The Conceptual Framework for the International Classification for Patient Safety

Version 1.0 for Use in Field Testing
2007 - 2008

(ICPS)

World Health Organization

Prepared by Drafting Group of the
Project to Develop the International Classification for Patient Safety

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Table of Contents

Page

Introduction 4
Key Concepts, Definitions and Preferred Terms 6
Incident Type 14
Patient Outcomes 30
Patient Characteristics 31
Incident Characteristics 32
Contributing Factors/Hazards 38
Mitigating Factors 44
Detection 45
Organizational Outcomes 46
Ameliorating Actions 47
Actions to Reduce Risk 48

Introduction

Although the results of the first large-scale study of adverse events were published over thirty years ago[1], the field of patient safety has only gained widespread attention in the last decade.[2,3,4] In this time, there has been a rapid increase in the number of publications and reports in this area, but interpretation and comparison have been compromised by a lack of common understanding and language. A need was thus identified for a comprehensive classification, populated by concepts with agreed definitions[5,6] which should be described by "preferred terms" from the major languages of the world. The consistent use of such terms and concepts in conjunction with a comprehensive but adaptable classification will pave the way for researchers to understand each others' work, and will facilitate the systematic collection, aggregation and analysis of relevant information from all available sources, allowing comparisons between facilities and jurisdictions, and over time. The classification should be applicable across the full spectrum of healthcare from primary care to highly specialized areas and should be able to be used in conjunction with existing processes and systems.[6]

An opportunity to address this need was presented by the launch of the World Alliance for Patient Safety of the World Health Organization (WHO).[7] A group was formed under the auspices of the World Alliance to develop the International Classification for Patient Safety (ICPS).[8] It was decided that a classification (an arrangement of concepts based on similarities) instead of a taxonomy (a set of rules to name entities based upon their location within a particular structure) was needed. It was also decided to use concepts and terms with meanings as close as possible to those in colloquial use and to avoid long definitions with several "qualifiers", but instead to start with simple, basic definitions, and then "build" by defining the key terms used in these definitions. The main consideration in coming up with the definitions was that they should convey the appropriate meaning and be brief and clear, without unnecessary or redundant qualifiers. They are also, whenever reasonable, consistent with concepts from other terminologies and classifications in the Family of International Classifications of the WHO. This makes it necessary to read the terms and their definitions in the sequence provided in the next section.

The conceptual framework for the ICPS is shown in Figure 1. How some key terms and concepts relate to the ICPS is shown in Figure 2. In the next section a narrative, in a logical sequence, incorporates the definitions of the key concepts with the preferred terms and some descriptions and comments. The definitions are listed in Table I in the sequence in which they are discussed in the narrative, and the terms defined are listed in alphabetical order in Table 2.

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1 Mills DH, ed. Medical insurance feasibility study. A technical summary. *West J Med* 1978;128:360-5.

2 Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err is Human: Building a Safer Health System.* Washington DC: National Academies Press, 2000.

3 Department of Health. *An Organisation with a Memory - Report of an Expert Group on Learning from Adverse Events in the NHS Chaired by the Chief Medical Officer*. London: The Stationery Office, 2000.

4 Runciman WB, Moller J. *Iatrogenic Injury in Australia.* Adelaide: Australian Patient Safety Foundation, 2001. Available at <http://www.apsf.net.au>

5 World Alliance for Patient Safety. *International Classification for Patient Safety.* http://www.who.int/patientsafety/taxonomy/en/

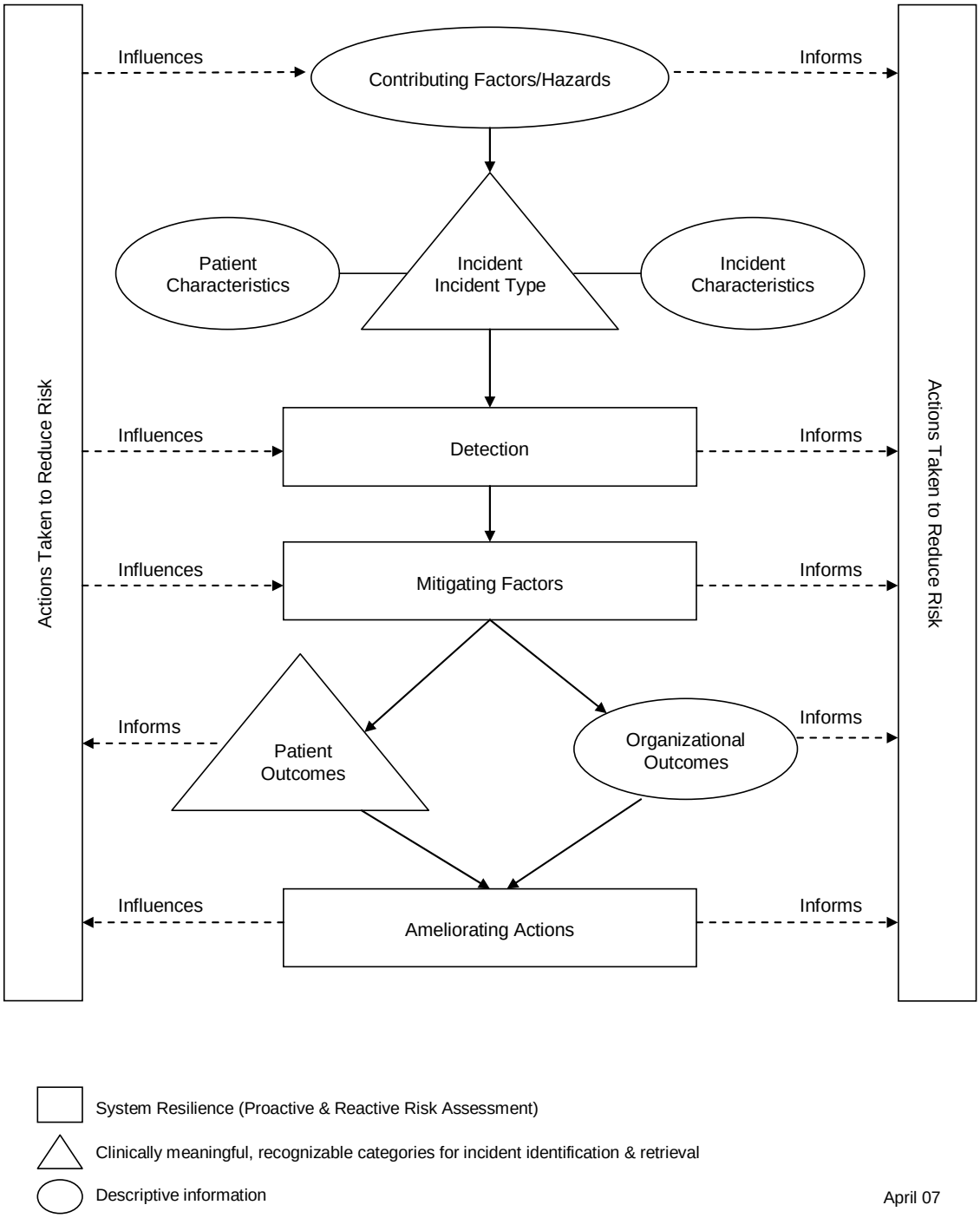
6 Runciman WB, Williamson JA, Deakin A, *et al*. An integrated framework for safety, quality and risk management: an information and incident management system based on a universal patient safety classification. *Qual Saf Health Care* 2006;15 Suppl 1:i82-90.

7 World Health Organization. *World Alliance for Patient Safety: Forward Programme 2005*. Geneva: World Health Organization, 2004. Available at: www.who.int/patientsafety/en/brochure_final.pdf

8 World Health Organization. *Project to Develop the International Patient Safety Event Taxonomy: Report of the WHO World Alliance for Patient Safety Drafting Group, 24-25 October 2005*. Geneva: World Health Organization, 2005. Available at: http://www.who.int/patientsafety/taxonomy/Final_Report_of_Drafting_Group05.pdf

Figure 1.

Conceptual Framework for the International Classification for Patient Safety



Legend: The solid lines enclose the 10 major classes of the ICPS and represent the semantic relationships between them. The dotted lines represent the flow of information.

Key Concepts, Definitions and Preferred Terms

As foreshadowed in the Introduction, in order to keep the definitions as succinct as possible, concepts are progressively introduced so as to allow understanding to be "built", starting with the terms in the title of the ICPS (classification, patient, safety). The terms in **bold** have been deemed ICPS preferred terms; where terms have been highlighted in this way, the agreed definitions follow.

A **classification** is an arrangement of **concepts** (bearers or embodiments of meaning) into **classes** (groups or sets of like things, such as "Contributing Factors", "Incident Types" and "Patient Outcomes") and their subdivisions to express the **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 particular Incident Type. Similarly, Mitigating Factors are associated with Incident Type and Outcomes, as steps cannot be taken to interfere with the progression of an incident until its nature has been determined, and the outcomes will not occur until these attempts have reached their conclusion.

The ICPS allows assignment of features of incidents on the basis of common characteristics; this facilitates their later extraction for analysis. Each class has hierarchically arranged subdivisions populated by concepts (for example, "fatigue/exhaustion" under the class "Contributing Factors"). Concepts impart the essence of a notion using a term. Concepts may be represented by a number of terms that allow for regional dialects, different languages, clinicians, disciplines and hospital preferences. Preferred terms to describe the concepts have been chosen as "natural categories" (see below), or terms with meanings as close as possible to those in colloquial use.[9]

Concepts may inherit characteristics from their "parents" (a parent-child or subsumption relationship), or represent selected agreed qualities, properties or features of the concept in question which are not inherited (an "attribute" relationship). For example, "endotracheal tube" and "tracheotomy tube" are children of "artificial airway", whereas the list of medical devices has an attribute-type relationship to the incident type "medical devices/equipment/property", and is not one of its children. Concepts have been organized hierarchically in the classification according to natural mapping. Natural mapping is the grouping of the subsets or attributes of a class or concept in a representation reflecting the real world.[9]

A **patient** has been defined as a person who is a recipient of healthcare and **healthcare** has been defined as services received by individuals or communities to promote, maintain, monitor or restore health. For the purposes of the ICPS, patients are referred to rather than clients, tenants or consumers, although it is recognized that a healthy pregnant woman, a child undergoing immunization, the occupant of a halfway house or an adolescent seeking counseling may not be regarded, and may not regard themselves, as patients. Healthcare is not limited to medical care provided by others, and includes self-care. **Health** has been defined "as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity", consistent with the World Health Organization definition.

Safety has been defined as freedom from hazard, and **hazard** as a circumstance, agent or action which can lead to or increase risk. A **circumstance** has been defined as any factor connected with or influencing an event, agent or person(s); an **event** as something that happens to or involves a patient; and an **agent** as a substance, object or system which acts to produce change. For the purposes of the ICPS it is implicit that all these terms (and others, such as quality and outcome) are meant to be interpreted in the context of patient safety.

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[9] Norman DA. *The Psychology of Everyday Things.* New York: Basic Books, 1998.

Patient safety is defined as freedom for a patient from unnecessary harm or potential harm associated with healthcare. **Healthcare-associated harm** is harm arising from or associated with plans or actions taken during the provision of health care rather than an underlying disease or injury.

A **patient safety incident** is an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient, and has a more constrained meaning than the term incident which, when used in a general context, has a wider meaning as an event or circumstance which could have resulted, or did result, in harm to *any person and/or* a complaint, loss or damage. Please note for purposes of the ICPS, a patient safety incident will be hereafter referred to as an incident.

The use of the term "unnecessary" in the definition of patient safety incident is in recognition that errors, violations, patient abuse and deliberately unsafe acts occur in healthcare and are unnecessary incidents, whereas certain forms of harm, such as an incision for a laparotomy, are necessary. The former are incidents, whereas the latter would not be regarded as one.

Incidents may arise from both unintended and intended acts. Errors are, by definition, unintentional, whereas violations are intentional, even though they may become routine in certain contexts. An **error** may be defined as a failure to carry out a planned action as intended or application of an incorrect plan, and may manifest by doing the wrong thing (an error of commission) or by failing to do the right thing (an error of omission), at either the planning or execution phase. Thus, if it is agreed that screening for bowel cancer should be by regular testing for occult blood, then a screening colonoscopy in the absence of prior occult blood testing comprises an error of commission (over servicing), and a failure to arrange testing for occult blood an error of omission (under servicing). A **violation** implies deliberate deviation from an operating procedure, standard or rule. Both errors and violations increase risk, even if an incident does not actually occur. **Risk** is the probability that an incident will occur.

An **adverse event** is an incident which results in harm to a patient. **Harm** implies impairment of structure or function of the body and/or any deleterious effect arising therefrom. Harm includes disease, injury, suffering, disability and death and may thus be physical, social or psychological. **Disease** is defined as a physiological or psychological dysfunction, **injury** as damage to tissues caused by an agent or circumstance and **suffering** as the experience of anything subjectively unpleasant. Suffering includes pain, malaise, nausea, vomiting, 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 **near miss** is an incident that did not cause harm (also known as a close call).

A **contributing factor** is defined as a circumstance, action or influence (such as poor rostering or task allocation) which is thought to have played a part in the origin or development of an incident, or to increase the risk of an incident. Contributing factors may be external (ie not under the control of a facility or organization), organizational (such as unavailability of accepted protocols), be related to a staff factor (a cognitive or behavioral defect in an individual, a lack of supervision, poor team work or inadequate communication) or be related to a patient factor (such as behavior).

Incidents are classified into a number of different incident types. An **incident type** is a descriptive term for a category made up of incidents of a common nature, grouped because of shared agreed features. An incident type is a "parent" natural category under which many concepts (also comprising natural categories) may be grouped; they may be "children" of the parent incident type or attributes (see above under the description of classes, concepts and natural mapping).

A natural category is a descriptor (usually a short phrase) which is brief, easily and commonly understood. It captures the essence of an event or circumstance or of associated characteristics or attributes and is not constrained by being restricted to any class or property. To take an example from the workplace – 40 of 100 incident reports describing why staff are late for work might be assigned to the following natural categories: could not find car key; child sick – no other carer; had a puncture or flat tyre; alarm clock did not go off; or usual car park full. These phrases capture the essence of each incident and most observers would categorize them in the same way (e.g., a higher rate of inter-rater reliability). Natural categories constitute an informal classification system, used by a specific professional or cultural group. They reflect a social consensus about what matters, or what is worthy of notice, in a given context. In this case, the context is patient safety.

Incident types are not exclusive categories. An incident may need to be assigned to several incident types, although a "business rule" may be developed to allow a "principal" incident type to be nominated so that all incidents may be counted. One rule is to nominate the incident which led most directly to any harm or potential harm as the principal incident type. Thus, for example, for an incident in which an infusion pump was set up wrongly and delivered an overdose of a sedative, causing respiratory arrest, the drug overdose (the medication incident type) would be selected as the principal incident type rather than the equipment problem. Other examples of incident types are healthcare associated infection, documentation problems and problems with a clinical administration process.

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

Terms commonly used in relation to medication incidents include adverse reactions and side effects. An **adverse reaction** is defined as unexpected harm arising from a justified action where the correct process was followed for the context in which the event occurred. Recurrence of a known adverse reaction may be preventable (such as an allergic reaction to a drug, by avoiding re-exposure). A **side effect** is a known effect, other than that primarily intended, relating to the pharmacological properties of a medication. An example of an adverse reaction would be unexpectedly getting neutropenia when that particular drug is not known to have this effect. An example of a side effect would be when nausea, pruritis or urinary retention are encountered when morphine has been given to alleviate pain.

It is useful to try to identify when an incident is preventable. **Preventable** has been defined as being accepted by the community as avoidable in the particular set of circumstances.

Detection is defined as an action or circumstance that results in the discovery of an incident. This may be by noticing an error via a monitor or alarm, by a change in patient condition or by an audit, review or risk assessment. Detection mechanisms may be part of the system (such as low pressure disconnect alarms in breathing circuits) or may result from a checking process or from vigilance and "situation awareness".

A **mitigating factor** is defined as an action or circumstance which prevents or moderates the progression of an incident towards harming a patient. The damage mechanism has already started, but has not yet led to the maximum possible harm.

The term "error recovery" has been used to describe the combined detection and mitigation sequence. In this context recovery does not refer to clinical recovery (recuperation) but to the process of recovering from an incident that has started. An example of error recovery would be reconnecting a breathing circuit after a disconnect alarm had given warning that there was a disconnection. By collecting information about how and why "saves" are made, system design, training and education can be informed.

Patient outcome is defined as the impact upon a patient which is wholly or partially attributable to an incident. Where harm has occurred, the **degree of harm** is defined as the severity and duration of any harm, and the treatment implications, that result from the incident. It would seem, from first principles, desirable to record the nature, severity and duration of harm separately. However, in practice, there are substantial problems in doing this and nearly all attempts to link degree of harm conflate these parameters. **Organizational outcome** is defined as the impact upon an organization which is wholly or partially attributable to an incident. Examples would be adverse publicity and additional use of resources.

