The Canadian Patient Safety Dictionary

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"We dissect nature along lines laid down by our native language.... Language is not simply a reporting device for experience but a defining framework for it."

Benjamin Lee Whorf
Thinking in Primitive Communities, 1956

1.0 Foreword

Safe patient care is fundamental to quality health-care services. Recognizing the need for discussion and action on patient safety, in September 2001 *The Royal College of Physicians and Surgeons of Canada* hosted a one-day forum on the topic at its Annual Conference. A round-table discussion led to the formation of the *National Steering Committee on Patient Safety*. Five working groups targeted issues and solutions in the areas of the system; regulatory/legal; measurement/evaluation; educational/professional development; and information/communication. The Steering Committee and working groups developed an integrated national strategy for patient safety. The culmination of their collective work was released in the 2002 report: *"Building a safer system: a national integrated strategy for improving patient safety in Canadian health care'*.[1]

The need for a dictionary of patient-safety definitions was identified early in the discussions and decisions of the Systems Issues Working Group.[2] The relatively recent explosion of research and literature related to patient safety has been accompanied by an increase in safety-related terms. While some terms are clearly defined, for example, 'incidence', others are not, for example, 'incidents'. In addition, different authors, professions, and organizations have assigned their own interpretations to various terms. If we, as professionals, and as members of society, are to learn from less than optimal events in the health system, then we need to have a common language and understanding of the terms that are central to the enterprise of patient safety.

As members of the Systems Issues Working Group, we developed a draft mini-glossary of patient-safety terms[3] as a reference for the proposed national strategy. Significant time and effort were invested in developing a more complete and definitive dictionary.[4] However, we were unable to finish all aspects of the background research and writing of the document within the specified timelines. Now, with the support of *The Royal College of Physicians and Surgeons of Canada*, under the Project Management of Ms Pierrette Leonard, with the research assistance of Librarian Ms Cecile Farnum, and with the sponsorship of *Health Canada*, we have produced a *Canadian Patient Safety Dictionary*. As

1. National Steering Committee on Patient Safety. 2002. Building a safer system: a national integrated strategy for improving patient safety in Canadian health care. Available at: *http://rcpsc.medical.org.*
2. See Appendix A of Building a Safer System, for a list of the working-group members.
3. See Appendix D of Building a Safer System, for the mini-glossary.
4. Dictionary: "A book dealing with the individual words of a language (or certain specified classes of them), so as to set forth their orthography, pronunciation, signification, and use, their synonyms, derivation, and history, or at least some of these facts: for convenience of reference, the words are arranged in some stated order, now, in most languages, alphabetical; and in larger dictionaries the information given is illustrated by quotations from literature; a word-book, vocabulary, or lexicon." Oxford English Dictionary, 2nd Edition on CD-ROM, Version 3.0, 2002

is evident from the dictionary, we are indebted to work done in other countries such as Australia, the United Kingdom and the United States. The authors are also appreciative of the efforts of the various individuals who read earlier drafts of this Dictionary and provided invaluable suggestions for improvement.

Terms are initially described using traditional or health-care dictionary definitions and then their use illustrated with quotations from the literature. Problems with various terms are identified, and recommendations to deal with these problems are also included to promote discussion and new insights. However, in doing so, we remain mindful of the words of Thomas Hobbes: "For the errors of Definitions multiply themselves". *Leviathan 1651; Part I; Chapter iv: 15*

The Dictionary is intended to have wide appeal to three major audiences. These are a primary audience consisting of all members of the health-care community, such as nurses, doctors, pharmacists and hospital administrators. The second audience includes researchers, faculties and libraries for health-care disciplines and law, lawyers, and regulatory authorities. The third target audience is the general public, for whom the Dictionary may be a helpful tool for understanding the language of patient safety.

We hope this Dictionary will form an important source of information for patient-safety terms, and will stimulate discussion within and across all audiences. We will be delighted if our joint efforts contribute to an international 'common language of safety'.

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October 2003

2.0 Introduction

Definitions within the Dictionary are based on the belief that modern health care is provided in a highly complex environment. Patients' outcomes are due, not only to their underlying illness(es), but also to the interaction of many other factors, such as their socio-economic status, their home environment, as well as, of course, the nature of the treatment provided and the characteristics of the health-care system. It is for this reason we have included terms, such as structure and system, in this document that might not, at first glance, be considered relevant to a patient-safety dictionary.

Describing terms in a patient-safety dictionary is challenging, as their descriptions are often intricately intertwined. We have tried to tease these meanings out to make them a *little* less circular. We have not always been successful and overlap is inevitable to some degree. A reference to one inevitably results in a discussion about the other and questions typically arise. Is the system just the patient and his or her nurse and doctor, or is the health-care system something larger? Like language generally, the terms in this document mutually support each other. Remove or alter one and you threaten the others.

a. Purpose of a Dictionary of Patient-Safety Terms

Definitions of terms

We believe that it is essential to recognize that multiple definitions for the same word may lead to confusion, as may a lack of knowledge of the different meanings, or a lack of understanding of the differing sense in which a word might be used. For example, the word 'table', when used as a noun is defined as a piece of furniture with a flat top and one or more legs providing a level surface on which to put things. 'Table' can also be defined as a set of facts or figures systematically arranged, especially in columns. When the word 'table' is used as a verb, it is defined as to bring forward for discussion or to postpone consideration of a matter. For this reason, we provide, where possible, a clear statement of the meaning of the terms, and their object, purpose or function.

Examples of use of terms

If the definitions are not clear, then we are limited in our abilities to understand the underlying problems, and even more limited in trying to attend to them. Furthermore, without common use of terms, studies of health-care problems carried out in one country are not readily transposable elsewhere. However, not only do we need clear definitions, we also need to use the words clearly. For example, on occasion, even well understood terms are misused, such as substituting 'incidence' for 'incidents'. For this reason, we will provide examples from the literature of use of the term.

Critical appraisal of terms

Developing a shared, comprehensive understanding of the terminology is essential for learning and applying the lessons from patient-safety research, and for co-coordinating effective local, regional and national activities in this important aspect of health care. Certain terms were defined some years ago,

and although thinking about safety in health care has evolved, a few definitions continue to be used verbatim. Although to suggest that certain definitions should be reconsidered might generate some controversy, we believe that it is important to stimulate discussion about terms and phrases. For this reason, we provide, where possible, a critical appraisal of current definitions and use of certain terms.

Taxonomy and language of terms

Where appropriate, the taxonomy of certain terms is delineated and illustrated. For example, the term 'unsafe acts' includes 'errors', 'violations', and 'sabotage'. Thus, there is a taxonomy or relationship among these three terms that provides a structured representation of part of the domain of knowledge about safety. However, we do not provide a detailed hierarchical classification for every term. First, other groups are already engaged in such activities. Second, we were limited in the time available for our project. Our primary goal was to produce an English Dictionary of selected terms in health-care safety. Further development of a proper taxonomy could be one of the tasks taken over by the *Canadian Patient Safety Institute*. In addition, because of the very nature of this work and its reliance on specific aspects of the language and the meaning of words, the authors believe it would be inappropriate to offer a French translation of the terms in the English Dictionary. By necessity, an equivalent French language Dictionary should be developed by a team of experts familiar with the French terminology associated with patient-safety definitions.

b. Development of this Dictionary

Terms in the Dictionary were identified from recognized resources and research in patient safety. Dictionaries, glossaries and various other health-care reference resources from Australia, Canada, the United Kingdom and the United States formed a core resource of the research process. Additionally, to provide examples from the literature and to highlight the complexity of many of the terms and the existence of differences in usage, literature searches were carried out using many of the major medical databases (*MEDLINE, PubMed*). (See Section 9.0)

c. Organization of this Dictionary

The Dictionary is not alphabetical. It begins with a definition and description of the terms 'patient safety' and 'system', as these terms are critical for the project as a whole. They form a starting point for understanding how the patient-safety dictionary project began and how the health-care system functions as a whole. With this perspective as a foundation, other health-care and patient-safety terms in use today are subsequently defined and described. For those who appreciate the order the alphabet induces, our recommended usage of terms may be found in the Alphabetical Summary. (See Section 11.0.)

Terms in the Dictionary and Alphabetical Summary are preceded by an **'S*P*O'** icon (**S*P*O**), which relates the terms to the "**S**tructure (**S***P*O), **P**rocess (S***P***O** and/or **O**utcome" S*P***O** format, according to which letter(s) is/are bolded. This format captures where, in the schema of events, attention needs to be directed.

Each of the terms listed is described using the following headings.

