappropriate prescribing which may be under prescribing or overprescribing. Prescription may be incomplete or illegible. Indent errors arise from requesting the wrong drug, dose or form. Dispensing error is similar to indent error, prolonged delay also indicates dispensing error. Errors in administration are action errors. Documentation errors - medication may be administered but not documented or documented but not administered.

A balanced prescription answers nine questions (adapted from the MedicationAppropriateness Index):-

1. Indication: is the drug indicated?
2. Effectiveness: is the drug prescribed, effective for the condition?
3. Diseases: are there important co-morbidities that could affect the response to the drug?
4. Other similar drugs: is the patient already taking another drug with the same action?
5. Interactions are there clinically important drug-drug interactions with other drugs that the patient is taking?
6. Dosage: what is the correct dosage regimen (dose, frequency, route, formulation)?
7. Orders: what are the correct directions for giving the drug and are they practical?
8. Period: what is the appropriate duration of therapy?
9. Economics: is the drug cost-effective?

The mnemonic for this list is 'i.e. do I dope?'

### **Detection, Reporting and Analysis of Medication Errors**

It is very important to understand the above classification in order to prevent, detect and analyse medication errors. Policies and procedures will be only as good as the reporting and analysis of the factors that lead to the event.

The NHS and MHRA in UK are working together to improve medication error reporting and governance of error related learnings. MHRA has a reporting algorithm for both medication errors and adverse drug reactions. Medication errors are reported to the NRLS by health care professionals and patients. These are reviewed by Risk / Complaint managers and forwarded to the Medicines Safety officers (MSO). Online reports are then submitted by the MSO to the NRLS and in turn forwarded to the MHRA, which may ask for further details if required. Adverse Drug Reactions are reported directly to MHRA through a system of Yellow cards. The system ensures an integrated reporting, analysis and learning route for medication errors. The success of this system depends on the quality of DATA submitted.

Several accreditation guidelines emphasise the importance of preventing medication errors. In India the NABH certification is the most widely accepted and sought after. The guidelines lay down a chapter on Management of Medication (MOM), which includes standards and objective elements to prevent and detect medication errors<sup>15</sup>.

Reporting of errors has an inherent problem. Those who make mistakes fear punitive and disciplinary action. Reporting system and tools should be readily available and easy to understand and should capture the relevant information correctly.

Knowledge based errors can be prevented and minimized by crosschecking, education of staff, use of bar coding and computerised prescribing systems. Rule based errors can be tackled through proper education and reinforcement. Action based errors and Memory based errors can be avoided by cross checking, using checklists, proper labelling of medication and computerised reminders.

According to several studies the error rates observed were as follows:

1. Prescribing error rate in hospital, 7% of prescription items<sup>16</sup>;
2. Prescribing errors rate in general practice, 5% of prescriptions of which 0.18% were severe errors<sup>17</sup>: With a billion prescription items prescribed in primary care in the NHS in England annually. This research predicts 1.8 million serious prescribing errors each year
3. Dispensing error rate in hospitals, 0.02 - 2.7% of dispensed medicines<sup>18</sup>;
4. Dispensing error rates in community pharmacies, 0.01 - 3.32% dispensed medicines<sup>18</sup>;
5. Medicine administration errors in hospital, 3 - 8%<sup>19</sup>.

Education of staff and induction of new joiners to acquaint them to the forms and formats available as well as the policies of the work place go a long way in reducing medication errors.

In the NABH accreditation standards, the chapter on MOM stresses on standards related to Policies and procedures on

1. Pharmacy services: procurement, storage, prescriptions, dispensing administration and monitoring of medication.
2. Hospital formulary: listing of drugs approved for use, list of essential drugs that must be available, procurement of drugs not on the formulary.
3. Segregation of look-alike sound-alike medication. Availability of emergency medication and proper checks to replenish and avoid stock outs. Identification of medication with low therapeutic index. Policy on control and issue of narcotics and psychotropic substances.
4. Prescriptions: minimum requirements, good practices / guidelines for rational prescription. Prescription audits
5. Eligibility to write prescriptions
6. Standardization of orders and where they are to be written on case sheets.
7. Policies on use of chemotherapeutic agents, radioactive agents and implants and medical devices.

Medication errors should be reported voluntarily and readily. They should be proactively sought with the help of a clinical pharmacologist. Reporting should be done at the earliest to prevent near misses (unplanned event that does not result in injury or damage to patient as it is averted in the nick of time ) and no harm (event occurs but the adverse effect does not).

The error reporting form should capture the relevant information which is then analysed to get to the root cause and later discussed with the stakeholders to prevent such errors from occurring in the future. A sample error reporting form is as per annexure 1 and adverse drug reaction reporting format annexure 2.

Quality indicators to keep a check on the management of medication are

1. Medication errors: Total number of medication errors per total inpatient days, expressed as a percentage. Errors related to drug, dose, frequency is checked every day on treatment sheets, number of dose consumed is cross verified with number of dose issued, time of administration is checked, documentation on treatment sheet is verified.
2. Adverse drug reactions: Total number of adverse drug reactions per total deaths or discharges expressed as a percentage. The attending doctor or staff will report the ADR and the details of the history and event noted in detailed and forwarded for further evaluation.

3. Medication charts with error prone abbreviations: percentage of charts with error prone abbreviations per number of charts reviewed. Charts are reviewed for use of any abbreviation which is not approved by Pharmacy & Therapeutic Committee which is noted on medication error form.
4. High alert medication developing into adverse drug reactions: Percentage of patients developing adverse drug reactions per number of patients receiving high alert medication.

## **Conclusion**

A medication error is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient. Medication errors are most often trivial errors. However occasionally they can be serious and it is important to detect them. Detection of medication errors begins with reporting of such events. The estimated frequency of occurrence of medication errors depends on the method of detection used. Several factors contribute to this increase in medication errors and adverse drug events. Policies and procedures will be only as good as the reporting and analysis of the factors that lead to the event. The success of this system depends on the quality of DATA submitted. Several accreditation guidelines emphasise the importance of preventing medication errors. Education of staff and induction of new joiners to acquaint them to the forms and formats available as well as the policies of the work place go a long way in reducing medication errors.



**6. Levels of Severity / Remarks :**

Level 0	Detected & corrected before administration
Level 1	Did not result in patient harm
Level 2	No change in vital signs but required close monitoring
Level 3	Change in vital signs, required close monitoring
Level 4	Resulted in the need for another drug / treatment
Level 5	Resulted in permanent harm to the patient
Level 6	Resulted in patient death

**7. Corrective actions taken : Yes / No (Mention Details)**

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**8. Preventive actions taken : Yes / No (Mention Details)**

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**9. Closure Date :**

**10. Signature of HOD :**

**Committee Review : (Date of review and brief summary of review)**

Annexure 2 - adverse drug reaction reporting format.

Patient Identification Details  
(BARCODED STICKER)

## SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

(Reference : CDSCO ADR Reporting Form)

Date & Time : \_\_\_\_\_ Department : \_\_\_\_\_

### 1. Suspected Adverse Drug Reaction :

Type of reaction : \_\_\_\_\_

Describe incidence in details :

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### 2. Immediate action taken :

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### 3. Suspected Medication(s)

S.No.	Name (brand/ generic)	Manufacturer	Batch No.	Exp. Date	Dose	Route	Frequency	Date started	Date stopped
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4. **Reaction abated after drug stopped or dose reduced?**  
(tick whatever is applicable)

Yes	No	Unknown	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. **Reaction reappeared after reintroduction :**  
(tick whatever is applicable)

Yes	No	Unknown	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. **Seriousness of the reaction**  
(tick whatever is applicable)

Death (dd / mm / yy)	<input type="checkbox"/>
Congenital anomaly	<input type="checkbox"/>
Required intervention	<input type="checkbox"/>
Life threatening	<input type="checkbox"/>
Hospitalization	<input type="checkbox"/>
Disability	<input type="checkbox"/>
Other (Specify)	<input type="checkbox"/>

7. **Outcomes** (tick whatever is applicable)

Fatal	<input type="checkbox"/>
Continuing	<input type="checkbox"/>
Recovering	<input type="checkbox"/>
Recovered	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
NA	<input type="checkbox"/>
Other (Specify)	<input type="checkbox"/>

8. **Adverse drug reaction card issued :**  
(tick whatever is applicable)

Yes  No

9. **Person Reporting :**

Name \_\_\_\_\_ Designation : \_\_\_\_\_

Sign :

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Dr.Sippy Batra\*

## Duty of Hospitals in Protecting Patients' Rights

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### Abstract

*Patient rights today are an important issue which is advocated in many hospitals. All staff members are taught about it and how truly it is implemented, is still a question that needs to be answered. With increasing awareness and patients self education on the disease process, outcomes, benefits and risks it becomes imperative to put in practice ethical code of conduct and maintain transparency with the relations. This paper discusses various aspects involved in patient's rights and the hospitals' responsibility to honour them letter and spirit. It also mentions about a sample survey carried out in a tertiary care oncology set up in June 2015 to assess patients and staff awareness on patient's rights and their practical implementation.*

### Introduction

With rising frequency, television news channels and the print media are reporting hospital and nursing home doctors and paramedical staff being held accountable for 'negligence' leading to injuries or deaths These are only the tip of the iceberg - below the surface lurks a much larger issue - patients' and families' dissatisfaction with the clinical care and lack of transparency

It is not uncommon to find patients' families complaining that their doctor is keeping them in the dark about a diagnosis or prognosis. The doctors, they say, order blood tests and pathological investigations without making themselves clear about what these tests are for and what they could lead to; whether they are to shed more light on the patient's condition or, to change the line of treatment, or for a more precise diagnosis. A sense of frustration at the lack of information pervades families in virtually every hospital and clinic. The doctor walking away from anxious relatives with nothing more than a pat on the shoulder - and sometimes only a shrug - is a standard frame in TV serials and film scenes in hospitals.

Over the years, countless incidents around the country have drawn attention to the problems of medical negligence, and related cover-up of information to deny

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\* Quality Head, Jaipur Golden Hospital, Delhi (e mail-quality.head@jghdelhi.net, sippybatraa@gmail.com)

patients' families knowledge of what happened in medical centres. Here are a few illustrative examples.

- In October 1989, Zairunnisa Parekh died at the Jaslok Hospital, Mumbai, of peritonitis. Her husband Yusuf and son Mushtaq immediately began a case of negligence against the doctors stating that they were denied a copy of her medical records by the hospital.
- Raghunath Raheja, whose wife Bhagwati Raheja died after a by-pass surgery at Mumbai's Nanavati Hospital also states that he was refused a copy of the medical records.
- In 1992, 26-year-old Venkatesh Iyer filed a petition in the Mumbai High Court seeking immediate payment of Rs.10 lakhs from Bombay Hospital, for urgent medical treatment overseas to rectify the severe damage done to him on account of negligent treatment by the hospital medical staff. The respondents were the medical director and superintendent and the head of the Radiation Therapy Department at the time, Dr. Arvind Kulkarni. According to the petition, Iyer's complications arose after Venkatesh was administered a second dose of radiation in one spot, causing the irradiated lower abdomen to burst open, leaving a gaping hole from which there was continuous leakage of mucus, blood and fecal matter as the intestine had ruptured through radiation.
- On 11 July 2001, Sandhya Karmakar, 36, mother of a ten-year-old boy, died in hospital in Kolkata. She had been admitted for an appendectomy on 26 June. The surgery went fine, but a surgical mop was left behind in her abdomen. Surgeon performed a second surgery to remedy the error on July 3 to take out the mop. Some leakage developed so there had to be a third surgery on July 7. It was later discovered that Doctor who had performed the appendectomy had left the entire post-operative process including suturing to his nursing staff at the operation theatre. The death certificate cited cardio-respiratory failure resulting from a post-operative case.

