# Introduction to Patient safety incident reporting and learning system

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Introduction

- **Learning objective**: To introduce patient safety incident reporting and learning systems (PSI RLS)

- **Topics covered:**
  - What is a PSI RLS
  - Key definitions and concepts of patient safety incident
  - Different requirements of different levels of PSI RLS (institutional, sub-national, national)
  - Linkage with ICD 11 (if possible)

World Health Organization

Patient Safety Incident Reporting and Learning Systems
Technical report and guidance
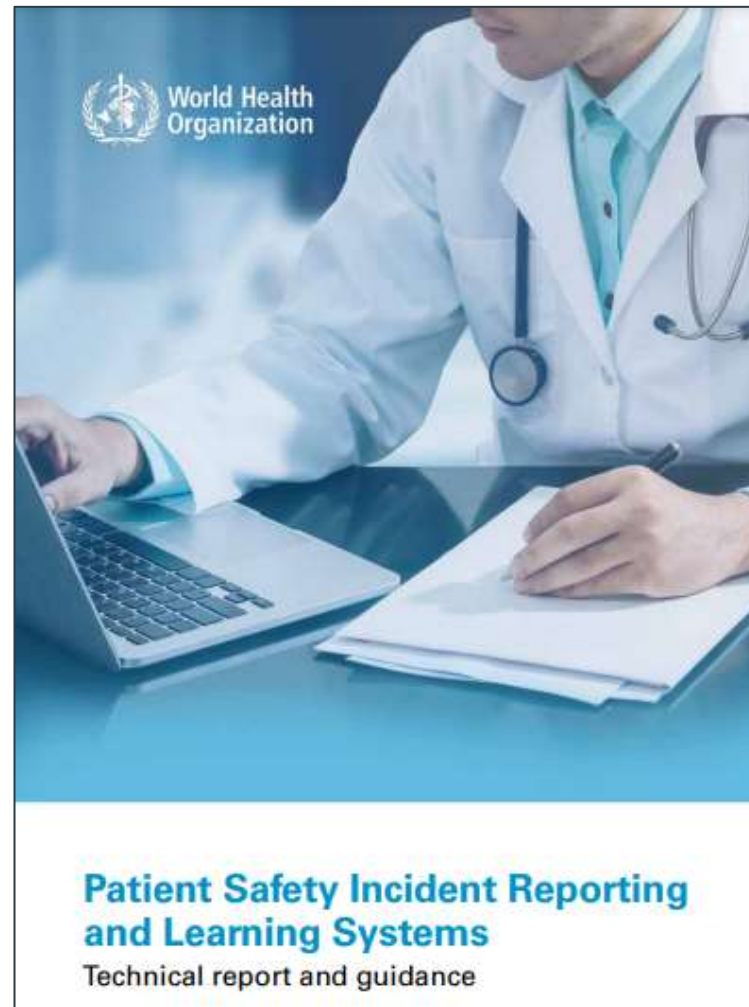
Published in 2020 by WHO to provide practical guidance on establishment and effective use of PSI RLS

Guidance

Aims to provide comprehensive advice on how to design, operate and use a successful PSI RLS:

Covered in this module:

▶ Understanding a patient safety incident reporting and learning system

To be covered in other modules:

▶ Creating a positive environment for reporting

▶ Identification and recording of incidents

▶ Choosing the information to be captured

▶ Uses of incident reports

▶ Review and investigation of individual incidents

▶ Systemic insights from aggregated incident data

▶ Learning, formulating action and managing change

▶ Openness and independence of data analysis

▶ Information and clinical governance

▶ Engaging patients and families

World Health Organization

Patient Safety Incident Reporting and Learning Systems
Technical report and guidance

What is a PSI RLS?

- It is an information system that:
  - Captures patient safety incidents that occurred in health facilities that were reported by healthcare staff. PSIs identified by alternative methods for detecting incidents should also be captured in the system.

- PSI RLS fulfil one or more of five main functions:
  - public accountability
  - response to the patients and families involved
  - communications alert route
  - barometer of risk within health care
  - foundation for learning and improvement.

Key definitions and concepts of patient safety incident

▶ **Ameliorating action**: an action taken or circumstances altered to make better or compensate any harm after an incident.

