Understanding the application of patient safety incident reports

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Introduction

Learning objective: To understand the application of Incident reports

Topics covered:
- Main purpose of collecting incident reports
- What data elements to be collected (Minimal information model)
- How to collect data
- How to assess the quality of data/incident reports
Main purpose of collecting PSI is:

- To formulate action to prevent (or reduce the risk of) a similar incident in the care setting where it occurred = reducing future harm;
- To communicate information that could lead to the prevention of a similar incident elsewhere in a country’s health system or globally;
- To aggregate with other reports to produce larger volumes of data capable of providing the maximum possible understanding of the problems in the system that led to the harm (or risk of harm);
- For education and training;
- For research, development and improvement;
- For public reporting and accountability;
- For open disclosure to patients and families.
Choosing the information to be captured

- Two options when deciding what information will be captured:
  - decide what information you want to collect or
  - adopt one of the commercially available or open source-based tools (software) for incident reporting.

- Systems should capture and assemble information in three main domains:
  1. **Description** (what happened), including patient characteristics, incident characteristics and location;
  2. **Explanation** (why it happened), including perceived causes of the event, contributing factors and mitigating factors;
  3. **Remedial measures** (the actions that were taken as a result), including reviewing processes and procedures, redesign, educational measures and organizational changes.

Be clear whether data falling into these categories are provided only by reporters (and therefore may be early, provisional, partial and possibly incorrect) or constitute information captured in the reporting system after more thorough investigation has taken place.
What data elements to be collected - Minimum information model

WHO Propose a minimal common architecture for incident reporting systems in 2005 and 2009. Led to the formulation of the Minimal Information Model for patient safety incident reporting and learning system (MIM PS). Assist countries to establish systems of reporting in order to allow aggregation and analysis of data at a higher level.
Minimum information model

<table>
<thead>
<tr>
<th>BASIC MIM PS</th>
<th>ADVANCED MIM PS</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Structured part</td>
<td>a) Structured part</td>
</tr>
<tr>
<td>PATIENT INFORMATION</td>
<td>PATIENT INFORMATION</td>
</tr>
<tr>
<td>Age</td>
<td>Age</td>
</tr>
<tr>
<td>Sex</td>
<td>Sex</td>
</tr>
<tr>
<td>INCIDENT TIME</td>
<td>INCIDENT TIME</td>
</tr>
<tr>
<td>INCIDENT LOCATION</td>
<td>INCIDENT LOCATION</td>
</tr>
<tr>
<td>AGENT(S) INVOLVED</td>
<td>CAUSES</td>
</tr>
<tr>
<td>(Suspected) cause?</td>
<td>CONTRIBUTING FACTORS</td>
</tr>
<tr>
<td>Contributing factor?</td>
<td>MITIGATING FACTORS</td>
</tr>
<tr>
<td>Mitigating factor?</td>
<td></td>
</tr>
<tr>
<td>INCIDENT TYPE</td>
<td>INCIDENT TYPE</td>
</tr>
<tr>
<td>INCIDENT OUTCOME</td>
<td>INCIDENT OUTCOME</td>
</tr>
<tr>
<td>RESULTING ACTION</td>
<td>RESULTING ACTIONS</td>
</tr>
<tr>
<td>REPORTER’S ROLE</td>
<td>REPORTER’S ROLE</td>
</tr>
<tr>
<td>b) Free text part</td>
<td>b) Free text part</td>
</tr>
</tbody>
</table>

MIM PS assist countries to establish systems of reporting in order to allow aggregation and analysis of data at a higher level. * Further work is needed on data categories, especially those dealing with causation.

- **Basic MIM PS**
  - eight data categories,
  - recommended as a good model for initiating reporting systems in settings and countries where these do not already exist.

- **Advanced MIM PS**
  - 10 data categories,
  - Recommended for settings with functional reporting systems already in place.

