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Ministry of Health, Nutrition & Indigenous Medicine

Guidelines for Adverse Event / Incident Reporting

Introduction

Patient safety is a major concern for all healthcare providers. It appears perverse that patients can suffer harm when they are being treated and cared for. However, healthcare is complex and its outcome is influenced by many factors. It is inevitable that within any healthcare system patients may be harmed, and in every encounter there is the potential for harm to occur. This has been recognized since the time of the physicians of Ancient Greece and Rome – 'First, do no harm.'

Safest place for patients is a Hospital. Are hospitals as safe as we think they are? Vast number of misconducts, negligence and adverse events are recorded from these patient care institutions. 'Patients are harmed from their health care either resulting in permanent injury, increased Length of Stay (LOS) in hospitals and even death. Adverse events occur not because bad people intentionally hurt patients but rather that the system of health care today is so complex that the successful treatment and outcome for each patient depends on a range of factors, not just the competence of an individual health-care provider' . There is no institution that can provide total patient safety. Risk that patients have to face is not homogeneous. It differs according to how sick the patient is, number of interventions he /she has to go through and duration of the stay. Unless substantial changes in the system are made, the vulnerable have to carry the burden of errors.

In Sri Lanka, there are many reported as well as unreported cases related to patient safety. Moreover, there are allegations that hospitals are covering up these incidents. Necessity of initiating patient safety culture in health care system and a compensation mechanism has been raised. It was found that medical staff lacks proper awareness on patient safety and its importance. Blame and shame leads to underreporting. In turn the organization lacks the opportunity to learn from its errors and prevent / mitigate future adverse events.

Patient safety is a new concept introduced to Sri Lankan health care system. "To Err is Human; Building a Safer Health System" was an eye opener which highlighted patient safety and patient safety culture. Health sector has learnt safety culture from other highly reliable organizations such as aviation, nuclear power industry etc. Similar to those organizations, the highly reliable health care providers have an inbuilt patient safety culture.

Directorate of Healthcare Quality & Safety, Ministry of Health, Nutrition & Indigenous Medicine

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Purpose of Reporting

In seeking to improve safety, one of the most frustrating aspects for patients and professionals alike is the apparent failure of health-care systems to learn from their mistakes. Too often neither health-care providers nor health-care organizations advise others when a mishap occurs how to prevent from their experiences. Also they do not share what they have learned when an investigation has been carried out. As a consequence, the same mistakes occur repeatedly in many settings and patients continue to be harmed by preventable errors.

One solution to this problem is reporting: by the Consultant, Medical Officer, Nursing Sister, Nursing Officer or other provider within the hospital or health-care organization, and by the organization to a broader audience through a system-wide reporting system. Some believe that an effective reporting system is the cornerstone of safe practice and, within a hospital or other health-care organization, a measure of progress towards achieving a safety culture. At a minimum, reporting can help identify hazards and risks, and provide information as to where the system is breaking down. This can help target improvement efforts and systems changes to reduce the likelihood of injury to future patients.

Objective

The objective of this guideline to facilitate the improvement or development of reporting systems that receive information that can be used to improve patient safety. 85-90% of errors occur due to system failures and only 10-15% of errors due to individual failures. The reporting system mainly focuses on the system failures. This reporting system is not to punish or find fault with any healthcare personnel but to improve the systems for a safe healthcare delivery. Also this reporting allows learning through:

Reporting can lead to learning and improved safety through:

- **Generation of "alerts"** regarding significant new hazards, for example, complications of a new drug.
- **Dissemination of "lessons learnt"** by health-care organizations from investigating a serious event.

- **Analysis of many reports** can reveal **unrecognized trends and hazards** requiring attention, insights into underlying systems failures and generate recommendations for "best practices" for all to follow.

The ultimate success of a reporting system is whether the information from the reporting system is used appropriately to improve patient safety in the healthcare delivery.