▶ **Contributing factor**: a circumstance, action or influence that is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.

▶ **Detection**: an action or circumstance that results in the discovery of an incident.

▶ **Error**: failure to carry out a planned action as intended or application of an incorrect plan.

▶ **Event:** something that happens to or involves a patient.

▶ **Hazard**: a circumstance, agent or action with the potential to cause harm.

Key definitions and concepts of patient safety incident

▶ **Incident**: any deviation from usual medical care that either causes an injury to the patient or poses a risk of harm, including errors, preventable adverse events and hazards.

▶ **Incident characteristics**: selected attributes of an incident.

▶ **Incident type**: a descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features.

▶ **Mitigating factor:** an action or circumstance that prevents or moderates the progression of an incident towards harming a patient.

▶ **Never event**: a patient safety incident that results in serious patient harm (physical or psychological) or death. Also referred to as adverse event/sentinel events.

▶ **Patient characteristics**: selected attributes of a patient.

Key definitions and concepts of patient safety incident

▶ **Patient outcome**: the impact upon a patient that is wholly or partially attributable to an incident.

▶ **Patient safety**: a framework of organized activities that creates cultures, processes and procedures, behaviours, technologies, and environments in health care that consistently and sustainably: lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce its impact when it does occur.

▶ **Root cause analysis**: a systematic iterative process whereby the factors that contribute to an incident are identified by reconstructing the sequence of events and repeatedly asking why? until the underlying root causes have been elucidated.

Classification of PSI*
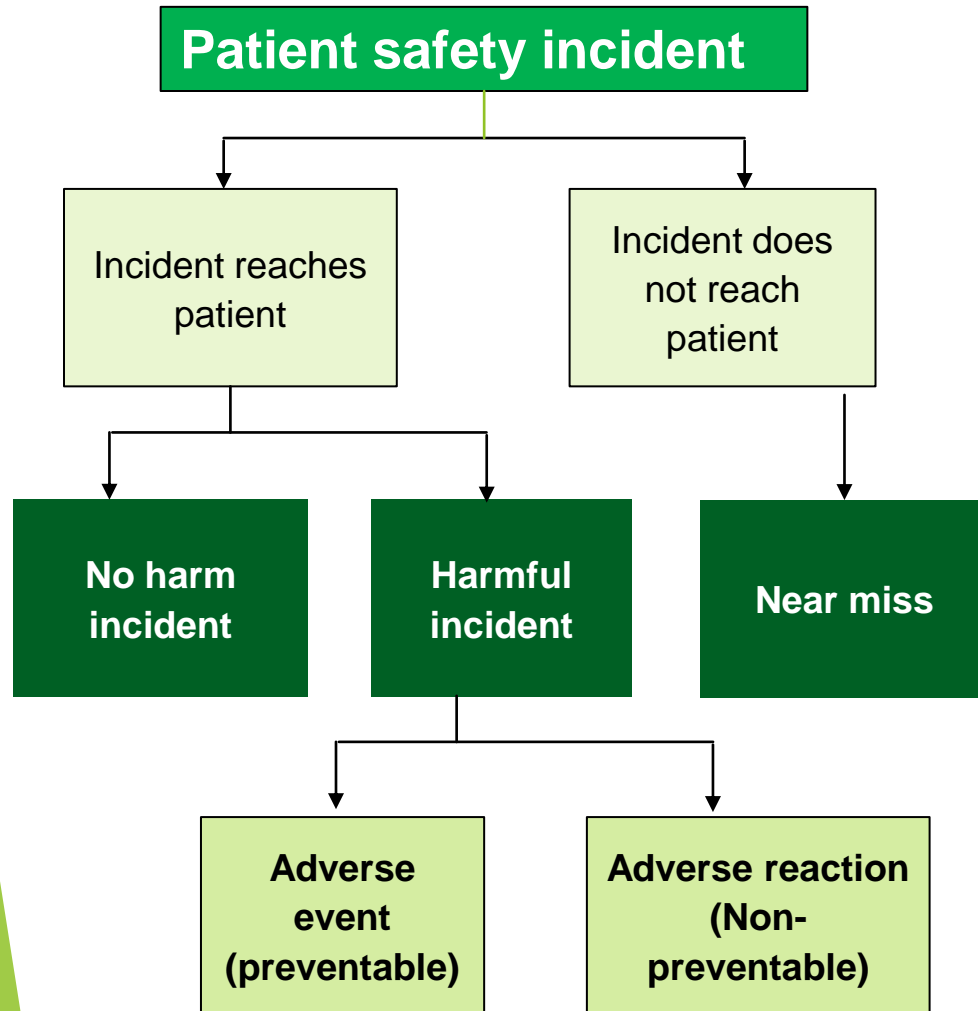
- **No harm incident**: one in which an event reached a patient, but no discernable harm resulted (for example, if the unit of blood was transfused, but was not incompatible)

