More than words

Conceptual Framework for the International Classification for Patient Safety

Version 1.1

Final Technical Report
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World Health Organization

Patient Safety

A World Alliance for Safer Health Care

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Executive Summary

This *Final Technical Report* provides a detailed overview of the conceptual framework for the International Classification for Patient Safety (ICPS), including a discussion of each class, the key concepts with preferred terms and the practical applications.

The World Alliance for Patient Safety convened a Drafting Group to initiate and take forward a work program. The Drafting Group set out to define, harmonize and group patient safety concepts into an internationally agreed classification in a way that is conducive to learning and improving patient safety across systems.

The purpose of the International Classification for Patient Safety is to enable categorization of patient safety information using standardized sets of concepts with agreed definitions, preferred terms and the relationships between them being based on an explicit domain ontology (e.g., patient safety). The ICPS is designed to be a genuine convergence of international perceptions of the main issues related to patient safety and to facilitate the description, comparison, measurement, monitoring, analysis and interpretation of information to improve patient care.[1]

It is important to note that the ICPS is not yet a complete classification. It is a conceptual framework for an international classification which aims to provide a reasonable understanding of the world of patient safety and patient concepts to which existing regional and national classifications can relate.

The Drafting Group has developed the conceptual framework for the ICPS, consisting of 10 high level classes:

1. Incident Type
2. Patient Outcomes
3. Patient Characteristics
4. Incident Characteristics
5. Contributing Factors/Hazards
6. Organizational Outcomes
7. Detection
8. Mitigating Factors
9. Ameliorating Actions
10. Actions Taken to Reduce Risk

The ICPS concepts by class are contained in the *Technical Annex*.

48 key concepts have been defined and assigned preferred terms to facilitate understanding and transfer of information relevant to 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 patient safety.

[1] International Classification for Patient Safety Statement of Purpose - http://www.who.int/patientsafety/taxonomy/ICPS_Statement_of_Purpose.pdf

The conceptual framework for the ICPS was designed to provide a much needed 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.

This document provides background information about the Drafting Group and the development of the conceptual framework for the ICPS (Chapter 1), a detailed overview of the conceptual framework for the International Classification for Patient Safety, including a discussion of each class (Chapter 2), the key concepts with preferred terms (Chapter 3), and the practical applications of the conceptual framework for the ICPS (Chapter 4). Acknowledgements are in Chapter 5. The ICPS concepts by class are listed in the *Technical Annex 1* and the glossary of patient safety concepts and references is contained in *Technical Annex 2*.

Chapter 1
Background

The Fifty-fifth World Health Assembly passed resolution WHA55.18 in May 2002. WHA55.18 called upon Member States to "pay the closest possible attention to the problem of patient safety and to establish and strengthen science-based systems necessary for improving patients' safety and quality of care."[2] The Assembly urged the WHO to develop global norms and standards and to support efforts by Member States to develop patient safety policies and practices.

In October 2004, WHO launched the World Alliance for Patient Safety. The project to develop an international classification for patient safety was identified as one of the key initiatives in the Alliance's 2005 Forward Programme (Taxonomy for Patient Safety).

What is a classification?

A classification comprises 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. It is important to distinguish a classification from a reporting system, which provides an interface to enable users to collect, store and retrieve data in a reliable and organized fashion.

The International Classification for Patient Safety (ICPS) is not yet a complete classification. It is a conceptual framework for an international classification which aims to provide a reasonable understanding of the world of patient safety and patient safety concepts to which existing regional and national classifications can relate.

Drafting Group

The Drafting Group was comprised of experts from the fields of patient safety, classification theory, health informatics, consumer/patient advocacy, law and medicine. From the start, the Drafting Group realized that the "problems do not lie with the words we use but rather with the underlying concepts."[3] This means that it is the conceptual definitions that are important, as well as the terms or labels assigned to the concepts. Without universally accepted conceptual definitions, understanding will continue to be impeded.

To guide its work, the Drafting Group followed a set of principles:

- The purpose and potential users and uses for the classification be clearly articulated;
- The classification be based upon concepts as opposed to terms or labels;
- The language used for the definitions of the concepts be culturally and linguistically appropriate;
- The concepts be organized into meaningful and useful categories;
- The categories be applicable to the full spectrum of healthcare settings in developing, transitional and developed countries;
- The classification be complementary to the WHO Family of International Classifications[4,5,6];
- The existing patient safety classifications be used as the basis for developing the international classification's conceptual framework[7,8,9,10]; and

[2] Fifty-Fifth World Health Assembly. Res. WHA55.18. 18 May 2002
[3] Perneger, T. Borges on classification. *Int J for Qual in Health Care* 2006;28(4):264-265.
[4] World Health Organization, Family of International Classifications Overview (2004, June). http://www.who.int/classifications/en/
[5] World Health Organization. International Statistical Classification of Diseases and Related Health Problems. 10th Revision. Version for 2006 (ICD-10). http://www.who.int/classifications/icd/en/index.html
[6] World Health Organization Drug Dictionary (maintained by *the* Uppsala Monitoring Centre), 2004. http://www.who.int/medicines/services/medicines_etools/en/

- The conceptual framework be a genuine convergence of international perceptions of the main issues related to patient safety.

How was the conceptual framework developed and key concepts identified and defined?

The Drafting Group developed the conceptual framework for the ICPS over the course of three years. [11] There has been a strong commitment to ensuring the conceptual framework for the ICPS is a genuine convergence of international perceptions of the main issues related to patient safety. The validity of the conceptual framework for the ICPS was evaluated through a two-round web-based modified Delphi survey[12] and an in-depth analysis by technical experts representing the fields of safety, systems engineering, health policy, medicine and the law[13].

The conceptual framework for the ICPS and the 48 key concepts and preferred terms were also evaluated for cultural and linguistic appropriateness by native French, Spanish, Japanese and Korean-speaking technical experts.[14,15,16] The technical experts that participated in the validity testing and cultural/linguistic evaluation found the conceptual framework for the ICPS to be fit for purpose, and meaningful, useful and appropriate for classifying patient safety data and information.

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[7] Chang, A, Schyve P, Croteau R, O'Leary D, Loeb J. The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events. *Int J Qual Health Care* 2005;17:95-105. http://www.who.int/patientsafety/taxonomy/NQF_Standardizing_Patient_Safety_Taxonomy_Jan202006.pdf

[8] The National Reporting and Learning System, National Health Service, National Patient Safety Agency. http://www.npsa.nhs.uk/nrls/reporting/

[9] Runciman WB, Williamson JAH, Deakin A, Benveniste KA, Bannon K, Hibbert PD. An integrated framework for safety, quality and risk management: an information and incident management system based on a universal patient safety classification. *Quality & Safety in Health Care.* 2006;15(Suppl 1):i82-90. http://www.apsf.net.au/

[10] The Eindhoven Classification Model for System Failure (ECM) and The Prevention and Recovery Information System for Monitoring and Analysis – Medical (PRISMA). The Netherlands: Eindhoven University of Technology. http://www.who.int/patientsafety/taxonomy/PRISMA_Medical.pdf

[11] History of the Project to Develop the International Classification for Patient Safety – http://www.who.int/patientsafety/taxonomy/evolution/en/index.html

[12] World Health Organization, Alliance for Patient Safety (2007, May) *Report on the Results of the Web-Based Modified Delphi Survey of the International Classification for Patient Safety*. Geneva, Switzerland.

[13] World Health Organization, Alliance for Patient Safety (2008, April). *Report of the WHO World Alliance for Patient Safety Challenge Group Meeting - Validity Testing of the Conceptual Framework for the International Classification for Patient Safety, 11-12 April 2008. Geneva.*

[14] World Health Organization, Alliance for Patient Safety (2008, October). *Report of the WHO World Alliance for Patient Safety Meeting with Francophone Technical Experts – Cultural and Linguistic Evaluation of the Conceptual Framework for the International Classification for Patient Safety, 13 October 2008. Paris, France.*

[15] World Health Organization, Alliance for Patient Safety (2008, October). *Report of the WHO World Alliance for Patient Safety Meeting with Spanish and Latin American Technical Experts – Cultural and Linguistic Evaluation of the Conceptual Framework for the International Classification for Patient Safety, 15 October 2008. Madrid, Spain.*

[16] World Health Organization, Alliance for Patient Safety (2007, November). *Report of the WHO World Alliance for Patient Safety Meeting with Technical Experts from the South East Asian and Western Pacific Regions of the WHO, 26 November 2007, Tokyo, Japan.*

Chapter 2
The Conceptual Framework for the International Classification for Patient Safety

Introduction

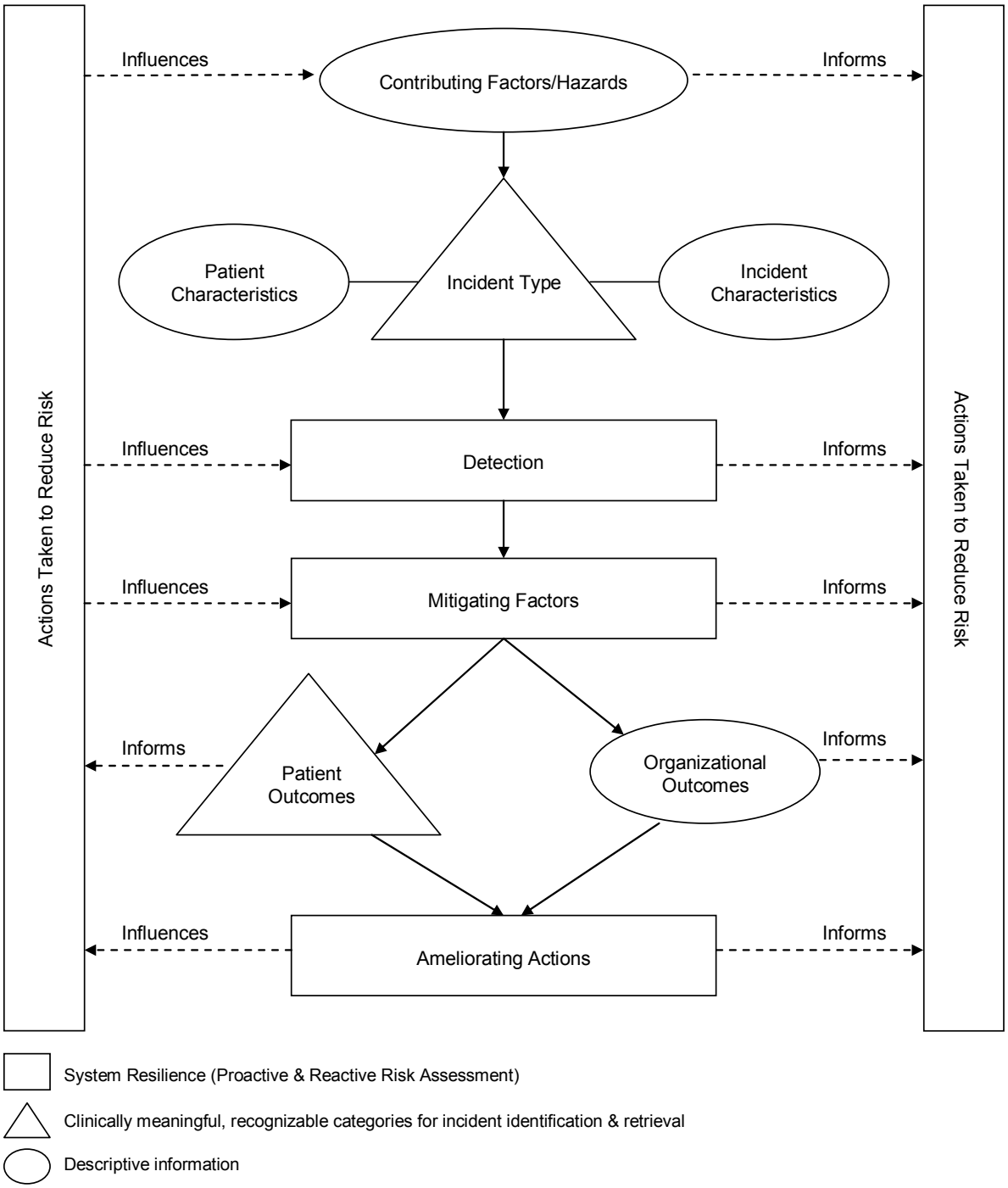
This chapter describes the 10 high level classes which comprise the conceptual framework for the International Classification for Patient Safety. The conceptual framework aims to provide a comprehensive understanding of the domain of patient safety. It aims to represent a continuous learning and improvement cycle emphasizing identification of risk, prevention, detection, reduction of risk, incident recovery and system resilience; all of which occur throughout and at any point within the conceptual framework.

The 10 high level classes are:

1. Incident Type
2. Patient Outcomes
3. Patient Characteristics
4. Incident Characteristics
5. Contributing Factors/Hazards
6. Organizational Outcomes
7. Detection
8. Mitigating Factors
9. Ameliorating Actions
10. Actions Taken to Reduce Risk

Each class has hierarchically arranged subdivisions (see Technical Annex 1). These concepts may be represented by a number of terms that allow for regional dialects, different languages, different clinical disciplines and/or provider or patient preferences.

The Conceptual Framework for the International Classification for Patient Safety



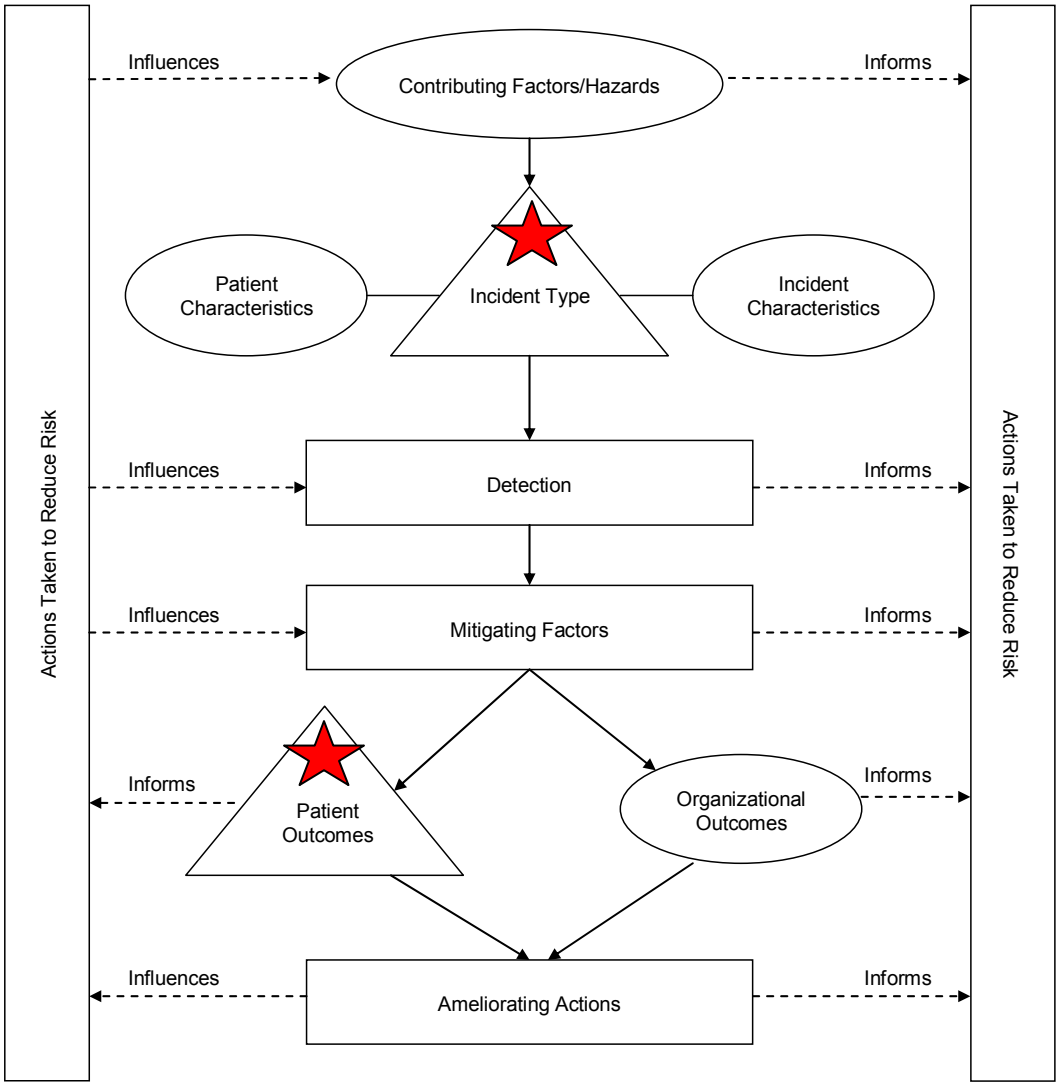
The solid lines represent the semantic relationships between the classes. The dotted lines represent the flow of information.

INCIDENT TYPE AND PATIENT OUTCOME

The class, *incident type*, is a descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features, such as “clinical process/procedure” or “medication/IV fluid” incident. Although each incident type concept is distinct, a patient safety incident can be classified as more than one incident type.

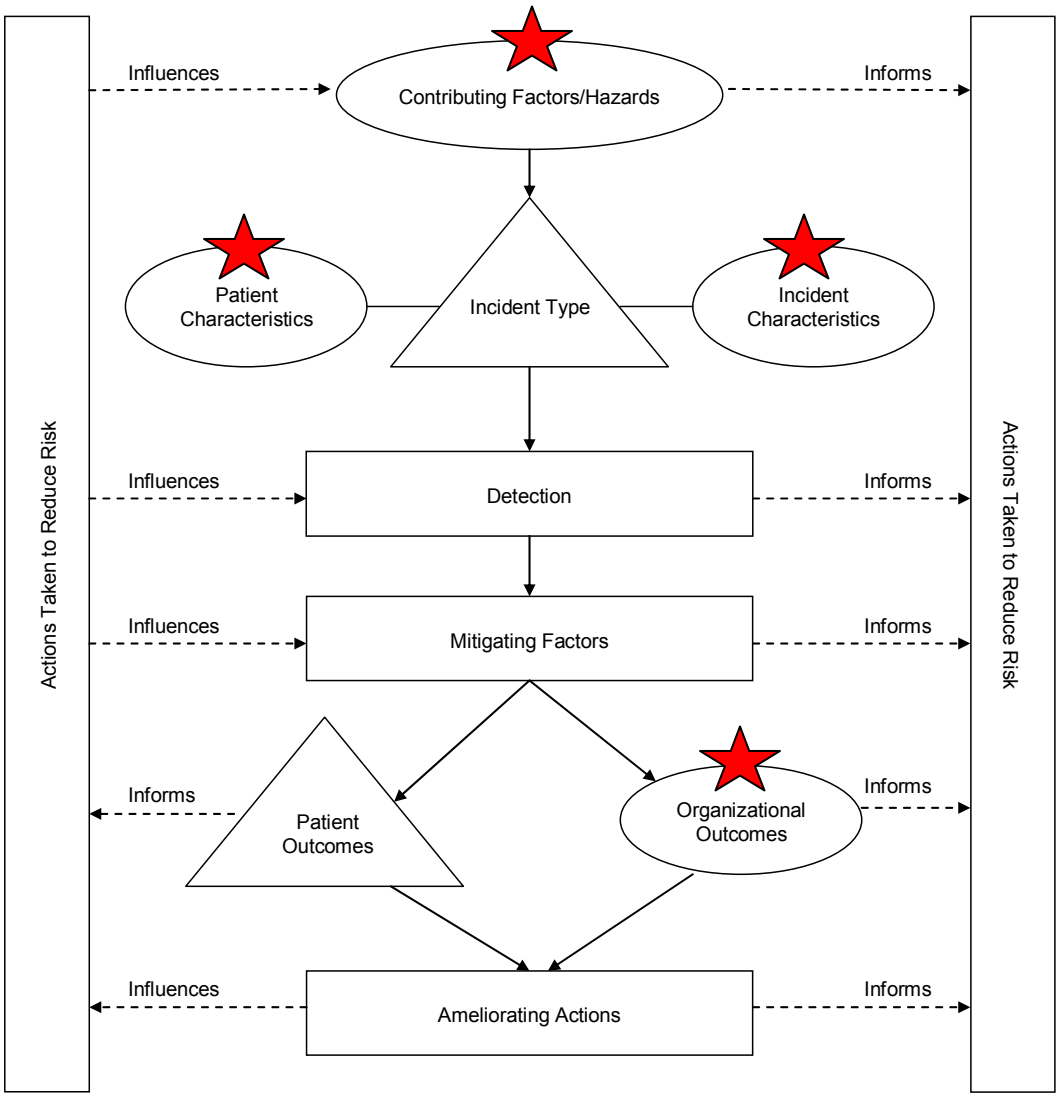
The class, *patient outcomes*, contains the concepts that relate to the impact upon a patient which is wholly or partially attributable to an incident. Patient outcomes can be classified according to the type of harm, the degree of harm, and any social and/or economic impact.

Together, the classes *incident type* and *patient outcomes* are intended to group patient safety incidents into clinically meaningful categories.



PATIENT CHARACTERISTICS, INCIDENT CHARACTERISTICS, CONTRIBUTING FACTORS/HAZARDS, AND ORGANIZATIONAL OUTCOMES

Pertinent descriptive information that provides context for the incident is captured by four classes: *patient characteristics, incident characteristics, contributing factors/hazards, and organizational outcomes*.



Patient characteristics categorize patient demographics, the original reason for seeking care and the primary diagnosis.

Incident characteristics classify the information about the circumstances surrounding the incident such as where and when, in the patient's journey through the healthcare system, the incident occurred, who was involved, and who reported.

Contributing Factors/Hazards are the circumstances, actions or influences which are thought to have played a part in the origin or development of an incident or to increase the risk of an incident. Examples

are human factors such as behavior, performance or communication; system factors such as work environment; and external factors beyond the control of the organization, such as the natural environment or legislative policy. More than one contributing factor and/or hazard is typically involved in a single patient safety incident.

Organizational outcomes refer to the impact upon an organization which is wholly or partially attributable to an incident. Organizational outcomes indicate the consequences directly to the organization such as an increased use of resources to care for the patient, media attention or legal ramifications as opposed to clinical or therapeutic consequences, which are considered patient outcomes.

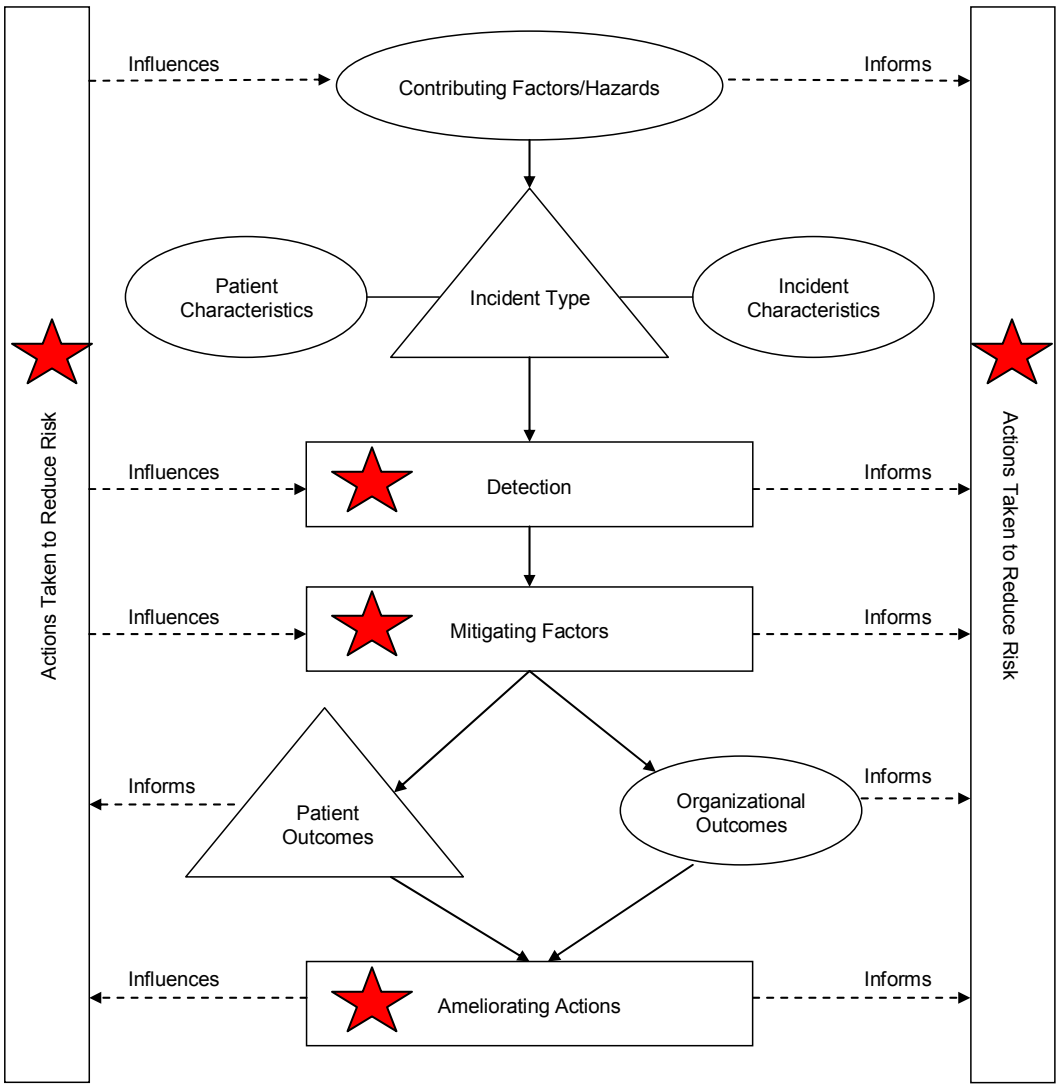
A complex relationship exists between incident type and contributing factors. The same incident or circumstance may be perceived as an incident or a contributing factor, depending on the context, circumstance or outcome.

An incident always has a set of contributing factors. Although an incident can be a contributing factor to the origin or development of another incident, some contributing factors can not be incidents in their own right. An incident can therefore be designated as a principal incident type depending on context specific business rules (e.g., the incident most proximal to the identified patient outcome), design of an information system or type of data analysis.

For example, if a patient with atrial fibrillation on warfarin got up at night to go to the bathroom, and slipped and fell resulting in no discernable harm, the patient safety incident would be considered a no harm incident and the incident type would be categorized as a “patient accident - fall”. If this patient had been found the following morning unrousable on the floor, then it is likely that the patient safety incident would be considered a harmful incident (adverse event) and the incident type would be regarded as “clinical management”. The fall would be considered a contributing factor involving “staff factors”, “work environment factors”, and “organizational/service factors”.

DETECTION, MITIGATING FACTORS, AMELIORATING ACTIONS AND ACTIONS TAKEN TO REDUCE RISK

The classes *detection, mitigating factors, ameliorating actions* and *actions taken to reduce risk* capture information relevant prevention, incident recovery, and system resilience.



Detection and mitigating factors together represent incident recovery (i.e., secondary prevention). Ameliorating actions are those used in the rescue phase of incident recovery (i.e., tertiary prevention).

Actions taken to reduce risk represent the collective learning from the information classified in all 10 classes necessary to result in system improvement, reduction of risk and improvement in patient care.

The concept of incident recovery,[17] derived from industrial science and error theory, is particularly important if learning from patient safety incidents is to occur.[18,19] It is the process by which a contributing factor and/or hazard is identified, understood and addressed thus stopping the contributing factor or hazard from developing into a patient safety incident. Incident recovery and *resilience* (in the context of the ICPS *resilience* is "the degree to which a system continuously prevents, detects, mitigates or ameliorates hazards or incidents" so that an organization can "bounce back" to its original ability to provide core functions) provide the context for discussion of detection, mitigation, amelioration and reduction of risk.

Detection is defined as an action or circumstance that results in the discovery of an incident. For example, an incident could be detected by a change in the patient's status, or via a monitor, alarm, audit, review, or risk assessment. Detection mechanisms may be built into the system as official barriers or informally developed.

Mitigating factors are actions or circumstances which prevent or moderate the progression of an incident toward harming the patient. Mitigating factors are designed to minimize the harm to the patient after the error has occurred and triggered damage control mechanisms. Together, detection plus mitigation can impede the progression of an incident from reaching and/or harming a patient. If the incident does result in harm, ameliorating actions can be introduced.

Ameliorating actions are those actions taken or circumstances altered to make better or compensate any harm after an incident. Ameliorating actions apply to the patient (clinical management of an injury, apologizing) and to the organization (staff debriefing, culture change, claims management).

Actions taken to reduce risk concentrate on steps taken to prevent the reoccurrence of the same or similar patient safety incident and on improving system resilience. Actions taken to reduce risk are those actions taken to reduce, manage or control the harm, or probability of harm associated with an incident. These actions may be directed toward the patient (provision of adequate care, decision support), toward staff (training, availability of policies/protocols), toward the organization (improved leadership/guidance, proactive risk assessment), and toward therapeutic agents and equipment (regular audits, forcing functions). Detection, mitigating factors and ameliorating actions both influence and inform the actions taken to reduce risk.

[17] Also referred to as "error recovery" or "recovery"
[18] van der Schaaf, T. W. A framework for designing near miss management systems. In van der Schaaf, T. W., Lucas, D. A. and Hale, A. R. (eds) Near miss reporting as a safety tool. Oxford, Butterworth-Heinemann Ltd, 1991.
[19] van der Schaaf TW, Clarke JR, Ch 7 – Near Miss Analysis. In Aspden P, Corrigan J, Wolcott J, Erickson S, (eds). Institute of Medicine, Committee on Data Standards for Patient Safety, Board on Health Care Services. Patient Safety: Achieving a New Standard for Care. Washington DC: National Academies of Sciences, 2004.

Chapter 3
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".[20]

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.

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

[20] 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/

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.[21,22] 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.

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.

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[21] Reason J. *Human Error*. New York: Cambridge University Press, 1990.

[22] Runciman WB, Merry AF, Tito F. Error, blame and the law in health care – an Antipodean perspective. *Ann Intern Med* 2003; 138: 974-9.

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.[23,24,25] In the context of the conceptual framework for the ICPS, the degree of harm is as follows:

[23] 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].
[24] 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].
[25] 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[26] and probabilistic risk analysis[27]. 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.[28]

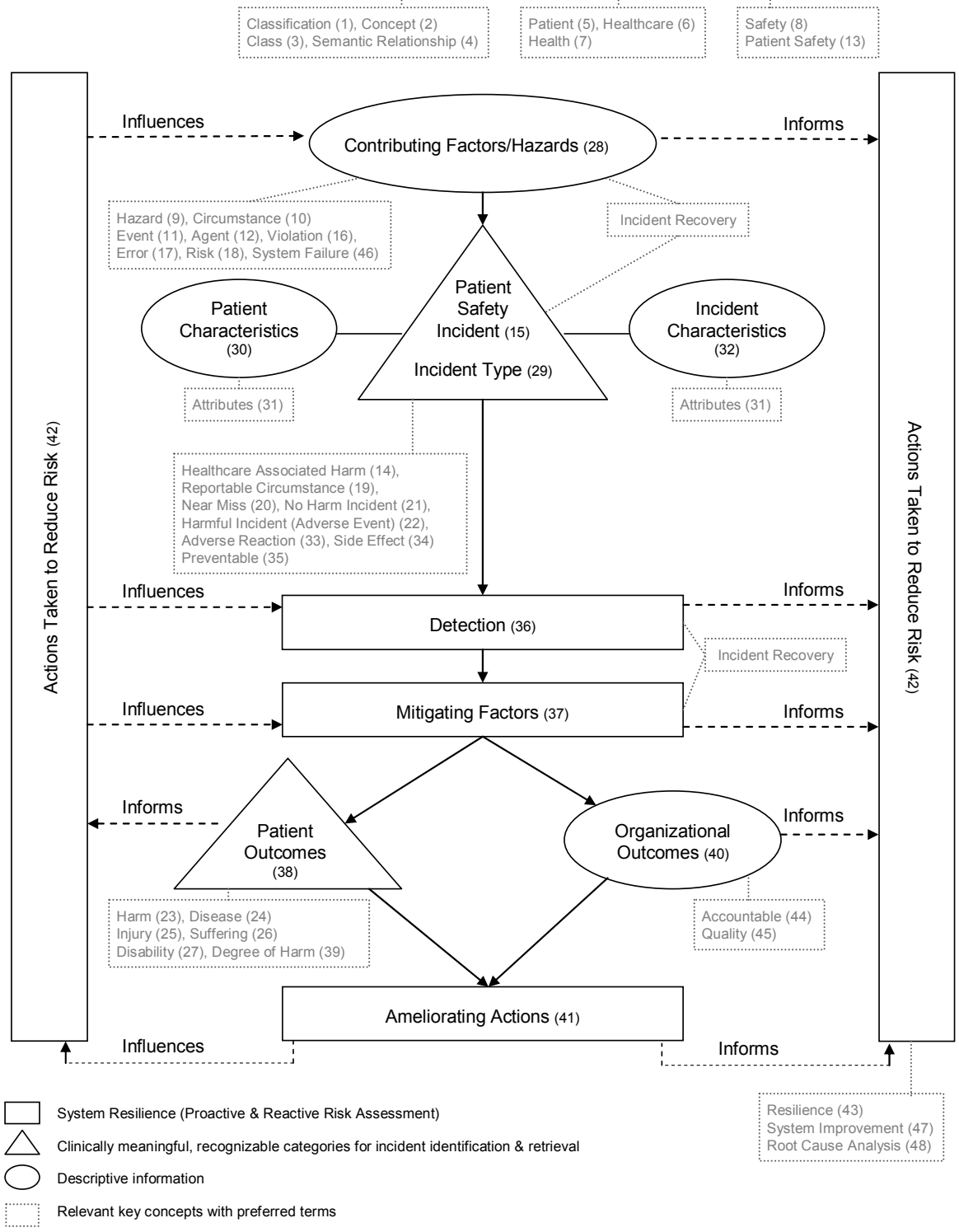
[26] Senders JW, FMEA and RCA: the mantras of modern risk management. *Qual Saf Health Care* 2004;13:249-50.
[27] Marx DA, Slonim AD. Assessing patient safety risk before the injury occurs: an introduction to sociotechnical probabilistic risk modeling in health care. *Qual Saf Health Care* 2003;12(Suppl 2):ii33-8.
[28] 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.

Conceptual Framework for the International Classification for Patient Safety



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.

Preferred Terms:

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.

Chapter 4
Practical Applications

The Drafting Group designed the conceptual framework for the International Classification for Patient Safety to provide a much needed method of organizing patient safety data and information so that this data and information could be aggregated and analyzed.

A well developed conceptual framework for the ICPS could have wider valued for advancing the field of patient safety by:

- facilitating the description, comparison, measurement, monitoring, analysis and interpretation of information to improve patient care;
- enabling the categorization of patient safety data and information so it can be used for epidemiological and health policy planning purposes by health care professionals, researchers, patient safety reporting system developers, policy-makers and patient/consumer advocacy groups; and
- providing an outline for developing a patient safety curriculum by setting forth an essential data element set that describes the current knowledge of the domain of patient safety.

By providing a structure for organizing data and information, a classification is the structural underpinning of a reporting system. A reporting system built upon a well developed classification comprised of essential data element pertinent to patient safety provides an interface to enable users to collect, store and retrieve relevant data in a reliable and organized fashion. This facilitates learning about the "science of safety" and informs the development of educational and training materials.

The conceptual framework for the ICPS can also be used in conjunction with existing reporting systems to achieve similar outcomes. Existing reporting system data elements can be mapped to the concepts contained within each of the 10 classes that comprise the ICPS or used for secondary coding.

The data and information obtained from reporting systems, despite whether the reporting system was newly created or existing, can be aggregated into a mineable database, analyzed and used to identify sources of and contributing factors to risk, alert healthcare professionals of problems/potential problems, and/or evaluate existing systems. These data and information can be used to evaluate and develop an individual organization's systems, policies and procedures. The collective experiences of many organizations can inform an individual organization on how to proceed when faced with potential or actual risk or patient safety incident. By examining the experiences of other organizations which dealt with the same or similar situations, an organization currently dealing with the situation can see what actions taken to reduce risk were successful and why. The resultant learning can aid policy-makers when developing regional, national or international health policy.

