

Surgical Risk Management In Developing Countries

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Abstract

Across the world the healthcare industry is adopting systematic approach to decrease risk of harm to patients. Since there are no published statistics from developing countries we have to rely on the western literature. In this article we have tried to analyse the clinical risk factors in surgery in general and various modalities for improving patient safety especially in developing countries and various protocols which can be applicable with review of literature.

INTRODUCTION

OWAM (1) An organization with memory published by UK Health Department has reported:

- 850000 adverse events occur in NHS hospitals/yr.
- Additional Hospital days costing 2 billion pounds/yr
- Adverse events are unintended, half are avoidable
- 30 to 50 % complications in patients undergoing surgical treatment are preventable.(2)

“To err is human: building a safer health system.” (3). The Errors can be those of Commission (we do the wrong thing) or Omission(we do not do the right thing).(4).

Human error cannot be eliminated and the removal or punishment of the individual does not change the environment that produced the error in the first place. It is by appropriate error management that adverse events can be reduced. (5).

DEFINITION OF RISK MANAGEMENT

A comprehensive definition of risk management as per joint Australian/ NZ standard is “ the culture processes and structures that are directed towards realizing potential opportunities whilst managing adverse effects.”(6)

In short “ It is a process for improving the safety and quality of care through reporting, analyzing and learning from adverse incidents involving patients.”

In healthcare setting, this definition helps to dispel some misconceptions regarding risk management.

Surgery is inherently safe and duty of surgeon should be two fold.

- First and foremost “ do not harm” mantra from time of Hippocratic oath.
- Second to be able to achieve maximum care by careful planning, testing and regulation of the surgeons training/competence.
- Catastrophic events although rare may arise from small accumulations of events that individually may not be noticed.

SCOPE OF RISK MANAGEMENT

- RM is tool for improving quality care. Poor quality leads to litigation .Helps to learn from claims.
- RM is not only about incident reporting. The identified risks have to be analyzed , treated and monitored > reactive RM.
- Proactive RM” effective utilization of resources in order to minimize patient safety incidents. Fire drills, scenario training is one example of PRM.
- RM applies equally to all stakeholders in an organization, clinicians, managers, non clinicians.

BASIC QUESTIONS TO BE ADDRESSED IN

RISK MANAGEMENT.

- Risk Identification: “what could go wrong”
- Risk Analysis” chances of going wrong and impact
- Risk Treatment” Minimize chances of happening or mitigate damage when it has gone wrong”.
- Risk Control, sharing and learning.” what can we learn from things that have gone wrong ?.

PERSPECTIVE OF PATIENT SAFETY

Demarcation between Clinical and non clinical risk is not always clear cut. Adverse event may result from culmination of clinical as well as non clinical failures. For e.g. Medication error (clinical risk) or as result of fall from a trolley (non clinical risk).Other factors which are contributory may be diverse as poor staffing, organizational culture, inadequate staffing etc.

APPLICATION OF RISK MANAGEMENT

RM may be applied at any level of an organization. Hospital Management may devise local strategy for e.g. infection control in the hospital. Individual departments can identify changes in routine working practices for quality patient care. for e.g. planning joint surgical procedures with other specialties vascular surgeon, neurosurgeon, plastic surgeon

At individual level clinicians may co ordinate working or surgical endeavors with seniors or subspecialty colleagues in cases where he is anticipating difficulty. Equally important is the application of RM to paramedical staff for improving patient care.

ORGANIZATION FOR RISK MANAGEMENT

RM cannot be managed in isolation but within the framework that integrates all aspects of clinical governance including clinical audit, guidelines education and training, complaints and claims handling, health, safety, research and service development.

Foremost for any organization is to nurture safety culture with provision for necessary resources, which is only possible with strong leadership, teamwork, communication, patient involvement and training. Communication within and between team is a key safety issue.

Care while transferring patient from one health professional to another and this should happen in atmosphere of non blame culture. (7)

RM in all clinical departments should be linked with hospital wide strategies and initiatives. Hospitals must have a multidisciplinary risk management risk committee who will work on written RM strategy and facilitate the efforts of everyone in managing risks in their own clinical practice.

RISK IDENTIFICATION.

All clinical areas should either check up systems prospectively to flag up possible sources of patient safety incidents or retrospectively look at things that did go wrong. Internal sources of RI include risk assessment conducted in clinical areas as wards, OT, fracture clinic, daycare unit. Incident reporting, clinical audit, workshops, complaints and claims, surveys.