In these, and in many other cases, patients or their families inevitably had to seek intervention from courts and other agencies to actually discover what happened to the patient. Invariably, hospital deny any wrong-doing, and the onus is on the accuser to prove what actually happened - which he cannot without the information to do it, which is held by the accused institution or practitioner!

High illiteracy in the country also tilts the balance in favour of doctors who are aware of the limited means and more limited understanding of these weak men and women. Even the educated and better-off are vulnerable; withholding information is a strategy to stop the patient from approaching another doctor, thus being forced to spend his money - necessary or not - in the current facility.

While the fear of large punitive awards can serve as a deterrent to many hospitals and doctors, this is not a sufficient solution in the long run. What is needed is a better program of overseeing staff conduct in medical institutions, and a streamlined mechanism for continuously improving standards of medical care. A greater emphasis on patients' right to information about their condition and treatment would provide a big boost to this transformation.

## Materials and Methods

A sample survey was carried out in a tertiary care oncology set up in June 2015 to assess patients and staff awareness on patient's rights and their practical implementation.

The aim of the study was to know on ground practice and awareness of staff. The parameters for assessment were :

- a. Patient / Staff awareness on the subject
- b. How well the patients were counseled about the financial costs before the treatment
- c. Information about procedure/ surgery / treatment plan
- d. Awareness about procedure to give feedback/ lodge complaints / give suggestion

The results were put in the excel sheet and quantified in terms of complete awareness (10), partial awareness (5) , No awareness (0)

## Results:

### Patients/ Relations Awareness:

- It was found out that only 4% of patients were completely aware of the patient rights, 24% were partially aware & 72% were completely unaware of their rights.
- 36% of the patients were completely aware of the financial aspects of the treatment, whereas 64% patients had an idea about the approximate cost of the treatment.
- As far as the information about surgery/ procedures is concerned, 22% of patients were completely aware but 78% had an idea of what the procedure / surgery is all about.
- 24% of the patients were completely aware of the procedure of lodging complaints/ giving feedback etc. but 76% had no idea.

### **Staff Awareness:**

- As far as the staff is concerned, 40% were fully aware of the patient rights, and 43% were partially aware. 17% of the staff had no idea of the patient rights.
- Maximum staff was aware that they have to explain about the care to be given (87%), patient's privacy needs to be respected (62%) , procedure to give feedback/ complaints is informed to the patients by 51% of staff, 40% of staff were aware on financial education of patients as a patient right.
- Amongst staff interviewed, following awareness pattern was observed - Housekeeping (89% aware), nurses (82%), front office (78%) & doctors (66%) respectively.

### **Discussion**

The study revealed various interesting facts that we encounter in everyday practice.

- Many a times, patients / relations are made aware of their rights but in anxiety/ hurry, they focus on other areas of hospital processes.
- In many instances, different relations accompany patients to the hospital, which may lead to relative unawareness of information.
- The process of Informed consent needs a detailed discussion between patients and treating team so as to have a clear understanding of the procedure/ surgery, its benefits, expected complications and results.
- Rounds by administrative team to seek feedback about the services of the hospital are not only informative but also lead to further dissemination of information at various stages of treatment.
- Communication acts as a bridge between patients/ relations and hospital team. We must envision to create an environment that fosters effective communication and improvement by means of creating more opportunities to seek patient feedback, sort queries and bond with the patients etc

### **Suggested Actions:**

On the basis of above study, following actions were suggested:

- Visual display of the patient rights and responsibilities via LCD's in waiting areas of OPD's, Radiology, Sample collection rooms etc.
- Administrative Rounds after Patient Admission to provide proper counseling.
- Distribution of bilingual patient rights pamphlets to all the patients entering the hospital or at the time of registration.
- Mandatory Pre- Admission counseling for every patient by Front office staff.

## **Conclusion**

Patient rights are important aspect of patient dealing in day-to-day scenarios. Extensive training and implementation on ground can help prevent many unforeseen circumstances that can hamper the image of the hospital in the long run.

Dr.Naveen Chugh\*

## Risk Identification, Assessment and Management in Healthcare Sector

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### Abstract

*Risk management is an important aspect of healthcare setup. It is imperative that all the organisations have a system in place. Recent court rulings and legislation put a big liability on the healthcare setups with regards to patient safety and quality of care. NABH and other accreditation bodies also mandate risk management in their standards. Healthcare setups need to give serious consideration to implementing and strengthening risk management systems in their organisations to protect their assets, reduce financial loss and standing in the community.*

### Introduction

A situation involving exposure to danger. This is the definition given by oxford dictionary. It also gave five other definitions when the word is used as a noun and four other definitions when the word is used as a verb. <sup>1</sup>

Another search on businessdictionary.com <sup>2</sup> revealed the following definitions of risk.

A probability or threat of damage, injury, liability, loss, or any other negative occurrence that is caused by external or internal vulnerabilities, and that may be avoided through preemptive action.

2. Finance: The probability that an actual return on an investment will be lower than the expected return. Financial risk is divided into the following categories: Basic risk, Capital risk, Country risk, Default risk, Delivery risk, Economic risk, Exchange rate risk, Interest rate risk, Liquidity risk, Operations risk, Payment system risk, Political risk, Refinancing risk, Reinvestment risk, Settlement risk, Sovereign risk, and Underwriting risk.

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\* General Manager & Quality Head, HCG group of hospitals, Bangalore (email: drnchugh@gmail.com , chughee@gmail.com)

3. Food industry: The possibility that due to a certain hazard in food there will be a negative effect to a certain magnitude.

4. Insurance: A situation where the probability of a variable (such as burning down of a building) is known but when a mode of occurrence or the actual value of the occurrence (whether the fire will occur at a particular property) is not. A risk is not an uncertainty (where neither the probability nor the mode of occurrence is known), a peril (cause of loss), or a hazard (something that makes the occurrence of a peril more likely or more severe).

5. Securities trading: The probability of a loss or drop in value. Trading risk is divided into two general categories: (1) Systemic risk affects all securities in the same class and is linked to the overall capital-market system and therefore cannot be eliminated by diversification. Also called market risk. (2) Nonsystematic risk is any risk that isn't market-related or is not systemic. Also called nonmarket risk, extra-market risk, or unsystemic risk.

6. Workplace: Product of the consequence and probability of a hazardous event or phenomenon. For example, the risk of developing cancer is estimated as the incremental probability of developing cancer over a lifetime as a result of exposure to potential carcinogens (cancer-causing substances).

Going forward from here I thought the best definition for risk in a healthcare set up would be a combination of the two dictionaries mentioned above which would define risk as A situation involving exposure to danger where a probability or threat of damage, injury, liability, loss, or any other negative occurrence that is caused by external or internal vulnerabilities exist and that may be avoided through preemptive action.

Risks are inherent in every activity we do or don't do in our daily life. We can only manage them to minimize their bad effects within the resources available to us at that point of time. To maximize this management these actions of managing must be done at and within an appropriate time.

To minimize a risk, the risk has to be managed. This again gets us to a question of risk management.

### **What is risk management?**

Oxford Dictionaries define risk management <sup>3</sup> as (In business) the forecasting and evaluation of financial risks together with the identification of procedures to avoid or minimize their impact.

Business dictionary <sup>4</sup> defines risk management as the identification, analysis, assessment, control, and avoidance, minimization, or elimination of unacceptable risks. An organization may use risk assumption, risk avoidance, risk retention, risk transfer, or any other strategy (or combination of strategies) in proper management of future events.

So if we combine these two definitions we get a broader definition of risk management which is forecasting and evaluation of risks together with the identification of procedures to avoid or minimize their impact which includes identification, analysis, assessment, control, and avoidance, minimization, or elimination of unacceptable risks through strategies like risk assumption, risk avoidance, risk retention, risk transfer, or any other strategy (or combination of strategies) in proper management of future events.

To manage a risk one needs to formulate a decisive risk management plan. The plan has to have components which are very specific to the risk in question.

Risk to a healthcare setup broadly comes from these areas.

- Legislation
- Patient safety and Employee safety
- Operations
- Finance
- Existing and future policy
- Ethics

As aptly said by the author in a article on the Website of Scranton University which can be viewed at (<http://elearning.scranton.edu/resource/business-leadership/purpose-of-risk-management-in-healthcare>)

“The hazards of not preparing for potential issues can have significant, long-term effects. Neglecting to have comprehensive risk management plans in place can compromise patient care, increase liability risks, and result in financial losses. Thus potential risks have to be evaluated and measured in terms of their potential negative effects. Based on the risk assessment, an organization-specific management plan should be developed, implemented, and monitored.”

Professionals who typically work in the areas of risk management in the healthcare setup apart from doctors include:

- Financing, insurance, and claims management
- Operations and Incident management

- Emergency preparedness
- Quality Department

To begin making a risk management plan one needs to needs to identify the risks correctly. This identification can be done in many ways. A few are mentioned below.

1. SWOT Analysis
2. Task Analysis - Process Mapping
3. FMEA
4. Brainstorming
5. Delphi Technique
6. Nominal Group Technique
7. Analogy Based on previous history
8. HIRA - Hazard Analysis and Risk Assessment

### **SWOT Analysis**

SWOT analysis is a precursor to strategic planning and is performed by a panel of experts who can assess the organization from a critical perspective (Gibis et al. 2001). The primary aim of strategic planning is to bring an organization into balance with the external environment and to maintain that balance over time (Sackett, Jones, and Erdley 2005). Organizations accomplish this balance by evaluating new programs and services with the intent of maximizing organizational performance. SWOT analysis is a preliminary decision-making tool that sets the stage for this work.<sup>5</sup>

Any management school will swear by this technique. SWOT analysis is the analysis of one's Strengths, Weakness, Opportunities and Threats. Strengths and Weakness are of Internal origin whereas Oppurtunities and Threats are of External origin

A Typical SWOT Analysis is presented is presented in Table No: 1 below.

**Table No: 1 SWOT Analysis of a Hospital**

	Helpful	Harmful
Internal Origin	<p>Strengths</p> <p>Qualified and Experienced Doctors                      Good Infrastructure                      Organizational Efficiency                      Good Community Standing                      Latest Technology.                      Documented Protocols                      Dedicated Quality Department</p>	<p>Weaknesses</p> <p>Lack of Adequate Financial Resources                      Reliance on marketing team for improving business.                      Shortages of Critical Staff                      Non Compliance with statuettes.                      No Benchmarking</p>
External Origin	<p>Opportunities</p> <p>Growing population                      More people taking medical insurance                      NABH Accreditation</p>	<p>Threats</p> <p>Governmental regulation                      Reduced tariff for Governmental scheme patients                      No timely payments from the insurance companies and Governmental agencies                      Poaching of Staff at all levels.                      Technology becoming obsolete fast.</p>

**Task Analysis.** <sup>6</sup>

Task analysis is a technique that can be used to reduce high level system goals to individual actions or procedures. It can be used to help understand the similarities and differences between different types of procedures, and to allow methodological study and understanding of the requirements for the successful completion of a given procedure.

