MANDATORY INCIDENT REPORTING THROUGH LEGISLATIVE FRAMEWORK: TOWARDS ENHANCING PATIENT SAFETY CULTURE IN HEALTHCARE SETTINGS

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Abstract

Incident Reporting is the cornerstone for improving patient safety as it provides valuable insights on the events leading to the death and injuries of patients in healthcare settings. The availability of such report would enable healthcare providers to take the necessary steps to prevent similar incidents from occurring in the future. Further, an incident report would also be able to identify potential lawsuits and deviations from standard operating procedures. Nevertheless, as incident reports may be open to discovery during litigation process, healthcare providers tend to refrain from giving an honest and accurate account of what has transpired during the incident fearing that they may be reprimanded and punished by the court of law. Therefore, in having a proper legislative framework that mandates incident reporting with provisions that state clearly rules on confidentiality accompanied by regulations on sanctions-free reporting would ultimately encourage healthcare providers to actively report under an environment that is open, fair and non-punitive. Various jurisdictions around the globe such as the United States, Japan and Denmark have employed legislation to introduce a variety of incident reporting systems suited to their local climate. This may provide valuable lessons to countries who wish to introduce or improve their incident reporting systems in ensuring that the occurrence of adverse events are being documented, discussed and prevented. Despite the fallibility inherent to health care delivery, the occurrence of adverse events can be reduced through a commitment of quality improvement in fostering a just culture of safety in the healthcare setting.

Keywords: Incident Reporting; Patient Safety; Legislative Framework

Introduction

Issues in patient safety have become a national and global concern. Major reports and studies from various countries reveal that there are real opportunities to make healthcare safer by learning about the problems within the system and using this information to generate improvement in the delivery of care. One of the ways of achieving this is by enacting laws that either mandate or encourage healthcare providers to set up 'Incident Reporting' system as a measure towards achieving a safety culture as reporting helps to identify hazards, risks

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and potential improvements that can be done. This approach has been advocated by the Institute of Medicine (IOM) which recommended for a nationwide mandatory 'Incident Reporting' to be established for the collection of standardized information by governments about adverse events that result in death or serious harm. Such information will make it possible for healthcare providers to learn from the incident and hinder the re-occurrence of preventable adverse events (IOM, 2000). However, Recommendation 7 of the Council of Europe Member asserts that one of the main features of such a system is that it should be non-punitive in purpose, voluntary, anonymous (Council of Europe, 2006). The focus should be on improving organisational performance rather than on individual blame. The system should protect the identity of the individuals involved and abide by all relevant confidentiality laws and regulations. This will ultimately encourage healthcare workers to actively report under an environment that is open, fair and non-punitive.

Methodology

Qualitative Research Method – Doctrinal Analysis

Result and Discussion

'Incident Reporting' in health care setting is the process that collects and documents information about an event or circumstance that could or did cause unexpected or unwanted harm, loss or damage to individuals involved in the healthcare delivery (Dickinson, M. 2013). This process captures information on errors, injuries, non-harmful errors, equipment malfunctions, process failures or other hazards (WHO, 2005). The information collected will usually be documented in a standardised form prepared by the healthcare provider. Subsequently, an 'Incident Reporting' system refers to "the processes and technology involved in the standardization, formatting, communication, feedback, analysis, learning, response and dissemination of lessons learned from reported events' (WHO, 2005, at p. 8).

Objectives of 'Incident Reporting'

The objectives of executing an incident report can be seen as follows:

(i) Capturing essential information
Incident reports are administrative tools to capture information on an unexpected outcome occurring at a healthcare facility, taking into account the extent, types and causes of errors, adverse events and the 'near misses' (Dearmon, V., 2013).

(ii) Communicate information
Incident reports are used to communicate information to relevant stakeholders, particularly, to healthcare management and risk managers to respond to the immediate needs of the individuals involved and take the necessary remedial action to re-establish a safe environment. Communication to the affected parties and their families would be crucial at this juncture to curb the desire to litigate.

(iii) Promotion of Learning

The fundamental role of incident reporting systems is to enhance patient safety by learning from failures of the health care system. Health-care errors are often provoked by weak systems and often have common root causes which can be generalized and corrected. Although each event is unique, there are likely to be similarities and patterns in sources of risk which may otherwise go unnoticed if incidents are not reported and analysed (European Commission, 2014).