- Dictionary definition
- Health-care dictionary definition (where available)
- Use in the literature
- Discussion
- Recommended use

d. References

We have tried to include a wide-range of references. Where possible, these are shown in the text by the (first) author's name and year of publication, except for some literary quotes, for which the full

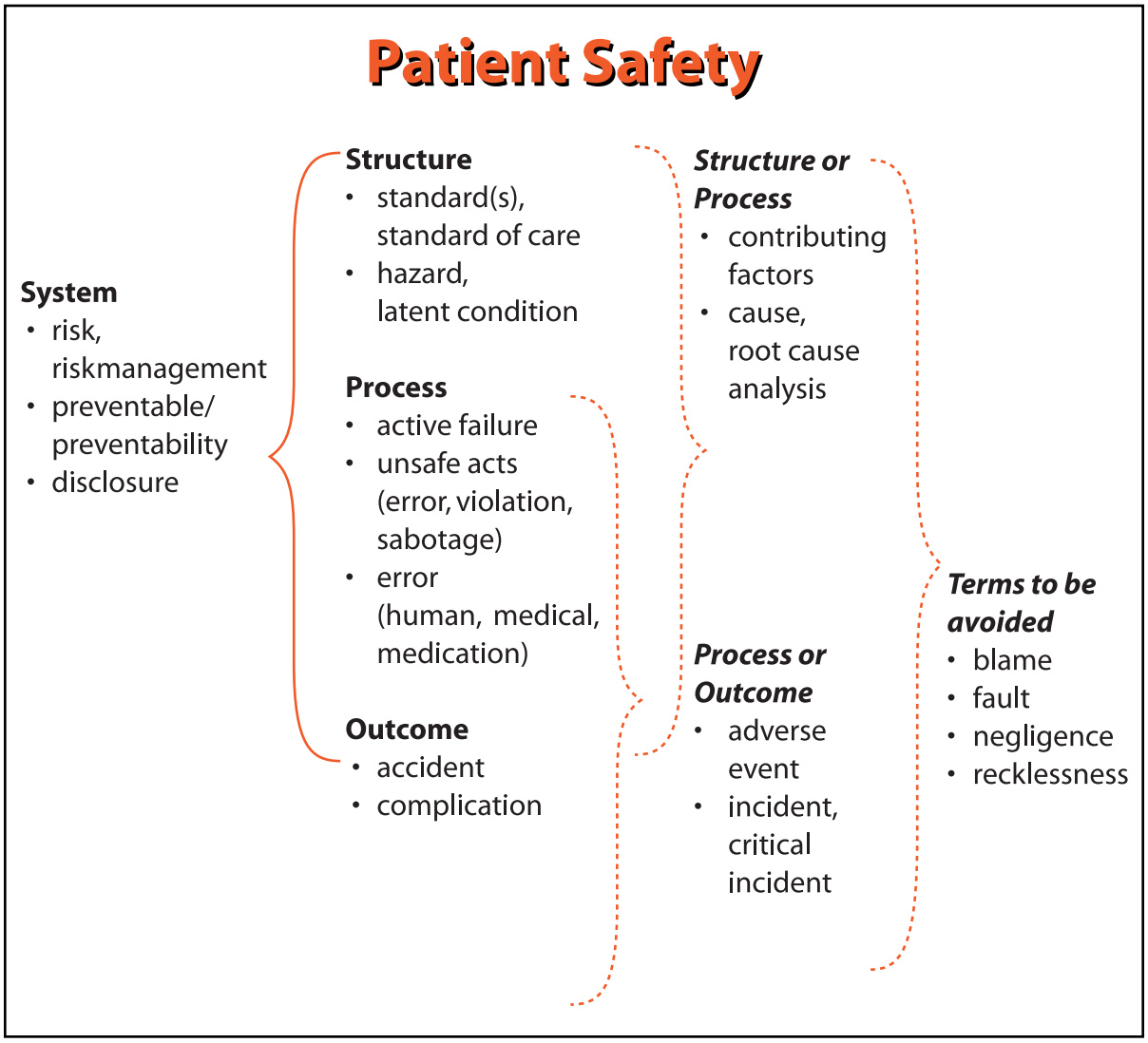
reference is given in the text. References are then listed in Section 10.0 near the end of the Dictionary, using a modification of the Vancouver format (Author(s) AA. Title. Journal Year; Issue #: Page # range). For ease of retrieval, journal names are not abbreviated. Electronic references are listed when available. A web reference and date of retrieval are also provided for information obtained from the Internet. Many of the literary quotes are taken from the *Oxford English Dictionary*, an invaluable resource for the historical origin of words.

e. Scope of the Dictionary

Finally, every effort was made to accommodate as many definitions as possible before the printing of this first *Canadian Patient Safety Dictionary*. The authors recognize that this Dictionary is a living document that will need to be updated on a regular basis as terms are added, challenged or deleted. The authors believe that the responsibility for future editions could be included as part of the mandate of the *Canadian Patient Safety Institute*. In time, more extensive, specialty-specific, and French editions[1] of the Dictionary could emerge to enhance the common language of patient safety that is already available.

Words of a famous lexicographer inspired, but also cautioned, us. "Dictionaries are like watches," wrote Samuel Johnson, "the worst is better than none, and the best cannot be expected to go quite true." *Mrs. Piozzi. Anecdotes of Samuel Johnson, 1786*

[1] (Note des auteurs : Une édition française distincte (non pas une traduction) de ce Dictionnaire sur la sécurité des patients est en voie de développement grâce à l'appui de Santé Canada. Veuillez noter qu'une traduction française des chapitres 1.0 *Foreword* et 2.0 *Introduction* est disponible en consultant la version électronique du Dictionnaire à http://rcpsc.medical.org/french/publications.)



When reviewing terms, the reader may find it useful to consult this schematic diagram of the relationships among the terms.

3.0 Patient safety

Dictionary definition

Safety means "being safe, exemption from hurt or injury, freedom from danger". *OED. Oxford English Dictionary. 2nd Edition on CD-ROM, Version 3.0, 2002 (hereafter referred to as OED)*

Use in the literature

> "Out of this nettle, danger, we pluck this flower, safety." *Shakespeare. Henry IV, Part I, II, iii, 11*

> "Put another way, human practitioners are not so much the cause of occasional sporadic accidents as they are the active agents that regularly contribute to success. When they carry out their roles successfully, they are the active creators of safety. Safety research tries to identify factors that undermine practitioners' ability to do this successfully." *Cook et al, 1998*

Discussion

Safety in health care is usually defined in a negative way, as the absence of hurt or injury, as a result of unsafe acts.

> "The term 'patient safety' as used here applies to initiatives designed to prevent adverse outcomes from medical errors. The enhancement of patient safety encompasses three complementary activities: preventing errors, making errors visible, and mitigating the effects of errors." *QuIc, 2000*

While this is clearly important, safety should also entail a more expansive, positive definition, such as abiding by practices and achieving outcomes that are compatible with striving for optimal patient outcomes and health-care indices. The *Canadian Council on Health Services Accreditation* provides a definition of the term that includes strategies for attaining the concept: Safety is "the prevention and mitigation of unsafe acts within the health-care system. Strategies for improving patient safety include:

- creating a culture that supports the identification and reporting of unsafe acts;
- effective measurement of patient injuries and other relevant outcome indicators; and
- tools for developing or adapting structures and processes to reduce reliance on individual vigilance". *CCHSA, 2003*

Thus, our health-care institutions ought to be seen as 'safe houses' wherein patients, in receiving the best health care available, are not exposed to avoidable dangers.

> "A major objective of any health-care system should be the safe progress of consumers through all parts of the system. Harm from their care, by omission or commission, as well as from the environment in which it is carried out, must be avoided and risk minimized in care delivery processes." *NSW Health, 1999*

However, safety sometimes carries an implication that there will never be adverse outcomes. Human beings are generally accepted as fallible except if they provide health-care services, where perfection is routinely expected and rarely achieved. A move away from relying on the personal vigilance of health-care professionals and toward implementing a broader system perspective will facilitate the objective of improving patient safety. Our health-care system will never be 'safe' — 'safety' is a fleeting property of evolving complex systems. Safety is a goal to be striven for, not a conclusion that will ever be reached.

It should be noted that the terms safe or safety are not synonymous with the terms secure or security. Security is defined as the "safeguarding of the interests of a state, or organization, person, etc., against danger, especially from espionage or theft; the exercise of measures to this end; the maintenance of secrecy about military movements or diplomatic negotiations; in espionage, the maintenance of cover." (*OED*) A false sense of security can breed complacency about ever-present threats to the well being of patients and citizens generally. "Security is mortals' chiefest enemy," wrote Shakespeare (*Macbeth III; v: 32*), implying, we think, that a secure system is not necessarily a safe one.

Recommended use

That **patient safety** be defined as 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.

4.0 System

S*P*O 4.1 System

Dictionary definition

"A set of assemblage of things connected, associated, or interdependent, so as to form a complex unity; a whole composed of parts in orderly arrangement according to some scheme or plan; rarely applied to a simple or small assemblage of things." *OED*

Health-care dictionary definition

"1. Separate but related elements that are pulled together to form a common result; the coordination of various elements of a program to accomplish a goal; an organized set of components consisting of interdependent parts that make up a whole. 2. A group of components that are drawn together and work together, that can change or affect one another, and that rely on the actions or activities of each and all components to reach a goal or objective using inputs, processes, outputs, and feedback; an arrangement of interrelated and interdependent parts that have a common set of goals." *Timmreck, 1997*

Use in the literature

"By Systemes; I understand any numbers of men joyned in one Interest, or one Businesse." *Hobbes. Leviathan 1651; Part ii. Chapter xxii; 115*

"A system is a set of interdependent elements interacting to achieve a common aim. These elements may be both human and non-human (equipment, technologies, etc)." *Kohn et al, 2000*

Discussion

The term 'system' may be used to indicate both the entirety of health care and the components within the system. The distinction is not always clearly made and in some cases may create misunderstandings or confusion. Indeed, the extent and diversity of the health-care system are often overlooked or minimized by members of the public and perhaps even health-care professionals themselves. To ensure a comprehensive understanding of the broader perspective of 'system' it is helpful to think of it as:

"a grouping of inter-related components that act together in an environment to achieve a particular outcome." *DeGreene, 1970*

This definition has three parts: a "grouping of inter-related components", that "act together", to "achieve a particular outcome". These three parts can be related to the three phases of medical care described by Donabedian: Structure, Process, and Outcome. Thus, a system is:

1. a grouping of components, such as resources and organization (Structure),
2. that act together (Process),
3. to achieve a particular result (Outcome).

