The World Health Organization
World Alliance for Patient Safety
Project to Develop an International Patient Safety Event Classification

The Conceptual Framework of an International Patient Safety Event Classification

Original

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This document has been produced by the Drafting Group for the World Health Organization, World Alliance for Patient Safety, Project to Develop an International Patient Safety Event Classification.

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1.1 Introduction

The World Alliance for Patient Safety introduced the Project to Develop an International Patient Safety Event Taxonomy as one of its six programs in its Forward Program 2005. The goal of this project is to develop a comprehensive standard classification on patient safety, usable by all WHO Member States to facilitate improved information sharing, learning and system change in order to reduce health care-related harm. The International Patient Safety Event Classification, as it is now known, will enable the global healthcare community to review, evaluate and learn from near miss and adverse event data at the international level as well as develop evidence-based preventive strategies by eliciting, capturing and analyzing factors relevant to patient safety in an adaptable yet consistent way across the entire spectrum of health care and across cultures and languages. While the World Alliance emphasized the need to strive for maximum comparability of patient safety information on an international level, it recognized this may not be achievable. Global health care systems are at varying stages of development. To increase the possibility of maximum comparability, the International Patient Safety Classification will (1) follow the WHO Family of International Classification specifications, (2) be concept driven, (3) add value to the current classifications and reporting systems in use in various countries, (4) be inclusive of a wide range of stakeholders, (5) map easily to existing classifications with relatively low resource expenditure, (6) capture adverse event and near miss data, and (7) be sensitive to cultural and language issues.

The World Alliance established a Drafting Group, comprised of patient safety and classification experts, to guide the development of the International Patient Safety Event Classification. The first official meeting of the Drafting Group was held on 24-25 October 2005 in Vancouver, British Columbia. At this meeting, the Drafting Group defined the mission and purpose of the project and developed a strategic plan to achieve its goal. A meeting was held on 21 March 2006 in Geneva, Switzerland, to further articulate and refine the conceptual framework for the classification. The World Health Organisation’s World Alliance for Patient Safety Drafting Group was charged with developing “a conceptual framework for an international patient safety classification that is comprehensive and that is comprised of concepts, axes, factors, and attributes.” We have subsequently decided to use the term “class” instead of “axis” and “factors”. Factors are represented in several classes.

1.2 Definitions used in this document

1.2.1 Patient Safety Event

While it is acknowledged that other international classifications use the term “incident”, it was decided for purposes of the Project to Develop an International Patient Safety Event Classification, the term “event” would be used instead of “incident”.

The working definition of a patient safety event is “an event which resulted in, or could have resulted in, unintended harm to a patient by an act of commission or

omission, not due to the underlying medical condition of the patient.”  

1.2.2 Classification

A classification is an “arrangement of concepts into classes and their subdivisions to express the semantic relations between them; the classes are represented by means of a notation.”  

Classification involves the categorisation of relevant natural language for the purposes of systematic analysis within a single field of concepts.

1.2.3 The International Patient Safety Event Classification

The draft Conceptual Framework (and its components) has been referred to in this document as the “International Patient Safety Event Classification” (IPSEC). This name is consistent with WHO terms for other health reference terminologies in the WHO Family of International Classifications (WHO-FIC).

1.2.4 Classes, Concepts and Relationships

“Classes”, “Concepts”, and “Relationships” are the main components of the Conceptual Framework.

A class is a group or set of like things. Classes are high-level data elements which comprise the information model or framework. Several levels of classes have been defined within the Conceptual Framework.