- **Harmful incident**: an incident that results in harm to a patient (for example, the wrong unit of blood was transfused, and the patient died from a haemolytic reaction).

- **Near miss**: an incident that did not reach the patient (for example, a unit of blood being connected to the wrong patient's intravenous line, but the error was detected before the transfusion started)

- **Adverse event**: is an incident that results in preventable harm to a patient

- **Adverse reaction**: unexpected and non-preventable harm resulting from a justified action where the correct process was followed for the context in which the event occurred.

* World Health Organization conceptual framework for the International Classification for Patient Safety

Why develop PSI RLS?

▶ Make risk visible to reduce future harm of the PSIs that are reported

The ultimate output must be tangible change in the way health care is organized to improve safety.

Note: Few places around the world has achieved successful and sustainable elimination of the risk for future patients. This should not lead to the value of patient safety incident reports being disregarded.

Supporting processes to reveal the risks that health care poses to patients:

- robust ways of identifying new and existing risks
- clear prioritization of risks
- mechanisms to escalate serious risks
- methods for analysing and investigating sources of risk
- systematic monitoring of existing risks.

Reporting should also inform local responses to risks and drive the improvement in safety. Five processes could support this:

- setting of a clear safety agenda
- communication of risks to relevant staff
- allocation of accountability for resolving risks
- engagement of local staff in risk analysis and improvement processes
- production of actionable and practical information.

Ten facts on reporting and learning systems

1. **Learning**: should yield learning to improve safety and not simply be a vehicle to communicate failure.

2. **Safety culture**: Point of care staff will report incidents if they are protected from blame and retribution, involved in follow-up investigation and improvement, and able to see regular reductions of risks to patients.

3. **Limitations of data**: Underreporting happens in the health care and other sectors; this should not lead to the value of patient safety incident reports being disregarded.

4. **WHO reporting model:** The WHO Minimal Information Model for Patient Safety Incident Reporting and Learning Systems helps to identify minimal data elements to be captured for incident reporting, including both structured information capture and free text narrative elements.

5. **Aggregation and systemic insights**: The aggregation of incident reports should use classification systems oriented towards creating systemic insights that help transform policies and processes.

Ten facts on reporting and learning systems

6. **Causation:** Incident report can provide some insights into the causation of harm and its potential preventability but seldom a definitive view; further information gathering, review, investigation, analysis, and discussion are necessary to establish the factors and influences that led to the incident and their interrelationship (the how? and the why?).

7. **Investigation:** Lack of a consistently high standard of investigation and action planning too often hinders effective risk reduction within health care.

8. **Large-and small-scale systems**: Establishing and maintaining a comprehensive, large-scale patient safety incident reporting system at national level, or in a big health organization, requires technical expertise and resources. Consideration could be given to starting on a smaller scale.

9. **Improvement**: Finding and designing solutions that will prevent future harm is difficult. The process contains two important parts: first, the intervention itself (the "technical" part); and second, the implementation of the intervention within the complex organizational and social systems that comprise modern health care (the "management of change" part).

10. **Patients and families:** Involvement of patients and families who have suffered avoidable harm is vital and valuable in improving patient safety.

Requirements to setup a fully-fledged PSI RLS

▶ financial resources

▶ information technology infrastructure

▶ skilled informaticians

▶ investigators and other personnel

▶ confidentiality and data security policies

▶ analysis and interpretation

▶ protocols for dealing with clinical governance concerns

▶ reporting rules and channels

▶ feedback and release of information.

Essential to consider the above prior to setting up a PSI RLS to ensure to the system achieves its full potential.

