The Conceptual Framework for the International Classification for Patient Safety

Version 1.1

FINAL TECHNICAL REPORT

Chapter 3
The International Classification for Patient Safety Key Concepts and Preferred Terms

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World Health Organization

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International Classification for Patient Safety
Key Concepts and Preferred Terms

Introduction

This chapter describes the identification and development of the key concepts for the International Classification for Patient Safety. These concepts represent the start of an on-going process of progressively improving a common international understanding of terms and concepts relevant to the domain of patient safety. This is a pre-requisite for some of the action areas identified by the WHA55.18:

- determination of global norms, standards and guidelines for the definition, measurement and reporting of adverse events and near misses in healthcare;
- promotion and framing of evidence-based policies; and
- international benchmarking.

The consistent use of key concepts with agreed definitions and preferred terms, in conjunction with a comprehensive but adaptable conceptual framework, will pave the way for researchers to understand each others' work and facilitate the systematic collection, aggregation and analysis of relevant information. This will allow comparison between facilities and jurisdictions, and allow trends to be tracked over time.

The Drafting Group agreed that:

- concepts and terms should be applicable across the full spectrum of healthcare from primary to highly specialized care and should be consistent with the existing processes and systems;
- concepts should, whenever possible, be consistent with concepts from other terminologies and classifications in the WHO-Family of International Classifications;
- definitions of the concepts and the preferred terms should reflect colloquial uses;
- definitions of the concepts should convey the appropriate meanings with respect to patient safety;
- definitions should be brief and clear, without unnecessary or redundant qualifiers, starting with basic definitions and then "building" upon them for each subsequent definition; and
- key concepts and preferred terms be "fit-for-purpose" for the conceptual framework for the ICPS.

Forty-eight concepts were identified and definitions and preferred terms agreed. The concepts defined and chosen represent a collection of basic building blocks to enhance the study of patient safety and facilitate understanding and transfer of information.

Other sets of definitions and terms of relevance to patient safety exist. The primary consideration in identifying key concepts, and defining and assigning preferred terms to them was to ensure that the definitions would be "fit-for-purpose" in the specific context of the conceptual framework for the ICPS. Given the plethora of terms, concepts and definitions, it is inevitable that some will differ from others.

The Drafting Group drew upon a large number of sources (dictionaries, literature, internet) to develop the definitions for the key concepts. The sources have not been explicitly linked to specific definitions, as the original prime sources of the information and the first use of the concepts or terms in the context of patient safety are often obscure. The Drafting Group made many refinements to the conceptual definitions as a result of input from technical experts during seven face-to-face meetings, numerous teleconferences and email exchanges. Linking specific references to concepts would entail a high risk of

misattribution. Nevertheless, the Drafting Group believed it is important to know the etiology of the definitions and preferred terms for the key concepts (see Technical Annex 2).

Definition of concepts

How the key concepts with preferred terms chosen relate to the conceptual framework for the ICPS is shown in the semantic framework diagram. The preferred terms are listed alphabetically followed by the key concepts with definitions. The semantic diagram, alphabetical list of preferred terms and conceptual definitions are at the end of this chapter.

Concepts are progressively introduced to allow understanding to be "built", starting with the concepts in the title of the conceptual framework for the International Classification for Patient Safety (classification, patient, safety). The terms in italics have been deemed ICPS-preferred terms. Where terms have been italicized, the agreed definition for the relevant concept follows.

A *classification* is an arrangement of *concepts* (bearers or embodiments of meaning) and *classes* (groups or sets of like things, e.g., contributing factors, incident type, and patient outcomes) and their subdivision linked to express their *semantic relationships* between them (the way in which they are associated with each other on the basis of their meanings). For example, contributing factors precede and play a role in the generation of any incident type. Similarly, detection precedes mitigating factors and is followed by outcomes; the progression of an incident cannot be limited until it has been detected and its nature determined, and outcomes cannot be described until attempts at limitation have exerted their influence.

