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Are Incident Reporting Systems in Healthcare Systems a Requirement for Improving Patient Safety? A Review

Fernando G.H.S[1], Thushari Bandara[2], Makani Purva[1]

[1]Hull University Teaching Hospital, NHS Trust, United Kingdom, [2]Department of Medical Laboratory Science, Faculty of Allied Health Sciences, University of Ruhuna, Sri Lanka

*Correspondence: ghsfernando@gmail.com https://orcid.org/0000-0001-7356-6257

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Abstract

Adverse events such as medical errors, injuries, or equipment failures which could harm patients, caregivers, or other individuals or has the potential to harm them are known as medical incidents. Avoidance of unintended or unexpected harm to people during the provision of healthcare is mandatory. In healthcare settings incident reporting refers to collecting healthcare incident data with the aim of enhancing patient safety and quality of care. This review aims to discuss the practice, usefulness and drawbacks of Incident Reporting System (IRS) in healthcare systems. The history of adverse events assessment in hospital setup runs back till 1980s. Since then, many developed countries have put emphasis on the establishment of IRSs in their health systems. In 2005, the World Health Organization issued a guideline to be followed on the establishment of incident reporting systems in healthcare organizations. Benefits of incident reporting in healthcare systems include prevention of reoccurrences of adverse events, provision an updated knowledge and understanding about risk events, create lessons and promote safety-minded culture. It saves a considerable sum of money of the healthcare budget in the long run. Under-reporting is the main challenge in incident reporting. It is recommended to implement comprehensive IRSs in health services in all developing countries in order to drive good medical practice and to ensure the safety and quality of patient care.

Key words: *Incident Reporting System, Healthcare Systems, Effectiveness, Patient Safety, Quality of Care*

1. Introduction

A healthcare incident or adverse event is an unfavorable event such as a medical error, patient injury, or equipment failure, which harms a patient, caregiver, or other individuals or has the potential to harm them (1). Patient safety is the avoidance of unintended or unexpected harm to people during the provision of health care (1). Patient safety is essential component in the healthcare service since the occurrence of adverse events due to unsafe care is likely one of the ten leading causes of death and disability in the world (2). It is estimated in developed countries that one in every ten patients are harmed while receiving treatment from the hospital (3). About 134 million adverse events and 2.6 million deaths are reported from hospitals annually in low- and middle-income countries (LMICs) and are reported (4). These figures indicate that medical errors cause serious consequences on the patients.

Incident reporting in healthcare refers to collecting health care incident data with the aim of improving quality of patient safety and care. Incident reporting identifies safety hazards and guides the development for proper interventions to mitigate risks, thereby reducing harm. An Incidents Reporting System (IRS) enables organization to identify the common errors and their causative factors (5-12) and it is well accepted in the industrial sector such as Aviation industry which reports very less amounts of errors compared to health (13). At present, IRSs have been implemented in health sector of many developed countries (12-16) in the world including the United Kingdom (UK), Australia, United States (USA) and Japan. Expert committees have been appointed in some organization to analyse the adverse events to recommend and establish preventive measures (15-17). The system itself incur a high cost to the organization including training of the staff. However, IRSs provide valuable insights as to how and why patients could be harmed at the organizational level (8).

Studies have conducted regarding the IRSs in various countries. Majority of the studies have identified that IRSs have clear positive impacts on patient safety and have reported that they improve the attitudes and knowledge of the staff over the patient care (18). Some studies have not identified a clear idea on the effectiveness of the IRS (19). Some studies question on the effectiveness and the cost of IRS (20). A UK study has estimated that the monthly cost of the IRS is equivalent to the work of 1,184 UK National Health Service (NHS) employees per month. This was basically for completing the relevant incident forms (21). However, most of the developed countries have spent a considerable amount of their healthcare budget to implement IRSs. This review aims to discuss the practice, usefulness and drawbacks of IRSs in healthcare systems.

2. Methodology

A literature search was performed using the databases Medline, Google Scholar and PubMed. Search terms used are 'Incidents Reporting System', 'effectiveness', 'patient safety' and 'patient care. The literature search was confined to articles in the English language. Since there were few numbers of articles on the topic, a specific time period was not considered for the literature review. About 64 relevant articles were studied and among them there were 15 directly related articles.