Weaknesses of most reporting systems in health care

1. **Underreporting is the norm**, although its degree varies. Reporting systems detect 7–15% of adverse events. This depends mainly on:

   ▶ prevailing culture,

   ▶ whether incidents are considered as an opportunity to learn or as a basis for enforcing individual accountability and apportioning blame.

   ▶ staff perceptions about the difference their reports will make and how easy it is for them to convey the information that they are required to.

2. Volume of reports made can be very high; there may be **insufficient time, resources and expertise dedicated or committed to carrying out the analysis r**equired.

3. Balance of activity within reporting systems often goes on collecting, storing and analysing data **at the expense of using it for improvement.**

Weaknesses of most reporting systems in health care (Cont.)

4. Poor specification of what is to be reported;

5. Overinterpretation of incident analyses to judge safety performance;

6. Selectivity and incompleteness of data;

7. Taxonomies and classifications that do not enable aggregation of reports into categories that reliably highlight system weaknesses;

8. Lack of investment in analysis compared to reporting.

Three major challenges in delivering greater benefits from PSI RLS

1. Difficulty **of establishing a safety culture** that is based on blame-free reporting and in which learning is more powerful than judgement. Too often, individuals are held to account when poorly designed systems and processes of care have resulted in errors by conscientious members of staff.

2. **Core data** of many patient safety incident reporting systems **are the reports initially made by a member of staff**, sometimes with additional local information gathering. Thus, the cause of the incident and the prospects of **learning from it are too often a matter of local opinion.** Detailed multidisciplinary investigation, including expert inputs, in-depth interviews with those involved and reconstruction of the events that occurred, is less commonly undertaken.

3. Process of **achieving sustainable reductions in risk and improvements in patient safety seldom works well**. Measures such as issuing new guidelines, one-off training initiatives and sending out alerts have been shown in other high-risk settings to be relatively weak change strategies.

Different requirements of different levels of PSI RLS (institutional, sub-national, national)

► **RLS fall into one of three types:**

  ➢ **small scale**: clinical department or team, 500 incidents or less per year;

  ➢ **medium scale**: large hospital or group of health facilities, thousands of incidents per year;

  ➢ **large scale**: national or regional health system or very large group of health care facilities, 10 000 or more incidents per year (in some cases tens of thousands).

► Irrespective of the size and scale of the PSI RLS all areas of guidance will be directly relevant and important for consideration in how the system is designed, coordinated and operated.

Note: Globally, as many as four out of 10 patients are harmed in primary and ambulatory care settings while receiving health care. Therefore, also consider these settings when setting up PSI RLS

Linkage with ICD 11 (if possible)

- In order to aggregate and compare incidents, reports should use modern classification systems such as International Classification of Diseases (ICD)-11, which allows coding of harm in terms of:

  - cause,

  - mode or mechanism, and

  - outcome in digital health environments.

  Aggregated and comparable incident data will provide systemic insights that help transform policies and processes.

- The conceptual model for quality and patient safety used in ICD-11 is based on the WHO conceptual framework for the International Classification for Patient Safety and is compliant with the Minimal Information Model for Patient Safety Incident Reporting and Learning Systems.Patient safety events can be recorded based on the International Classification for Patient Safety.

- It had not been possible to document patient injuries properly with the previous revision of the ICD; however, ICD-11 includes a system for documenting patient safety events and near misses.

- ICD-11 will be used fully from 2022, with implementation currently under way

Self-assessment tool to evaluate PSI RLS based upon WHO guidance (refer slide 3)

Purpose of the self-assessment tool is to:

Identify gaps in, strengthen, and further develop existing systems

Guide those who do not currently have a RLS but wish to develop one.

Note: it is not a formal audit process or to produce a score.

