Development and Formative Evaluation of an Innovative, National Near-miss Reporting System for Curative Healthcare Institutions in Sri Lanka

Paula Bowman[1], Reece Hinchcliff[2], Munasinghage Priyanwada Jayalath[3], Dilantha Dharmagunawardene[1], and Samath Dhamminda Dharmaratne[4]

[1]Queensland University of Technology School of Public Health and Social Work
[2]Griffith University School of Applied Psychology Mount Gravatt Campus
[3]Government of Sri Lanka Ministry of Health Sri Lanka
[4]University of Peradeniya Faculty of Medicine

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Abstract

Background: Near-misses are errors that have the potential to cause an adverse event but fail to do so because of chance or because they are intercepted. By 2021, Sri Lanka had only established systems for maternal and blood transfusion services. Methods: A new, holistic near-miss reporting system was developed and piloted at a large tertiary hospital in 2022 to guide subsequent nationwide implementation. During the pre-interventional phase, national-level consultative meetings (n=20), key informant interviews (n=10) and focus groups (n=22) were convened with purposively selected representatives of professional colleges, academia, medical administrators, and senior staff of the participating hospital to identify existing methods of reporting near-misses. A near-miss reporting format and guidelines were designed with input from national-level consultative meetings. Training on the new system for medical and nursing officers, periodic reminders to staff, and dissemination of preventive measures for patient safety incidents were implemented as interventions. A pre-post evaluation was conducted to identify the effect of the new system, and stakeholders' views on potential for nationwide implementation. Results: Eight near-misses were reported three months following implementation, compared to none prior to implementation. Study participants expressed satisfaction with the new system's user-friendliness, clarity, non-punitiveness, voluntary nature, and confidentiality protection. The system was perceived to be suitable for national implementation following refinements. Conclusions: This evidence-based near-miss reporting system, combined with the complementary activities implemented in the pilot setting, should now be introduced into additional hospitals before national implementation to further enhance its design, support from stakeholders, and quality and safety impact.

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Full names of the authors and full contact details of the corresponding author:

Munasinghage Priyanwada Jayalath Dilantha Dharmagunawardene Samath Dhamminda Dharmaratne Paula Bowman (Corresponding Author) Email - paula.bowman@qut.edu.au Reece Hinchcliff

Author's institutional affiliations

Munasinghage Priyanwada Jayalath Post Graduate Trainee in Medical Administration, Ministry of Health, Sri Lanka Dilantha Dharmagunawardene Consultant in Medical Administration, Ministry of Health, Sri Lanka11Current Affiliation – School of Public Health and Social Work, Queensland University of Technology, Australia Samath Dhamminda Dharmaratne Director, Post Graduate Institute of Medical Sciences of Peradeniya, Sri Lanka Paula Bowman (Corresponding Author) Lecturer, School of Public Health and Social Work, Faculty of Health, Queensland University of Technology Reece Hinchcliff Professor, Academic Lead, and Programme Director in Health Services Management, School of Applied Psychology, Griffith University, Australia

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Abstract and Key Words

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Conclusions: This evidence-based near-miss reporting system, combined with the complementary activities implemented in the pilot setting, should now be introduced into additional hospitals before national implementation to further enhance its design, support from stakeholders, and quality and safety impact.

Highlights

- Evidence-based
- Intervention
- Near-miss reporting system
- Guidance for LMICs

Key Words

Quality Improvement, Patient Safety, Healthcare Near-misses, Near-miss Reporting Systems, Intervention Study, Low- and Middle-Income Countries

Ethics Approval

Ethical clearance was obtained from Post Graduate Institute of Medicine, University of Colombo (ERC/PGIM/2021/222)

Main Text

Introduction

The World Health Organization (WHO) defines a near-miss as an error that has the potential to cause an adverse event (patient harm) but fails to do so due to chance or because it is intercepted (1). There is a relationship between adverse events and near-misses because, according to Heinrich's Law, "for every adverse event, there are 30 minor injuries and 300 near-misses" (2). Near-misses are considered red flags for future adverse events, offering an opportunity to analyse and address causal factors (3).