Circumstances Requiring Incident Reporting

Incident reporting will be required in circumstances that deviate from the usual medical care, which causes injury to the patient or poses a risk of harm such as the following:

(i) Adverse event

An adverse event is an injury related to medical management, in contrast to complications of disease (Hiatt, H, 1989). Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable and are not always caused by an error (WHO, 2005).

(ii) Error

Error has been defined as "the failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning)" (Kohn, L. et. al. 1999). However, reporting of errors regardless of the existence of an injury would at times cause the number of errors reported to be overwhelming. Therefore, some sort of threshold is usually established such as "serious" errors, or those with the potential for causing harm (WHO, 2005).

(iii) "Near miss" or "close call"

"A near miss" or "close call" is a serious error or mishap that has the potential to cause an adverse event, but fails to do so by chance or because it was intercepted. It is assumed that the underlying systems failures for near misses are the same as for actual adverse events. Therefore, understanding their causes should lead to systems design changes that will improve safety. A key advantage of a near miss reporting system is that as there has been no harm, therefore, the reporter is not at risk of being blamed or exposed to potential law suits. On the contrary, the reporter may be praised for having intercepted an error and prevented an injury on time (WHO, 2005).

(iv) Hazards and unsafe conditions

Hazards include any threat to safety, for instance, unsafe practices, conduct, equipment, labels and names. Reporting of hazards is another way of achieving the prevention of harm without the need to learn from an injury. Within a health-care organization, hazard reports are able to raise alerts about unsafe conditions. With appropriate analysis, these reports can provide valuable information for changes to systems design (WHO, 2005).

Mandatory and Voluntary Incident Reporting

Reporting systems can be operated in a mandatory and voluntary basis. Voluntary reporting is much more preferred by healthcare providers as they are given more autonomy on what to report and will be independent from any regulatory and accrediting bodies or other healthcare community stakeholders (Institute for Safe Medication Practices, 2000). Voluntary reporting systems are also favoured due to its non-punitive attributes (Barach, P. & Small, S.D., 2000). However, voluntary reporting leads to irregular standardisation due to the inconsistency in the information gathered. The lack of consistency may affect the proper analysis of the causes of the incident which will eventually prevent effective remedial steps from being taken. In this respect, voluntary reporting may be more suitable for errors which are not related to death and serious injuries (Institute for Safe Medication Practices, 2000). Mandatory incident reporting on the other hand, will be able to identify a standardised set of serious reportable events that would facilitate public accountability for adverse events that have occurred in the delivery of health care. The occurrence of a serious preventable adverse event in healthcare such as operating on wrong body part, transfusing wrong type of blood suggest that a flaw exist in the organisation which necessitate mandatory reporting. Accountability requires healthcare providers to report their performance and investigate specified occurrences to enforce compliance with accepted standards of care for ensuring safety and this can be achieved by having a standardised set of reportable events (Kizer, K.W. & Stegun, M.B., 2005). Nevertheless, mandating reports has been criticised if it leads to punitive measures and blameworthiness. Punishment and blame is considered a powerful barrier to collaborative problem solving. Therefore, the benefits of mandatory reporting systems can be gained if the adverse consequences of the disclosure and issues of confidentiality are being dealt with.

The Importance of Legislative Framework in Mandatory Incident Reporting

In encouraging and mandating disclosure of adverse events, the role of legislations and policies tend to be very significant. This is due to the fact that the information gathered during the reporting exercises can be subjected to varying degrees of legal protection. Issues on confidentiality and levels of evidentiary protection for information submitted to reporting systems can be mapped out in relevant provisions in the legislation and policies.