> "There is a tendency on the part of some individuals to take an either-or position, to the effect that one need only be concerned with one of the three dimensions. This tendency is not logical; all three must be considered. Clearly certain structure is needed; and equally clearly, there is no way to change outcome except through changing process, since "outcome 'tells on' process". (*Slee et al, 1996*)

Thus, the system is made up of all three components.

Systems can be characterized in different ways, for example, by the number of components, how these components interact (the degree of complexity) and by how the systems function (the degree of coupling).

a. 'Complexity' is often used to describe types of systems, for example, 'complex man-machine systems'. Strictly speaking, the term applies to the nature, number and familiarity (or visibility) of possible interactions of system components. If interactions are complex, they are of "unfamiliar sequences, or unplanned and unexpected sequences, and either not visible or not immediately comprehensible". (*Perrow, 1984*) In contrast, if interactions are simple, they are those "in expected and familiar production or maintenance sequence, and those that are quite visible even if unplanned". (*Perrow, 1984*) Complexity can (and is) also used to describe the activities of a system. The more steps in a process and the greater their interdependence, the greater the complexity of the process.
b. 'Coupling' describes how a system functions. This is the nature of the interaction between system components: whether or not what happens in one part of the system has a direct effect on another part. The degree of coupling ranges from "loose" to "tight". (*Perrow, 1984*) Tightly coupled systems, especially complex ones, are less likely to tolerate perturbations and are more prone to failure than are loosely coupled systems.

This definition of 'coupling' does not match that used in the following quotation.

> "What is the health-care system like? It is an enormous number of diverse and semiautonomous elements: ambulance services, emergency care, diagnostic and treatment systems, outpatient clinics, medical devices, home care instruments, patient-monitoring equipment, testing laboratories, and many others. All of these elements are loosely coupled in an intricate network of individuals and teams of people, procedures, regulations, communications, equipment, and devices that function in a variable and uncertain environment with diffused, decentralized management control." *Van Cott, 1994*

In this quotation, 'loosely coupled' implies elements that are "decentralized and fragmented", such that the health-care delivery system is best described as a "nonsystem". *Kohn et al, 2000*

A variety of other system characteristics have been described in the literature, for example, redundancy, adaptability, resiliency, self-monitoring and self-correcting. However, a complete summary is beyond the scope of this Dictionary.

Recommended use

That **system** be reserved for use when describing the entirety of health care and be defined as a set of interdependent components interacting to achieve a common aim. Within the system, these components may be classified in various ways. One classification is based on socio-geographic factors: national, provincial, organizational/institutional, health-care provider, and patient/family. System characteristics include complexity and coupling.

S*P*O 4.2 Terms associated with the system

4.2.1 Risk, Risk management

S*P*O 4.2.1a. Risk

Dictionary definition

"To hazard, endanger; to expose to the chance of injury or loss." *OED*

Health-care dictionary definition

"In health promotion and public health, this is the chance that an event or exposure will lead to some disease, condition, disability, or even death. Risk has also been used to describe the probability of some unfavourable outcome of a health- or medically related event or experience. Association and risk can be measured statistically and statistical probabilities generated regarding the chance of risk." *Timmreck, 1997*

Use in the literature

"He that runs the risque deserves the fair." *Centlivre S. A Bold Stroke for a Wife 1718: i. i*

"Risk is best defined as the chance or probability of bad consequence. This may be either fatal (death) or non-fatal (dysfunction), with the latter classified as disease, discomfort and dissatisfaction. Risk can apply to any of the players in the system, i.e., both the patient and the health-care workers." *Davies, 1996*

Discussion

Risk is a very broad term with differing definitions that are not always clear. These definitions include:

- the overall possibility of an injury, as in 'by refusing treatment, he risked immediate death';
- the probability of a hazard, as in 'the risk of an anesthetic-related death is about 1 in 250,000'; and
- the actual hazard, as in 'open sharps buckets are a risk to operating-room personnel'.

An all-encompassing health-care perspective of risk is defined by the CCHSA as "... the chance or possibility of danger, loss, or injury. For health-services organizations this can relate to the health and well-being of clients, staff, and the public; property; reputation; environment; organizational functioning, financial stability, market share, and other things of value." (*CCHSA, 2001*) In health care, patients undergo tests and treatments with the expectation that complications will not occur, or that, if they do occur, then the positive aspect of the test or treatment will outweigh the negative aspects. In accepting a health-care intervention, patients "run risks" and hope to "win the fair", to use Centlivre's phrase, that is, to benefit by the intervention. Health-care workers ought to, but do not always, warn patients of the risks of complications before tests or treatments are undertaken.

Recommended use

That **risk** be defined as the probability of danger, loss or injury within the health-care system.

S*P*O 4. 2.1b Risk Management

Medical Dictionary Definition

"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 which do occur in such a manner that their cost is minimized. The latter might involve, for example, special attention to personal relations with the injured party, attempts to reach satisfactory settlement without lawsuit, and the like. Risk financing involves the procurement of adequate financial protection from loss, either through an outside insurance company or through some form of self-insurance." *Slee et al, 1996*

Use in the literature

"Risk management is a term adapted from the insurance industry. In the business world, the purpose of risk management activities has been to 'minimize claims, stabilize premium rates, remain competitive, and earn a profit'. The application of this concept to health care has led to an acceptance in some areas that the aim of risk management is to have (health-care workers) 'minimize the number of patient injuries' and to 'conduct themselves in such a way that patients will not be motivated to seek legal redress for injuries that do occur'. This point of view suggests that care-givers are motivated by the fear (and cost) of litigation, rather than by the primary welfare of their patients." *Davies, 1996*

Discussion

The word 'risk' in the term 'risk management' does not carry the meaning of the 'probability' of harm. Instead, it means the 'hazard'

"In the context of hospital operations, the term risk management usually refers to self-protective activities meant to prevent real or potential threats of financial loss due to accident, injury, or medical malpractice." *Baker & Norton, 2002*

A few risk management companies do actively refer to 'hazard management' as a key activity, as in "the organizational activities designed to prevent patient injury or moderate the actual financial losses following an adverse event." (*CCHSA, 2003*) Currently the term risk management is most often used to describe activities undertaken at an organizational, rather than individual practitioner, level.

Recommended use

That **risk management** in health care be defined as organizational activities designed to prevent patient injury or moderate the actual financial losses following an adverse outcome.

S*P*O 4.2.2 Preventable/Preventability

Dictionary definition

"That may be prevented, capable of prevention." *OED.*

Use in the literature

'This immense loss... due to preventable causes.' *Lubbock J. Addresses Political and Educational 1879, viii: 147*

"Many of the adverse events we identified were neither preventable nor predictable, given the current state of medical knowledge — for example, idiosyncratic drug reactions in patients who had not taken the drugs previously,

postoperative myocardial infarctions in young patients without previous evidence of heart disease, and adhesive intestinal obstructions." *Leape et al, 1991*

Discussion

First, the term preventable carries within it the implication of choice. For example, preventability of an adverse event has been defined as:

"an error in management due to failure to follow accepted practice at an individual or system level"; accepted practice is "the current level of expected performance for the average practitioner or system that manages the condition in question". *Bates et al, 1995*

Second, the concept of preventability is often tied with negligence.

"Although studies find moderate agreement between independent assessments of adverse events, judgements regarding whether such events were preventable or involved negligence vary greatly. Moreover, many events described as preventable errors may actually exert little impact on patient prognosis, at least in hospitalized patients who already have multiple acute and chronic conditions that affect their short-term prognosis. When confronted with a case of a patient injury caused by administration of the wrong drug or the performance of an invasive procedure on the wrong patient, few would debate branding the incident as 'preventable adverse event' and searching for ways to prevent it." *Hofer & Hayward, 2002*

Third, the 'threshold' for preventability continues to shift and this shift is often outside the control of practitioners.

"Over 5% of admissions were associated with a preventable in-hospital event, of which nearly half had an element of systems failure. The elderly, ethnic minority groups, and particular clinical areas were at higher risk." *Davis et al, 2003*

Fourth, the origin of the word is from the Latin "praevenio", to hinder or make impossible.

"Just as clinicians use a different diagnostic list for analyzing symptoms or a list of risk factors for assessing disease, so, too can clinicians use a classification and listing of process errors and preventable adverse events to 'diagnose' and 'prevent' patient harm from medical care." *Elder & Dovey, 2002*

Yet, we will never be able to make errors or harm from health care impossible. In the same vein, the phrase 'preventable deaths' is illogical, because no death is truly preventable. Rather, some deaths are untimely and their too early occurrence might be avoided in some cases, given what was known at the time.

Recommended use

That **preventable** be used with caution, and without implying either negligence or harm.

S*P*O 4.2.3 Disclosure

Dictionary definition

"The action of disclosing or opening up to view; revelation; discovery, exposure, an instance of this." *OED*

Health-care dictionary definition

"1. Revelation. 2. That which is disclosed, told, or revealed. 3. The impartation of secret information." *Timmreck, 1997*

Use in the literature

"An unseasonable disclosure of flashes of wit." *Boyle R. Occasional Reflections on Several Subjects. 1665*

"The AMA's Code of Medical Ethics states that situations occasionally occur in which a patient experiences significant medical complications that may have resulted from the physician's mistake or judgement. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred. Only through full disclosure is a patient able to make informed decisions regarding future medical care." *Rosner et al, 2000*

Discussion

Disclosure of adverse events, incidents, and outcomes in health care is rapidly becoming the expected norm. Health-care workers remain inhibited in embracing this expectation due to fear of legal repercussions, despite changing views in the legal profession.