Most high-income and several middle-income countries have implemented national-level near-miss reporting systems that routinely collect relevant data from hospitals (4). However, recent research identified few countries in the South and Southeast Asian regions with these systems in place (5). Sri Lanka does not have a comprehensive, holistic national-level near-miss reporting system other than for the specific issues of maternal near-misses (managed by the Family Health Bureau (FHB) and near-misses related to blood transfusion (managed by the National Blood Transfusion Services (NBTS) (6). Limited research has been conducted regarding near-misses in Sri Lanka, confined solely to maternal near-misses (7).

This interventional study, supported by the Sri Lankan Ministry of Health, had the following objectives: 1) explore gaps in the current issue-specific near-miss reporting systems; 2) use this information to develop a more comprehensive, holistic, and effective system; and 3) encourage healthcare professionals to report near-misses and take actions to prevent their recurrence in the future. The overarching aim was to strengthen the structures and processes used for reporting near-misses in Sri Lanka and, in doing so, advance the national quality and safety agenda.

Methodology

This study was conducted in three phases: pre-interventional, interventional, and post-interventional. Several qualitative research methods were used during the pre-and post-interventional phases. Ethical clearance was obtained from the Ethics Review Committee, Post Graduate Institute of Medicine, University of Colombo. Permission to carry out the project was obtained from the Ministry of Health, Deputy Director General – Medical Services I, Director- Directorate of Healthcare Quality & Safety (DHQS), Director- FHB, Director -NBTS, Provincial Director of Health Services – Western Province, Regional Director of Health Services – Colombo and the Head of the Institution of DGH Avissawella.

The study was conducted from February 2022 to December 2022 in the District General Hospital (DGH) – Avissawella, the only District General Hospital in Colombo district- the capital of Sri Lanka. The hospital comprises all major specialties, theatre, and ICU facilities, and almost all sub-specialties that a District General Hospital should have (8). Considering the service availability, practical feasibility, and administrative support for implementation, the research team selected the site mentioned above to pilot the project.

Pre-intervention Phase

The two existing, topic-specific near-miss reporting systems and adverse event/incident reporting systems were critically analysed during the pre-intervention phase. Consultative meetings, key informant interviews (KIIs), and focus group discussions (FGDs) were conducted by the principal investigator (PI) using semi-structured guides until theoretical saturation was achieved (9). Study tools were validated through input from officials from DHQS, and pre-testing was undertaken with FHB and NBTS staff. These guides were

designed to extract information from purposively selected participants about their perceptions and opinions about near-misses, near-miss reporting, key barriers, and recommendations for developing and implementing a national reporting system.

An initial consultative meeting was held with a purposively selected sample of 20 representatives from prominent professional colleges and academic centres, e.g. Sri Lanka College of Surgeons, Sri Lanka College of Obstetricians and Gynaecologists, Sri Lanka College of Anaesthesiologists, Sri Lanka College of Physicians, Sri Lanka College of Paediatricians, University of Colombo, etc.

These representatives, who were specialist medical officers in several specialties, were from different hospitals in different geographical areas in the country. Since they were experienced senior specialists, they possessed a clear understanding and knowledge about the near-misses that occur in their units.

KIIs were held with the present and two previous Directors of the DHQS, the National Programme Manager of the Maternal Morbidity/Mortality Surveillance Programme of the FHB, the Head of the Hemovigilance Unit – NBTS, and three purposively selected heads of the institutions and two Special Grade Nursing Officers (SGNO) (equivalent Chief Nursing Officers) of DGH Avissawella. FGDs were held with eight Consultants (Group 1) and 14 Nursing Sisters and Unit in-charge Nursing Officers (Group 2) of DGH Avissawella.

Intervention

A process map, then Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis, was completed to identify bottlenecks in reporting systems and pragmatic methods available to strengthen current systems. The outcomes of these analyses are presented in Figure 1. Based on the gaps identified in the pre-intervention phase, the following interventions were agreed upon by the project team:

- refinement of existing process and systems for near-miss reporting.
- development of guidelines to facilitate near-miss reporting; and
- the design of a user-friendly near-miss reporting format.