A concept is a bearer of meaning and is found at leaf/node level in a system, using a tree analogy. Concepts are distinct and unambiguous and can be described by a notion (a word or a phrase). Concepts are organised hierarchically according to meaningful semantic relationships informed by clinical knowledge. These serve to

2 Runciman WB Shared Meanings: preferred terms and definitions for safety and quality concepts. MJA 2006 184;10: S41-S43


5 World Health Organisation Family of International Classifications June 2004


8 Cimino JJ. Desiderata for Controlled Medical Vocabularies in the Twenty-First Century. Meth Inform Med. 1998; 37:394-403

9 Cimono JJ, Clayton PD, Hripscsak G, Johnson SB. Knowledge-based approaches to the maintenance of a large controlled medical terminology. JAMIA 1994; 1:35-50
populate the classes in the Conceptual Framework. Concepts may be represented by multiple terms that allow for regional dialects, different languages, clinicians, disciplines and hospital preferences; some may be designated “preferred terms” in a particular environment.

Examples of classes and concepts are a class is Patient Outcome containing concepts such as anaphylaxis, skin tear, or excessive pain; the class Contributing Factors contains concepts such as policy/procedure violation, staff rostering, and patient unwell.

Concepts are mutually exclusive and non-redundant. Concepts should not map to more than one area of the classification.

The Conceptual Framework, its components, and its relationships with electronic information systems together with some concepts and terms, are shown in Figure 1. The Conceptual Framework is how the IPSEC will group the concepts into logical, related sets.

In this document, examples of concepts are denoted by italicised words and classes by bold italicised words.

Hierarchical and Attribute Relationships

The Conceptual Framework can have relationships that are either hierarchical or attribute type relationships. Subclasses in the Conceptual Framework have subsumption relationships to their “parents” and not attribute type relationships. A subclass subsumption relationship inherits all the characteristics of its parent class; it is a more specialised subset of the class and is like an “is-a” relationship in SNOMED-CT; sometimes also called parent-child relationships. An attribute relationship provides a description of the qualities or properties of the concept and these are not necessarily inherited from the parent.

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11 Cimono JJ, Clayton PD, Hripcsak G, Johnson SB. Knowledge-based approaches to the maintenance of a large controlled medical terminology. JAMIA 1:1 1994:35-50


Figure 1: The relationship between the Conceptual Framework and other components of the International Patient Safety Event Classification
1.3 Purpose of the Classification

The purpose of the classification is to allow information about an event to be deconstructed and translated into a common (coded) language and to create an electronic record that can be compared with other records and analysed as part of a larger set of data.\textsuperscript{15} 16 This process allows for statistical analysis, learning, and resource prioritisation.

1.3.1 Near miss data

The classification is designed to classify information from both near misses and adverse events. Runciman (2006)\textsuperscript{17} defines “near misses” as “incidents which do not cause harm”, whilst an “adverse event” is an “incident resulting in harm to a person receiving health care”. Kaplan\textsuperscript{18} defines a “near miss” as “the potential for harm may have been present, but unwanted consequences were prevented because some recovery action was taken”, and a “no harm event” as “the event actually occurred but no harm was done”. Near misses are 7-100 times more frequent than adverse events.\textsuperscript{19} 20 21 22

Heinrich (1931) was the first author to recognise that the causal pathways of near misses may be similar to accidents which cause injury.\textsuperscript{23} This causal continuum assumption has not yet been firmly established in healthcare.\textsuperscript{24} The value of near miss data has been recognised in industries such as aviation where low probability accidents have the potential to have serious consequences.\textsuperscript{25} In health, near miss analysis provides opportunities for learning about weaknesses in the care delivery

\textsuperscript{15} Aspden P, Corrigan JM, Wolcott J, Ericksen SM (Editors) Patient Safety Achieving a New Standard of Care. Institute of Medicine of the National Academies 2004

\textsuperscript{16} Cimino JJ. 1998 op cit

\textsuperscript{17} Runciman WB Shared Meanings: preferred terms and definitions for safety and quality concepts. 2006 Med J Aust; Vol 184 (10): S41-43

\textsuperscript{18} Kaplan H.S. Event Reporting and Patient Safety. You can’t fix it if you don’t know about it.