"The courts have held that the doctrine of informed consent requires such disclosure. Given that patients have a legal right to be told what *may* go wrong with the proposed treatment, it must surely follow that they also have a right to be told what has in fact gone wrong." *Robertson, 2002*

Various authors and organizations have proposed a 'no-fault' insurance system to compensate those harmed by health care, in part to provide fairer compensation for the harm caused and also to mitigate the fear of legal repercussions.

"In a 'no-fault' compensation system an expert panel will assess whether the injury has been caused by health care, but the patient does not have to prove negligence in order to be eligible for compensation." *Vincent, 2003*

Disclosure is sometimes confused with reporting. The latter is done for purposes of system improvement and reports are made to the appropriate responsible individuals or organizations. Disclosure of harm is done out of respect for patients as individuals who have a right to know what was done to them and disclosure is then made to the patient and/or his/her partner/family. The *Canadian Nurses Association* Code of Ethics states that:

"Nurses must admit mistakes and take all necessary actions to prevent or minimize harm arising from an adverse event". *CNA, 2002*

While this statement is laudable, care must be taken not to equate a mistake (one particular type of error) with harm. In addition, the term "to prevent" must also be looked on with caution. (See Section 4.2.2 above.) There is also an important difference between the disclosure of harm and the admission of fault. There may be disclosure of facts without admission of liability. *Hébert 2001*

Difficulty sometimes arises in knowing when and what one should disclose. The threshold for disclosure is actual harm or a realistic threat of harm: where either of these is present, then there is an obligation to disclose.

"The purpose of this policy is to affirm the College's position that patients are entitled to be informed of all aspects of their health care. This includes the right of a patient to disclosure of harm that may have occurred to him or her in the course of receiving health care." *CPSO, 2003*

Where an event causes no harm and no possibility of doing so, the need to disclose is optional.

Recommended use

That **disclosure** be understood as the imparting, by health-care workers to patients or their significant others, of information pertaining to any health-care event affecting (or liable to affect) the patient's interests. The obligation to disclose is proportional to the degree of actual harm to the patient (or the realistic threat of such) arising from an adverse outcome.

5.0 Terms that reflect Structure, Process or Outcome

S*P*O 5.1 Structure

5.1.1 Structure

Dictionary definition

"The mutual relation of the constituent parts or elements of a whole as determining its peculiar nature or character; make, frame." *OED*

Health-care dictionary definition

"1. The arrangement of the details of a part; the manner of formation of a part. 2. A tissue or formation made up of different but related parts. ..." *Stedman, 2000*

"In strategic planning or quality assurance management, this is the organizational setup and layout of the organization, which is reviewed to see how resources are used, how effective processes are, and how the setup and layout of the organization affect outcomes and overall quality." *Timmreck, 1997*

Use in the literature

'Of the Vse (use), Figure and Structure of the Hand.' *Crooke, H. Microcosmographia: or, The Whole Body of Man. 1615; VIII iv: 730*

"Structure represents all components of the facility, organization or department. These components include administration, where the work is carried out (environment, physical plant), by whom (personnel), and with what (equipment). *Eagle & Davies, 1993*

Discussion

The term 'structure' is not unlike the term 'system'. Both represent a single entity as well as the components that combine to form that entity.

"Elements are united in a whole which presents certain properties as a whole... and the properties of the elements are dependent on the whole." *Boudan, 1971*

A related term is structural indicator. This provides a measure for the type and amount of resources *available* to a health system or organization to deliver programs and services. Structural review "is concerned with such things as the adequacy of facilities and equipment; the qualification of medical staff and their organization; the administrative structure and operations of programs and institutions providing care; fiscal organization and the like." *Donabedian, 1966*

Recommended use

That **structure** be defined as a supporting framework or essential parts. It includes all elements of the health-care system that exist before any actions or activities take place.

S*P*O 5.1.2 Terms associated with Structure

5.1.2.1 Standard(s), Standard of care

5.1.2.1a Standard(s)

Dictionary Definition

"An authoritative or recognized exemplar of correctness, perfection, or some definite degree of any quality." *OED*

Health-care dictionary definition

"1. Generally, a measure set by competent authority as the rule for measuring quantity or quality; a minimum acceptable level of performance, effectiveness, efficiency, quality, or outcomes. 2. In health-care delivery, conformity with standards is usually a condition of licensure, accreditation, or payment for services. Standards may be defined in relation to the actual or predicted effects of care; the performance or credentials of professional personnel, and the physical plant, governance, and administration of facilities and programs. In the PRO program, standards are professionally developed expressions of the range of acceptable variation from a norm or criterion." *Timmreck, 1997*

Use in the literature

"Among the Romans, Horace is the Standard of Lyric, and Virgil of Epic Poetry." *Felton, H. A Dissertation on Reading the Classics, and Forming a Just Style. Written in the year 1709, and addressed to the Right Honourable John Lord Roos, the present Marquis of Granby. London: Printed for Jonah Bowyer, 1713: 147*

"The HIPAA security and privacy requirements are specifically designed using guidelines rather than hard and fast standards. These guidelines provide flexibility in scaling solutions for small to large organizations to address the law as well as to accommodate advances in technology. However, this very flexibility causes a quandary for smaller organizations because it's unclear how far an organization can scale back and still meet the law's requirements." *Proctor et al, 2003*

Discussion

As defined in health-care dictionaries, and used in the literature and other glossaries, the word standard carries two meanings. First the word may mean 'level', as in:

"A measure of quality or quantity, established by an authority, by a profession, or by custom, which serves as a criterion for evaluation." *Slee et al, 1996*

Second, the term may refer to a rule, as in:

"Something that serves as a basis for comparison; a technical specification or written report by experts." *Stedman, 2000*

This latter meaning is often used when contrasting standards and (clinical practice) guidelines, where guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health-care for specific clinical circumstances." *Field & Lohr, 1990*

"There are three types of standards in health care: structure, process, and outcome standards. Structure refers to evaluation of the setting in which care is rendered and the resources that are available. Process refers to evaluation of the actual activities carried out by the care given. Outcome refers to evaluation of the results of activities in which the nurse has been involved (what the result is for the patient)." *Miller, 1997*

In Canada, the *Canadian Council on Health Services Accreditation* has developed a set of standards that describe a "desired and achievable level of performance against which actual performance can be compared." (*CCHSA, 2001*) Health-care organizations may elect to have their performance compared to the standards through an accreditation process by the CCHSA.

Recommended use

That standard(s) be used in the sense of a level or measure, rather than a rule or policy.

S*P*O ***5.1.2.1b Standard of care***

Health-care dictionary definition

"The principles and practices which 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 which are overriding; ...in other words, the *first* standard of care is that the individual patient's needs come before the 'general' standard." *Slee et al, 1996*

Legal definition

"Under our legal system every person is required to act in such a way as not to cause an unreasonable risk of harm to others. The standard against which individuals are measured is that of the 'reasonable person', and conduct which fails to meet this standard and causes injury to another will render the wrongdoer liable for damages. Persons who hold themselves out as possessing special skills or abilities must practice their art, profession, or business so as to meet a standard of conduct equivalent to that of a reasonably competent member of their group. Accordingly, the standard of care required of a doctor is that of a reasonable medical practitioner considering all the circumstances." *Picard & Robertson, 1996*

Use in the literature

"Acute hypoxemic respiratory failure (AHRF) is an important cause of mortality and morbidity in the pediatric age group. Despite varied etiologies and different population characteristics the aims of therapy are to achieve adequate oxygenation and ventilation. Positive pressure ventilation is currently the standard of care." *Shah et al, 2003*

Discussion

References to 'standard of care' sometimes relate to allegations of negligence.

"Theoretically, the medical malpractice system assesses cases on the basis of a single standard of medical appropriateness. Thus, in theory, presented with a set of facts regarding a patient's signs and symptoms, the actions of a physician in response, and the relevant standard of care for medical appropriateness as indicated by expert testimony, the legal system should be able to determine whether the defendant physician met the standard and provided medically appropriate care." *Liang, 1999*

However a broader view incorporates the perspective of evidence-based interventions, as given in the following example.

> "To have a national standard of care that stipulates that the nurse must record the patients' pain rating and must provide treatment based on what the patient says, not on what the nurse believes, has guided pain practice positively." *Bell & Wheeler, 2002*

Recommended use

That standard of care be as found in a policy or clinical guideline, or in common practice — a set of steps that would be followed or an outcome that would be expected.

S*P*O *5.1.2.2 Hazard, Latent condition*

S*P*O *5.1.2.2a Hazard*

Dictionary definition

> Potential for "loss or harm; peril, jeopardy." *OED*

Use in the literature

> "Slave, I have set my life upon a cast, And I will stand the hazard of the Day." *Shakespeare. Richard III, V, iv, 10*

> "Unsanitary food handling is a major public health hazard. There are over 4,100 mobile food vendors operating in New York City, and of these, approximately forty percent are processing vendors-mobile food units on which potentially hazardous food products are handled, prepared, or processed." *Burt et al, 2003*

Discussion

In aviation and other industries, a hazard is

> "any event, condition, or circumstance which, if left uncorrected or unchanged, could possibly result in an accident or incident". *Transport Canada, 2003*

The term hazard applies to all involved, both passengers and all aviation personnel, as well as the general public. In contrast, in health care, the term hazard represents a potential source of harm, but often only when referring to health-care workers and to public health issues. For example:

> "Health hazard is a danger or risk to health that is posed by such things as contaminants and hazardous conditions (e.g. pollution, disease outbreaks), sewage, garbage disposal, drinking water quality, air quality, food safety, vermin and animal control, public facilities' safety and private and public accommodations' sanitation and safety." *CCHSA, 2001*

In addition, there is often confusion between the terms hazard and risk, as in the definition above. The following quotation provides a clear differentiation.