An 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 any harm to a patient, such as fixing a fracture after a fall, whereas healthcare system ameliorating factors reduce any loss or damage to an organization arising from an incident. For example, good public relations management after a well publicized disaster will ameliorate any long-term effects on the reputation of a facility.

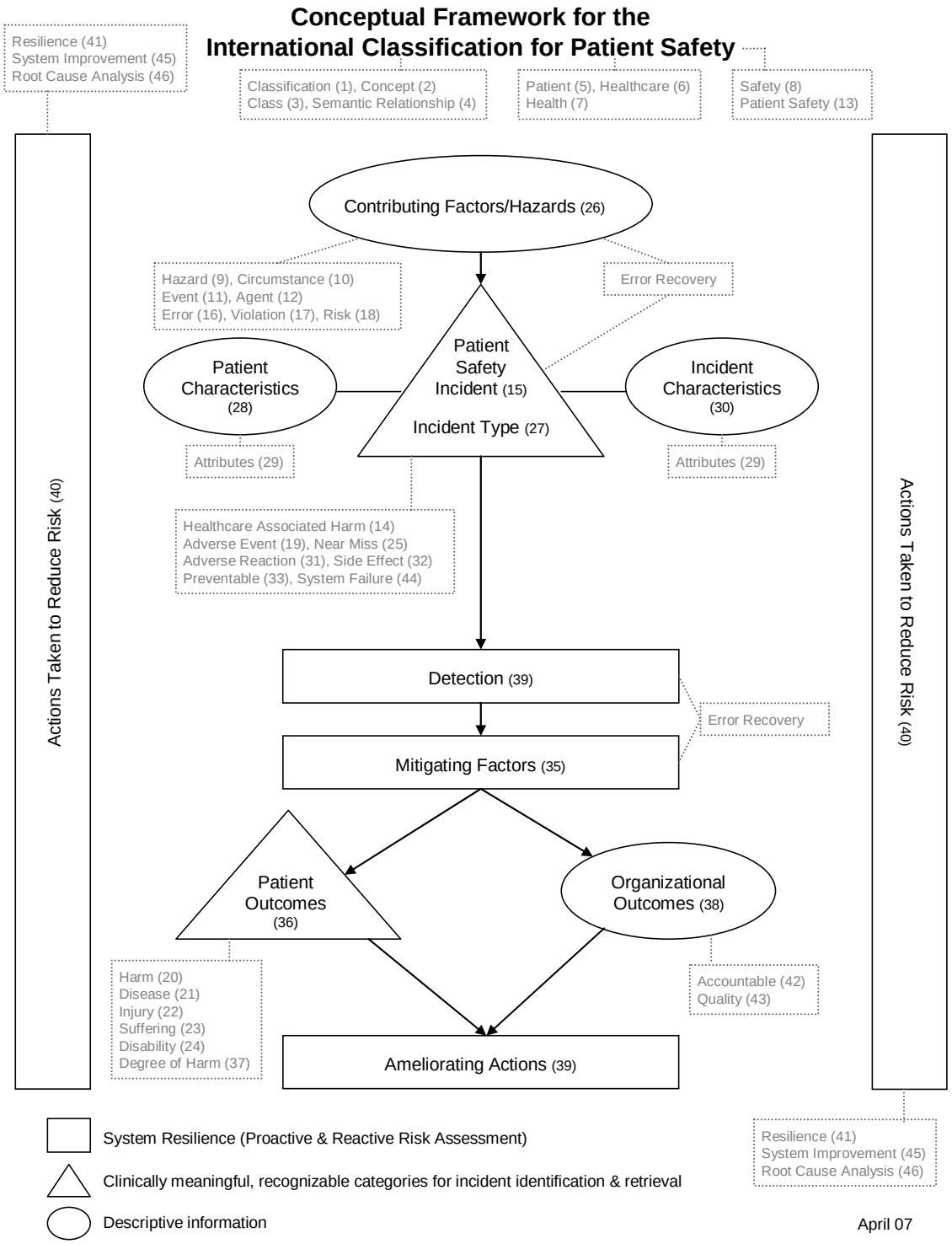
Actions taken to reduce risk are defined as actions taken to reduce, manage or control the harm, or probability of harm, associated with an incident. An action can relate directly to incidents and contributing factors, detection, mitigating factors or ameliorating actions and can be pro-active or reactive. Pro-active actions may be identified by techniques such as failure mode and effects analysis and probabilistic risk analysis, whereas reactive actions are those taken in response to insights gained after an incident (see root cause analysis, below, for an example).

Resilience refers 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 core functions as soon as possible after incurring damage.

A number of terms are commonly used with respect to organizational management. **Accountable** is defined as being held responsible. The terms negligence and liability are listed below, but are not considered core definitions as these may vary depending on the jurisdiction. **Quality** is defined as 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 or a patient. An example of a latent factor would be a breathing circuit disconnect alarm with no power failure warning or battery backup. **System improvement** is defined as 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. A process to counter the latent failure just described would be to modify the equipment to alarm when the power supply is compromised, or to always use an additional device such as expired air capnography set up so as to alarm if carbon dioxide is not detected. Finally, **root cause analysis** is defined as 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 (contributing factors/hazards) have been elucidated. "Why" should be iteratively asked until the investigating team runs out of facts – they should not guess or speculate. The team should also stop the process when the identified contributing factors or hazards require counter measures which are beyond the influence of the organization. These are known as "stopping rules", and help to determine when a root cause analysis team should stop the investigative process and move on to defining the problems and recommending corrective strategies.

Concepts defined and terms chosen so far simply represent a collection of basic building blocks to enhance the study of patient safety. Changes will be necessary as our understanding widens and needs are identified. Translation into other major languages will be necessary and has been started. There are more concepts which will need to be defined, and decisions made with respect to which terms should be preferred and which terms avoided. Certain qualifiers should be regarded as implicit when these terms are used in the context of the ICPS. For example, it should be assumed that the term "incident" refers to a *patient safety* incident, implying *harm or potential harm.* The same applies to terms such as *quality* and *system failure.* Used in this way the concepts defined and terms chosen so far will facilitate understanding and transfer of information relevant to patient safety amongst the increasing number of people with an interest in this area.

Figure 2.



Legend: The solid lines enclose the 10 major classes of the ICPS and represent the semantic relationships between them. The dotted lines link relevant preferred terms which have been defined in the text. The numbers represent the sequence in which they appear in the text and in Tables 1 and 2.

Table 1. List of Preferred Terms and Definitions for Key Concepts

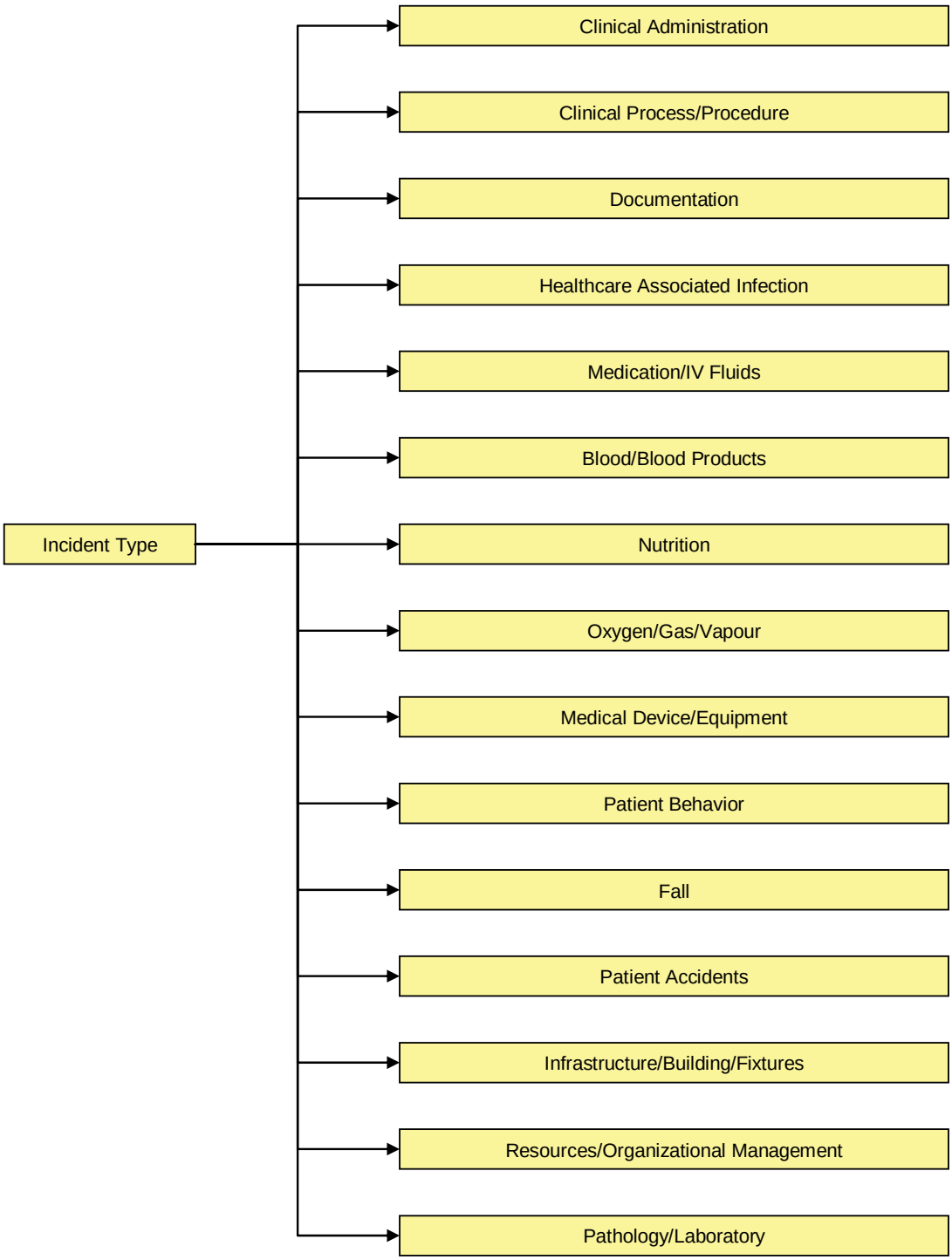
1. **Classification**: an arrangement of **concepts** into **classes** and their subdivisions to express the **semantic relationships** between them.
2. **Concept**: a bearer or embodiment of meaning.
3. **Class**: a group or set of like things.
4. **Semantic relationship**: the way in which things (such 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**: freedom from **hazard**.
9. **Hazard**: a **circumstance, agent** or action that can lead to or increase risk.
10. **Circumstance**: any factor connected with or influencing 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**: freedom, for a patient, from unnecessary harm or potential harm associated with **healthcare**.
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 rules.
18. **Risk**: the probability that an **incident** will occur.
19. **Adverse event**: an **incident** which results in **harm** to a patient.
20. **Harm**: impairment of structure or function of the body and/or any deleterious effect arising there from.
21. **Disease**: a physiological or psychological dysfunction.
22. **Injury**: damage to tissues caused by an **agent** or **circumstance**.
23. **Suffering**: the experience of anything subjectively unpleasant.
24. **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**.
25. **Near Miss**: an **incident** that did not cause **harm**.
26. **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**.
27. **Incident type**: a descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features.
28. **Patient characteristics**: selected **attributes** of a **patient**.
29. **Attributes**: qualities, properties or features of someone or something.
30. **Incident characteristics**: selected **attributes** of an **incident**.
31. **Adverse reaction**: unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred.
32. **Side effect**: a known effect, other than that primarily intended, related to the pharmacological properties of a medication.
33. **Preventable**: accepted by the community as avoidable in the particular set of circumstances.
34. **Detection**: an action or **circumstance** that results in the discovery of an **incident**.
35. **Mitigating factor**: an action or **circumstance** which prevents or moderates the progression of an **incident** towards harming a **patient**.

36. **Patient outcome**: the impact upon a patient which is wholly or partially attributable to an **incident**.
37. **Degree of harm**: the severity and duration of harm, and the treatment implications, that result from an **incident**.
38. **Organizational Outcome**: the impact upon an organization which is wholly or partially attributable to an **incident**.
39. **Ameliorating action**: an action taken or **circumstances** altered to make better or compensate any **harm** after an **incident**.
40. **Actions taken to reduce risk**: actions taken to reduce, manage or control the harm, or probability of **harm** associated with an **incident**.
41. **Resilience**: The degree to which a system continuously prevents, detects, mitigates or ameliorates **hazards** or **incidents**.
42. **Accountable**: being held responsible
43. **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.
44. **System failure**: a fault, breakdown or dysfunction within an organization's operational methods, processes or infrastructure.
45. **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**.
46. **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.

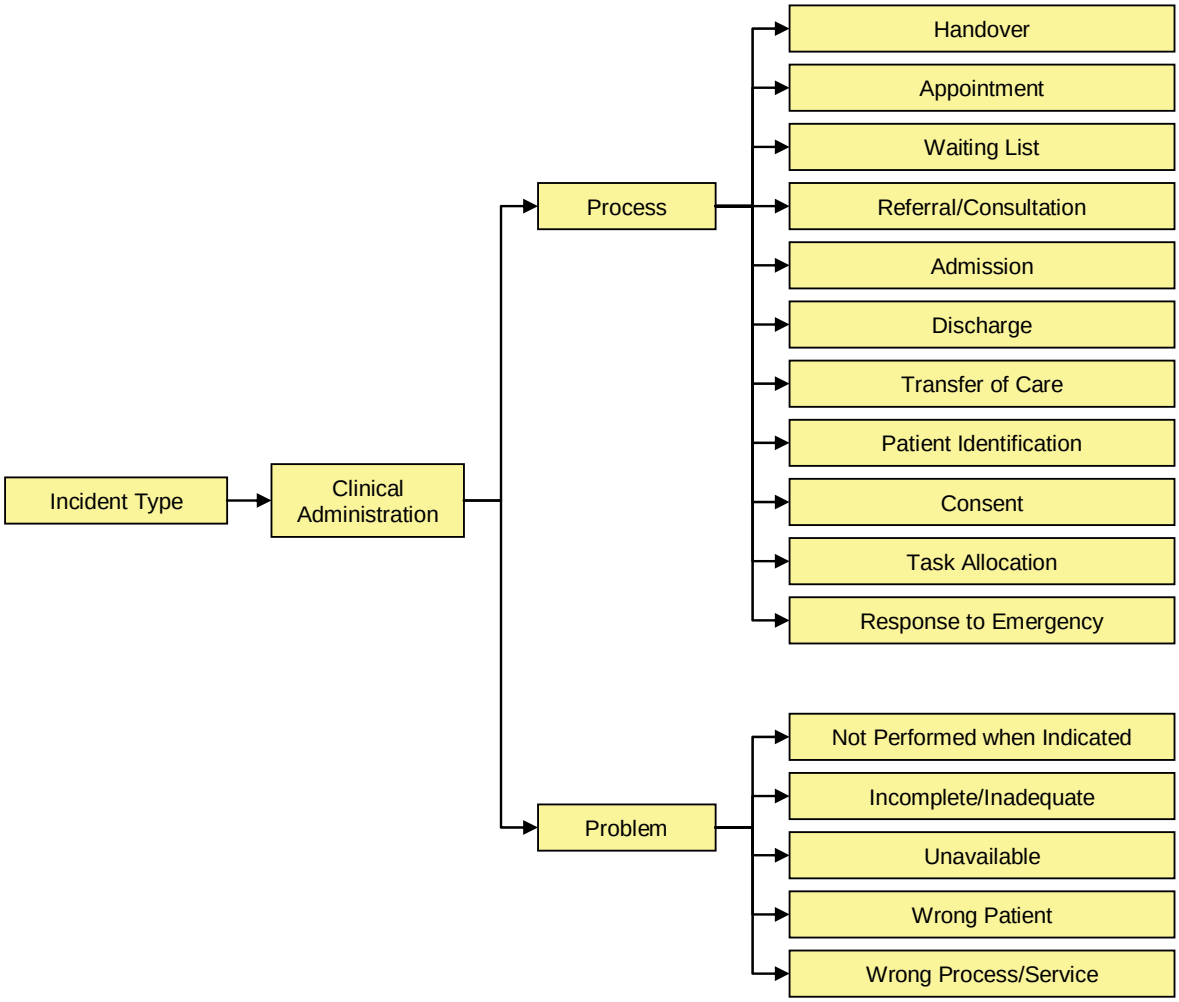
Table 2. List of Preferred Terms for Key Concepts in Alphabetical Order
(the numbers refer to the sequence in which these preferred terms appear in the text)