It is also termed as ‘Process Mapping’ by a few. Task analysis if mapped in a flow diagram is even more beneficial

Specific analysis is to be done for every procedure by studying the documented protocols and observation of the procedure followed by discussions with the persons performing the procedure. Task analysis is used for the development of fine tuned detailed procedural-based error-capture checklists for observational studies. Task Analysis complements FMEA.

## **FMEA - Failure Mode and Effect Analysis**

<sup>7</sup> Failure Modes and Effects Analysis (FMEA) is a technique that attempts to predict how critical each possible failure in the system is by taking into account frequency, severity, and detect ability, in order to identify those failures that provide the greatest risk. It is used to identify the areas with the greatest risk and to develop methods for reducing those risks. From the task analysis, each element is assigned one or more failure modes, from which effects are predicted. Each failure mode was scored from 1 to 10 on three dimensions; chance of failure, severity of failure, and chance of detection. These three scores were then multiplied together to give a criticality index, which defines the level of risk for each failure. The higher the score, the more serious the potential for failure, and so the more priority should be placed on avoiding that failure mode.

FMEA technique allows:

- a) To evaluate and measure the hazards of a process malfunction.
- b) To decide where to execute improvement actions.
- c) To measure the outcome of those actions.

## **Delphi technique**

It is a type of interview technique. The interview is anonymous. It is used when there may be conflicts or it is used to get comments from confrontation, or when “competitors” brainstorming is not recommended.

## **Nominal Group Technique**

Nominal Group Technique allows a certain Individual degree of Brainstorming prioritization. It's a mix of Fast and effective individual and group participation. It lessens the “chaos” of brainstorming.

## **HIRA - Hazard Analysis and Risk Assessment**

HIRA is an activity which is done to help answer the following questions.

- a) What hazards exist in an area?
- b) How frequently do they occur?
- c) How severe can their impact be?
- d) Which hazards pose the greatest threat?

It is a systematic risk assessment tool that can be used to assess the risks of various hazards.

There are three reasons why a HIRA is useful.

- a) It helps to prepare for the worst, most likely risks.
- b) Allows for the creation of SOPs, training programs, and plans based on the most likely scenarios.
- c) Saves time and resources by concentrating on high rated hazards.

ISO 31000: 2009 says the following which is useful for an HIRA<sup>11</sup>.

**Risk assessment** is a process that is, in turn, made up of three processes: risk identification, risk analysis, and risk evaluation.

**Risk identification** is a process that is used to find, recognize, and describe the risks that could affect the achievement of objectives.

**Risk analysis** is a process that is used to understand the nature, sources, and causes of the risks that you have identified and to estimate the level of risk. It is also used to study impacts and consequences and to examine the controls that currently exist.

**Risk evaluation** is a process that is used to compare risk analysis results with risk criteria in order to determine whether or not a specified level of risk is acceptable or tolerable.

Now that the risks have been identified a plan has to be put in on how to manage the risk.

### **Risk Management Plan.**

*ISO 31000: 2009 defines a risk management plan as:*

An organization's risk management plan describes how it intends to manage risk. It describes the management components, the approach, and the resources that will be used to manage risk. Typical management components include procedures, practices, responsibilities, and activities (including their sequence and timing). Risk management plans can be applied to products, processes, and projects, or to an entire organization or to any part of it.

<sup>8</sup> A Risk Management Plan as defined by Wikipedia is a document that a manager prepares to foresee risks, estimate impacts, and defines responses to issues. It also contains a risk assessment matrix. A risk is "an uncertain event or condition that, if it occurs, has a positive or negative effect on a project's objectives."

*The best way to make a risk management plan is to make a risk management matrix. The matrix has the elements as described in table No: 2 below.<sup>9</sup>*

**Table No: 2**

Sl No:	Risk / event	Out-come	Other areas affected	Existing or proposed risk reducing actions in place or proposed	Consequence	Likelihood of happening	Risk Rat-	Additional risk treatment actions required	Additional resource re-quired	Risk owner and target date	Re-marks

### **NABH and Risk Management<sup>10</sup>**

*National Accreditation Board for Hospitals and Healthcare Providers ( NABH) is a body which runs and provides the accreditation process in INDIA .It is a constituent body of the Quality Council of India. NABH has in its Standards for Hospitals, 3<sup>rd</sup> Edition made mention of risk assessment and management as below.*

*CQI.4b Monitoring includes risk management.*

*ROM.6a Management ensures proactive risk management across the organisation.*

*ROM.6b Management provides resources for proactive risk assessment and risk reduction activities.*

*FMS.1a and FMS.8a,b,c talks about HIRA.*

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k.r. catchpole 1 p.j. godden2 a.e.b. giddings 3 g. hirst 4 t. dale 4 m. utley 2  
s. gallivan 2 m. de leval 1 ([http://www.academia.edu/1319567/identifying\\_and\\_reducing\\_errors\\_in\\_the\\_operating\\_theatre](http://www.academia.edu/1319567/identifying_and_reducing_errors_in_the_operating_theatre))
- <sup>7</sup> BS5760 part 5, 1991
- <sup>8</sup> [https://en.wikipedia.org/wiki/Risk\\_management\\_plan](https://en.wikipedia.org/wiki/Risk_management_plan)
- <sup>9</sup> <http://www.education.tas.gov.au/dept/legislation/risk>
- <sup>10</sup> <http://www.nabh.co>
- <sup>11</sup> ISO 31000:2009

Dr. Amar S Biradar\* & Dr. V. Vishnu Reddy\*\*

## Quality Healthcare Services through Clinical Audit

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### Abstract

*The past few decades have witnessed major changes and evolving trends in the hospital and healthcare industry. The focus has shifted from mere treatment of illness to a more holistic approach that is supported by the best amenities and infrastructure. However due to the massive expansion of the hospital set-up, there is now a very crucial need to monitor, assess and evaluate the healthcare services being provided. This is why clinical audits have become an integral aspect in the functioning of all major hospitals today. An audit is basically a major tool in quality improvement practices. Hospital audits enable the comparison of ongoing practices with expected standards; thereby leading the way to improvement of services being provided. This Journal contains practical tips for clinical audit and is aimed at all hospital staff who wish to evaluate and improve their clinical practice. Clinical audit is a professional tool which enables clinicians to feel confident that “what they do is as good as it could be, as good as it ought to be and that it makes a difference to patient care”.*

### Introduction

Clinical and Healthcare Audit involves comparing current practice to evidence based best practice in the form of standards, identifying areas for quality improvement and implementing changes to practice to meet the standards. It is the duty of all healthcare professionals to ensure they deliver care to the highest standard to their patients/clients so by definition all staff should be auditing their work. Clinical and Healthcare Audit ideally should be multi- disciplinary but uni-disciplinary audits may also be conducted. Each department/specialty/service within the organization should have an annual programme of audit based on the criteria for audit selection e.g. **high risk, high cost, and high volume**. The effectiveness of the audit and the implementation of changes should be evaluated by re-auditing. In fact healthcare audit is the final step in evidence based healthcare. It is the duty of all clinicians to ensure that they deliver the best care to their patients. All clinicians should be auditing their work. Clinicians have a duty to use the findings of audit to improve

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\* Hospital Administrator, Dept of Clinical Audit, Yashoda Super speciality Hospital, Malakpet, Hyderabad (e mail-dr.amar@yashoda.in, dr.amarnath21@gmail.com)

\*\* Chief Operating Officer, Yashoda Super Specialists Hospital, Malakpet, Hyderabad (e mail-dr.vishnureddy@yahoo.com)

clinical care and move towards best practice i.e. audit is an essential tool for **Continuous Quality Improvement (CQI)**. Audit should not be seen as a standalone CQI activity but should be part of a structured organizational quality and risk management programme.

## Background

Clinical audit has a history stretching back to the work of *Florence Nightingale* (1800s) and *Ernest Codman* (early 1900s). Both *Nightingale and Codman* monitored mortality and morbidity rates in their respective institutions. Nightingale used an epidemiological method of review, monitoring rates of nosocomial infections in relation to standards of hygiene. Codman introduced the idea of systematic record review as a way of identifying errors.

**Technical Definitions of a Clinical Audit:** The Department of Health in “Working for Patients”, 1989 defined a clinical audit as- “*The systematic critical analysis of the quality of clinical care, including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome and quality of life for the patient.*”

The National Institute for Clinical Excellence (NICE) defined a clinical audit in the “Principles for Best Practice in Clinical Audit”, NICE, 2002 as- “*A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit standards and the implementation of change.*”

## What are the various types of audit?

1. **Standards-based audit** - This involves a cyclical process that begins with defining the standards, collecting relevant data to measure the current practice against those standards, and finally implementing required changes.
2. **Peer review** - This involves an overall evaluation of the quality of care provided by a clinical team with the aim being to improve clinical care. Peers can discuss ‘interesting’ or ‘unusual’ cases to ascertain, whether the best care was provided.
3. **Patient surveys and focus groups** - This involves obtaining users’ views about the quality of care they have received through patient feedback forms and hand-outs.
4. **Adverse occurrence screening and critical incident monitoring / significant event audit**- This involves conducting a peer review of cases which have caused concern or which have resulted in unexpected outcomes. A multidisciplinary team discusses individual anonymous cases to reflect upon the way the team functioned. One can gain significant learning for the future from such an audit.

## **Another approach to selecting topics for audit-**

The Donabedian (1966) classification of **structure**, **process**, and **outcome** can be used to focus on areas of practice from which a topic may be selected.

**Structure;**

The setting and resources (what you need- staff, buildings and equipment required to deliver a service), e.g.

- Resuscitation equipment in a GP surgery.
- Accessibility of service for disabled individuals.

**Process;**

The practices/methods of care (what you do) which may be specific to:

- Clinical process, e.g. post-operative pain management, communication with patients at first appointment.
- Organizational/administrative process, e.g. system for patient recall, discharge practice, waiting times, medical records management.

**Outcome;**

The effect of healthcare on a patient's health status (what you expect), e.g. blood pressure control, weight increase in young people with anorexia after intervention'.

Other sources of information/indicators for topics for audit could include:

- **Morbidity and Mortality** meetings
- Risk register
- Activity information - e.g. throughput, re-admissions, waiting lists
- Alerts received relevant to your service
- Analysis of consumer feedback
- Complaints, satisfaction surveys, focus groups, consumer panels.
- Peer review meetings
- Morbidity and mortality meetings
- Minutes of team meetings
- Review of external inspection reports e.g. Accreditation reports, Health etc.

**Significance of a clinical audit**

It allows healthcare personnel to systematically analyze their practices and care services to

- 👉 **Identify and promote the good practices**
- 👉 **Root out and discontinue the inefficient practices**

The result of a clinical audit is improvement of the patient care systems; by developing solutions for the identified problems and implementing effective service systems.