3. Results

Medical Errors

Avoidance of the medical errors has become an international concern. Several studies conducted all over the world have reported an unacceptably high rates of medical injury and preventable deaths (22). According to the Institute of Medicine, about 45000-98000 medical errors have reported from USA annually (23). Research has found that medical errors as the 3rd leading course of death in USA and they were responsible for 9.5% of the total deaths (23). Thirty percent of patients are reported in USA with medical, medication or laboratory investigation errors and it is reported to be 22% in UK (24). Harvard medical practice study found that about 3.7% of the hospital admissions were due to adverse events (24-25) and 7% of them ended up with permanent disabilities. Fourteen percent of the patients with permanent disabilities have died due to disabilities. Similar percentage of adverse events have been reported in studies conducted in Colorado and Utah (26, 27). Australia

has reported 16.5% of hospital admissions are due adverse events and half of them were preventable (28). A study done in developing counties using 15548 records have showed that 8.2% of the events are at least due to one adverse event and 83% of them were preventable, while 30% of them have caused deaths (29). Further, it has reported that more than 75% of the patients do not report the mistakes done by the doctors (24).

History of introducing IRS to the healthcare system

IRS has first been used by the aviation industry, allowing pilots and other aviation professionals to confidentially report near misses or close call events in the interest of improving aviation safety (30). The first adverse events assessment in a hospital set up has taken place in New York in 1984 (31). The vaccine adverse event reporting system was established in the USA in 1990 by the Centres for Disease Control and Prevention (CDC), as a national early warning sign to ensure safety (32). A high concern regarding the importance of having IRS was evoked after releasing of the Institute of Medicine (IOM) report on 'To Err Is Human: Build-in a Safer Health System', in 1999 (33). Considering the value of IRS, the World Health Organization (WHO) issued a guideline in 2005, to be followed on the establishment of IRSs in healthcare organizations (22). After that most of the countries around the world including UK, USA, |Australia and Japan adopted IRS to their health systems considering it as a national requirement, in order to ensure the patient safety (34-37).

Reported outcomes of the IRS

Several studies have highlighted the positive impacts of IRS on the patient safety (8). An observational study conducted at a University hospital in Spain has reported a statistically significant reduction in near misses or adverse events by 63.15%, related to medication (p=.044), after implementation of IRS (38). The same study and some other studies as well have recognized that most of the identified adverse events required fever resources to implement preventive measures to ensure patient safety (19, 39). Studies have identified that implementation of IRS is useful to identify both human and systemic factors contributing to human errors (40). A study done at two large hospitals in London found that majority of the staff perceived the IRS as having positive effects on patient safety (41). It has found that the knowledge generated by the IRS is used instrumentally to change practices through changing staff attitude and knowledge (42). Studies have found that implementation of IRS improved the system of medication preparation, processing, and delivery which is contributing to an enhanced safety culture (43, 44). A study conducted at a paediatric hospital in London reported a reduction of medication errors from 9.8 % to 6.0% per year after implementing the IRS (45). Wolff and colleagues found a significant reduction of falls in the hospital after implementation of the IRS which has been the commonest adverse event (46). Another study conducted in a medium-secure hospital in Wales found a significant reduction of adverse events after implementation of a preventive plan which was developed as a result of IRS (47).

Patient safety is directly related to the skills and knowledge of the healthcare staff. Several IRS studies have emphasized the needs of staff training in different procedures (43, 45, 48, and 49). Adverse drug reactions reported through IRS have been analysed and as result 75 drug products have been removed from the market while special requirements for prescription or restricted distribution has been recommended for 11 drugs, ensuring the patient safety (50). Some studies related to IRS have reported implementation of new strategies to prevent errors, however, their outcomes have not been reported (51). After analysing incidents in 36 Trinity hospitals and affiliates in the USA, Conlon et al have introduced changes for the practice. This study has found 26% reduction in severity adjusted mortality rates since 2005 and reduced liability costs which showed some evidence of effectiveness for improving patient safety in macro level (52). Further, it is revealed that the recommended actions and safety information from the IRS may be useful for employees to promote safety awareness and improve clinical processes (53). It has been statistically proven that more preventable incidents reported by the staff through the IRS than documentary review system and also it is less costly to identify the errors (approximately $15 000 vs $54 000) (54). According to a pilot study conducted in two acute hospitals in London, about 10.8% of the

patients have experienced adverse events and half of them were preventable. Further, some adverse events have been very serious and dangerous to both patients and staff (55). The same study has estimated that the total cost to the NHS on these adverse events in extra bed days alone to be around £1billion per year. About 80% of the errors in complex systems are found to be due to human errors (56, 57). Most of the preventive measures in the anaesthesiology have been implemented as a result of identified errors to ensure patient safety (58). A study showed that 98.8% of the preventive actions have been taken in hospitals after analysing the reported incidents, to ensure patient safety (59). An IRS was established in a tertiary care hospital in South India to find out the medication errors. A total of 1310 medication errors have been reported to this IRS, from 20256 inward patients with an incident rate of 6.4%. In a root cause analysis, it has found that most common reasons are as distractions, heavy workload and communications issue (59). Similar study done in a large tertiary care hospital in Saudi Arabia has reported 1.5% of errors as medication errors. Most of them were preventable and wrong frequency has been the most common error (60). However, a study done in a tertiary care hospital in London found that medication errors were law related to pharmacists' discharge medication orders (61). Some studies done in London found that there are difficulties in using incident reports to improve safety in healthcare since it does not provide data on how to improve safety (41). However, studies have found implementing an IRS is effective on reduction of the further harm to patients in hospital care settings (19).

