Abstract—The concept of risk management in hospital had its beginning in the 1970s in the USA, following court decisions which established the corporate liability of the hospital for the quality of care and holding medical staff liable for quality of care. The formal program of risk management is a necessity in all health care facilities in the USA and a prerequisite for accreditation of hospitals. Progressive hospitals in developing countries with western trained physicians are initiatiing the process of risk management as a safeguard against becoming defendants in major medico-legal lawsuits by making risk management an integral component of hospital management.

Index Terms—Hospitals, liability, medical negligence, risk management.

I. INTRODUCTION

The concept of risk management has been used in banking and insurance services since the early 1970’s. Risk management has been an accepted practice in industries in the West since the 1900s and in hospitals in the U.S. since the mid-1970s. However, the activities related to risk management have been in place for decades without the specific name of “Risk Management.” The term risk management in the curriculum of postgraduate studies in hospital administration in Asian countries is almost absent. Yet, the graduates of these postgraduate programs will be at the helm of the hospital industry. They will have little or no appreciation of the critical importance of the continuing process of risk management in the delivery of quality care and sustainability of the hospital in the long run.

Risk management activities were inducted into the health care industry in response to the growing national malpractice insurance costs. As of the 1970’s, the risk management function was essentially comprised of Quality Assurance nurses performing incident report and trending in acute care hospitals, but there was little to no proactive prevention of control activities [1].

Risk management is defined as the systematic process of identifying, evaluating, and addressing potential and actual risk [2]. Generally speaking, risk management is the process to protect the assets and minimize financial loss to the organization. Managing risk is a proactive function. It is taking action to reduce the frequency and severity of unexpected incidents, reduce the impact of legal claims, and promote high reliability performance, system design, and the uniqueness of each patient exposes the organization to the potential for liability.

Risk management should be a common thread throughout the entire organization. It is recommended that each employee and volunteer should be charged with risk management. A designated person appointed as Risk Manager should be responsible for integrating all components of the program. In hospitals, this is typically the Risk Manager, in inpatient settings, it could be Quality Manger. In outpatient settings, it is frequently the Head Nurse or Office Manager.

II. MALPRACTICE CLAIMS AGAINST HOSPITALS

The concept of risk management in hospital in India is in its infancy. The cases of malpractice do not come to the public attention because India as opposed to the USA is not as litigious in health care as USA.

The human value in India is not what it should be as in developed countries, especially as in the West. It has been noticed that medical doctors do not testify as expert witnesses in medico-legal cases in India. If a doctor comes as an expert witness, there will be over a dozen doctors present in the court room which can intimidate the expert witness and develop animosity toward the expert witness.

The famous court decisions in Darling vs Charleston Community Hospital (200 NE 2d 149, 211 NE 2d 53, Ill, 1964, 1965) in 1965 established the corporate liability of the hospital for quality of care and the Corleto vs Shore Memorial Hospital (138 N.J. Super. 302 (1975) 350 A. 2d 534) established that the medical staff could be held liable for quality of care [3].

It was following these two landmark decisions in the U.S. that effective risk management assumed major importance because of increasing number of claims against hospitals, higher damages, and bad publicity affecting hospitals [4]. The malpractice cases against doctors and hospitals in the U.S. reached a crisis stage in early 1980’s. The price of insurance in the commercial market became so high that many hospitals established their own captive insurance or trust arrangements for self-insurance. This was the beginning of formal “incident reporting” and the addition of in-house risk managers to analyze trends and suggest interventions to prevent or mitigate claims.

The challenges being faced by hospitals in the U.S. due to general increase in claims frequency and increasing larger awards in several states where there is no cap on the magnitude of awards have resulted in: (i) A renewed awareness and concern about patient safety and medical errors, (ii) decreased insurance availability, (iii) increased financial risk that must be assumed through higher retentions or deductibles, (iv) higher premiums, (v)minimal, if any,
coverage enhancements, and often coverage exclusions, and (vi) more selectively by insurance carriers [5].

III. ESSENTIALS OF RISK MANAGEMENT PROGRAM

Following are the basic essentials of the risk management program in a hospital:

1) Appointment of a Risk Manager who will have the support of the governing board, CEO, medical staff, and other segments of the hospital community.

2) Risk Manager to make the rounds and meet department heads to acquaint each of them with his/her responsibilities.

3) Implement the following six-step program with the cooperation of the Risk Management Committee to ensure that the hospital is doing all it can in the area of risk management.

(a) Identification of situations in the hospital that could produce an incident that would result in financial loss.

(b) Evaluation of incident reports for at least six months and comparing available data on incidents in other hospitals to be able to identify those situations in the hospital that are likely to yield an incident.

(c) Elimination of needlessly dangerous procedures that are performed on the premises, sale of equipment that can result in product liability suits.

(d) Reduction of risks so that the hospital can feel comfortable in instituting an internally funded and operated insurance mechanism.

(e) Transfer of liability by having "hold harmless" agreement with drug and equipment manufacturers.

(f) Insurance coverage through the best option among the commercial, captive, and self-insurance by itself or in a combination to meet the needs of the hospital in the most reliable and cost-effective manner [6].