**Three dimensional advantages of a clinical audit:**

Better Patient Care	Better Staff Development	Better Management
<i>Allows consistency of treatment services.</i>	<i>Allows multi-disciplinary team communication and working.</i>	<i>Allows risk management assessment and reduces litigation/complaints.</i>
<i>Allows quality and effectiveness of care.</i>	<i>Improves awareness of latest procedural guidelines.</i>	<i>Improves clinical cost effectiveness by supporting bids for resources.</i>
<i>Improves patient satisfaction.</i>	<i>Identifies training needs among staff to improve professional development.</i>	<i>Identifies need for organisational changes.</i>

**Clinical Research versus Clinical Audit:** To understand the basic difference between clinical research and audit very simply and clearly just analyze the two sentences below:

Research is aimed at asking- ***“Are we prescribing the right antibiotic for the treatment?”***

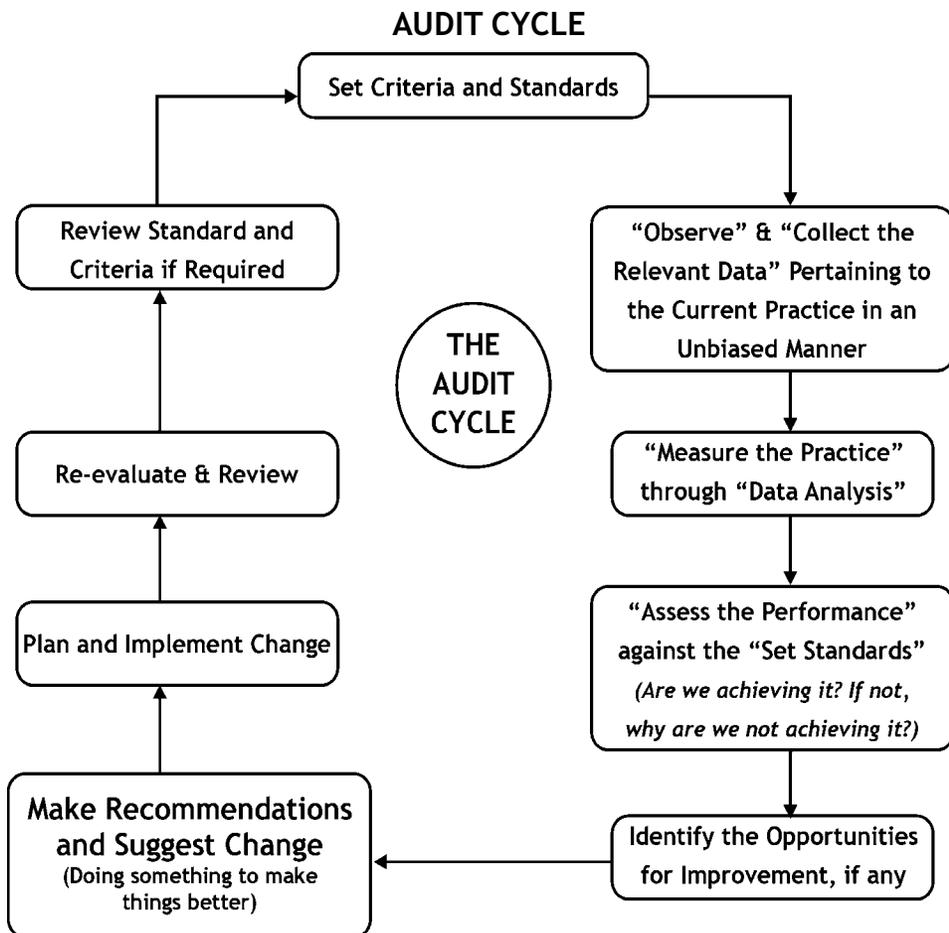
Audit is aimed at asking- ***“Are we prescribing this antibiotic in the right way for the the treatment?”***

Research	Audit
Searches for new information and knowledge.	Makes sure that existing knowledge is being practiced efficiently.
Makes use of experimental studies like randomised control trials.	Makes use of comparative studies between a current practice and the best practice.
Makes use of wide range of statistics to reach inferences. followed.	Makes use of simple descriptive statistics to describe the current practice being
Provides proof for clinical guidelines and policies.	Measures how well current care conforms to clinical policies and guidelines.
Can be applied to the general population.	Relates only to the local population group where it is carried out.

**Practical pointers to ensure the success of your clinical audit:**

- Provide the right and appropriate training to the involved audit staff.
- Choose the topic wisely and keeping in mind priority: Audits are highly effective when done in relation to areas where there is low adherence to the recommended practice.
- Obtain support from the organisation.

- Involve all the relevant staff members (doctors, nurses, patient representatives) and maintain a team approach.
- Always follow strict confidentiality and avoid the blame game culture.
- Decide on a realistic time frame and adhere to it.
- Decide and set optimal standards rather than ideal impossible benchmarks.
- Invest in good data collection IT systems.



### **UNDERSTANDING A CLINICAL AUDIT STEP-WISE;**

#### **1. Establish a topic or an issue that needs audit**

The best way to choose the audit topic is to think of aspects of healthcare services that

- Exhibit large costs
- Exhibit risk issues
- Exhibit wide variance
- Exhibit need for new treatment approach
- Exhibit the concerns of the local population

Any area of high volume, risk or cost would be a good audit topic

Ask yourself:

- What are the most commonly followed practices in the hospital?
- Which of the practices and services cost the most and have high fee?
- Which are the areas where a new treatment or new guidelines are being implemented?
- Which are the areas that most colleagues or patients have expressed concern about, or where practice or outcomes vary drastically?

Highlights of a good audit topic:

- Should involve self audit
- Should address a crucial practice area
- Should tackle a recurrent quality issue
- Should have appropriate clinical support
- Should make use of clear-cut audit measures
- Should have the potential to achieve improved quality of patient care

#### **2. Involve all the appropriate concerned personnel**

The best audit team comprises of a multi-level group of members right from the

- i. Base level staff ( to give real time information of practices being followed)
- ii. Patients( to inform about needs and expectations versus services received)
- iii. Senior level authorities and management ( to implement the decided changes)

#### **3. Set-up the standards and criteria**

Standard refers to the specified level of care that needs to be provided and also defines how the care should be provided. Standards are developed from best practice evidence in the specific areas of care.

Keep your standards SMART: An acronym to keep in mind while setting audit standards

Specific- should cover only one topic

Measurable- should be measurable in a practical way

Achievable- should be something that is reasonable for staff to achieve

Relevant- should be an issue that is important to patients and staff

Timescale- should be measurable within a reasonable period of time

### Types of Standards

- a. **Minimum standard:** The lowest standard of performance that can be accepted. Minimum standards help distinguish between acceptable and unacceptable practices.
- b. **Ideal standard:** The care possible to be given under ideal conditions, with absence of constraints.
- c. **Optimum standard:** Between the minimum and the ideal. It represents the care standard most likely to be achieved under normal practice conditions. All the audit team members should together decide and arrive at an optimum standard.

**Evidence information for the clinical audit can be obtained from sources such as**

- Books
- Journal articles, reviews, letters, comments and editorials
- Reports from DoH, Royal Colleges
- National guidelines, NSFs
- Local care plans, protocols, guidelines etc
- Patient information leaflets (NHS, charities and self help groups)

#### 4. *Collect and analyse the data*

**The best way to collect only relevant and precise data for the audit is to always remember**

- The objective of the audit.
- The patient group to be included, with noted exceptions.
- The healthcare staff involved in the patient care.

#### **Data sources include**

- Patient case sheets
- Patient and staff questionnaires
- Recording particular cases of significance
- Reviewing healthcare policies and guidebooks

#### **Considerations for data collection include**

- What type of data will be collected
- Where will the data be sourced from
- Who will perform the task of data collection

#### **Ethical consideration during data collection include**

- The data collected should be relevant only to the objectives of the audit
- The staff and patient confidentiality should be regarded

#### **How to analyze the data collected?**

Always analyze what the data speaks to you, for data cannot lie!

**Tools for data analysis-** A paper note pad and pen, calculator or computer excel spreadsheet are sufficient and effective for data analysis in a clinical audit.

Once the data is recorded it becomes easy to analyze where the standards have been met and where there exists a gap. Then the reason for the gap between the standard and current practices can be understood. Finally the data can be used as a pointer towards methods of improving care in the deficient areas.

#### **5. *Compare performance with criteria and standards***

The results of the data analysis are compared with criteria and standards. The final step of the analysis is concluding how well the standards were met and, if not, identifying reasons why the standards were not met in all cases. Suggestions are then given focussing on improvement measures. Theoretically any case in which the standard (criteria or exceptions) was not met in 100% of cases suggests a potential for improvement in care. In practice, where standard results were close to 100%, it could be considered acceptable.

## 6. *Implementing change*

The audit results are documented in the form of an audit report or presentation for the management and concerned personnel to be informed.



An action plan is formulated after discussion.



Recommended changes are finalised and documented for implementation henceforth.



One staff is given responsibility to review how the action plan is being implemented.



Call for a re-audit at a later stage to check if the changes implemented were able to bring about the expected difference.

***Limitations of clinical audit:*** The effectiveness and value of clinical audit as a quality improvement method depends on a number of variables. These include the:

- Clarity and measurability of the criteria and standards chosen,
- Quality of the data available,
- Engagement of clinicians
- Involvement of consumers
- Skills and training of participants,
- Time involved undertaking an audit,
- Use of information technology
- Feedback provided,
- If and how the findings are translated into quality improvement Strategies
- Evaluation of improvement strategies (closing the loop)

*Use clinical audit as a helpful mechanism for reviewing the quality of routine care provided at your hospital and not as a means to criticise any individual/group performance. When performed meticulously by well trained staff a clinical audit definitely paves the way for self-assessment and enhanced healthcare practices.*

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Dr. Bhawna Gulati\*

## Compliance Vs Excellence in Hospitals

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### Abstract

*Defining the vision, mission and objectives of an organization is of utmost importance to the top management as all the organizational policies and procedures; and activities of staff has to align to the above to achieve the ultimate goal of the organization. The aim of the organization may be compliance to standards laid for regulation or certification or accreditation, as the case maybe. On the other hand, the organization may look at achieving excellence in its services provided to patients by continuously improving both clinical and non-clinical operations. The article touches upon issues such as regulation, certification, accreditation and excellence in services in hospitals. It also describes how achieving excellence is much beyond than mere compliance to standards.*

### Introduction

Compliance is conforming to a rule like a specification, policy, standard or law.

Compliance could be a regulatory compliance wherein an organization has to adhere to the rules and regulations laid down by the government/regulating body. This is essential and mandatory for any organization to function as they are the basic minimum standards in terms of infrastructure, equipments and staff that needs to be in place for the organization to get a license to operate.

Compliance could also be obligatory as in case of compliance to standards. Standards as laid by certain Certification Bodies like International Organization for Standardization (ISO) focusing on internal policies and procedures and functioning of the organization. They are voluntary guidelines which are generic in nature and are applicable to all industries. An organization has a liberty to design its own policy and procedures within the framework provided by the certification body to suit the needs of the organization. If the organization is found to be compliant to these standards on assessment by a third party, they get a written document certifying them by the Certification Body.

