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A systematic assessment of adverse event reporting in selected state hospitals in Sri Lanka

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Abstract

Background/Aim: Patient safety is an integral component of health care. Adverse event reporting plays a key role in ensuring patients' safety. The Sri Lankan Ministry of Health has introduced guidelines and a system of adverse event reporting. Here we assess the pattern of adverse event reporting in selected 46-line ministry hospitals.

Methods: The adverse events reported in the year 2019 were analyzed. The frequency of reporting of each event was assessed. The issues in relation to adverse event reporting and root causes were assessed through focus group discussions with selected hospital administrators.

Results: Most reported events were "patient falls", contributing to 30.46% of the total. Availability of guidelines, well-established quality management units, and a non-punitive non-fault-finding approach to adverse event reporting and analysis process were identified as strengths of the system. But lengthy paper-based documentation process was recognized as a major weakness.

Conclusion: Although the state health sector of Sri Lanka has an established system of adverse event reporting, it is mostly limited to non-clinical events such as falls. Fear of blame and shame among staff and the lengthy paper-based reporting system have negatively affected the process.

Keywords: Adverse event reporting, Patient safety, Hospitals, Sri Lanka

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Ethics Committee Approval
As this was based on secondary data and no patients involved, ethical clearance was not required. Administrative approval was obtained from Director,Healthcare quality and Safety, Ministry of Health, Sri Lanka.

Conflict of Interest
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Introduction

Consensus has grown globally that learning from patient safety events is vital in making healthcare safer [1]. Patient safety is defined as the absence of preventable harm to a patient during the process of health care and the reduction of risk of unnecessary harm associated with health care to an acceptable minimum, where an acceptable minimum denotes the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other options in treatment [2].

It is understood that each point in the process of healthcare carries a certain degree of inherent unsafety [3]. For improvement and assurance of safety in healthcare, every defect should pave the way to improve processes [4].

In 2016, the Sri Lankan Ministry of Health introduced guidelines on adverse event reporting and launched readmission forms [5]. The recognized categories of adverse events to be reported by health care institutions – as per the general circular [5] – are listed in Table 1.

Table 1: Types of adverse events reported by state health care institutions in Sri Lanka, with examples.

Types	Examples
Blood/blood products related	wrong patient/ wrong blood type
Documentation related	Wrong/incomplete information
Process related	Postponement of surgery
Healthcare-associated infections	Surgical site infections/ventilator-associated pneumonia
Infrastructure related	Non-fitting trolley/lack of bed railings leading to patient falls
Medical equipment related	Computer malfunction/ Breakdown of surgical tools
Medication-related	Wrong patient/wrong drug
Nutrition-related	Wrong diet
Patient accidents	Falls

Reporting adverse events was expected to facilitate learning and improve safety by generating "alerts" regarding significant new hazards and disseminating "lessons learned" by healthcare organizations from investigating a serious event. Analysis of many reports, which may reveal unrecognized trends and hazards requiring attention, creates insights into underlying systems failures and generates recommendations for "best practices" for all to follow.

In Sri Lanka, the focal body for National Quality Assurance Programme in Health is the Directorate of Healthcare Quality & Safety (DHQS), which is under the administrative purview of the Ministry of Health. Each government healthcare institution has a Quality Management Unit (QMU) to undertake the planning, implementation, and monitoring of the National Quality Assurance Programme with the guidance of DHQS [6]. DHQS conducts quarterly quality performance reviews with the participation of all health care institutions in the country.

The adverse event/incident reporting form introduced by the Ministry of Health Sri Lanka comprises two parts, Part A and Part B. Part A could be completed by any health care worker in their own language. The form is completed immediately after the occurrence of the adverse event, within 24 h and once the area and people are safe. The form is filled out before changing each duty shift. All the adverse events related to clinical management were supposed to be reported by the consultant or a designee. All such reports are seen by the respective consultant or a senior doctor assigned by the consultant. The adverse events associated with the non-clinical management, such as falls, could be reported by the Nursing Sister or a nurse. The nature of the adverse event is expected to be mentioned briefly in the relevant part of the document. The immediate measures are taken to manage the adverse event also need to be mentioned in brief.