A *patient* is a person who is a recipient of *healthcare*, itself defined as services received by individuals or communities to promote, maintain, monitor or restore health. Patients are referred to rather than clients, tenants or consumers, although it is recognized that may recipients such as a health pregnant woman or a child undergoing immunization may not be regarded, or regard themselves, as patients. Healthcare includes self-care. *Health*, as defined by the World Health Organization, is the "state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".[1]

Safety is the reduction of risk of unnecessary harm to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment.

Hazard is a circumstance, agent or action with the potential to cause harm.

A *circumstance* is a situation or factor that may influence an event, agent or person(s).

An *event* is something that happens to or involves a patient and an *agent* is a substance, object or system that acts to produce change.

Patient safety is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment.

[1] World Health Organization. Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organizations, no. 2, p. 100) and entered into force on 7 April 1948. www.who.int/en/.

Healthcare-associated harm is harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury.

A *patient safety incident* is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. In the context of the ICPS, a patient safety incident will be referred to as an incident. The use of the word "unnecessary" in this definition recognizes that errors, violation, patient abuse and deliberately unsafe acts occur in healthcare. These are considered incidents. Certain forms of harm, however, such as an incision for a laparotomy, are necessary. This is not considered an incident. Incidents arise from either unintended or intended acts. Errors are, by definition, unintentional, whereas violations are usually intentional, though rarely malicious, and may become routine and automatic in certain contexts.

An *error* is a failure to carry out a planned action as intended or application of an incorrect plan. Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or execution phase.[2,3] Thus, if screening for bowel cancer involves regular testing for occult blood, then a screening colonoscopy in the absence of prior occult blood testing comprises an error of commission (the application of an incorrect plan), whereas failure to arrange testing for occult blood would constitute an error of omission. A *violation* is a deliberate deviation from an operating procedure, standard or rule. Both errors and violations increase risk, even if an incident does not actually occur.[12,13] *Risk* is the probability than an incident will occur.

An incident can be a reportable circumstance, near miss, no harm incident or harmful incident (adverse event). A *reportable circumstance* is a situation in which there was significant potential for harm, but no incident occurred (i.e., a busy intensive care unit remaining grossly understaffed for an entire shift, or taking a defibrillator to an emergency and discovery it does not work although it was not needed). A *near miss* is an incident which did not reach the patient (e.g., a unit of blood being connected to the wrong patient's intravenous line, but the error was detected before the infusion started). A *no harm incident* is one in which an event reached a patient but no discernable harm resulted (e.g., if the unit of blood was infused, but was not incompatible). A *harmful incident (adverse event)* is an incident that results in harm to a patient (e.g., the wrong unit of blood was infused and the patient died from a haemolytic reaction).

Harm implies impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or psychological. *Disease* is a physiological or psychological dysfunction. *Injury* is damage to tissues caused by an agent or event and *suffering* is the experience of anything subjectively unpleasant. Suffering includes pain, malaise, nausea, depression, agitation, alarm, fear and grief. *Disability* implies any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with past or present harm.

A *contributing factor* is a circumstance, action or influence (such as poor rostering or task allocation) that is thought to have played a part in the origin or development, or to increase the risk, of an incident. Contributing factors may be external (i.e., not under the control of a facility or organization), organizational (e.g., unavailability of accepted protocols), related to a staff factor (e.g., an individual cognitive or behavioral defect, poor team work or inadequate communication) or patient-related (e.g., non-adherence). A contributing factor may be a necessary precursor of an incident and may or may not be sufficient to cause the incident.

[2] Reason J. *Human Error*. New York: Cambridge University Press, 1990.
[3] Runciman WB, Merry AF, Tito F. Error, blame and the law in health care – an Antipodean perspective. *Ann Intern Med* 2003; 138: 974-9.