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\* Associate Professor, Administrative Staff College of India (ASCI), Hyderabad (e-mail bgulati5@gmail.com)

Compliance to Accreditation Standards is also followed by some organizations wherein standards are defined by Accreditation Bodies like National Accreditation Board for Hospitals & Health Care Providers, NABH (in India), Joint Commission JCI (in US), Accreditation Canada (In Canada), Australian Council of Health Care Standards (ACHS) etc. These standards are specific and focus on technical aspects of that particular industry. If the organization is found to be compliant to these standards on assessment by a third party, they are accredited by the Accreditation Body.

Though the standards are based on best practices of the industry but usually its compliance is not seen at all times in most of the organizations. It is generally observed that nearing the day of assessment of the organization by a third party, adherence to standards is at its peak. The organization has a tendency to become lax after receiving the certification or accreditation. Again just prior to the time of renewal of the certification or accreditation the drive towards compliance restarts. Also some of the work in certification and accreditation has a mixed response and is seen as unnecessary by the staff of the hospital and for getting the certificate only.

On the other hand excellence in providing services is the other extreme end of the quality spectrum. It is an attitude and constant drive to deliver the best to the patient at all times irrespective of if any inspector or third party is watching or not. It is the ability of the organization to consistently meet and manage the patient's expectations. The vision of the organization which is aiming at achieving Excellence is by creating an organization culture of continuous quality improvement. The organization culture is such embedded that the able leadership supports empowering of staff, staff taking ownership, problem solving and team work. It is an amalgam of clinical excellence and exceptional personal care. The focus is continuously improving the quality of current processes.

Service excellence can be achieved by the innovative measures like Kaizen, Lean, Six Sigma, Continuous quality improvement and these measures growing in an incremental manner.

**Kaizen:** is a quality initiative which brings in efficiency in processes by not simply planning for change but also rapidly implementing low cost improvement measures in the focused area.

**Lean & Six Sigma:** Are methodologies to improve quality and adding value to processes by eliminating waste and reducing variation in the processes. It is not cost-reduction program but a whole system management strategy.

**Continuous quality Improvement:** Quality improvement is an ongoing effort to improve products, services or processes could be gradual improvement over time or sudden improvement.

In United States, Malcolm Bridge Award Model has been designed based on the excellence models. It is believed that since the processes, technology and people all are interrelated and not any one alone can improve in isolation. Thus needs of the entire three have to be balanced and improved together.

Excellence in Clinical Services is an essential component for achieving quality in health care. Earlier Quality initiatives like lean, six sigma were focusing on the non clinical operations to reduce cost and enhance quality. Clinical operations of the hospital were an ignored area because the maximum administrators and performance improvement staff did not have a clinical background so they never understood the intricacies of the clinical excellence or were too intimidated by the clinicians. Even if they had a clinical background they do not want to rub the top performing clinicians in a wrong way who may take their patients to a competitor hospital. With advent of time, hospitals have realized that it is crucial to focus on the how the care is being delivered and involve the clinicians in the whole process of achieving excellence to make the hospital more financially sustainable, patient focused and physician friendly. Initiatives like regular monitoring of key indicators of the hospital, maintaining hand hygiene by care providers, preventing Hospital acquired infections, developing Standard Treatment protocols for procedures, defining policy for use and type of antibiotics, rational use of medication, medical audits, measures for risk assessment and management, preventing medication errors, monitoring incidents like sentinel events, adverse events, surgical errors, shorten average length of stay etc are to name a few. The doctors are involved and made the co leaders for bringing the change. The doctors develop Standard Treatment protocols and treatment standards for common diagnoses and the procedures, based on evidence based medicine, to reduce the variability in care being provided. This is supported by streamlining processes including admission and discharge processes and rational supply utilization. This ensures that all patients receive quality care which is evidence based and is reproducible. The outcomes also improve and thus increase in patient and staff satisfaction. A medical audit is done to ensure that these protocols are being followed and appropriate corrective and preventive actions are being taken to fill in the gaps found in audit.

Credentialing and privileging for doctors and nurses is another new initiative being done. The qualification, training and skills of the care providers are verified from their respective training organizations/peers/references/previous employers and they are provided privileges accordingly. Any cases of litigations and negligence against the care providers are being verified. Earlier doctors were getting attached to a particular hospital; were considered as Gods and they felt it was their right to

provide all aspects of care (history, examination, procedure/surgery, follow up etc) to patients. Nowadays based on competence (qualification, experience, training, skills) of the doctor or the nurse, he/she is provided the privilege to provide certain aspects of care only for which they were found competent as the responsibility of patient safety is ultimately on the hospital. The privileges of the doctors and nurses are communicated to other departments also for better coordination. The privileges of the care providers are reviewed from time to time. An audit is done to ensure that the doctors are practicing as per the privileges given to them.

In the year 2012, Medicare in USA have started a system of rewarding hospitals that by linking high quality care provided to their patients with the Hospital Value based purchasing programme. For the first time hospital will be paid based on the quality of service they provide and not just fee for service. This created a revolution. Awards like Health Grade Distinguished Hospital for Clinical Excellence award were started for the hospital with lowest risk adjusted mortality and complication rates.

Excellence is much beyond compliance, thus in the process of achieving excellence in one's services, compliance comes as a byproduct automatically. If the organization has inbuilt a system of providing best practices at all times and taking corrective and preventive action for avoiding repetition of any errors, third party assessment on any day, even a surprise check will find the organization compliant to standards (in certification and accreditation models third party assessment visits are usually planned in advance).

Most of the organizations go for certifications and accreditations due to market-driven forces and the competitive hospital having them. In contrast organizations going for excellence in services are mostly driven by commitment and passion of the top management towards continuously improving quality in their set up.

The common belief that the cost involved in achieving excellence is higher than in achieving compliance is misleading. The reality is the cost involved in achieving excellence is an investment and not a cost at all as through excellence the organization saves the cost of redoing tasks, performing duplication or unnecessary tasks. The organization also ensures that they are delivering reliable and high quality of services and products to its patients/customers and also efficient people management and internal processes.

An organization aiming towards achieving excellence in services may have a longer path to cover but is far greater achiever not only for stakeholders involved and also for a long term development of the brand of the hospital. Thus we need to move from a culture of compliance to culture of achieving excellence in the organization for building the credibility of the organization.

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Ravi Bhoothalingam\*

## The Silk Road as a Global Brand\*\*

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### Abstract

*The Silk Road was a name coined by the German geographer Ferdinand von Richthofen to describe the mosaic of trade routes within and across Asia to Europe, developed over the last 2000 years. The name evokes images of exploration and adventure, of Marco Polo and Ibn Batuta, and has been elaborated in myth, legend, song and poetry. More recently, China has 'appropriated' and re-invigorated this powerful 'brand name', making it the vehicle for its proposed Maritime Silk Road and overland Silk Road Economic Belt, through its strong advocacy and financial backing for these ventures. How will these gigantic and ambitious connectivity projects—which will ultimately link all of Asia with connections onwards to Europe and Africa—alter the world as we know it? What is our national interest here, and how should India respond?*

Ladies and gentlemen, good evening to all of you. At the outset, may I thank Mr. Susim Datta, Chairman of the Court of Governors of the Administrative Staff College of India (ASCI), and its Director-General Mr. Ravi Kant, for so kindly inviting me to deliver this lecture. It is always a pleasure to return to the gracious precincts of ASCI and to the city of Hyderabad with both of whom I have a long association. I treasure these occasions to renew my friendships and to be re-invigorated by Hyderabad and its people.

Hyderabad is a particularly appropriate place to speak about the Silk Road. Situated at the geographic centre of India and well-connected with all its parts, Hyderabad has a multi-cultural and multi-ethnic present and past. This was indeed the record of many Silk Road towns. And what better location than ASCI—a renowned centre of management and administrative science—to discuss the place of global brands? So, this evening, I shall start with some of the history of the Silk Road, and then why I regard it as a global brand. Thereafter, we shall look at contemporary reality by focusing on China, its recent Silk Road proposals and their significance. Finally, the overall implications and the choices before India.

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\* Founder & Chairman, Manas Advisory and Member, Court of Governors, ASCI

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## The Silk Road in history

The Silk Road was never a single road, as the name might suggest. This term was coined by the German geographer Ferdinand von Richthofen in the late nineteenth century to describe the interlocking mosaic of trade routes within and across Asia to Europe, which developed over the last 2000 years. The name is evocative of images of exploration and adventure, of intrepid travelers such as Marco Polo and Ibn Batuta, and has been engraved in world memory through myth, legend, song and film. Samarkand, Bukhara, Yarkand, Kashgar and Khiva are only some of the resplendent names of the way stations along the Silk Road. Courage, curiosity, stamina and imagination are the primary emotions associated with a traverse of these routes, which was indeed a brave enterprise in those times.

It is indeed the case that one of the earliest goods to be transported on these roads was silk from China. At one point, not only the aristocratic ladies of Rome but also its gentlemen were so besotted with purchasing fine Chinese silk, that the outflow of gold to China threatened to upset the financial stability of the Roman Empire. It required the Emperor Tiberius himself to intervene, banning the use of silk by men.<sup>1</sup>

Of course, many other products apart from silk travelled along this vast network of roads—ivory, gold, silver, tea, fruits and nuts, paintings, sculptures, manuscripts and ideas and doctrines of many types—religious, scientific, illusionary, revolutionary or merely eccentric. At one end of the Road was China, while India, Persia, Arabia, the Levant and Europe were destinations as well as origins of different branches of this complex array of tracks, roads, waterways and caravanserais. Trade and transfer of goods, ideas and services across this vast terrain were mediated by many middlemen and bankers. For a long time, Parthians occupied such positions, but later on Indian bankers from Sind and Gujarat gained renown as dependable financiers whose *hundis* were honoured from Moscow to Mongolia.

The most celebrated ‘product’ to travel the Silk Road was of course Buddhism, taken from India over the north-western passes of the Hindu Kush and across what is now Xinjiang, to reach into the heart of China. There followed a great interflow of trade, cultural intercourse, exploration and scholarly interaction between India and China. There is a wealth of literature on these intrepid travelers such as Xuan Zang and Kumarajiva, amongst many others. Both Amartya Sen<sup>2</sup> and Lokesh Chandra<sup>3</sup> have documented the range of artistic and scientific exchanges with China. More recently, a remarkable publication co-created by a team of Indian and Chinese scholars—the “Encyclopaedia of India-China Cultural Contact”<sup>4</sup> co-sponsored by India’s Ministry of External Affairs—has listed over 700 scholars, travelers and *gurus* who contributed to cultural interpretation and understanding between the two civilizations.