\textsuperscript{21} Heinrich HW (1931) op cit in Aspden P, Corrigan JM, Wolcott J, Ericksen SM 2004 et al


\textsuperscript{24} Aspden P, Corrigan JM, Wolcott J, Ericksen SM 2004 et al

\textsuperscript{25} United States Bureau of Transportation. Research Project #7 Expand the collection of “near-miss” data to all modes. http://www.bts.gov/publications/safety_data_action_plan/project_07.html
system and the ways in which the system is able to recover from dangerous or risky situations.

Reporting of risks, circumstances and hazards associated with health care should be encouraged. This will provide a more proactive use for the Classification, in contrast to the traditional approaches of counting the dead or how many things have gone wrong.

1.3.2 Learning

A Report of the WHO World Alliance for Patient Safety Drafting Group stated that the classification “will enable the global healthcare community to review, evaluate and learn from near miss and adverse event data at the international level as well as develop evidence-based preventive strategies.”

Although it has long been recognised that medical care has the potential to cause harm, general acknowledgement that much iatrogenic injury may be due to human error or system failures has been slower to emerge. Safety reporting systems with a focus on learning are well established in some other industries, such as aviation and the nuclear industry. Whilst the context of reporting in aviation and healthcare will be different, there is much common ground in respect of the principles of reporting, attitudes and behaviours.

It is now recognised that the genesis of errors lie in both active (or immediate) and latent failures. These contributing factors can be grouped under headings such as “organisational”, “staff”, “clinical”, “process”, “team”, “patient”, “environmental” and “external”.

Characterising these failures and designing corrective strategies accordingly into layers of defence (below) is necessary for patient safety problems to be tackled adequately:

- Designing error-proof systems;
- Trapping errors: making it easier for the system to pick up errors before they cause harm;
- Mitigating errors: making it easier for the system to detect harm early enough to minimise its impact;
- Learning from errors: making it easier for the system to learn from occasions.

27 Aspden P, Corrigan JM, Wolcott J, Ericksen SM et al
where the safety nets listed above have failed.

Consumers

It is important that the views of consumers of health care participate in the process of learning about patient safety issues. They can have a unique voice in the health care system by participating in health care decisions, reporting things that go wrong, and being actively involved in the solutions to patient safety issues. It is intended that the IPSEC can classify events reported from consumer complaints and reporting.

1.3.3 Linking Classes to Purpose

The classification converts so called natural language\textsuperscript{32} (sourced from event descriptions) into relatively discrete atomic concepts.\textsuperscript{33} The coded information can subsequently be post-coordinated to form natural categories\textsuperscript{34} \textsuperscript{35} that are readily understood by, and useful to health clinicians, analysts, administrators and decision makers.\textsuperscript{36}

This will establish a common language to improve communication and permit transmission and comparison of data across disciplines, services, time, and jurisdictions.\textsuperscript{37}

The classes \textit{Event Type} and \textit{Patient Impact/Outcomes} are mainly associated with grouping events into recognisable groups, whilst the other classes are mainly associated with learning activities.

It should be acknowledged that there are finite resources available to classify events, and in most cases, it is unlikely that the whole classification will be completed. Therefore, the approach needs to suggest which classes or part of classes should be completed in preference to others.

The classes associated with event identification and retrieval (\textit{Event Type} and \textit{Patient Impact/Outcomes}) are considered as core classes around which other data can be collected. These classes allow events to be grouped in clinically meaningful ways according to natural categories and then retrieved. Once the events have been retrieved, they can then be analysed for their \textit{Contributing Factors, Preventive Factors, Recovery Factors} and \textit{Mitigating Factors}.

\begin{itemize}
\item \textsuperscript{32} World Health Organisation 2004 op cit
\item \textsuperscript{34} Runciman WB, Edmonds MJ, Pradhan M Settings Priorities in Patient Safety Qual Saf Health Care 2002; 11:224-229
\item \textsuperscript{35} Norman DA The Psychology of Everyday Things New York: Basic Books
\item \textsuperscript{36} Dovey S, Hickner J, and Phillips B Developing and using Taxonomies of Errors in Walshe K and Boaden R Patient Safety Research into Practice 2006 Open University Press Maidenhead UK
\item \textsuperscript{37} World Health Organisation 2004 op cit
\end{itemize}
1.4 Scope of the Classification

1.4.1 Quality versus Safety
Safety is just one of the dimensions of the quality of healthcare, along with access, timeliness, efficacy, efficiency, appropriateness and acceptability. 38

The defining characteristics of patient safety are: 39

1. It is concerned primarily with the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from healthcare itself. It addresses events that span the continuum of ‘errors’ and ‘deviations’ to accidents.