Incidents are classified into a number of different types. An *incident type* is a category made up of incidents of a common nature, grouped because of shared agreed features and is a "parent" category under which may concepts may be grouped. Incident types include clinical administration, clinical process/procedure, documentation, healthcare-associated infection, medication/IV fluids, blood/blood products, nutrition, oxygen/gas/vapour, medical device/equipment, behavior, patient accidents, infrastructure/building/fixtures, and resources/organizational management.

Patient Characteristics are selected attributes of a patient, such as patient demographics or the reason for presentation to healthcare. *Attributes* are qualities, properties or features of someone or something. *Incident characteristics* are selected attributes of an incident such as care setting, treatment status, specialties involved and date of an incident.

With reference to an agent, an *adverse reaction* is unexpected harm arising from a justified treatment. For example, unexpected neutropenia due to a drug not known to have this effect is an adverse reaction. Recurrence of a previously encountered adverse reaction may be preventable (e.g., avoiding re-exposure of a patient with a drug allergy). A *side effect* is a known effect, other than that primarily intended, related to a medicine's pharmacological properties, such as nausea after morphine has been given to alleviate pain.

Preventable is being accepted by the community as avoidable in the particular set of circumstances. *Detection* is an action or circumstance that results in the discovery of an incident (e.g., by noticing an error by a monitor or alarm, by change in patient condition, or by a risk assessment). Detection mechanisms may be part of the system, such as low pressure disconnect alarm in a breathing circuit, may result from a checking process or from vigilance and "situational awareness". A *mitigating factor* is an action or circumstances that prevents or moderates the progression of an incident towards harming a patient. The mechanism by which damage may occur is already in train, but has not yet led to either any or the maximum possible harm. The term "recovery" has been used to describe the combination of detection and mitigation; it does not refer to clinical recovery (recuperation) but to the process of recovering from an incident that has started. Reconnecting a breathing circuit after a disconnect alarm warning is an example of recovery. By collecting information about how and way "saves" are made, system design, training and education can be informed.

Patient outcome is the impact upon a patient which is wholly or partially attributable to an incident. Where harm has occurred, the *degree of harm* is the severity and duration of any harm, and any treatment implications, that result from an incident. It would seem, from the guiding principles, desirable to record the nature, severity and duration of harm separately. Whilst in pure terms one might argue for classifying each separately, in reality most harm scales recognize these elements are conflated within the natural assessment that is made when assigning a degree of harm. Previous attempts to rank the degree of harm tend to conflate these parameters into one scale.[4,5,6] In the context of the conceptual framework for the ICPS, the degree of harm is as follows:

[4] NSW Health. Incident Management. Policy Directive PD2007…061. July 2007. Sydney: New South Wales Health, 2007. www.health.nsw.gov.au/policies/2007/pdf/PD2007...-61.pdf [Accessed 11 February 2008].
[5] VA National Center for Patient Safety. *VA National Patient Safety Improvement Handbook*. Washington DC. Department of Veterans Affairs, US Veterans Health Administration, 2002. www.va.gov/NCPS/Pubs/NCPShb.pdf [Accessed 11 February 2008].
[6] National Patient Safety Agency. eForm User Guide v4. www.eforms.npsa.nhs.uk/staffeform/help.ALL/eForm_Help.htm [Accessed 27 November 2008].

- None – patient outcome is not symptomatic or no symptoms detected and no treatment is required.
- Mild – patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g., extra observation, investigation, review or minor treatment) is required.
- Moderate – patient outcome is symptomatic, requiring intervention (e.g., additional operative procedure; additional therapeutic treatment), an increased length of stay, or causing permanent or long term harm or loss of function.
- Severe – patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function
- Death – on balance of probabilities, death was caused or brought forward in the short term by the incident.

Incidents also affect healthcare organizations. *Organizational outcome* is the impact upon an organization that is wholly or partially attributable to an incident (e.g., adverse publicity or additional use of resources).

Ameliorating action is an action taken or circumstance altered to make better or compensate any harm after an incident. Patient ameliorating factors are actions taken or circumstances altered to make good harm to a patient, such as fixing a fracture after a fall. Whereas healthcare system ameliorating factors reduce loss or damage to an organization, such as good public relations management after a publicized disaster to improve the effects on a facility's reputation.