A successful reporting and learning system to enhance patient safety should have the following characteristics:

- Reporting is safe (i.e. non-punitive) for the individuals who report. Also reporting should no focus on targeting or find fault with anyone;
- Reporting leads to a constructive response;
- Expertise, adequate resources and training are available to allow for meaningful analysis of reports;
- The reporting system must be capable of disseminating information on hazards and recommendations for changes.

The reporting of incidents is most effective when the data collected are analysed (at local, district as well as national levels with the professional colleges) and recommendations are disseminated and acted upon by those with the responsibility and mandate to act.

Definition of Terms

(WHO Draft Guidelines for Adverse Event Reporting & Learning Systems 2005)

No.	Term	Definition
i	Safety	Freedom from accidental injuries.
ii	Incident (or adverse incident)	Any deviation from usual medical care that causes an injury to the patient or posses a risk of harm. Includes errors, preventable adverse events, and hazards.
iii	Adverse event	An injury related to medical management, rather than the complications of disease. 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.
iv	"Near-miss" or "close call"	Serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted. Also called potential adverse event.
v	Hazard	Any threat to safety, e.g. unsafe practices, conduct, equipment, labels, names.
vi	System	A set of interdependent elements (people, processes, equipment) that interact to achieve a common aim.

Guidelines of filling the Adverse Event / Incident Reporting Form (Please find the process of adverse event / incident reporting in Annexure I)

Part A

Part A can be filled by any health care worker in their own language. This may be different from a unit / ward where the patient received treatment. The adverse event / incident form must be completed immediately after the occurrence of the adverse event and the area and people are safe. For example, if a patient had a fall, it is important to attend the patient immediately and give appropriate treatment. Also to see the reason for fall, immediately remove the root cause of a fall (if the fall is due to wet floor, make arrangements to dry the floor area).

Then fill the form. The form should be filled within 24 hours. For the staff working in shift duties, they have to fill the form before they hand over to the staff of next duty shift.

Serious adverse events / incidents **MUST** be reported to the Head of the Institution and the relevant consultant as soon as possible.

All the adverse events related clinical management should be reported by the consultant, Senior Registrar, Registrar, Medical Officer or Intern House Officer. All such reports must be seen by the respective consultant or any other Senior Medical Officer assigned by the consultant.

The adverse events associated with the non-clinical management (such as fall) can be reported by the Nursing Sister or the Nursing Officer.
The nature of the adverse event must be mentioned briefly in the relevant cage. The immediate measures taken to manage the adverse event / incident should mention in the next cage in brief.

Part B

Part B should be filled by the head of the unit. It can be a Consultant, Medical officer, Nursing Sister/in charge nurse, Chief pharmacist, Chief MLT, Chief Radiographer, Officer in-charge of a unit etc.

Root causes and contributing factors relating to the adverse event should write after a brief discussion with relevant staff in the unit / ward. Based on the risk factors, root causes and contributing factors, preventive measures need to be taken or recommended.

The officer writing the form can write the category of staff member who is directly involved adverse event / incident which is optional. Then the outcome an also the type/types of the adverse event / incident should be ticked off. A list of types of adverse events and incident is provided at the other side of the form,

A copy of the form must be retained in the ward. Also s separate register must be maintained to record the details of all the adverse event forms filled and sent to the QMU.

Once the Adverse event/Incident report form is filled it should be sent to the Quality Management Unit (QMU). At the QMU, when the adverse event form is received it must be entered in a designated register. . When a form is received, date and time of the reception should be notified. It is then sent for the information and authorization to the head of the institution after notifying the date and time of notification.

Once it is received the categorization of the adverse event/incident based on the International Classification of Patient Safety should be filled by Quality Management Unit (QMU). It is recommended to consult Head of the Institution. The head of the institution should go through the form and provide his comments and authorize to carry out further root cause analysis if necessary. If Director has requested to further investigate on the adverse event / incident, the MO / QMU should analyze the incident with the relevant consultant and / or other stakeholders. There should not be any criticism or breach of confidentiality at any point of this process. Every attempt should be taken not to find fault with any individual unless there is a gross negligence. During the analysis quality improvement tools such as Why-Why Diagram, Fish-Bone Diagram or Problem Tree can be used.