Furthermore, the hospital will have the following components as an integral part of their risk management program [7].

1. In-hospital grievance or complaint mechanism.

2. Continuous collection of data with respect to negative health care outcomes.

3. Medical care evaluation mechanism.

4. Educational programs for hospital's staff personnel engaged in patient care activities.

5. Continual refinement of risk management procedures and make them an integral part of the JCAH standards.

It should be stressed that the key to a successful risk management program is its loss control program. All necessary steps should be taken to have an effective loss control program through institutional commitment, documentation, education, developing a functional organizational model, improving communications, and continuing evaluation.

IV. INCIDENT REPORTING AND RISK MANAGEMENT

Incident reporting is an integral part of risk management. Studies on reporting of adverse events suggest that healthcare professionals, particularly doctors, are reluctant to report adverse events to a superior. The results show that healthcare professionals, as might be expected, are most likely to report an incident to a colleague when things go wrong. The reporting of incidents to a senior member of staff is also more likely, irrespective of outcome for the patient, when the incident involves the violation of a protocol. It appears that, although the reporting of an incident to a senior member of staff is unlikely, particularly among doctors, it is most likely when the incident represents the violation of a protocol with a bad outcome [13],[19]. The culture of medicine with its emphasis on professional autonomy, collegiality, and self-regulation is unlikely to foster the reporting of mistakes [14].

Since risk management is the process of controlling incidents which are inconsistent with the normal practice and activities of the hospital, incident reporting becomes the foundation stone of a sound system of managing risks. Incident reporting process is designed to accomplish the following tasks [8]:

1. Identifying and detecting risks.
2. Assigning values to risks.
3. Anticipating losses.
4. Deciding upon objective steps to minimize the impact on the patient and the hospital.

An incomplete or incorrect incident report can impede the detection process. It is recommended that the incident report should:

1. Fully describe exactly what transpired.
2. Be simple and practical in format and take the least amount of time and effort to complete.
3. Contain the name, address, age, and condition of the individual involved, along with exact location, time, date, and description of the occurrence.
4. Have physician's examination data.
5. Include checklist or questions to remind the reporter to include such items as bedrail status, reason for hospitalization, description of those involved, witnesses, and extent of out-of-bed privileges.

V. RISK MANAGEMENT COMMITTEE

It is recognized that committee structure is essential for the proper and effective functioning of the risk management program. The Assistant Administrator for Quality Control will chair the Risk Management Committee which will have representatives from the following departments:

1. Quality Assurance
2. Blood Bank
3. Medical Audit
4. Infection Control
5. Safety and Security
6. Accreditation
7. Education
8. Physicians
9. Nurses
10. Legal Counsel
11. Tissue Committee
12. Professional Liability Committee
13. Professional Practices Committee
14. Medical Discipline
15. Medical—Legal Committee
16. Antibiotic Use
17. Therapeutics
18. Pharmacy
19. Medical Records
20. Utilization Review Committee

The purpose of the Risk Management Committee will be to assist the Risk Manager in fulfilling the responsibilities of the position to minimize injuries to patients, visitors, and employees, and financial loss to the hospital.

VI. STRENGTHENING OF RISK MANAGEMENT PROGRAM

In view of the rapid changes in all facets of the health care industry, there is a need to continually strengthen both monitoring and evaluation of the risk management program. Following are some of the needed areas of strengthening [9] - [12]:

1) Continuing education of staff and responsible key persons.
2) Monitoring and evaluation of the integrated programs.
3) Communication with peers at local, regional, state, and national organizations in order to improve the program at the hospital.
4) Discovering situations that present potential for accidents.
5) Availability of sophisticated data on past occurrences.
6) Identifying areas of high risk in the hospital.
7) Development of an incident report form to meet the contemporary needs.
8) Requiring the staff to file incident reports immediately after incidents have taken place.
9) Reporting physician and nurse related incidents.
10) Monitoring and improving quality of care provided by physicians and other providers because increasing numbers of claims are holding hospitals liable for everything that occurs within them (hospital premises).
11) Continuing support of all segments of the hospital community.
12) Statistical data from both internal and external sources.
13) Patient representative program characterized by integrity and ability to level with the patient.
14) Reduce the level of risk sufficiently so that the hospital can assume that risk itself through the less expensive self-insurance.
15) Elimination of needlessly dangerous procedures and prescribed medicines even though safer substitutes may be found.

A survey by accreditation agency like Joint Commission International (JCI) can be helpful. The survey is designed to be individualized to each organization. To be consistent and support the organization’s efforts to improve performance accreditation is highly recommended. During an accreditation survey, the JCI evaluates an organization’s performance in terms of functions and processes aimed at continuously improving patient outcomes. This assessment is accomplished through evaluating an organization’s compliance with the applicable standards in the JCI Accreditation Manual, based on the following [15]:

1) Tracing the care delivered to patients.
2) Verbal and written information provided to JCI.
3) On-site observations and interviews by Joint Commission surveyors.
4) Documents provided by the organization.