Actions taken to reduce risk are actions taken to reduce, manage or control any future harm, or probability of harm, associated with an incident. Such actions can affect incidents, contributing factors, detection, mitigating factors or ameliorating actions, and can be pro-active or reactive. Pro-active actions may be identified by techniques such as failure mode and effects analysis[7] and probabilistic risk analysis[8]. Reactive actions are taken in response to insights gained after incidents have occurred (e.g., root causes analysis).

Resilience references to the degree to which a system continuously prevents, detects, mitigates or ameliorates hazards or incidents. Resilience allows an organization to "bounce back" to its original ability to provide care functions as soon as possible after incurring damage.

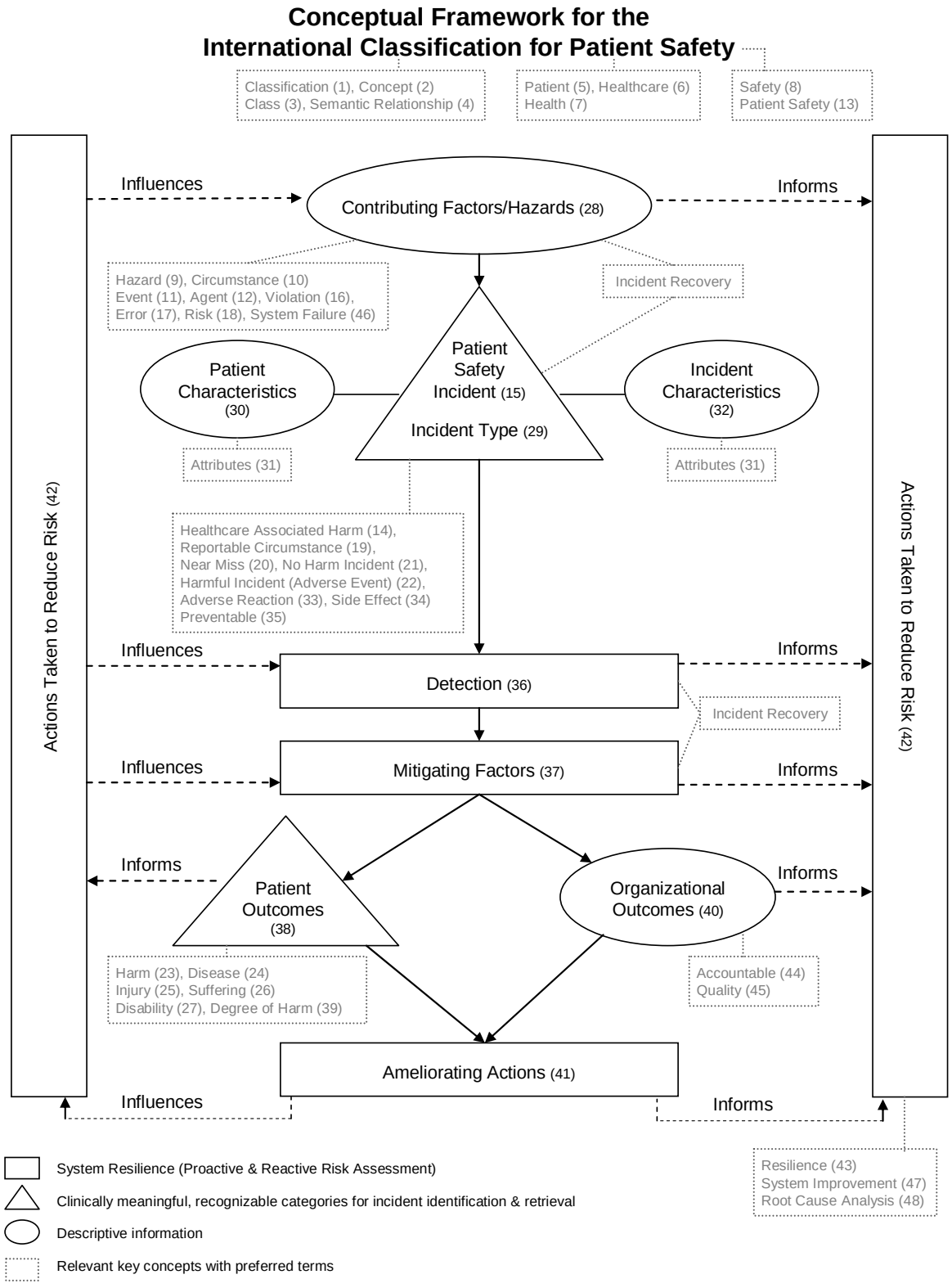
A number of terms are commonly used regarding organizational management. *Accountable* is being held responsible. *Quality* is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. *System failure* refers to a fault, breakdown or dysfunction within an organization's operational methods, processes or infrastructure. Factors contributing to system failure can be latent (hidden or apt to elude notice) or apparent, and can be related to the system, the organization, a staff member or a patient. A latent factor might be a breathing circuit disconnect alarm with no power failure warning or battery backup.[9]