"A hazard is a set of circumstances or a situation that could harm a person's health, while risk is often defined by scientists as the likelihood (or probability) that harm will occur from a particular hazard." *Repacholi & Muc, 1999*

Recommended use

That **hazard** be defined as a set of circumstances or a situation that could harm a person's interests, such as their health or welfare.

S*P*O *5.1.2.2b Latent condition*

Use in the literature

"Latent conditions are to technological organizations what resident pathogens are to the human body. Like pathogens, latent conditions — such as poor design, gaps in supervision, undetected manufacturing defects or maintenance failures, unworkable procedures, clumsy automation, shortfalls in training, less than adequate tool and equipment — may be present for many years before they combine with local circumstances and active failures to penetrate the system's many layers of defences. They arise from strategic and other top-level decisions made by governments, regulators, manufacturers, designers and organizational managers. The impact of these decisions spreads throughout the organization, shaping a distinctive corporate culture and creating error-producing factors within the individual workplaces"." *Reason, 1997*

Discussion

Latent conditions were previously known as 'latent failures' *Reason 1990a*

Recommended use

That **latent condition** be defined as the structural flaws in the system, or 'resident pathogens', that predispose to adverse outcomes, and that it be used as a term instead of 'latent failure'.

S*P*O 5.2 Process

5.2.1 Process

Dictionary definition

"Something that goes on or is carried on; a continuous action, or series of actions or events; a course or method of action, proceeding, procedure. *OED*

Health-care dictionary definition

"It is commonly stated in quality management that three things can be measured: structure, process and outcome. Process refers to the things done (for a patient, for example). Clearly certain structure is needed; and equally clearly, there is no way to change outcome except through changing process, since "outcome 'tells on' process". *Slee et al, 1996*

Use in the literature

"What then, in Causes can there be an infinite processe; and can no End bee found?" *Fotherby M. Atheomastix Claring Foure Truthes Against Atheists and Infidels 1622; ii. iii. §3: 217*

"Creating a safe process, whether it be flying an airplane, running a hospital, or performing cardiac surgery, requires

attention to methods of error reduction at each stage of system development: design, construction, maintenance, allocation of resources, training, and development of operational procedures." *Leape, 1994*

Discussion

It is essential to clearly delineate which phase of the system is being dealt with (that is, structure versus process versus outcome) when considering problems and solutions within the health-care system.

"Process refers to measures which describe the characteristics of the system in operation. These measures describe what is done (tasks) and how it is done (methods)." *Eagle & Davies, 1993*

Although the process might seem obvious, as in a "goal-directed, interrelated series of actions, events, mechanisms, or steps" (*JCAHO*) or a "systematic series of actions directed to some end" (*Spath, 2000*), there is sometimes confusion, especially with respect to Outcome.

"... one may think of an unbroken chain of antecedent means followed by intermediate ends which are themselves means to still further ends. ... This formulation provides a useful approach to evaluation. It may be designated as the measurement of procedural end points and included under the general heading of 'process' because it rests on similar considerations with respect to values, standards and validation." *Donabedian, 1966*

A process indicator is a reflection of the functioning of a specific process and can be a useful proxy for understanding this aspect of a system. Process indicators provide a measure of the activities and tasks undertaken to achieve program or service objectives. *CCHSA, 2001*

Recommended use

That **process** be defined as a course of action, or sequence of steps, including what is done and how it is done. Examples of these interrelated activities within the health-care system include decision making, problem solving and communication.

S*P*O 5.2.2 Terms associated with Process

S*P*O *5.2.2.1 Active failure*

Dictionary definition

Failure: "A lapse, a failing, a fault, an infirmity; failing to produce an expected outcome, something due or required; becoming exhausted or running short." *OED*

Use in the literature

"Haste in every business brings failures." *Herodotus. The Histories of Herodotus Book VII, c430-424 BC; Chapter 10*

"Active failures are errors and violations committed by those in direct contact with the human-system interface. Their consequences are apparent almost immediately, or at least within a few hours." *Reason, 1994*

"Errors and violations committed at the 'sharp end' of the system — by pilots, air traffic controllers, police officers, insurance brokers, financial traders, ships' crews, control room operators, maintenance personnel, and the like. 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." *Baker & Norton, 2002, from Reason, 1997*

Discussion

The term 'failure' has been used in three different ways. First, failures can represent a type of Outcome, as in the operation was a failure or the more personal 'I am a failure'. This use carries with it a suggestion of 'blame & shame'. Second, failures can be seen to be a type of Process — as in 'active failures'. These are events / actions / processes that fail to achieve their expected aims — they fall short of their stated goal. While many failures contribute to accidents, not all do. Third, the term 'latent failure' was originally defined as the structural flaws in the system, or 'resident pathogens' that constitute predisposition to active failure. However, the term 'latent failure has now been replaced by the term 'latent condition'.

Recommended use

That **active failure** be defined as an event/action/process that is undertaken, or takes place, during the provision of direct patient care and fails to achieve its expected aims. While active failures may contribute to patient injury, not all do.

S*P*O *5.2.2.2 Unsafe acts*

> "Viewed from this perspective, the unsafe acts of those in direct contact with the patient are the end result of a long chain of causes that originates (for the purposes of systemic improvement, at least) in the upper echelons of the system. ...Unsafe acts then are like mosquitoes. You can try to swat them one at a time, but there will always be others to take their place." *Reason, 1994*

There are three major types of unsafe acts: errors, violation and sabotage.

S*P*O *5.2.2.2a Errors*

— see 5.2.2.3 (next section)

S*P*O *5.2.2.2b Violation*

Dictionary definition

> "Infringement or breach, flagrant disregard or non-observance, of some principle or standard of conduct or procedure, as an oath, promise, law, etc., an instance of this." *OED*

Use in the literature

> 'Without any violation of the principles of the constitution.' *Gibbon E. The Decline and Fall of the Roman Empire 1776; Volume 1. Chapter III. Part I: 75*

> "One may err without committing a violation; a violation need not involve error." *Reason, 1990b*

Discussion

Violations represent deviations "from safe operating procedures, standards or rules". *(Reason, 1997)* There are four types of violations:

- exceptional — the exception;
- necessary — "commonly provoked by organizational failings with regard to the site, tools or equipment";

- routine — "typically involve corner-cutting at the skill-based level of performance — taking the path of least effort between two task-related points";
- optimizing — or "violating for the thrill of it". *(Reason, 1997)*

There is occasionally confusion between errors, in which no rules are broken, and violations. This may arise from historical use of the term error.

'Wher law lacketh, errour groweth.' *Gower J. Confessio Amantis or Tales of the Seven Deadly Sins 1393; Prologus: 511*

In general, violations represent intentional breaking of one or more rules; however, they are not associated with any intention to harm. In addition, although the examples given above are negative, violations can be positive, if used, for example, to prevent greater harm from happening to a patient.

S*P*O *5.2.2.2c Sabotage*

Dictionary definition

"To perform or execute badly...to destroy wilfully to ruin, destroy, or disable deliberately and maliciously (frequently by indirect means)." *OED*

Use in the literature

'We have lately been busy deploring the sabotage of the French railway strikers.' 1910, *Church Times 1910; 11 November: 631/2*

"However, we are mostly interested in deliberate violations, where the actions — though not their possible bad consequences — are intended. These non-malevolent acts should be distinguished from sabotage in which both the act and the damaging outcome are intended." *Reason, 1997*

Discussion

A related term is 'intentional unsafe acts'. As they pertain to patients, these 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". *(NCPS-DVA 2003)* This definition would equate to either an optimizing violation or to sabotage. Both are very rare events in health care.

Recommended use

There are three types of unsafe acts: error, violation and sabotage. **Error** should be defined as the failure to complete a planned action as it was intended or when an incorrect plan is used in an attempt to achieve a given aim (see next section). **Violation** should be defined as a deliberate deviation from standards, rules or safe operating procedures. **Sabotage** should be defined as an activity in which both the act(s) and the harm or damage are intended.

S*P*O *5.2.2.3 Error (human, medical, medication)*

S*P*O *5.2.2.3a Human error*

Dictionary definition

"The condition of erring in opinion; the holding of mistaken notions or beliefs; an instance of this, a mistaken notion or belief; false beliefs collectively. Something incorrectly done through ignorance or inadvertence; a mistake, e.g. in calculation, judgement, speech, writing, action, etc." *OED*

Health-care dictionary definition

"1. A defect in structure or function. 2. In biostatistics: 1) a mistaken decision, as in hypothesis testing or classification by a discriminant function; 2) the difference between the true value and the observed value of a variate, ascribed to randomness or misreading by an observor; 3. False positive and false negative results in a dichotomous trial 4. A false or mistaken belief, in biomedical and other sciences, there are many varieties of error, for example due to bias, inaccurate measurements, or faulty instruments." *Stedman, 2000*

Use in the literature

"Though error bee blinde, she sometimes bringeth forth seeing daughters." *Hall J. Horae Vacivae1646*

"... for most people error means that something has been done which was: not intended by the actor; not desired by a set of rules or an external observer; or that led the task outside its acceptable limits." *Senders & Moray, 1991*

"Error will be taken as a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some chance agency." *Reason, 1990b*

Discussion

Errors are the processes by which planned actions fail to achieve their desired ends.