Accountable (42)
Actions taken (40)
Adverse event (19)
Adverse reaction (31)
Agent (12)
Ameliorating action (39)
Attributes (29)
Circumstance (10)
Class (3)
Classification (1)
Concept (2)
Contributing factor (26)
Degree of harm (37)
Detection (34)
Disability (24)
Disease (21)
Error (16)
Event (11)
Harm (20)
Hazard (9)
Health (7)
Healthcare (6)
Heathcare-associated harm (14)
Incident characteristics (30)
Incident type (27)
Injury (22)
Mitigating factor (35)
Near miss (25)
Organizational outcome (38)
Patient (5)
Patient characteristics (28)
Patient outcome (36)
Patient safety (13)
Patient safety incidents (15)
Preventable (33)
Quality (43)
Resilience (41)
Risk (18)
Root cause analysis (46)
Safety (8)
Semantic relationship (4)
Side effect (32)
Suffering (23)
System failure (44)
System improvement (45)
Violation (17)

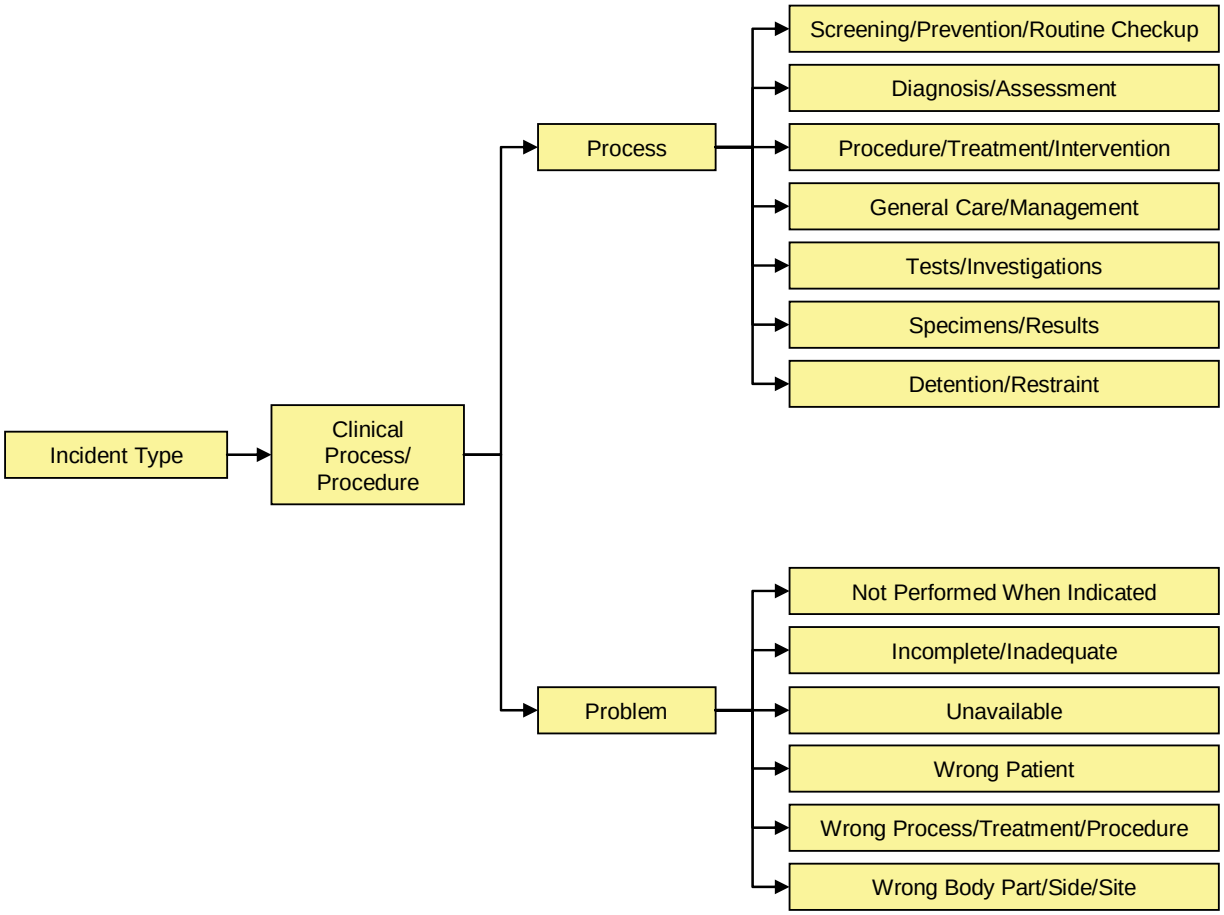
Incident Type



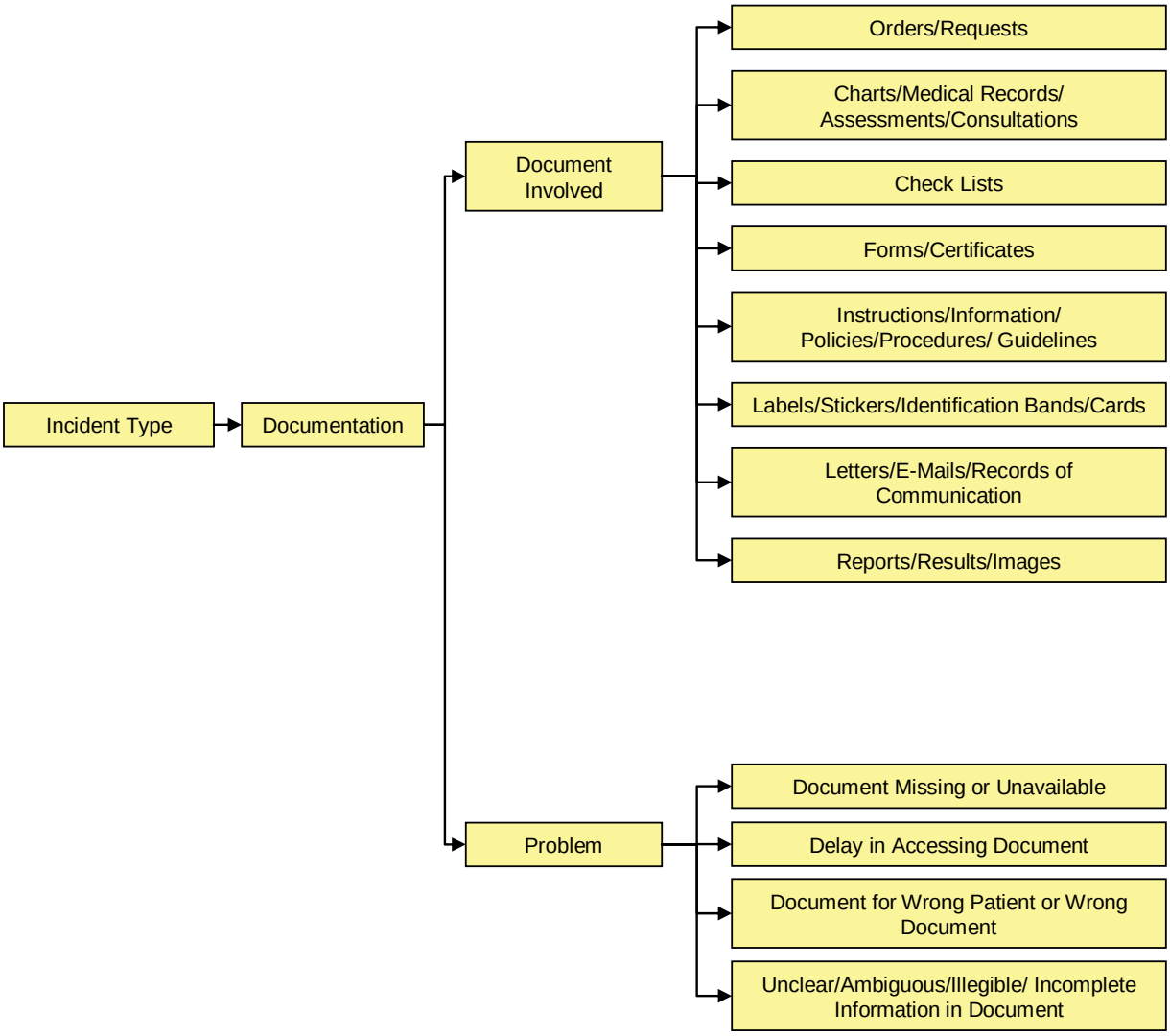
Incident Type – Clinical Administration



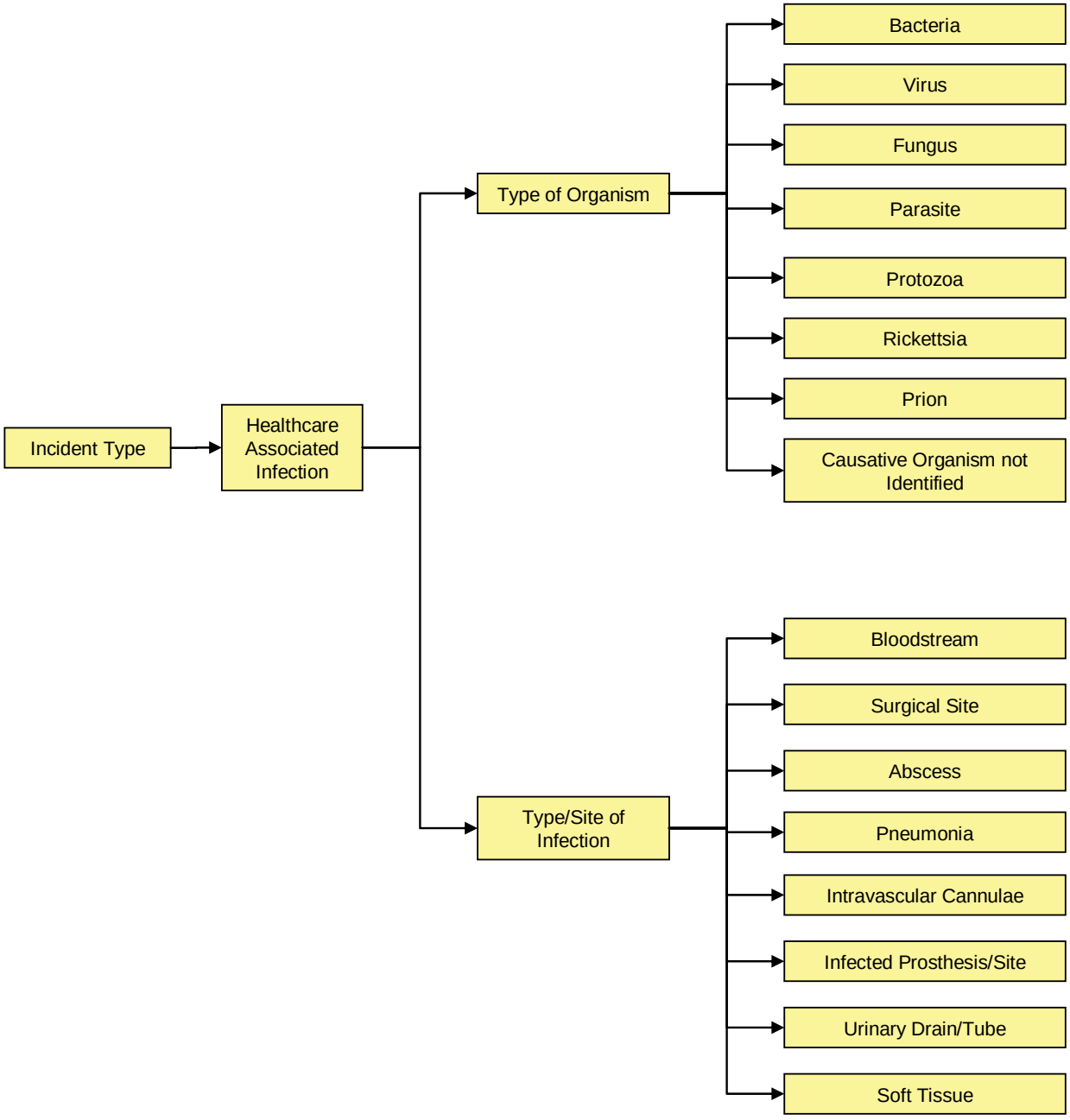
Incident Type – Clinical Process/Procedure