India's own remarkable role in the millennium before 1200 A.D. was as the lead provider of advanced education in Buddhism as also the arts, sciences and medicine at its great Universities of Nalanda, Vikramashila and Taxila, amongst others. Students from across Asia journeyed here by land and across the seas, often stopping off at Srivajaya (in present-day Indonesia) to learn Sanskrit. The sea-route to India was also well-travelled by pilgrims and traders, who often arrived by the land route and exited by sea or vice versa. In the early 15<sup>th</sup> century came the celebrated seven voyages of exploration and trade by the Ming Emperor's great fleet of huge 'treasure-ships' led by Admiral Zheng He. Zheng He assembled a multinational crew from all over Asia for his voyages which reached right up to East and South Africa. The Admiral is known to have remarked particularly on the skills of the Indian navigators and pilots that he took on board in Calicut and Cochin.<sup>5</sup>

The Silk Roads were in fact an early example of globalization at work, and this was exemplified particularly during the Mongol Empire of the 13<sup>th</sup> century. The Mongols unified the vast mass of Eurasia practically from Beijing to Belgrade, creating the largest free-trade zone ever known, ensuring wide and cheap distribution of goods. Genghis Khan, in particular, abolished torture and mutilation, and employed talented people of many nationalities in his army and civil administration. He established religious freedom across the Empire and instituted the practice of diplomatic immunity for ambassadors.<sup>6</sup> The Mongol international postal service—fast horses with relief riders and horses at regular way-stations—remained the quickest way of getting news from Vienna to Vladivostok until the Trans-Siberian Railway came 600 years later. Unfortunately, history has painted Genghis and the Mongols generally as blood-thirsty barbarians who committed atrocities on a gigantic scale. Actually, modern historical and archaeological research suggests that they were not much worse than their contemporaries in Europe and Asia. But since the Mongol armies were small compared to the competition, Genghis encouraged the spread of stories of terror and invincibility so as to encourage wholesale surrender of his enemies.<sup>7</sup> However, in the Mongol case unlike others, their history has been written entirely by the losers—the Chinese, Arabs, Persians and Europeans—and therein lies the reason for such portrayal.

### **The Silk Road becomes a Brand**

With such a colourful and evocative history, it is not surprising that the words 'Silk Road' (or 'Silk Route') produce a range of strong emotions and vivid associations. This is the very essence of a 'brand', as defined in classical management literature. In the crowded market-place of today where we are surrounded by myriad offerings, it is important for a product to differentiate itself and present a clear identity associated with some visible values and positive emotions. Almost like a person, a strong brand creates a personality around itself, thus elevating it from being a mere thing of utility to something around which stories can be told. Marketing

*gurus* have gone to great lengths to create psychological profiles and ‘brand personalities’. But what is more important to note is that some of the brands’ attributes rub off on to those associated with it—its consumers as also its producers. Hence the value of a great brand. Consider the mental image we have, say, of a BMW driver as opposed to the owner of a Maruti 800. After all, Sunzi’s ‘The Art of War’—today a text book of management science—teaches that bloodless victory lies in capturing the mindspace of the opponent<sup>8</sup>, or in this case, the customer.

Consider now—in this light—the two announcements that China’s President Xi Jinping made in September and October 2013 respectively. The first was made in Kazakhstan where he announced the ‘Silk Road Economic Belt’, and the second in Indonesia, where he announced the launch of China’s ‘Maritime Silk Road’. (Taken together, these two initiatives are known as ‘One-Belt-One-Road’ or OBOR, for short.) Along with the announcement was an invitation to various countries to become partners in these two ventures. But what was the substantive content of his announcement? The ‘Silk Road Economic Belt’ envisages a massive network of roads, railways, pipelines, communication links, bridges and other hard and soft infrastructure designed to promote trade, travel and the interflow of goods and services across the land routes of Asia. These would be built under a Chinese initiative and partly financed by them, but in consultation with their Asian partners. And likewise, the ‘Maritime Silk Road’ envisages connecting China’s eastern coast with Europe via Asia and Africa through the sea-lanes, and thus involves a corresponding development of shipping, ports and maritime infrastructure on a similar basis.

Had President Xi said just this in plain terms, as an international banker might have done, it would have drawn interest in the financial pages of the media and been commended as a highly imaginative venture. But just that. However, the ‘Silk Road’ brand name brought in a whole new dimension. The world media were entranced but also somewhat mystified, since details were scarce. But the magic words ‘Silk Road’ in either case ensured that media attention remained focused for many weeks on these issues, with little detail but much speculation. Moreover, as the initiator of the idea, China itself gained from the halo around the ‘Silk Road’— of free-flowing goods and services, movement of people and ideas, of ‘common prosperity’, and ‘a shared economic future’, of the rhetoric of cooperation and togetherness rather than competition and power-play. But this feeling was (and still is) not entirely one-sided; there remains some skepticism—in varying measure—about China’s motives and intentions and about the larger game that is being played out over the Asian continent and across the seas. It is to this subject that we now turn.

### **The Geo-politics and Geo-economics of the Silk Roads**

What is China’s motivation behind the Silk Road ventures? We can offer two reasons which work separately but simultaneously and are organically linked. The first is

geo-economics. China's government is attempting to move the economy from being propelled mainly by investment to one powered by consumption demand. But in the meantime, there is huge surplus capacity in China's infrastructure and heavy machinery sectors. Chinese investment abroad through the OBOR initiative would activate demand for these goods, maintaining if not expanding the employment therein. China's huge \$ 4 trillion fund of foreign reserves could support much of their foreign investment programme, supplemented by whatever can be marshaled through its newly-created Silk Road Fund, as also from the recently-formed Asian Infrastructure Investment Bank and the (BRICS) New Development Bank. Infrastructure and connectivity are the main barriers to trade today, since tariff levels around the world have dropped sharply. Removal of trade barriers and the creation of free-trade areas in its adjoining regions is also in China's overall interest. Moreover, several of China's poorer provinces—Tibet and Xinjiang amongst them—lie on China's borderlands, and connecting the neighbouring economies through them would act as a spur to their overall development.

But it is not just about economics; obviously—China's self-interest alone can never suffice as a rationale. Thus, the geo-political packaging and messaging around OBOR speaks about its *raison d'être* as the 'common development' and 'common prosperity' of all the countries participating in the venture. It is a tide that will lift all boats, goes the narrative; whilst some may gain more than others, the overall results will be value-additive. This is a powerful argument and thus serves to create—for China—a support base for its riposte against the United States' 'Pivot to Asia'. This 'Pivot', along with the US-inspired Trans-Pacific Partnership (TPP) from which China would be excluded (as would India) are the two prongs of what China sees as a clear China-containment strategy. But if OBOR looks attractive, China's regional neighbours might well look at the alternative trade partnerships on offer, such as the Regional Comprehensive Economic Partnership (RCEP), or the Free Trade Association of the Asia-Pacific (FTAAP). Both these schemes—supported by China—are more flexible and make lesser demands from emerging economies than the US-laid terms for TPP. Surely, would not the building of a wide community of nations of different political hues who all stand to benefit through OBOR, create for China a strong countervailing force to any attempts to contain China, whether economic or geopolitical?

It is here that we return to the concept of the global brand. As every marketer knows, if the brand—however strong—is not launched correctly, the product may not succeed. And the Chinese very nearly took a mis-step when they announced the OBOR. Whilst they had spoken in general of a consultative approach to OBOR, they presented it without prior consultation, much as one would offer a delicious pre-cooked meal which could not fail to delight any and all of those who tasted it. Most countries invited to join were at first somewhat nonplussed by this approach. Over that same period, several Chinese delegations hastily visited all these countries

(including India) to explain and reaffirm that the entire venture would proceed on a consensual and cooperative basis. Finally, over 30 countries (other than India and Bhutan) who were invited by China did indeed express their wish to participate, and endorsed the proposal. They calculated that in overall terms the benefits through connectivity were enough to outweigh any problematic issues, none of which were obvious enough on the surface to warrant a refusal at this point of time.

### The Indian dilemma

India, however, has been reticent about its answer to Beijing's invitation to join OBOR, and has—not very convincingly—cited lack of detail and insufficient discussion of the proposal as reasons for its silence. Here, India is caught in a conflict between its heart and its head. The heart—already hurt by the 'stab-in-the-back' of 1962 and its ensuing 'trust deficit'—looks at India's self-respect and self-perception of its own standing in Asia, and rebels against an initiative which seems to endorse an inexorable drift towards an ultimately Sino-centric Asia. But the head is quite aware of the hard realities facing China as well as the benefits to India of signing on to a venture that will link us ever closer to the dynamic supply chains and consumer markets of Asia. But in an uproariously democratic set-up as in India, voters and governing elite alike seem more influenced by the heart, perhaps inflamed by our gladiatorial TV channels! Hence the dilemma.

Still, however understandable the public emotions or elite discomfort, no responsible Government can allow such feelings to supercede the national interest. So what does India's national interest indicate? Should not the development of India and prosperity of Indians be the prime consideration?

For a start, the Indian rupee has depreciated by 40% compared to the Chinese RMB over the last 5 years so the fear that Chinese goods will 'flood' the Indian landscape seems exaggerated. In several areas—many auto-components for example—Indian products are competitive. Moreover, Silk Road or no, India must in any case set its manufacturing house in order and address the obstacles to its competitiveness, if we are to fulfill the promise of jobs for our youth, and gain from our 'demographic dividend'. The OBOR connectivity might be just the external stimulus that we need to provide a sense of urgency for this agenda. Remember, in the 'nineties, Indian industry responded splendidly to the 'opening up' of the Indian economy and the reduction of import tariffs, despite early misgivings.

Secondly, Chinese investments can speed up the provision of infrastructure in India, and as 'the ease of doing business' in India improves, it will become more attractive to Chinese capital which is increasingly exposed to greater risk elsewhere. Further, as China moves up the value chain, opportunities for Indian industry (and for other countries) will arise to take advantage of the increasing consumer demand from China for a variety of goods and services.

But will India have to play second fiddle to a resurgent Middle Kingdom, a China that may ‘rule the world’<sup>9</sup> or eclipse the United States in its domination of the world economy?<sup>10</sup> This possibility, again, seems remote—on several counts. One, China’s manifold internal problems—economic, social, environmental and demographic—are of such magnitude that there is no guarantee of that country’s inexorable progression to global leadership. Two, the United States cannot be written off so soon as a nation in decline: its rebound after the global economic crisis of 2008-09 has been better than most, and despite its political gridlock, its recent Cuba and Iran policies have shown a spirit of resilience and acceptance of ground realities. More relevant, its power in science, innovation and new-age business cannot be denied. Three, a clutch of other countries such as Japan, Australia, Indonesia, Iran, Russia, Turkey and Brazil will in no way be easy push-overs for China. What is most likely is that no clear ‘Master of the Universe’ will emerge, nor any permanent alliances, but a shifting spectrum of power-relations amongst nations. India will need to learn to move deftly within this changing matrix.

### **How India can use OBOR?**

So can India leverage OBOR to its own advantage? The answer is ‘yes’, and there are three ways to do so, all of which offer challenges. The first, as mentioned above, is to use OBOR as a stimulus to trigger a manufacturing revolution in India and to enable ‘Make in India’ to become a major supplier to much of Asia. This could address the issue of employment for our burgeoning population of young people. Of course, setting our own house in order will be the key, but the window of opportunity will not remain open for long. Even now, countries like Myanmar, Bangladesh, Vietnam and Cambodia, are competing for investment from China and as sites to relocate its low-cost manufacturing industry. Indeed, India’s strengths in Information technology and telecommunication can be used to radically change the very definition of low-cost manufacture, making it neither based on raw manual labour as in the past, nor on robotized automated plants requiring few human beings.