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More than words

Technical Annex 1

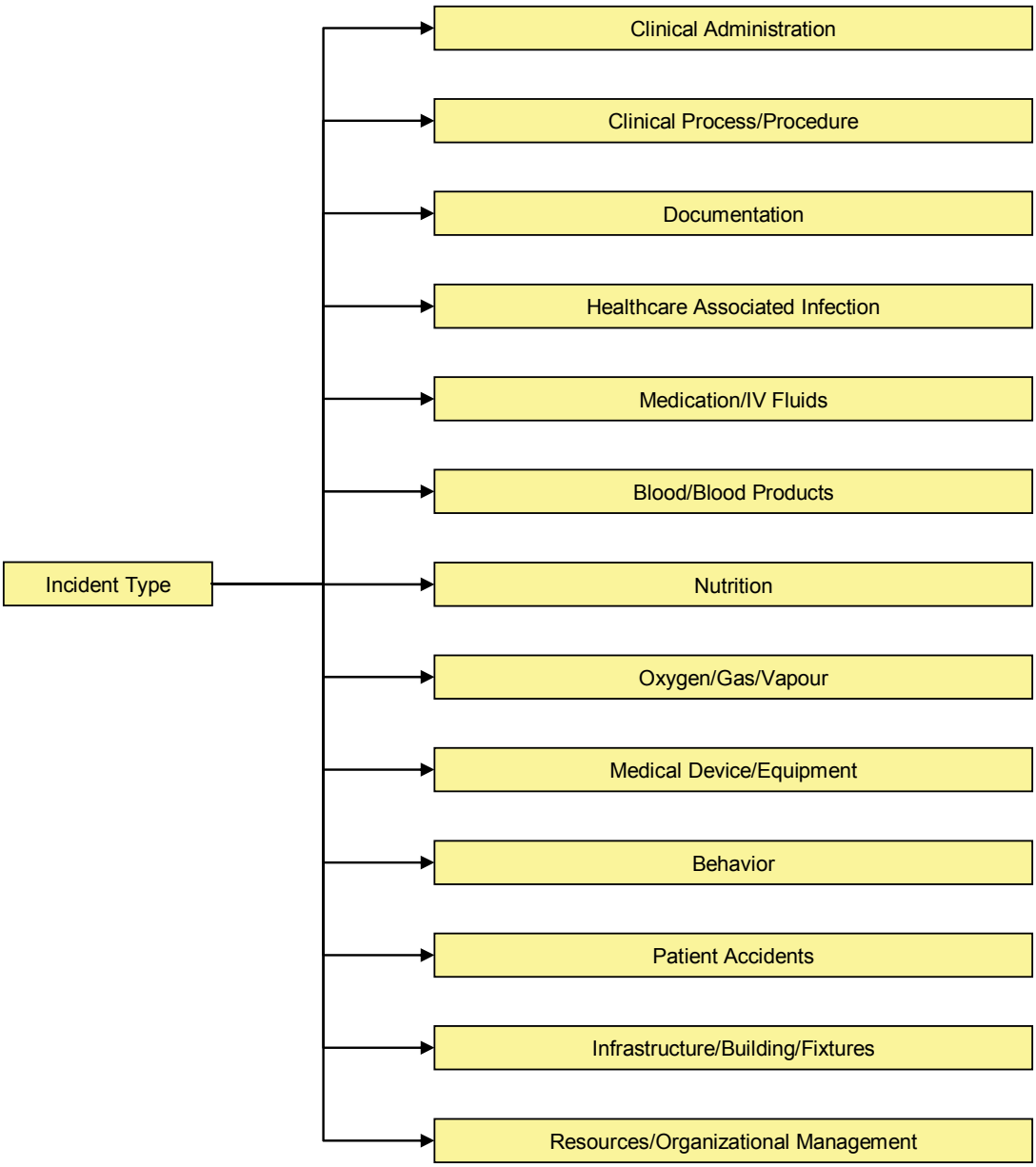
International Classification for Patient Safety Concepts by Class

Conceptual Framework for the International Classification for Patient Safety

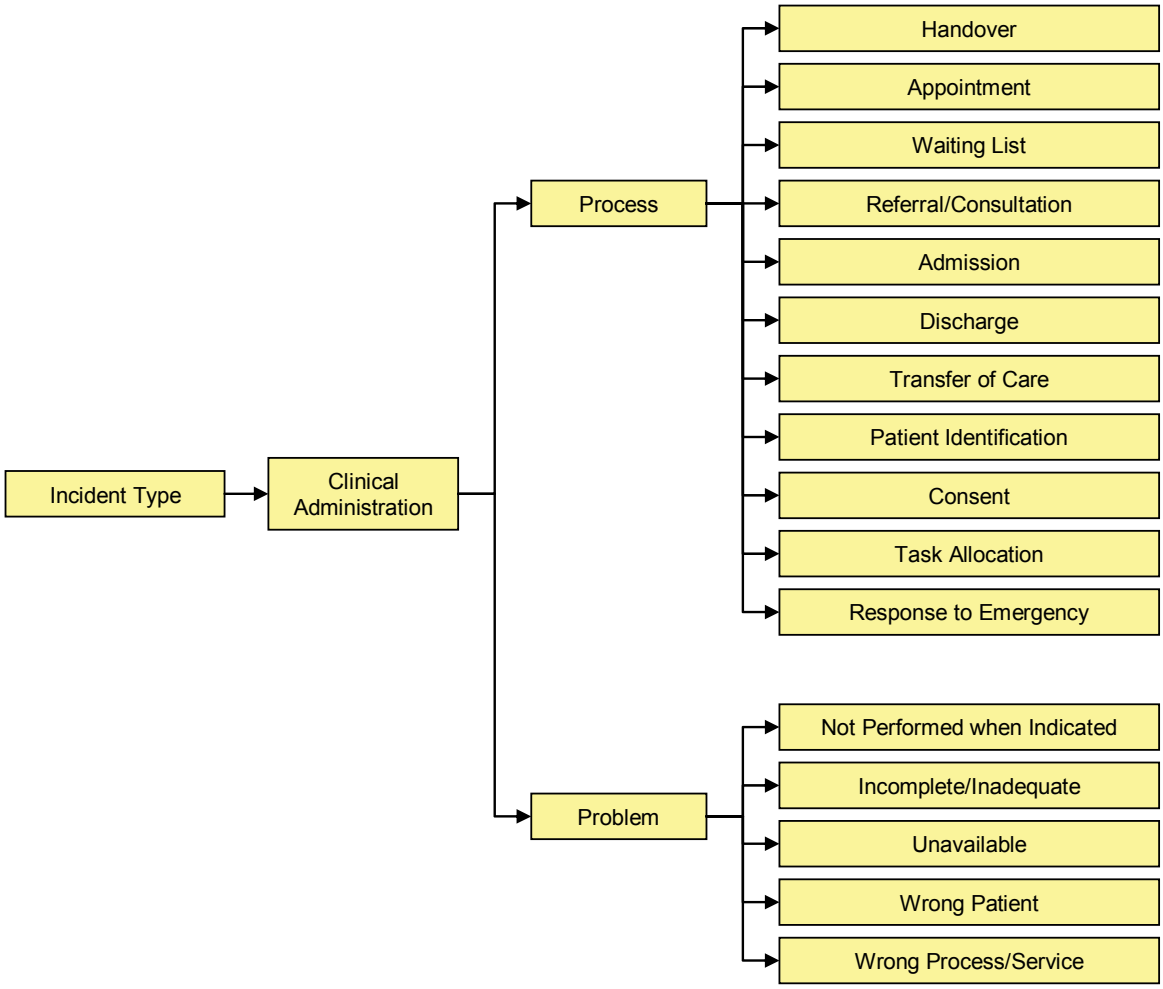
Version 1.1

World Health Organization | Patient Safety
A World Alliance for Safer Health Care

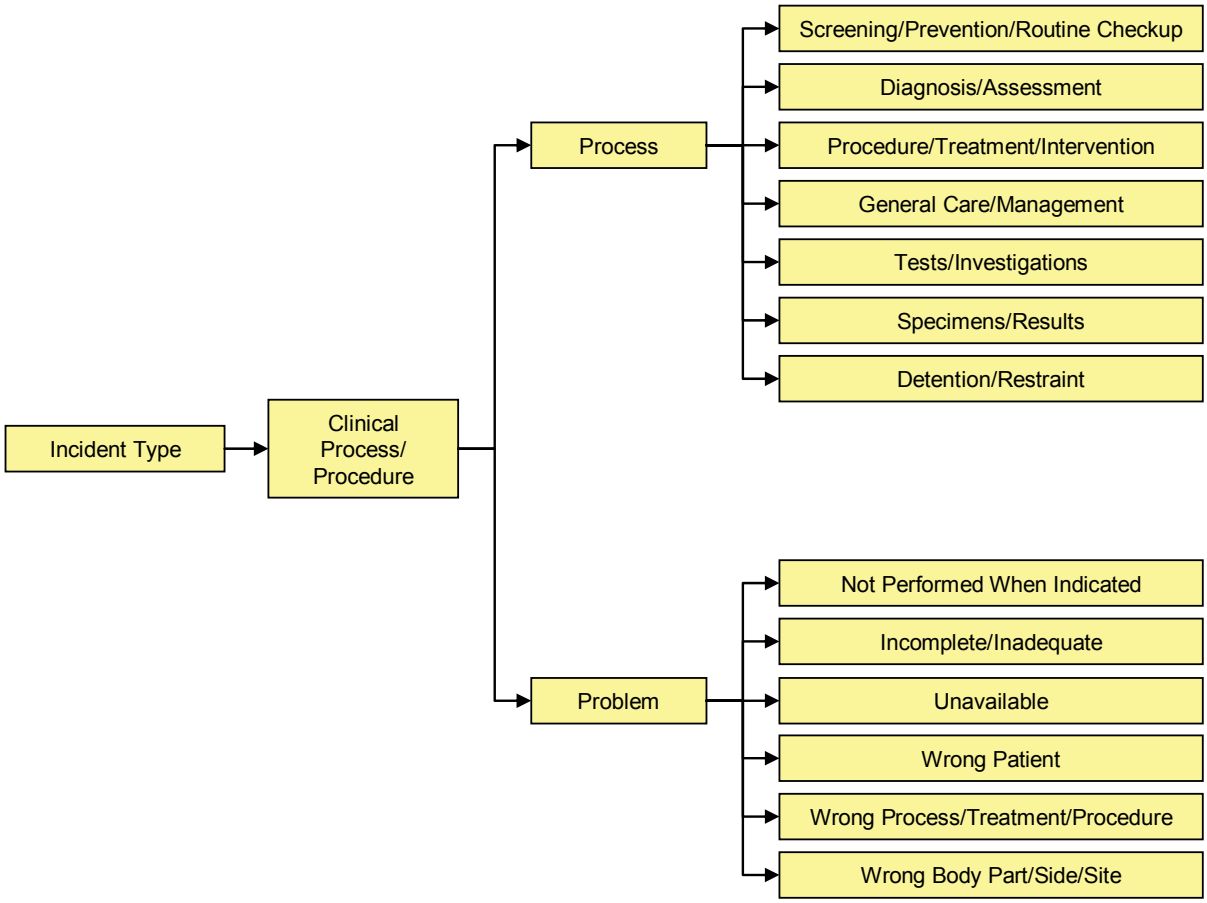
Incident Type



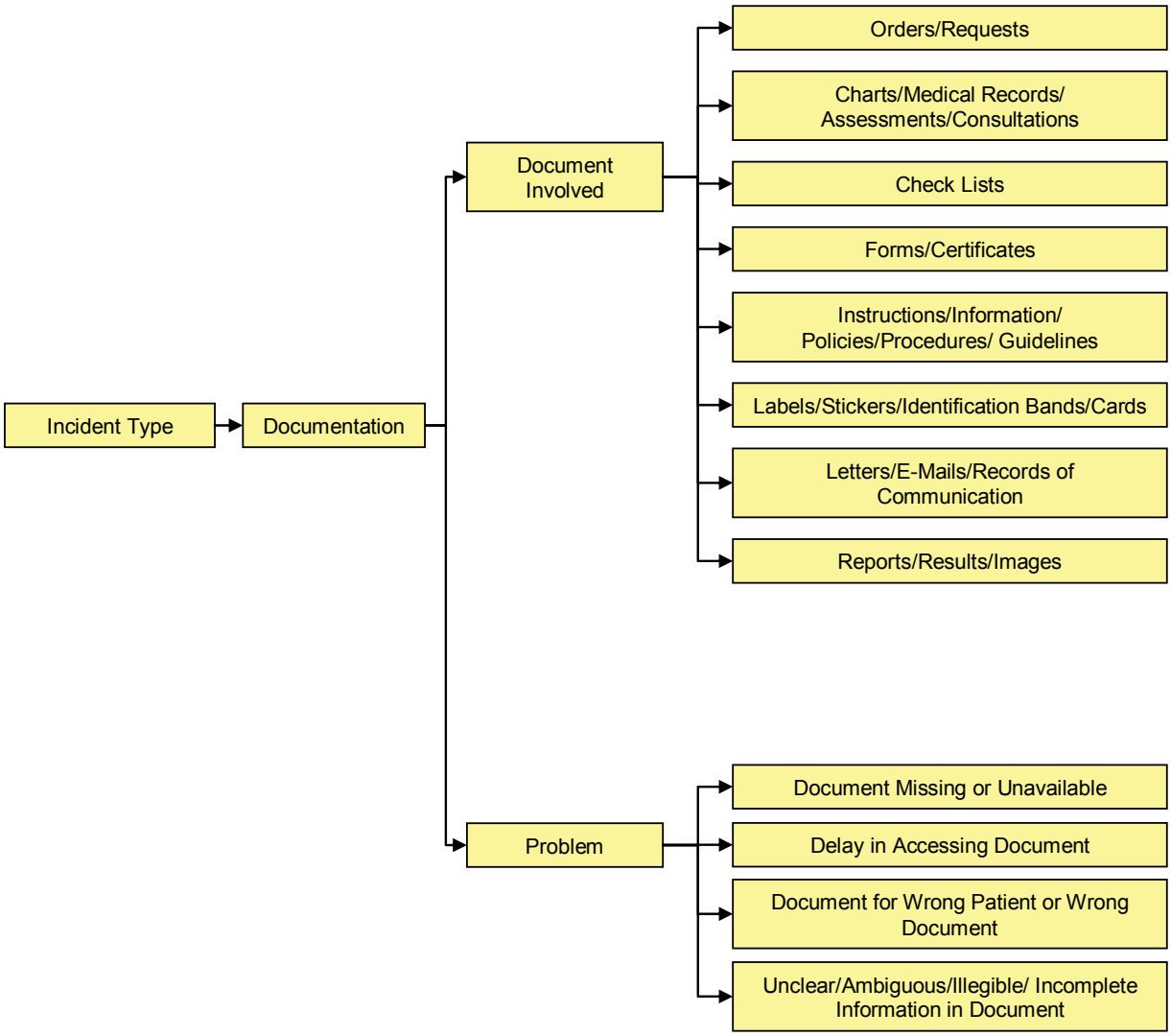
Incident Type – Clinical Administration



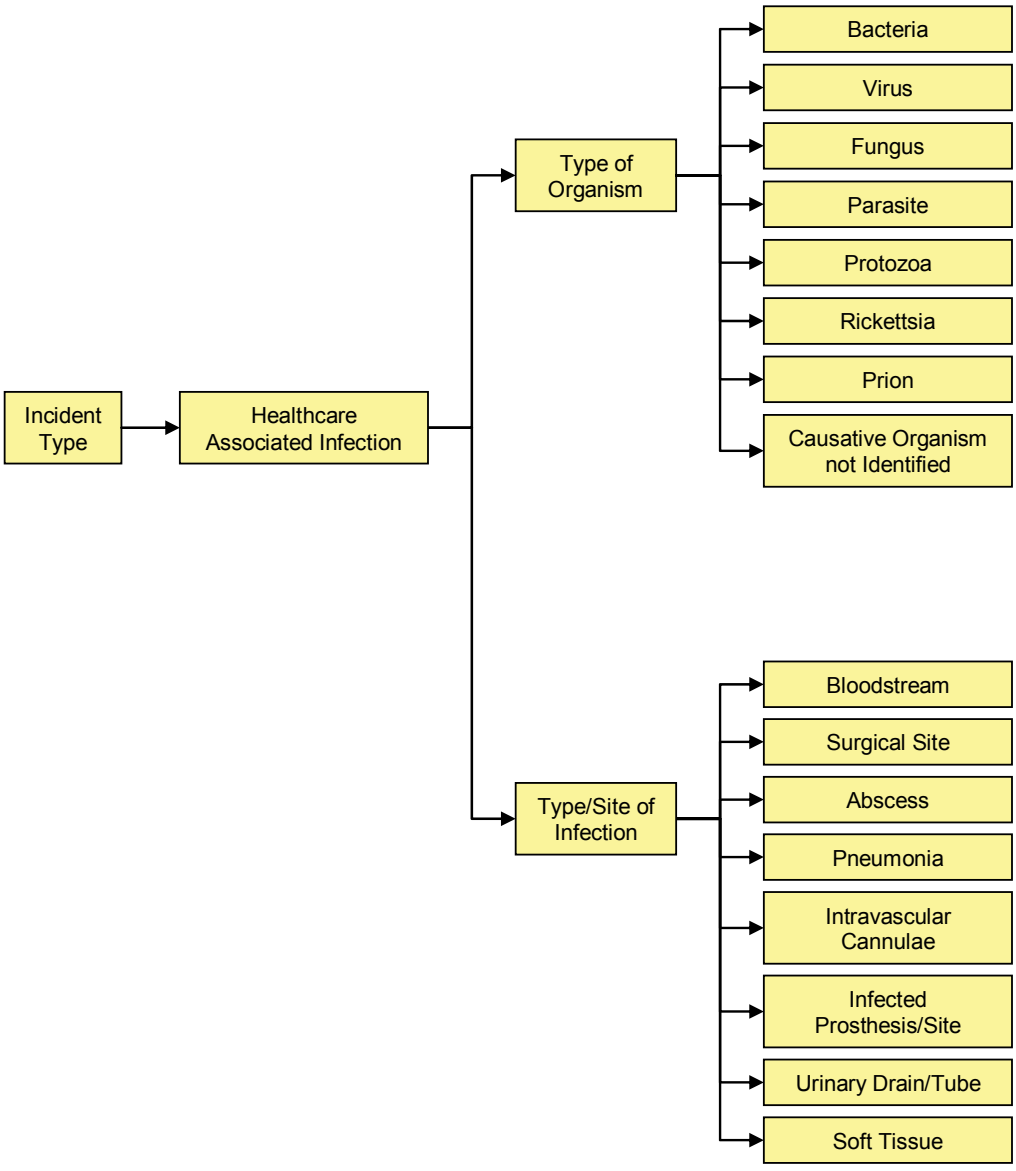
Incident Type – Clinical Process/Procedure



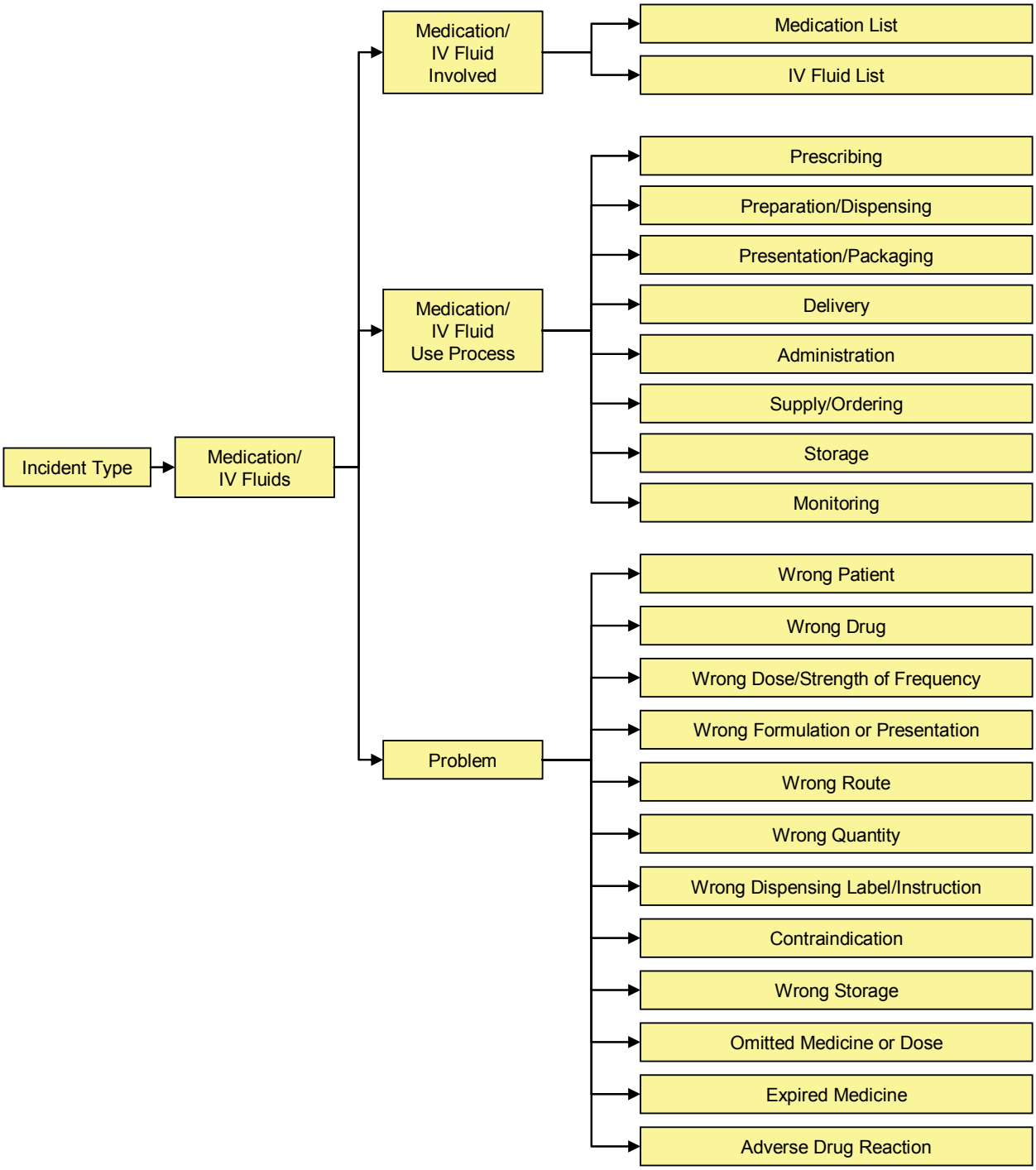
Incident Type – Documentation



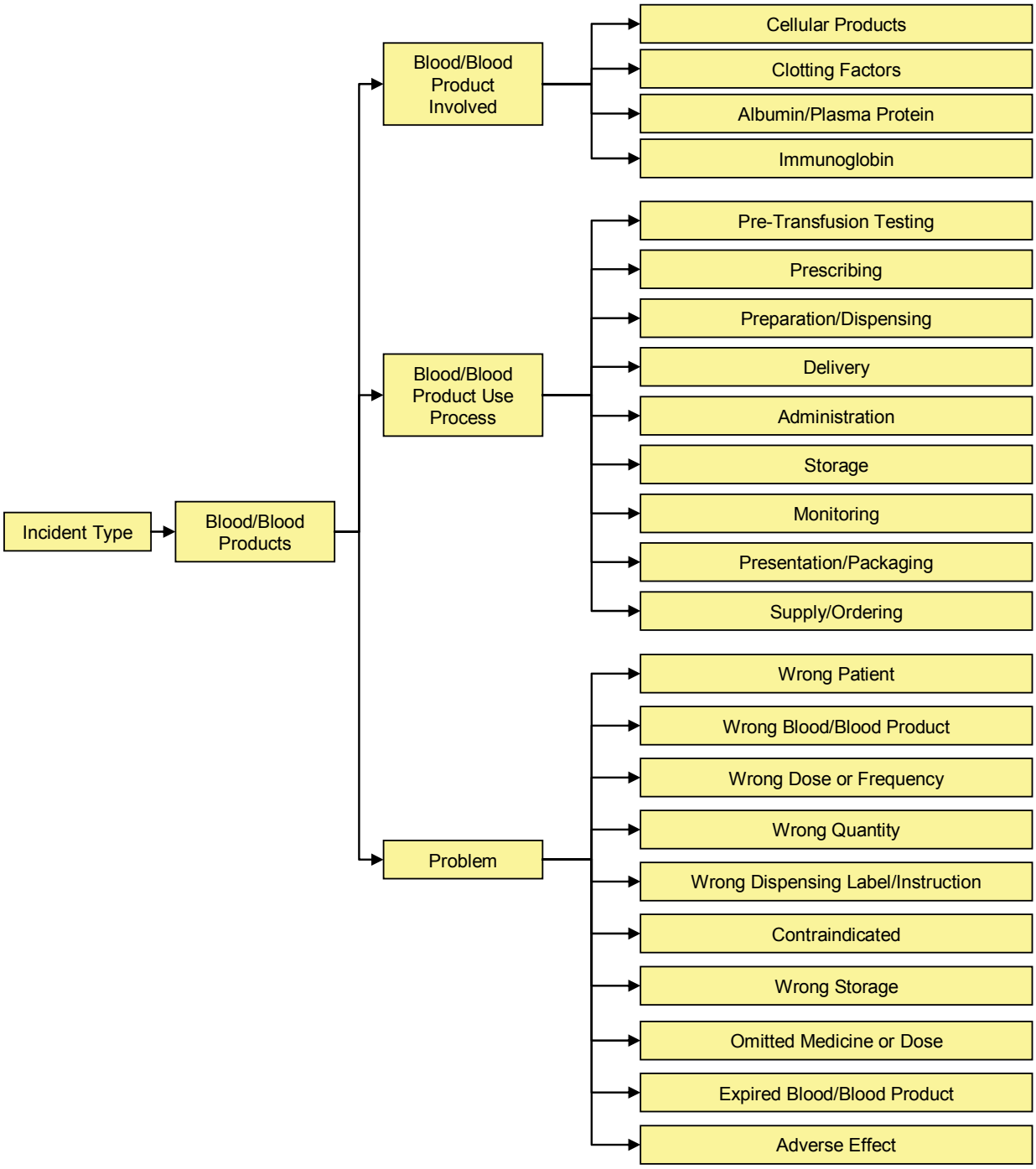
Incident Type – Healthcare Associated Infection



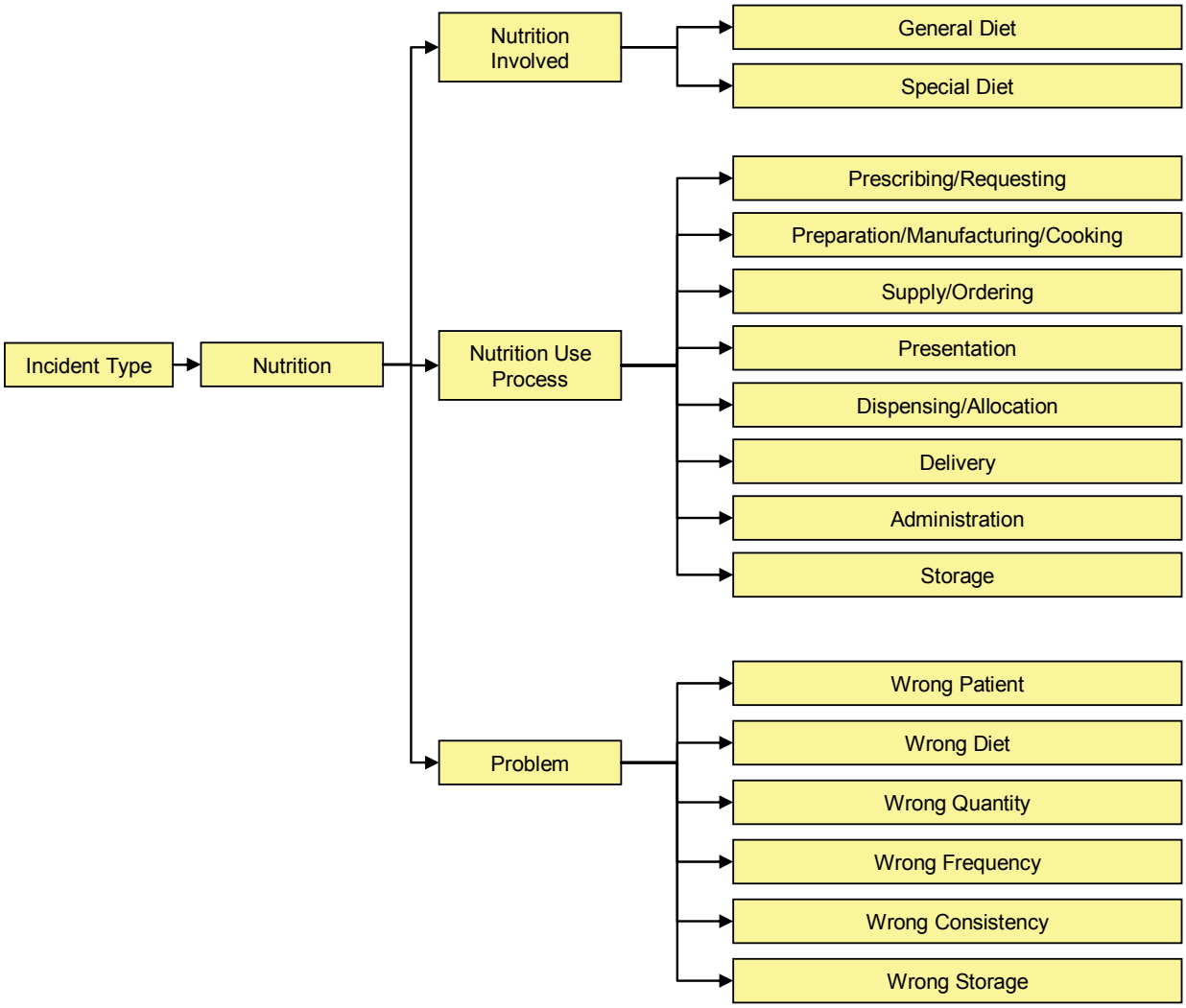
Incident Type – Medication/IV Fluids



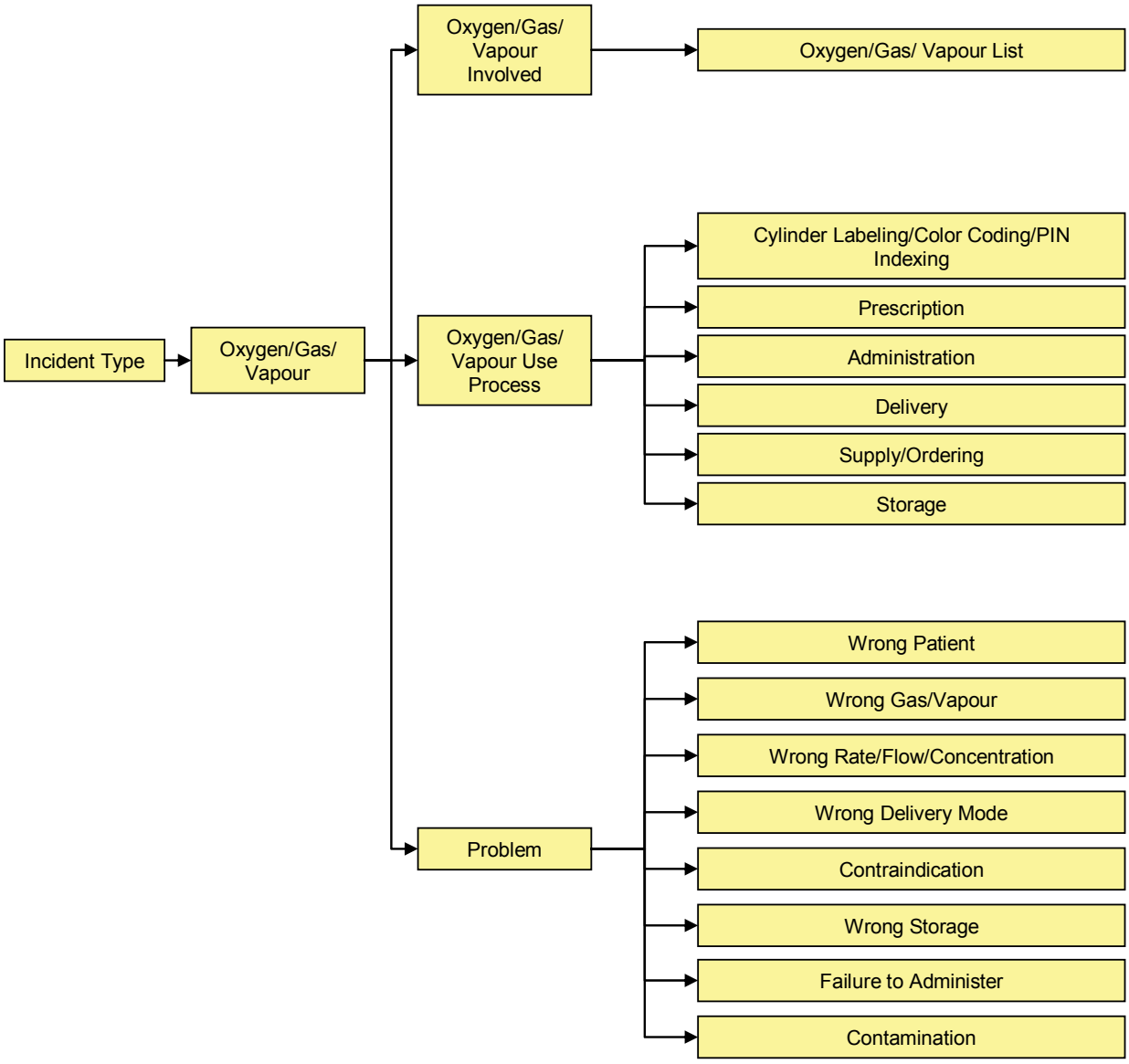
Incident Type – Blood/Blood Products



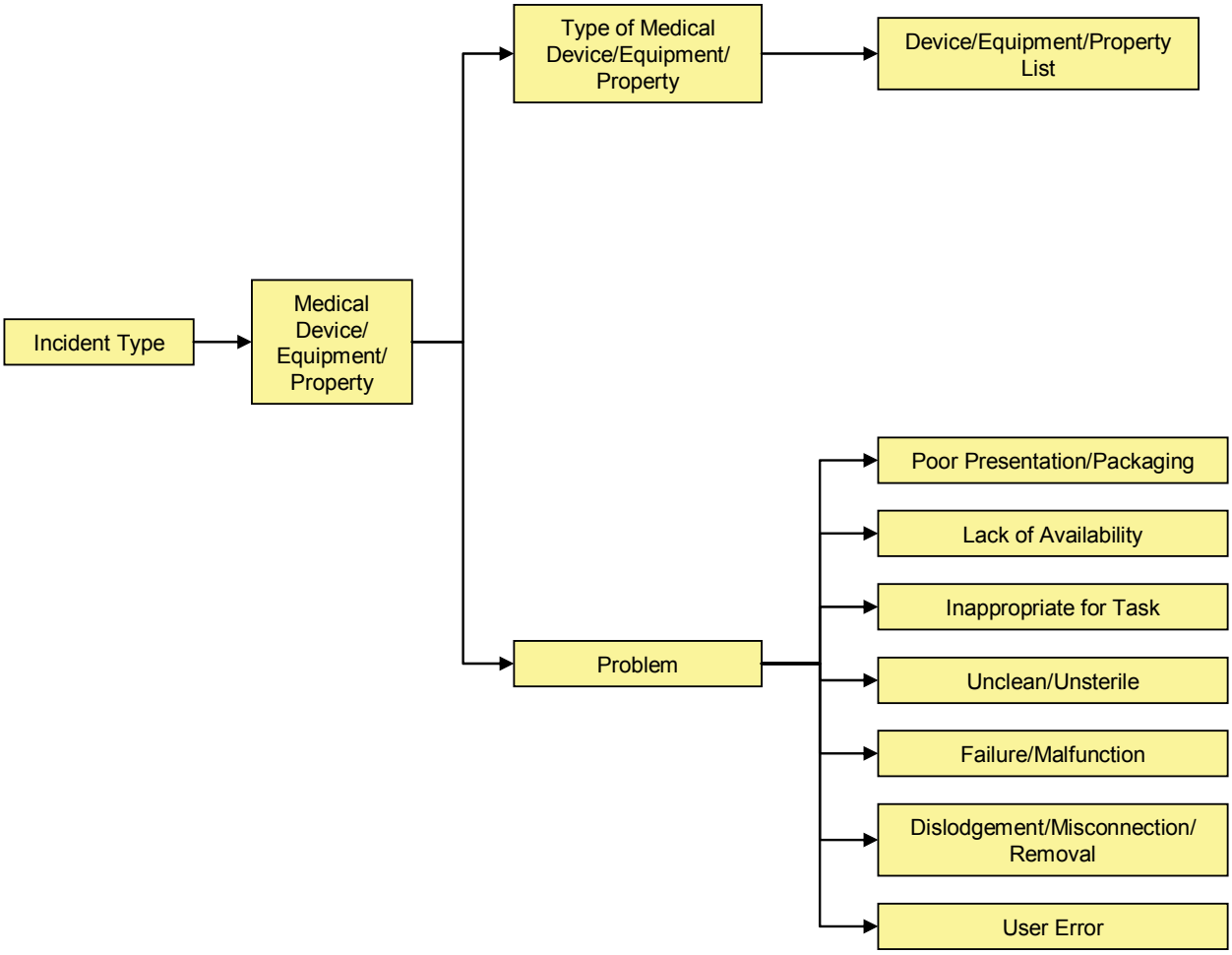
Incident Type – Nutrition



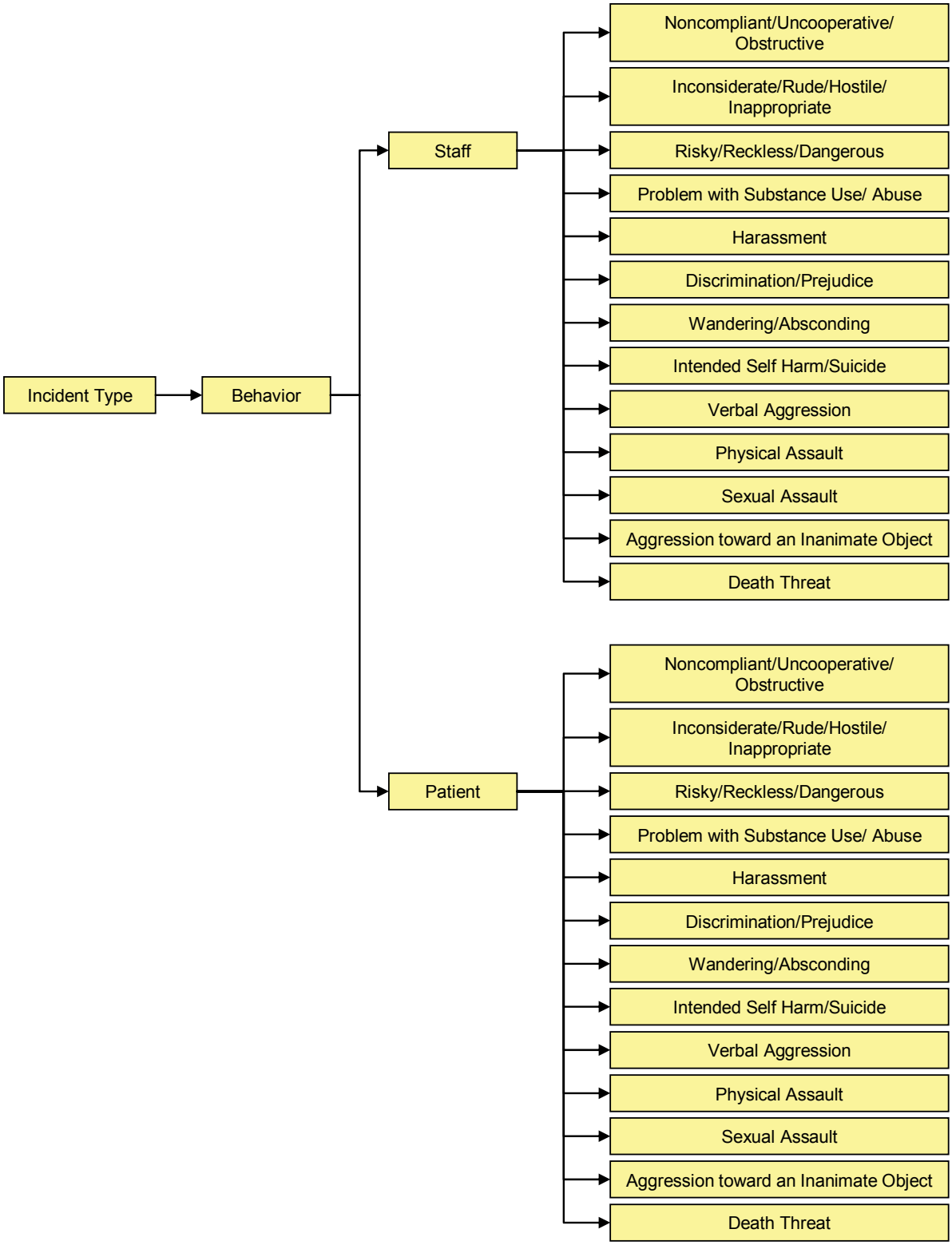
Incident Type – Oxygen/Gas/Vapour



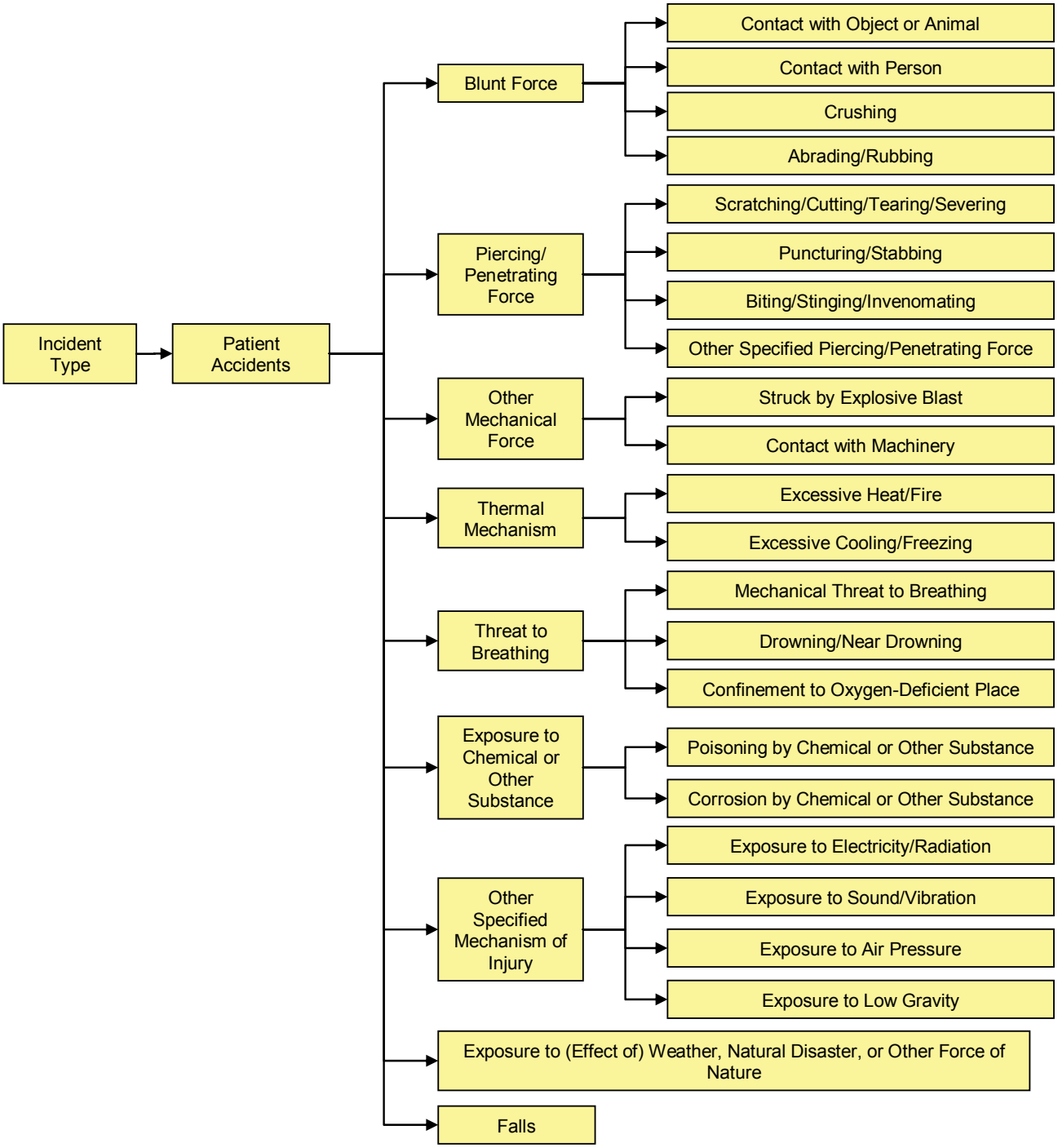
Incident Type – Medical Device/Equipment/Property