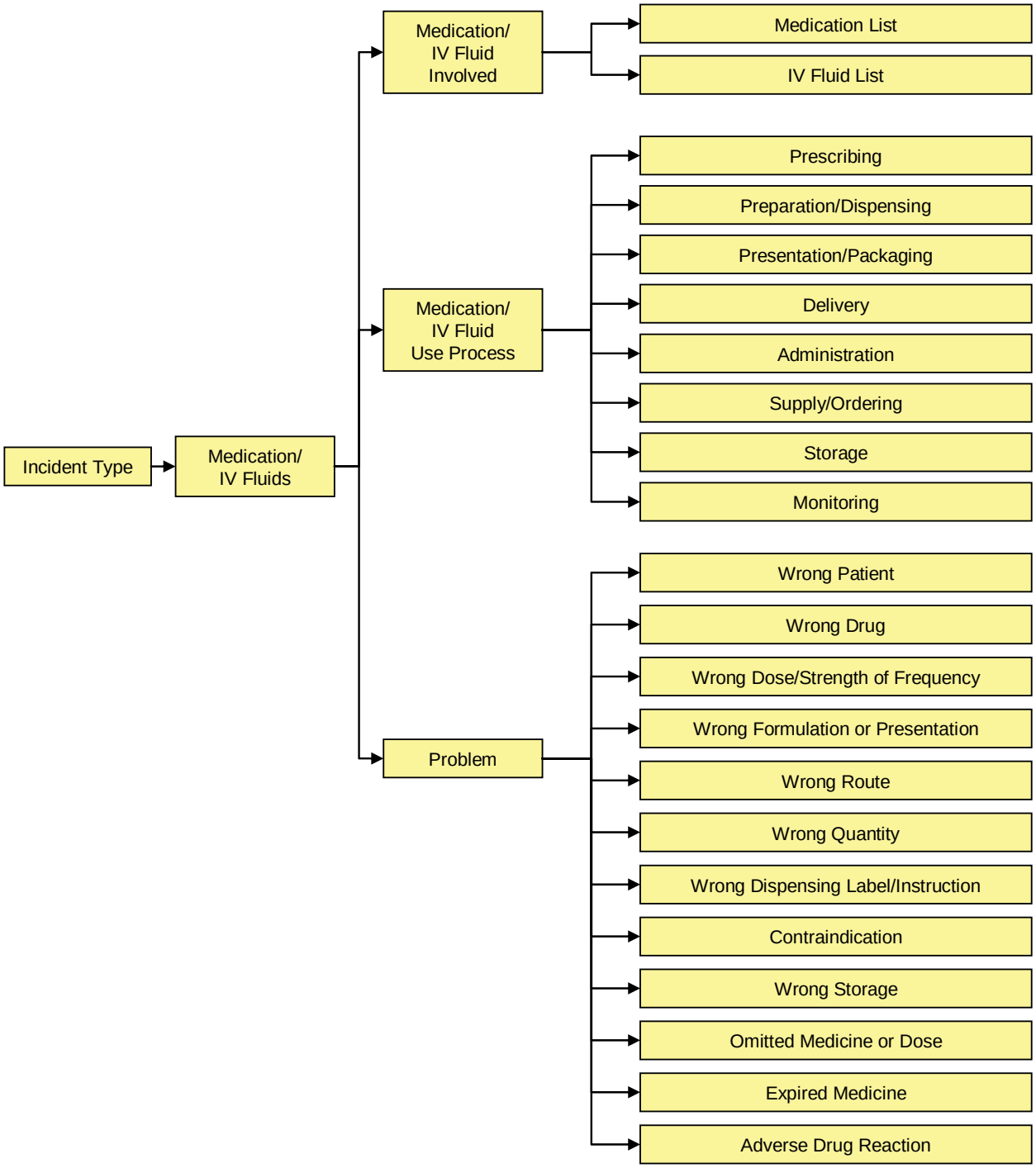
Incident Type – Documentation



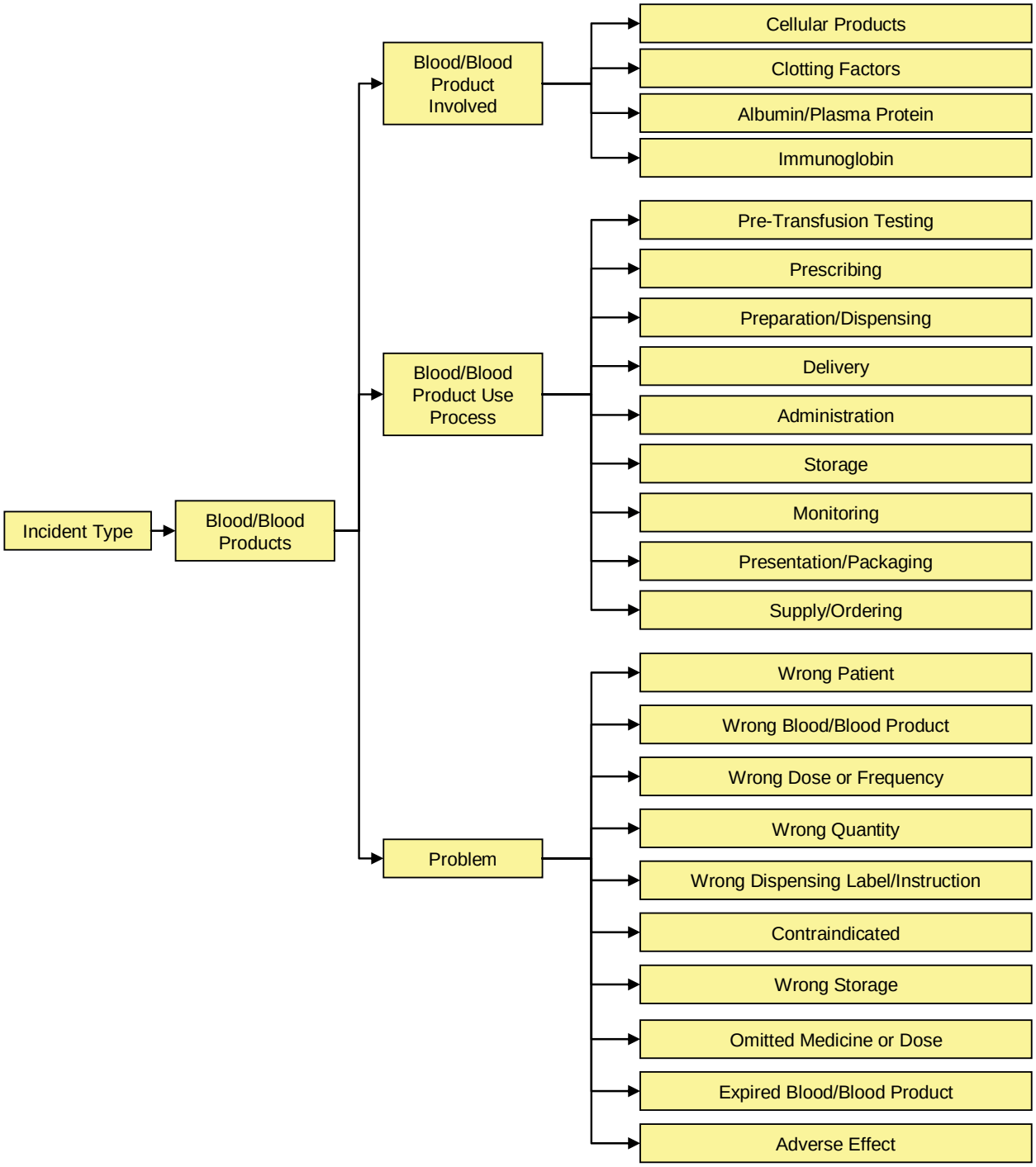
Incident Type – Healthcare Associated Infection