2. It emerges from the interactions of the components of the healthcare system. It is more than the absence of adverse outcomes, but also includes avoidance of identifiable ‘preventable’ errors or occurrences. Safety does not reside in a person, device or department. Improving safety depends on learning how safety emerges from the interaction of the components of the system.

3. It is related to ‘quality of care’, but the two concepts are not synonymous. Safety is an important subset of quality. To date, activities to manage quality have not focused sufficiently on patient safety issues.

The scope of the Classification is limited to safety, although it is recognised that safety concepts are also relevant to other quality dimensions, for example, appropriateness.

1.4.2 Who does the Classification refer to?

The classification should be capable of capturing the salient details of all events or circumstances which could have, or did lead to unintended and/or unnecessary harm to a person, traditionally known as the patient.

The conceptual framework is intended to be inclusive of a wide range of circumstances when people come into contact with the health system. Examples are healthy pregnant woman, with no complications, who has an outpatient appointment with an obstetrician, a person obtaining advice/counselling from mental health services for mild depression, a healthy baby having rubella and measles immunisation injections.

1.5 The Relationship between Reporting Systems and the IPSEC

It is important to distinguish between patient safety reporting systems and the IPSEC. Reporting systems generally have a wider scope than classification systems both in terms of their functionality and the data that they capture, analyse and report on.

Classification systems provide the underlying concepts, their definitions, and their hierarchical structure within classes. Reporting system provide an interface to enable users to collect, aggregate, report on, and administer data. They may also include systems to manage the workflow in response to events. Reporting systems may be

38 Kohn LT, Corrigan JM, Donaldson MS, editors. To Err is Human Building a Safer Health System. 1999. Institute of Medicine - Committee on Quality of Health Care in America.

39 Vincent C. 2006. op cit adapted from the US National Patient Safety Foundation 2000
configured to facilitate differential organisational responses to events of differing severity. One of the functions of a reporting system is to enable the boxes designated as “tools” in Figure 1. Reporting systems may be focused on specific types of events (eg blood transfusion events or sentinel events), areas of practice (eg intensive care units), or particular levels of the health system (department, health service, jurisdiction, or national).40

A health service- or jurisdictional-wide reporting system may be required to capture data related to events other than those pertaining to patient safety. Areas such as occupational health and safety incidents and patient complaints (not associated with patient safety) may be captured and analysed. These event types are not within scope of the IPSEC and may require additional or supplementary classification systems for coding.

1.5.1 Event Source

The Conceptual Framework is designed to accommodate patient safety data obtained from a variety of sources. We believe it is important for this information to be recorded as each information source offers different sorts of insights and lessons.41 42 The information on event sources will not be recorded in the IPSEC, as it is metadata, and should be recorded in the associated reporting system and may be relevant only to different implementations or realms.

Examples of these sources include:

- Root cause analyses;
- Medical record reviews;
- Incident reports;
- Complaints;
- Consumer reporting;
- Sentinel events;
- Coroner’s reports; and
- Medico-legal cases.