Figure 1 SWOT Analysis of the Existing Near-miss Reporting Systems and Adverse Event / Incident Reporting System in Sri Lanka

Near-miss Reporting System	
Strengths	**Weaknesses**
1. Already established near-miss reporting systems to report maternal near-misses and near-misses related to blood transfusion (N-S1) 2. Provision of feedback via annual reports of the NBTS near-miss reporting system (N-S2) 3. non-punitive reporting systems (N-S3) 4. Voluntary reporting system at NBTS (N-S4) 5. Mandatory reporting system at FHB (N-S5) 6. User-friendly reporting system at NBTS (N-S6) 7. NBTS and FHB carrying out the administrative functions related to reporting (N-S7)	1. Unavailability of a system to report other near-misses in day-to-day clinical practice (N-W1) 2. Need to reveal the identity of the reporting officer (N-W2) 3. Less user-friendliness of the "Maternal near-misses Reporting Form" (N-W3) 4. Unavailability of a well-established mechanism to incorporate the preventive measures into the system as "best practices" (N-W4)
Opportunities	**Threats**
1. Competent and well-trained health workforce (N-O1) 2. Availability of a designated directorate (DHQS) to provide technical guidance on patient safety and quality improvement programmes (N-O2) 3. Heads of the institutions are trained on patient safety and quality improvement in healthcare (N-O3) 4. Well-established QMUs in most hospitals (N-O4) 5. Availability of a designated MO/NO for the QMU (N-O5)	1. Inadequate knowledge of most HCWs about near-misses and near-miss reporting (N-T1) 2. Negative perceptions among most HCWs about near-misses and reporting of near-misses (N-T2) 3. Influence from powerful trade unions in the health sector (N-T3) 4. Competing for other interests of some HCWs (e.g.: Consultants' perception that this is a performance evaluation and that it will affect the private practice) (N-T4)
Adverse Event / Incident Reporting System	
Strengths	**Weaknesses**
1. Already established adverse event/incident reporting systems supported by a guideline prepared by DHQS (A-S1) 2. Provision of feedback via annual reports (A-S2) 3. Non-punitive reporting system (A-S3) 4. Voluntary reporting system (A-S4) 5. User-friendly reporting system (A-S5) 6. Anonymous reporting system (A-S6)	1. Unavailability of a well-established mechanism to incorporate the preventive measures as "best practices" at the National level (A-W1)
Opportunities	**Threats**
1. Competent and well-trained health workforce (A-O1) 2. Availability of a designated directorate (DHQS) to provide technical guidance for quality improvement programmes in the health sector (A-O2) 3. Heads of the institutions are trained on patient safety and quality improvement in healthcare (A-O3) 4. Well-established QMUs in most hospitals (A-O4) 5. Availability of designated MO/NO at QMUs (O5)	1. Inadequate knowledge of some HCWs about adverse events/incident reporting (A-T1) 2. Negative perceptions among most HCWs about adverse events/incidents and reporting those (A-T2) 4. Competing for other interests of some HCWs (e.g.: Consultants in private practice) (A-T3)

The results, in combination with key findings elicited through a desktop, non-systematic scan of the peer-

reviewed literature, were used to design a draft near-miss reporting form and guidelines, which were reviewed and finalized with input at the second and the third national-level consultative meetings. These were held with the participation of the Director - DHQS, representatives from purposively selected professional colleges and academia (as mentioned above), and purposively selected hospital administrators who are well experienced in health care management in different levels of hospitals in different areas in the country.

Conduct of training programmes

Training programs were conducted for medical and nursing officers to improve their knowledge and alleviate negative perceptions about near-misses and near-miss reporting processes. During these programs, the newly designed near-miss reporting form and guidelines were introduced to the medical officers and nursing officers of the hospital.

Changes to structures and processes

An internal circular signed by the Director about the near-miss reporting process was distributed among the units by the Nursing Officer (NO) – Quality Management Unit (QMU) with a folder containing the near-miss reporting forms and the national guideline. The in-charge nursing officers were instructed to keep the folder accessible to any health care worker (HCW). Details of the intervention were shared in the social media groups of HCWs and conveyed by the head of the institution during consultant meetings and unit in-charge meetings. A near-miss reporting form box was established in front of the QMU to drop the completed forms confidentially. Fortnightly reminders about near-miss reporting were shared in staff social media groups, and periodic feedback was provided at consultant meetings and in-charge meetings to improve reporting.

Post-intervention Phase

Separately designed KII and FGD guides were used to assess the effectiveness of the package of interventions. The designing and pre-testing of semi-structured guides followed the same process as the pre-intervention phase. During the post-intervention phase, feedback about the new reporting system was elicited from the head of the institution, consultants, SGNOs, sisters in charge, and in-charge nursing officers.