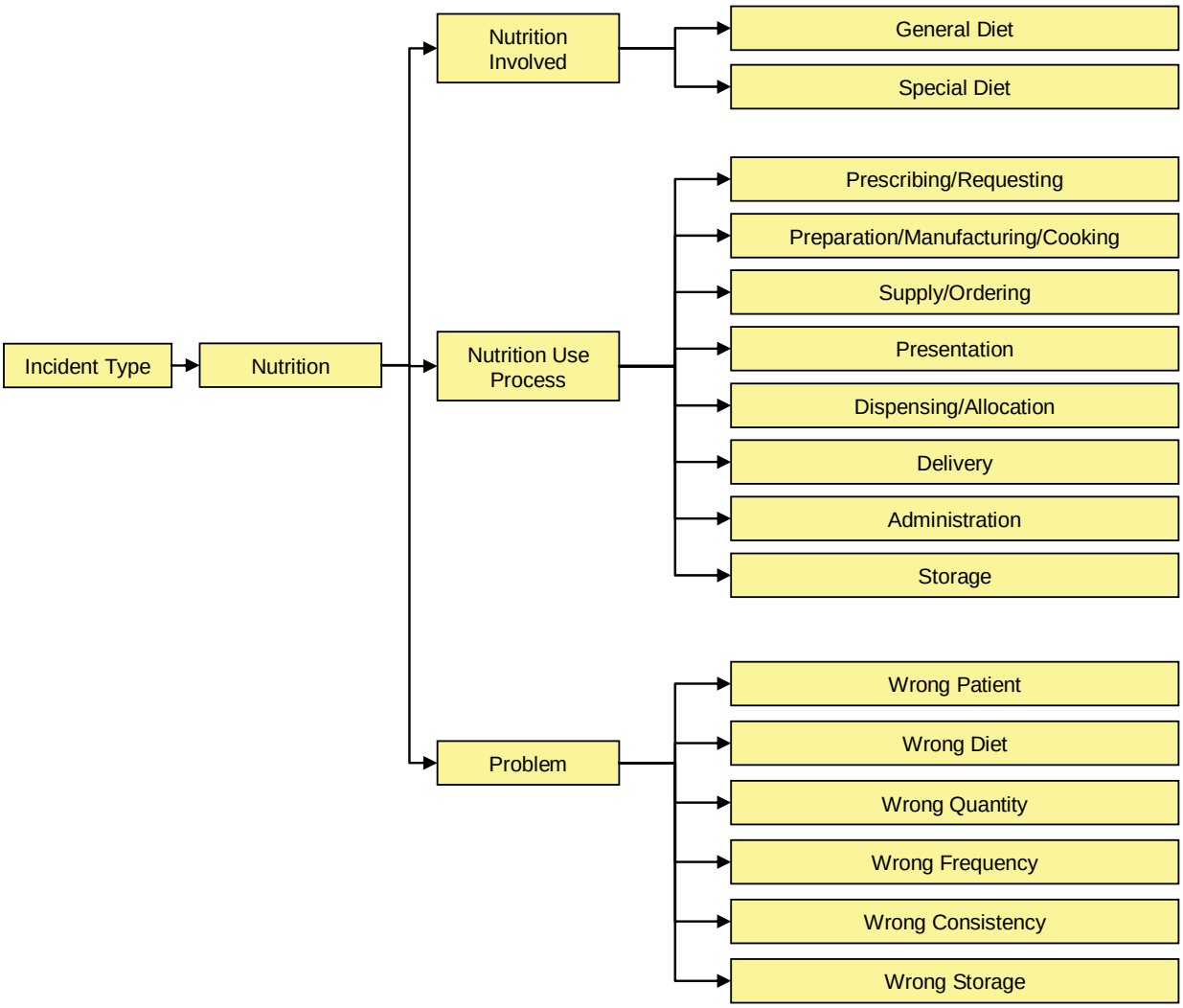
Incident Type – Medication/IV Fluids



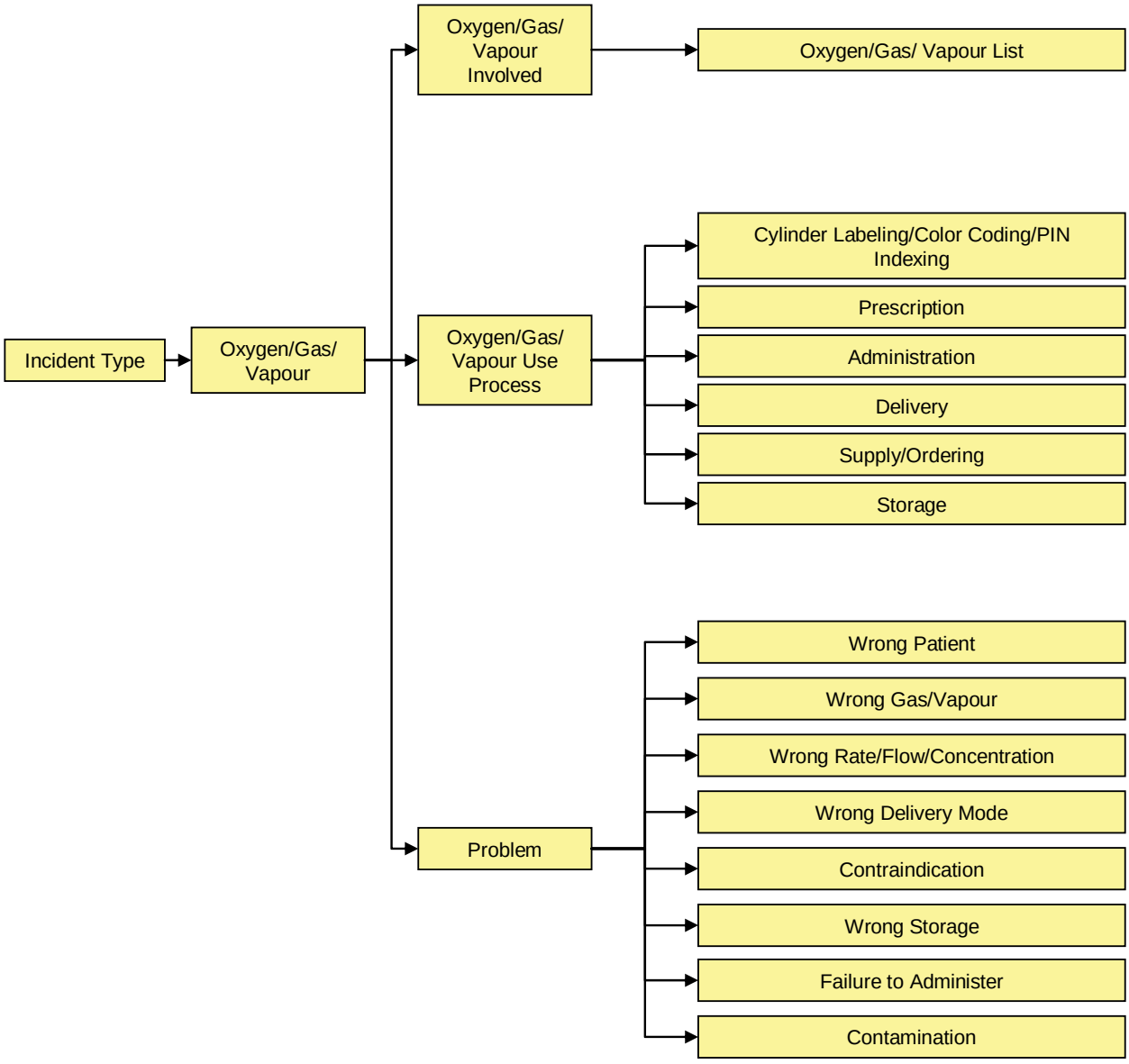
Incident Type – Blood/Blood Products



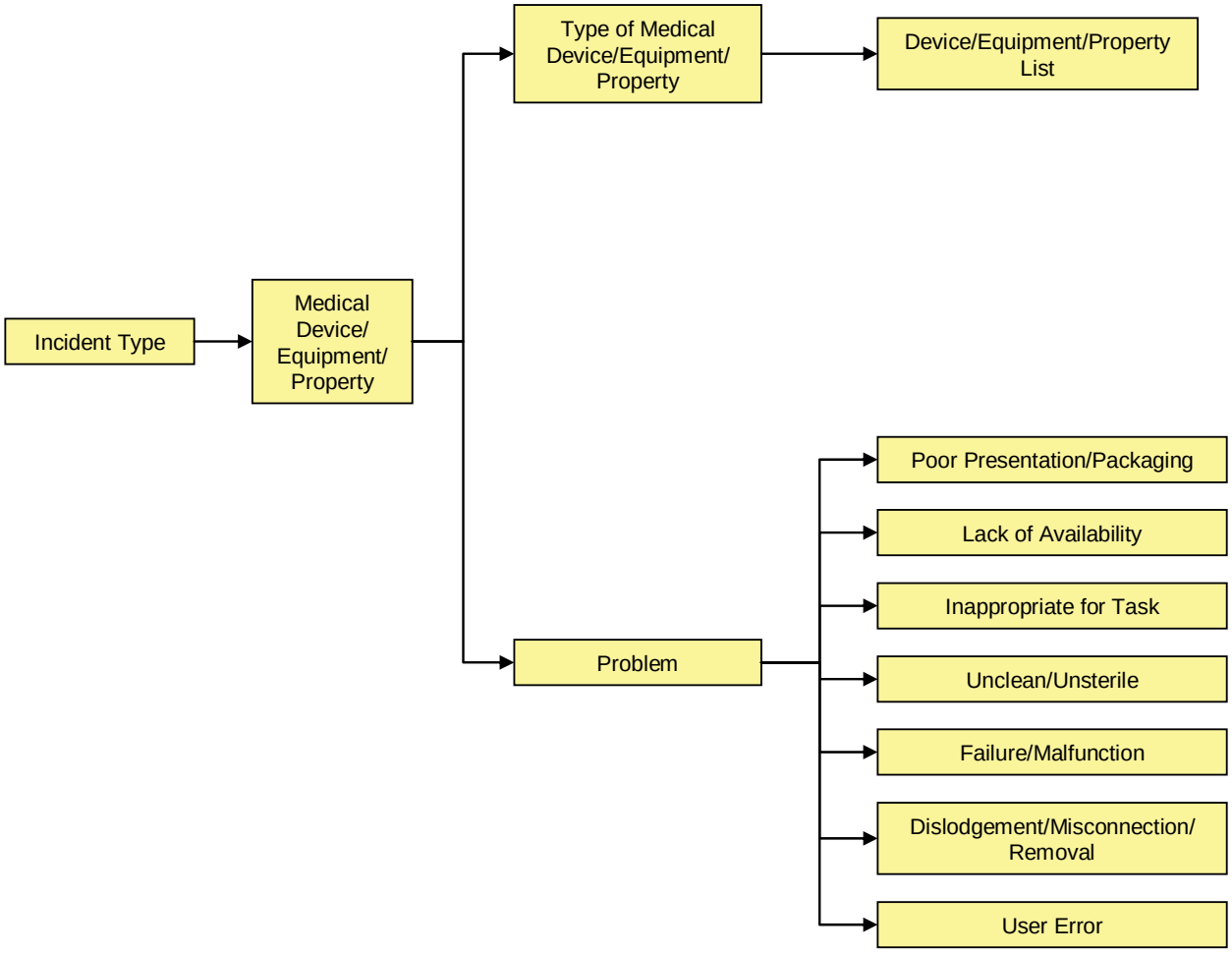
Incident Type – Nutrition



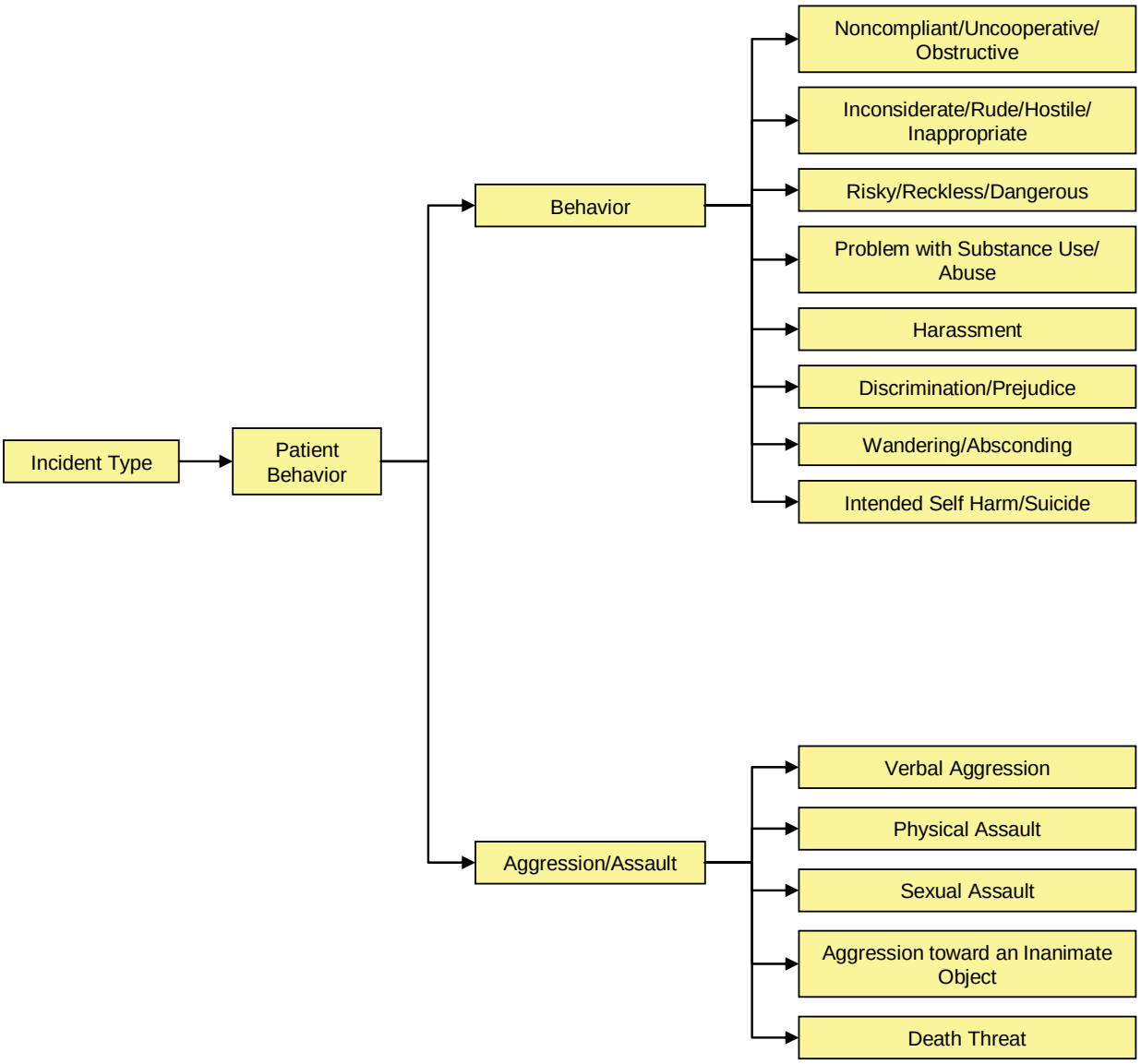
Incident Type – Oxygen/Gas/Vapour



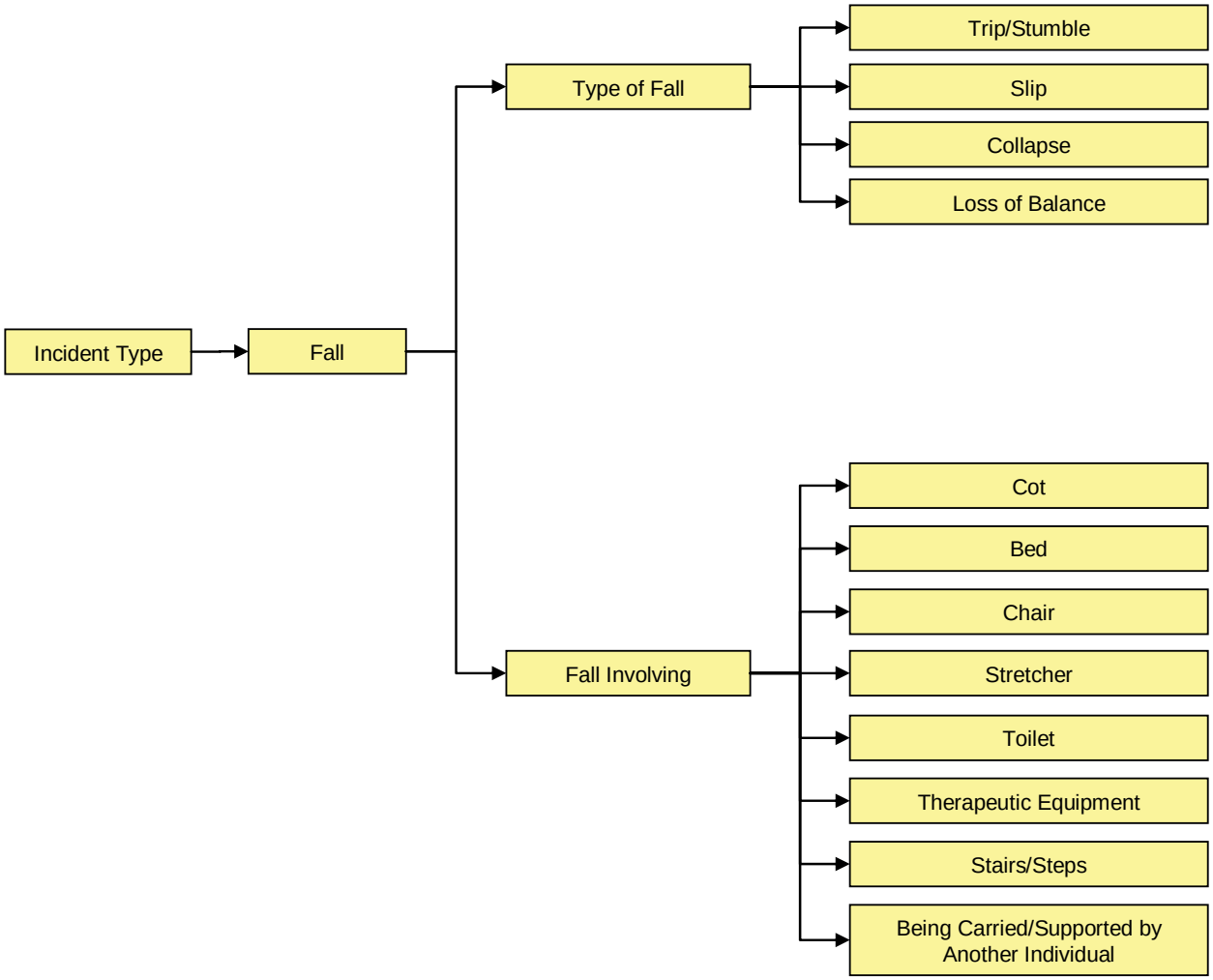
Incident Type – Medical Device/Equipment/Property



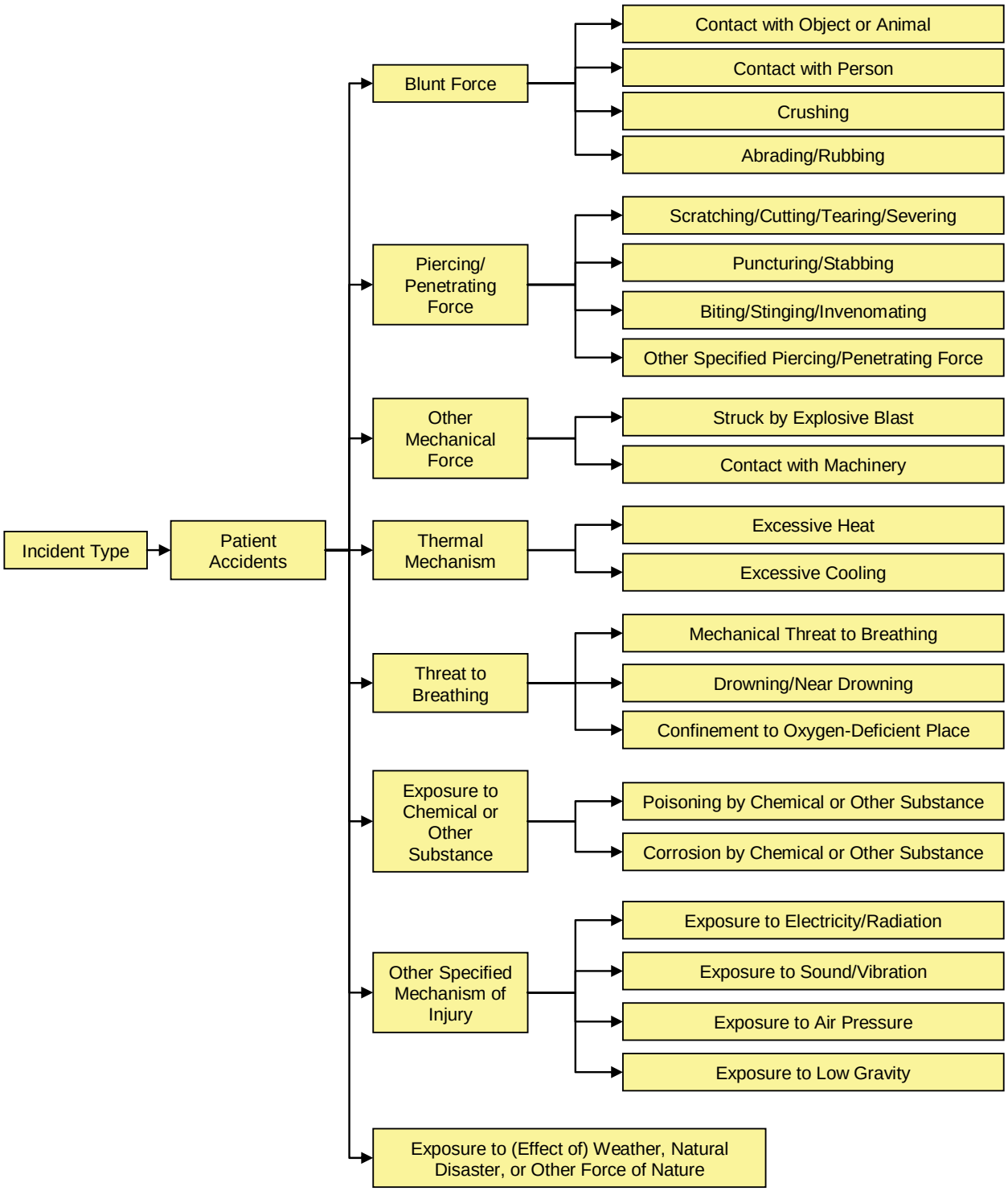
Incident Type – Patient Behavior



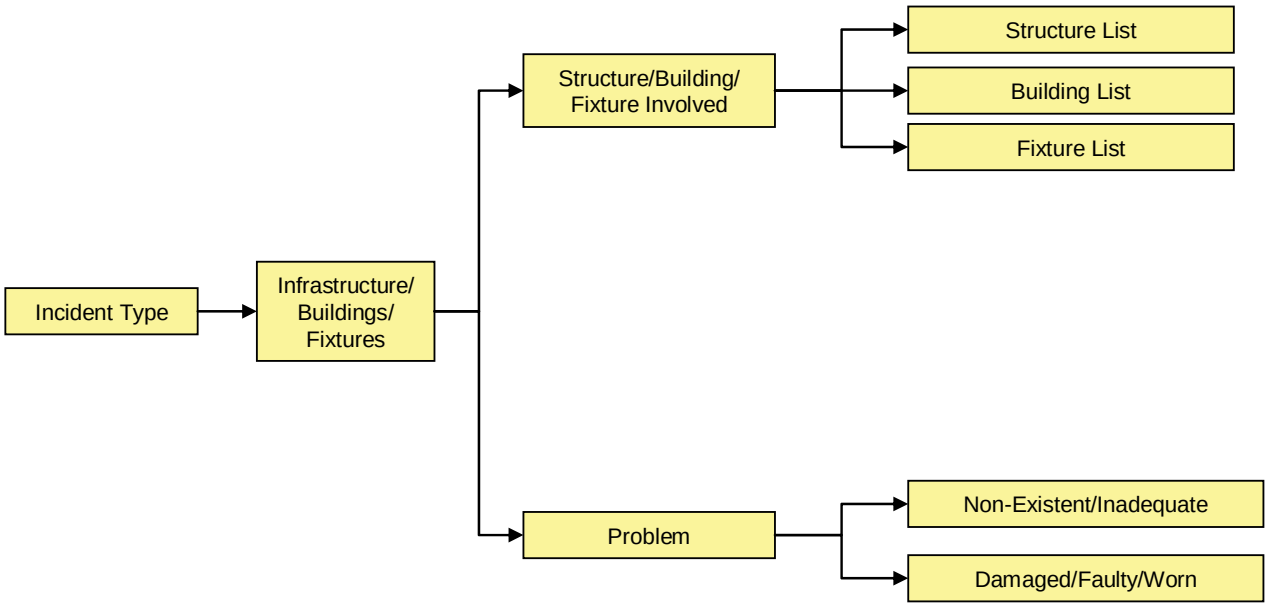
Incident Type – Fall



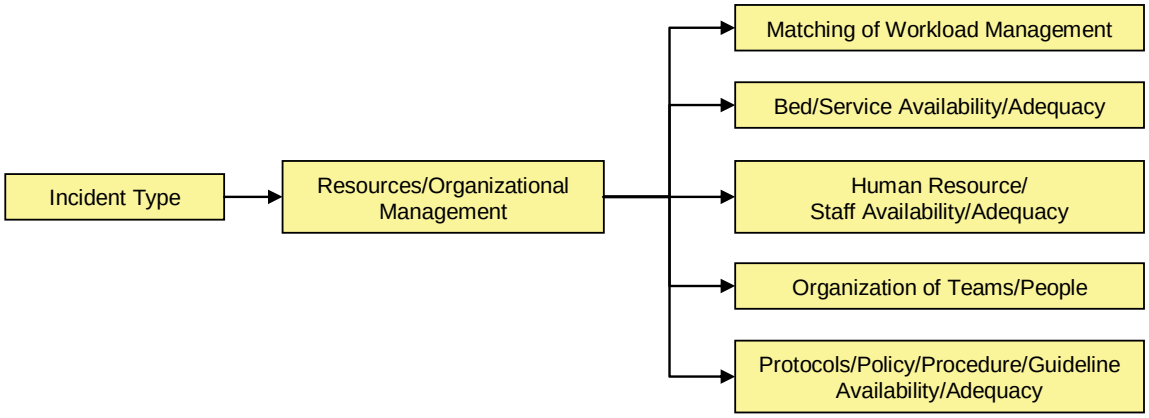
Incident Type – Patient Accidents



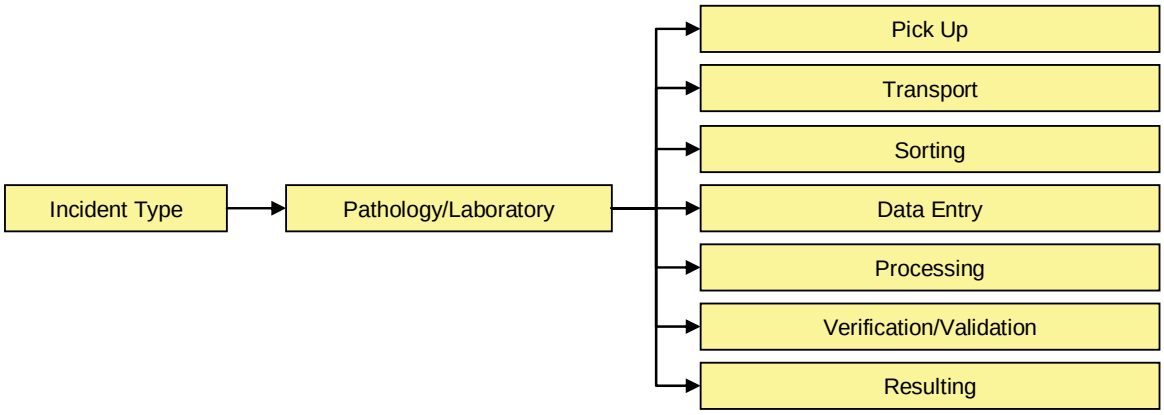
Incident Type – Infrastructure/Buildings/Fixtures



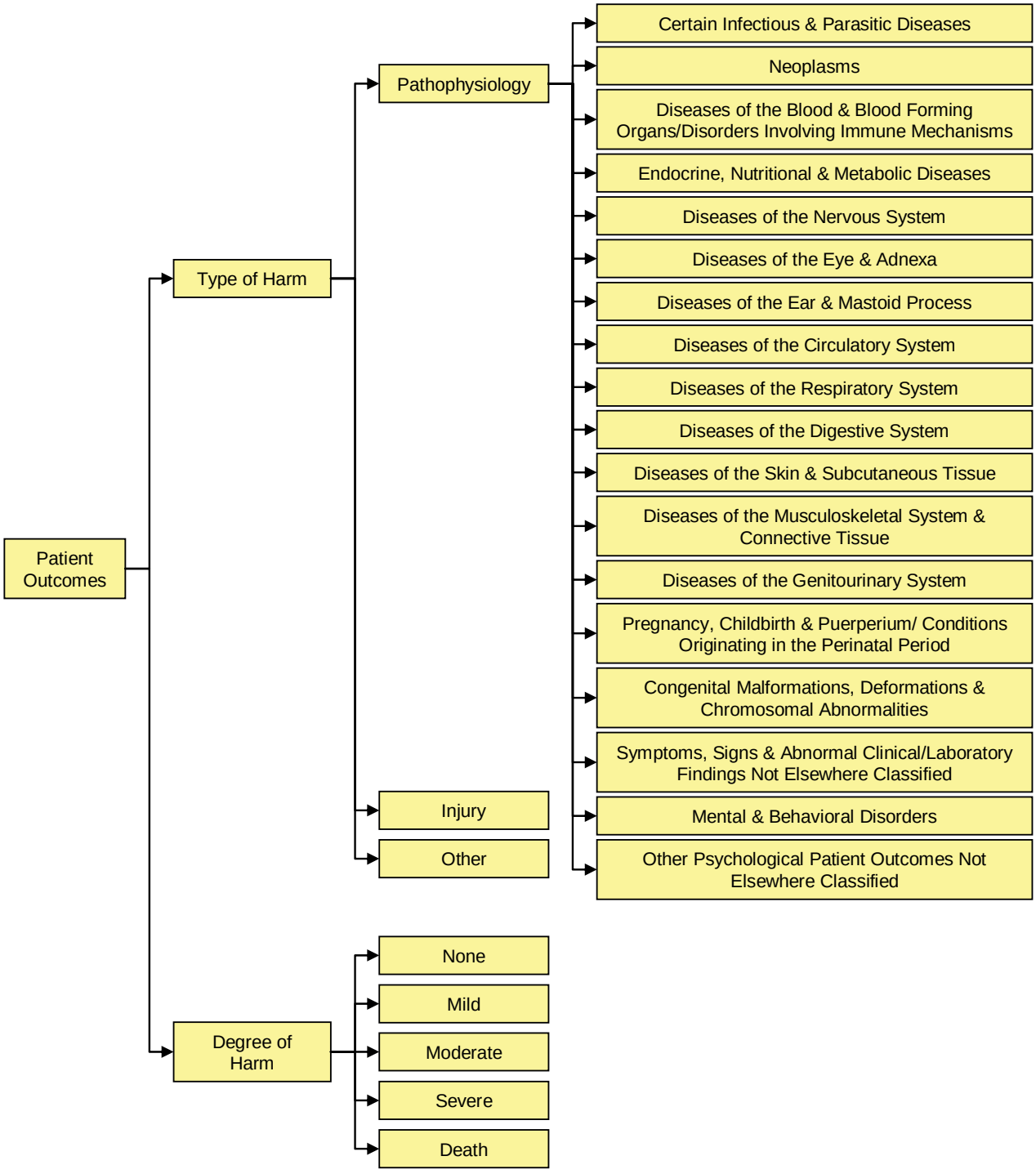
Incident Type – Resources/Organizational Management