Part B is meant to be filled by the Head of the unit. Root causes and contributing factors related to the adverse event are noted after a brief discussion with relevant staff in the unit/ward. Preventive measures could be recommended based on the risk factors, root causes, and contributing factors. The officer completing the form could note the category of the staff member directly involved in an adverse event/incident, but it is not compulsory. The outcome must be mentioned, and the type of adverse event is supposed to be ticked off. A list of adverse events and incidents was provided on the other side of the form (Table 1). A copy of the document is retained in the ward. A separate register is maintained in the ward to record the details of all the adverse events reported.

A copy of the completed adverse event/incident report form is sent to the QMU. The categorization of the adverse event/incident based on the International Classification of Patient Safety [7] was carried out by QMU. It is then sent for the information and authorization to the head of the institution to carry out further root cause analyses, if necessary. The medical officer of QMU analyzes the incident with the relevant consultant and/or other stakeholders. Any criticism or breach of confidentiality at any point in the process is not to be allowed. Instruments and tools recommended for analysis include Why-Why Diagram, Fish-Bone Diagram, and Problem Tree. Preventive actions are recommended and written in the form.

Selected important and serious adverse events could be discussed in the monthly clinical meetings of the hospital to enable learning from experience and prevent such events in future in other wards/units. But it is stressed that no individual should be criticized during any of these proceedings.

A summary of the adverse event/incident is sent to the Directorate of Healthcare Quality & Safety (DHQS) of the Ministry of Health quarterly. DHQS analyzes the events of the report and discusses with the relevant professional colleges as required.

The objectives of the current study were to assess the process of adverse event reporting and analyze the reported events in selected state hospitals in Sri Lanka.

Materials and methods

The current study was a descriptive mixed-method assessment that included cross-sectional, and retrospective components carried out in June 2020.

During the cross-sectional component, we studied the process of adverse event reporting in the state health service of Sri Lanka. A focus group discussion and a survey of relevant document formats were carried out. There were ten participants in the focus group: five medical administrators, three medical consultants, and two medical officers attached to the quality management units in hospitals. Participants were selected based on convenience. During the focus group discussion, the participants evaluated the current adverse reporting system regarding strengths, weaknesses, opportunities, and threats (SWOT). The qualitative inputs generated were subjected to thematic analysis.

The incidents reported by selected hospitals in 2019 were studied retrospectively. All the line ministry hospitals that participated in quarterly performance reviews conducted by DHQS in 2019 were considered. The hospitals that had not completed the reporting procedure were excluded. Desk review of adverse event reporting forms sent from the selected hospitals was carried out with a checklist designed based on the guidelines and standards for adverse event reporting, as per the General Circular by the Ministry of Health [5].

Results

Forty-six (46) line ministry hospitals were included in the study. The adverse events reported belonged to seven categories, and it was revealed that the majority (30.46%) of adverse events reported were falls (Table 2).

Table 2. Frequency distribution of adverse events reported from selected hospitals in the year 2019

Type of adverse event	Reported frequency (Number and percentage)
Falls	3145 (30.46%)
Treatment/Diagnosis issues	671 (6.49%)
Drugs/Intravenous infusions/ Blood transfusion issues	2373 (22.97%)
Surgery/Anesthesia-related issues	128 (1.24%)
Laboratory reports related issues	1415 (13.71%)
Labor related issues	44 (0.43%)
Other	2548 (24.68%)
Total	10324

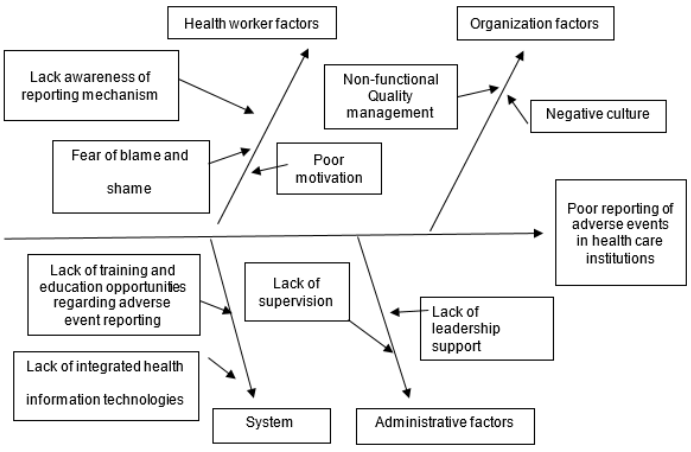
The results of the SWOT analysis of the process of adverse event reporting by health care institutions are depicted in Table 3.