External sources of risk identification: confidential enquiries, guidelines, protocols released from time to time. Two form of system failures are identified.

- Active Failures >these are immediate errors at point of interaction between human and system.
- Latent Failures> arise from areas as organization and its culture, staff training and competence.

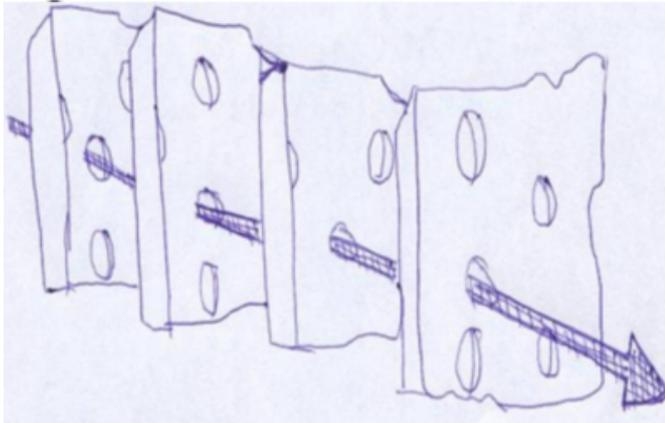
Any system has multilayered defensive barriers to reduce errors.

Defensive layers can be technical (alarms, physical, automatic shutdown) human(surgeon, nurses, anesthetists) and documentation(guidelines, sop etc). The system approach to reduce error requires defenses, barriers and safeguards.(5).

To explain this a Swiss Cheese Model of system failure where presence of hole in any slice(defensive layer) will not lead to an error as the next layer is intact to block its progress. If holes align the error can be perpetuated leading to an incident. These holes arise due to active or latent conditions.

Figure 1

Figure 1: Swiss cheese model



- Active Failures in surgery take a variety of forms: slips, lapses, fumbles, mistakes and procedural violations.(8, 9)
- Slips occur due to failure of concentration (e.g failure to remove wound swab before wound closure).
- Lapses arise from failure of memory (forgetting two drugs interact e.g heparin and NSAIDS).
- Fumbles actions performed incorrectly (damage to nerve during surgery).
- Mistakes where actions are as per plan but plan is inadequate to achieve the outcome.
- All these errors result from some deviation. In Slips, lapses and fumbles actions deviate from intention at level of execution. Mistakes are knowledge based and problem lies at higher level of problem assessment, solving and formulating the plan.

LATENT FAILURES

Latent conditions remain dormant for a long time (5,8).It is like smoke alarm without a battery. Exist within organization due to failure to correct attitude ,supervision and safety culture. Latent failures are easy to predict unlike active failures and should be sought and corrected before an adverse event occurs. Avoiding inappropriate or ineffective treatment is therefore a primary task.

PRE OPERATIVE

Error in the initial diagnosis arise in elective surgical cases.

Site and side errors are more obvious errors. Referral system should be effective as each yr, more and more patients are referred to hospitals. Delays due to referral to ill equipped hospitals or inappropriate surgeon are not tracked easily. continuity of care can be ensured if time period between diagnosis and admission for treatment is streamlined.

INTRA OPERATIVE

Operation theatre is most vulnerable site for adverse events to occur .(10)Three separate groups interact here Nurses, surgeons, anesthetists. Good coordination and inter professional team training is required to improve this area of high risk. Operating outside ones expertise, misidentification of anatomy and inexperience contributes risk (11). but experience at the same time does not provide immunity. Communication failure between the working teams is the most important cause of failure in various surgical procedures and is the greatest threat to the patient.(12, 13).

POST OPERATIVE

Post operative period can often be marred by complications and effects of active adverse events Incidence of hospital resistant infections as MRSA, respiratory, urinary ,wound infection, DVT, pulmonary embolism etc can be reduced if not prevented by focusing and enforcing better practices. Implementation of strict post operative protocols as per national and international recommendations is mandatory and goes long way in mitigating litigations claims.

Non technical skills are as important as technical skills and go long way in improving clinical risk management as it involves cognitive skills (leadership, teamwork and co-operation .(14)

ROOT CAUSE ANALYSIS. RCA(WHAT WENT WRONG)

Earliest point at which action could be taken. RCA” is the methodology that questions the how and why in a structured and objective way to investigate all the factors that led to the incident” Key steps are outlined in London protocol (15) as>

- Identify the incident/ take decision to investigate.
- Select members of investigation team.
- Gather all data and physical findings and chronology of events.
- Identify contributory factors (lack training/supervision)

- Identify delivery problems(incorrect decision, failure to act)
- Devise action plan
- Involve patients and families in the process.