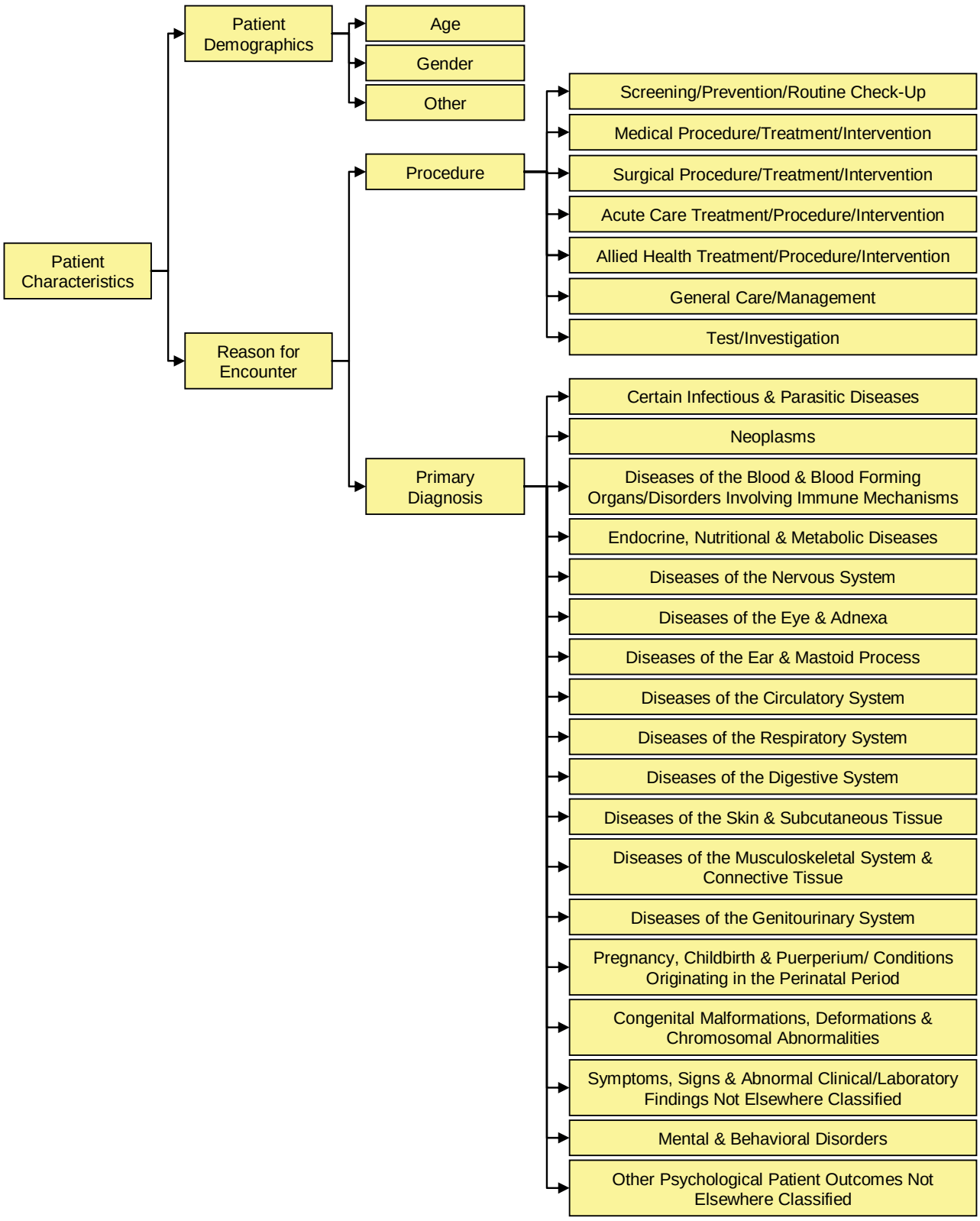
Incident Type – Pathology/Laboratory



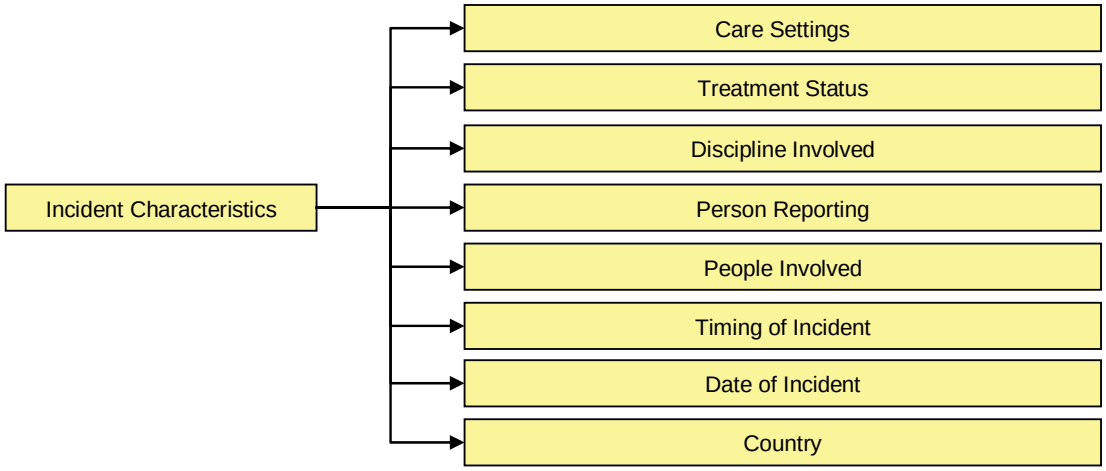
Patient Outcomes



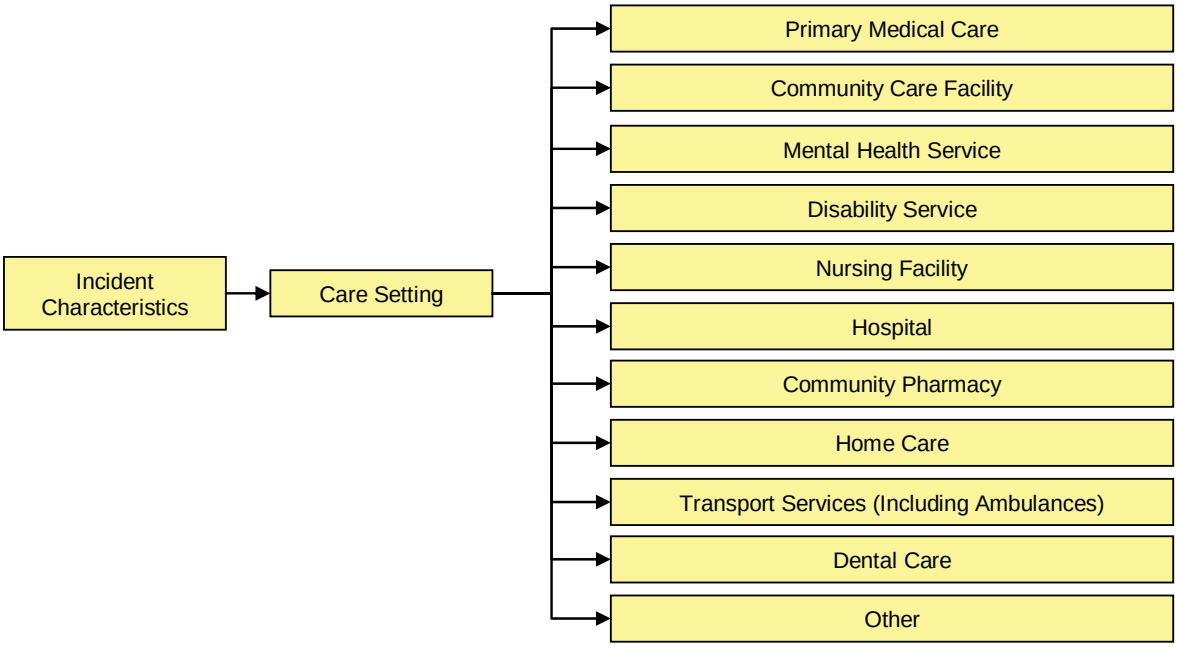
Patient Characteristics



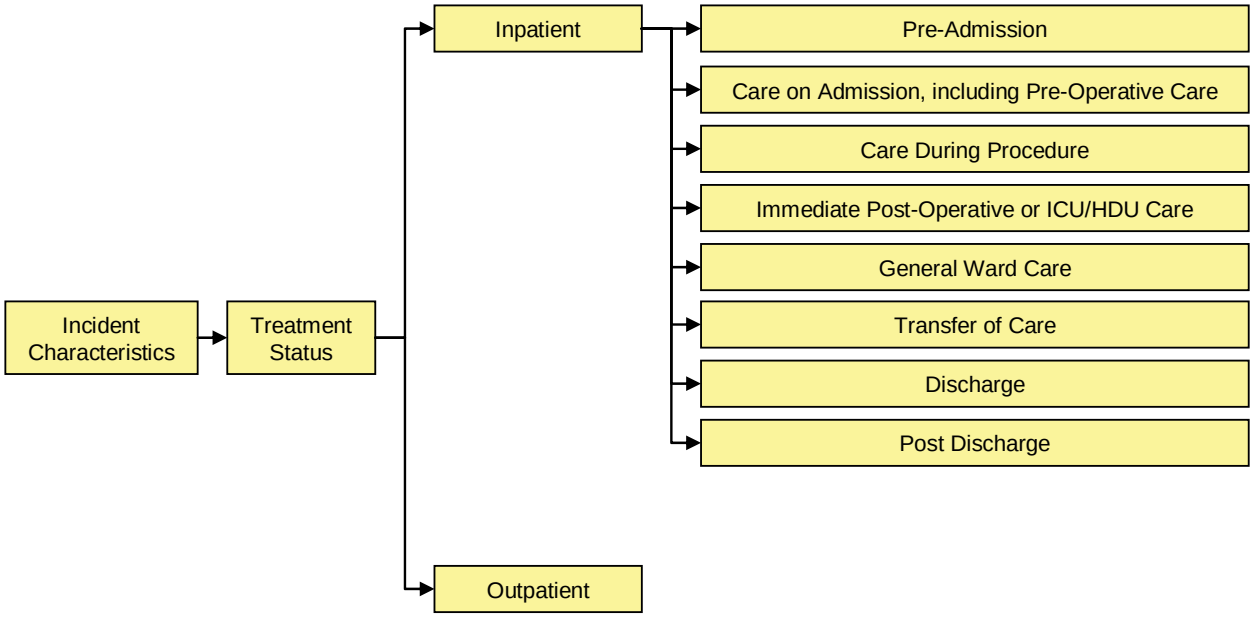
Incident Characteristics



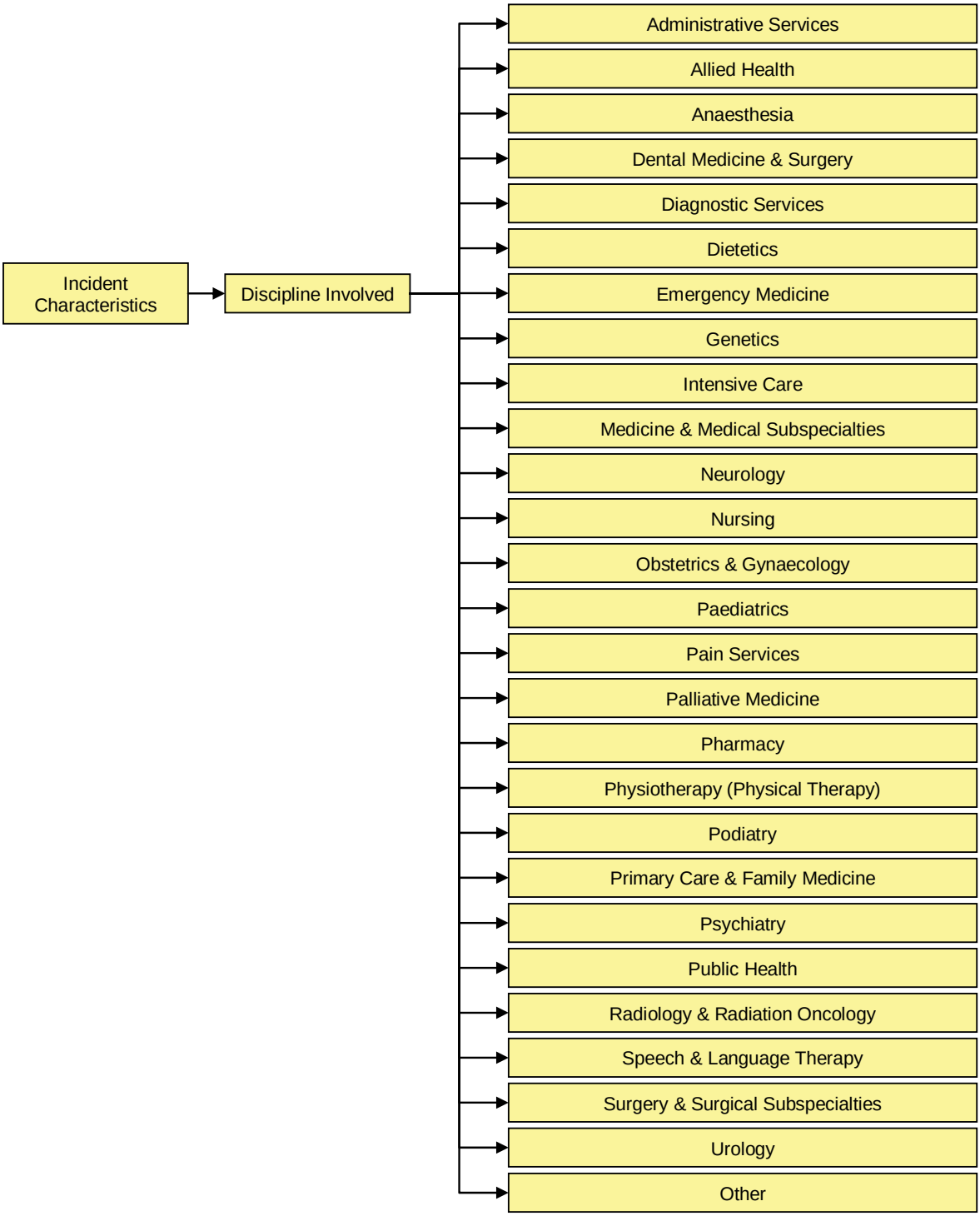
Incident Characteristics – Care Setting



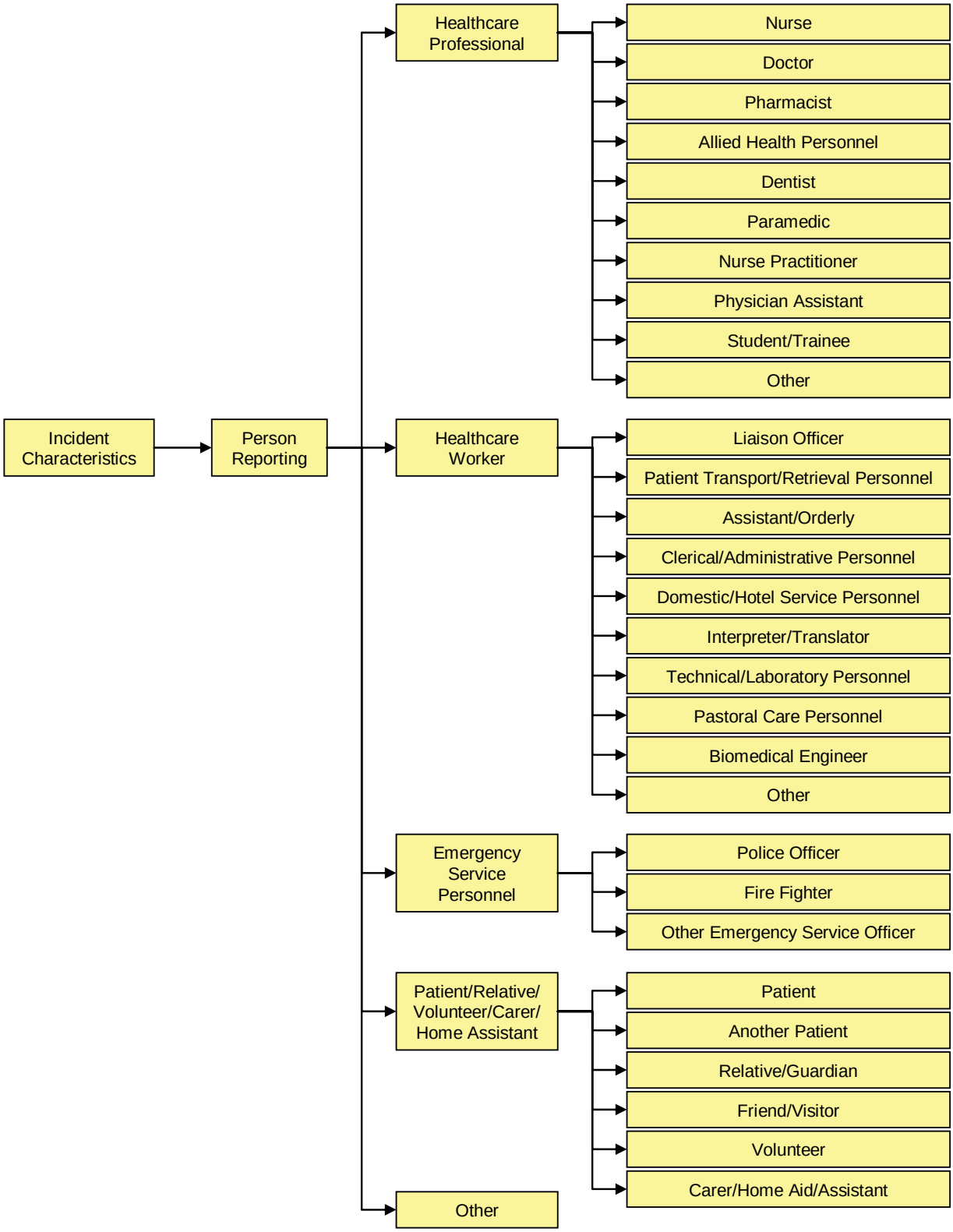
Incident Characteristics – Treatment Status