In both cases, the MIM PS should have a free text part along with eight or 10 data categories.
### Definition and rational MIM PS data elements

<table>
<thead>
<tr>
<th>Data element</th>
<th>Definition</th>
<th>Rational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient information</td>
<td>Data related to a patient that has been subject to a safety incident.</td>
<td>To anonymously describe the patient to whom the incident occurred.</td>
</tr>
<tr>
<td>Sex</td>
<td>Gender attribute of a patient that refers to the biological and physiological characteristics that define men and</td>
<td>To identify possible biological sex categories risks of occurrence of an incident.</td>
</tr>
<tr>
<td>Age</td>
<td>The age or period of life of the patient at which the incident happened.</td>
<td>To identify the paediatric, adult or geriatric risks of occurrence of an incident.</td>
</tr>
<tr>
<td>Data element</td>
<td>Definition</td>
<td>Rational</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Time</td>
<td>Date and time of day when the incident occurred</td>
<td>To describe when the event occurred and understand the timeline of the incident.</td>
</tr>
<tr>
<td>Location</td>
<td>Physical environment in which a patient safety incident occurred.</td>
<td>To describe the place where the event occurred. n No identifying place names should be mentioned, however.</td>
</tr>
<tr>
<td>Incident type (see slide 11 for classification)</td>
<td>A descriptive term for a category made up of incidents of a common nature, grouped according to shared, agreed features</td>
<td>To clearly identify the variety of incident.</td>
</tr>
<tr>
<td>Data element</td>
<td>Definition</td>
<td>Rational</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Agents involved</td>
<td>Agent with the potential to cause harm.</td>
<td>To identify the agents used before, during or after the incident without inferring any causal relation with the incident. For the purpose of the present information model, the agent category means the product, device, person or any element involved in the incident.</td>
</tr>
<tr>
<td>Contributing factors (see slide 11 for classification)</td>
<td>Any agent <em>thought to have played</em> a part in the origin or development of an incident, or to increase the risk of an incident.</td>
<td>To list agent(s) involved in generating or enhancing an incident.</td>
</tr>
<tr>
<td>Cause(s)</td>
<td>Agent that <em>contributed</em> to an incident in a way that this specific incident happened. Any agent involved as the cause of the incident should only be indicated after a root cause analysis has been performed and should not be presented at the reporting stage.</td>
<td>To list the agent(s) that can generate an incident, alone or in combination.</td>
</tr>
<tr>
<td>Mitigating factor</td>
<td>Agent that prevents or moderates the progression of an incident towards harming a patient or to reduce the risk of an incident.</td>
<td>To list agent(s) considered to reduce incidence occurrence or impact.</td>
</tr>
</tbody>
</table>

*Definition and rational MIM PS data elements (cont.)*
<table>
<thead>
<tr>
<th>Data element</th>
<th>Definition</th>
<th>Rational</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incident outcome (see slide 11 for classification)</strong></td>
<td>All impacts upon a patient or an organization wholly or partially attributable to the incident.</td>
<td>To describe all outcomes and consequences of a given incident. For the purpose of this information model, outcomes of a patient safety incident are limited to “patient outcomes” and “organizational outcomes”.</td>
</tr>
<tr>
<td><strong>Resulting action (s)</strong></td>
<td>All actions resulting from an incident.</td>
<td>To identify immediate or indirect action related to the patient or the organization, resulting from an incident. Such actions may aim to improve a situation that emerged as a result of an incident either in terms of patient outcome or of organizational outcome, with a view to preventing the reoccurrence of the same type of incident.</td>
</tr>
<tr>
<td><strong>Reporter’s role</strong></td>
<td>Role played in the incident by the person who collected and submitted the information about the incident</td>
<td>To analyse heterogeneous sources of information and the way different people describe a given incident</td>
</tr>
</tbody>
</table>
Conceptual framework for the international classifications of patient safety (ICPS)

- **Classification** = “a set of concepts linked by semantic relationships. It provides a structure for organizing information to be used for a variety of other purposes, including national statistics, descriptive studies, and evaluative research”