1.6 Structure of the Classification

An outline of the components of the International Patient Safety Classification Conceptual Framework is shown in Figure 2. The Conceptual Framework has ten top-level classes comprising:


42 Runciman W. Lessons from the Australian Patient Safety Foundation: setting up a national patient safety surveillance system—is this the right model? Qual Saf Health Care 2002;11:246-251
<table>
<thead>
<tr>
<th></th>
<th>Event Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Event Characteristics</td>
</tr>
<tr>
<td>3</td>
<td>Patient Characteristics</td>
</tr>
<tr>
<td>4</td>
<td>Patient Impact / Outcomes</td>
</tr>
<tr>
<td>5</td>
<td>Organisational Outcomes</td>
</tr>
<tr>
<td>6</td>
<td>Contributing Factors</td>
</tr>
<tr>
<td>7</td>
<td>Preventive Factors</td>
</tr>
<tr>
<td>8</td>
<td>Recovery Factors</td>
</tr>
<tr>
<td>9</td>
<td>Mitigating Factors</td>
</tr>
<tr>
<td>10</td>
<td>Actions Taken.</td>
</tr>
</tbody>
</table>
Figure 2: Structure of the Conceptual Framework of the International Patient Safety Event Classification

- **Contributing Factors***
  - Influences
  - Lead to
  - Event Type
  - Has
  - Patient Characteristics
  - Event Characteristics
  - Patient outcomes
  - Actions Taken
  - Organization Outcomes

- **Preventive Factors (+)**
  - Influences
  - Lead to

- **Recovery Factors**
  - Influences
  - Lead to

- **Mitigating Factors**
  - Influences

* includes system and latent factors

Framework class
- Core framework class

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Definitions and examples of the classes and their subclasses are shown in Table 1. For sources of the definitions see the accompanying document related to the concepts contained in the IPSEC.

**Table 1: Definitions of Classes within the International Patient Safety Event Classification**

<table>
<thead>
<tr>
<th>Class</th>
<th>Definition</th>
<th>Examples of concepts that may be included</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Event Type</strong></td>
<td>The characteristics distinguishing a group or class of patient safety events. A patient safety event is a process or act of omission or commission that resulted in hazardous health care conditions and/or unintended harm to the patient. An event is identified by a generalized high-level, discrete, auditable term or group of terms. The terms have good face validity.</td>
<td>- Falls</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Medication</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Nutrition</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Clinical Care</td>
</tr>
<tr>
<td><strong>Patient Impact/Outcomes</strong></td>
<td>The result of the performance (or non-performance) of a function or one or more processes, services, or activities carried out in a health care context affecting the patient.</td>
<td>- pneumothorax</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- cut/abrasion</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- fractured NOF</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- anaphylaxis</td>
</tr>
<tr>
<td><strong>Organisational Outcomes</strong></td>
<td>The impact upon an organisation which is wholly, or partially, attributable to a patient safety event.</td>
<td>- adverse media outcome</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- legal action</td>
</tr>
<tr>
<td><strong>Patient Characteristics</strong></td>
<td>The distinguishing features or traits specific to the patient.</td>
<td>- admission diagnosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- age</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- gender</td>
</tr>
<tr>
<td><strong>Event Characteristics</strong></td>
<td>The distinguishing features or traits specific to the event and the circumstances or facts that surround the event.</td>
<td>- care setting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- staff speciality involved</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- medication involved</td>
</tr>
</tbody>
</table>
# The Conceptual Framework of an International Patient Safety Event Classification

<table>
<thead>
<tr>
<th>Class</th>
<th>Definition</th>
<th>Examples of concepts that may be included</th>
</tr>
</thead>
</table>
| **Contributing Factors** | A circumstance, action or influence which plays a part in the genesis of a patient safety event. | - Fatigue  
- skill based error, or violation  
- inadequate documentation |
| **Actions taken**    | Something done by an individual or a health care organisation to prevent, remedy or mitigate the occurrence or reoccurrence of a real or potential patient safety event. | - Risk management review  
- changing document formats |
| **Preventive factors** | An effort or action taken in advance to pre-empt an occurrence of a patient safety event. | - improved training /education  
- fatigue management strategies  
- timely emergency responses |
| **Mitigating factors** | A circumstance, action or influence that played a role in diminishing the impact of a patient safety event. | - early recognition of the event or circumstance  
- good communication between staff  
- effective protocol |
| **Recovery Factors** | An action taken to stop circumstances or influences from turning into a patient safety event. | - detection by physiological monitors |
1.6.1 Stability of Classes
Classes are intended to be stable but the concepts within each class can be updated as technology and knowledge changes or becomes available.43

1.6.2 The Classification’s relationship with the WHO Family of International Classifications
The classification will be able to interface with health reference44, derived45 and partial46 classification systems within the WHO-FIC (Figure 3).