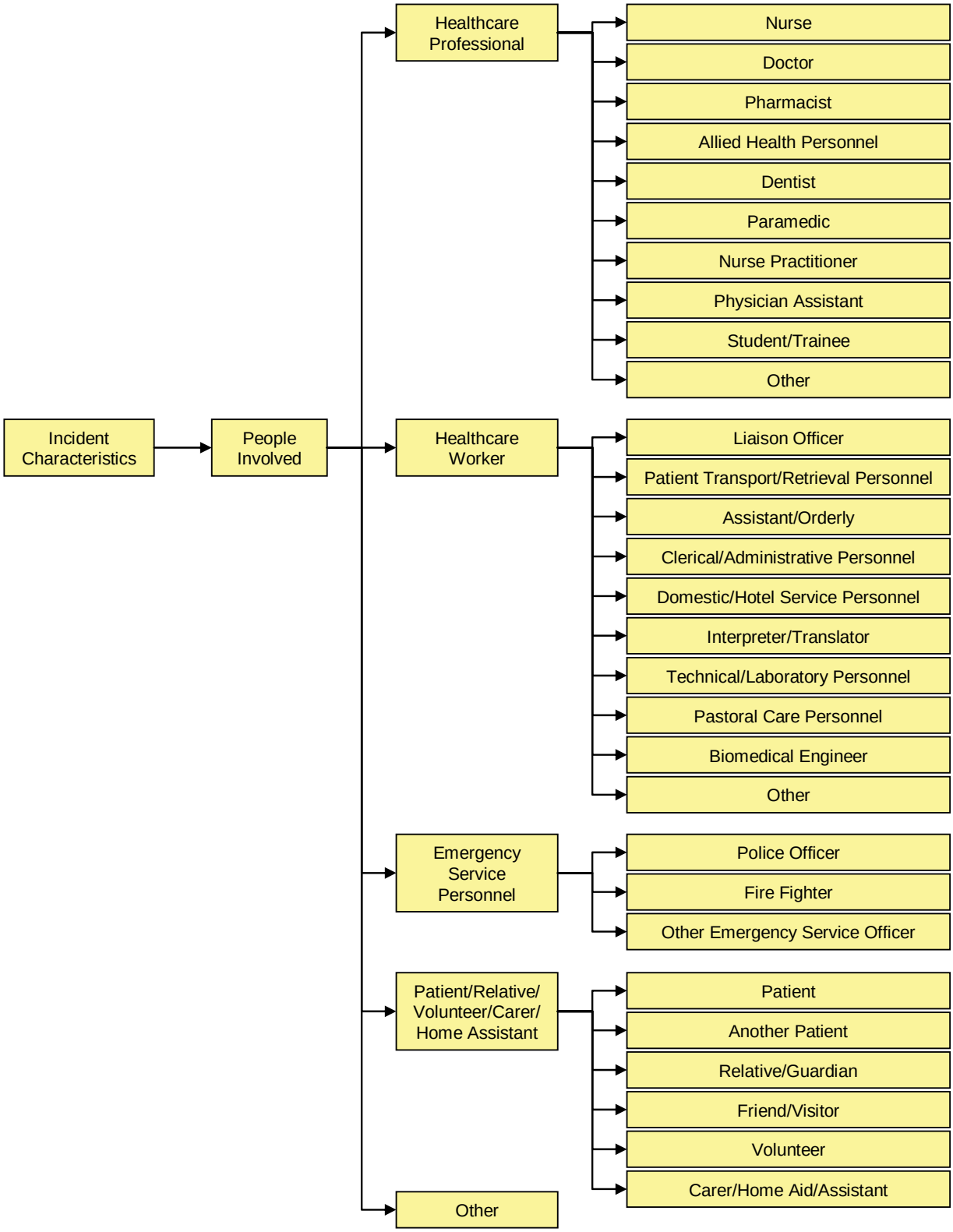
Incident Characteristics – Disciplines Involved



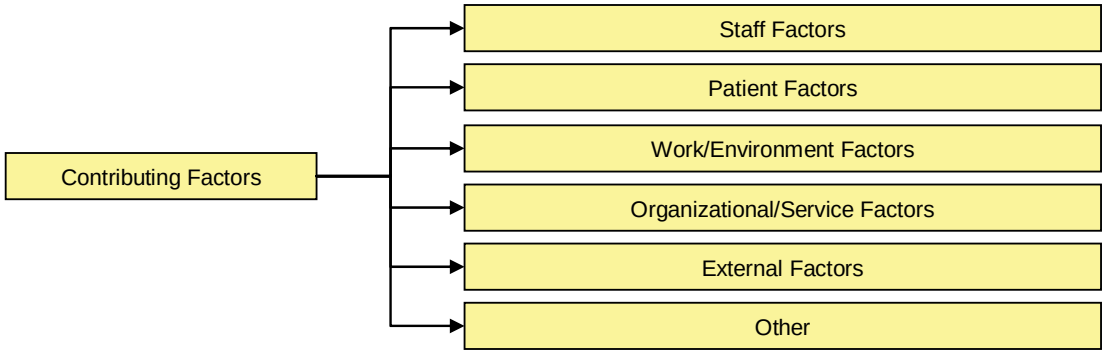
Incident Characteristics – Person Reporting



Incident Characteristics – People Involved

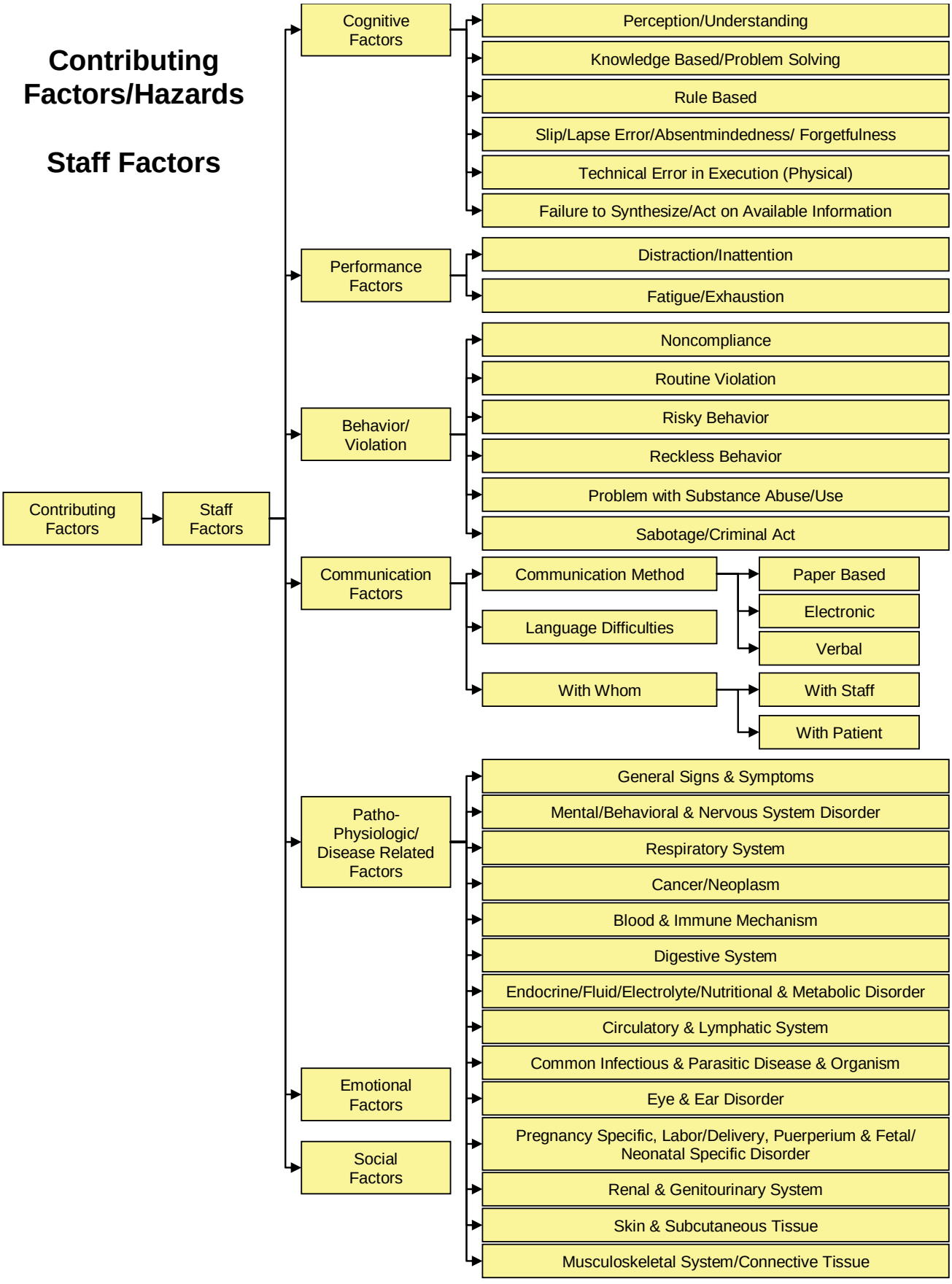


Contributing Factors/Hazards



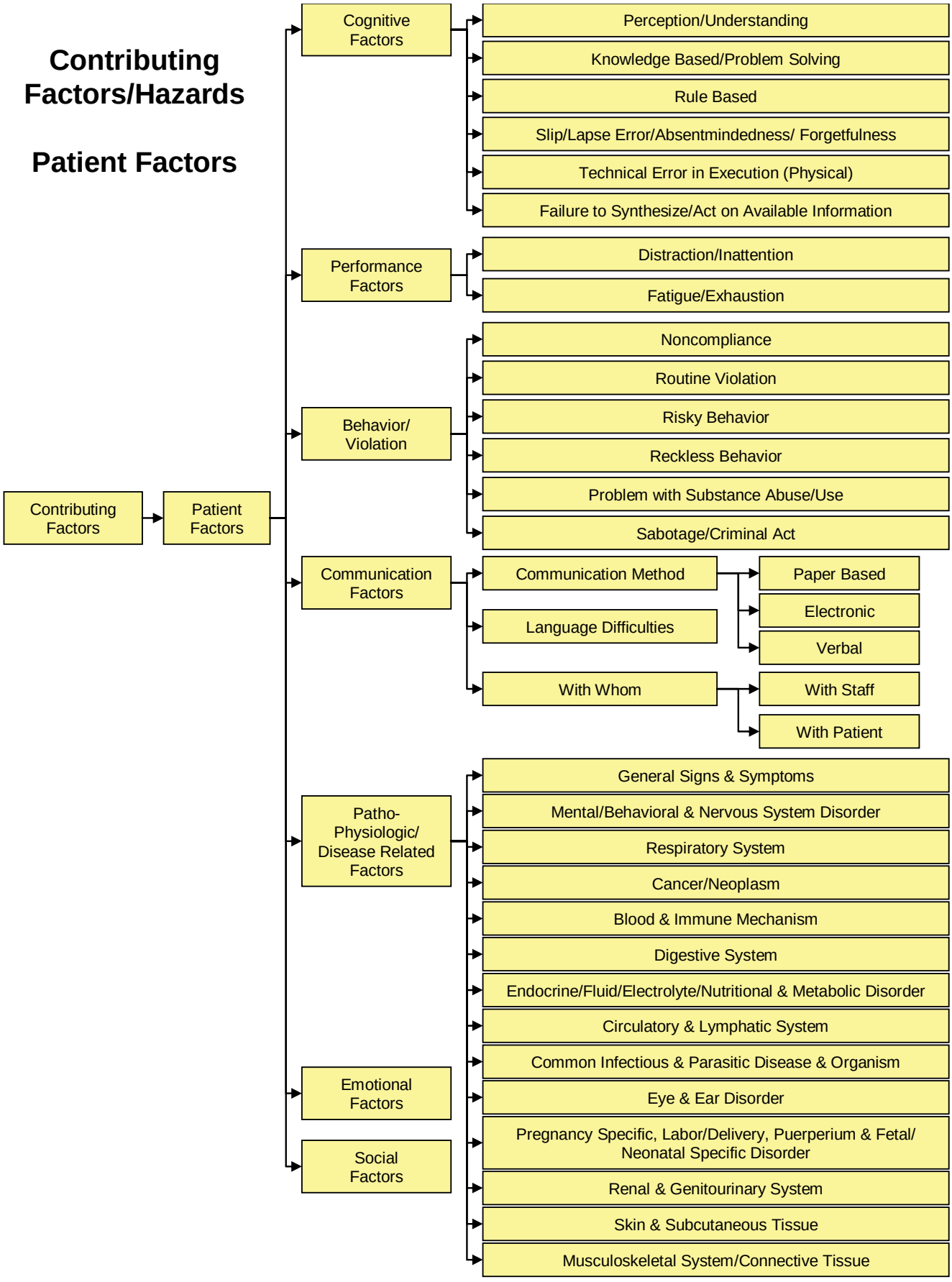
Contributing Factors/Hazards

Staff Factors

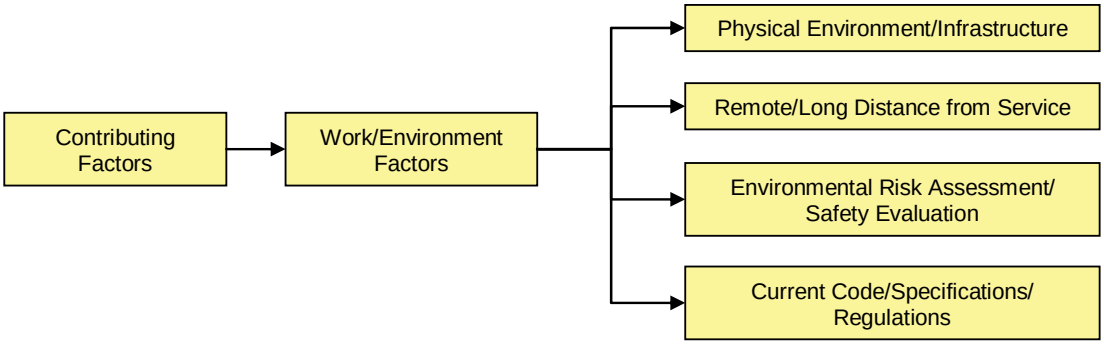


Contributing Factors/Hazards

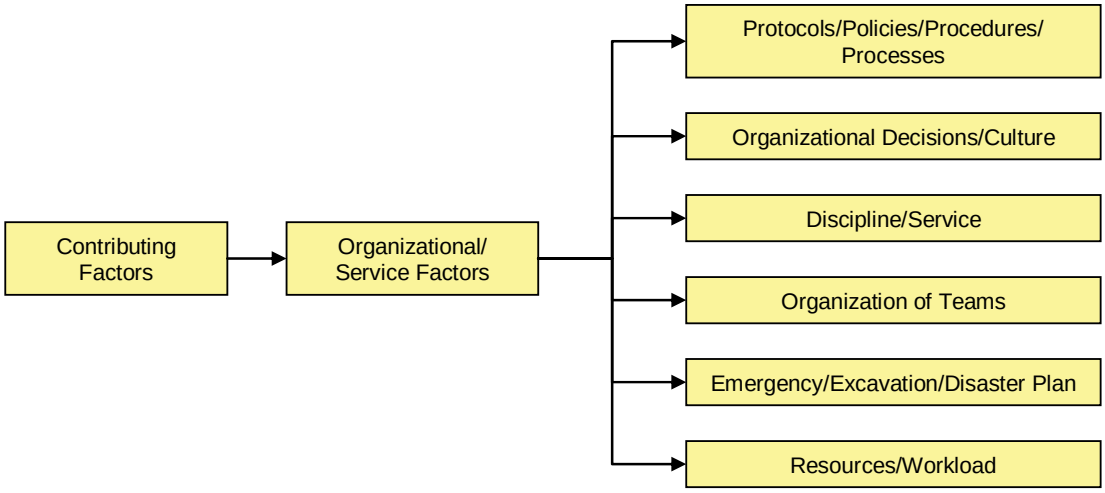
Patient Factors



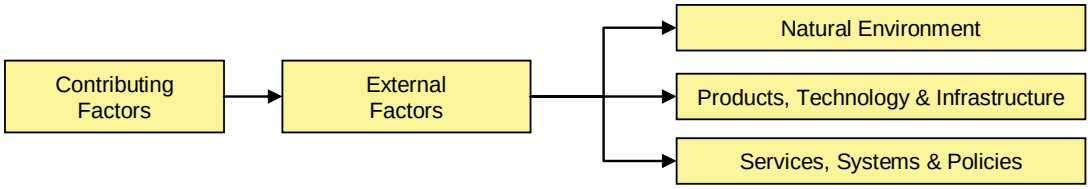
Contributing Factors/Hazards - Work/Environment Factors