- Conceptual framework for ICPS = method of organizing patient safety data and information so that it can be aggregated and analyzed to:
  - Compare patient safety data across disciplines, between organizations, and across time and borders;
  - Examine the roles of system and human factors in patient safety;
  - Identify potential patient safety issues; and
  - Develop priorities and safety solutions

- Outlines proposed classification for MIM PS data elements for:
  - Contributing factors,
  - Incident types and
  - Outcome (organization and patient).
Classification for incident type

Sub classification for each main classification

- Clinical Administration
  - Handover
  - Appointment
  - Waiting List
  - Referral/Consultation
- Process
  - Admission
  - Discharge
  - Transfer of Care
  - Patient Identification
  - Consent
  - Task Allocation
  - Response to Emergency
- Problem
  - Not Performed when Indicated
  - Incomplete/Inadequate
  - Unavailable
  - Wrong Patient
  - Wrong Process/Service

- Clinical Administration
  - Nutrition
  - Oxygen/Gas/Vapour
  - Medical Device/Equipment
  - Behavior
  - Patient Accidents
  - Infrastructure/Building/Fixtures
  - Resources/Organizational Management
Classification for contributing factor

Sub classification for each main classification
Classification for mitigating factors
Classification for patient outcomes

- Patient Outcomes
  - Type of Harm
    - Pathophysiology
      - International Classification of Diseases
      - International Classification of Primary Care 2nd ed
    - Injury
      - International Classification of Diseases
      - International Classification of External Causes of Injury
    - Other
  - Degree of Harm
    - None
    - Mild
    - Moderate
    - Severe
    - Death
  - Social and/or Economic Impact
    - International Classification of Functioning, Disability and Health
Classification for organizational outcomes
How to collect data – Clear policy

Important to note:

- A clear policy about how incidents are defined and recognized must be available, and all staff should be aware of it.

- Staff must be clear as to what constitutes an incident. This can be:
  - a broad and general specification (in which case, staff are allowed maximum discretion in what to report) or
  - guidance that only certain categories of incident must be reported (in which case, reporting will be very focused, but staff may be uneasy about having to overlook incidents that they are concerned about) or
  - some systems also encourage patients and family members (who are in the care environment) to identify incidents.
How to collect data – Methods

The recording or capturing of information about incidents usually takes place in one of four main ways (which will vary between settings of different resource levels):

- on a paper reporting form with or without addition of later documentation;
- on a paper reporting form with information subsequently transferred by a data clerk to an electronic record;
- directly by the reporter into an electronic record;
- into an electronic record after follow-up work that may involve further information gathering or investigation before data entry.

Some reporting systems have an additional route of reporting, such as a telephone hotline, for serious incidents that require urgent escalation, and immediate investigation to protect patients.
How to assess the quality of data/incident reports

- **Training**
  - Several point of care staff in each service area should receive training in reviewing incidents and in the techniques of in-depth analysis (whilst understanding the strengths and limitations of methods such as root cause analysis).
  - Training should ensure competence in reviewing, analysing and designing responses to incidents; the emphasis should be placed on continuing practice of a skill, not just a certificate of competence.

- **Full reviews on incidents**
  - directly engage those involved in the care that resulted in the incident;
  - other participants should include staff with content knowledge of the area of service or procedure (but independent of the incident), and those with expertise in human factors.
  - Local incident review should seek to target systemic weaknesses that led to the incident and create insight for wider systemic strengthening across the organization and its services.
How to assess the quality of data/incident reports (cont.)

- **Policy**
  - There should be a clearly understood policy on which incidents should be reported to any national-level reporting system, if existing.
  - Where volume of incidents are high (not able to look at all of them), there should be a clear policy on which categories should be reviewed and investigated. This should include less serious incidents (including near misses) as well as serious incident reports.

By using information, and gaining experience on its strengths and limitations, the scope for improvement in data quality and utility will be enhanced.
Sir Liam Donaldson
Patient Safety Envoy World Health Organization

“To err is human, to cover up is unforgivable, but to fail to learn is inexcusable”.

Need to understand the application of patient safety incident reports
Thank you!