Figure 3: Schematic Representation of the WHO Family of Classifications

<table>
<thead>
<tr>
<th>Related Classifications</th>
<th>Reference Classifications</th>
<th>Derived Classifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>International Classification of External Causes of Injury (ICECI)</td>
<td>International Classification of Functioning, Disability and Health (ICF)</td>
<td>The ICD-10 Classification of Mental and Behavioural Disorders</td>
</tr>
</tbody>
</table>

Concepts in the IPSEC can reference and interact with the International Classification of Diseases (ICD) and the International Classification of Functioning, Disability and Health (ICF). Ideally, once finalized, the IPSEC will be included as one of the Related Classifications.

43 Institute of Medicine of the National Academies op cit 2004

44 Reference classifications cover the main parameters of the health system, such as death, disease, functioning, disability, health and health interventions. WHO reference classifications are a product of national agreements. They have achieved broad acceptance and official agreement for use and are approved and recommended as guidelines for international reporting on health. (Source: WHO 2004 op cit)

45 Derived classifications are based upon reference classifications. Derived classifications may be prepared either by adopting the reference classification structure and categories, providing additional detail beyond that provided by the reference classification, or they may be prepared through rearrangement or aggregation of items from one or more reference classifications. Derived classifications are often tailored for use at the national or multinational level. (Source: WHO 2004 op cit)

46 Related classifications are those that partially refer to reference classifications, or that are associated with the reference classification at specific levels of the structure only. Procedures for maintaining, updating and revising statistical classifications of the family encourage the resolution of problems of partial correspondence among related classifications, and offer opportunities for increased harmony over time.
1.6.3 Event Type

An Event Type comprises a high level description of the event and exhibit face validity\(^{47}\) and criterion validity.\(^{48}\) They form a list of a “manageable” number of concepts without artificially constraining it.

1.6.4 Outcomes

There are two separate classes for Organisational Outcomes and Patient Impact / Outcomes. It should be acknowledged that there may be difficulties obtaining data for both Organisational Outcomes and Patient Impact / Outcomes. Outcomes that are time dependent or patient safety events that are detected by another agency involved in a patient’s care are two examples. A time dependent example is a missed diagnosis of a tumour by medical imaging. This clearly may have a significant outcome for that patient however linking the missed diagnosis and the outcome is problematic. Events may be also detected by another health care provider, such as a primary care provider, who has taken over the care of the patient on discharge from hospital. Another WHO-FIC classification\(^{49}\), the International Classification of Diseases links to concepts within Patient Impact / Outcomes.

1.6.5 Event Characteristics

Event Characteristics are the distinguishing features or traits of the event and the circumstances or facts that surround a particular situation, or event. The classes in Event Characteristics are shown in Figure 4.

Figure 4: Event Characteristics Classes

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\(^{47}\) Face Validity: it measures what it claims to measure. A simple test is to ask a knowledgeable person about the phenomenon if he or she thinks that the measure represents the phenomenon. Reference: Ovretveit J. Evaluating Health Interventions. 1998. Open University Press, Buckingham, UK.


\(^{49}\) World Health Organisation June 2004 op cit
1.6.6 Patient Characteristics

Level 3 classes exist under the level 2 class *Patient Demographics* - they are *Age*, and *Gender*. *Ethnicity* was not included due to the difficulty of developing a set of concepts that will be acceptable world-wide.

The level 2 class *Patient Procedures* maps to another WHO classification - the International Classification of Health Interventions (ICHI).

The International Classification of Diseases links to the *Patient Admission Diagnosis*.

**Figure 5: Patient Characteristics Classes**

1.6.7 Contributing Factors

A *Contributing Factor* is any circumstance, action or fact, that played a reinforcing role in bringing it about.