4. Discussion

Hospital associated errors are common even in the developed countries. It has been reported that the preventable adverse events are a leading cause of death in the United State and at least 44,000 to 98,000 Americans are dying in the hospitals each year as a result of medical errors. National cost has been estimated to be between $37.6 billion and $50 billion for adverse events and between $17 billion and $29 billion for preventable adverse events in the USA (62). These estimations could always be lower than the actual figures due to under reporting of the incidents due to the fear of disciplinary actions (63-66). Therefore, IRS plays a pivotal role in the reduction of errors to ensure patient safety in health care settings (19).

IRS has been implemented in the majority of NHS trusts in UK and reports have analysed according to the incident reporting framework developed by the NHS. These data are shared within the country to take preventive measures. (67). It has been proved that the implementation of IRS not only increased the reporting but also increased the knowledge of the heath staff on patient management (14). Establishment of IRS has led to develop the staff attitudes on reporting ward incidents (14, 68) expecting patient safety improvements (69). However, the value of developing a system to educate staff regularly on the IRS has been emphasized to assure the sustainability (14).

It is proved that same errors are happening repeatedly, and patients continue to be harmed by preventable errors (22). WHO has proven that incidents reporting itself improve the patient safety through minimizing repeated errors (22). During incidents analysing process, clinical staff engage themselves on that, acquiring higher knowledge and become the owners of the IRS and it helps to motivate them to improve patient safety (41). Some studies have estimated that direct observation is more cost effective to identify errors than regular reporting system to improve safety. However, most of the latent failures are not detected in direct observation since they happened in different places and at different times (58). IRS is not just a quantitative event, it is a systematic analysis of incidents, causative factors and preventive measures associated with incidents (70). It is reported that more than 10% of the patients admitted to UK experience adverse events and more than half of them are preventable and management of these adverse events cost more than 1billion pounds per year (71). This emphasises the value of implementing IRS in developing countries in order to save a considerable amount of money from the health budget (55, 72). In order to implement an efficient and effective IRS, the leaders at each level of the organization must play important roles. Leadership from executives, line managers, and informal network leaders throughout organisations have to understand their key roles in IRS (73). Leaders engaged in IRS need to create a sense of shared purpose, build effective

relationships, make connections between action and reflection enabling actionable knowledge and energising knowledgeable actions to ensure patient safety (73, 74). Leaders should use institutional resources not just to collect data, but also to analyse the events in order to make effective and practical recommendations which becomes the ultimate value of the system. At the initial stage of IRS establishment, institutions have faced many challengers due to poor knowledge of the frontline workers on IRS and its benefits (41). It has been proved that there is a significant correlation between numbers of incidents reported and the number of workshops conducted on the IRS (19). Therefore, the importance of providing sufficient knowledge to the staff on IRS and getting feedback is highlighted by multiple studies (14,53). IRS should not be just a place to notify staff about the incidents. It should provide a healthy forum to express ideas on how to reduce risks. Staff should be informed about the actions taken as a result of their reporting efforts. In order to maintain the sustainability of the IRS the person who reports an event should receive timely feedback and the voluntary reporting should be encouraged.

Under-reporting is the main challenge in incident reporting. This occurs due to the fear of legal ramifications, blame, shame or guilty of punishments, lack of time for reporting, loosing of details with time and as a result of not having an easy reporting system. Further, not having trust in follow-up and lack of encouragement and interest from administration discourage the reporting. Lack of training on IRS and low levels of feedback are also contributary for the unsuccessful IRS.

Developed countries are already considering IRS as a mandatory requirement in their health services guaranteeing the appropriate actions are taken to protect patients. IRS will continue to be an important influence on improving patient safety in healthcare organization in the developed countries.

5. Conclusions

Incident reporting helps prevent reoccurrences of adverse events, provides an updated knowledge and understanding about risk events, create lessons and promote safety-minded culture in healthcare systems. It saves a considerable sum of money of the healthcare budget in the long run. IRS plays a major role in healthcare services specially in the developed countries. It is recommended to implement comprehensive IRSs in health services in all developing countries in order to drive good medical practice and to ensure patient safety and the quality of care. This should begin with the development of an incident reporting policy for each county and upper hand has to be taken centrally by establishing quality governance unit at the Ministry of Health.

Author contributions

SF, TB and MP designed the study, searched literature, evaluated findings and draft the manuscript. All authors read and approved the final manuscript.

Conflict of interest

There is no conflict of interest to declare.

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