"An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., an error of planning)." *Kohn et al, 2000*

There are three types of errors:

- slips (which "relate to observable actions and are commonly associated with attentional or perceptual failures");
- lapses (which are "more internal events and generally involve failures of memory");
- mistakes (which are failures "with the mental processes involved in assessing the available information, planning, formulating intentions, and judging the likely consequences of the planned actions"). *Reason, 1997*

The term error, is commonly used interchangeably with mistakes, miscalculations, misapprehensions, misconceptions, and misunderstandings, but may, at times, also be understood to include such other terms as slip-ups, bloopers, blunders, and 'oopsies' ('Oops': An exclamation expressing apology, dismay, or surprise, used especially after making an obvious mistake". *OED*)

Some use of the term also connects the making of a single error with a patient suffering an adverse outcome, as in:

"An act of commission or omission that caused, or contributed to the cause of, the unintended injury." *Wilson et al, 1990.*

In fact, adverse outcomes are due to a combination of factors, including errors. While "human error may sometimes be the factor that immediately precipitates a serious failure, there are usually deeper, systemic factors at work." (*NHS, 2000)* Early identification and correction of these factors can help to decrease the probability of the failures occurring.

Often a connection is made between the making of an error with moral failing on the part of the individual making the error. For example, the OED definition of slip-up is:

> "the act of slipping-up; a mistake; a blunder", where the definition of blunder is "a gross mistake from carelessness. A departure from moral rectitude; a transgression, wrong-doing. In modern use conveying the notion either of something not wholly voluntary, and so excusable, or of something imprudent as well as blameable." *OED*

The other problem comes with the terms 'latent error' and 'system error'. More than a decade ago Reason defined two kinds of errors:

- active errors: "whose effects are felt almost immediately", and
- latent errors: "whose adverse consequences may lie dormant within the system for a long time, only becoming evident when they combine with other factors to breach the system's defences". *Reason, 1990*

The term 'active error' is now referred to as an 'active failure' — one type of unsafe act (see above) and 'latent errors' as 'latent conditions' (see above). However, the term 'latent error' has sometimes been interpreted to mean any 'system error'.

> "In this paper, we identify 8 methods used to measure errors and adverse events in health care and discuss their strengths and weaknesses. We focus on the reliability and validity of each, as well as the ability to detect latent errors (or system errors) versus active errors and adverse events." *Thomas & Petersen, 2003*

While all errors in the health-care system are system errors, not all latent conditions are errors. To label them errors is either to apply the term incorrectly and/or to miss other contributing factors. Furthermore, no complex system / process can ever be error-free, suggesting error can never be eliminated or prevented. Error rates, however, can be reduced.

> "Errors are the symptoms that reveal the presence of latent conditions in the system at large." *Reason, 1997*

Thus, errors, when uncovered, can be opportunities for learning.

Recommended use

That **human error** be defined as the failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim.

S*P*O *5.2.2.3b Medical error*

Use in the literature

The term 'medical error' is frequently used in the medical literature.

> "Aside from studies of medication errors, the literature on medical error is sparse, in part because most studies of iatrogenesis have focused on injuries (e.g., the Harvard Medical Practice Study)." *Leape, 1994*

and

> "Because of the intensely personal nature of medicine and because of the ostensibly curative, helping, and ameliorative nature of the medical process, the consequences of medical error are viewed with more alarm than those in many other enterprises." *Senders, 1994*

Discussion

The term medical error emerged from the literature in an effort to isolate and describe errors primarily attributable to doctors. An argument against this narrow focus is reflected in the following quotation.

> "A medical error is an error that happens in a medical setting and is made by someone who is engaged in a medical activity." *Senders, 1994*

In contrast, the definition of 'medical error' given by the Quality Interagency Coordination Task Force (QuIC) is:

> "an adverse event or near miss that is preventable with the current state of medical knowledge." *QuIC, 2000*

The QuIC definition is problematic with respect to two aspects. First, the definition equates medical error (an action) to an outcome. We quote Senders:

> "An error must not be defined by an adverse or serious outcome. An adverse outcome or accident may happen with no antecedent error. This may occur if the intention was the proper one, the action was properly executed, and the outcome was not certain." *Senders, 1994*

Second, the QuIC definition also suggests that medical errors are preventable. (See above for a discussion of this term.)

> "Much as human behavior in a medical setting is still behavior and not medicine, human error in a medical setting is still error and not medicine. Medical error must be considered to be the result of the expression of error in a situation in which there are medically significant things to be done and done wrong. If an error that was expressed in a medical setting instead happened to occur in a nuclear power plant, the only differences would be in the words used." *Senders, 1994*

Recommended use

That **medical error** be no different from a definition of the term 'error', where error is the failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim.

S*P*O *5.2.2.3c Medication error*

Health-care dictionary definition

> "In the process of health-care delivery, especially the administration of drugs and other substances to patients, this is a mistake or failure in medication processing and administration. The multiple levels of personnel, the transcription process from prescriptions, and the prescription-filling process in the pharmacy and mix-ups by physician or nurses just prior to administration all have the potential to contribute to an error in drug administration. Adherence to the five R's of medication administration (right medication, right dosage, right patient, right time, and through the right route such as intravenous, intramuscular, or oral) helps eliminate errors in the process of administering medications." *Timmreck, 1997*

Use in the literature

> "Medication-related error has been studied extensively for several reasons: it is one of the most common types of error, substantial numbers of individuals are affected, and it accounts for a sizable increase in health care costs." *Kohn et al, 2000*

Discussion

The term 'medication error' was first defined in January 1997, as:

> "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." *USP, 1997*

This definition has been in use for several years. At the time of its drawing-up, the concept of preventability was paramount. This definition also includes the confusing use of the term 'systems' differentiated from 'products' and 'procedures'.

Two related terms were similarly defined by Health Canada's Canadian Coalition on Medication Incident Reporting and Prevention (CCMIRP). These terms are 'medical misadventure' and 'medication incident'.

> Medication Misadventures: "A hazard or incident that: is an inherent risk when medication therapy is indicated, is created through either omission or commission by the administration of a medicine or medicines during which a patient may be harmed, with effects ranging from mild discomfort to fatality, whose outcome may or may not be independent of the pre-existing pathology or disease process, may be attributable to incident (human or system or both), immunologic response, or idiosyncratic response, is always unexpected or undesirable to the patient and health professional." *CCMIRP, 2002*

> Medication Incident: "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. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use." *CCMIRP, 2002*

However, both of these definitions are also problematic. The first, in part, is because of use of the term 'misadventure', which the OED defines as "Ill-luck, bad fortune.... a piece of bad fortune; a mishap or misfortune"; the seeming equating of the terms 'hazard' and 'incident'; and the differentiation between 'human incident' and 'system incident'. The second, in part, is because of inclusion of the concept of preventability within the definition and again the confusing use of the term 'systems'.

Recommended use

That **medication error** be defined as the failure to complete a planned action as it was intended, or when an incorrect plan is used, at any point in the process of providing medications to patients.

S*P*O 5.3 Outcome

S*P*O 5.3.1 Outcome

Dictionary definition

"That which comes out of or results from something visible or practical result, effect or product." *OED*

Health-care dictionary definition

"A term used very loosely, particularly in evaluating patient care and the health-care system, and its components. When used for population or the health-care system, it typically refers to changes in birth or death rates or some similar global measure. In contrast, it may refer to the 'outcome' (finding) of a given diagnostic procedure. It may also refer to cure of the patient, restoration of function, or extension of life, sometimes with an attempt to introduce into the calculation some quantification of the quality of life. When used in quality management, it is difficult to find in what dimensions and at what time in the history of the patient's problem outcome is to be determined." *Slee et al, 1996*

Use in the literature

"For the outcome of war (lies) in hands, (that) of words in counsel." *Homer. The Iliad. 800 BC. Book XVI, 630*

"The outcome of medical care, in terms of recovery, restoration of function and of survival, has been frequently used as an indicator of the quality of medical care." *Donabedian, 1966*

Discussion

Outcome is both a simple term, representing "the cumulative effect of health and disease and of health care on patients/clients" (*Spath, 2000*) and an all-encompassing term.

"Outcome represents the final results of the organization. These results may be defined according to simple study of what has been accomplished (audit) and assessment of results in comparison with internal and external standards (evaluation).... Examples of Outcome measures include the five D's: death, disease, disability, discomfort, and dissatisfaction. A sixth D refers to dollars, the cost of treatment of complications, including legal action." *Eagle & Davies, 1993*

Outcomes may be positive or negative. If the latter, then the related terms 'adverse outcome' and 'bad outcome', are sometimes used, and may be defined as "failure to achieve a desired outcome of care." (*Kohn et al, 2000*) However, it must also be remembered that the health care provided is not the only factor that can influence outcome. Many other factors play a contributory role, some in part as the "result of the performance (or non-performance) of a function(s) or process(es)." (*JCAHO, 2003a*) These contributory factors also include the patient's underlying or presenting condition, activities and behaviours.

When outcome is measured, specific indicators can be used.

"For patient care teams that provide direct or indirect client/patient care, outcome indicators should be client/patient related and should measure those changes in the clients'/patients' health status that can be attributed to preceding care and service (i.e. processes and structures). For environment, human resources, and information management teams, and the leadership and partnerships team, where the link between service delivery and client/patient health is not a direct one, outcome indicators should measure the desired end results of the processes." *CCHSA, 2001*

Recommended use

That **outcome** be defined as a product, result or practical effect. In health care, outcomes may be measured in a variety of ways, but tend to reflect the health and well-being of the patient and associated costs.