In some systems, Contributing Factors can be positive or negative in their effect on an event.\(^50\)\(^51\) In the proposed Conceptual Framework, positive factor concepts will be either *Preventive Factors*, *Recovery Factors*, or *Mitigating Factors*, and negative factors will be *Contributing Factors*.

The Contributing Factor classes have been derived from theoretical models of complex systems error (Rasmussen\(^52\), Reason\(^53\)\(^54\), Eindhoven\(^55\), Marx\(^56\)). The concepts embedded within the classes should still be largely empirically driven; that is, concepts should represent notions, ideas and the vocabulary used by clinicians to describe contemporary cases. However some concepts have been informed by, or derived from, patient safety theories and the scientific literature eg knowledge-based errors, skill-based errors, violations, risk-taking behaviour.

The importance of Contributing Factors cannot be under-estimated; simply counting errors is insufficient to prevent re-occurrences.\(^57\) However, a classification in which mistakes are coded

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51 National Patient Safety Centre. National Reporting and Learning System Service Dataset with Help
55 Van der Schaaf, TW. Near Miss Reporting in the Chemical Process Industry. Eindhoven: Technische Universiteit Eindhoven
56 Marx D. Patient Safety and the “Just Culture”: A Primer for Health Care Executives. Columbia University
57 Ferner RE and Aronson JK. Terminology in Medical Errors. In press.
according to their putative mechanisms, such as knowledge-based errors, rule-based errors, and skill-based errors may help stakeholders to learn from the events and prevent re-occurrences. 58

Figure 6: Contributing Factors Classes

1.6.8 Event Modifiers

Preventive Factors, Recovery Factors and Mitigating Factors are all termed Event Modifiers. They can change the course of an event - they can prevent a set of circumstances or latent factors that could have resulted in an event, or they can minimise the impact of an event after it has occurred.

Preventive Factors, Recovery Factors, Mitigating Factors are defined in Table 1 above. Kanse and Van der Schaaf59 60 have distinguished between planned and unplanned recovery steps.61 Planned recovery steps involve the activation of defences or barriers that are built into the organization to avoid negative consequences. 62 63 Examples of barriers or defences are automatic safety controls, or procedures to follow under certain conditions. 64 Such procedures can either be formally documented rules or work instructions, or unwritten but approved and generally followed work practices that people learn on the job or via specific training. 65 Use of a circuit disconnect alarm and double checking medication administration procedures are planned Recovery Factors. Unplanned recovery steps are usually more ad-hoc and depend on the creative problem solving abilities of the people involved.66 Even though a person who performs such unplanned recovery steps may have performed the steps before and may have devised a plan for what to do, as long as these steps are not a standard practice and are not

58 Ferner RE and Aronson JK. Op cit.
known to everyone in the same job, the steps qualify as unplanned behaviour. A staff member noticing that a medication is the wrong dose just prior to administration or a staff member lunging to stop a patient falling is an unplanned recovery.

**Preventive Factors** can be related closely to **Contributing Factors** in a converse relationship. This means that the management of particular **Contributing Factors** can prevent the event occurring.

**A Mitigating Factor** occurs after the event has occurred and reduces the impact or severity of a potential outcome to the patient and / or organisation, for example, good crisis management.

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Appendix A: Event Sources applicable to the IPSEC

Root Cause Analysis (RCA)

RCA is a process analysis method, which can be used to identify the factors that cause adverse events. It aims to answer questions posed by high risk, high impact events—notably, what happened, why it occurred, and what can be done to prevent it from happening again.

Risk managers and other health care personnel use RCA analytical methods to investigate (‘drill down’ into) serious incidents (including near misses) to identify the underlying causes and to guide solutions to address safety system failures.

RCA is normally only performed on high risk, high impact events, such as sentinel events. The RCA process should not be performed for incidents involving criminal acts or requiring disciplinary action.