Table 3: SWOT analysis of the current adverse event reporting process

Strengths Availability of Ministry guidelines in adverse event reporting Availability of well-established quality management units in hospitals networked with the Directorate of Health care Quality and safety The non-punitive non-fault-finding approach in the adverse event reporting and analysis process	**Weaknesses** The lengthy manual documentation process Lack of motivation of staff Lack of forum/platform at the institutional level to discuss adverse events Poor supervision by the Head of the institution
Opportunities Availability of national quality performance review, which provides a platform for discussion Enthusiasm for professional colleges	**Threats** Blame and shame culture in some settings Fear of litigation

The overall opinion of the focus group discussion participants regarding the rate of reporting the adverse events was that an actual number of adverse events was far more than reported. The root cause analysis of under-reporting of adverse events was carried out with the participation of the focus group (Figure 1).

Figure 1. Root cause analysis of under-reporting of adverse events



The focus group pointed out that the common belief of health workers was that errors in the health sector were inevitable and mostly unmanageable. The group's opinion was that it has contributed to creating an idea among health workers that incident reporting was 'pointless'. It was also stated that reporting could be discouraged by excessive administrative procedures. The participants stated that health workers were apprehensive about the increased potential for administrators to engage in the regulation of medical quality using reported incident data.

Discussion

Investigation of critical incidents was reported first in the 1940s by Flanagan as a technique to improve safety and performance among military pilots [8]. The National Patient Safety Agency was established as a Special Health Authority in England and Wales in 2001, which has been responsible for the national reporting and learning system to collect, analyze, and learn from all types of patient safety incidents [9]. Adverse event reporting systems have been a key tool to enhance organizational learning from incidents in a range of high-risk non-health organizations [10], including commercial aviation, the rail industry, and at nuclear power stations. Although adverse event reporting has been instituted in healthcare systems in many countries around the globe, positive experiences similar to those of non-health high-risk organizations are yet to be fully realized.

A successful reporting and learning system to enhance patient safety should be non-punitive for the individuals who report and should not focus on targeting or finding fault with anyone [11]. The successful improvement in patient safety through the analysis of incident reports is less likely without achieving a blame-free culture [12].

The reporting of incidents is most effective when the data collected are analyzed at local, district, and national levels with the participation of professional colleges and scholars through anonymous reporting, meaningful feedback, and ease of reporting [13]. Expertise, adequate resources, and training should be made available to allow for meaningful analysis of reported adverse events to better health services delivery. The recommendations must be disseminated and acted upon by those with the responsibility and mandate to act for the full benefits of adverse event disclosure to be achieved. In the Sri Lankan setup, the establishment of DHQS has been a huge strength in encouraging adverse event reporting and associated further quality improvement activities, which should be wisely utilized to connect all stakeholders in the process.

Although many healthcare organizations worldwide have implemented adverse event reporting systems with the aim of learning from experience to prevent adverse events and medical errors [14], under-reporting of adverse events is a recognized international health concern [15]. If the concerns of the possibility of being punished could be eliminated by guaranteeing legal immunity, the level of reporting would be much improved in the health sector.

Learning from patient safety incidents is difficult if the information is incomplete [16]. Globally, adverse event reporting has become a central element in effective patient safety systems, though their growth and implementation have been slow and

sluggish (Battles and Stevens 2009). The Sri Lankan adverse event reporting model also suffers from inadequate and incomplete documentation. The paper-based nature of reporting system in the country could have negatively contributed to the scenario.

Understanding the factors that determine the behavioral intention of healthcare professionals to comply with adverse event reporting is of utmost importance in the successful implementation of such a system. Some international researchers have noted that healthcare professionals were more likely to report a serious event [17] due to the better integrity of the reporting system, which was not seen in the current study. It was noted in the study that there was a tendency to better report adverse events with less gravity, such as falls, than those with more severity, which could be explained by fear of blame and shame associated with cultural issues [18].

The factors impeding the bringing of adverse events could be projected not only by professional, national, and organizational cultures but also by healthcare practice structural issues, including safety systems, rules, and regulations [19]. Knowledge, trust, and management support determine the healthcare workers' acceptance of adverse event reporting systems while minimizing negative organizational norms towards incident reporting.