RISK ANALYSIS , EVALUATION AND TREATMENT.

To manage risk effectively assign risk score. Risk Score is derived by multiplying severity of incident by the likelihood of its occurrence. Likelihood rating considers how frequently the incident is expected to occur. Risk score matrix is devised within which risk score of 20 or higher is deemed as unacceptable. Fig 2..

Figure 2

Figure 2: Risk Score Matrix

| Likelihood/ severity | | 1 | 2 | 3 | 4 | 5 |
|----------------------|--------------|-----|-------------|-------------|--------------|--------------|
| 1 | Low | Low | Low | Low | Low | Low |
| 2 | Slight | Low | Low | Significant | Significant | High |
| 3 | Moderate | Low | Significant | High | Very high | Very high |
| 4 | Major | Low | Significant | Very high | Very high | Unacceptable |
| 5 | Catastrophic | Low | High | Very high | Unacceptable | Unacceptable |

Risk treatment is based on appropriate course as influenced by risk score .Risk treatment can be in form of elimination, substitution, reduction or acceptance of risk.

RISK REGISTERS

All clinical areas should have risk registers in electronic format. Risk identified should be entered in the register with columns showing risk evaluation, control and residual risk. Residual risks exceeding threshold are escalated to departmental register and significant risks from the register are in turn escalated to a hospital risk register.

Risk register is not a static document, it is modified from time to time as new risks emerge.

SURGICAL RISK MANAGEMENT IMPLEMENTATION> STEPS.

Standard operating Procedures (SOPs) are available for only minority of surgical procedures. Performing instrument

checks and swab counts during intra operative period are common sop. SOPs if followed strictly simplifies routine working in OT and reduces opportunities for error > upstream effect. Helps in ensuring safety and high reliability in organization.

Pre-operative check lists common among anesthetists prior to induction, reduces equipment failure. Check lists should be developed to assess availability and functioning of equipment in OT prior to any procedure. Check list can be compiled as per local context and modified wherever necessary. Check lists are not substitute for personal vigilance. May divert attention from more urgent task and provoke complacency.

Free and honest error reporting :this forms most challenging part of SRM. Traditional “train and blame” culture must be replaced by informed culture where error is accepted. Right culture “characterized by shared passion for quality fairness” Commitment all levels of management is needed to ensure an organizational response.

Teamwork training nowadays is intergral part of risk management. Emphasis on Training in non technical skills and OT safety improvement is part of surgical training

- Most of Royal colleges in UK are addressing this and there is effort at national level in some of developing countries to integrate this in the RM strategy.
- These programs help to teach theatre staff, paramedics, anesthetists as well as surgeons about the technical and non technical aspects of safety in OT and other clinical outcomes including delays, cancellations, complications and reporting of clinical incidents.
- Lot of emphasis is laid inter professional teamwork.

HUMAN ERROR

All health care workers in the modern world are subject to high levels of physical and psychological stress and this can influence their performance and lead to errors. Errors can result from fatigue, mental overload, excessive work, poor commitment and poor decision making (16). This can be reduced if not eliminated by addressing judiciously these problems.

APPRAISAL

This is a parallel development in RM. The individual at any level in the organization has to show involvement in continued education and professional development and standing to clients and employers Also to show ones involvement in audit projects and learning from complaints and errors.

RISK MANAGEMENT --- CHALLENGES

There is lot of underreporting in surgical disciplines in developing countries due to poor record keeping and problems with audit and most of the national health institutions have no unified risk management strategy. There is poor dissemination of recommendations and follow up and added to this protocols are not laid up at national or state levels for various surgical disciplines and even when they are there is no revision of such protocols as per international standards. Another factor which adds to problem is lack of transparency and blame culture .

CONCLUSION

- Accept that one can make errors.
- Build a safety culture, report errors freely/honestly. Publication of risky businesses.
- Learn from errors made by root cause analysis.
- Implement solutions to prevent harm. Code blues / trauma code/ emergency drills.
- Involve and communicate with patients freely.
- No system or practice can guarantee freedom from errors or its consequences.
- Constant revision of protocols. Every RM strategy will bring its own hazards.
- Responsibility ultimately lies with each individual

to maintain vigilance and improve patient safety.

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