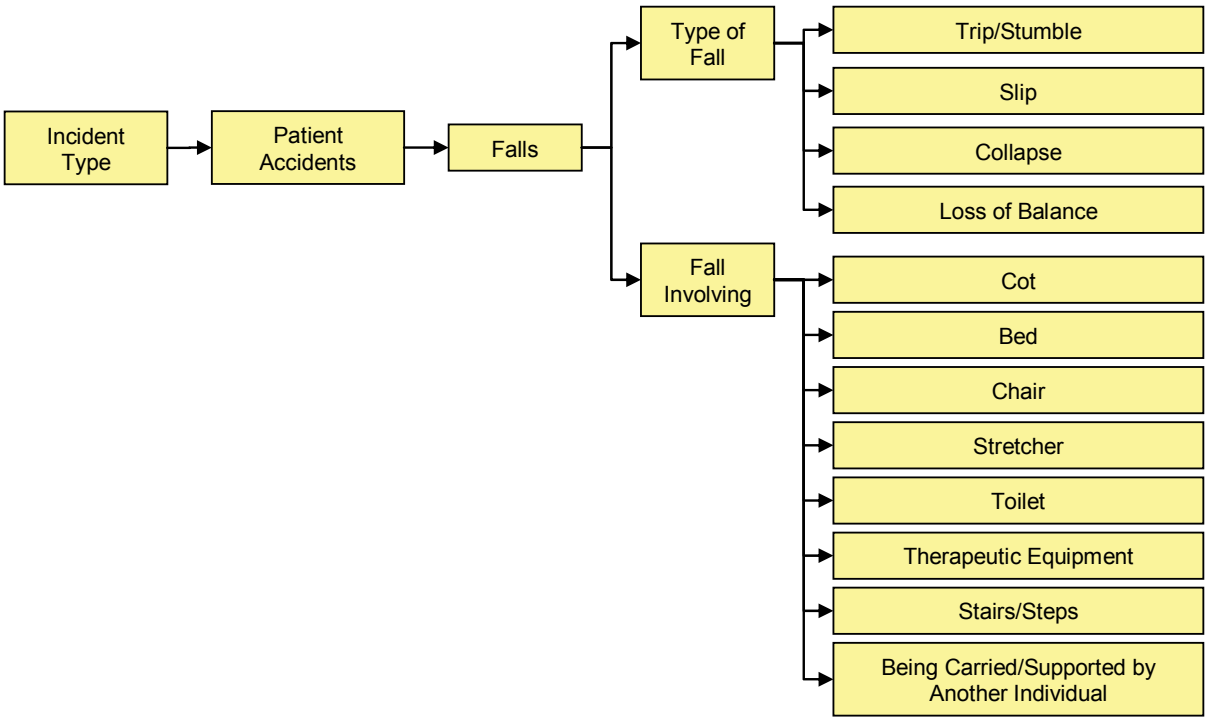
Incident Type – Behavior



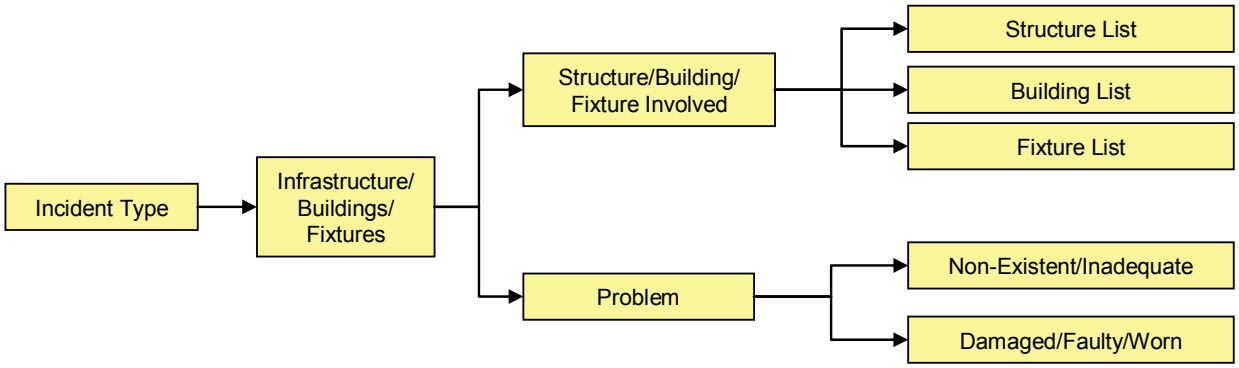
Incident Type – Patient Accidents



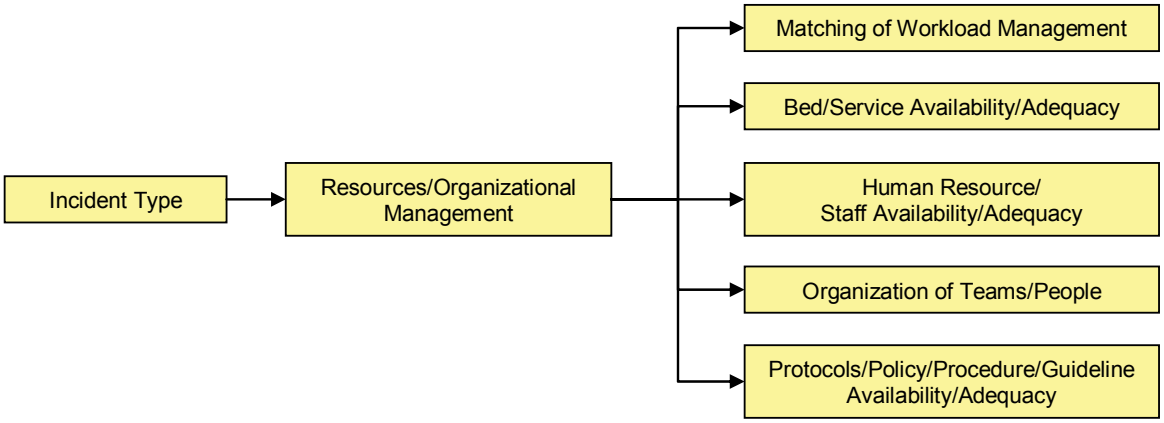
Incident Type – Patient Accidents – Falls



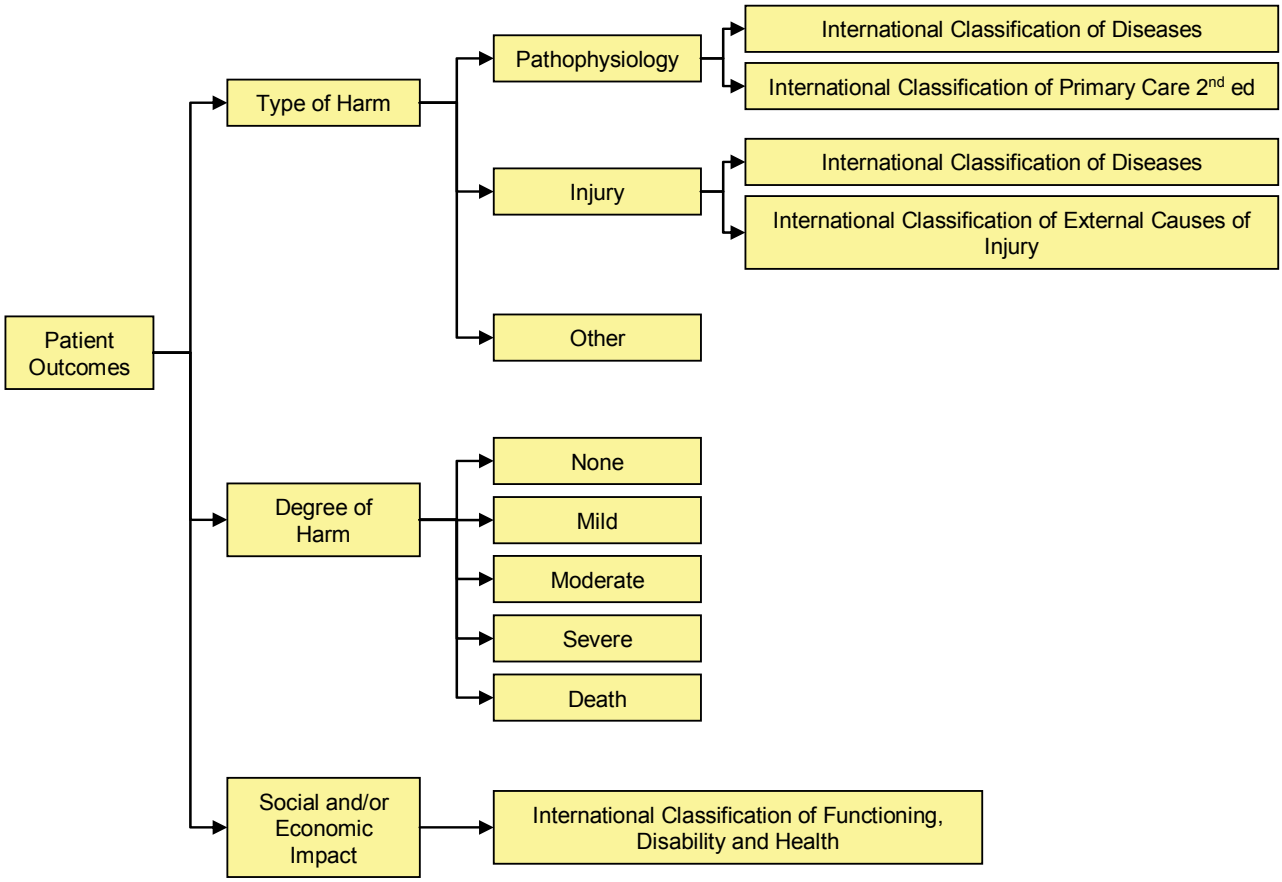
Incident Type – Infrastructure/Buildings/Fixtures



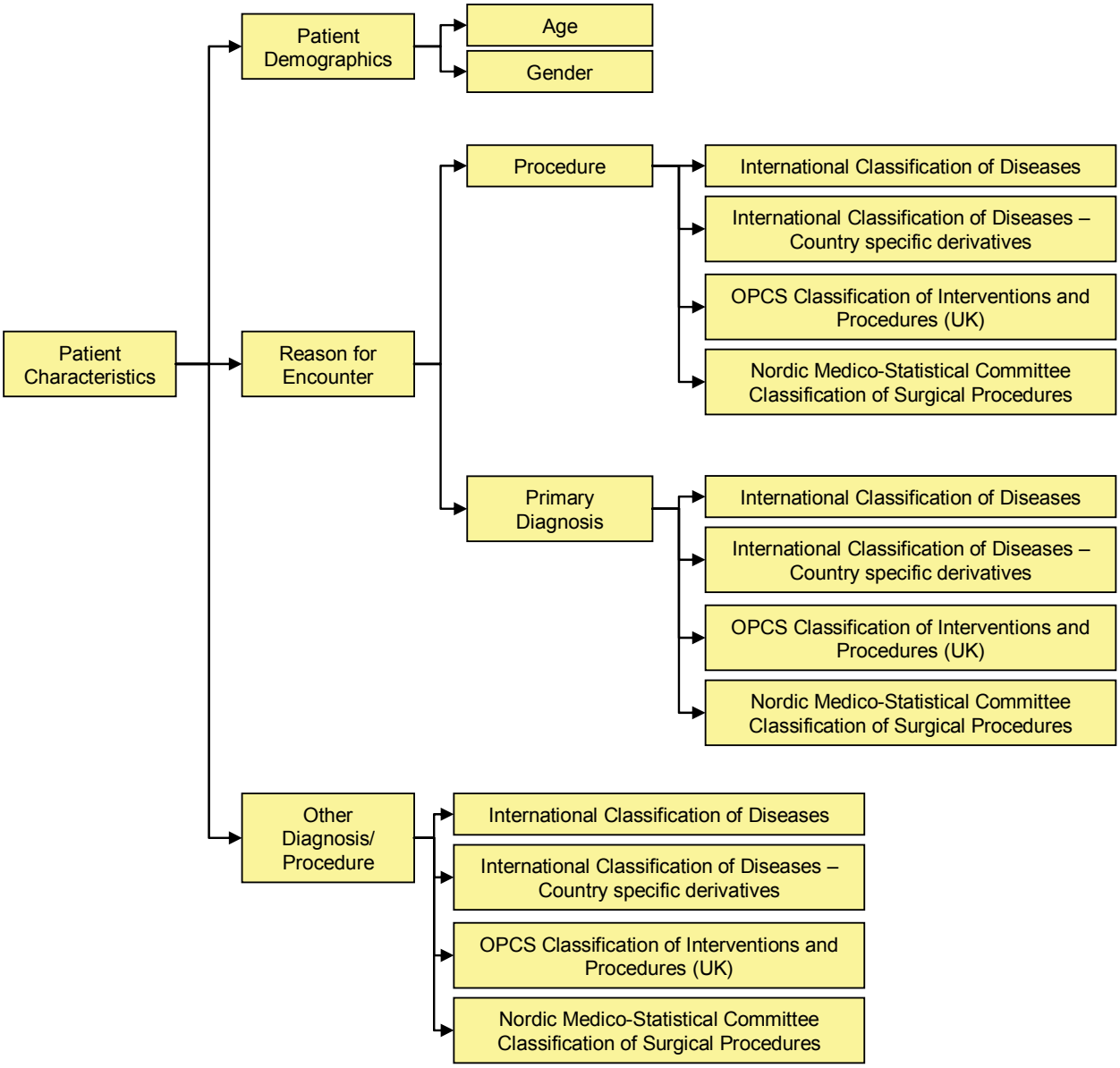
Incident Type – Resources/Organizational Management



Patient Outcomes



Patient Characteristics



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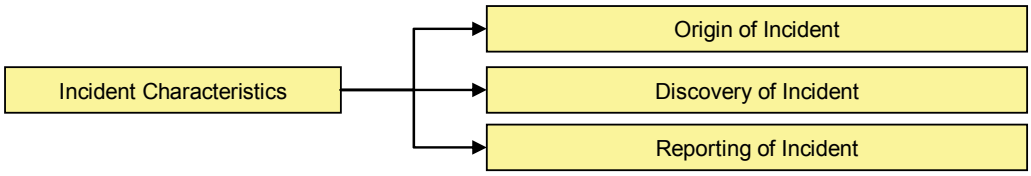
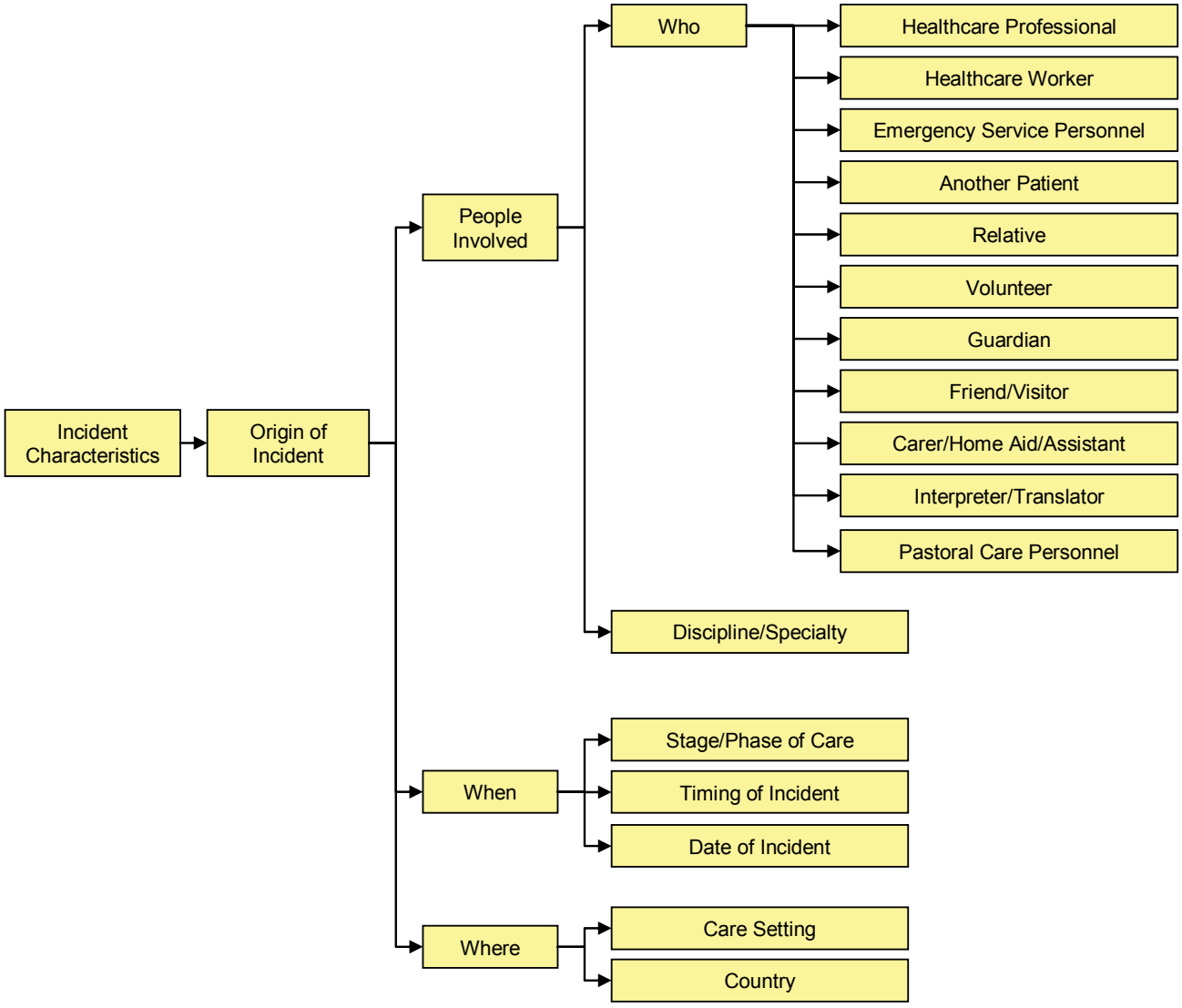
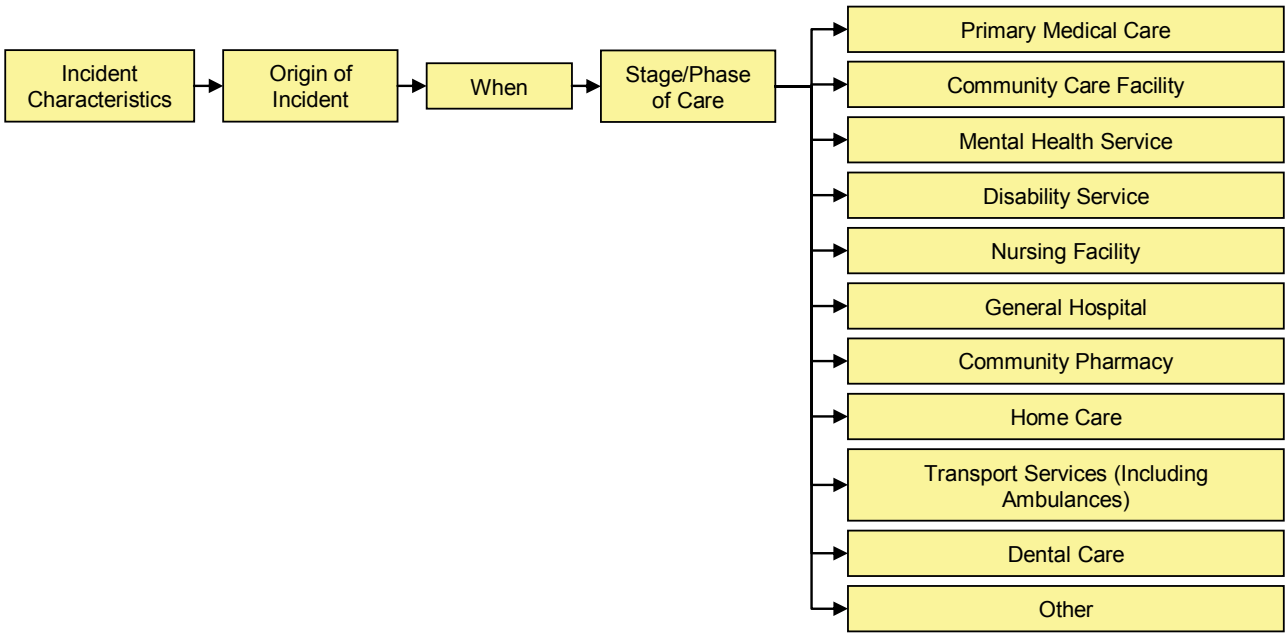


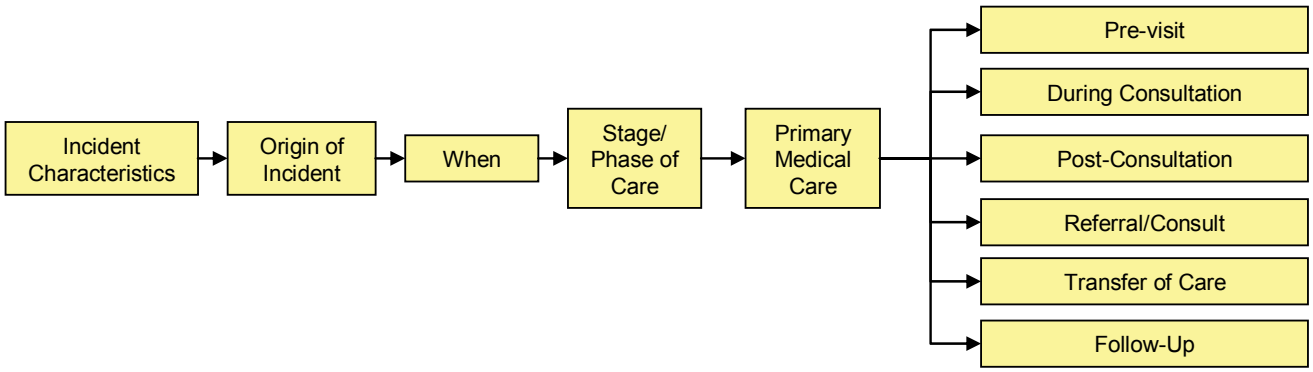
Incident Characteristics – Origin of Incident



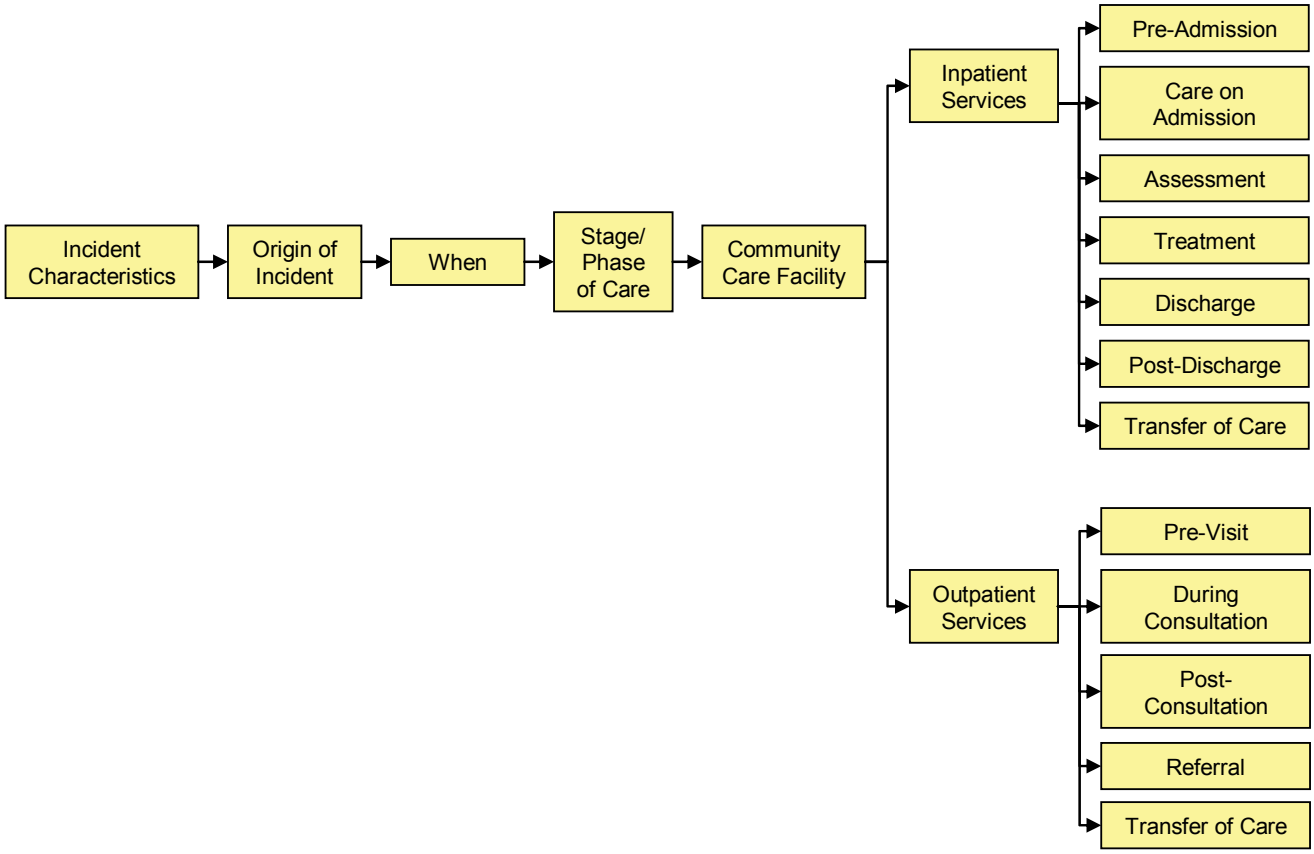
Incident Characteristics –
Origin of Incident – When – Stage/Phase of Care



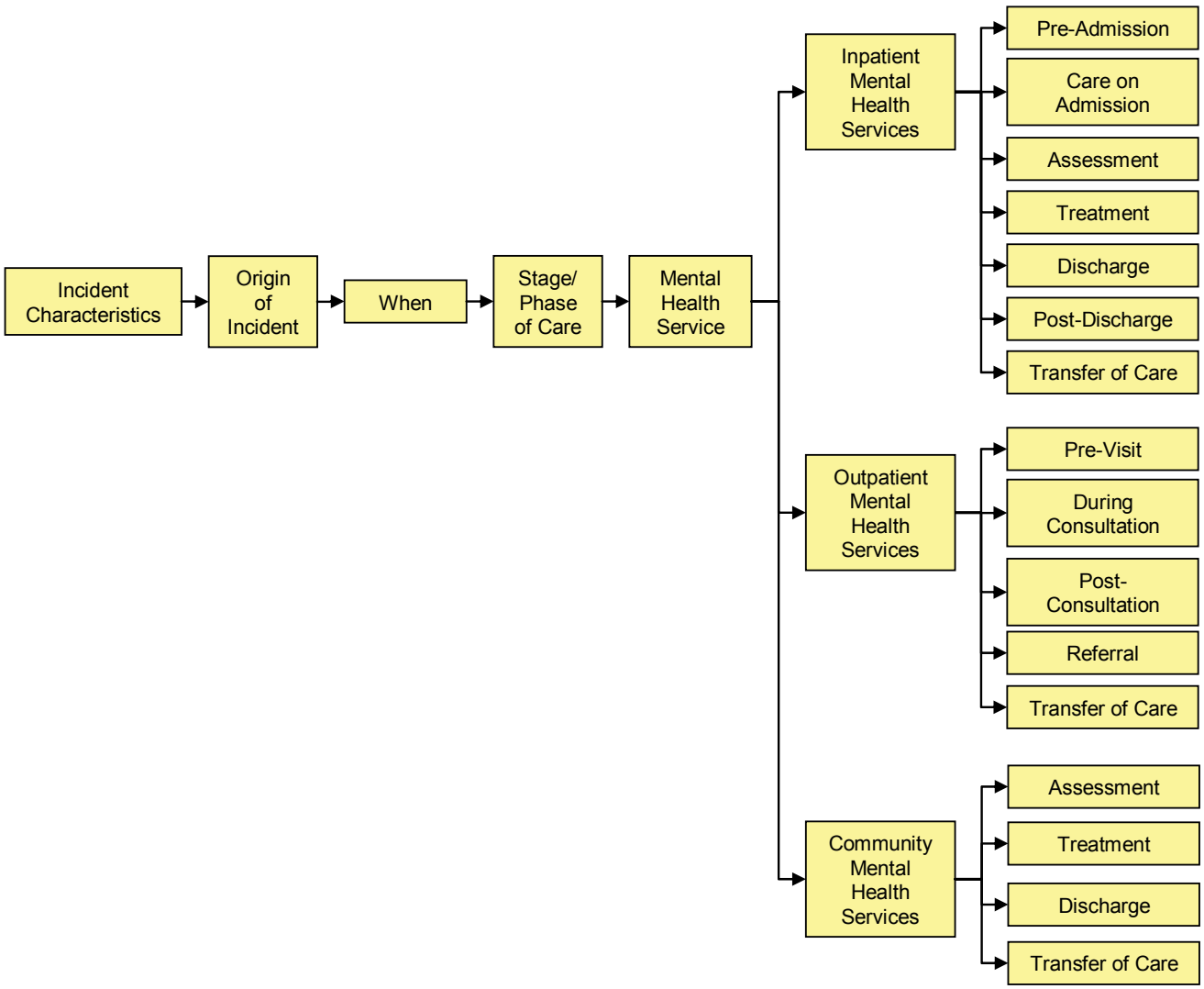
Incident Characteristics –
Origin of Incident – When – Stage/Phase of Care



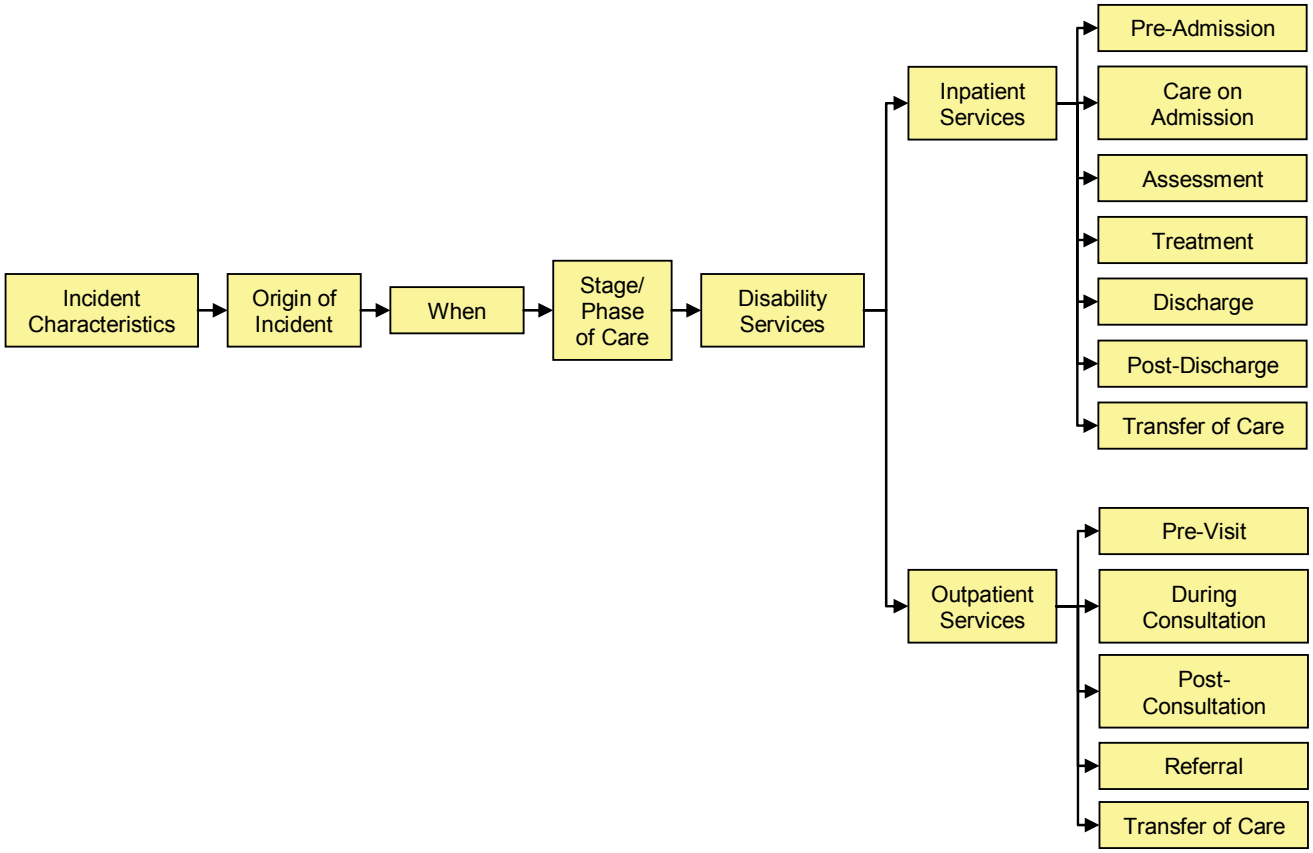
Incident Characteristics –
Origin of Incident – When – Stage/Phase of Care