Overview of Jurisdictions with Legislative Framework on Mandatory Incident Reporting

(i) The United States of America

Healthcare error is the third leading cause of death in the United States of America (National Vital Statistics Report. 2012) as the number of premature deaths associated with preventable harm to patients in hospital is estimated to be more than 400,000 per year (James, J.T, 2013). In 1999, the Institute of Medicine (IOM) recommended for a nationwide mandatory reporting system for state governments to collect standardised information about adverse medical events resulting in death and serious harm (IOM, 2000). The Federal Government's Quality

Interagency Coordination Committee (QuIC) concurred with the IOM's recommendation for greater health care error and adverse event reporting and recommended that the National Quality Forum (NQF) "identify a set of patient safety measurements that should be a basic component of any medical errors reporting system" and thereby standardize data collection and reporting by States in January 2000 (QuIC, 2000). Presently, there are 27 adverse event-reporting systems in 27 States, in which 26 systems are mandatory while one state, namely, Oregon has a voluntary adverse reporting system. Amongst the 26 states that have mandatory systems include California, Colorado, Connecticut, District of Columbia, Florida, Georgia, Illinois, Indiana, Kansas, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Hampshire, New Jersey, New York, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington. The reporting system in Oregon is administered through the Oregon Patient Safety Commission, which is a semi-independent state agency charged by the Oregon Legislature with reducing the risk of serious adverse events occurring in Oregon's healthcare system and encouraging a culture of patient safety (Hanlon, C. et. al., 2015). Reports from facilities are confidential and non-discoverable. Similarly, the Illinois Medical Studies Act, 735 ILCS 5/8-2101 provides that all information and statements collected about a health professional's competence in the course of internal quality control, for the purpose of improving patient care, is privileged and confidential, thus, not discoverable (Schostok, K.V. 2011). In Pennsylvania, the reporting system is administered through the Pennsylvania Patient Safety Authority, an independent state agency which was established under Act 13 of 2002, the Medical Care Availability and Reduction of Error Fund ("Mcare") Act. The Authority's role is non-regulatory and non-punitive (Hanlon, C. et al., 2015). In the state of Minnesota, the Adverse Health Care Events Law was passed 2003 to enhance both accountability and transparency (MDH, 2009). The law required hospitals and a hospitals and ambulatory surgical centres to report to the Minnesota Department of Health (MDH) whenever serious adverse health events occurred. Reportable events under the Adverse Health Care Events Law include "(i) surgery or an invasive procedure on the wrong part of the body or the wrong patient, or performing the wrong surgery or invasive procedure on a patient; (ii) foreign objects left in the body after surgery or an invasive procedure; (iii) falls associated with death or serious disability; (iv) serious pressure ulcers (bedsores); (v) medication errors associated with serious disability or death; (vi) patient suicide or attempted suicide resulting in serious disability; and (vii) criminal events such as sexual or physical assault" (MDH, 2009, at p. 4). Since 2003, nearly 800 adverse health events have been reported to MDH under the reporting law and evaluation on implications of the law that has been conducted through focus groups, interviews, and surveys found that "(i) 72 percent of responding facilities feel much safer; (ii) patient safety is on a higher priority agenda in the organisation (iii) adoption of best practices has improved dramatically, particularly in the areas of sharing of adverse events data with boards of directors, staff and other facilities, patients and family members (iv) facilities across Minnesota have made numerous changes in policies, processes, and approaches to prevention of the most common types of adverse events" (MDH, 2009, at p. 2). Similarly, Utah and Maine had specifically noted that their mandatory reporting systems have raised facility awareness of adverse events and helped foster facility trust, which had resulted in regular communication and an increased willingness among facilities to disclose adverse events (Hanlon, C. et.al., 2015).