S*P*O 5.3.2 Terms associated with Outcome

S*P*O *5.3.2.1 Accident*

Dictionary definition

"An occurrence, incident, event; anything that happens without foresight or expectation; cause, or is an unusual effect of a known cause; a casualty, a contingency." *OED*

Health-care dictionary definition

"An unplanned or unintended but sometimes predictable event leading to injury, e.g., in traffic, industry, or a domestic setting, or such an event developing in the course of a disease." *Stedman, 2000*

Use in the literature

'This accident so pitous (piteous) was to here." *Chaucer. Troylus and Cryseyde. 1375; Book III: 918*

"Accident is a word with a rich philosophical pedigree and an interesting etymological history. Aristotle used it to define nonessential or extrinsic characteristics. Thus, people and things had substantial and accidental qualities. Two legs were not a substantial quality of humans; they were an accidental quality because some animals also walk on two legs, and a man or woman with one leg is no less human. Greek, Roman, and medieval philosophers applied Aristotelian philosophy to questions of law and causation... About the 14th century, at the peak of Norman influence, the English began to use another meaning of the word, the meaning commonly understood today: to happen by chance; a misfortune; an event that happens without foresight or expectation." *Loimer & Guarnieri, 1996*

Discussion

In some fields, such as in aviation, the term accident is used to define a serious adverse outcome:

"an occurrence associated with the operation of an aircraft ... in which a person is fatally or seriously injured ..., the aircraft sustains damage or structural failure ..., or the aircraft is missing or is completely inaccessible" *ICAO, 1984*

In health care, however, an accident is defined as:

"an unplanned, unexpected and undesired event, usually with an adverse consequence." *Senders, 1994*

or

"an event that involves damage to a defined system that disrupts the ongoing or future output of the system." *Kohn et al, 2000*

To many, the term 'accident' is misleading. First:

"Although most people use the term medical errors, what they talk about are medical accidents." *Senders, 1994*

Second, as with outcomes, accidents can be both positive (a 'happy accident', a fortuitous occurrence) or negative. Third, the dictionary definition and current use suggest that accidents occur because of fate, chance or bad luck, are therefore devoid of rational explanation or predictability, and that the accident could neither have been foreseen nor 'prevented'. This view is reinforced by current use of the related term, 'accidentally'. In fact, accidents are the end result of a chain of events, actions and circumstances. In some accidents there may be progression and evolution through one or more close calls (also known as 'near misses' or 'near hits') to the final outcome. While some accidents are "the consequence of error some are not. Fortunately not all errors lead to accidents." *Senders & Moray, 1991*

Two views of use of the word accident are offered.

> "The use of the word 'accident' in the title of the excellent new book *Medical Accidents* stands in stark contrast to its abandonment in other disciplines, such as the study of traffic safety. Fifteen years ago Doege argued in an editorial in the *New England Journal of Medicine* that it was time "for medicine to dispose of the idea of `accident' and `accidental injury'". *Evans, 1993*

Others have also provided persuasive arguments that the numerous layers of meaning within the word 'accident' suggest that it should not be used in medical or other similar publications, despite the fact that it is widely used.

> "Accidents are not unpredictable. For many years safety officials and public health authorities have discouraged use of the word 'accident' when it refers to injuries or the events that produce them. An accident is often understood to be unpredictable — a chance occurrence or an 'act of God' and therefore unavoidable. However, most injuries and their precipitating events are predictable and preventable. That is why the *BMJ* has decided to ban the word accident." *Davis & Pless, 2001*

For these reasons, we prefer the term 'adverse outcome' rather than 'accident' when describing the failure to achieve a desired outcome of care. An 'adverse outcome' is an undesired product, result or practical effect, including an injury or complication.

Recommended use

That an **accident** be defined as an adverse outcome that was NOT caused by chance or fate. Most accidents and their contributing factors are predictable and the probability of their occurrence may be reduced through system improvements.

S*P*O *5.3.2.2 Complication*

Dictionary definition

> "An additional disorder that arises during the course of an existing one." *OED*

Health-care dictionary definition:

> "1. one or more disease(s) concurrent with another disease. 2. the occurrence of two or more diseases in the same patient. 3. an injury or disorder occurring in a patient with a pre-existing condition." *Miller, 1997*

> "A detrimental condition that arises during a hospital stay. The patient then requires more treatment, thus prolonging the length of the stay in the hospital. This is any disease condition that worsens or arises from a hospital stay, is

observed and treated in the hospital, and modifies the course of the patient's illness, treatment, and hospital stay. (Some studies have shown that a complication prolongs the length of stay by at least 1 day in approximately 75% of the cases)." *Timmreck, 1997*

Use in the literature

"All the parts in complication roll, And every one contributes to the whole. *Jordan T. Poems. 1685"*

Complications have been defined for the purpose of coding health records. An example from ICD — 9 is:

"999.2 OTHER VASCULAR COMPLICATIONS
Chief complaint of phlebitis, following infusion, perfusion, or transfusion. Thromboembolism, following infusion, perfusion or transfusion. Thrombophlebitis, following infusion, perfusion, or transfusion. (*Excludes the listed conditions when specified as due to implanted device (996.60-996.69) postoperative, Not Otherwise Specified (997.2)." ICD-9*

Discussion

Complications can stress the interconnectedness of elements in the delivery of health care (the structure and process behind a poor outcome). The term can also be understood to suggest that the poor outcome was unavoidable. "What else did you expect? It's a recognized complication." This language, commonly heard in health care, wrongly implies that complications are to be fatalistically expected.

Recommended use

That **complication** be defined as a disease or injury that arises subsequent to another disease and/or health-care intervention.

6.0 Terms that may reflect Structure or Process

S*P*O 6.1 Contributing factors

Dictionary definition

"To give or furnish along with others towards bringing about a result; to lend (effective agency or assistance) to a common result or purpose." *OED*

Use in the literature

"Why is human error so prevalent? Is it at the root of the majority of accidents or a contributing factor?" *Van Cott, 1994*

Discussion

The search for contributing factors may be endless.

"Contributing factors are additional reasons, not necessarily the most basic reason that an event has occurred." *NCPS-DVA, 2003*

Also, the term 'contributory factors' is used interchangeably.

"The most recent delineation of contributory factors to the genesis of critical incidents and accidents comes from research into large-scale technological disasters; for example, the Bhopal pesticide plant, the Challenger space shuttle, the Chernobyl and Three Mile Island nuclear power plants, and the Herald of Free Enterprise car ferry." *Davies, 1995*

Recommended use

That **contributing factors** be defined as the reason(s), situational factor(s), or latent condition(s) that played a role in the genesis of an adverse outcome.

S*P*O 6.2 Cause, Root cause analysis

S*P*O 6.2a Cause

Dictionary definition

"That which produces an effect, that which gives cause to any action, phenomenon, or condition. Cause and effect are correlative terms." *OED*

Health-care dictionary definition

"That which produces an effect or condition; that by which a morbid change or disease is brought about." *Stedman, 2000*

Use in the literature

"Every cause of a cause is cause of thyng caused." *Usk T. The Testament of Love. 1385; Book. Chapter 1: 508*

"Hindsight bias means that things that were not seen or understood at the time of the accident seem obvious in retrospect. Hindsight bias also misleads a reviewer into simplifying the causes of an accident, highlighting a single element as the cause and overlooking multiple contributing factors. Given that the information about an accident is spread over many participants, none of whom may have complete information, hindsight bias makes it easy to arrive at a simple solution or to blame an individual, but difficult to determine what really went wrong." *Kohn et al, 2000*

Discussion

It is tempting for individuals and organizations to look for the sole 'cause' of a misfortune. Such a simplistic, uni-dimensional approach is not possible when attempting to understand and improve patient safety. A related term is causation.

"The act by which an effect is produced. In epidemiology, the doctrine of causation is used to relate to certain factors (predisposing, enabling, precipitating, or reinforcing factors) to disease occurrence. The doctrine of causation is also important in the fields of negligence and criminal law." *JCAHO, 2003a*

There are a variety of descriptive terms for refining the meaning of cause. They include:

Proximate cause: "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." *JCAHO, 2003a*

Underlying 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" *JCAHO, 2003a*

Recommended use

That **cause** be identified as an antecedent set of actions, circumstances or conditions that produce an event, effect, or phenomenon. A cause may be proximate (immediately precede) or remote (a factor in predisposing to) the event, effect, or phenomenon.

S*P*O 6.2b Root Cause Analysis

Dictionary definition

That upon or by which a person or thing is established or supported; the basis upon which anything rests. In phrases denoting completeness or thoroughness, as to the root(s), by the root(s), etc. The bottom or real basis, the inner or essential part, of anything." *OED*

Use in the literature

"He didn't trust us, Dick-that's the root cause." *Wainwright, J. Day of Peppercorn Kill. 1977; 191*

"Root Cause Analysis is 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." *NCPS-DVA, 2003*

"All too often, however, root cause analysis as currently practiced falls short of asking and answering the toughest questions. It is important to recognize that root cause analyses are by definition reactive, because they explore the reasons for errors that already have happened." *Goldmann & Kaushal, 2002*

Discussion

Individuals and organizations may be tempted to focus on identifying a single 'root' cause, for example, the erring practitioner, when in fact there is a complex interaction of many factors.

"It cannot be assumed that a human error is the root cause of an accidental stream of events." *Rasmussen, 1994*

"A limited number of studies focus directly on the causes of adverse events, but attempts to classify adverse events according to 'root causes' are complicated by the fact that several interlocking factors often contribute to an error or series of errors that in turn result in an adverse event." *Kohn et al, 2000*

Recommended use

That **root cause analysis** be defined as 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.