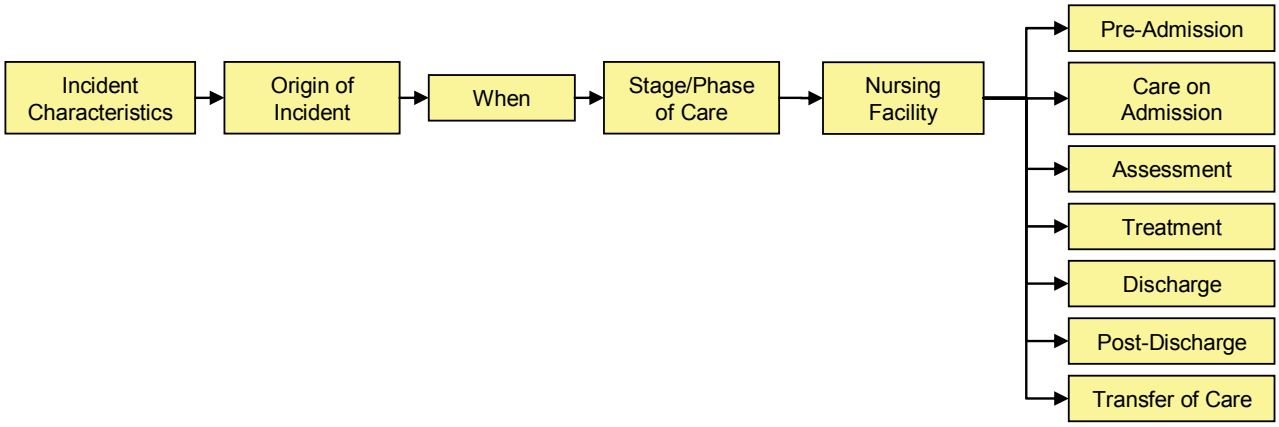
Incident Characteristics –
Origin of Incident – When – Stage/Phase of Care



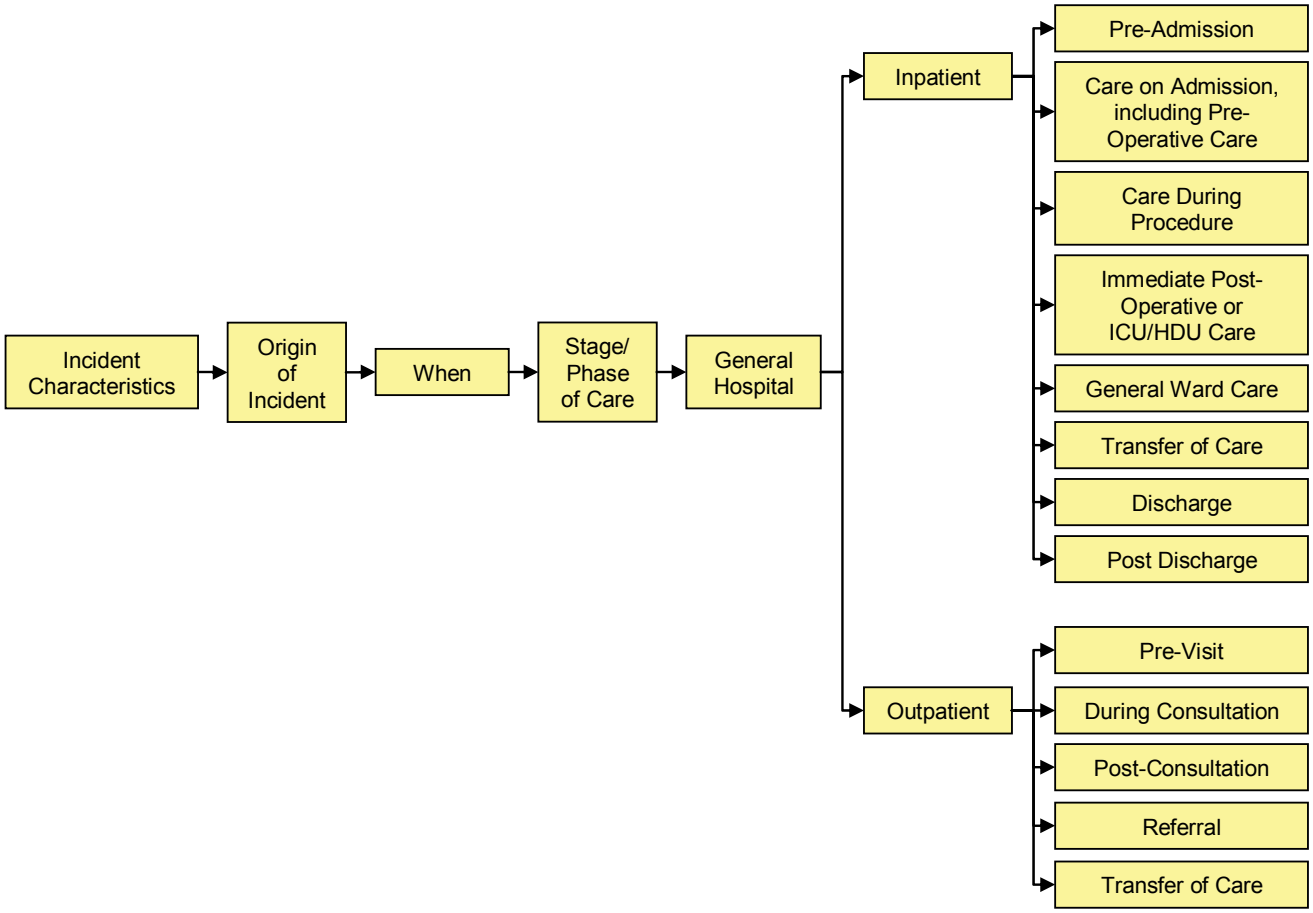
Incident Characteristics –
Origin of Incident – When – Stage/Phase of Care



Incident Characteristics –
Origin of Incident – When – Stage/Phase of Care



Incident Characteristics –
Origin of Incident – When – Stage/Phase of Care



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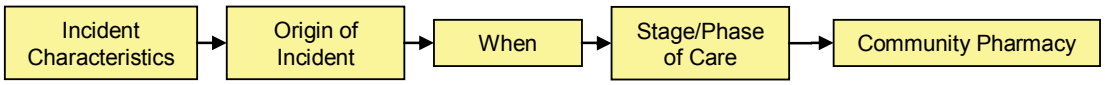
Origin of Incident – When – Stage/Phase of Care



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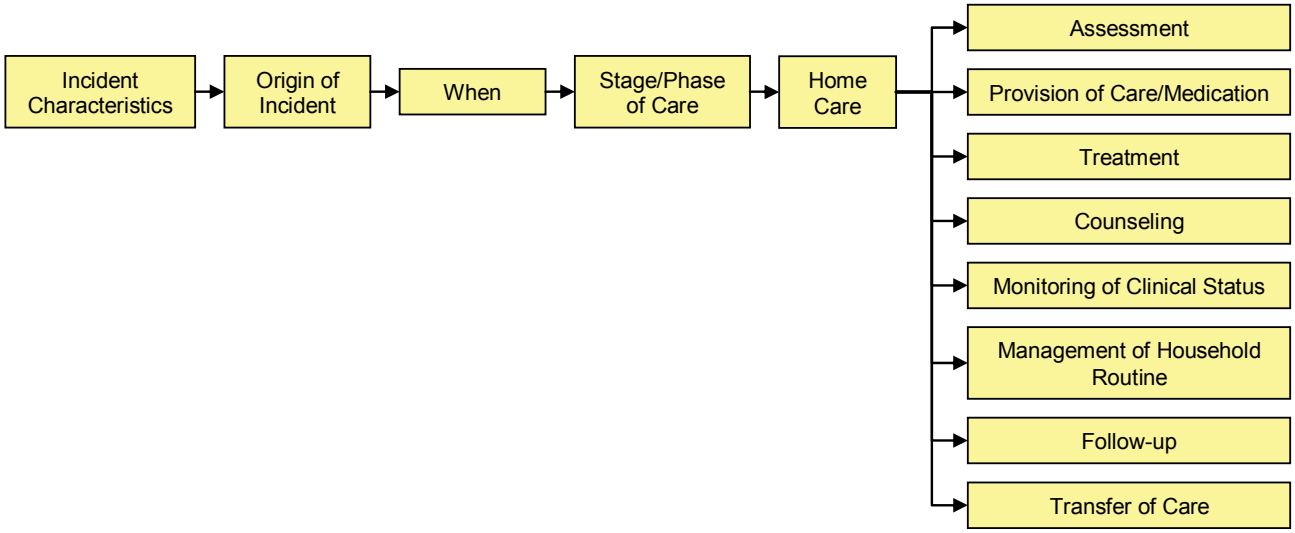
Origin of Incident – When – Stage/Phase of Care



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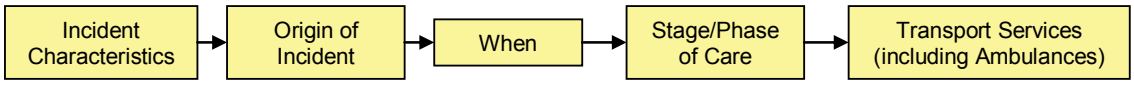
Origin of Incident – When – Stage/Phase of Care



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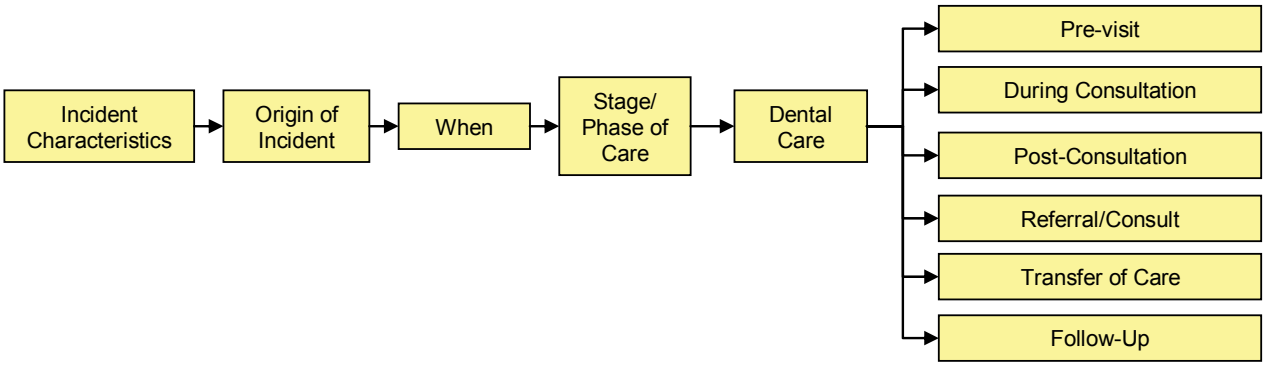
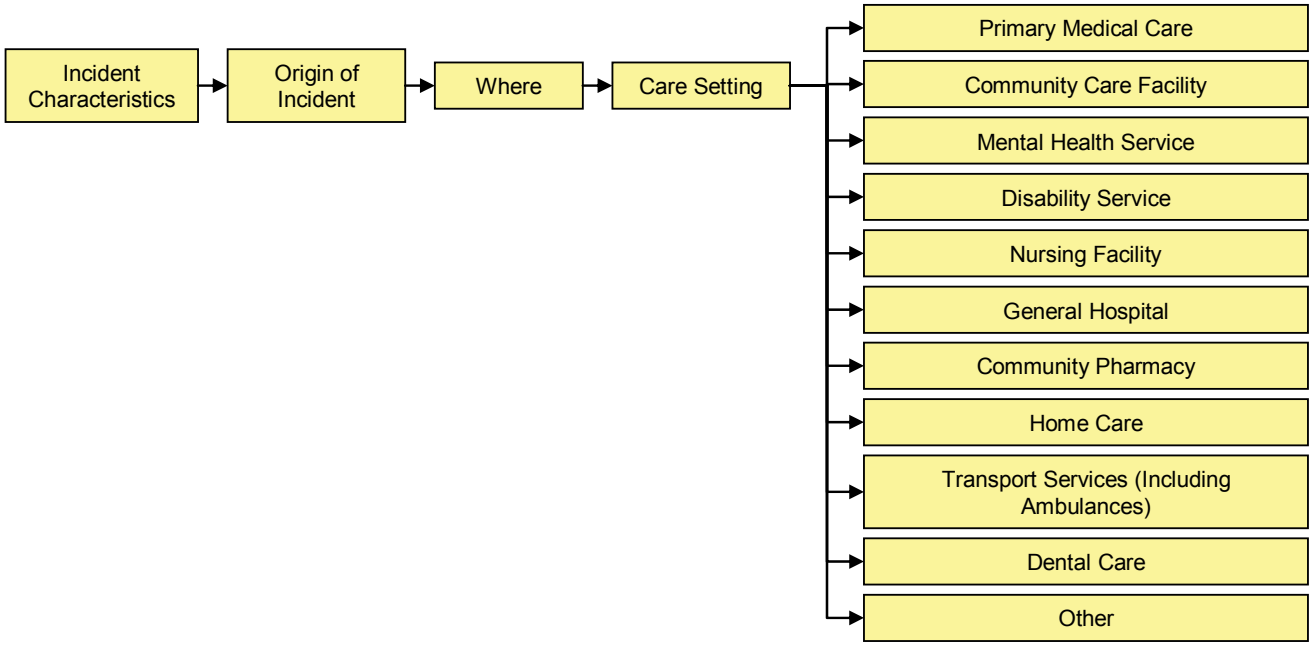
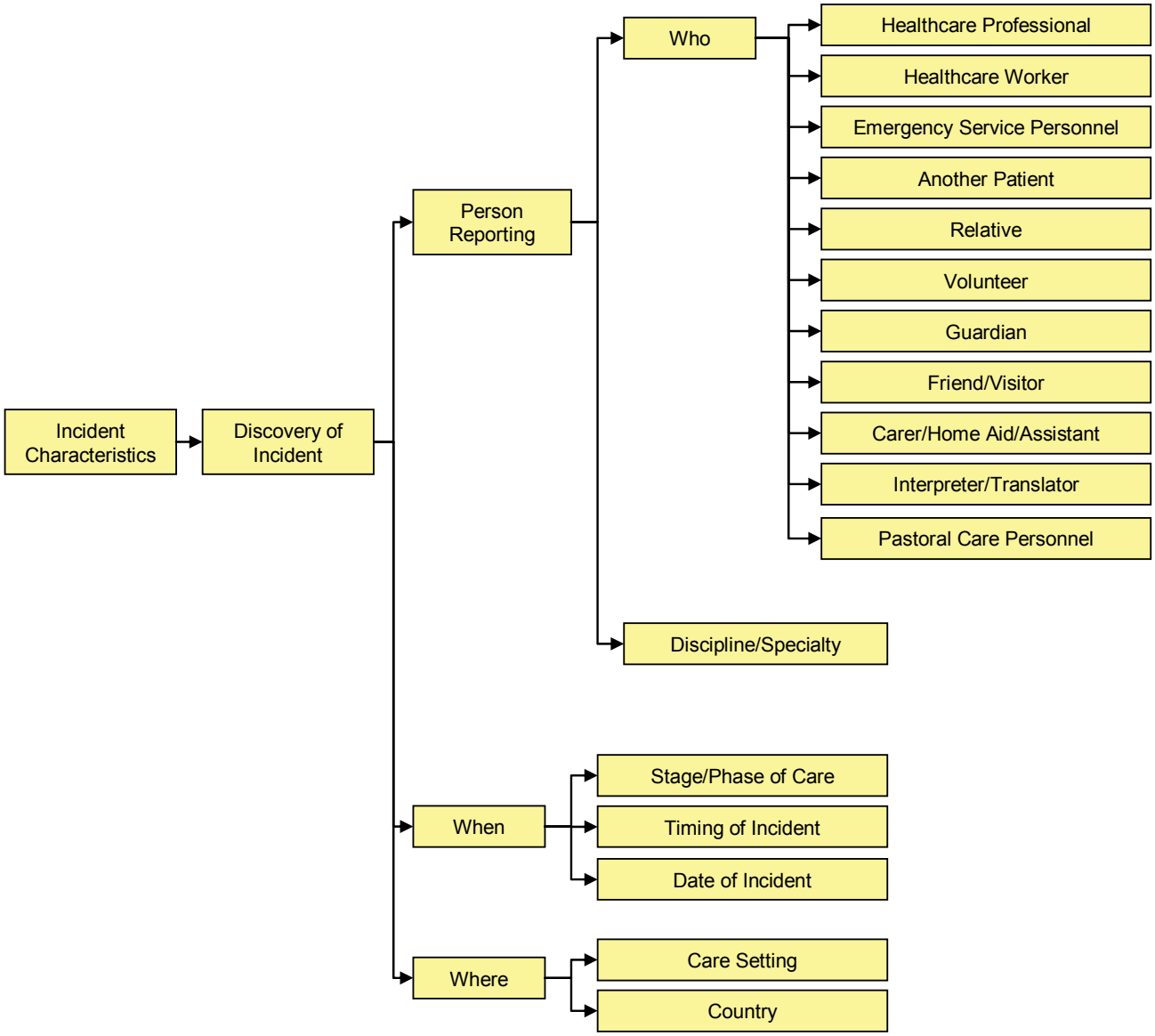
Origin of Incident – When – Stage/Phase of Care



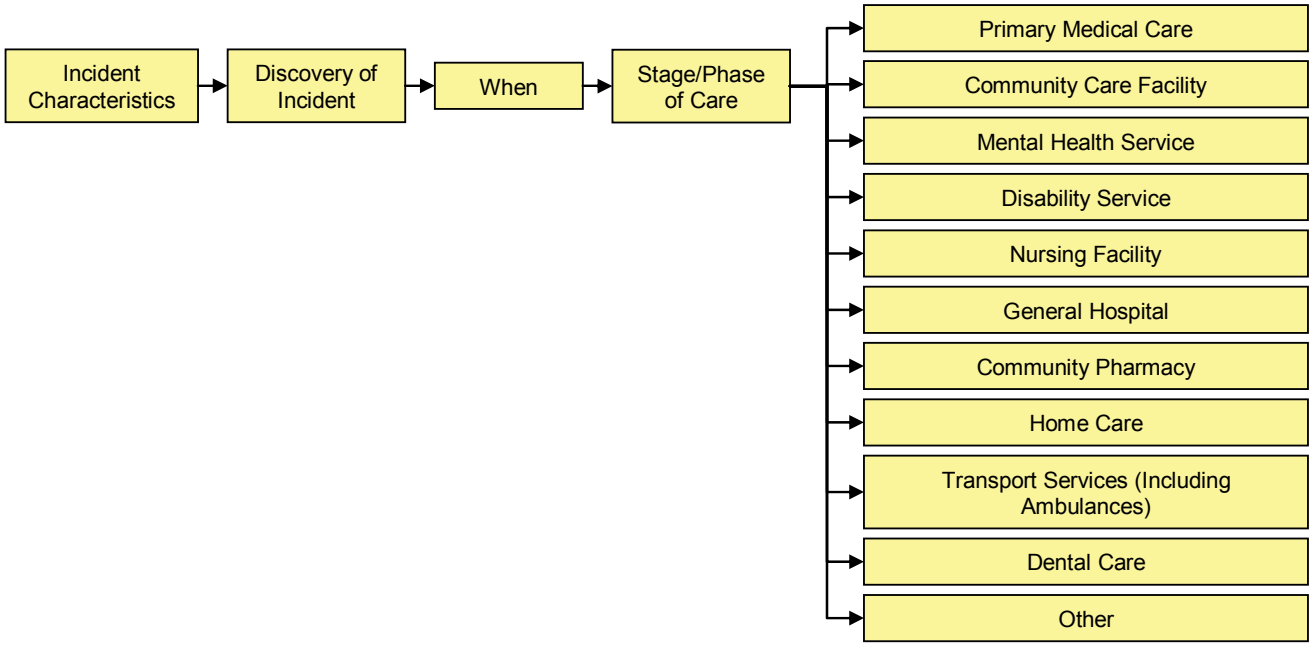
Incident Characteristics –
Origin of Incident – Where – Care Setting



Incident Characteristics – Discovery of Incident



Incident Characteristics –
Discovery of Incident – When – Stage/Phase of Care



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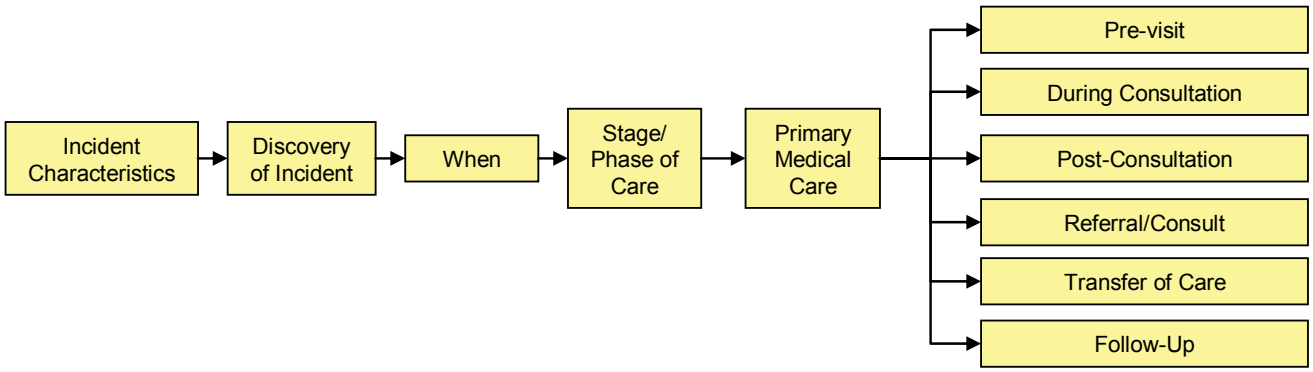
Discovery of Incident – When – Stage/Phase of Care



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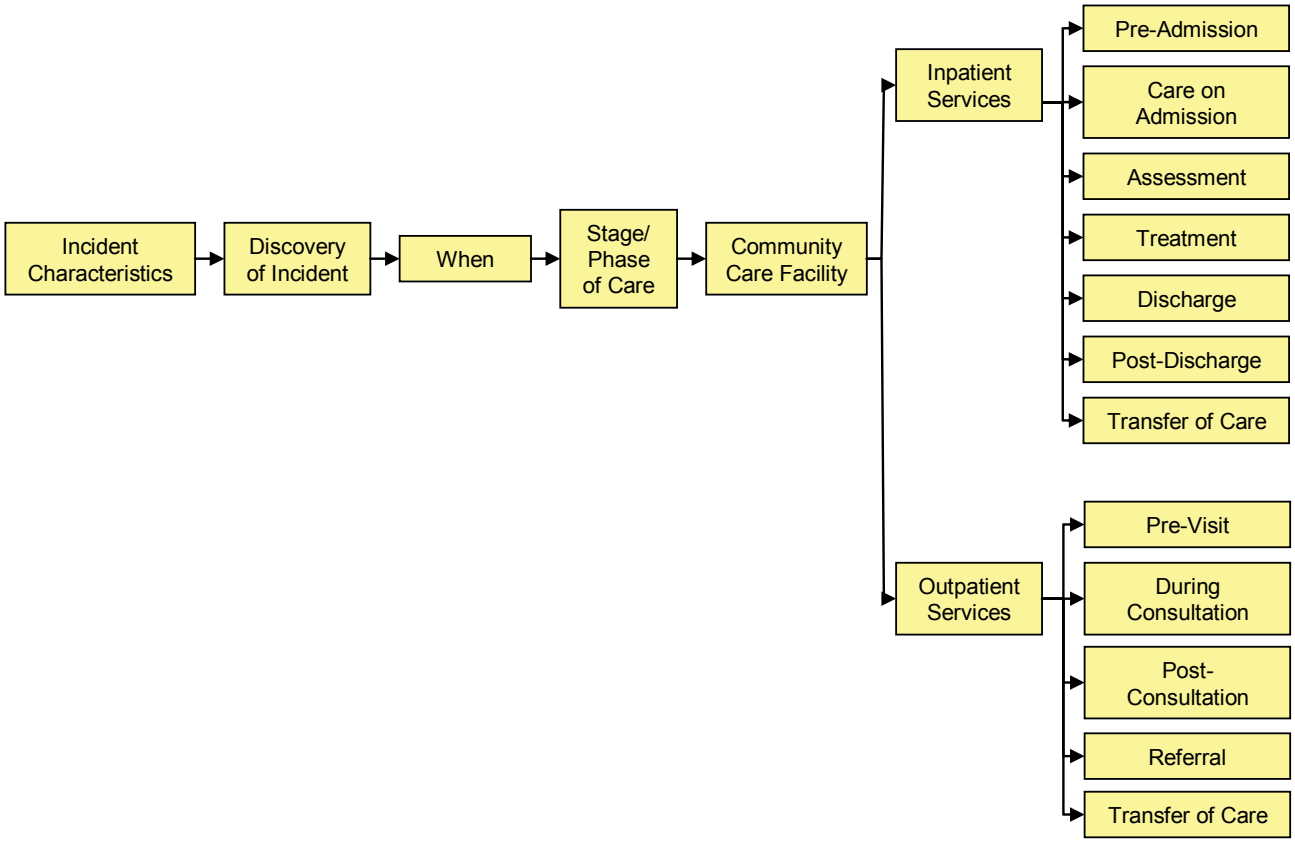
Discovery of Incident – When – Stage/Phase of Care



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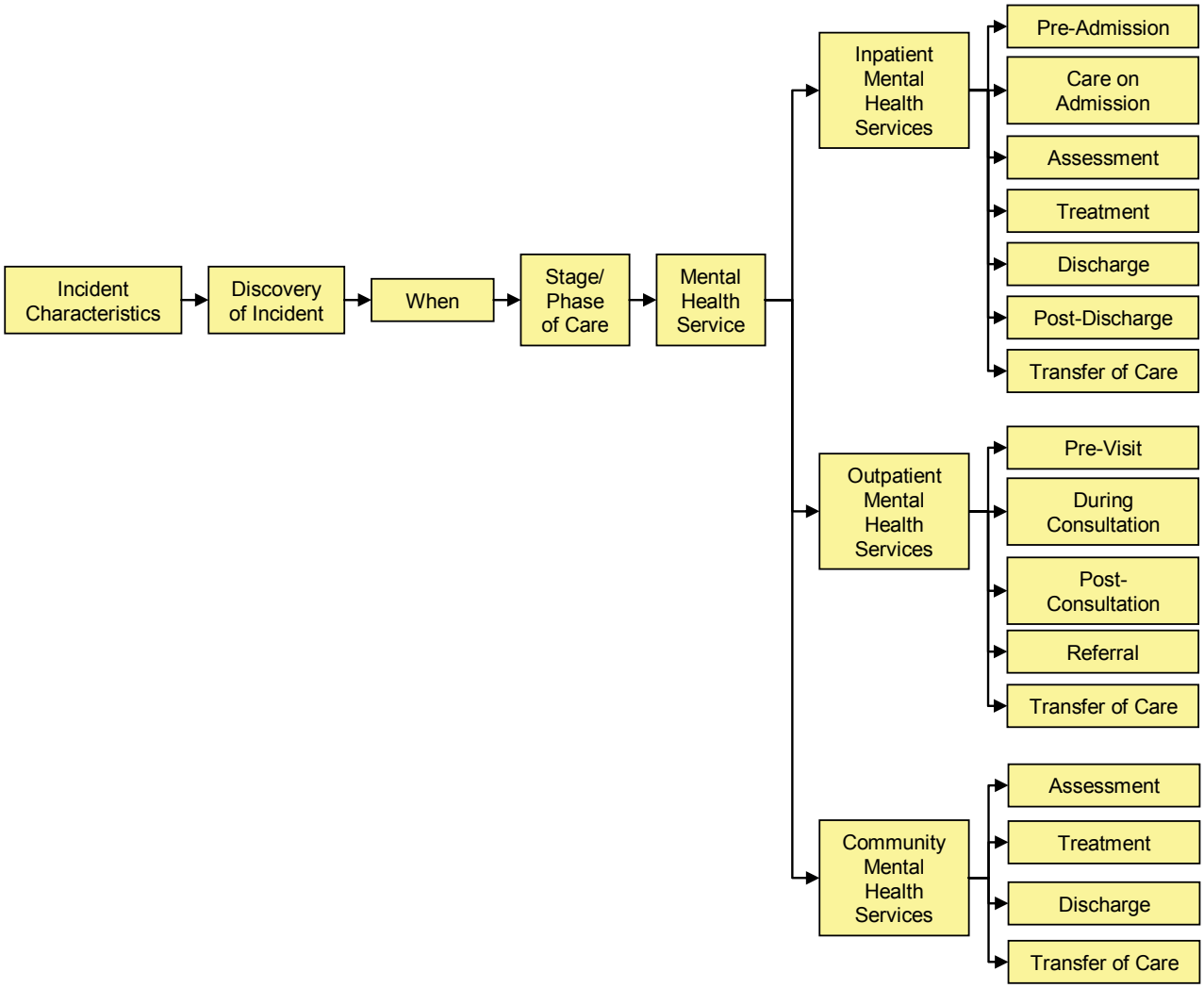
Discovery of Incident – When – Stage/Phase of Care



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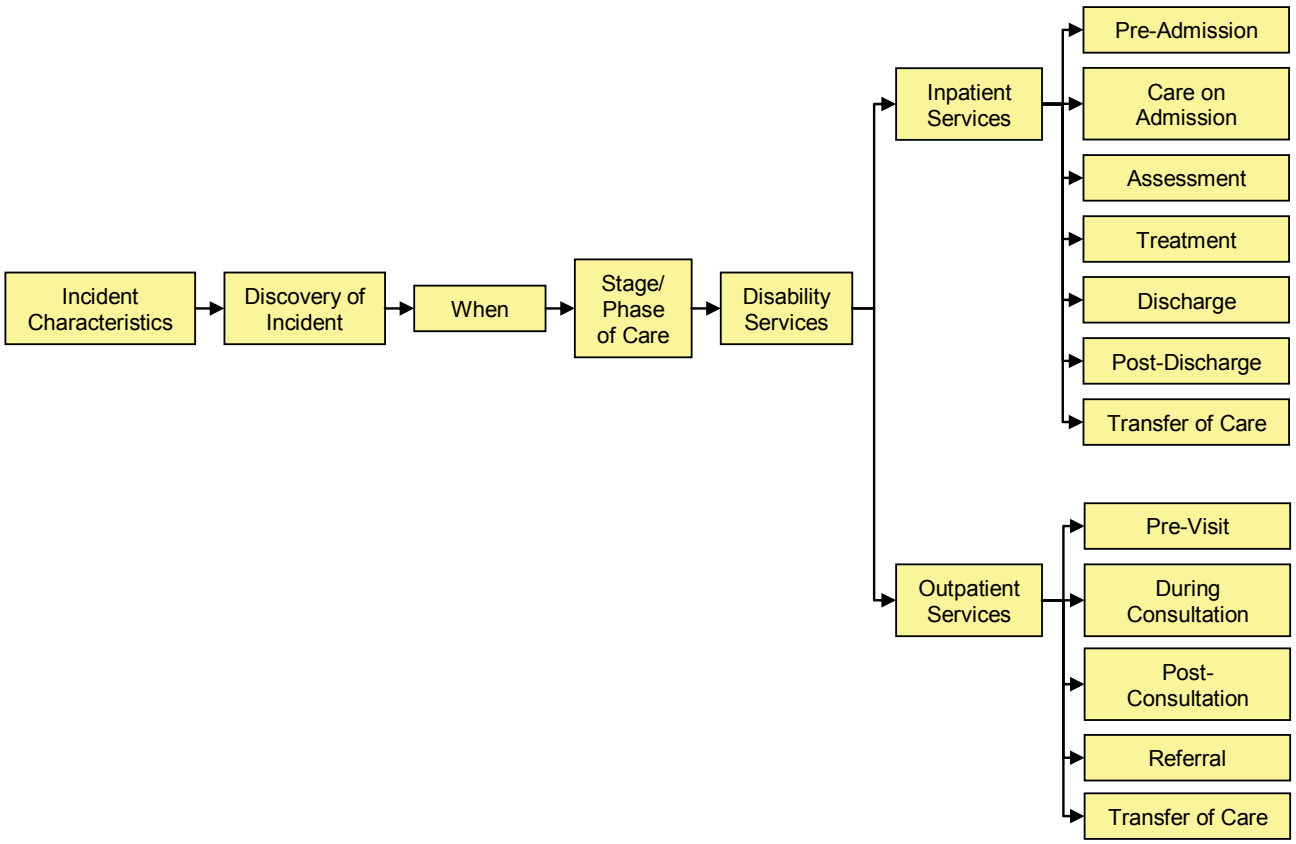
Discovery of Incident – When – Stage/Phase of Care



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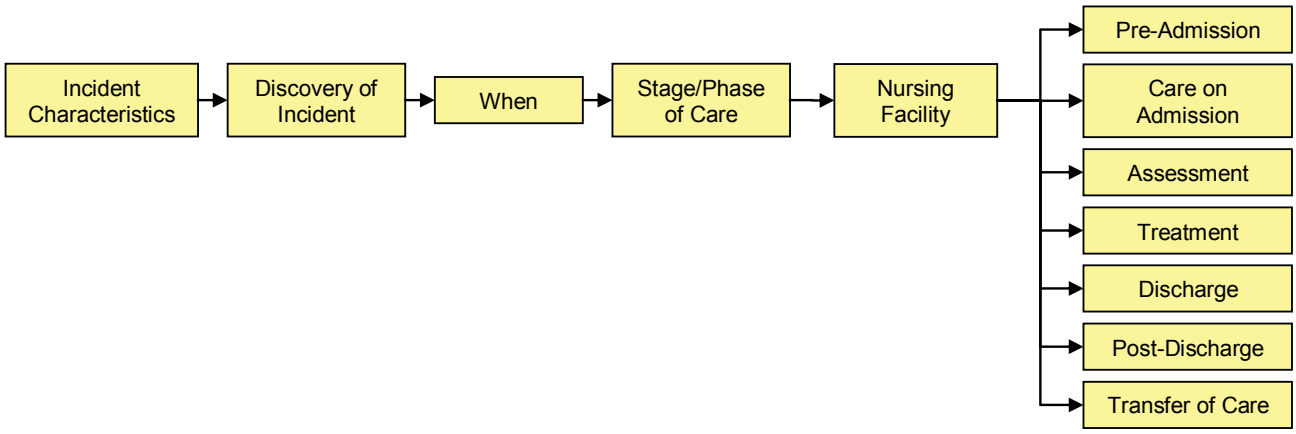
Discovery of Incident – When – Stage/Phase of Care



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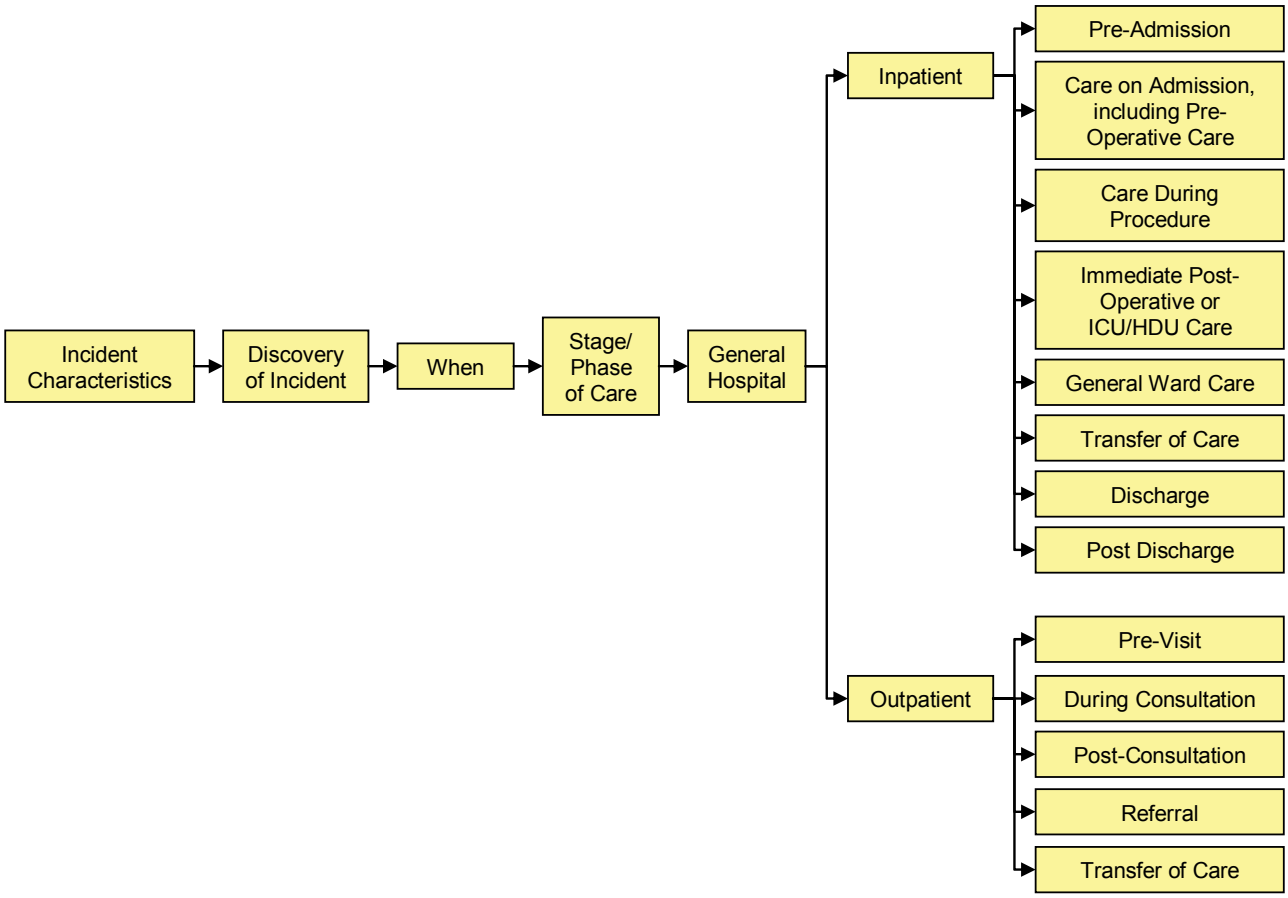
Discovery of Incident – When – Stage/Phase of Care



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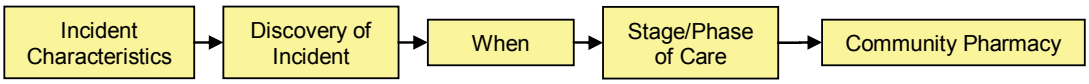
Discovery of Incident – When – Stage/Phase of Care