A second area is to use the OBOR impetus to accelerate India’s connectivity and integration with its own backyard—the South Asian neighbourhood—a process that has already started. The shadow of China—like Banquo’s ghost—will soon be a looming presence in SAARC in any case, so why not use its clout to our advantage? India’s central geography and long-standing ties with its neighbours cannot easily be replaced overnight by Beijing. An Indian initiative to ensure easy movement of goods, capital, technology and people throughout the sub-continent will add immeasurably to its welfare—and to India’s stature as the pivot—and not the bully—of the region.

The third area harks back to India’s Silk Road past when India was the fount of higher education in Asia. Why can we not reclaim this position? If there is one thing all Asians want regardless of their status, it is a good education for their children.

India has lagged in providing places for foreign students in its University system. Yet the Indian higher educational infrastructure—stressed as it is and with quality yielding to quantity—still has many strengths. The English language is one of them, and the sheer spread and reach of India’s higher educational system is another. If India could offer students from neighbouring countries a larger number of seats and special incentives, it would go a long way to improve its image amongst its smaller neighbours. Again, with the creative use of I.T. and modern technology, the costs of expanding capacity in the education sector can be minimized, whilst the increase in foreign students (and faculty) will add diversity and vitality to Indian campus life and the quality of education. And few bonds are more lasting than memories of a great educational experience at a young age in a foreign land.

### In conclusion...

India must embrace and not shun the Silk Roads. Rather, we must proudly— and with confidence—reclaim the place that we once had as one of its primary destinations, and indeed origins. India can add immeasurably in many dimensions to the range and quality of connectivity that the Silk Roads offer. China may be bigger and stronger, but it has several vulnerabilities, as has India. But the many complementarities between these two nations have not been explored in depth, and this connection offers an opportunity to do so.

“I have not told half of what I saw” said Marco Polo, describing the wonders of the Silk Road whilst dictating his memoirs to his secretary. The ancient roads he traversed led to a mythical land of milk and honey; the Silk Roads of the modern age too will lead to different wonders. We may have to create many of them. That is the challenge before us and we should rise up to it.

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K.Padmanabhaiah\*

## Redesigning Administration to Propel India into World League\*\*

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Mr.SM Datta (Chairman, Court of Governors, ASCI), Dr.SK Rao (the then Director-General, ASCI), and distinguished ladies and gentlemen, I deem it a privilege to deliver the Foundation Day Lecture of ASCI. This institution played a historic and important role in the development of the country. ASCI, which was established in 1956, five years before the first IIMs had come up at Ahmedabad and Calcutta, was the place of pilgrimage for senior managers from the government and private sector for many years. As new management schools came up, the importance of ASCI declined to some extent. But I think ASCI can once again play a great role in reshaping Indian administration, as the country is poised to enter into the world league.

Indian economy grew at a trend rate of 8.6% per annum during the seven-year period of 2003-04 to 2010-11. There has been a steep decline from 2011-12 onwards, a period when massive scams surfaced. 2012-13 and 2013-14 were described as a period of policy paralysis. We need not go into the reasons for the growth and decline. There are also economists who believe that India's economy tends to rise and fall with the global economy, and it is nothing to do with the party in power.

This year's election, which brought in a party with a clear majority in the Lok Sabha, with a PM who is honest, clear headed, focussed, development-oriented and modern in outlook, roused the expectations and aspirations of all and particularly the youth. Government has already come up with some inspiring schemes like, Make in India, Job-oriented growth, Digital India, Smart cities, Bullet trains, *Jan Dhan Yojana*, *Swachh Bharat*, Cleaning up of Ganga, Linking up of rivers, and many more.

The international economic scene also seems to favour India as a destination for investments. Duetsche Bank estimated that savings glut in Europe and China and other emerging economies would lead to excess funds of \$3 trillion in the next five

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\* Former Union Home Secretary, Govt of India and Member, Court of Governors, ASCI

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years which can come to India if business confidence is built. Oil price has touched a low for many years. Balance of payments position is comfortable. Inflation is at a low level. Market sentiment is very positive. There is no doubt that there is a potential for growth. India has been the 10<sup>th</sup> largest economy in the world for the last four years, and there are forecasts that it would be the third largest economy after China and USA by 2028.

Government has made some bold decisions like the coal ordinance permitting in a limited way entry of private sector into that domain, FDI in defense, and in construction industry, some labour reforms etc. But as one observer has put it: "There is a longing for a revolution, but there is yet no clear idea of where to go next and how. The new government still has to design the process, let alone implement it."

There are 5 issues which the government has to address:

- a) Improve working of public sector enterprises in critical areas like steel, coal, mining, power, railways, ports.
- b) Improve social sector, namely education, skill development, health.
- c) Build effective and efficient partnerships with private sector; And, build business confidence of local and foreign investors.
- d) Improve provision of government services to the citizens.
- E) Improve physical infrastructure.

Encompassing all these, it must make civil service efficient and accountable. All these must lead to improving business confidence and citizen confidence.

Let us see what is the ground reality in all these areas:

i) As regards Public Sector Enterprises, a recent report of Planning Commission says that 738 central projects on which an amount of Rs.5.6 lakh crore has already been spent, are stalled. They require another Rs.5.7 lakh crore for completion. Of these, 83% are held up with delays ranging from 3 months to 12 years. The main reasons for the delay are fund constraints, contractual disputes, agitations, and import of machinery, equipment procurement, and changes in designs.

There are chronic delays in completion of irrigation projects. Modernization of Indian steel plants suffers from similar delays and cost escalations. Decision making is very slow. For example, the Navi Mumbai airport was cleared in principle by the Union cabinet in 2007. It got environmental clearance only in 2010. But till now there is no further progress. I have been hearing about Trans harbor bridge near Mumbai for the last 20 years. Tenders were called a few times but no further action seems to have taken place. Our Public sector banks are performing poorly in comparison with the private banks operating here.

The example of SEZs, especially in Andhra Pradesh, is an example of grabbing of valuable land for real-estate purposes under the garb of developing exports. Out of 78 SEZs sanctioned in AP, only 36 are operational. Extraordinary projections were made regarding exports, foreign exchange and employment to be generated but the actual achievements till date are 6%, 21% and 6.5% respectively.

The massive over-runs in cost and time, failure in improving productivity, and in setting up of washeries in the coal sector, dismal failure in meeting targets in setting up new power plants and in power generation, failure in conservation of petroleum products, repeated failures in rural water supply schemes, and in providing low cost housing are other failures of the public sector.

The only few areas of success are in IT, telecom and space.

ii) As regards social sector, India ranks at a low 136 out of 187 countries on Human Development Index. Our neighbor Sri Lanka is at rank 73. Educational standards in our schools, government as well as in most private schools, are abysmally low in international comparisons.

iii) When it comes to Public-Private Partnership (PPP) projects, the Highway sector has been touted as the best example. It was the largest PPP road building program in the world. 239 projects involving 21746 km were awarded. Only 21% of the length (4541 Km) was completed. One newspaper described the subject as “Highway to Nowhere”. Construction work is yet to start on projects involving 24% of the road length. This dismal failure is due to over optimistic bids, government not meeting its obligation of land acquisition etc. Government’s calculations were that PPP projects would be cheaper than government works. But this did not turn out to be correct. In this background, the new Minister’s statement that he would achieve a target of 30 km per day seems highly unrealistic, specially with the new and complex Land Acquisition Act in place. Government announced the concept of PPPP(4P) projects, the last P standing for people, whose co-operation would be sought for land acquisition.

iv) As regards investor confidence, in various global indices like Ease of Doing Business, Corruption Perception Index, Globalization Index, Global Competitiveness Index, Misery Index (unemployment and inflation rate), Index for Public Trust in Politicians etc, India ranks very low. In some of these indices, India ranks lower than other SAARC countries. In the Ease of Doing Business index of the World Bank which is based on 10 sub indices, India has been 132 to 134 ranks (out of 189 countries) for the last 6 years. In the latest revision, it has gone down further to Rank 146. In the Corruption Perception Index prepared by the Transparency International, India ranks at 94 out of 177 countries. It has now improved to 85<sup>th</sup> rank. Still we have a long way to go to improve business confidence.

On the positive side, India ranks very high, on IT industry Competitiveness Index, E-readiness Index, Network Readiness Index, and Space Competitiveness Index.

v) As regards provision of Government services to the citizens, there exists the menace of harassment and bribes. This malady is omnipresent, except in few States where e-services are provided. Even in these states, last mile linkage is yet to be improved, as the functioning of Common Service Centres is not satisfactory in some States. Though there are Rights-based legislations (for food, work, education, and for health in a few States), there are lot of leakages; but things are improving with *Aadhar* cards, DBT scheme, and e-services. Citizens Charter and Grievance Redressal Bill, and the Electronic Delivery of Services Bill 2011 have been pending since 2011. It is necessary to pass these Bills at the earliest. Similarly, a Bill on “Corrupt Public servants (forfeiture of Property)” and a Bill on “Electronic delivery of Services,” if introduced, would improve governance.

The question I want to address is, can the Government deliver on the promises? The question arises because of my past experience of many decades with administration. When a new Chief Minister talks of single window clearance, or that all clearances would be given in 15 days or so, I get a feeling of *déjà vu*, as these are the type of statements I have been hearing ever since I joined service. Some of the iconic projects being announced now, were also announced by governments in the past, which had massive electoral mandates, but have not progressed in any substantial way.

For instance, take the Ganga project. A Ganga Action Plan-I was launched during 1986-2000 (14 years). Nothing much happened. Then Ganga Action Plan-II was launched in 2001 with an outlay of Rs.2285 crore. In 2009, a separate organization “National River Ganga Basin Authority” was created. In 2011, a major project, “Mission Clean Ganga” was launched with the World bank Aid of \$ 1 Billion. Incidentally, ASCI is also involved with this, having signed an MOU with the Authority in May 2014. There are no authentic studies to find out the outcome of all these projects related to cleansing of the Ganges. Now the Government calls the scheme “*Namami Gange*”. There is no doubt that cleaning Ganga is a massive and complex project but the main problem is lack of proper design of the project, lack of authority, lack of concerted action, and lack of accountability.

Linking up of rivers is an old concept and Dr.K.L.Rao, the renowned Engineer and the then Minister for Irrigation, made such a proposal in mid 60s. In 2003, Shri Vajpayee stated: “The first mission of my Government is on networking of rivers.” What seems possible is, interlinking of some intra-state minor rivers. The rest of the project may not be feasible in the near future. Incidentally, the performance of Ministry of Water resources has been dismal. There are massive delays in completion of projects, and a huge gap between the irrigation potential created and irrigation

potential used. The main issue is, lack of co-ordination between the Irrigation and Agriculture departments of the State governments. *Jala yagnam* of the erstwhile Andhra Pradesh is a classic example of massive corruption in the irrigation sector. None of the projects made any progress.

The Union Government has now launched an eminently desirable scheme *Swatchh Bharat*. A scheme of similar nature, called Total Sanitation Campaign(TSC), was launched in 1999 with an aim of eradicating open defecation by 2010, which was later revised to 2017. The name was changed in 2003 to “*Nirmal Bharat Abhiyan*”, and a sub scheme called “*Nirmal Gram Puraskar*” was introduced. Film star, Vidya Balan was named campaigning ambassador. However, a review in 2011 revealed that only 11.6% of Gram Panchayats, 3% of the blocks, and 2% of Zilla Parishads in the country got the *Nirmal Gram Puraskars*. This project shows that government must realize that it is possible to change cultural norms only by community-led programs and that requires inspiring leadership. One hopes that the new program would succeed due to leadership of the new PM.