(ii) Japan

Amongst the various patient safety initiatives that have been taken is implementing a wider use of internal reporting systems for hospitals and a system for common usage of information and evaluation by building a system using medical associations to provide and collect information. As such, the Japan Council for Quality Health Care (JCQHC), a third party hospital accreditation organisation, has been tasked to collect 'medical near-miss/adverse event' information for the promotion of patient safety and medical adverse event prevention (Hirose, M. et al., 2003). In 2014, JCQHC reported the occurrence of 3194 adverse events including those that resulted in death or injury of patients in 993 institutions. This figure was alarming as the number of adverse events occurrences nearly tripled since 2005 (Otake, T, 2015). In response to this, the amendment to the Japan Medical Care Act was made in 2014 which established the Medical Accident Investigation System which is also known as *iryojiko chosa seido* (Otake, T., 2015). The new system came into operation on October 1, 2015 and made it mandatory for all healthcare institutions in Japan to report any 'unexpected deaths' in relation to medical care to a medical accident investigation support centre and perform medical accident investigation to identify the cause of the accident (Japanese Nursing Association, 2014). The number of mandatory reporting medical institutions as of 31st December 2014 is 275 hospitals and the number of reported accidents collected from January 1st to December 2014 is 2911 cases, which include 225 cases resulting in death. According to Articles 6 – 10 of the Medical Care Act, administrators of hospitals, clinics or birthing center shall undertake measures for (i) the establishment of policies to ensure safety in medical care; (ii) the implementation of training for employees; (iii) measures to ensure safety in medical care in other relevant hospitals, clinics or birthing centers. Further, according to Articles 1 - 11(i) of the Act, administrators of the hospitals shall ensure medical safety based on regulations described in Articles 6 - 10 in (i) preparing guidelines for medical safety control; (ii) holding committee meetings on medical safety control; (iii) training staff in medical safety control; and (iv) taking improvement measures aimed at ensuring medical safety, such as, reporting of medical accidents that occur within medical institutions. Medical accidents subjected to this system are "death or stillbirth which are caused or suspected to have been caused by care provided by employees of the medical institutions, and which are unforeseen by the administrator" (Ministry of Health, Labour and Welfare Japan, 2016). An internal investigation will be performed and outcome of the investigation outcome will be collected by a private third party institution known as the 'Medical Accident Investigation Support Centre'. This Centre is tasked to analyse the result of the accident with the objective of preventing its recurrence and improving the safety and quality of healthcare. Once a healthcare institution concludes that an unexpected death has occurred, it will probe the case and the investigative teams must include outside experts to ensure impartiality. They must explain the results of their investigations to relatives of the deceased and submit a report on each case to the Japan Medical Safety Research Organisation so that they are able to analyse the information and propose steps to avoid repeated fatal mistakes (Otake, T., 2015). This step is considered very beneficial in making hospitals more transparent and accountable in the light of the rising reported cases.

(iii) Denmark

The Act on Patient Safety in the Danish Health Care System came into force January 1, 2004. The objective of the Act is to improve patient safety by gathering, analysing and communication knowledge on adverse events in the Danish healthcare system. The law obligates health care professionals to report specified adverse events to a national database. To support learning, this national mandatory system is sharply separated from the system of sanctions (WHO, 2005). In the first twelve months the system was in place, 5740 adverse events were being reported (Lundgaard, M. et. al., 2005). In 2013, about 182,000 reports from the healthcare system were submitted to the database (European Commission, 2014). The Act protects healthcare providers from sanctions to facilitate the reporting of adverse events to the learning system. Thus, a health provider cannot, as a result of reporting an adverse event, be subjected to disciplinary action (Lundgaard, M. et. al., 2005) by his or her employer, supervisory measures by the National Board of Health or penal sanctions by the courts. The Act also states that "reporting on adverse events from the regional council and the municipal council to the National Agency for Patients' Rights and Complaints shall be anonymised with regard to the patient concerned as well as the reporting individual" and the "information on the identity of the person that has submitted a given report may only be shared with the individuals in the same region or municipality who are responsible for following up on the report" (European Commission, 2014, at p. 28). Thus, information on the identity of the person who has submitted a report may only be shared with the individuals in the same local organisation that are responsible for following up on the report. The case handler at local level should also ensure that a person's identity is only included in specific fields of the reporting form. In this way, the identity of the persons can be erased before data is transferred to the central level (European Commission, 2014). This approach keeps incidents confidential and anonymous.

Conclusion

From the experience of several jurisdictions, creating 'Incident Reporting' systems through a legislative framework has been a catalyst for improvements in patient safety standards as well as promoting transparency and open disclosure. Undeniably, effective reporting system is the cornerstone of safe practice and a measure of progress towards achieving a safety culture. It helps reduce the likelihood of injury to future patients and facilitate healthcare providers to learn from their mistakes. Enacting laws that either mandate or encourage health care providers to set up a comprehensive 'Incident Reporting' which is open, fair and non-punitive creates the right incentives as well as safeguarding the legal protection of affected parties.

Acknowledgment

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