The data from consultative meetings, KIIs, and FGDs were recorded with the consent of participants and then transcribed. Thematic analysis was executed according to a pre-defined framework framed upon the KII and FGD guides. Coding was completed using a Thematic Analysis approach (10, 11). Analysis was led by the first author, with ongoing input from the broader research team. Quotes were captured and presented below to exemplify the main themes identified.

Results

The results are provided separately for the pre-and post-intervention phases.

Results of the pre-interventional phase

Thematic Analysis of Consultative Meetings

Several key issues were identified as the major bottlenecks in the current systems, including inadequate HCW knowledge about near-misses and adverse events/incidents; negative perceptions of HCWs about near-misses, adverse events/incidents, and reporting processes; poor user-friendliness of the existing near-miss reporting systems; and a lack of a well-established mechanism to incorporate preventive measures as best practices to be implemented across all healthcare institutions. The major gaps identified were that the existing near-miss reporting systems in Sri Lanka covered only maternal near-misses or those related to blood transfusions and that the current reporting forms were not user-friendly.

Thematic Analysis of KIIs and FGDs

Results of the KIIs held at the national and institutional levels during the pre-intervention phase are illustrated in Figure 2. The results of the FGDs of the pre-intervention phase are illustrated in Figure 3.

Figure 2 Thematic Analysis of KIIs (Pre interventional phase)

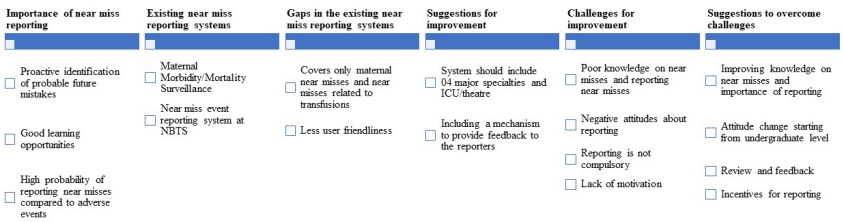
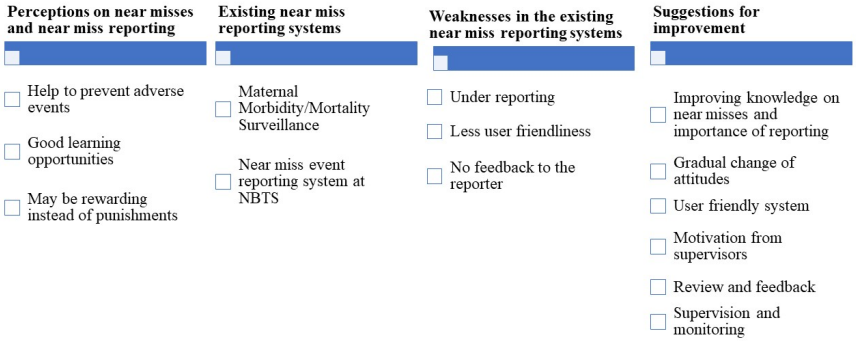


Figure 3 Thematic Analysis of FGDs (Pre interventional phase)



Reasons for under-reporting and strategies to improve reporting .

Reasons for underreporting were highlighted at the initial national-level consultative meeting and the pre-interventional phase KIIs and FGDs. Exemplifying quotes are presented below.

"Although we have a designated Directorate for Healthcare Quality and Safety, policies and guidelines, the HCWs' negative attitudes of HCWs contribute a lot to the reporting of near-misses. They think, "Why should we report?" and "Reporting will highlight our mistakes." If we want to improve reporting, we should include the importance of near-misses and reporting of those in the undergraduate and postgraduate curricular of HCWs,' and they should be given a good orientation about these at the time of recruitment." (DHQS- A)"At [an] institutional level, lack of staff (designated medical officers for hospital QMUs), and frequent transfers of trained staff are significant barriers to reporting, because to maintain a successful reporting system, there should be a designated person who can monitor, analyse and provide feedback on the reports. In addition, HCWs' ignorance and negative attitudes are also barriers." (DGH Avissawella- B).

Results of the post -interventional phase.

Results of the KIIs and the FGDs during the post-interventional phase are illustrated in Figure 4 and Figure 5, respectively.