[7] Senders JW, FMEA and RCA: the mantras of modern risk management. *Qual Saf Health Care* 2004;13:249-50.
[8] Marx DA, Slonim AD. Assessing patient safety risk before the injury occurs: an introduction to sociotechnical probabilistic risk modeling in health care. *Qual Saf Health Care* 2003;12(Suppl 2):ii33-8.
[9] Myerson K, Ilsley AH, Runciman WB. An evaluation of ventilator monitory alarms. *Anaesth Intens Care* 1986;14:174-85.

System improvement is the result or outcome of the culture, processes and structures that are directed towards the prevention of system failure and the improvement of safety and quality. Processes to counter the latent failure described would include modification of the equipment to alarm when the power supply is compromised, or use of an additional device, such as a capnograph, to alarm if carbon dioxide is not detected in expired air.

Finally, *root cause analysis*, a reactive form of risk assessment to inform the development of actions taken to reduce risk, is a systematic iterative process whereby the factors that contribute to an incident are identified by reconstructuring the sequence of events and repeatedly asking "why" until the underlying root causes (contributing factors or hazards) have been elucidated.

Some concepts were excluded because their meanings vary across jurisdictions (e.g., negligence), they have discipline-specific meanings (e.g., accident – in aviation meaning the loss of an aircraft hull), are already being used with special meanings in a WHO classification (e.g., misadventure or sequela), or the conceptual definitions cannot be made universal. As a result, other concepts of relevance to patient safety and across all healthcare environments have been developed. For example, the concept healthcare-associated harm was included instead of iatrogenic and nosocomial harm. Iatrogenic and nosocomial harm are associated with physicians and hospitals, respectively. Healthcare-associated harm there acknowledges that healthcare is provided by a number of different individuals, including patients, in a variety of care settings (inpatient, ambulatory, mental health and community facilities, home, etc.). It should also be noted that this list of key concepts is dynamic. It will, and should, grow as knowledge in the field of patient safety grows.



The solid lines represent the semantic relationships between the classes. The black dotted lines represent the flow of information. The shaded dotted lines link the relevant concepts to the classes. The numbers next to the preferred terms represent the sequence in which they appear in the text and in glossary.