VII. STAFF TRAINING AND RISK MANAGEMENT

The Joint Commission on Accreditation of Healthcare Organisations (JCAHO) reports that orientation and training failures were the second most common root cause of sentinel event. The survey covered the years 1995-2004. Lack of or limited staff training were found to be the most common staffing-related factor in root cause analyses [16].

Many organizations have been using teams as a means of achieving organizational outcomes (such as productivity and safety). Research has indicated that teams, especially those operating in complex environments, are not always effective. There is a subset of organizations in which teams operate that are able to balance effectiveness and safety despite the complexities of the environment (for example, aviation, nuclear power). These high reliability organizations (HROs) have begun to be examined as a model for those in other complex domains, such as health care which strives to reach status of high reliability [17].

Staff training is crucial to the successful management of risk exposures resulting from the interaction of humans and biomedical technology. The need for staff training in general and cross training to meet particular needs is not limited to permanent personnel of the facility. The increased use of clinical staff from per diem pools and commercial companies that provide individuals for short- or long-term assignments raises significant orientation and training challenges for health care facilities. However, public expects that all staff authorized by a health care facility to use a piece of medical technology are competent to do so, regardless of the individual's employment status[18].

The institution must be prepared to meet the full spectrum of biomedical technology training needs. This can range from initial training in the use and support of a new piece of equipment, ongoing in-service training to individualized remedial training when indicated. Depending on the complexity of the biomedical technology in use clinical providers may require education about the equipment. For example, others whose responsibilities include maintenance or calibration, such as biomedical engineering personnel and those responsible for routine cleaning, disinfecting, or sterilization of certain medical devices also need customized in-service training [18].

The health care organisation must ensure adequate supervision of the clinical practice of each of its professionals. This process is frequently included in the organisation’s credentialing and peer review programs. Health care organisations must develop and implement competency-based performance parameters for each professional category. The scope of competencies required should be in accordance with the regulatory requirements of each professional group [18].
VIII. TRAINING AND AWARENESS AMONG PATIENTS, FAMILIES, AND NON-MEDICAL PERSONNEL

It is important to create awareness amongst staff as well as patients, families and non-medical personnel regarding safety rules and regulations applicable to the respective countries. They should be informed about various law and enactments. The need for training and awareness is not limited to hospital-based sites. It also applies to leased settings in which health care organization employees provide ambulatory health care services, but the building owner furnishes the housekeeping staff. The public is increasingly aware of biomedical devices, such as automatic external defibrillators (AED) at airports and businesses. Television series featuring scenarios using such biomedical technology have become popular. This can encourage a cavalier among lay people about the significant realities involved in biomedical technology. For example, in at least one reported case, a death occurred when a worker in housekeeping service "playing with a defibrillator" placed the paddles on a coworker's chest[20]. Similarly harm may occur if the respective staff is not trained for precautions in diagnostic and other procedures.

Situations that involve unauthorized access to or handling of biomedical devices by non-institutional personnel are not new. When protective containers for used needles and other sharps came into widespread use there were instances of children trying to access units that were within their reach. The red colour brick-shaped "sharps container" resembled a popular building block for children. Children have also been involved in serious incidents with electric beds during upward or downward movement of the bed [18].

Inadvertent unplugging of an intravenous pump by untrained staff can result in shut-off due to battery depletion, which at times can go unrecognized. This can cause potentially serious patient care ramifications [18].

IX. FIRE SAFETY PLAN AND EMERGENCY DRILLS

Every country, state or province has its own code for fire safety. In India, it is essential to prepare fire safety plan according to Clause C-8 (Annex - E) of part-4 of National Building Code of India, 2005 duly incorporating the following important components [21]:

1) Fire Safety Director/ Dy. Fire Safety Director.
2) Fire Wardens and Deputy Fire Wardens.
3) Building Evacuation Supervisor.
4) Fire Party.
5) Occupants Instructions.
6) Fire Command Station, Signs

Before fire & emergency drills are planned in hospital, the following points must be of prime consideration [21]:

1) The purpose of fire and emergency drills.
2) Formulation of fire drills routine.
3) Instruction and training.
4) Details of fire drills.
5) Frequency of drills.

The fire and emergency drills should be conducted at least quarterly for the first two years. Thereafter fire & emergency drills shall be conducted once in every six months. The fire and emergency drills should not be allowed to become stereotype as the situation under actual fire conditions may vary widely. For example a stair case may be unsuitable due to smoke or other causes. Before arranging a fire and emergency drill where a staircase is presumed to be blocked, it is essential that an alternative safe route is available which leads to open air and safety [21].

X. CONCLUSIONS

Risk management has become an integral part of hospital administration in most of the developed countries in general and the USA in particular. However, the needed attention to the concept and process of risk management in the developing countries is yet to be given. Since we are living in a global village and with advances in communication technology, the day is not far when patients will initiate law suits against the health care providers and hospitals for medical malpractice and negligence threatening patient safety. It is recommended that hospitals give serious consideration to implementing and /or strengthening risk management programs to protect their assets and minimize financial losses.

REFERENCES

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