Figure 4 Thematic Analysis of KIIs (Post interventional phase)

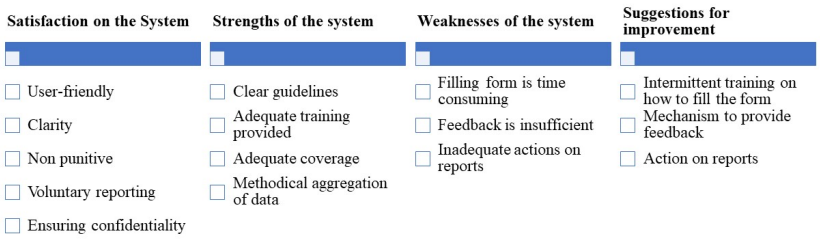
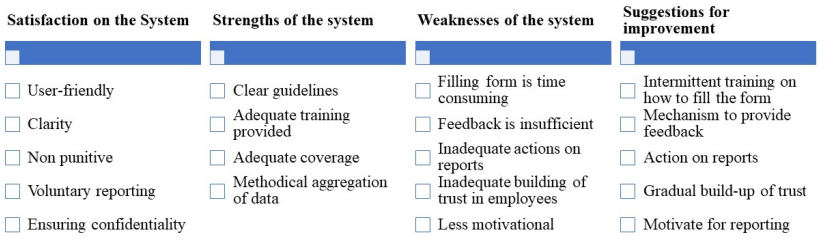


Figure 5 Thematic Analysis of FGDs (Post interventional phase)



A total of eight near-misses were reported during the intervention period of three months. Three near-misses were radiology or laboratory-related, and two were related to the patient monitoring process of detecting circulatory problems on time and preventing patient harm. The details are depicted in Table 1. No adverse events/incidents were reported during the same three months.

Table 1: Summary of Near-Misses Reported at DGH Avissawella from 01.07.2022 to 30.09.2022

Category	Type	Category number	Frequency
Drug administering process	Detecting a wrong dosage before administering/Detecting a wrong drug infusion rate set before administering	DA3	01
Radiology/ Laboratory	Detecting delayed/missed important/critical radiological or laboratory investigation	RL3	03
Patient monitoring process	Detecting circulatory problems on time and preventing patient harm	PM1	02
	Detecting airway problems on time and preventing patient harm	PM2	01
Other	A critical patient missed ECG monitoring for a brief period.		01
Total			**08**

The training programs held for medical officers and nursing officers might have helped to improve knowledge of near-misses and the importance of reporting near-misses, as well as alleviated negative perceptions. Nevertheless, during the post-interventional FGDs, the following views and suggestions were brought forward.

"The new near-miss reporting system has not won the trust of the employees yet. It does not motivate the employees to report near-misses. Therefore, we suggest holding intermittent training programs, establishing a mechanism to provide feedback, and gradually building trust among employees." (DGH Avissawella-C)"We believe that once the employees get used to the system and understand the true value of reporting, the habit of reporting may be absorbed into the organizational culture." (DGH Avissawella-C)

Discussion

The importance of national near-miss reporting systems is universally accepted. This pilot study provides an evidence-based foundation for implementing the first comprehensive national system in Sri Lanka.

Although this study was implemented at DGH Avissawella only, the intention is for it to be gradually expanded to other healthcare institutions to enable ongoing evaluations and refinement before national implementation. Both the initial pilot and intended future rollout have been assisted through multi-stakeholder support, including from the national focal point on patient safety and quality (DHQS).

The main interventions carried out in this study were identified through a scan of the international literature and a comprehensive analysis of existing process problems in Sri Lanka, including the need to design a user-friendly near-miss reporting form and guidelines. Since inadequate knowledge of near-misses and negative perceptions about reporting were identified as bottlenecks to implementing the key interventions, these were addressed through training programs. The initial pilot findings have emphasized that the new reporting system is user-friendly, non-punitive, voluntary, and confidential.

Feedback from system users was generally positive, but some users mentioned that filling out the form was

time-consuming, feedback was insufficient, inadequate actions were taken on reports, the system was less motivational, and the trust of all employees had not yet fully gained**.** At the initial stage, considerable time may have been required to fill out the form as it was unfamiliar. Once HCWs become more used to filling out the forms during their routine work, the time required for reporting may be reduced, facilitating staff engagement and effective implementation.