GLOSSARY OF KEY CONCEPTS AND PREFERRED TERMS

Preferred Terms:

Accountable (# 44)
Actions taken to reduce risk (# 42)
Adverse reaction (# 33)
Agent (# 12)
Ameliorating action (# 41)
Attributes (# 31)
Circumstance (# 10)
Class (# 3)
Classification (# 1)
Concept (# 2)
Contributing Factor (# 28)
Degree of harm (# 39)
Detection (# 36)
Disability (# 27)
Disease (# 24)
Error (# 16)
Event (# 11)
Harm (# 23)
Harmful incident (adverse event) (# 22)
Hazard (# 9)
Health (# 7)
Healthcare (# 6)
Healthcare-associated harm (# 14)
Incident characteristics (# 32)
Incident type (# 29)
Injury (# 25)
Mitigating factor (# 37)
Near miss (# 20)
No harm incident (# 21)
Organizational outcome (# 40)
Patient (# 5)
Patient characteristics (# 30)
Patient outcome (# 38)
Patient Safety (# 13)
Patient safety incident (# 15)
Preventable (# 35)
Quality (# 45)
Reportable circumstance (# 19)
Resilience (# 43)
Risk (# 18)
Root cause analysis (# 48)
Safety (# 8)
Semantic relationship (# 4)
Side effect (# 34)
Suffering (# 26)
System failure (# 46)
System improvement (# 47)
Violation (# 17)

Definitions of Key Concepts:

1. **Classification**: an arrangement of **concepts** into **classes** and their subdivisions, linked so as to express the **semantic relationships** between them.

2. **Concept**: a bearer or embodiment of meaning.

3. **Class**: a group or set of like things.

4. **Semantic relationship**: the way in which things (such as **classes** or **concepts**) are associated with each other on the basis of their meaning.

5. **Patient**: a person who is a recipient of **healthcare**.

6. **Healthcare**: services received by individuals or communities to promote, maintain, monitor or restore **health**.

7. **Health**: a state of complete physical, mental and social wellbeing and not merely the absence of **disease** or infirmity.

8. **Safety**: the reduction of risk of unnecessary **harm** to an acceptable minimum.

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

10. **Circumstance**: a situation or factor that may influence an **event**, **agent** or person(s).

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

12. **Agent**: a substance, object or system which acts to produce change.

13. **Patient Safety**: the reduction of risk of unnecessary **harm** associated with **healthcare** to an acceptable minimum.

14. **Healthcare-associated harm**: **harm** arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying **disease** or **injury**.

15. **Patient safety incident**: an **event** or **circumstance** which could have resulted, or did result, in unnecessary **harm** to a **patient**.

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

17. **Violation**: deliberate deviation from an operating procedure, standard or rule

18. **Risk**: the probability that an **incident** will occur.

19. **Reportable circumstance**: a situation in which there was significant potential for harm, but no incident occurred.

20. **Near miss**: an **incident** which did not reach the patient.

21. **No harm incident:** an **incident** which reached a patient but no discernable harm resulted.

22. **Harmful incident (adverse event)**: an **incident** which resulted in **harm** to a patient.

23. **Harm**: impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes **disease**, **injury**, **suffering**, **disability** and death.

24. **Disease**: a physiological or psychological dysfunction.

25. **Injury**: damage to tissues caused by an **agent** or **event.**

26. **Suffering**: the experience of anything subjectively unpleasant.

27. **Disability**: any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with past or present **harm**.

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

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

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

31. **Attributes**: qualities, properties or features of someone or something.

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

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

34. **Side effect**: a known effect, other than that primarily intended, related to the pharmacological properties of a medication.

35. **Preventable**: accepted by the community as avoidable in the particular set of circumstances.

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

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

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

39. **Degree of harm**: the severity and duration of harm, and any treatment implications, that result from an **incident**.

40. **Organizational outcome**: the impact upon an organization which is wholly or partially attributable to an **incident**.

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

42. **Actions taken to reduce risk**: actions taken to reduce, manage or control any future harm, or probability of **harm,** associated with an **incident**.

43. **Resilience**: The degree to which a system continuously prevents, detects, mitigates or ameliorates **hazards** or **incidents**.

44. **Accountable**: being held responsible

45. **Quality**: the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

46. **System failure**: a fault, breakdown or dysfunction within an organization's operational methods, processes or infrastructure.

47. **System improvement**: the result or outcome of the culture, processes, and structures that are directed toward the prevention of **system failure** and the improvement of **safety** and **quality**.

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