Tool consists of six sections:

- Environment for reporting
- Reporting rules and content
- Analysis and investigation
- Governance
- Action and learning
- Patient and family engagement

Rate your current/ planned PSI RLS to assess its strengths against key points:

- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly agree

1. Environment for reporting

▶ It is easy for health care professionals to make a report

▶ Staff have time to make a report

▶ Staff are absolutely clear on what needs to be reported

▶ Staff receive personalized feedback on progress and action resulting from their report

▶ Most staff are motivated to make reports Staff are encouraged to make reports, and blame and disciplinary action are exceptional (i.e. only in cases of serious misconduct)

▶ The leadership of the health care organization has provided and committed to policies that establish a safety culture and makes its commitment visible Reporting rules and content

▶ There are clear criteria and definitions for what constitutes a patient safety incident

▶ There are clear rules for what kinds of incident should be reported

▶ Staff are provided with training on the purpose of reporting

▶ Staff are provided with training on how to complete an incident report form, in terms of what information to include

2. Reporting rules and content

▶ It is clearly understood whether reporting is voluntary or mandatory (or under what circumstances both operate)

▶ The content of incident reports covers as a minimum the elements of the MIM PS

▶ Incident reports contain structured information capture and free text narrative commentary

▶ It is possible to return to a reporter to gather further information It is clear what types of incident should be analysed locally (e.g. within a hospital) and what types nationally

▶ A telephone hotline (appropriately staffed and skilled, and with rigorous governance arrangements) is in place for staff to report serious incidents that require escalation, immediate investigation, and action to protect other patients

▶ Within the reporting system, there is a specific mechanism for patients and family members to make reports

3. Analysis and investigation

- Data are aggregated to a recognized classification system
- Aggregated data regularly produce systemic insights
- Feedback is provided to staff to acknowledge their report and to clarify any additional details needed
- There is access for staff to analyses and a skilled analytical function to process raw data
- Reports of aggregated data are regularly made public, with appropriate interpretative commentary
- Reports of aggregated data are made available to agencies or organizations involved in, or accountable for, safety assurance or improvement, tailored to the needs of these agencies or organizations
- A substantial proportion of incidents are further investigated at local level
- Some incidents (or clusters of incidents) are further available at national level
- Further investigation of incidents is not restricted only to those involving death or severe harm (some low harm, no harm and near miss incidents are also examined)
- Further investigation of incidents involves a structured approach (such as root cause analysis)
- Further investigation of incidents almost always involves appropriate expert input
- Further investigation involves all relevant staff, patients and families, and regularly includes expertise in human factors
- Detailed and more robust data that are collected through investigation, and the resulting deeper analysis, are incorporated and recorded back into the reporting system

4. Governance

▶ The incident reporting system is managed and maintained by an independent agency or organization

▶ Incident reports are anonymized so that no patient, staff member or other individual can be identified by reading the report

▶ The management of the reporting system – with appropriate safeguards to confidentiality – would be able to identify situations where there was an immediate danger to patients

▶ There is an oversight process to identify and resolve problems with any aspect of the incident reporting system

▶ There is adequate technical and information technology infrastructure to maintain a high standard in all aspects of the incident reporting system

5. Action and learning

▶ A formal framework is in place to specify, communicate and prioritize action on the risks identified by reporting data and their analysis

▶ Proper counselling and support is provided for staff who have been involved in serious incidents (the "second victims")

6. Patient and family engagement

▶ Incidents are always disclosed to victims of harm and their families

▶ Accounts of patients' and families' experience of harm are regularly discussed at the governing body level

▶ Patients and families who have suffered harm are provided with ongoing psychological and other support, free of charge, if they wish to receive it

▶ Victims of harm are provided with additional treatment and care as required, free of charge, and by a new clinical team if that is their preference

▶ Patients and families who have suffered harm are involved in designing action to reduce the likelihood of a recurrence (if they so wish)

▶ Patients and families who have suffered harm play a major role in education and training of students and health care staff

Message from Sir Liam Donaldson
Patient Safety Envoy World Health Organization

'My main message to readers of this document is to urge them to **understand the purpose, strengths and limitations of patient safety incident reporting**. Data derived from incident reports can be **very valuable** in understanding the scale and nature of harm arising from health care, **provided that the properties of the data are reviewed carefully and conclusions are drawn with caution**. The use of incident reporting systems for true learning in order to achieve sustainable reductions in risk and improvements in patient safety **is still work in progress**. It **can be and has been done**, but not yet on the scale and with the speed that compares with some other high-risk industries. That is what we must all strive for. I hope that this technical guidance will help the journey to a position where we can show patients and their families how we used this learning to give them care that is safe and dependable, every time they need it.'

Thank you!