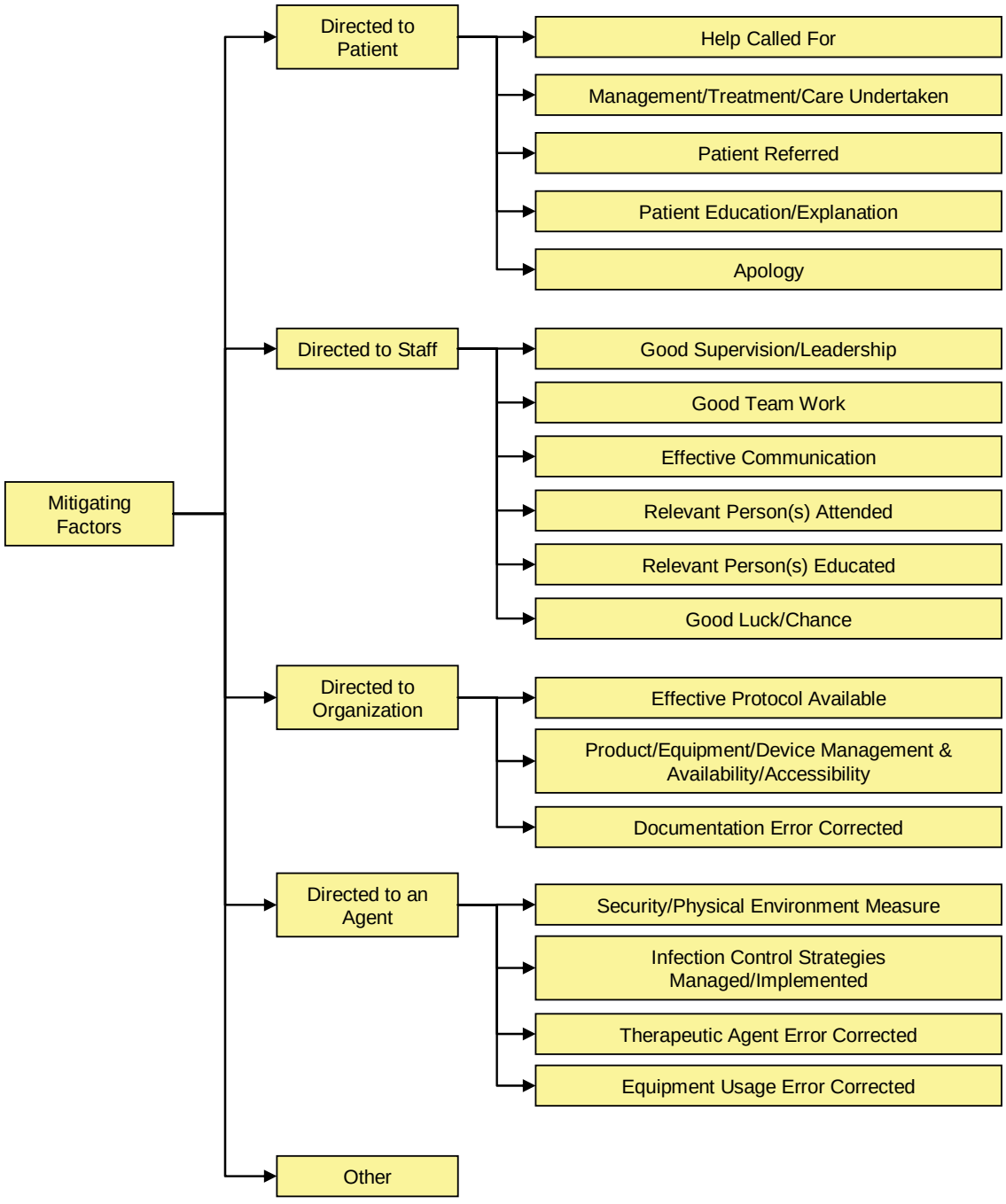
Contributing Factors/Hazards - Organizational/Service Factors

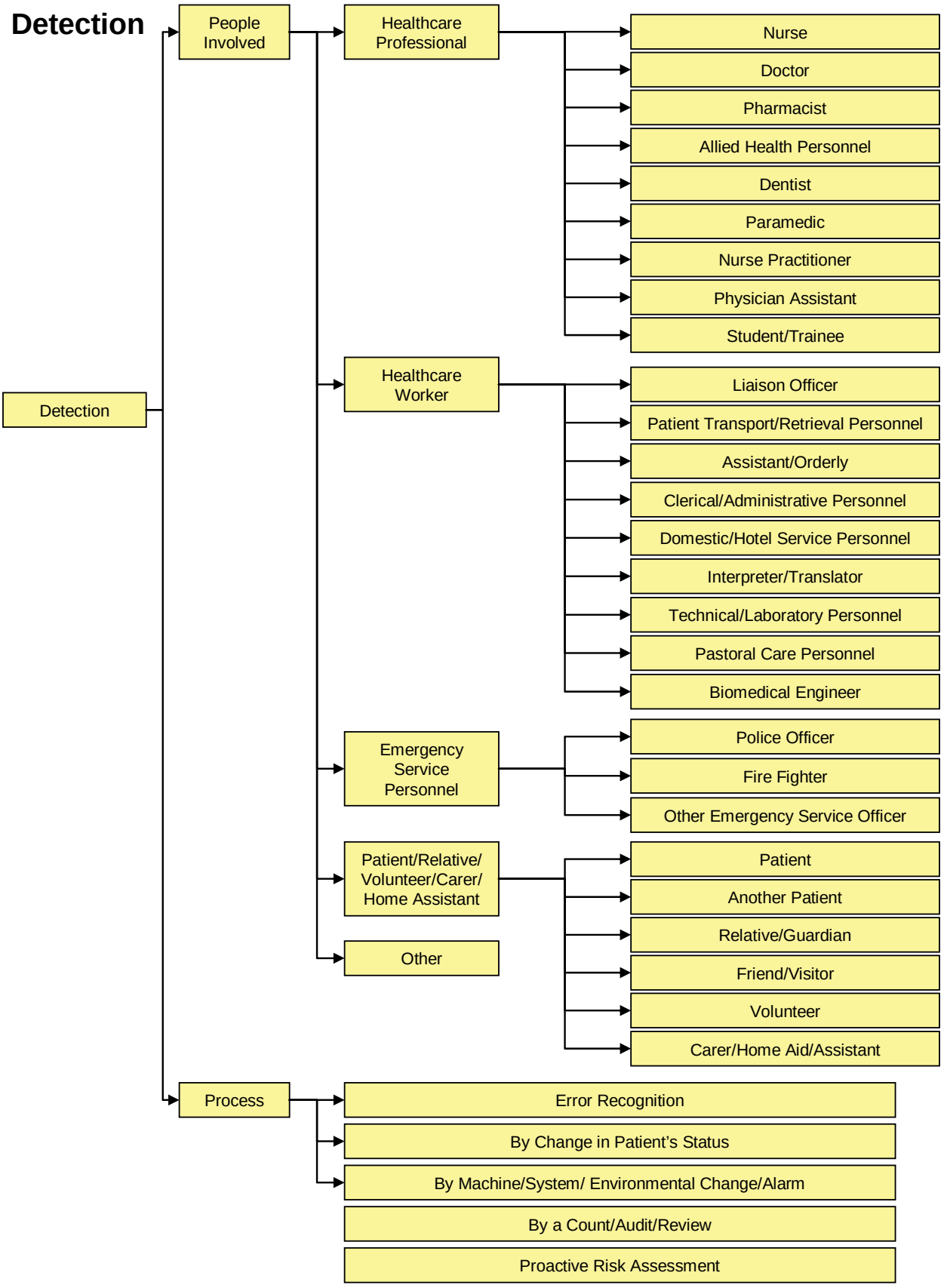


Contributing Factors/Hazards - External Factors

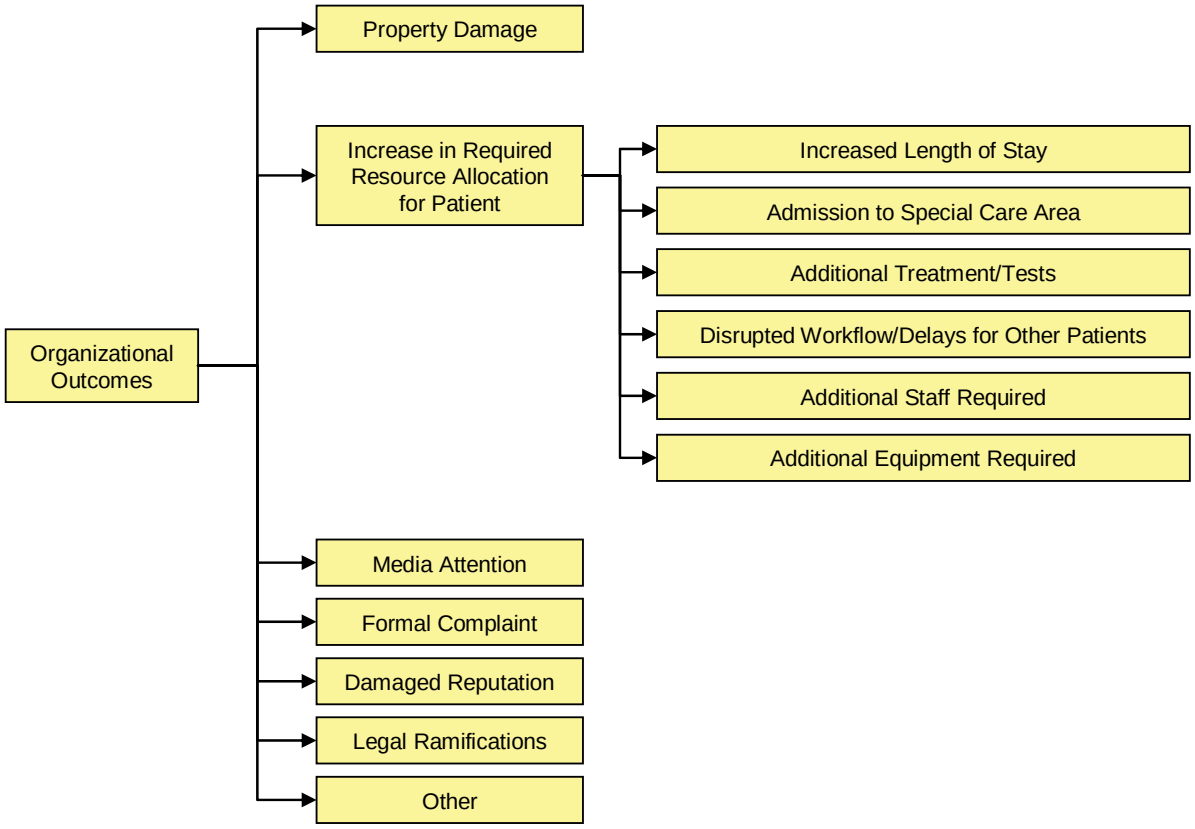


Mitigating Factors

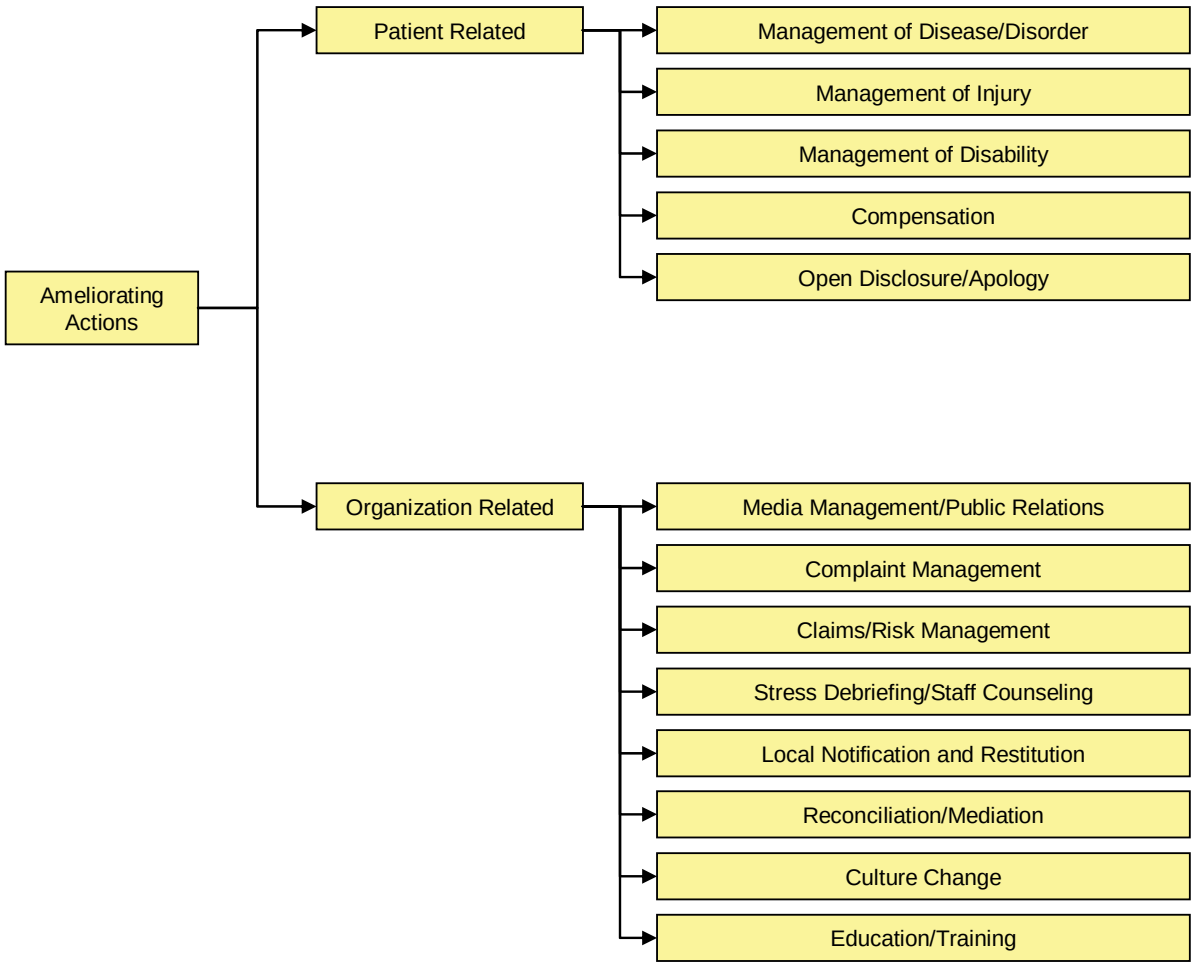




Organizational Outcomes



Ameliorating Actions



Actions to Reduce Risk