Participants of national consultative meetings, KIIs, and FGDs mentioned that the system should be voluntary to gain the employees' trust without resistance. Accordingly, the new Sri Lankan system is voluntary, in contrast to (for example) the Swedish and Danish systems (1). In Finland's reporting system, the analysis and dissemination of results are only completed at the local hospital level (12). In contrast, the proposed Sri Lankan system will undertake analysis and dissemination of results both at the national and local hospital levels. This approach is more similar to the system used in Japan, where, in addition to the national-level reporting system, healthcare providers use their own reporting and learning systems at the local hospital level (13).

The new Sri Lankan processes result in verbal feedback being provided during consultant and in-charge meetings. During the pilot, the discussion of two near-miss cases, including feedback and information about preventive measures taken, was conducted only with the staff involved, and other staff were unaware of the actions taken. In the reporting system of Switzerland (CIRRNET), feedback is provided through Quick-Alerts, published in specialist journals and the Patient Safety Foundation website (12). Furthermore, in a study in Western North Carolina, regular reminders and feedback were used to improve reporting (14). In 2017, Japanese researchers identified that enhanced feedback for reporters promoted voluntary in-hospital reporting (4). Aligning with best practice principles arising from this published research, the new Sri Lankan system involves a streamlined mechanism to provide feedback to healthcare professionals and use a periodic reminder system via social media groups to improve reporting.

Two studies from the United States have shown that the provision of incentives for staff for reporting led to more successful reporting at the initial stage of implementation (14, 15), but the continuation of reporting in an established system was not dependent on incentives (15). However, this approach has been criticized because these incentives may not be available in more resource-constrained settings (16). In addition, it was postulated that incentives may lead to biases, create issues in the quality of reporting, and become impossible to remove without threatening the system's sustainability and viability (16). For this reason, quality and safety stakeholders in other countries have developed successful near-miss reporting systems that are not dependent on the provision of monetary incentives to motivate behaviour change (17). Due to the above reasons, the financial constraints present within the Sri Lankan health system, and the desire to create a sustainable, long-term system, our pilot study did not use financial incentives to facilitate implementation.

Under-reporting of near-misses was a major bottleneck identified in implementing a successful near-miss reporting system during this study, which is similar to experiences in other settings (18). The literature suggests that providing training and education about near-misses and the importance of reporting near-misses, as well as ensuring the confidentiality of reporters and a blame-free culture, are important considerations in developing a near-miss system (19), and these principles informed the design and implementation of the new Sri Lankan system.

We found that HCWs' inadequate knowledge and negative perceptions had adversely affected the pre-existing level of reporting. For this reason, before implementing the new system, HCWs were given training on near-misses and the importance of reporting near-misses to reframe their perceptions more positively. However, it was found that more than training alone was needed to fundamentally improve the reporting behaviour of the participants. The project team postulates that once the habit of reporting is incorporated into organizational culture and when the new system has built trust among all employees, reporting behaviour is expected to improve over time. This illustrates the importance of viewing the development of the new system as just one element of the overall quality and safety agenda rather than as a standalone panacea capable of 'solving' all existing problems.

A more extended implementation period will be required for the new reporting system to produce the level of detailed near-miss data required to reach reliable conclusions about how similar or different Sri Lankan near-misses are to other countries. The project team is actively working towards this objective, using these pilot results as the foundation for this ongoing body of work.

Limitations

This reporting system was implemented in a single setting, and the findings cannot be generalized to other hospitals at this stage. The reporting was expected only from two categories of staff: medical officers and nursing officers. Therefore, at this stage of the implementation process, we cannot predict the level of compliance of other staff categories to the new reporting system. These limitations will be addressed through the broader trial of the reporting system in additional hospitals over the next year.

Conclusion

Although there are two current issue-specific near-miss reporting systems in curative healthcare institutions in Sri Lanka, there needs to be an inclusive near-miss reporting system covering all major specialties. The level of reporting of the existing systems is also unsatisfactory. This study provides a foundational evidentiary basis upon which the pilot can now be extended to other institutions, with the intention of the system being further refined before national implementation. This systematic, gradual approach will maximise the uptake and effectiveness of the new national system. A similar process is advocated for other countries in the region that do not currently have a near-miss reporting system. Quality and safety stakeholders from the region are encouraged to contact the project team to discuss opportunities for ongoing regional learning and collaboration.

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