The main principles of a RCA investigation are to:

- focus on systems and processes, not individual performance
- be fair, thorough and efficient
- focus on problem solving
- use recognised analytical methods
- use a scale of effectiveness to develop recommendations.

Medical record reviews

Medical record review provides a basis for systematically identifying iatrogenic injury through the detailed review of randomly sampled medical records. The aim of medical record reviews is to determine the type, frequency and severity of adverse events. Investigators create a set of generic (non-disease and non-procedure specific) screening criteria. Usually nurses review the medical records during this screening phase. All positive findings are subsequently reviewed by one or more of the investigators to determine the presence or absence of adverse events and then they may be reviewed in group sessions to confirm the proof required and to ensure proper coding.

Large scale medical record reviews have been undertaken in Canada, the United States, Australia, Denmark, and New Zealand. These studies have...
reported adverse event rates per admission of between 7.5% to 12.9% for and rates of permanent harm or death from adverse events in the range of 0.4% and 2.0%.

Incident reports

This involves the reporting of harmful or potentially harmful incidents, traditionally for local management and follow-up, when all those involved are identified. This is usually done when a patient has been harmed, but may also be done when there has been the potential for harm. In some jurisdictions documentation is required whenever there has been a significant departure from the routine care of a patient. In some systems, special reporting processes have been developed to address particular problems such as laboratory errors and equipment failure.

Increasing, incident reporting systems are being aggregated at a national level eg in Denmark, the National Reporting Learning System in England and Wales, and the Anaesthetic Incident Monitoring Study in Australia and New Zealand.

The strength of incident reporting lies in its potential to identify corrective strategies.

Complaints and Consumer Reporting

Users of the health system have a unique expertise in relation to their own health and their perspective on how care is actually provided. Consumer complaints and reporting are unique sources of information for health care services on how and why adverse events occur and how to prevent them. As well as reducing future harm to patients, management of complaints and consumer reporting can restore trust and reduce the risk of litigation, through open communication and a commitment to learn from the problem and prevent its recurrence.

It should be noted that not all complaints are related to the patient safety matters, but may be associated with broader quality issues. These incidents should not be classified using the IPSEC.

Sentinel events

A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

80 Capstick B. Incident reporting and claims analysis. Clinical Risk, 1995, 1: 165-167
Such events are called "sentinel" because they signal the need for immediate investigation and response. 86

In the United States, organizations accredited by JCAHO are expected to identify and respond appropriately to all sentinel events occurring in the organization or associated with services that the organization provides, or provides for. Appropriate response includes conducting a timely, thorough and credible root cause analysis, implementing improvements to reduce risk, and monitoring the effectiveness of those improvements. 87

Coroner’s reports

Coronal reports and recommendations form a potentially rich source of information about adverse events that can be classified. A good example of aggregated coronial data is the National Coroners Information System (NCIS), a national internet based data storage and retrieval system for Australian coronial cases. 88 Information about every death reported to an Australian coroner since January 2001 is stored within the system, providing a valuable hazard identification and death prevention tool for coroners and research agencies.

The NCIS has a primary role to assist coroners in their role as death investigators, by providing them with the ability to review previous coronial cases that may be similar in nature to current investigations, enhancing their ability to identify and address systematic hazards within the community.

Medico-legal cases

Medico-legal files for actual or potential claims are opened in about 2% of hospital admissions per year in Australia. Of these, about one-quarter of such files proceed to some sort of settlement or to litigation. Information related to medico-legal claims has been used successfully in the USA 89 90 91 92 and Australia 93 94 to improve patient safety.

86 Joint Commission on Accreditation of Healthcare Organisations. Sentinel Events. Op cit
87 Joint Commission on Accreditation of Healthcare Organisations. Sentinel Events. Op cit
88 National Coroners Information System, About NCIS. 2006. Victorian Institute of Forensic Medicine
93 Runciman WB. Iatrogenic Harm and Anaesthesia in Australia. Anaesthesia and Intensive Care; Jun 2005; 33, 3; Health & Medical Complete. pg. 297