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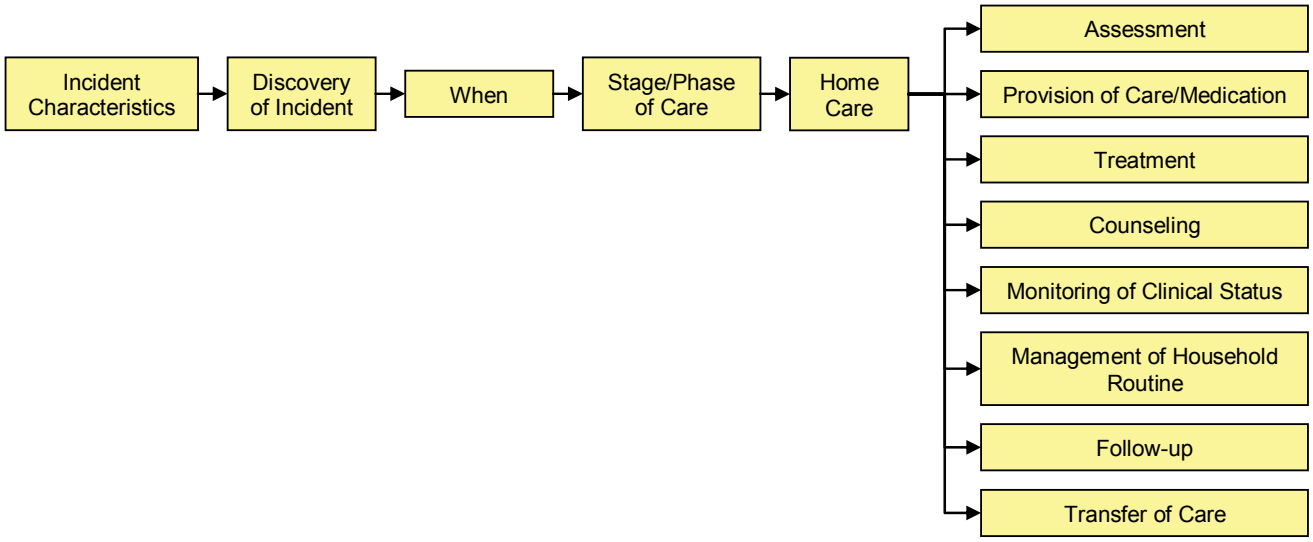
Discovery of Incident – When – Stage/Phase of Care



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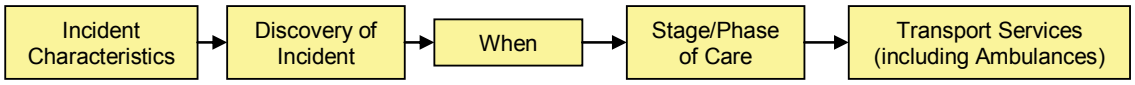
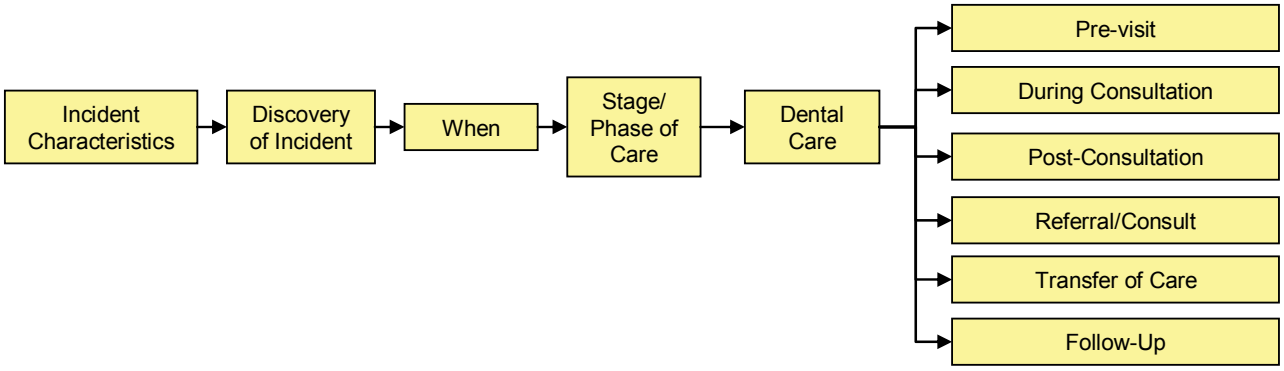
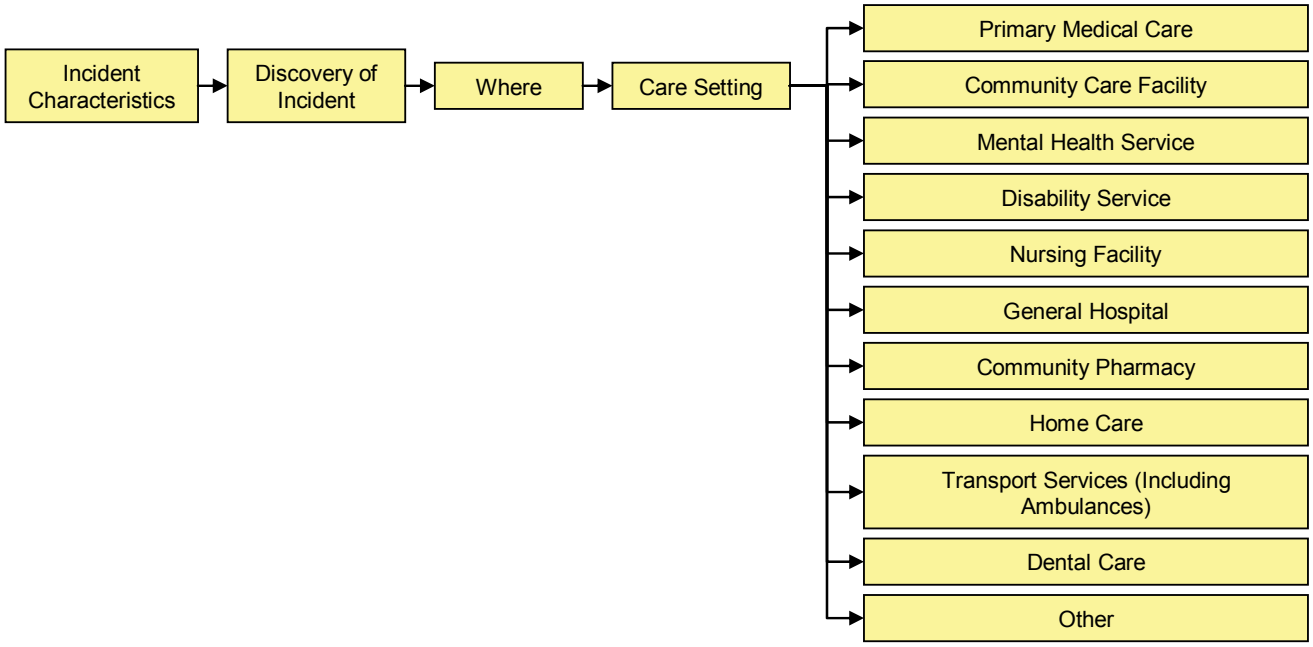
Discovery of Incident – When – Stage/Phase of Care



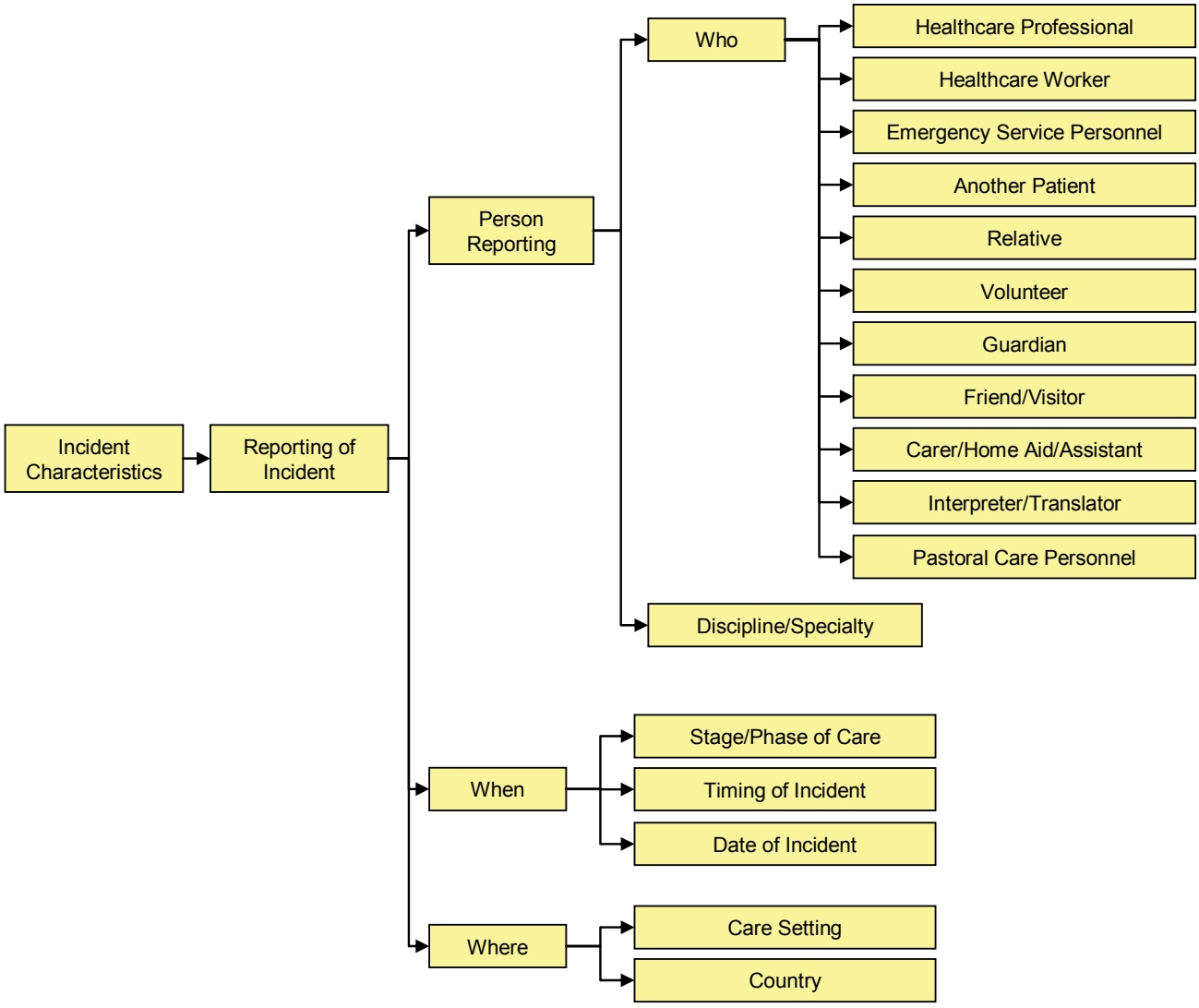
Incident Characteristics –
Discovery of Incident – When – Stage/Phase of Care



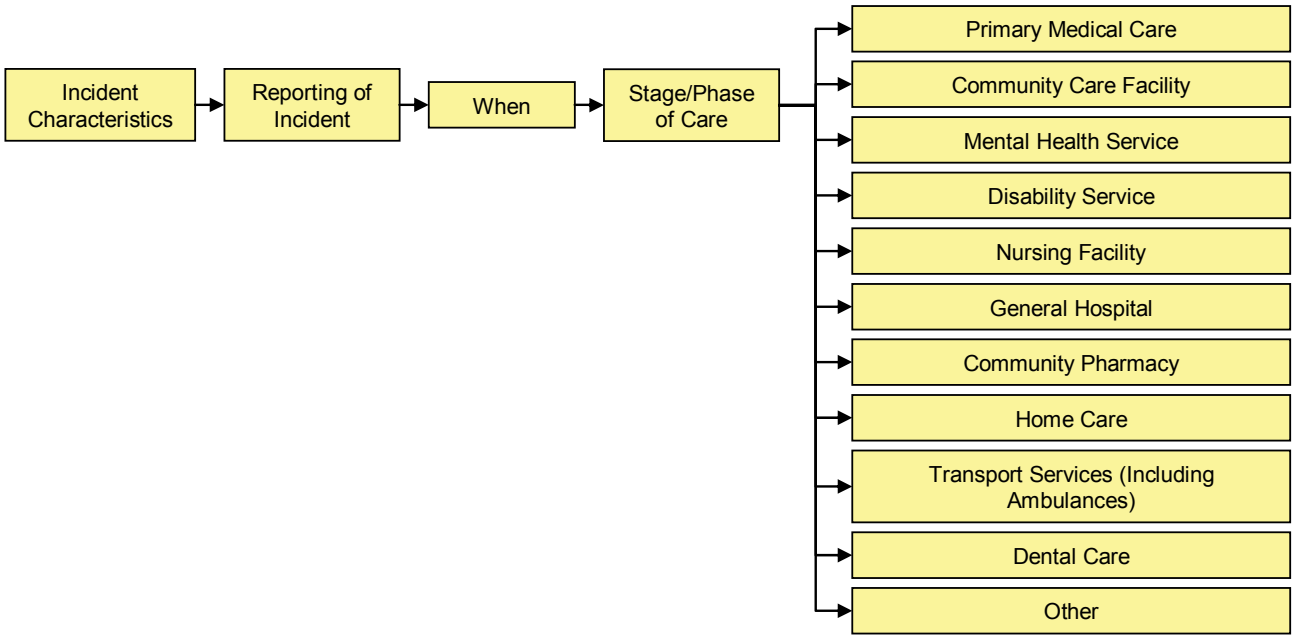
Incident Characteristics –
Discovery of Incident – Where – Care Setting



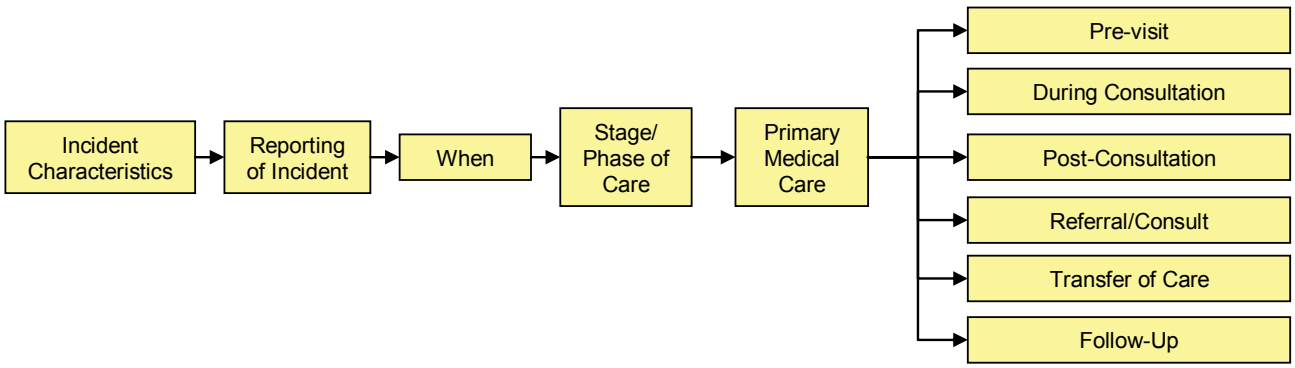
Incident Characteristics – Reporting of Incident



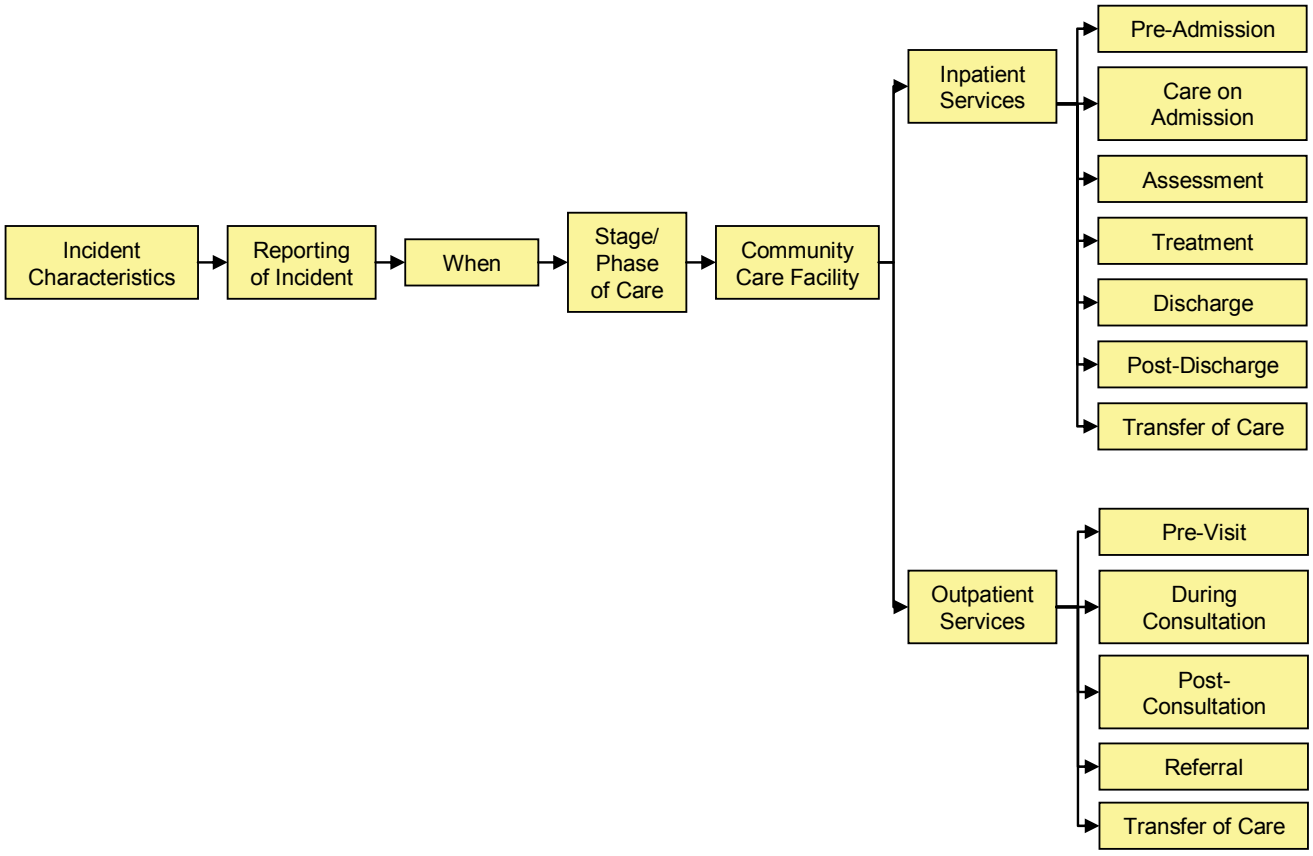
Incident Characteristics –
Reporting of Incident – When – Stage/Phase of Care



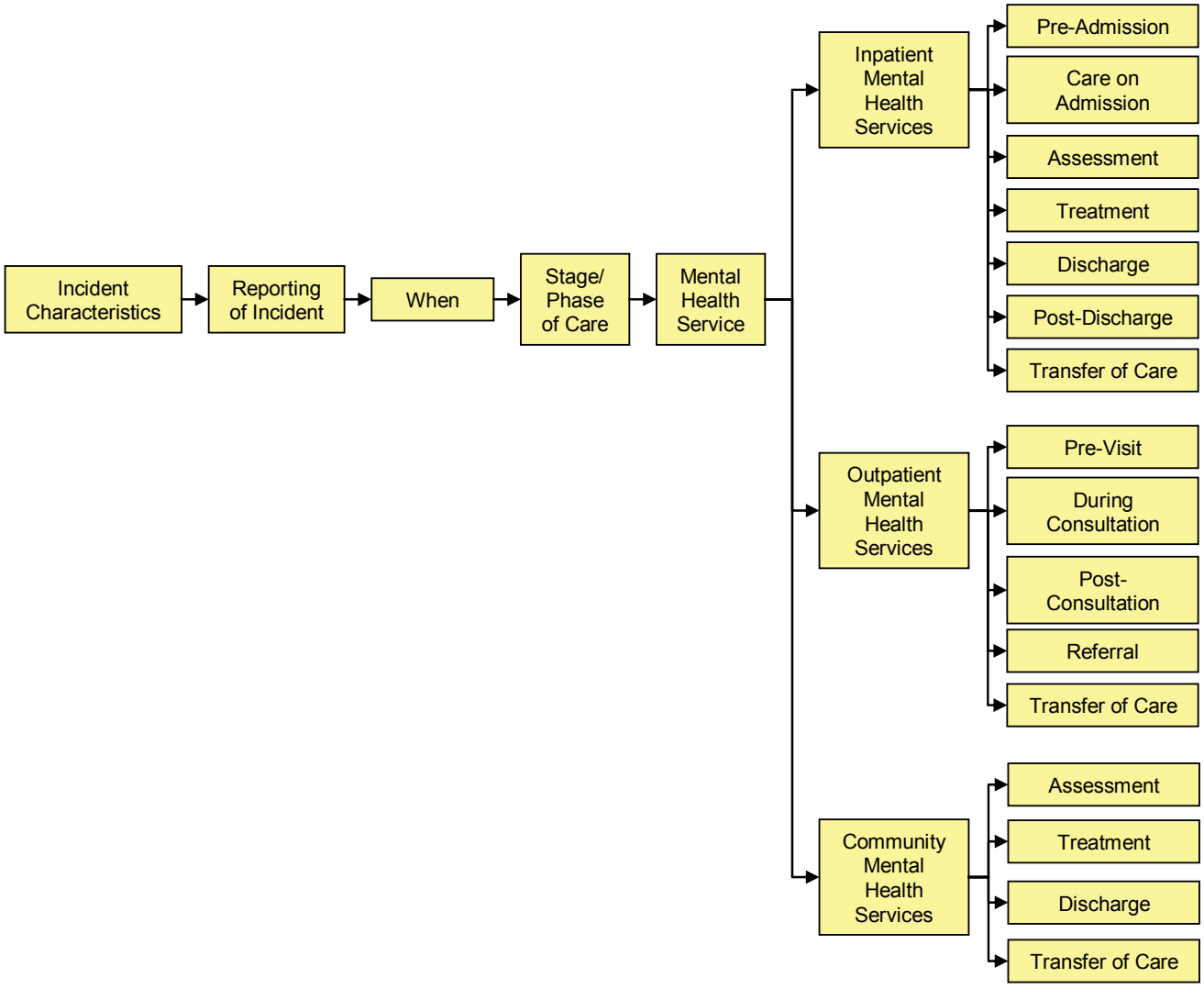
Incident Characteristics –
Reporting of Incident – When – Stage/Phase of Care



Incident Characteristics –
Reporting of Incident – When – Stage/Phase of Care



Incident Characteristics –
Reporting of Incident – When – Stage/Phase of Care



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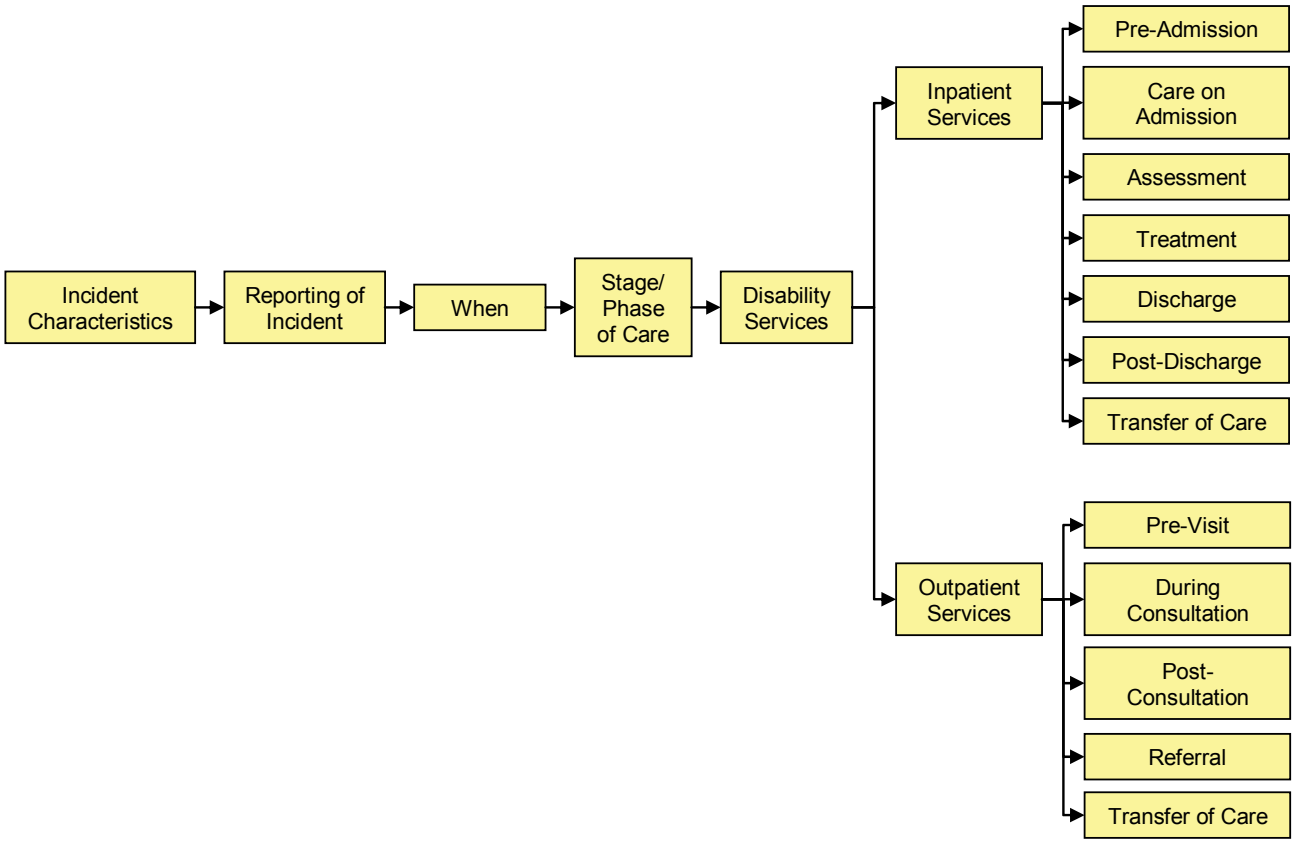
Reporting of Incident – When – Stage/Phase of Care



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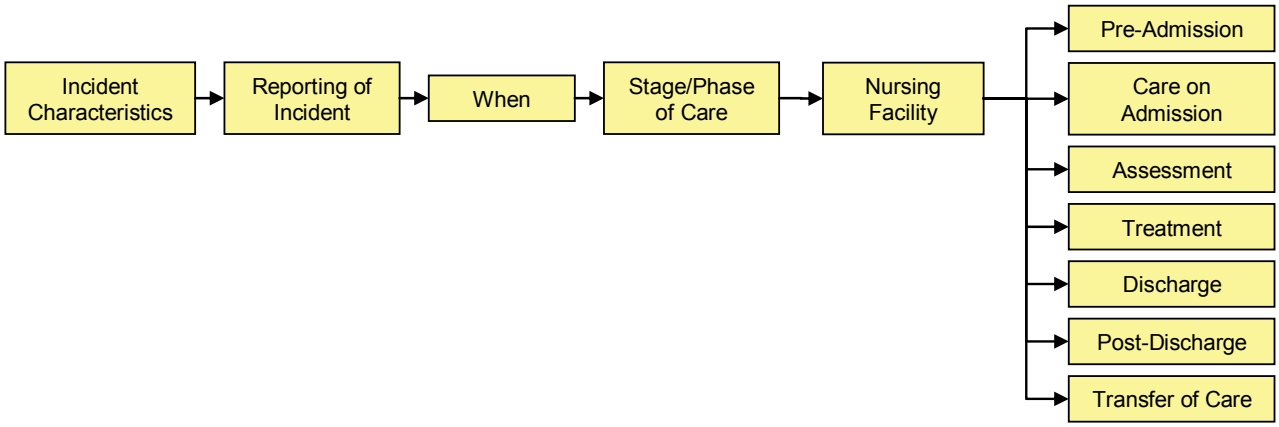
Reporting of Incident – When – Stage/Phase of Care



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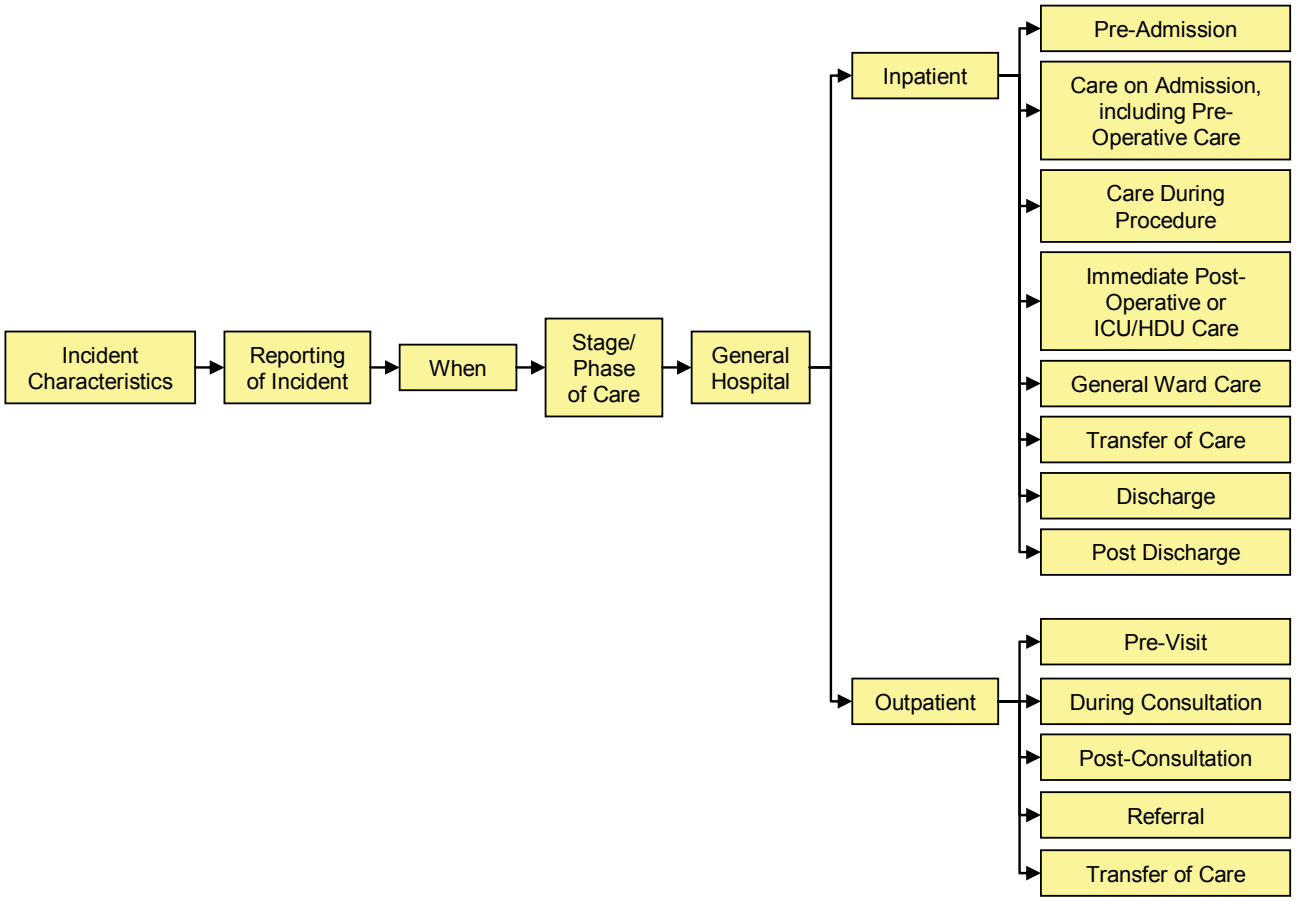
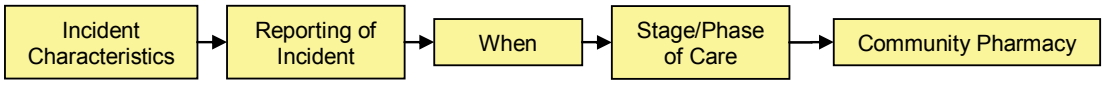
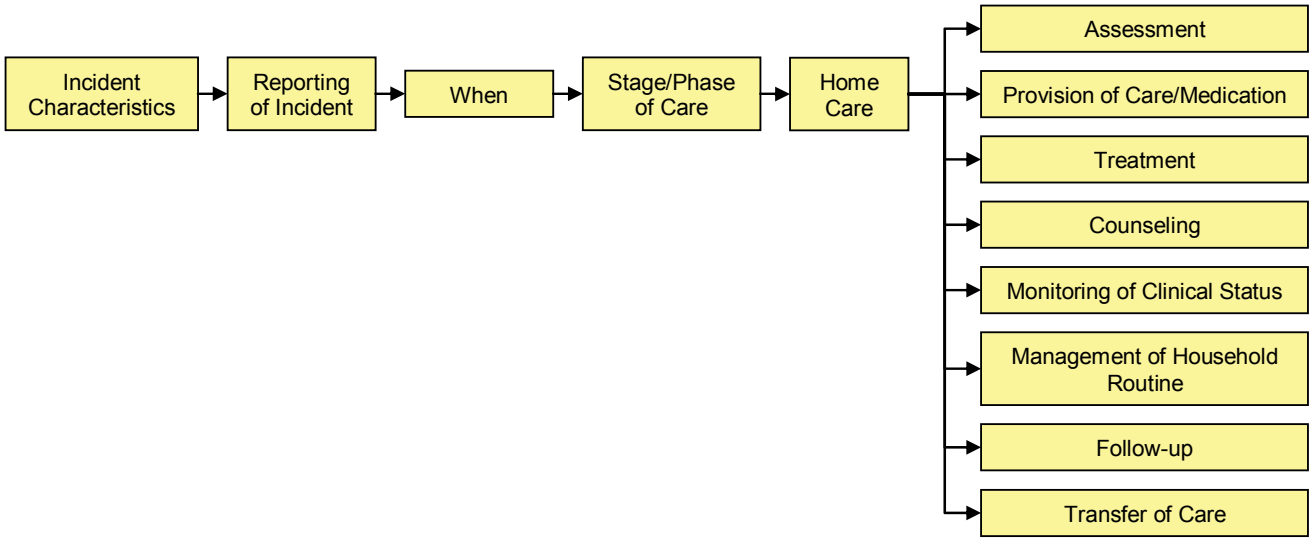
Reporting of Incident – When – Stage/Phase of Care



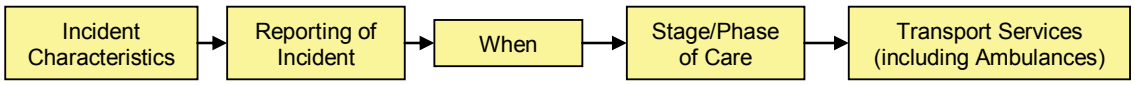
Incident Characteristics –
Reporting of Incident – When – Stage/Phase of Care



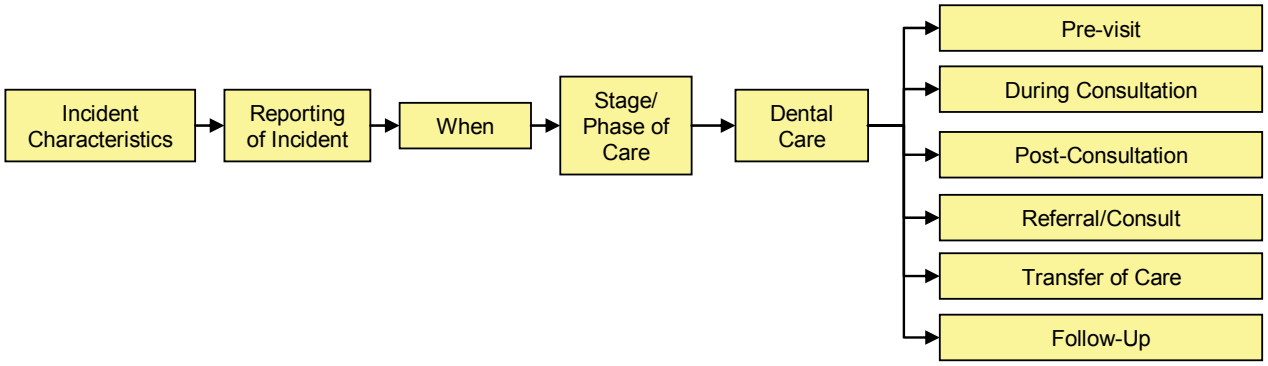
Incident Characteristics –
Reporting of Incident – When – Stage/Phase of Care



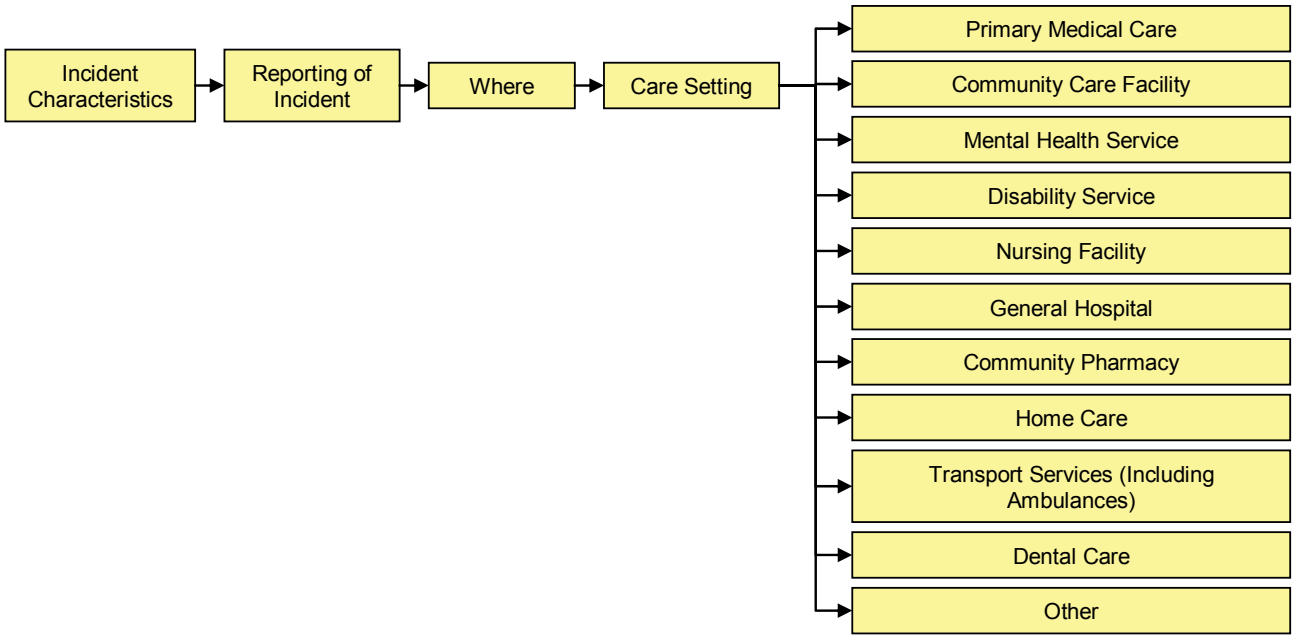
Incident Characteristics –
Reporting of Incident – When – Stage/Phase of Care