Under-reporting of adverse events is a major concern in health care safety. The reasons for under-reporting include lack of awareness of reporting mechanism, poor leadership support, poor training and education regarding adverse event reporting, fear of punishment, and negative organizational culture. Adverse event reporting must become a culturally accepted activity within the healthcare community. An adverse event reporting system should be user-friendly and supported by leadership. Reporting becomes efficient when it is felt comfortable and assured to be free of negative consequences.

Health systems should be able to provide efficient technical support, training, and awareness programs for health workers involved and adequate resources to implement the adverse event reporting system. Ensuring a legal immunity against the possibility of using adverse event reporting data for disciplinary actions would remedy undue fear of punishment.

Conclusion

Although the state health sector of Sri Lanka has an established system of adverse event reporting, most reporting was limited to non-clinical events, such as falls. The staff seemed to have self-inhibitions in reporting relating to fear of blame and shame. The nature of the process of adverse event reporting being paper-based and cumbersome with repeated documentation has prevented it from being fully effective and popular.

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References

1. Battles JB, Stevens DP. Adverse event reporting systems and safer healthcare. Qual Saf Health Care. 2009;18(1):2.
2. World Health Oraganization. Patient safety. 2020. Available from: https://www.who.int/patientsafety/en/
3. Robertson JJ, Long B. Suffering in silence: medical error and its impact on health care providers. J Emerg Med. 2018;54(4):402–9.
4. Battles JB, Stevens DP. Adverse event reporting systems and safer healthcare. Qual Saf Health Care. 2009;18(1):2–2.
5. Ministry of Health, Sri Lanka. General Circular 01-38/2016; Implementation of Adverse Event Reporting & Readmission Forms [Internet]. 2016. Available from: http://www.health.gov.lk/CMS/cmsmoh1/upload/english/01-38-2016-eng.pdf
6. Ministry of Health, Sri Lanka. General Circular Letter No. 01-29/ 2009 National Quality Assurance Programme in Health. 2009.
7. Runciman W, Hibbert P, Thomson R, Van Der Schaaf T, Sherman H, Lewalle P. Towards an international classification for patient safety: key concepts and terms. Int J Qual Health Care. 2009;21(1):18–26.
8. Flanagan JC. The critical incident technique. Psychol Bull. 1954;51(4):327–58.
9. Cousins DH, Gerrett D, Warner B. A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years (2005-2010): Review of medication incidents over 6 years. Br J Clin Pharmacol. 2012;74(4):597–604.
10. Gong Y, Kang H, Wu X, Hua L. Enhancing patient safety event reporting: a systematic review of system design features. Appl Clin Inform. 2017;08(03):893–909.
11. Farley DO, Haviland A, Champagne S, Jain AK, Battles JB, Munier WB, et al. Adverse-event-reporting practices by US hospitals: results of a national survey. Qual Saf Health Care. 2008;17(6):416–23.
12. Cooper J, Edwards A, Williams H, Sheikh A, Parry G, Hibbert P, et al. Nature of blame in patient safety incident reports: mixed methods analysis of a national database. Ann Fam Med. 2017;15(5):455–61.
13. Mahajan RP. Critical incident reporting and learning. Br J Anaesth. 2010;105(1):69–75.
14. Wu J-H, Shen W-S, Lin L-M, Greenes RA, Bates DW. Testing the technology acceptance model for evaluating healthcare professionals' intention to use an adverse event reporting system. Int J Qual Health Care. 2007;20(2):123–9.
15. Stergiopoulos S, Brown CA, Felix T, Grampp G, Getz KA. A survey of adverse event reporting practices among US healthcare professionals. Drug Saf. 2016;39(11):1117–27.
16. Anderson JE, Kodate N. Learning from patient safety incidents in incident review meetings: Organisational factors and indicators of analytic process effectiveness. Saf Sci. 2015;80:105–14.
17. Sarvadikar A, Prescott G, Williams D. Attitudes to reporting medication error among differing healthcare professionals. Eur J Clin Pharmacol. 2010;66(8):843–53.
18. Waring JJ. Beyond blame: cultural barriers to medical incident reporting. Soc Sci Med. 2005 May;60(9):1927–35.
19. Moumtzoglou A. Factors impeding nurses from reporting adverse events: Adverse events in nursing. J Nurs Manag. 2010;18(5):542–7.

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