Prevention action taken based on the adverse event / incident should be written in the form. If there are any other vital facts identified, it should be also mentioned in the form.

Category of Adverse Event / Incident (Adopted from ICPS)

	Category	Example
1	Blood / Blood Products	Request for a blood product for the wrong patient; or blood with the wrong blood type was administered to a patient
2	Clinical Administration	Wrong document were filled out for admission; or a patient was treated by different doctor than previously discussed
3	Clinical Process / Procedure	A delay in treatment due to postponement of surgery; or a diagnosis is missed
4	Documentation	Patient chart was missing; or information on patient chart was incorrect or missing
5	Health care associated infection	Patient develops infection near the surgical site, due to a gauze that has been left behind in the wound
6	Infrastructure	Trolley does not fit into the lift, or a nurse slips on wet floor or a patient fall.
7	Medical / equipment	Computer malfunction or surgical tools that break or are unsterile
8	Medication fluids	Wrong drug is administered to the patient; or patient has not received medication
9	Nutrition	Wrong quantity or wrong sort of drip-feed is administered
10	Oxygen / gas / vapour	Patient returns from procedure and a nurse forgets to connect the oxygen
11	Patient accidents	patient has fallen out of bed; or patient that to connect the oxygen
12	Resources / organizational management	Understaffing or no available beds
13	Behaviour	Treatment of patients by staff was inconsiderate or rude

Certain serious adverse events / incidence can be discussed in the monthly clinical meetings. This is mainly to learn from experience and prevent such events in future in other wards / units. At any point of these meetings, no individual should be criticized.

Then after keeping of this form, a summary of the adverse event / incident should be sent to the Directorate / Healthcare Quality & Safety (D / HQS) of Ministry of Health quarterly. The name of the hospital, the unit and the health personnel involved in the incident need not to mention when sending to the D /HQS. D / HQS will analyze these events and discuss with the relevant professional colleges if there epidemiology or serious adverse events or if there a increasing trend of a particular event / incident.

PROCESS OF HANDLING ADVERSE EVENTS / INCIDENTS

Adverse Event is assessed by a MO and the relevant Consultant is informed immediately. If the consultant is not available, Head of the Institution should be informed

Fill the Adverse Event Report Form Part A (by any health staff)

Appropriate management of the victim (may be better as some times investigations are needed)

❖ Investigate on the Adverse Event by the relevant unit by the consultant or an officer designated by the consultant
❖ Find the root causes and take immediate Preventive action

Send the form to the QMU while keeping a copy in the ward

If severe – transfer to the closest specialized institution

If mild – manage in the ward

QMU after entering details sent the form to head of the institution for information and authorization

Head of the institution provide authority for further study of the adverse event / incident. MO/QMU to carry out root cause analysis and submit recommendations

Discuss the event at the monthly review meeting with the findings

Development of a mechanism to avoid such events in the future

Implementation of such decisions made and monitoring

Publish in the Annual Report. Disseminate your experience to other hospitals (publication, presentation in Annual Review meetings) to help other institutions to avoid such incidents

Evaluate at the monthly meeting and improve further

Records maintained at the QMU; a report sent to D / HQS quarterly; seek help from relevant consultant whenever necessary

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Grading of Incident Severity (Adopted from Department of Health, Social Services and Public Safety in the Northern Ireland)

The initial assessment of an incident should be performed quickly, even when all facts may not be available. There is always scope to re-grade as facts and issues emerge over time and following investigation.

Actual Incident Severity (according to the facts available)

In determining the actual severity consider the outcome of the incident in terms of harm to people / resources / environment / reputation / quality.

Severity of incident   High Level Descriptors

	(see Impact Table for a more detailed list)
Catastrophic	Incident with widespread implications to services
Major	Significant disruption to service
Moderate	Short term disruption to services
Minor	No interruption to services
Insignificant evident	No adverse outcome but risk potential