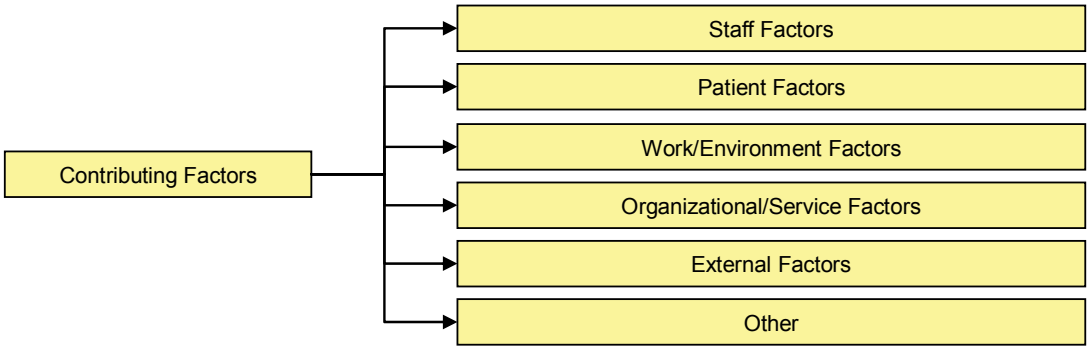
Incident Characteristics –
Reporting of Incident – When – Stage/Phase of Care



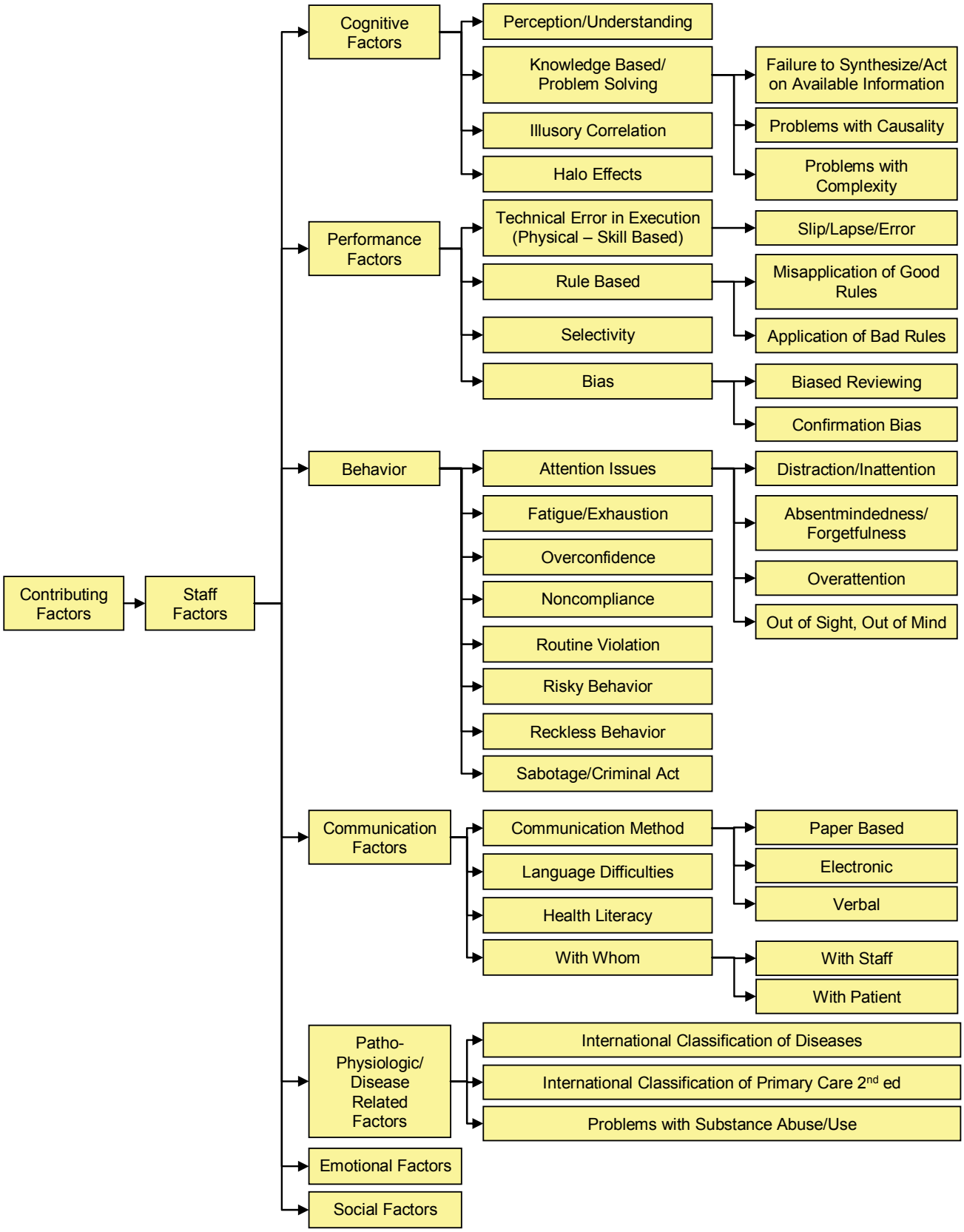
Incident Characteristics –
Reporting of Incident – Where – Care Setting



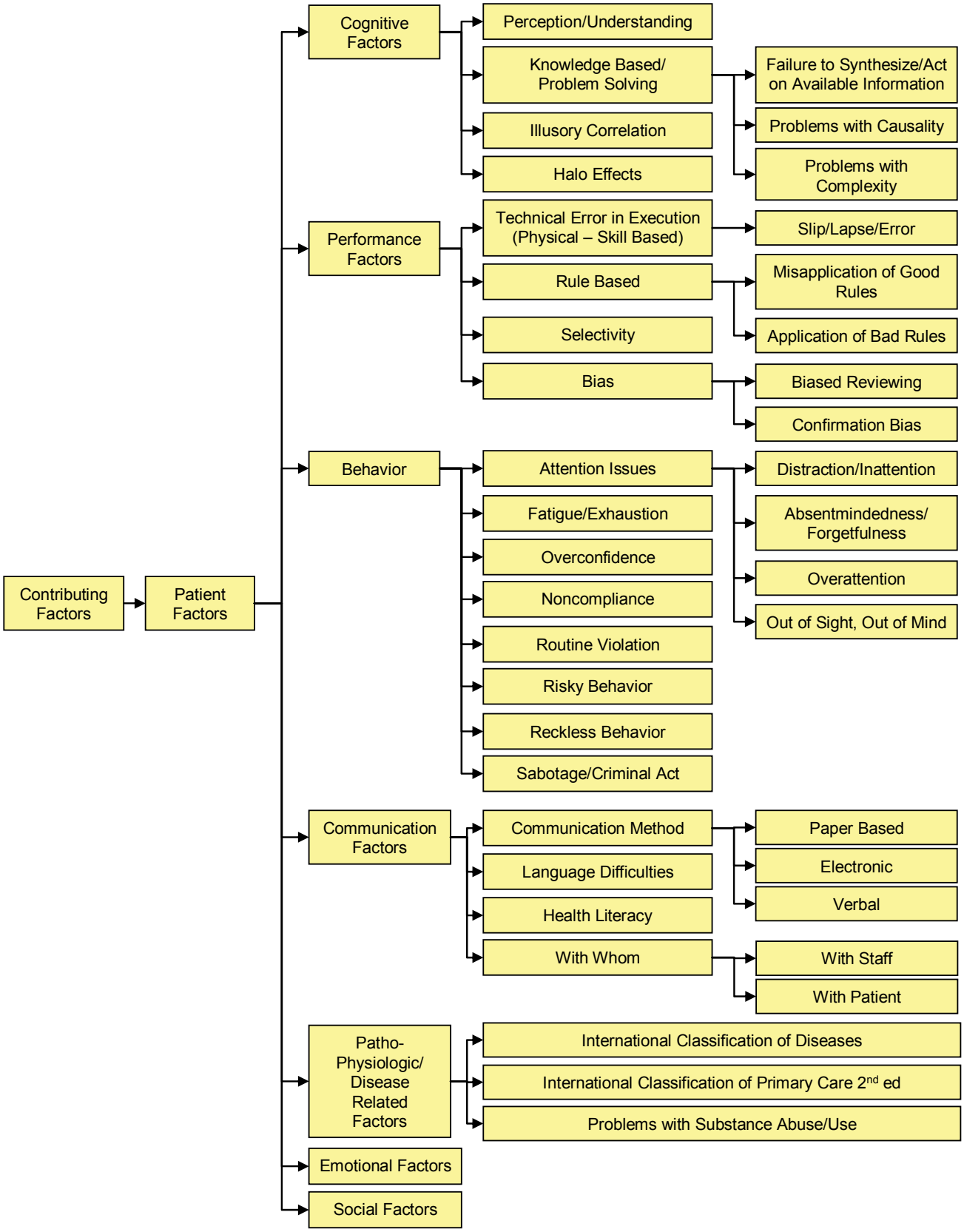
Contributing Factors/Hazards



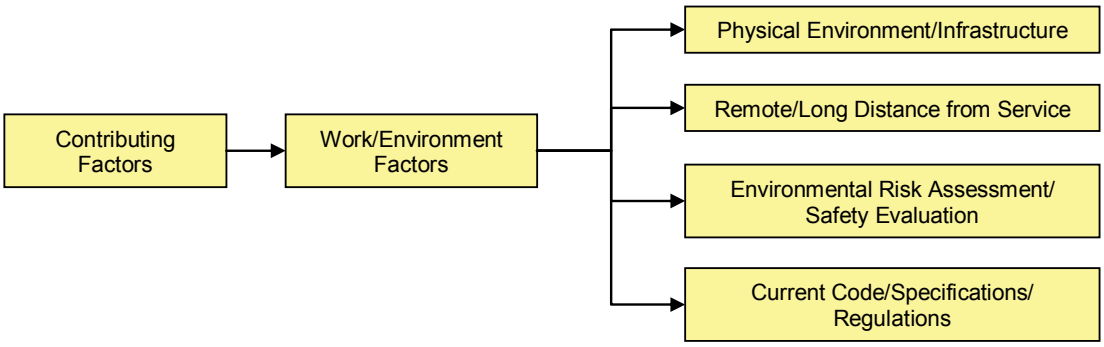
Contributing Factors/Hazards - Staff Factors



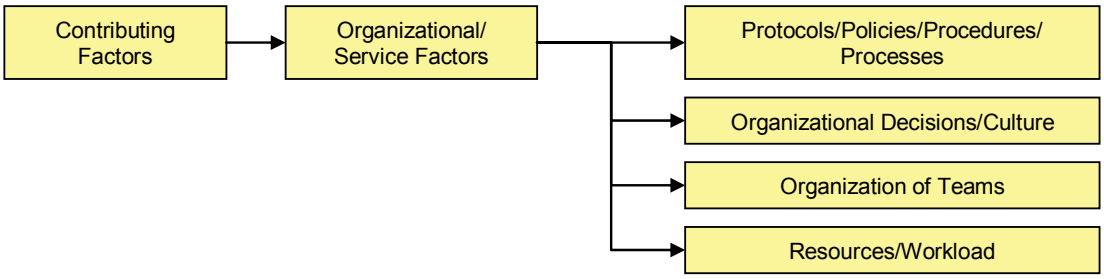
Contributing Factors/Hazards – Patient Factors



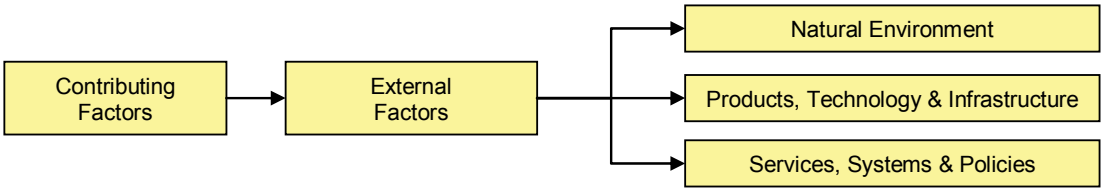
Contributing Factors/Hazards - Work/Environment Factors



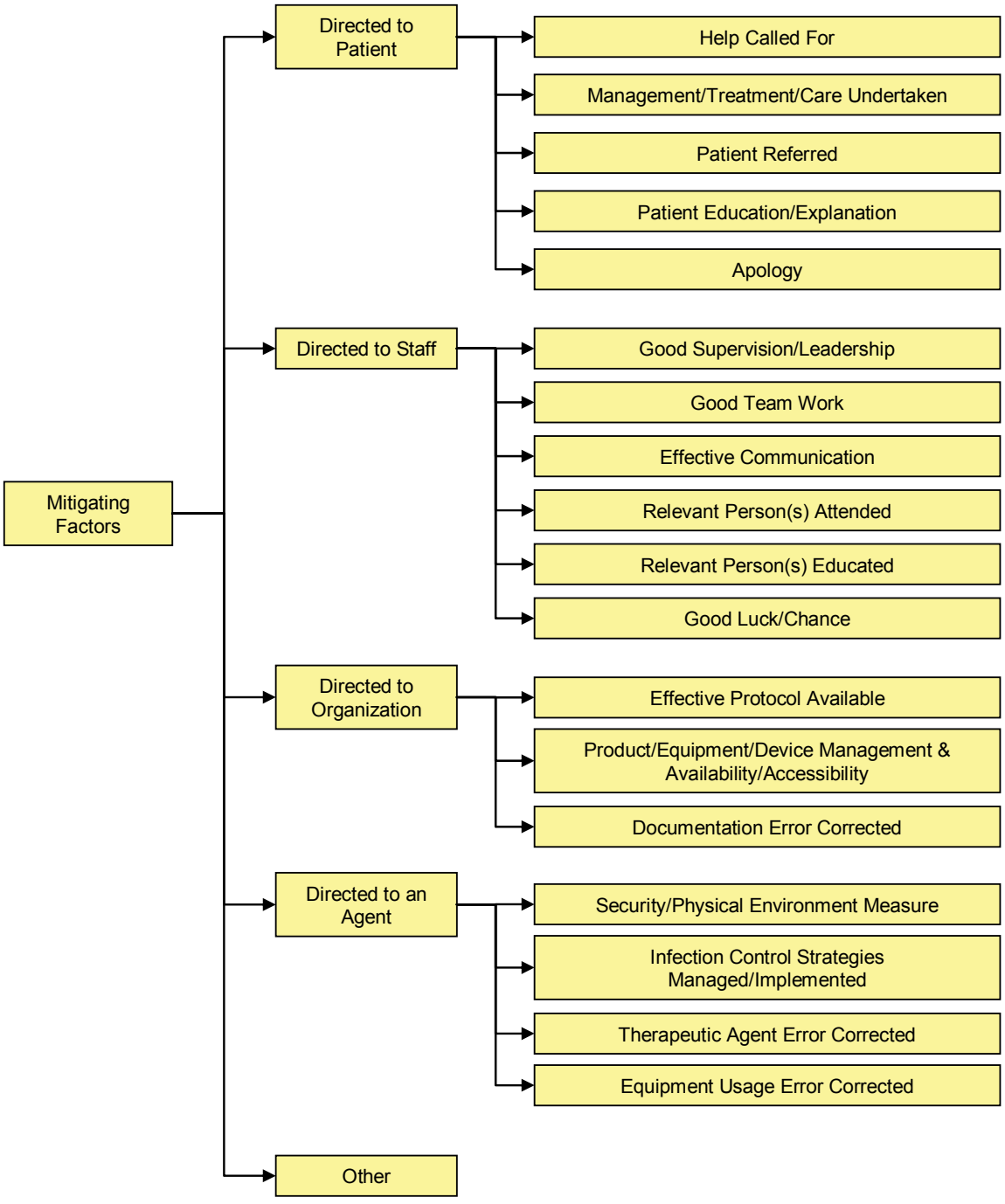
Contributing Factors/Hazards - Organizational/Service Factors



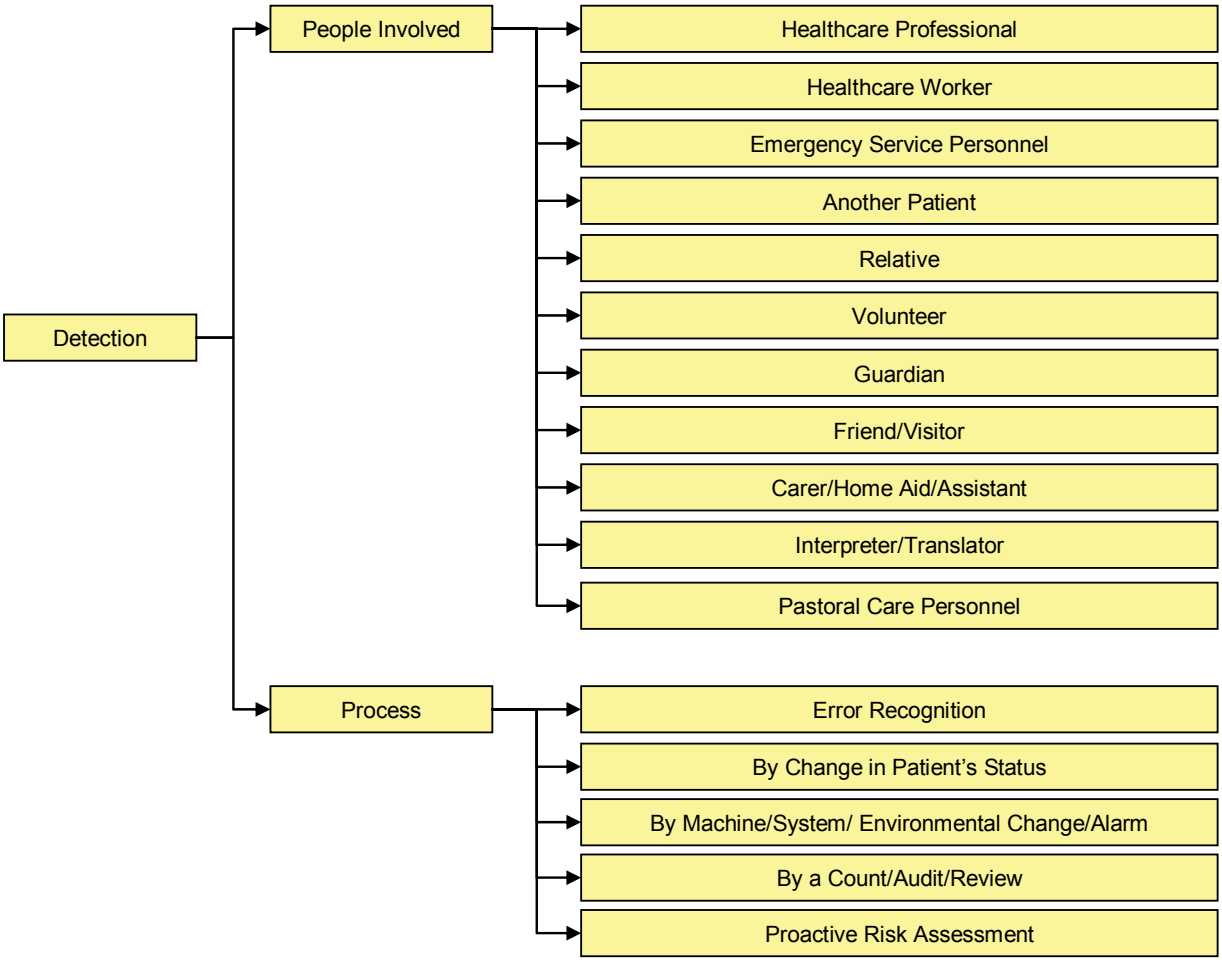
Contributing Factors/Hazards - External Factors



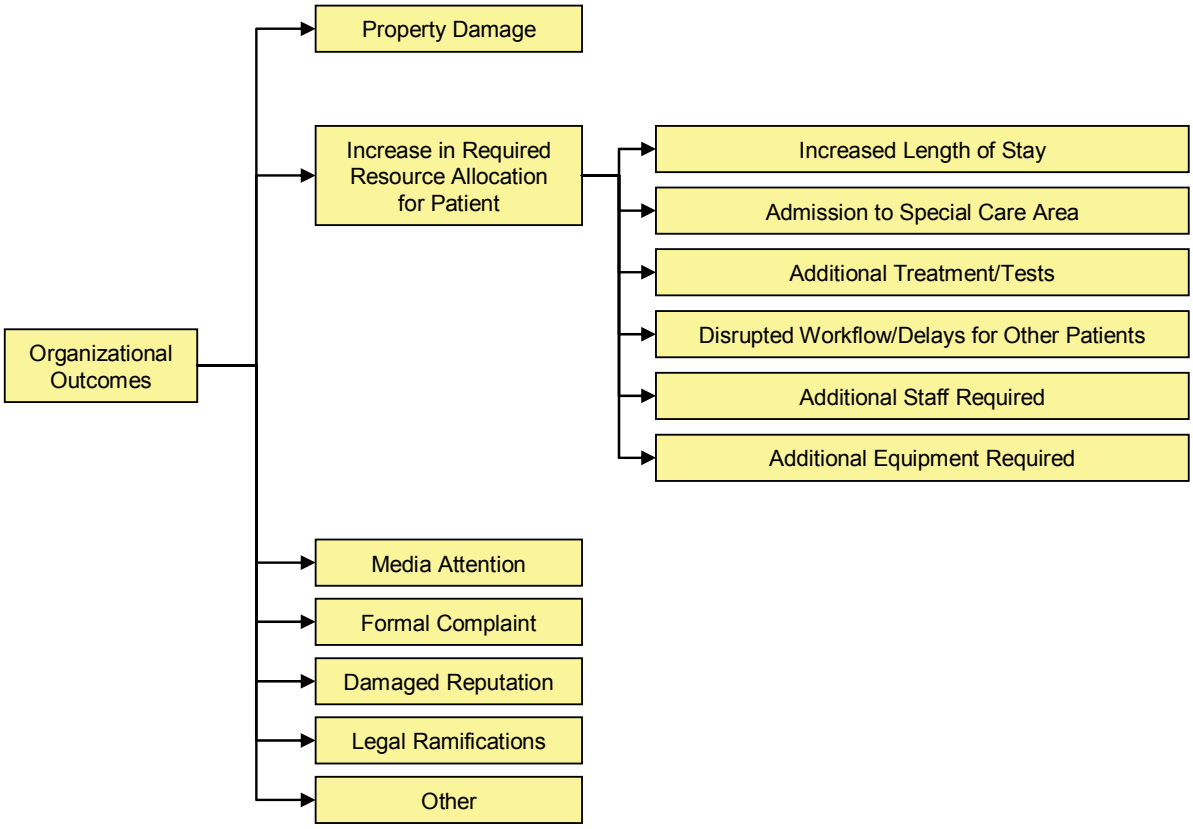
Mitigating Factors



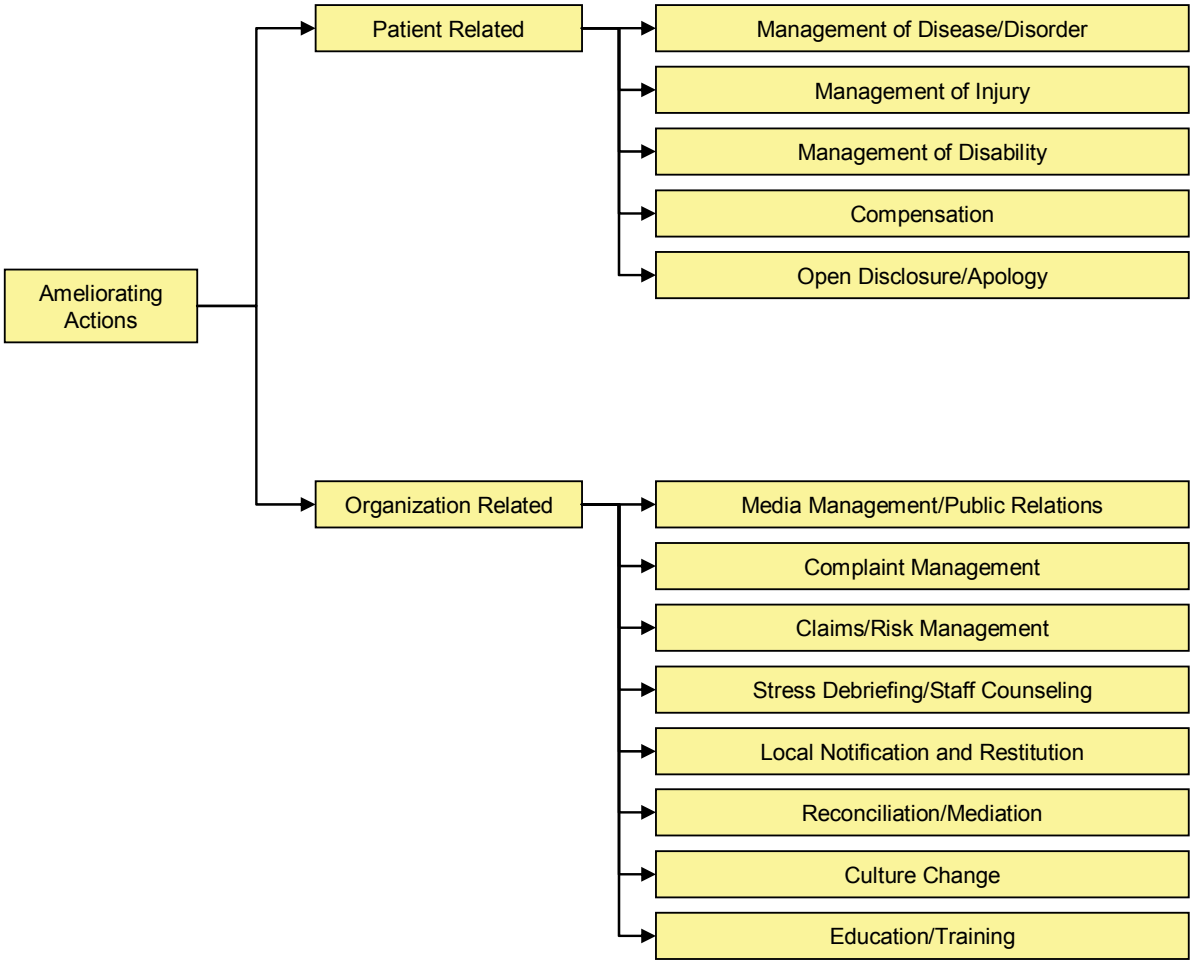
Detection



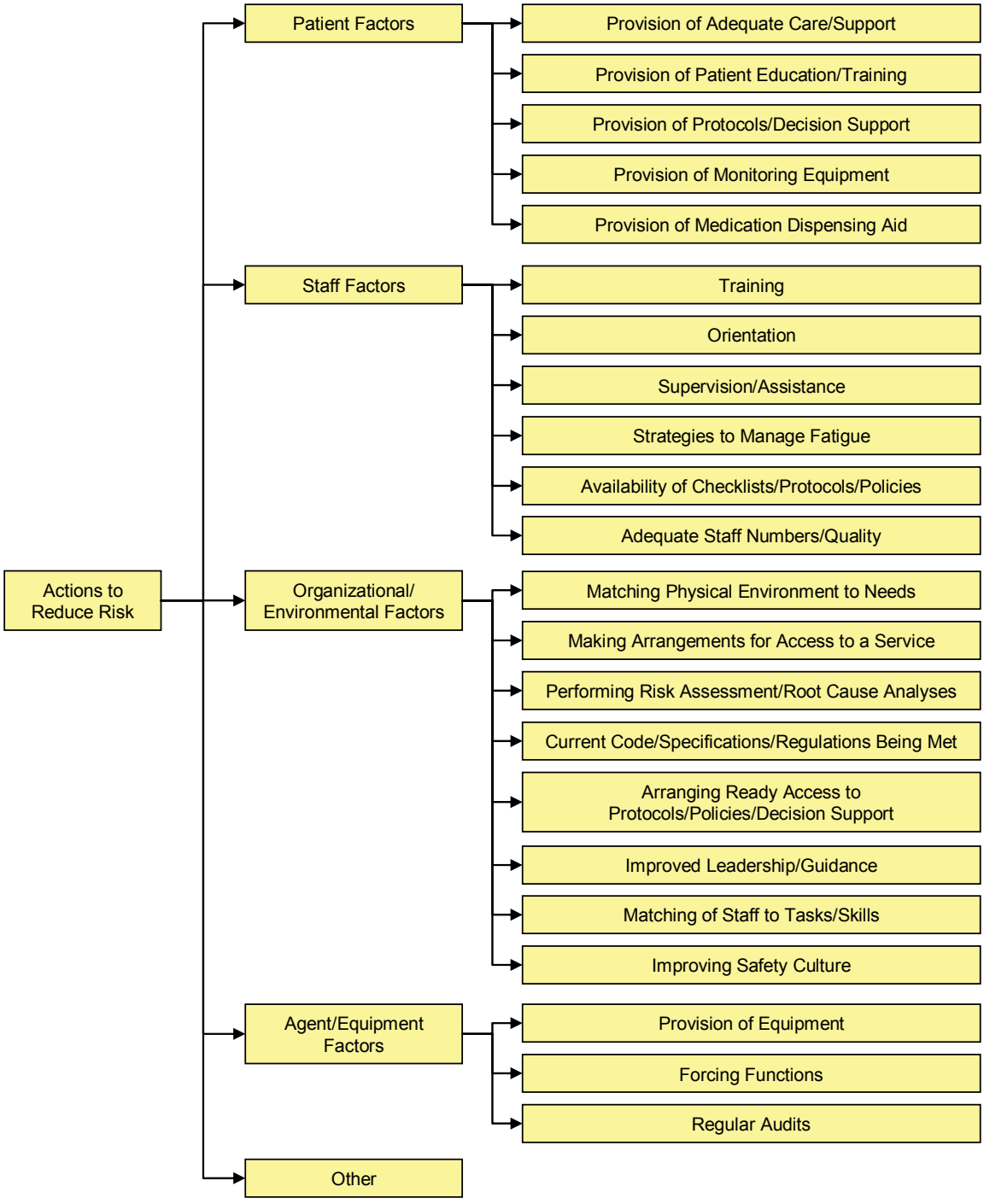
Organizational Outcomes



Ameliorating Actions



Actions to Reduce Risk



More than words

Technical Annex 2
Glossary of Patient Safety Concepts and References

Conceptual Framework for the International Classification for Patient Safety
Version 1.1

World Health Organization

Patient Safety
A World Alliance for Safer Health Care

Term	Definition
Accident *See also adverse event*	1. An event that involves damage to a defined system that disrupts the ongoing or future output of the system.[1] *see also* 2 2. An unintentional and/or unexpected event or occurrence that may result in injury or death. [3] 3. An unplanned, unexpected, and undesired event, usually with an adverse consequence. [4] 4. An event that involves damage to a defined system that disrupts the ongoing or future output of system.[1] 5. An adverse outcome that was NOT caused by chance or fate.[5]
Accountable	Being held responsible.[100]
Accountability *See also public accountability*	1. The extent to which individuals are answerable to a higher authority; physicians are held accountable before the law, the Hippocratic oath, and their patients; . . . more recently, the physician's accountability to the patient has been broadened to include accountability to the public in general, insurance carriers, and government agencies at all levels.[3] 2. The obligation to provide, to all concerned, the evidence needed to (1) establish confidence that the task or duty for which is one is responsible is being or has been performed and (2) describe the manner in which that task is being or has been carried out. When accountability has been fulfilled, the authority that delegated the responsibility can be satisfied by evidence (rather than simply assertion) that the duties or tasks that have been delegated are being or have been adequately performed. Accountability must be defined in conjunction with responsibility. An individual or organization has responsibility (that is to say, an obligation) because some individual or body with authority has granted or delegated that responsibility. Failure to carry out the responsibility carries with it liability.[6]
Action taken to reduce harm	Actions taken to reduce, manage or control the harm, or probability of harm associated with an incident.[100]
Active error	An error that occurs at the level of the frontline operator and whose effects are felt almost immediately.[1]

Term	Definition
Active failures	1. Errors and violations committed at the "sharp end" of the system. . . . Such unsafe acts are likely to have a direct impact on the safety of the system, and because of the immediacy of their adverse effects, these acts are termed *active failures*.[7] 2. A failure that is precipitated by the commission of errors and violations. These are difficult to anticipate and have an immediate adverse impact on safety by breaching, bypassing, or disabling existing defenses.[8] 3. Active failures are unsafe acts (errors and violations) committed by those at the "sharp end" of the system (surgeons, anesthetists, nurses, physicians, etc.). They are the people at the human-system interface whose actions can, and sometimes do, have immediate adverse consequences.[9] 4. The unsafe acts committed by people who are in direct contact with the patient or system. Their actions and decisions may result in errors that can immediately impact safety.[10] 5. An event/action/process that is undertaken, or takes place, during the provision of direct patient care and fails to achieve its expected aim.[5]
Adverse device event *See also adverse event*	Any incident in which the use of medical equipment may have resulted in an adverse outcome for the patient.[2]

Term	Definition
Adverse drug event (ADE) *See also adverse event*	1. A patient injury resulting from a medication, either because of a pharmacological reaction to a normal dose, or because of a preventable adverse reaction to a drug resulting from an error.[11] 2. Any incident in which the use of a medication (drug or biologic) at any dose, a medical device, or a special nutritional product (e.g., dietary supplement, infant formula, medical food) may have resulted in an adverse outcome in a patient.[8] *see also* 2 3. A generic term for any undesired or unintended response to a drug occurring at doses appropriate for a person's status, that can be divided based on the presence or absence of an immune mechanism; . . . ADEs are therapeutic reactions that are noxious, unintended, and occur at doses used in man for prophylaxis, diagnosis, therapy, or modification of physiologic functions; the definition of ADEs excludes therapeutic failures, poisoning, or intentional overdoses.[3] 4. An injury from a drug-related intervention. These can include prescribing errors, dispensing errors, and medication administration errors.[12] 5. An injury or harm resulting from medical intervention related to a drug.[13] *see also* 14 6. Injury that results from the use of drugs. ADEs that are associated with a medication error are considered preventable, while those not associated with a medication error (e.g., known medication side effects) are considered nonpreventable.[15] 7. As defined by the World Health Organization, an adverse drug event is an event that is "noxious and unintended and occurs at doses used in man for prophylaxis, diagnosis, therapy, or modification of physiologic functions." Also, an injury resulting from medical intervention related to a drug. Note that this definition does not include mistakes in prescribing, providing, or administering drugs unless injury results.[6] 8. Any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.[16] 9. Administration [of a drug] outside a predefined time interval from its scheduled administration time, as defined by each health care facility.[17] 10. An injury from a medicine or lack of an intended medicine.[18] 11. A medication-related adverse event.[19]

Term	Definition
Adverse drug reaction (ADR) *See also adverse event*	1. Unintended, undesirable, or unexpected effects of prescribed medications or of medication errors that require discontinuing a medication or modifying the dose; require initial or prolonged hospitalization; result in disability; require treatment with a prescription medication; result in cognitive deterioration or impairment; are life-threatening; result in death; or result in congenital anomalies.[11] 2. An undesirable response associated with use of a drug that either compromises therapeutic efficacy, enhances toxicity, or both.[8] 3. An undesirable effect caused by a drug, usually excluding intentional or accidental poisoning and drug abuse. [20] 4. Any unexpected, unintended, undesired, or excessive response to a drug that requires discontinuing the drug (therapeutic or diagnostic); requires changing the drug therapy; requires modifying the dose (except for minor dosage adjustments); necessitates admission to a hospital; prolongs stay in a health care facility; necessitates supportive treatment; significantly complicates diagnosis; negatively affects prognosis; or results in temporary or permanent harm, disability, or death.[21] 5. An undesired side effect or toxicity caused by the administration of a drug. [6] 6. A response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.[22]

Term	Definition
Adverse event *See also accident, adverse drug event, adverse drug reaction, adverse patient occurrence adverse reaction, adverse serious event, bad outcome, clinical incident, close call, critical incident, dangerous situation, drug misadventure, error, event, harm, hazard, iatrogenic, incident, injury, life threatening adverse drug experience, medical error, medical injury, medical mishap, medical mistake, medication error, misadventure, mistake, near miss, no harm event, patient safety, patient safety incident (incident), potential adverse event, potential event, preparation error, prescribing error, preventable adverse drug event, preventable adverse event, preventable death, preventable error, reportable occurrence, sentinel event, serious event, serious outcome, slip, unexpected adverse drug experience, unpreventable adverse drug event, unpreventable adverse event*	1. An injury that was caused by medical management or complication instead of the underlying disease and that resulted in prolonged hospitalization or disability at the time of discharge from medical care, or both. [23 *see also* 24] 2. An undesired patient outcome that may or may not be the result of an error. [25] 3. An event or omission arising during clinical care and causing physical or psychological injury to a patient. [26] 4. A negative consequence of care that results in unintended injury or illness which may or may not have been preventable. [27] 5. An injury that was caused by medical management and that results in measurable disability. [28] 6. An injury caused by medical management (rather than by the underlying disease) which prolongs hospitalization, produces a disability at the time of discharge, or both; ... AEs are caused by drug complications, wound infections, and technical complications, and those due to negligence [caused by] diagnostic mishaps, therapeutic mishaps, and events occurring in the emergency room. [3] 7. An untoward, undesirable, and usually unanticipated event, such as death of a patient, an employee, or a visitor in a health care organization. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no permanent effect on the patient. [8] 8. Adverse events are untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic, or other facility. Adverse events may result from acts of commission or omission. [29] 9. An undesirable event occurring in the course of medical care that produces a measurable change in patient status. [30] 10. An event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient. [31] 11. An injury resulting from a medical intervention and not due to the underlying condition of the patient. [1 *see also* 15,19,22] 12. An unexpected and undesired incident directly associated with the care or services provided to the patient. [5] 13. An incident which results in harm to a patient. [100]
Adverse event triggers	Clinical data related to patient care indicating a reasonable probability that an adverse event has occurred or is occurring. [22,31]
Adverse outcome *See also adverse event*	An adverse outcome includes prolonged hospitalization, disability or death at the time of discharge. [2]