Compared to the past, decision-making and governance have become much more difficult and complex, due to more openness (thanks to the RTI Act, e-governance, media, and PILs), environmental and human rights issues, assertiveness of States on issues of federalism, desire of the Civil society and NGOs to be part of the decision-making process, activism of higher judiciary, technical nature of some of the ministries, pressures arising out of globalization, and vigilance aspects.

Let me consider the case of civil servants, the people charged with the responsibility of implementing government policies. Are our civil servants incompetent and lazy shirkers? Or are they cursed and do not care about the development of the country? The widely accepted assessment is that the members of the higher civil service in any branch are very intelligent and capable people with good managerial capability and hard working even in the most trying circumstances. Till recently they had not focussed on acquiring domain knowledge, but in the last one decade they have made serious efforts at acquiring domain knowledge through various training programs and through specialized education. Government also has been posting officers throughout their career in broad fields of administration such as agriculture, industries, trade & commerce, banking, insurance, capital markets, infrastructure, social infrastructure, scientific departments, defence, internal security, vigilance, etc. This trend needs to be strengthened. One more comment about Indian civil servants is that they are more powerful than their counterparts in many other parts of the world.

Then why do most knowledgeable observers think that Indian bureaucracy is negative? To quote a report of Hongkong-based Political and Risk Consultancy Inc, “Dealing with India’s bureaucracy can be one of the most frustrating experiences for any

Indian, let alone a foreign investor”. The same report further says: “Indian bureaucracy is rated the worst in Asia.”

All management experts agree that around 80% of the performance of any organization depends on the quality of the system used. The problems one faces while dealing with the government are rooted in these systems, the rules, policies and procedures. India is said to be the most over-regulated countries in the world.

But what is the status of our bureaucracy (in which I include the entire government machinery) and other institutions of our polity? There has been no radical overhauling or restructuring of any of these ever since independence. On the other hand, the rules and procedures have become more cumbersome, complex and a hindrance to a result-oriented approach. To begin with, the rules and procedures were not this complex. Nobody set out to make them that way. But over the period of decades, they have been calcified by years of CYA steps introduced to eliminate “waste, fraud and abuse” and in an effort to plug every imagined loophole. With the result various components of polity have become slow, inefficient, and unresponsive and in one word dysfunctional. All these are creaking and breaking down everywhere. That is why there is such a demand for reforms in every field, administrative reforms, police reforms, judicial reforms, financial sector reforms, tax administration reforms, public sector reforms, educational reforms, electoral reforms, health care reforms, reforms in vigilance set-up etc. A former Chief Minister of Andhra Pradesh has recently stated that the only institution which has improved its working in the last 67 years is the Election Commission. In every other institution, there is only deterioration.

Let me name a few important deficiencies of the system and what needs to be done

- a) **Responsibility not properly fixed:** There is no clear enunciation of responsibility. What each department has is a list of subjects allocated to it. There is also a list of subjects assigned to each Joint Secretary, who is in charge of a division within the department. There is not even a focussed mention of the objectives to be achieved.
- b) **Ex ante setting up of targets and inter-se priorities.**
- c) **Setting up of national targets** (as distinct from departmental targets), like power generation, improvement of various health parameters, achieving certain educational standards, tourism targets, etc. Achievement of these national targets would fall on a number of ministries. For instance, tourism promotion would involve a co-ordinated action by department of Tourism, Civil Aviation, Railways, Culture, Roadways, Urban Development, Metropolitan and Municipal Administrations, Forests and Environment etc.

Joint targets must be assigned to all these departments, and performance appraisal of each officer must depend on the achievement of national target. Tourism may look like a simple matter, but look at the co-ordination that is required to achieve success.

- d) **Accountability:** This is the greatest causality in Government. For instance, there is a gap between the targets for power generation, and the actual power generation. These targets have not been achieved year after year. Who is accountable for this under-achievement? Government's performance report would only say that Ministry of Power could not achieve the targets. Is this a satisfactory answer? Individuals make up the Ministry. You have to reward or punish them. You can not punish a Ministry.

Further, even if accountability is enforced in a Ministry, it is inward and upward in the government. This is not sufficient. We must enhance accountability outward to society and citizens, through such mechanisms as social audits, third party audits, and public hearings about performance of important ministries.

We should also introduce concepts like lateral accountability (for example, what do other civil servants or say Secretaries think about the performance of a particular Secretary viz. some sort of a peer review), and epistemic accountability (for example, what do technology professors around the world think about professors of IITs?)

- e) **A complete process re-engineering** to be done, followed by introduction of e-governance. This is to simplify and to eliminate unnecessary procedures. The Secretary concerned must be given this responsibility. He may appoint outside experts, but mandate to simplify should be clear.
- f) **A complete re-writing and simplification of all civil service manuals:** For all civil services-including all cadres, and at the Centre, State and All India Services- office manuals, departmental enquiry manuals and vigilance manuals should be rewritten. This should preferably be done before the 7<sup>th</sup> Pay Commission submits its report. It is good to know that some of the States have re-written their police manuals.
- g) **Reasonable tenures to officers:** Government of India rather strictly enforces the 5-year tenure rule to Joint Secretary level officers, though this got diluted to some extent in recent years . The real problem lies at the level of Secretary to government. The ideal solution would be to make tenure co-terminus with that of the elected government. However this would not be possible, as an officer would normally have about two years service left by

the time he becomes a Secretary. Hence, a Secretary should be continued on a post for two years irrespective of his date of superannuation. This way he/she can be held accountable for his/her work.

- h) **Rewarding performance:** For those who exceed the targets, there are various ways of rewarding other than giving performance-linked pay. Conferring prestigious civil service awards, Padma awards, and involving them post-retirement on prestigious bodies rendering policy advice to government, are some to mention.
- i) **Weeding out/retiring the bottom** (in performance) 25%, every year, and at the age of 50 and 55 years.
- j) **Reduction of supporting jobs:** There are a large number of supporting jobs like clerks/assistants, and peons. They need to be reduced, or re-trained (specially at the State level) to be teachers (in case of clerks), and policemen(in case of peons).
- k) **Budget reforms:** One year is too short for completion of major projects and programs in the government. Expenditure budgets should be fixed for 2 years, with an indicative budget for the 3<sup>rd</sup> year. Once a budget provision is available, no further approvals should be necessary from Finance Ministry or Planning Commission like body, for incurring expenditure.
- l) Lateral entry into government upto 25% at the level of Joint Secretary and above, especially for technocrats and domain experts.
- m) **File notings and decision-making** should not involve scrutiny at more than 3 levels (2 levels below the decision maker). This would avoid each file being processed from the noting assistant level.
- n) **Treat line jobs on par with staff jobs:** There is a great prestige attached to policy making jobs, compared to line jobs like heads of the departments etc. This bias in favour of secretariat jobs, vis-a vis field jobs should be removed.
- o) Similarly, the focus of cabinet meetings, which are held once a week, is on taking policy decisions. One cabinet meeting in a month should be exclusively devoted to a detailed review of implementation of previous decisions taken.
- p) **Political interference:** Prime Minister has assured Secretaries to government that there would be no undue political interference and also gave instructions that minister's directives should be given in writing. There are already such instructions and it is good that the PM reiterated the same.

There is an interesting study made to find out why India is good at organizing mammoth events like elections, census operations, *kumbh mela*, UID cards, and also space programs. The study showed that the factors are (i) no political interference, (2) focused objectives and (3) No or less discretion.

- q) **Rule-bound administration and purposeful administration and use of discretion:** I think that rule-driven administration is good in a regulatory environment, like giving state resources like mining permits, contracts etc, and a purpose-driven administration with a degree of discretion suits social sector, like education, health etc. It is necessary to make this distinction.

Another study focused on why IITs are some of the best institutions in the world. The finding is that the IIT bureaucracy (professors running the departments) are given autonomy and discretion in selecting the candidates, in devising the syllabus and in running their departments. The general feeling, however, is that discretion should be reduced to the minimum, since bureaucrats will always abuse their power. Then how does one explain the outstanding performance of IIT professor bureaucrats, who could have liberally misused their discretion. The study attributed the success, to the fact that IIT bureaucrats felt that they had a lateral accountability to colleague professors in the IIT, and an epistemic accountability (accountability across a profession and across countries).

- r) **Role of State Governments:** No amount of reform at the centre alone would result in better governance unless reforms are carried out at the level of state governments. The locus of action for a project/program, whether central, state or private, is at the State level, involving decisions on allotment and registration of land, water, power, labour, local taxes, municipal permissions, gram sabha permissions, roads including access roads, and law & order maintenance. The reforms and de-regulation have not made any impact on most of the State governments. It is now easy for an industrialist to set up a big plant, but a farmer cannot set up a brick kiln or excavate sand for repair of his house without bribing several petty officials.

Huge amounts of central funds flow to the states. Every year roughly Rs.6.5 lakh crore is transferred to states. This does not include subsidies like food, fertilizers, and kerosene/LPG. The transfer of funds should be linked to performance of the State government on certain agreed social and other indicators. Of course, the release of funds should also relate to the progress of the projects/schemes for which funds are being released. Today it is a case of “triumph of expenditure without responsibility” as an observer put it. Typical examples are misuse of funds for rural water supply and funds for completion of irrigation projects under construction.

Transfer of officers at the State level follows no rules or principles. There are no tenure rules. Anybody can be transferred anytime anywhere. It is essential that State secretaries also should have a tenure of 2-years. Civil service boards should be constituted in the States, to decide on the postings of Class I officers. All class II officers' postings should be done by Heads of the Departments. Some CMs may welcome these suggestions, since they can then escape pressures from MLAs for transfers etc. In some States transfers attain the status of an industry, "transfer industry".

### **Conclusion:**

There are a whole set of other issues like need for balanced regional development (by 2025,  $\frac{3}{4}$  of India's growth may come from 49 clusters in 183 districts). Special attention is paid to develop the areas deprived of development due to naxalism and insurgency. There is an urgent need to keep income disparities within limits, and avoid excessive zeal for new legislation; establish smooth federal relations, prevent fragmentation of administration by creating too many Ministries, etc.

But it is heartening to hear the Prime Minister saying that it is the PM and CMs who constitute the government, indicating a commitment to smooth federal relations. Similarly, by establishing the website mygov, he has started a serious exercise in participatory governance, think-tanks and research institutions like ASCI can play a vital role in advising government on better governance.

I thank ASCI for giving me this opportunity and I thank you for your attention.

## *Notes for Contributors*

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**Manuscript submission:** Copies of the paper, notes, or book reviews to be considered for publication must be sent to the Editor, *ASCI Journal of Management*, as a Word file attachment via e-mail. Additionally, a hard copy in 1.5 spacing—on one side of the paper, with sufficient margins on both sides—can also be sent. It is a condition for publication that the material sent is original work, which has neither been previously published nor been submitted for publication elsewhere. It is in the author's interest to submit a clearly written and carefully proofread manuscript.

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