Term	Definition
Adverse patient occurrence (APO) *See also adverse event*	An event that meets one or more criteria, such as the following: (1) a patient is injured, whether or not the hospital may be liable; (2) the admission was the result of an adverse result of outpatient care; (3) the patient was readmitted because of complications or incomplete care in the previous admission; (4) there were deficiencies in documentation, such as informed consent procedures or in the medical record; (5) unplanned surgery was done; (6) procedures were employed that did not meet the hospital's criteria for appropriateness; (7) a problem occurred with use of blood or blood components; (8) a nosocomial (hospital-acquired) infection occurred; (9) drug usage was inappropriate; (10) cardiac or respiratory arrest or death occurred; (11) there was an incident (such as a patient fall); (12) abnormal laboratory or x-ray findings were not followed up; (13) the stay was unusually short or long for the condition; (14) there were problems in obtaining services; or (15) there was patient or family dissatisfaction. These criteria are paraphrased from the Medical Management Analysis system for review of care, which depends heavily on screening for and reporting of APOs. [6]
Adverse reaction	Unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred. [100]
Adverse serious event *See also adverse event*	An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes the loss of limb or function. [32]
Agent	1. A chemical substance or biological substance or an organism capable of producing an effect. [6] 2. An active force or substance capable of producing an effect. [33] 3. A substance, object, or system which acts to produce change. [100]
Alert message	A computer-generated output that is created when a record meets prespecified criteria. [31]
Ameliorating action	An action taken or circumstance altered to make better or compensate any harm after an incident. [100]
Assertion knowledge	Primitive knowledge that cannot be defined from other knowledge. [31]
Attribution	Qualities, properties or features of someone or something. [100]
Bad outcome	Failure to achieve a desired outcome of care. [1]
Barrier analysis	[Method that] may be used to investigate accidents, considering the reasons for the failure of barriers [to errors] and whether sufficient barriers exist. [34]

Term	Definition
Benchmark	1. The performance, with respect to a given attribute, of an organization or individual whose performance is considered to be the goal of others. In the context of health care reform, benchmark performance would be that which delivers the best combination of results and cost; i.e., the "best" possible outcome may cost so much that it cannot be taken as a benchmark. [6] 2. A measure of comparative performance. [12] 3. A point of reference or standard by which something can be measured, compared, or judged, as in benchmarks of performance. [8]
Benchmarking	1. A system whereby health care assessment undertakes to measure its performance against "best practice" standards. Best practice standards can reflect (1) evidence-based medical practice (this is practice supported by current investigative studies of like patient populations), and (2) knowledge-based systems. Explicit in benchmarking is movement away from anecdotal and single-practitioner experience-based practice. [6] 2. An ongoing process that determines how other organizations have achieved optimal performance. [12] 3. Continuous measurement of a process, product, or service to those of the toughest competitor, to those considered industry leaders, or to similar activities in the organization in order to find and implement ways to improve it. This is one of the foundations of both total quality management and continuous quality improvement. *Internal benchmarking* occurs when similar processes within the same organization are compared. *Competitive benchmarking* occurs when an organization's processes are compared with best practices within the industry. *Functional benchmarking* refers to benchmarking a similar function or process in another industry. [8]
Best practices	Clinical, scientific or professional practices that are recognized by a majority of professionals in a particular field. These practices are typically evidence based and consensus-driven. [11]
Benign errors	Events that cause no harm or lack an adverse outcome. [35]
Biologicals	Medicines made from living organisms and their products, including serums, vaccines, antigens, and antitoxins. [11]
Blunt end	The blunt end of the system is the source of the resources and constraint that form the environment in which practitioners work. The blunt end is also the source of demands for production that sharp end practitioners must meet. [35]
Case-based reasoning	A decision support system that uses a database of similar cases. [31]
Causal continuum assumption	The assumption that the (failure) causal factor of consequential accidents are similar to those of nonconsequential near misses. [31]

Term	Definition
Causal factor *See also causation, cause, direct cause, immediate cause, proximate cause, underlying cause*	A factor that shaped the outcome of the situation. [38]
Causation *See also causal factor, cause, direct cause, immediate cause, proximate cause, underlying cause*	1. The establishment of a cause-and-effect relation between [an] allegedly negligent act and the purported injuries. [3] 2. The act by which an effect is produced. [8] *see also* 22
Cause *See also causal factor, causation, direct cause, immediate cause, proximate cause, underlying cause*	1. The act by which an effect is produced. [8] 2. An antecedent factor that contributes to an event, effect, result or outcome. A cause may be proximate in that it immediately precedes the outcome… A cause may also be remote, … thus contributing to the outcome. [22] *see also* 5
Causal analysis investigation *See also root cause analysis*	A process to investigate and analyses patient injuries and visitor incidents that identifies latent system failures and their causes. [2]
Circumstance	Any factor connected with or influencing an event, agent or person(s).[100]
Class	A group or set of like things.[100]
Classification *See also taxonomy*	1. A taxonomy that arranges or organizes like or related terms for easy retrieval. [2] *see also* 31 2. The ordering of entities into groups or classes on the basis of their similarity. [39] 3. An arrangement of concepts into classes and their subdivisions to express the semantic relationships between them.[100]
Clinical audit	1. A cycle of activities involving the measurement of care, comparison with a standard of some kind (whether process or outcome), and ideally interventions to improve quality where necessary. Most reliance is placed … on large-scale sampling. [29] 2. The analysis of the care of patients with common conditions to identify and correct weaknesses in management (preferably by using written protocols or guidelines).[40] 3. Organized review of current clinical procedures compared with pre-determined standards. Action is then taken to rectify any identified deficiencies in current practices. The review is repeated to see if the standards are being met. [14]

Term	Definition
Clinical data repository	Clinical database optimized for storage and retrieval for information on individual patients and used to support patient care and daily operations. [31]
Clinical incident *See also adverse event*	Incidents in a health care setting caused by clinical procedures that resulted, or could have resulted, in unexpected harm to the patient. [14]
Clinical information system	The components of a health care information system designed to support the delivery of patient care, including order communications, results reporting, care planning, and clinical documentation. [31]
Close call *See also near miss, potential adverse drug event, potential adverse event, potential error, potential event*	1. An event or situation that could have resulted in an accident, injury, or illness, but did not, either by chance or through timely intervention." [29] *see also* [2] 2. An event or situation that could have resulted in an adverse event but did not, either by chance or through timely intervention. [31] 3. Serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted. [19]
Cognitive science	An amalgamation of disciplines including artificial intelligence, neuroscience, philosophy, and psychology. Within cognitive science, cognitive psychology is an umbrella discipline for those interested in cognitive activities such as perception, learning, memory, language, concept formation, problem solving, and thinking. [41]
Common-cause variation *See also process variation, special-cause variation*	Variation in a process that is due to the process itself and is produced by interactions of variables of that process. Common-cause variation is inherent in all processes; it is not a disturbance in the process. It can be removed only by making basic changes in the process. [8]
Comparability	Ability to compare similar data held in different computer systems. Comparability requires that the meaning of data is consistent when shared among different parties. [31]
Competence	1. Having adequate skill and being properly qualified. [42] 2. An individual's skills, knowledge, and capability… meet defined expectations. [11]
Complaint	1. A generic term for a symptom of which a person is aware or that causes discomfort. [3] 2. An expression of dissatisfaction on the part of a patient or career [sic] … that represents a particular perception of events. A complaint may or may not reveal that a mistake or error has occurred. [43]
Complication	1. A detrimental patient condition that arises during the process of providing health care, regardless of the setting in which the care is provided. [8] *see also* [2] 2. A diagnosis occurring during hospitalization that is thought to extend the hospital stay at least one day for roughly 75% or more of the patients. [6] 3. A disease or injury that arises subsequent to another disease and/or health-care intervention. [5]

Term	Definition
Concept	A bearer or embodiment of meaning
Concept orientation	Elements of the terminology are coded concepts, with possibly multiple synonymous text representations and hierarchical or definitional relationships to other coded concepts. No redundant, ambiguous, or vague concepts exist. [31]
Concept permanence	The meaning of each coded concept in a terminology remains forever unchanged. If the meaning of a concept needs to be changed or refined, a new coded concept is introduced. No retired codes are deleted or reused. [31]
Conceptual model	A model of the main concepts of a domain and their relationships. [31]
Contributing factor *See also causal factor, causation, direct cause, immediate cause, proximate cause, underlying cause*	1. An antecedent factor to an event, effect, result or outcome similar to a cause. A contributory factor may represent an active failure or a reason an active failure occurred, such as a situational factor or a latent condition that played a role in the genesis of the outcome.[22] 2. Additional reasons, not necessarily the most basic reason that an event has occurred. [29] 3. The reason(s), situational factor(s), or latent condition(s) that played a role in the genesis of an adverse outcome. [5] 4. 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.[100]
Credentialing	1. The process of obtaining, verifying, and assessing the qualifications of a health care practitioner to provide patient care services in or for a health care organization… documented evidence of licensure, education, training, experience or other qualifications.[11] 2. The process of determining eligibility for hospital medical staff membership and privileges to be granted to physicians and other professionals in the light of their academic preparation, licensing, training, and performance. Privileges are granted by the hospital's governing body, ordinarily upon recommendation of the medical staff, usually via the medical staff's credentials committee. …Credentials and performance are periodically reviewed, and medical staff membership (and/or privileges) may be denied, modified, or withdrawn. [6]
Criterion standard	A method having established or widely accepted accuracy for determining a diagnosis, providing a standard to which a new screening or diagnostic test can be compared. Criterion standards can also be used in studies of the quality of care to indicate a level of performance, agreed to by experts or peers, to which individual practitioners or organizations can be compared. [8]
Critical incident	An incident resulting in serious harm… to the patient… when there is an evident need for immediate investigation and response. [5]

Term	Definition
Critical incident reporting *See also event reporting, incident reporting*	The identification of preventable incidents (i.e., occurrences that could have led, or did lead, to an undesirable outcome) reported by personnel directly involved in the process in question at the time the event was discovered. Incident reports may target events in any or all of three basic categories: adverse events, no harm events, and near misses.[44]
Critical incident technique	A set of procedures for collecting direct observations of human behavior in such a way as to facilitate their potential usefulness in solving practical problems and developing broad psychological principles. [45]
Dangerous situation *See also hazard*	Both active and latent failures exist that create a hazard increasing the risk of harm. [2]
Data element	The basic unit of information having a unique meaning and subcategories of distinct units or values. [31]
Data mining	The use of a basic set of tools to extract patterns from the data in a data warehouse.[31]
Decision error	A decision that unnecessarily increases risk. [46]
Degree of Harm	The severity and duration of harm, and the treatment implications, that results from an incident.[100]
Detection	An action or circumstance that results in the discovery of an incident.[100]
Diagnosis	1. A complex of "symptoms" (disturbances of appearance or function or sensation of which the patient is aware), "signs" (disturbances that the physician or another individual can detect), and "findings" (disturbances detected by laboratory, x-ray, or other diagnostic procedures, or response to therapy). [6] 2. The determination of the nature of a disease, injury, or congenital defect… made from a study of the signs and symptoms of a disease. [33]
Direct cause *See also causal factor, causation, cause, immediate cause, proximate cause, underlying cause*	A cause that sets in motion a chain of events that brings about a result without the intervention of any other independent source. [8]

Term	Definition
Disability	1. A substantial disruption of a person's ability to conduct normal life functions. [16] 2. A physical or mental impairment that substantially limits one or more of the major life activities of an individual. [27] 3. A limitation in a person's mental or physical ability to function in terms of work, learning, or other socially required activities to the extent that the person might be regarded as having a need for certain benefits, compensation, exemptions, [and/or] special training because of said limitations. Disabilities include impairment of hearing, mobility, speech, and vision; infection with TB, AIDS, or other contagion; malignancy; past history of alcohol or drug abuse; or mental illness. [3] 4. Any restriction or limitation resulting from an impairment of ability to perform an activity in an manner or with the range considered normal for a human being according to the *International Classification of Impairments, Disabilities, and Handicaps* (1980) published by the World Health Organization (WHO). The term *disability* reflects the consequences of impairment. [8] 5. Any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with past or present harm. [100]
Disease	1. An illness or disorder of the function of the body or of certain tissues, organs, or systems. Diseases differ from injuries in that injuries are the result of external physical or chemical agents. [6] 2. A physiological or psychological dysfunction. [100]
Disinfection	The use of a chemical procedure that eliminates virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial endospores) on inanimate objects. [36]
Dispensing error	Deviation from the prescriber's order, made by staff in the pharmacy when distributing medications to nursing units or to patients in an ambulatory pharmacy setting. [47]
Domain	Where a health care error or systems failure occurred and the type of individual involved. Subcategories are setting, staff, patient, and target. One of four interrelated subclassifications of the elements that comprise health care errors and systems failures. [48]
Drug allergies	A state of hypersensitivity induced by exposure to a particular drug antigen resulting in harmful immunologic reactions on subsequent drug exposures, such as penicillin drug allergy. [36]
Drug misadventure *See adverse event*	A broad label applied to adverse drug reactions, prescribing errors, and medication errors. [47]

Term	Definition
Effectiveness	1. The degree to which care is provided in the correct manner, given the current state of knowledge, to achieve the desired or projected outcome(s) for the individual. [11] 2. Care that is based on the use of systematically acquired evidence to determine whether an intervention, such as a preventive service, diagnostic test, or therapy, produces better outcomes than alternatives—including the alternative of doing nothing. [49] 3. The degree to which the effort expended, or the action taken, achieves the desired effect (result or objective). [6]
Efficacy	1. The degree to which the care of the individual has been shown to accomplish the desired or projected outcome(s). [11] 2. The extent to which a specific intervention, procedure, regimen, or service produces a beneficial result under ideal conditions. Efficacy is often used (incorrectly) as a synonym for effectiveness in health care delivery; it is distinguished from effectiveness, which concerns conditions that exist in reality—usual or normal circumstances—not ideal conditions.[8]
Efficiency	1. The relationship between the outcomes (results of care) and the resources used to deliver care. [11] 2. The relationship of the amount of work accomplished to the amount of effort required. [6]
Electronic health record	A repository of electronically maintained information about an individual's health care and corresponding clinical information management tools that provide alerts and reminders, linkages with external health knowledge sources, and tools for data analysis. [31]
Elements of performance	The specific performance expectations and/or structures or processes that must be in place in order for an organization to provide safe, high-quality care, treatment and services. [11]

Term	Definition
Error *See also adverse event*	1. The failure of a planned action to be completed as intended or use of a wrong, inappropriate, or incorrect plan to achieve an aim. [1] *see also* 2,5,26,29 2. The failure of planned actions to achieve their desired goal. [50] 3. Deviation in a process of care that may or may not cause harm to patients. [25] 4. An unintentional deviation from standard operating procedures or practice guidelines. [3] 5. An act of commission or omission that caused, or contributed to the cause of, the unintended injury. [24] 6. A generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome. [22] 7. Failure to carry out a planned action as intended or application of an incorrect plan. [100]
Error in decision	Decision that unnecessarily increases risk. [2]
Error of commission	1. An error that occurs as a result of an action taken. [8] *see also* 22 2. Providing patients with a medical intervention that results in an adverse event. [31] 3. Failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. [2]
Error of communication	Missing or wrong information exchange or misinterpretation or misunderstanding. [2]
Error of execution	A correct action that does not proceed as intended. [1]
Error of judgment	Error related to flawed reasoning. [51]
Error of negligence	Error due to inattention or lack of obligatory effort. [51]
Error of omission	An error that occurs as a result of an action not taken. [8] *see also* 22 Failing to provide the patient with a medical intervention from which the patient would have likely benefited. [31] Failure to carry out some of the actions necessary to achieve a desired goal. [2]
Error of planning	The original intended action is not correct. [1]
Error of procedure *See also rule-based error*	Procedures were followed with the wrong execution. [2]

Term	Definition
Error of proficiency *See also knowledge-based error*	Error due to lack of knowledge or skill. [2]
Error of violation	1. Conscious failure to adhere to procedures or regulation. [2] 2. A deliberate – but not necessarily reprehensible – deviation from those practices deemed necessary (by designers, managers and regulatory agencies) to maintain the safe operation of a potentially hazardous system. [22] 3. A deliberate deviation from standards, rules or safe operating procedures. [5]
Error severity codes (ESRD)	**Did not reach patient, potential injury:** Examples: prescription bottle labeled correctly but nurse notices wrong pills in bottle, wrong medications loaded in Pyxis or med drawer, nursing station keeps all multidose medication vials in same the same drawer or bin. The patient has to tell lab tech not to take blood from a specific arm, no signs or notes on order or care plan, no sign in room. **Reach patient—No Injury or effect on patient:** Examples: Missed antibiotics, double dose of pain meds, wrong lab tests done, Wrong limb x-rayed, diagnostic test done incorrectly. **Emotional injury:** Examples: Elopement or AMA [against medical advice], behavior health altercation between peers, wrongful confinement to a mental hospital, wrongful birth (birth after vasectomy, etc.), and fright, as well as fifth-degree sexual conduct (touching or unacceptable sexual behavior, with no physical harm) Use of restraints. **Minor Temporary:** Minor patient injury or increased patient monitoring or change in treatment plan (with or without injury) Length of stay increased by less than 1 day. Examples: error in setting or monitoring heparin levels requiring increased number of lab tests, missed insulin dose requiring change in dosing for next administration and/or increased glucose checks. Bruising, abrasions, skin tear, complaints of pain, small number of non-facial sutures. Minor self-inflicted injury, (scratches or cutting.) **Major Temporary:** A temporary injury that exceeds minor temporary or increases length of stay one day or more. Examples: facial sutures, minor fractures, severe drug reaction. **Minor Permanent:** A permanent injury that does not compromise basic functions of daily living. Examples: Loss of finger, loss of testicle or ovary, removal of bowel due to circulatory compromise, loss of teeth, second-degree sexual conduct (forced sexual contact via threat of violence or weapon, forced sexual contact that causes injury, or sexual contact with someone under 16 years old), retained sponge/needle. **Major Permanent:** Permanent injury that affects basic functions of daily living. Examples: Hip fracture, nerve damage from improper surgical positioning, missing limb, damage to sensory organ, first-degree sexual assault (forced sexual penetration via threat of violence or weapon, forced sexual penetration that causes injury, or sexual penetration of someone under 16 years old) **Extreme:** Examples: Brain damage, severe paralysis, death. [2]

Term	Definition
Event	1. A discrete, auditable, and clearly defined occurrence. [27] 2. Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards. [19] 3. Something that happens to or involves a patient. [100]
Event reporting *See also critical incident reporting, incident reporting*	The primary means through which adverse drug events and other risks are identified. The purposes of event reporting are to improve the management of an individual patient, identify and correct systems failures, prevent recurrent events, aid in creating a database for risk management and quality improvement purposes, assist in providing a safe environment for patient care, provide a record of the event, and obtain immediate medical advice and legal counsel. [52]
Evidence-based guidelines	1. Consensus approaches for handling recurring health management problems aimed at reducing practice variability and improving health outcomes. Guideline development emphasizes using clear evidence from the existing literature, rather than expert opinion alone, as the basis for advisor materials. [22,31] 2. Guidelines that have been scientifically developed based on current literature and are consensus driven. [11]
Failure mode	The manner in which a process has failed or could fail or the manner in which a failure is observed. The term may also refer to specific types of failure (for example, fractures, burns, deviations from expected values) or to degrees of failure (for example, catastrophic, partial, minimal). [53]
Failure mode and effect analysis (FMEA)	1. The systematic assessment of a process or product that enable one to determine the location and mechanism of potential failures. [54] 2. A risk assessment method based on the simultaneous analysis of failure modes, their consequences, and their associated risk factors. [55] *see also* 22
Fault tree analysis	A systematic way of prospectively examining a design for possible ways in which failure can occur. The analysis considers the possible direct proximate causes that could lead to the event and seeks their origins. Once this is accomplished, ways to avoid their origins can cause must be identified. [8]
Five rights of medication administration	Right patient, right drug, right dose, right time, and right route. [56]
Fixation error	The "persistent" failure to revise a diagnosis or plan in the face of readily available evidence that suggests a revision is necessary. [57]
Forcing functions	Something that prevents the behavior from continuing until the problem has been corrected. [2]
Genotype	Patterns about how people, teams, and organizations coordinate activities, information, and problem solving to cope with the complexities of problems that arise. The surface characteristics [phenotype] of a near miss or adverse event are unique to a particular setting and people. Genotypical patterns reappear in many specific situations. [58]

Term	Definition
Gold standard	A method, procedure, or measurement that is widely accepted as being the best available. It provides a reference point against which the performance of other methods, procedures, or measurements can be measured. [8]
Harm	1. Temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom requiring intervention. [17 see also 18,22] 2. The physical injury or damage to the health of people. (Sometimes the damage is not restricted to the health of people and financial loss is included.) [59] 3. Death, disease, injury, suffering and/or disability experienced by a person. [15] 4. Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury. [48] 5. Impairment of structure or function of the body and/or any deleterious effect arising there from.[100]
Hazard *See also dangerous situation*	1. A situation or event that introduces or increases the probability of an adverse event arising from a danger or peril, or that increases the extent of an adverse event. [8] 2. The potential source of harm (e.g., a hazard can be an error in the system itself or a misuse of the system). [59] 3. Any threat to safety, e.g. unsafe practices, conduct, equipment, labels, names. [19] 4. A set of circumstances or a situation that could harm a person's interests, such as their health or welfare. [5] 5. Anything that can cause harm. [48] 6. A circumstance, agent or action that can lead to or increase risk. [100]
Hazardous conditions	Any set of circumstances (exclusive of the disease, disorder, or condition for which the patient is undergoing care, treatment, and services) defined by the organization that significantly increases the likelihood of a serious adverse outcome. [11]
Hazard vulnerability analysis	The identification of potential emergencies and the direct and indirect effects these emergencies may have on the health care organization's operations and the demand for its services. [11]
Health	1. Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. [60] 2. A state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity.[100]

Term	Definition
Health care	1. Services of health care professionals and their agents that are addressed at (1) health promotion; (2) prevention of illness and injury; (3) monitoring of health; (4) maintenance of health; and (5) treatment of diseases, disorders, and injuries in order to obtain cure or, failing that, optimum comfort and function (quality of life). [6] 2. Care provided to individuals or communities by agents of the health services or professions for the purpose of promoting, maintaining, monitoring, or restoring health. Health care is broader than, and not limited to, medical care, which implies therapeutic action by or under the supervision of a physician. [8] 3. Services received by individuals or communities to promote, maintain, monitor or restore health. [100]
Health care-associated harm	Harm arising from or associated with plans or actions taken during the provision of health care rather than an underlying disease or injury. [100]
Health care organization	Entity that provides, coordinates, and/or insures health and medical services for people. [1]
Health care terminology	A collective term used to describe the continuum of code set, classification, and nomenclature (vocabulary). [31]
High-alert medications	1. Medications with the highest risk of causing injury through misuse (including chemotherapy, concentrated electrolytes, heparin, IV digoxin, and adrenergic agonists). [61] 2. Certain classes of medications that have consistently been identified as particularly serious threats to patient safety. These medications include concentrated electrolyte solutions such as potassium chloride, intravenous insulin, chemotherapeutic agents, intravenous opiate analgesics, and anticoagulants such as heparin and warfarin. [62]
High-reliability organizations (HROs)	Highly complex, technology-intensive organization. [7] Internal processes and external relationships are characterized by • a strong sense of mission and operational goals, • high technical competence and operational performance, • structural flexibility and redundancy, • next to hierarchical authority patterns also collegial ones with flexible decision making, • continual search for improvement through experience feedback, • reward structures for the discovery and reporting of error, [and] • an organizational culture of reliability. [63]
High-risk procedures	Surgical or other procedures that put the patient at risk of death or disability. [36]
High-risk process	A process that, if not planned and/or implemented correctly, has a significant potential for impacting the safety of the patient. [36]

Term	Definition
Hindsight bias	1. Finding out that an outcome has occurred increases its perceived likelihood. [64] 2. The tendency to oversimplify and assign simple (human error) causes to events during post-event investigations (i.e., knowing the outcome of an event skews our perception of contributing factors). [2]
Hospital acquired infection *See also infection, nosocomial infection*	An infection that was neither present nor incubating at the time of a patient's admission which normally manifests itself more than three nights after the patient's admission to [the] hospital.[14]
Human error *See also adverse event*	[A term usually] used to delineate one category of potential causes for unsatisfactory activities or outcomes. . . . Studies in a variety of fields show that the label *human error* is prejudicial and unspecific. [65]
Human factors	Study of the interrelationships between humans, the tools, equipment and methods they use, and the environments in which they live and work. [66 *see also* 2, 22]
Iatrogenic	1. An illness or injury resulting from a diagnostic procedure, therapy, or other element of health care. An iatrogenic illness is often confused with a "nosocomial" illness, which simply means an illness "occurring in a hospital." [6] 2. Injury originating from or caused by a physician…, including unintended or unnecessary harm or suffering arising from any aspect of health care management, including problems arising from acts of commission or omission. [31] 3. Any undesirable condition in a patient occurring as a result of treatment by physicians (or other health professional);… Pertaining to an illness or injury resulting from a procedure, therapy, or other element of care. [22]
Immediate cause *See also causal factors, causality, cause, direct cause, proximate cause, underlying cause*	The last of a series or chain of causes tending to a given result and, without the intervention of any further cause, subsequently producing the result or event. It is not necessarily the direct or proximate cause. [8]
Impact	The outcome or effect of a health care error or systems failure, commonly referred to as harm to the recipient of care. Harm may be psychological, physical, or nonmedical. One of four interrelated subclassifications of the elements that comprise health care errors and systems failures. [48]

Term	Definition
Incident *See also adverse event*	1. Involves damage that is limited to parts of a unit, whether the failure disrupts the system or not. [67] 2. Something that happened to the patient, a clinical outcome probably with harmful or potential harmful effects. [68] 3. An event that represents a marked negative deviation from the "standard of care" that occurs in a health care facility; … incidents include major substitution of medications or leaving a patient unattended for a prolonged period of time. [3] 4. An event in the hospital that does not comport with the standards of the hospital or that is unexpected and undesirable … An incident report is completed for each incident to assist in quality management and risk management. [6] 5. An event or occurrence that is usually unexpected and undesirable. [8] 6. An event or circumstance which could have, or did lead to unintended and/or unnecessary harm to a person, and/or a complaint, loss or damage. [22] 7. Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards. [19] 8. Events, processes, practices, or outcomes that are noteworthy by virtue of the hazards they create for, or the harms they case, patients. [5]
Incident Characteristics	Selected attributes of an incident. [100]
Incident reporting *See also critical incident reporting, event reporting*	1. A process used to document occurrences that are not consistent with routine hospital operation or patient care. [69] 2. A system in many health care organizations for collecting and reporting adverse patient occurrences, such as medication errors and equipment failures. It is based on individual incident reports. For several reasons, including fear of punitive action, reluctance of nonphysicians to report incidents involving physicians, lack of understanding of what a reportable incident is, and lack of time for paperwork, the effectiveness of incident reporting is limited. [8]
Incident type	A descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features. [100]
Individual accidents	Accidents in which a specific person or group is often both the agent and the victim of the accident. The consequences to the people concerned may be great, but their spread is limited. [7]
Individual errors	Errors deriving primarily from deficiencies in the physician's own knowledge, skill, or attentiveness. [70]
Infection *See also hospital acquired infection, nosocomial infection*	The transmission of a pathogenic microorganism to a host, with subsequent invasion and multiplication, with or without resulting symptoms of disease. [11]

Term	Definition
Infection control	1. The policies and procedures used to prevent the transmission of infection from one infected individual to another. The term is used in connection with the protection of the professionals and other employees who may have contact with the infectious patient, and the protection of other patients. Infection-control measures include the use of protective clothing, hand-washing, precautions against needle-sticks, decontamination (of the patient's environment and linens), disposal of wastes, and proper handling of laboratory specimens. [6] 2. An organizationwide program, including policies and procedures, for the surveillance, prevention, control, and reporting of infection. Examples of infection-control methods include hand washing, protective clothing, isolation procedures, and ongoing measurement of performance. [8]

Term	Definition
Informed consent	1. A process through which a physician informs a patient about the risks and benefits of a proposed therapy and allows the patient to decide whether the therapy will be undertaken.[71] 2. Voluntarily obtained and legally documented agreement by the patient to allow performance of a specific diagnostic or therapeutic procedure or procedures. [3] 3. A legal term referring to the patient's right to make his own treatment decisions, based upon knowledge of the relevant alternatives and the benefits and risks of each. An "informed consent" is the consent of the patient after he has been fully informed, by the physician proposing the treatment or procedure, of the risks, benefits, and alternatives. Failure to obtain informed consent prior to surgery or administration of treatment may result in legal liability. [6] 4. In law, the principle that a physician has a duty to disclose what a reasonably prudent physician in the medical community, in the exercise of reasonable care, would disclose to his or her patients about whatever risks of injury might be incurred from a proposed course of treatment, testing, or research. A patient, exercising ordinary care for his or her own welfare, and faced with a choice of undergoing the proposed or alternate treatment, testing, or research, or none at all, may then intelligently exercise judgment by reasonably balancing the probable risks against the probable benefits. [8] 5. Agreement or permission accompanied by full notice about what is being consented to. A patient must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins any such course. After receiving this information, the patient then either consents to or refuses such a procedure or treatment. [11] 6. Informed consent is the process by which a physician and patient discuss the possibility of the patient deciding to consent to a proposed preventive or therapeutic intervention. The outcome of this process is the patient's decision to receive or forego treatment. The process occurs in every medical specialty, happens every time the physician and patient discuss the patient's medical situation, and is tailored to the needs of the patient and to the specific medical circumstances. Informed consent is a significant component of the overall physician-patient relationship, involves shared decision making, is ethically and legally required and occurs before and separate from any form of documentation. Informed consent is neither a signature on a consent document nor a tool to avoid a lawsuit. [72]
Injury (bodily) **Injury**	1. The damage caused by an external force, as contrasted with an "illness," which simply indicates that the body is not in a healthy condition. [8] 2. Damage to tissues caused by an agent or circumstance.[100]
Intentional unsafe acts	Intentional unsafe acts… are any events that result from a criminal act, a purposefully unsafe act, an act related to alcohol or substance abuse, impaired provider/staff – or – events involving alleged or suspected patient abuse of any kind. [29]

Term	Definition
Interoperability	The ability of one computer system to exchange data with another computer system such that, at a minimum, the message from the sending system can be placed in the appropriate place in the receiving system. [31]
Intervening cause	Something that happens after an act of negligence and that causes the resulting injury. If the intervening cause is significant, it may relieve the person who was originally negligent of legal liability; in this case, it is called a "superseding" cause. [6]
Intervention	1. An action or actions intended to interrupt the course of events that are in progress. [6] 2. In the broadest sense, the act or fact of interfering so as to favorably modify a condition. [8]
Invasive procedure	A procedure involving puncture or incision of the skin or insertion of an instrument or foreign material into the body. [36]
Isolation	A means [in industry] to separate a process with high probability of failure from other processes to minimize the impact on the products being produced. [54]
Just culture	An environment which seeks to balance the need to learn from mistakes and the need to take disciplinary action. [22]
Judgmental error	An error that involves the inappropriate application of knowledge to the clinical situation. [73]
Knowledge-based error *See also error of proficiency, mistake*	1. [A mistake that] occurs in a novel situation where the solution to a problem has to be worked out on the spot without the help of preprogrammed solutions. This entails the use of slow, resource-limited but computationally powerful conscious reasoning carried out in relation to what is often an inaccurate and incomplete "mental model" of the problem and its possible causes. [50] 2. The conscious application of existing knowledge to the management of novel situations. [10]
Lapse	1. Internal events [that] generally involve failures of memory. [7] 2. Errors which result from some failure in the execution and/or storage stage of an action sequence,… largely involving failures of memory, that do not necessarily manifest themselves in actual behaviour and may be only apparent to the person who experience them. [22]

Term	Definition
Latent condition	1. Latent conditions occur when individuals such as managers or administrators take actions and/or make decisions that affect technical or organizational policy and procedures or the work environment. Their actions and decisions may have unintended consequences in the future that negatively impact patient care. [74] 2. Latent conditions arise from decisions made by designers, builders, procedure writers, and top level management. Latent conditions may lie dormant within the system for many years before they combine with active failures and local triggers to create an accident opportunity… Latent conditions can be identified and remedied before an adverse event occurs. [22] 3. Conditions that have delayed, unintended consequences that can impact safety at some point in the future. [10] 4. Structural flaws in the system, or 'resident pathogens', that predispose to adverse outcomes. [5]
Latent error	1. Errors in the design, organization, training, or maintenance that lead to operator errors and whose effects typically lie dormant in the system for lengthy periods of time. [1] 2. A defect in the design, organization, training or maintenance in a system that leads to operator errors and whose effects are typically delayed or lay dormant in the system for lengthy periods of time. [19 *see also* 22]
Latent failure	1. Delayed-action consequences of decisions taken in the upper echelons of the organization of system. They relate to the design and construction of plant and equipment, the structure of the organization, planning and scheduling, training and selection, forecasting, budgeting, allocating resources, and the like. The adverse safety effects of these decisions may lie dormant for a very long time. [75] 2. Latent failures are created as the result of decisions, taken at the higher echelons of the organization. Their damaging consequences may lie dormant for a long time, only becoming evident when they combine with local triggering factors … to breach the system's defenses. [50] 3. An error that is precipitated by a consequence of management and organizational processes and poses the greatest danger to complex systems. Latent failures cannot be foreseen but, if detected, they can be corrected before they contribute to mishaps. [8] 4. Small, individually innocuous systems faults that, if occurring in specific combination, can lead to catastrophic events. [2]
Liability	1. A broad term referring to all character of obligation, amenability, and responsibility for an act before the law. [3] 2. A broad legal term encompassing almost every responsibility (absolute, contingent, or likely). [8]
Liability (professional)	A legal obligation that is the result of performing (or failing to perform) something one does (or should have done) as a professional. [6]

Term	Definition
Life-threatening adverse drug experience *See also adverse event*	Any adverse drug experience that places the patient or subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred, i.e., it does not include a reaction that, had it occurred in a more severe form, might have caused death. [16]
Local trigger	An intrinsic defect or atypical condition that can create failures. [76]
Loss	(1) Any diminution of quantity, quality, or value of property resulting from the occurrence of some undesired event. (2) In insurance, the basis for a claim under the terms of an insurance policy. [8]
Malpractice *See also medical malpractice*	1. A failure of care or skill by a professional that causes loss or injury and results in legal liability. This narrow definition means the same as "professional negligence." Some use the term *malpractice* more broadly to describe all acts by a health care professional in the course of providing health care—including breach of contract—which may result in legal liability. [6] 2. Professional misconduct or unreasonable lack of skill in the performance of a professional act, a term that may be applied to physicians, lawyers, and accountants. [3] 3. Improper or unethical conduct or unreasonable lack of skill by a holder of a professional or official position, often applied to physicians, dentists, lawyers, and public officers to denote negligent or unskillful performance of duties when professional skills are obligatory. Malpractice is a cause of action for which damages are allowed. [8]
Mapping	The process of cross-linking terms from different terminologies so that comparisons and analysis can be undertaken. [31]
Medical error *See also adverse event*	An adverse event or near miss that is preventable with the current state of medical knowledge.[28 *see also* 2,14]
Medical injury *See also adverse event*	An adverse patient occurrence that may or may not have been avoidable. [8]

Term	Definition
Medical malpractice *See also malpractice*	1. Negligent conduct or unreasonable lack of skill in the performance of a medical task on the part of the physician or a party (e.g., a health care facility) in which that act or task occurs; most cases of medical malpractice fall under the rubric of civil law, i.e., a legal action filed by one person against another, rather than criminal law, i.e., a legal action filed by a state or the federal government against an offending person(s); medical malpractice is based on the theory of negligence, which is conduct that falls below the "standard of care" recognized by the law for protecting others against unreasonable risk of harm, i.e., deviation from accepted standards of care, resulting in harm to others; four elements must be alleged and proven in a court of law in order for the complaining party (the plaintiff) to sustain (win) a lawsuit for negligence: duty, breach of duty, damages, and causation. [3] 2. A judicial determination that there has been a negligent (or, rarely, willful) failure to adhere to current standard(s) of care, resulting in injury or loss to a patient and legal liability of the provider responsible for the negligent act. Since the judgment of malpractice is sociolegal and is made on a case-by-case rather than a systematic basis, standards and processes for determining malpractice may vary by area. [8]
Medical mishap *See also adverse event*	An actual or potential serious lapse in the standard of care provided to a patient or patients or harm caused to a patient or patients through the performance of a health service and/or health care professionals working within it. [77]
Medical mistake *See also*	A commission or an omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were any negative consequences. This definition excludes the natural history of disease that does not respond to treatment and the foreseeable complications of a correctly performed procedure, as well as cases in which there is a reasonable disagreement over whether a mistake occurred. [70]
Medical negligence	The [British] law of medical negligence operates on two principles: that the patient must agree to treatment and that treatment must be carried out with proper skill by the doctors involved. But it holds doctors and other health care professionals liable only for that subset of iatrogenic injury that occurs when there is a breach of the duty to use reasonable care and, as a consequence, the patient experiences an injury. . . . In principle, adverse outcomes consistent with "normal" risk must be borne by the patient. [78]
Medical technology	Techniques, drugs, equipment, and procedures used by health care professionals in delivering medical care to individuals and the systems within which such care is delivered. [1]

Term	Definition
Medication error *See also adverse drug event*	1. Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [79 *see also* 2,14] 2. A deviation from the prescriber's handwritten or typed medication order or from the order that the prescriber has entered into the computer system. Medication errors are typically viewed as related to administration of a medication, but they can also include errors in ordering or delivering medication. [47] 3. Any preventable event that may cause inappropriate medication use or jeopardize patient safety. [11] 4. An error in the processes of ordering, transcribing, dispensing, administering, or monitoring medications, irrespective of the outcome (i.e., injury to the patient). [15] 5. A failure of some kind in the process of medication administration. [6] 6. A discrepancy between what a physician orders and what is reported to occur. Types of medication errors include omission, unauthorized drug, extra dose, wrong dose, wrong dosage form, wrong rate, deteriorated drug, wrong administration technique, and wrong time. An omission medication error is the failure to give an ordered dose; a refused dose is not counted as an error if the nurse responsible for administering the dose tried but failed to persuade the patient to take it. Doses withheld according to written policies, such as for x-ray procedures, are not counted as omission errors. An unauthorized drug medication error is the administration of a dose of medication not authorized to be given to that patient. Instances of "brand or therapeutic substitution" are counted as unauthorized medication errors only when prohibited by organization policy. A wrong dose medication error occurs when a patient receives an amount of medicine that is greater or less than the amount ordered; the range of allowable deviation is based on each organization's definition. [8] 7. Any preventable event (i.e., professional practice, drug products, procedures, systems, prescribing, order communication, product labeling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use) that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. [18] 8. A deviation from an interpretable written prescription or medication order, including written modification of the prescription made by a pharmacist following contact with the prescriber or in compliance with the pharmacy policy [or] any deviation from professional or regulatory references, or guidelines affecting dispensing procedures. [22] 9. Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding' dispensing; distribution; administration; education; monitoring; and use. [22]

Term	Definition
Medication Safety	Freedom from accidental injury during the course of medication use; activities to avoid, prevent, or correct adverse drug events which may result from the use of medications. [22]
Microsystem	Organizational unit built around the definition of repeatable core service competencies. Elements of a microsystem include (1) a core team of health care professionals, (2) a defined population, (3) carefully designed work processes, and (4) an environment capable of linking information on all aspects of work and patient or population outcomes to support ongoing evaluation of performance. [1]
Misadventure *See also adverse event*	An accident or unintentional act, as in an occupation-related "homicide by misadventure"; in medicine, the term has become an elegant euphemism for a therapeutic error, as in a surgical misadventure in which the wrong leg was amputated. [3]
Mistake *See also adverse event, knowledge-based error, rule-based error*	1. An action that may conform exactly to the plan, but the plan is inadequate to achieve its intended outcome. [7] 2. A rule-based or knowledge-based error that is an error of conscious thought. Rule-based errors usually occur during problem-solving when a wrong rule is chosen—either because of a misperception of the situation and thus the application of the wrong rule, or because of misapplication of a rule, usually one that is strong (frequently used), that seems to fit adequately. [Knowledge-based] errors arise because of a lack of knowledge or misinterpretation of the problem. [80] 3. A deficiency or failure in the judgement and/or inferential processes involved in the selection of an objective or in the specification of the means to achieve it, irrespective whether or not the actions directed by this decision-scheme run according to plan; errors of conscious… including *rule-based errors* that occur during problem solving when a wrong rule is chose, and *knowledge-based errors* that arise because of lack of knowledge or misinterpretation of the problem. [22]
Misuse	When an appropriate service has been selected but a preventable complication occurs and the patient does not receive the full potential benefit of the service. [81]
Mitigating factors *See also recovery*	1. Some factors, whether actions or inaction such as chance or luck, may have mitigated or minimised a more serious outcome. [22] 2. An action or circumstance which prevents or moderates the progression of an incident towards harming a patient. [100]
Mitigation activities	Those activities an organization undertakes in attempting to lessen the severity and impact of a potential emergency. [11]
Monitor	1. Any parameter that is regularly and consistently used to evaluate the quality of care. [3] 2. To systematically keep track, with a view to collecting information and keeping a close watch over something. [8] 3. To observe or record relevant physiological or psychological signs. [82]

Term	Definition
Monitoring error	1. A failure to recognize or act upon visible data requiring a response. [83] 2. Failure to review a prescribed regimen for appropriateness and detection of problems, or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed theory. [22]
Near miss *See also close call, potential adverse drug event, potential adverse event, potential error, potential event*	1. An event that almost happened or an event that did happen but no one knows about. If the person involved in the near miss does not come forward, no one may ever know it occurred. [38] 2. A deviation from best practice in health care delivery that would have led to unwanted harm to the patient or to the mission of the organization, but was prevented through planned or unplanned actions. [1] 3. An event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention. [2 *see also* 29] 4. Any process variation which did not affect an outcome, but for which a recurrence carries a significant chance of a serious adverse outcome. [11] 5. A situation in which a medical error could have resulted in an accident, injury, or illness, but did not, either by chance or through timely intervention. [30] 6. An error of commission or omission that could have harmed the patient, but serious harm did not occur as a result of chance… prevention… or mitigation. [31] 7. An event that could have resulted in unwanted consequences, but did not because either by chance or through timely intervention the event did not reach the patient. [18] 8. Unexpected or unplanned events in the provision of care that could have, but did not, lead to harm, loss or damage. [14] 9. An incident that did not cause harm.[100]
Neglect	The absence of minimal services or resources to meet basic needs. Neglect… may also include placing the individual in unsafe or unsupervised conditions. [11]

Term	Definition
Negligence	1. Failure to exercise the skill, care, and learning expected of a reasonably prudent health care provider. [74] 2. Care provided failed to meet the standard of care reasonably expected of an average practitioner qualified to care for the patient in question,(SP-SQS 2005) or that fell below the standard expected of physicians in their community. [23] 3. Failure to use such care as a reasonably prudent and careful person would use under similar circumstances. [8] 4. The failure (usually on the part of a physician or other health care professional) to exercise ordinary, reasonable, usual, or expected care, prudence, or skill (that would usually or customarily be exercised by other reputable physicians treating similar patients) in the performance of a legally recognized duty, resulting in foreseeable harm, injury; or loss to another; negligence may be an act of omission (i.e., unintentional) or commission (i.e., intentional), characterized by inattention, recklessness, inadvertence, thoughtlessness, or wantonness; in health care, negligence implies a substandard deviation from the "standard of medical practice" that would be exercised by a similarly trained professional under similar circumstances. [3]
Negligent injuries	In negligent injuries, the standard of care and the procedures to prevent injury were well known, as was the likelihood of serious injury if they were not followed. [84]
No harm event	1. When an error does not result in an adverse event for the patient and the absence of injury is owed to chance. This differs from a near miss, in which injury is absent because the error was "caught." [44] 2. An incident occurs which reaches the patient, but results in no injury to the patient. Harm is avoided by chance or because of mitigating circumstances. [18]
Nomenclature	A set of specialized terms that facilitate precise communication by eliminating ambiguity. [31]
Non-clinical incident	Incidents in a health care setting not caused by clinical procedures that resulted, or could have resulted, in unexpected harm to the patient, for example a patient fall. [14]
Normal accident	When interactive complexity and tight coupling—system characteristics—inevitably produce an accident. . . . The odd term *normal accident* is meant to signal that, given the system characteristics, multiple and unexpected interactions of failures are inevitable . . . system accidents are uncommon, even rare; yet this is not all that reassuring if they can produce catastrophes. [67]
Normative error	An error that involves the failure to acknowledge or "own up" to one's limitations. [73]
Nosocomial infection *See also infection; hospital acquired infection*	1. An infection acquired while receiving care or services in the health care organization. [8,11] 2. Pertaining to or originating in a health care facility. [22]

Term	Definition
Occupational disability	A condition in which an employee is unable to perform the functions required to complete a job satisfactorily because of an occupational disease or an occupational accident. [8]
Operative risk	The probability of an adverse outcome and death associated with surgery and anesthesia. Decisions to proceed with surgery are based on conceptualized risk-benefit ratios, which can be accurate only when they are applied to groups of comparable patients undergoing similar procedures. The risks can be classified as patient related, procedure related, provider related, and anesthetic agent related. The patient's overall status may be assessed and scored by the American Society of Anesthesiologists' Physical Status Scale (ASA-PSS), which has been found to correlate with surgical outcome, although it was not originally developed as a predictor of risk. [8]
Organizational accident	Comparatively rare, but often catastrophic, events that occur within complex modern technologies. … Organizational accidents have multiple causes involving many people operating at different levels of their respective companies. [7]
Organizational model *See also person model, safety management*	[A model that is] linked to crisis management and can be considered as an extension of the engineering model. The underlying idea is that safety can be reached by the absence of latent factors which would increase the probability of human errors. Safety is measured by proactive methods… and means continuous control and adjustment of the system's basic processes, similar to the notion of total quality management. [63]
Organizational Outcome	The impact upon an organization which is wholly or partially attributable to an incident. [100]
Outcome *See also patient health outcome, patient outcome*	1. The result of the performance (or nonperformance) of a function(s) or process(es). [8] 2. A product, result or practical effect. [5]
Overuse	When a health care service is provided under circumstance in which its potential for harm exceeds the benefit. [81]
Partial disability	An illness or injury that prevents a person from performing one or more functions of his or her occupation or profession. [8]
Patient	A person who is a recipient of healthcare. [100]
Patient Characteristic	Selected attributes of a patient. [100]
Patient health outcome *See also outcome*	The result to a patient from performance (or nonperformance) of one or more processes, services, or activities carried out by health care providers. A patient health outcome represents the cumulative effect of one or more processes at a defined time, for example, survival to discharge following a gunshot wound to the chest or an acute myocardial infarction. [8]
Patient Outcome	The impact upon a patient which is wholly or partially attributable to an incident. [100]
Patient related factor	Failures related to patient characteristics or conditions, which are beyond the control of staff and influence treatment. [10]

Term	Definition
Patient safety *See also safety*	1. The avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of health care. These events include "errors," "deviations," and "accidents." Safety emerges from the interaction of the components of the system; it does not reside in a person, device, or department. Improving safety depends on learning how safety emerges from the interactions of the components. Patient safety is a subset of health care quality. [85] 2. Freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur. [1] 3. Actions undertaken by individuals and organizations to protect health care recipients from being harmed by the effects of health care services. [86] 4. Freedom from accidental injuries during the course of medical care; activities to avoid, prevent, or correct adverse outcomes which may result from the delivery of health care. [22] 5. The identification, analysis and management of patient-related risks and incidents, in order to make patient care safer and minimize harm to patients. [22] 6. The reduction and mitigation of unsafe acts within the health-care system, as well as through the use of best practices shown to lead to optimal patient outcomes. [5] 7. The prevention and mitigation of harm to patients. [48] 8. Freedom, for a patient, from unnecessary harm or potential harm associated with healthcare.[100]
Patient safety data	The broad and heterogeneous information that includes, but is not limited to, the description of incidents with medical errors or near misses, their causes, the follow-up corrective actions, interventions that reduce future risk, and patient safety hazards. [30]
Patient safety incident *See also adverse event*	An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.[100] *--referred to as an incident*
Patient tracer	The process of evaluating a patient's total care experience within a health care organization. [11]
Performance improvement	The continuous study and adaptation of a health care organization's functions and processes to increase the probability of achieving desired outcomes and to better meet the needs of individuals and other users of services. [11]
Permanent disability	A continuous condition resulting from illness or injury that prevents an individual from performing some or all of the functions of his or her occupation. [8]
Person model *See also organizational model, safety management*	The traditional occupational safety approach [to safety management] focusing mainly on errors, unsafe acts, and personal injuries. The underlying idea is that people are free to choose between safe or unsafe behavior. Errors are attributed mainly to psychological factors such as inattention, poor motivation, or lack of skills. Individuals are therefore the targets for safety management interventions. [63]

Term	Definition
Phenotype	1. Safety problems, failures in specific health areas, i.e., the superficial characteristics of the system as opposed to underlying mechanisms: prevalence and cause of medication errors by health care personnel in all settings; surgery or procedure on wrong part of body; errors in performance of hazardous activities (surgery, anesthesia, radiation therapy, etc.); misdiagnosis, selection of inappropriate treatment; and nosocomial infection. [85] 2. What happens, what people actually do or what they do wrong, what can be observed. Phenotypes are specific to the local situation and context—the surface appearance of an incident. [37]
Pharmacovigilence	The science and activities related to the detection, assessment, understanding and prevention of the adverse effects of pharmaceutical products. [22]
Potential adverse drug event	A serious medication error – on that has the potential to cause an adverse drug event, but did not, either by luck or because it was intercepted and corrected. [22]
Potential adverse event *See also close call, near miss, potential adverse drug event, potential error, potential event*	1. A serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted. [19] 2. An incident in which an error was made but no harm occurred. [13]
Potential error *See also close call, near miss, potential adverse drug event, potential adverse event, potential event*	Circumstances or events that have the capacity (potentiality) to cause error. [22]
Potential event *See also close call, near miss, potential adverse drug event, potential adverse event , potential error*	Any event that has not yet occurred but is perceived by care providers or skilled observers to have the likelihood of occurrence, given the right conditions. [48]
Potentially compensable event (PCE)	An adverse patient care event that ultimately may be involved in a liability claim. The event involves a disability (temporary or permanent) caused by health care management (including acts of commission and omission by health care providers). … A PCE is not the same as an adverse patient occurrence or negligence. [8]
Preparation error	Whatever type of medication error, of omission or commission, that occurs in the preparation stage when the medication has to be compounded or prepared by a pharmacist, a nurse, or the own patient, or a caregiver. [22]

Term	Definition
Prescribing error *See also adverse event*	1. A mistake made by the prescriber when ordering a medication. [47] 2. A medication error occurring during the prescription of a medicine that is about writing the drug order or taking the therapeutic decision, appreciated by any non intentional deviation from standard reference such as: the actual scientific knowledge, the appropriate practices usually recognized, the summary of the characteristics of the medicine product, or the mentions according to the regulations. A prescribing error notably can concern: the choice of the drug (according to the indications, the contraindications, the known allergies and patient characteristics, interactions whatever nature it is with the existing therapeutics, and the other factors), dose, concentration, drug regimen, pharmaceutical form, route of administration, duration of treatment, and instructions of use; but also the failure to prescribe a drug needed to treat an already diagnosed pathology, or to prevent the adverse effects of other drugs. [22]
Preventable adverse drug event *See also adverse event*	Any adverse drug event that would not have occurred if the patient had received ordinary standards of care appropriate for the time when this event occurred. [22]
Preventable adverse event *See also adverse event*	Adverse event that would not have occurred if the patient had received ordinary standards of care appropriate for the time. [22]
Preventable	Accepted by the community as avoidable in the particular set of circumstances. [100]
Preventability	1. Implies that methods for averting a given injury are known and that an adverse event results from failures to apply that knowledge. [84 *see also* 22] 2. An error in management due to the failure to follow accepted practice at an individual or system level. [87 *see also* 5]
Preventable event	An event that could have been anticipated and prepared for, but that occurs because of an error or other system failure. [27]
Preventable death	A death is considered preventable when the patient received poor care, and the poor care probably resulted in the patient's death. [1]
Prevention	Modification of the system … to decrease the probability of arisen the dreaded event and to return to an acceptable risk level; any measure aiming at reducing the frequency and the severity of the risk. [22]
Priority focus areas	Processes, systems, or structures in a health care organization that significantly impact the quality and safety of care. [11]
Process	1. A series of related actions to achieve a defined outcome. [22] 2. A course of action, or sequence of steps, including what is done and how it is done. [5]

Term	Definition
Process variation	The spread of process output over time. There is variation in every process, and all variation has causes. The causes are of two types: special or common. A process can have both types of variation at the same time or only common-cause variation. The management action necessary to improve the process is different depending on the type of variation being addressed. [8]
Professional liability	The legal obligation of a health care professional or organization resulting from a breach (performing something that was done or failing to perform something that should have been done), for which the law provides a remedy. A physician, for example, who fails to make a diagnosis resulting in patient injury is professionally liable for the injury. Professional liability is not the same as professional negligence. [8]
Professional negligence	Failure of a professional, such as a physician, to exercise the degree of care considered reasonable under the circumstances, with such failure resulting in an unintended injury to another party. Professional negligence is not synonymous with professional liability. [8]
Proximate cause *See also causal factor, causation, cause, direct cause, underlying cause*	1. An act or omission that naturally and directly produces a consequence. It is the superficial or obvious cause for an occurrence. Treating only the "symptoms," or the proximate special cause, may lead to some short-term improvements, but will not prevent the variation from recurring. In some jurisdictions, for an act to be considered the proximate cause of a loss or injury, it must be proved that, without the act or omission, the injury or loss would not have occurred. [8] 2. A legal term describing the direct cause of an injury. The proximate cause is that which in a natural sequence, unbroken by intervening factors, produced the injury, and without which the injury would not have happened. [6]
Public accountability *See also accountability*	The obligation or duty of specific individuals and/or institutions to make information about their actions or performance available to the public or a public organization or agency (or its designee) that has responsibility for oversight and is answerable to the general public. [27]
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. [100]
Quality control	A process that consists of measuring performance, comparing performance against goals, and acting on the differences when performance falls short of defined goals. [11]

Term	Definition
Quality of care	1. Degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. [1 *see also* 2] 2. The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. [11] 3. The degree of conformity with accepted principles and practices (standards), the degree of fitness for the patient's needs, and the degree of attainment of achievable outcomes (results), consonant with the appropriate allocation or use of resources. The phrase *quality of care* carries the concept that quality is not equivalent to "more" or "higher technology" or higher cost. The *degree of conformity* with standards focuses on the provider's performance, while the *degree of fitness* for the patient's needs indicates that the patient may present conditions that override strict conformity with otherwise prescribed procedures. [6]
Recklessness	The individual knows there is a risk, is willing to take that risk, and takes it deliberately… The individual performs an act that creates an obvious risk, and when performing the act has either given no thought to the possibility of such a risk, and having recognized that such a risk existed, goes on to take it. [22]
Recovery *See also mitigating factors*	An informal set of human factors that lead to a risky situation being detected, understood, and corrected in time, thus limiting the sequence to a near-miss outcome, instead of it developing further into possibly an adverse event. [22]
Reference terminology	Concept-oriented terminologies possessing characteristics such as a grammar that defines the rules for automated generation and classification of new concepts as well as combination of atomic concepts to form molecular expressions. [31]
Reliance on human checks	No tools or "memory aids" to assist in guiding an individual through the process of tools not used. (Human memory degrades as time goes by. Reliance on memory during multitasking is highly error prone). [2]
Reliance on vigilance	Process relies on frequent or constant observation to ensure accuracy. [2]
Reportable occurrence	An event, situation, or process that contributes to, or has the potential to contribute to, a patient or visitor injury or to degrade [practitioners'] ability to provide optimal patient care. Reportable occurrences can generally be divided into the following types based on severity: sentinel events, patient and visitor injuries (adverse events), nears misses, and safety concerns.[2]
Resilience	The degree to which a system continuously prevents, detects, mitigates or ameliorates hazards or incidents.[100]

Term	Definition
Risk *See also tolerable risk*	1. The likelihood, high or low, that somebody or something will be harmed by a hazard, multiplied by the severity of the potential harm. [26] 2. The likelihood of disease, injury, or death among various groups of individuals and from different causes. Individuals are said to be "at risk" if they are in a group in which a given causal factor is present. … This definition is that employed in public health. [6] 3. The combination of the probability of occurrence of harm and the severity of that harm. [59] 4. Exposure to events that may threaten or damage the organization or its interests. [88] 5. (1) The chance of occurrence of disease, injury, or death among various groups of individuals and from different causes. (2) Any measurable or predictable chance of loss, injury, disadvantage, hazard, danger, peril, or destruction. Risk to a health care organization may arise, for example, through general or professional liability or physical property damage. [8] 6. The chance of something happening that will have an impact on individuals and/or organisations. It is measured in terms of likelihood and consequence. [14] 7. The probability of danger, loss or injury within the health-care system. [5] 8. The possibility/probability of occurrence or recurrence of an event multiplied by the severity of an event. [48] 9. The probability that an incident will occur. [100]
Risk assessment	1. An assessment that examines a process in detail, including sequencing of events; assesses actual and potential risk, failure, or points of vulnerability; and, through a logical process, prioritizes areas for improvement based on the actual or potential patient care impact (criticality). [11] 2. The qualitative or quantitative estimation of the likelihood of (adverse) effects that may result from exposure to specified events or processes or from the absence of beneficial influences. [8] 3. The process that helps organisations understand the range of risks they face – both internally and externally, the level of ability to control these risks, the likelihood of recurrence and their potential impacts. It involves a mixture of quantifying risks and using judgement, assessing and balancing of risks and their benefits and weighing them, for example, against the cost. [14,22]
Risk containment	Immediate actions taken to safeguard patients from a repetition of an unwanted occurrence. Actions may involve removing and sequestering drug stocks from pharmacy shelves and checking or replacing oxygen supplies or specific medical devices. [8 *see also* 2]

Term	Definition
Risk management	1. In the context of hospital operations, … self-protective activities meant to prevent real or potential threats of financial loss due to accident, injury, or medical malpractice. [89] 2. One of a number of organizational systems or processes aimed at improving the quality of health care, but one that is primarily concerned with creating and maintaining safe systems of care. [88] 3. Clinical, administrative and manufacturing activities that organizations undertake to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itself. [11 *see also* 2,22] 4. The constellation of activities (planning, organizing, directing, evaluation and implementation) involved in reducing the risks of injury to patients and employees and reducing property damage or loss within health care facilities. [3] 5. The process of minimizing risk insurance to an organization at a minimal cost in keeping with the organization's objectives. Risk management includes risk control and risk financing. Risk control involves (1) developing systems to prevent accidents, injuries, and other adverse occurrences, and (2) attempting to handle events and incidents that do occur in such a manner that their cost is minimized. . . . Risk financing involves the procurement of adequate financial protection from loss, either through an outside insurance company or through some form of self-insurance. [6] 6. Identifying, assessing, analysing, understanding, and acting on risk issues in order to reach an optimal balance of risk, benefits and costs. [22] 7. Organizational activities designed to prevent patient injury or moderate the actual financial losses following an adverse outcome. [5] 8. The process of identification, assessment, analysis and management of all risks and incidents for every level of the organization, and aggregating the results at a corporate level, which facilitates priority-setting and improved decision-making to reach optimal balance of risk, benefit and cost. [14]
Risk points	Specific points in a process that are susceptible to error or system breakdown. They generally result from a flaw in the initial process design, a high degree of dependence on communication, nonstandardized processes, and failure or absence of backup. [16]
Root cause	1. The original cause for the failure or inefficiency of a process. [14] 2. The most fundamental reason an event has occurred. [29 *see also* 2]

Term	Definition
Root cause analysis (RCA) *See also causal analysis investigation*	1. A process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event.[11 *see also* 2,31] 2. Systematic process whereby factors that contributed to an incident are identified.[14] 3. A systematic process of investigating a critical incident or an adverse outcome to determine the multiple, underlying contributing factors. The analysis focuses on identifying the latent conditions that underlie variation in performance and, if applicable, developing recommendations for improvements to decrease the likelihood of a similar incident in the future. [5,18] 4. A systematic investigation technique that looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which the incident happened. The analysis focuses on identifying the latent conditions that underlie variation in performance and on developing recommendations for improvement to decrease the likelihood of a recurrence. [22] 5. A process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls. RCAs have the following characteristics: • The review is interdisciplinary in nature with involvement of those closest to the process. • The analysis focuses primarily on systems and processes rather than individual performance. • The analysis digs deeper by asking what and why until all aspects of the process are reviewed and all contributing factors are identified (progressing from looking at special causes to common causes). • The analysis identifies changes that could be made in systems and processes through either redesign or development of new processes or systems that would improve performance and reduce the risk of event or close call recurrence. To be thorough, an RCA must include: • A determination of the human and other factors most directly associated with the event or close call and the processes and systems related to its occurrence; (there is rarely only one underlying cause) • Analysis of the underlying systems through a series of why questions to determine where redesigns might reduce risk • Identification of risks and their potential contributions to the event or closecall. • Determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist. To be credible, an RCA must: • Include participation by the leadership of the organization (this can range from chartering the RCA team, to direct participation on the RCA team, to participation in the determination of the corrective action plan) and by individuals most closely involved in the processes and systems under review. • Be internally consistent (i.e., not contradict itself or leave obvious questions unanswered). • Include consideration of relevant literature. [29] 6. 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.[100]
Rule-base	A component of production rule system that represents knowledge as “if-then” rules. [31]

Term	Definition
Rule-based behavior	1. Familiar procedures applied to frequent decision-making situations. [35] 2. The application of existing rules or schemes to the management of familiar situations. [10]
Rule-based error *See also error of procedure, mistake*	1. [A mistake that] relates to problems for which the person possesses some prepackaged solution, acquired as a result of training, experience, or the availability of appropriate procedures. [50] 2. When a person fails to carry out a procedure or protocol correctly or chooses the wrong procedure. [74]
Safe care	Safe care involves making evidence-based clinical decisions to maximize the health outcomes of an individual and to minimize the potential for harm. [31]
Safety *See also patient safety*	1. The degree to which the risk of an intervention… and the risk in the care environment are reduced for a patient and other persons, including health care practitioners. [11] 2. The condition of being secure or safe from undergoing or causing injury, harm, or loss; any activity or element of the environment for which the risks of its use and disposal are considered acceptable is considered to be safe. [3] 3. The freedom from unacceptable risk. [59] 4. The freedom from accidental injury. [1] *see also* 19 5. A state in which risk has been reduced to an acceptable level. [14] 6. Freedom from hazard.[100]
Safety concern	Protocols, procedures, products, or equipment that are problem-prone, or risk-generating processes that may degrade [practitioners'] ability to provide optimal patient care. [2]

Term	Definition
Safety culture	1. [A culture that exhibits the following] five high-level attributes that [health care professionals] strive to operationalize through the implementation of strong safety management systems. (1) A culture where *all* workers (including front-line staff, physicians, and administrators) accept responsibility or the safety of themselves, their coworkers, patients, and visitors. (2) [A culture that] prioritizes safety above financial and operational goals. (3) [A culture that] encourages and rewards the identification, communication, and resolution of safety issues. (4) [A culture that] provides for organizational learning from accidents. (5) [A culture that] provides appropriate resources, structure, and accountability to maintain effective safety systems. [2] 2. The safety culture of an organization is the product of individual and group values, attitudes, perceptions competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management. [90] 3. Organizations with effective safety cultures share a constant commitment to safety as a top-level priority, which permeates the entire organization. Noted components include (1) acknowledgment of the high-risk, error-prone nature of an organization's activities, (2) a blame-free environment where individuals are able to report errors or close calls without punishment, (3) an expectation of collaboration across ranks to seek solutions to vulnerabilities, and (4) a willingness on the part of the organization to direct resources to address safety concerns. [71] 4. An integrated pattern of individual and organizational behavior, based upon shared beliefs and values, that continuously seeks to minimize patient harm which may result from the processes of care delivery. [22]
Safety incident *See also adverse event*	An event that, under slightly different circumstances, could have been an accident. [31]
Safety management *See also organizational model, person model*	1. Safety is managed by three different control strategies: • A feedback strategy, used for distributed sources of low hazards, which aims to control safety empirically by ongoing measurements according to a certain acceptable level of safety, operationalized in accident or injury rates. … Methods are oriented to past events. • A feedforward strategy, used for high-hazard systems in rapid change, aims to control safety by proper design and operation, taking into account mechanisms underlying the system hazards and the accident-producing processes. . . . Methods used to support this strategy are future oriented. • A combined feedforward and feedback strategy is used for concentrated sources of high hazards with slow change, aiming to control safety by an ongoing adjustment of feedforward methods according to experience gained by the use of feedback methods.[91] 2. Activities selected and implemented by the organization to assess and control the impact of environmental risk, and to improve general environmental safety. [11]
Semantic Relationship	The way in which things (such as classes or concepts) are associated with each other on the basis of their meaning.[100]

Term	Definition
Sentinel event *See also adverse event*	1. 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 risk thereof* includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called 'sentinel' because they signal the need for immediate investigation and response. [11 *see also* 2,18,22] 2. Any event that has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition. [48] 3. An unexpected occurrence or variation involving death or serious physical or psychological injury or the risk thereof. [1]
Serious event *See also adverse event*	1. [An event] that leads to or prolongs a hospitalization, contributes to or causes death, or is associated with cancer or a congenital anomaly. [92] 2. An event that results in death or loss of a body part or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from an inpatient health care facility or, when referring to other than an adverse event, an event whose occurrence is grave. [27]
Serious outcome	Death, a life-threatening condition, initial or prolonged hospitalization, disability, or congenital anomaly, or when intervention was required to prevent permanent impairment or damage. [93]
Sharp end	1. Practitioners at the sharp end actually interact with the hazardous process in their roles. [7 *see also* 2] 2. The immediate human–system or doctor-patient interface. [50] 3. Where practitioners interact directly with the hazardous process in their roles as… nurses, physicians, technicians, pharmacists, and others. [37]
Side effect	A known effect, other than that primarily intended, related to the pharmacological properties of a medication.[100]
Skill-based behavior *See also slip*	Routine tasks requiring little or no conscious attention during execution. [35 *see* also 10]

Term	Definition
Slip *See also skill-based behavior*	1. An unintended error or execution of a correctly intended action. [55] 2. An unconscious glitch in automatic activity. Slips are errors of action. A slip occurs when there is a break in the routine while attention is diverted. [80] 3. A type of error that results from automatic behavior, when subconscious actions that are intended to satisfy our goals get waylaid en route. [95] 4. Failure in the performance of highly developed skills. [96] *see also* 10 5. Error which result from some failure in the execution and/or storage stage of an action sequence… potentially observable as actions-not-as-planned… Slips relate to observable actions and are commonly associated with attentional or perceptual failures. [22]
Sound-alike drugs	Medications with similar names that can easily be mistaken for one another, especially when verbal orders are involved. [97]
Stakeholder	An individual who has an interest in the activities of an organization and the ability to influence it. A hospital's stakeholders, for example, include its patients, employees, medical staff, government, insurers, industry, and the community. [6]
Standard	1. A minimum level of acceptable performance or results or excellent levels of performance or the range of acceptable performance or results. [1] *see also* 2 2. A statement that defines the performance expectations, structures, or processes that must be in place for an organization to provide safe and high-quality care, treatment, and service. [11] 3. A measure of quality or quantity, established by an authority, by a profession, or by custom, that serves as a criterion for evaluation. [6] 4. A set of characteristics or quantities that describes features of a product, process, service, interface, or material. [31]
Standard – Data Interchange	A taxonomy that arranges or organizes like or related terms for easy retrieval. [31]
Standard - classification	A systematic arrangement or division of materials, products, systems, or services into groups based on similar characteristics. [1] *see also* 2
Standard – guide	A series of options or instructions that do not recommend a specific course of action. [1] *see also* 2

Term	Definition
Standard - of care	1. A level of competence in performing medical tasks that is accepted as reasonable and reflective of a skilled and diligent health care provider, which obliges a physician to confine his practice of medicine only to those areas of his expertise; such standards may be delineated by a hospital's medical staff bylaws or the standards published by a specialty college. [3] 2. The principles and practices that have been accepted by a health care profession as expected to be applied for a patient under ordinary circumstances. Standards of care are developed from a consensus of experts, based on specific research (where such is available) and expert experience. "Under ordinary circumstances" refers to the fact that a given patient may have individual conditions that are overriding; absent such considerations, a medical staff or nursing staff quality review committee will expect the generally accepted principles and practices to be carried out. [6] 3. Generally, in health care law, the degree of care that a physician, who possesses average skills and practices in the same or similar locality, should exercise in the same or similar circumstances. In cases involving specialization, however, certain courts have disregarded geographical considerations, holding that in the practice of a board-certified medical or surgical specialty, the standard should be that of a reasonable specialist practicing medicine or surgery in the same special field. If a physician's conduct falls below the standard of care, he or she may be liable for any injuries or damages resulting from that conduct. [8] 4. The principles and practices which have been accepted by a health-care profession as expected to be applied for a patient under ordinary circumstances. [5]
Standard - of practice	A procedure for performing one or more specific operations or functions. [1,2]
Standard - for reporting	Formally accepted or endorsed definitions and rules regarding the types of events reported to patient safety reporting systems, the data and information collected on these events, and the reporting formats used. [31]
Standard – specification	A statement of a set of requirements to be satisfied and the procedures for determining whether each of the requirements is satisfied. [1 *see also* 2]
Standard – terminology	A document comprised of terms, definition of terms, description of terms, explanations of symbols, abbreviations, or acronyms. [31]
Standard – of test method	1. A procedure for identifying, measuring, and evaluating a material, product or system. [1] 2. A definitive procedure for the identification, measurement, and evaluation of one or more qualities, characteristics or properties of a material, produce, system or service that produces a test result. [31]
Structure	The supporting framework or essential parts. It includes all elements of the health-care system that exist before any actions or activities take place. [5]
Suffering	The experience of anything subjectively unpleasant. [100]

Term	Definition
Surveillance	Routine collection and review of data to examine the extent of a disease, to follow trends, and to detect changes in disease occurrence. [31]
System	1. Set of interdependent elements (people, processes, equipment) interacting to achieve a common aim. [1 *see also* 2,19,22] 2. A regularly interacting or interdependent group of items forming a unified whole. [28] 3. A set of interrelated parts that work together toward a common goal. [11] 4. A category of factors or characteristics that interacts with characteristics of other systems or categories. [98] 5. A process by which a complex of people and machines (and other essential resources) work together in an orderly fashion to accomplish a given task. [6]
System complexity	Process with multiple steps and/or decision points. (Complex systems require excessive attention and can be tightly coupled.) Examples: a surgical tray arrives missing a critical component or a delayed or erroneous lab result; if there are no contingencies for these types of events, there could be significant consequences. [2]
System design	1. The primary objective of system design for safety is to make it difficult for individuals to err. But it is also important to recognize that errors will inevitably occur and plan for their recovery. Ideally, the system will automatically correct errors when they occur. If that is impossible, mechanisms should be in place to detect errors at least in time for corrective action. Therefore, in addition to designing the work environment to minimize psychological precursors, designers should provide feedback through instruments that provide monitoring functions and build in buffers and redundancy. [80] 2. Designing systems for safety requires specific, clear, and consistent efforts to develop a work culture that encourages reporting of errors and hazardous conditions, as well as communication among staff about safety concerns… 3. designing health care processes for safety involves a three-part strategy: (1) designing systems to prevent errors, (2) designing procedures to make errors visible when they do occur, and (3) designing procedures that can mitigate the harm to patients from errors that are not detected or intercepted. [49]
System engineering	The effective application of scientific and engineering efforts to transform an operational need into a defined system configuration through the top-down iterative process of requirements definition, functional analysis, allocation, synthesis, design optimization, test, and evaluation. (Good system engineering must be applied during the design and the development of medical systems.) [59]

Term	Definition
Systems analysis	1. The formal evaluation of an activity, method, procedure, or technique in which the entirety of the problem is examined in an attempt to improve the workflow. [3] 2. An analysis of the resources (personnel, facilities, equipment, materials, funds, and other elements), organization, administration, procedures, and policies needed to carry out a given task. The analysis typically addresses alternatives in each category, and their relative efficiency and effectiveness. [6] 3. The analysis of the resources (human, financial, material, and so forth), organization, administration, procedures, and policies needed to carry out a specific process. The analysis usually includes a list of options in each category and their relative merits. [8] 4. The evaluation of how well a health care organization's systems function. [11]
Systems approach	Using prompt, intensive investigation followed by multidisciplinary systems analysis… to [uncover] both proximal and systemic causes of errors... It is based on the concept that although individuals make errors, characteristics of the systems within which they work can make errors more likely and also more difficult to detect and correct. Further, it takes the position that while individuals must be responsible for the quality of their work, more errors will be eliminated by focusing on systems than on individuals. It substitutes inquiry for blame and focuses on circumstances rather than on character.[84]
Systems error	1. An error that is not the result of an indiviual's actions, but the predictable outcome of a series of actions and factors that comprise a diagnostic or treatment process.[28] 2. The delayed consequences of technical design or organizational issues and decisions. [35] 3. An error that is not the result of an individual's actions, but the predictable outcome of a series of actions and factors that comprise a diagnostic or treatment process. [2,28]
Systems failure **System failure**	1. The common categories [of systems failure] include failures of design (process design, task design, and equipment design) and failures of organization and environment (presence of psychological precursors such as conditions of the workplace, schedules, etc.; inadequate team building; and training failures). [99] 2. An adverse event caused by an error or other type of systems or equipment failure. [19] 3. A fault, breakdown or dysfunction within an organization's operational methods, processes or infrastructure.[100]
System improvement	The result or outcome of the culture, processes, and structures that are directed toward the prevention of system failure and improvement of safety and quality.[100]

Term	Definition
Taxonomy *See also classification*	1. A system for organizing information about patient safety, including threats to patient safety. [48] 2. System for naming and organising items into groups that share similar characteristics. [14] 3. The theoretical study of classification, including its bases, principles, procedures and rules. [39]
Technical error	An error that involves instrumental issues having to do with knowledge and skill. [73]
Temporary disability	An illness or injury that prevents an insured individual from performing functions of his or her usual occupation or profession for an interim period of time. [8]
Terminologies	Terminologies define, classify, and in some cases code data content. [31]
Threat to patient safety	Any risk, event, error, hazardous condition, or set of circumstances that has harmed patients or that could lead to patient harm. [48]
Tolerable risk *See also risk*	[A] risk that is accepted in a given context based on the current values of society. [59]
Total disability	An illness or injury that prevents an individual from performing any duty pertaining to his or her occupation or profession or from engaging in any other type of work for remuneration. [8]
Toxic substance	Chemicals that are present in sufficient concentration to pose a hazard to human health. [27]
Tripping	Failures in whole-body movement; these errors are often referred to as “slipping, tripping, or falling”—examples would be a sample tube slipping out of one’s hands and breaking, or tripping over a loose tile on the floor. [95]
Type	The perceptible, outward, or visible process that was in error or failed. Subcategories of type are communication, patient management, and clinical performance. One of four interrelated subclassifications of the elements that comprise health care errors and systems failures. [48]
Typology	A classification that is multidimensional and conceptual. A typology is characterized by labels or names. [39]
Underlying cause *See also causation, causal factor, cause, direct cause, immediate cause, proximate cause*	The systems or process cause that allow for the proximate cause of an event to occur. Underlying causes may involve special-cause variation, common-cause variation, or both. [8]
Underuse	The failure to provide a health care service when it would have produced a favorable outcome for a patient. [81]

Term	Definition
Unexpected adverse drug experience *See also adverse event*	Any adverse drug experience, the specificity or severity of which is not consistent with the current investigator brochure; or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the investigator brochure only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the investigator brochure only listed cerebral vascular accidents. ``Unexpected,`` as used in this definition, refers to an adverse drug experience that has not been previously observed (e.g., included in the investigator brochure) rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product. [16]
Unpreventable adverse drug event *See also adverse event*	An adverse drug event that does not result from an error but reflect the inherent risk of drugs and cannot be prevented given the current state of knowledge. [22]
Unpreventable adverse event *See also adverse event*	An adverse event resulting from a complication that cannot be prevented given the current state of knowledge. [28 *see also* 2,22]
Variation	The differences in results obtained in measuring the same phenomenon more than once. The sources of variation in a process over time can be grouped into two major classes: common causes and special causes. Excessive variation frequently leads to waste and loss, such as the occurrence of undesirable patient health outcomes and increased cost of health services. [8]
Violation	A deliberate deviation from an operating procedure, standard or rules.[100]

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