7.0 Terms that may reflect Process or Outcome

S*P*O 7.1 Adverse event

Dictionary definition

An adverse event is "detrimental, harmful to (any)one's interests; calamitous, antagonistic, actively hostile" *OED*

Health-care dictionary definition

"An occurrence in a health-care setting when something happens to a patient to injure or harm the patient, resulting in a malpractice or liability lawsuit. Adverse events can be incidents or more serious occurrences such as patient injury, required unplanned surgery, any nosocomial infection that has developed, an iatrogenic occurrence, inpatient admission being required because of something going wrong in an outpatient surgery or treatment, a readmission caused by incomplete care that led to complications, inappropriate procedures that fell outside of the hospital's guidelines, blood transfusion problems, adverse drug reaction, cardiac arrest, respiratory arrest, fall or accident to a patient, or wrongful death situations." *Timmreck, 1997*

Use in the literature

"What is an 'adverse event'? An adverse event, as defined by a similar Australian study, is 'an unintended injury or complication which results in disability, death or prolonged hospital stay and is caused by health- care management'. This is the definition that will be used by the researchers in the study." *CIHI, 2002*

Discussion

The term adverse event has been defined in at least three different ways. First the term has been defined as part of the Process that results in a patient suffering an adverse outcome.

"An event or omission arising during clinical care and causing physical or psychological injury to a patient." *NHS, 2000*

and

"An incident in which harm resulted to a person receiving health care." *ACSQHC, 2003*

Second, the term adverse event has been defined as an adverse outcome for a patient, in the form of an injury or complication, with various definitions increasing in complexity.

"A previously tested confidential self-report system was used to identify adverse events, which were defined as unexpected complications of medical therapy that resulted in increased length of stay or disability at discharge." *Petersen et al, 1998*

and

> "An AE was defined as an injury or complication which resulted in disability or prolongation of hospital stay and was caused by the health care received rather than by the disease from which the patient suffered. The AE either occurred during the hospital admission, or during an earlier contact with health-care services, and was responsible for all or part of the hospital admission." *Wilson et al, 1999*

and

> "an unintended injury caused by medical management rather than by the disease process and which is sufficiently serious to lead to prolongation of hospitalisation or to temporary or permanent impairment or disability to the patient at time of discharge." *Vincent et al, 2001*

Third, the term has also been less clearly defined, as

> "an undesired and unplanned occurrence, directly associated with the care or services provided to a patient/client in the health-care system". The occurrence may result from "commission or omission (e.g. administration of the wrong medication, failure to institute the appropriate therapeutic intervention, adverse reactions to a medication or negative outcomes of treatment, etc.) and can include problems in practice, products, procedures and systems." *CCHSA, 2003*

Recommended use

That **adverse event** be defined in one of three way:

1. An unexpected and undesired incident directly associated with the care or services provided to the patient;
2. An incident that occurs during the process of providing health care and results in patient injury or death;
3. An adverse outcome for a patient, including an injury or complication.

In view of the three different options, it is essential that the context be described whenever the term 'adverse event' is used. A preferable option would be to use an alternate term with a better-defined meaning.

S*P*O 7.2 Incident, Critical incident

S*P*O 7.2a Incident

Dictionary definition

> "1 a) Something that occurs casually in the course of, or in connexion with, something else, of which it constitutes no essential part; an event of accessing or subordinate character. b) An occurrence or event, sometimes comparatively trivial in itself, which precipitates or could precipitate political unrest, open warfare, etc. Also, a particular episode (air-raid, skirmish, etc.) in war; an unpleasant or violent argument, a fracas. 2. a) An occurrence or event viewed as a separate circumstance." *OED*

Health-care dictionary definition

> "An event in the hospital, or which is unexpected and undesirable. For example, a patient leaving against medical advice (AMA) or a patient's adverse reaction to administration of a drug might be classified by a hospital as 'incidents'. Sometimes 'incident' is used more narrowly to mean an accident (such as a fall) in which a patient is injured (or might

have been injured) and for which the hospital may be liable. An incident report is completed for each incident, to assist in quality management and risk management. See also adverse patient occurrence." *Slee et al, 1996*

"1. an unusual or noteworthy occurrence. 2. impinging upon, as incident radiation." *Miller, 1997*

Use in the literature

"Failures are inevitable incidents." *Anonymous. The Athenaeum, 1879; 6 September: 305/1*

"For this reason, no style of conversation is more extensively acceptable than the narrative. He who has stored his memory with slight anecdotes, private incidents, and personal peculiarities, seldom fails to find his audience favourable." *Johnson, S. The Works of Samuel Johnson. 1752; Volume 4: 188*

"Although incident reporting systems are intended to include major events such as surgical mishaps, incidents have traditionally been greatly underreported and the reports that are filed have involved largely slips, falls, and medication errors that may have little consequence." *Kohn et al, 2000*

"The concept of an untoward incident is one which has grown up within the NHS over the years. It is a loosely used term for which there is no standardised definition: Some characteristics of untoward incidents in the NHS — a serious event in which a patient or patients were harmed or could have been harmed; the event was unexpected; the event would be likely to give rise to serious public concern or criticism of the service involved." *NHS, 2000*

Discussion

The meaning of incident varies. An incident may be a small, but noteworthy, event.

"... the curious incident of the dog in the nighttime. 'The dog did nothing in the nighttime.' 'That was the curious incident.'" *Sir Arthur Conan Doyle. The Memoirs of Sherlock Holmes. Silver Blaze, 1894*

The incident may also refer to events causing harm.

"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." *ACSQHC, 2003*

An incident may also describe the harm that resulted, which:

"Involves damage that is limited to parts or a unit, whether the failure disrupts the system or not." *Perrow, 1984*

A frequent problem is that of confusion of 'incident' with the term 'incidence', especially when the subject is two or more 'incidents'. By definition, 'incidence' means "the number of new cases of a disease occurring within a defined population during a specific period of time." *(Goldfarb, 1997)* Here we present an example of the two terms used correctly.

"The reality is that the correlation between spearing incidents and incidence of paralysis is very low." *Heck, 2003*

Incidents may seem trivial and unimportant but they still deserve note because of the hazards or harms they cause patients to face or to undergo. Depending on the perspective of the organization collecting the data, the (potential) adverse outcome could be clinical or economic. Incidents are also worthy of notice if they are of a type previously unrecognized, they appear to evolve along a new pathway

and/or they are associated with new or different underlying contributory factors. These factors may therefore pose a new or different hazard not widely or previously recognized, in the form of a fault in the system or a problem with a clinical standard or guideline that is hazardous for patients. *ICAO, 1984*

Reporting systems work by encouraging and fostering reports by practitioners, by analyzing the reports and providing rapid responses to the reports. The seven characteristics of successful reporting systems are: trust (that errors will not be punished); independence (from any regulatory authority); ease of reporting (and hence of analysis); acknowledging (of the time and effort to report); motivation and promotion (to continue to report); investigation (of the incident where appropriate); and feedback (of identified hazards). *ICAO, 1984*

Recommended use

That **incident** be defined as including events, processes, practices, or outcomes that are noteworthy by virtue of the hazards they create for, or the harms they cause, patients. Incident reporting systems are meant to capture any and all incidents that are worthy of reporting. They often fail to do so because practitioners do not know what they should report.

S*P*O 7.2b Critical incident

Dictionary definition

> Critical: "Decisive state or turning-point, revealing a crisis or essential nature of some process." Critical path (from engineering) = "the most important elements of a process"; critical point (from physics/math) = "point at which some action, property or condition passes over into another, constituting an extreme or limiting case (e.g., critical angle, critical volume; 'to go critical')". *OED*

Health-care dictionary definition

> "In health-care administration, human resources management, an evaluation method that requires a supervisor to use statements by employees that describe the extremely good and extremely poor work or job-related activity or employee behaviour. The statements are referred to as 'critical incidents' and are used in performance appraisals to assess employees." *Timmreck, 1997*

Use in the literature

> "Key measures for improvement: Compliance with regulations on working hours assessed by diary cards; workload assessed by staff attendance on wards; patient safety assessed through critical incident reports." *Cass et al, 2003*

Discussion

The term 'critical incident' (CI) was first defined by John C. Flanagan, a psychologist in the Aviation Psychology Program of the US Army Air Force. Using what he called the 'critical incident technique', he evaluated the selection and training of air crews during World War II. His technique, a method of studying human performance, used distinct criteria for the direct observations of human behaviour, with an 'incident' being:

> "any observable human activity that is sufficiently complete in itself to permit inferences and predictions to be made about the person performing the act". *Flanagan, 1954*

'Critical' required the incident to occur

> "in a situation where the purpose or intent of the act seems fairly clear to the observer and where its consequences are sufficiently definite to leave little doubt concerning its effects". *Flanagan, 1954*

These first analyzes of 'critical incidents' led to criteria and recommendations for improvements in selection and training of pilots, requirements for combat leadership, designs for cockpits and instrument panels, and procedures to prevent and overcome in-flight vertigo.

This technique was then taken up by a team of researchers in the Department of Anesthesia at the Massachusetts General Hospital. The CI technique was modified and the definition changed to:

> "an occurrence that could have led (if not corrected and discovered in time) or did lead to an undesirable outcome ranging from increased length of hospital stay to death. It must also involve error by a member of the anesthetic team or a failure of the anesthesiologists' equipment to function; occur while the patient is under anesthetic care; be described in clear detail by an observer or a member of the anesthetic team and be clearly preventable." *Cooper et al, 1978*

Since then, the term has been defined in health care in both Canada and the United States as:

> "A human error or equipment failure that could have led (if not discovered or corrected in time) or did lead to an undesirable outcome, ranging from increased length of hospital stay to death." *Baker & Norton, 2002; NPSF, 2003*

The term 'critical incident' has also been equated with the term 'sentinel event' or "occurrences that are Subject to Review by the Joint Commission under the Sentinel Event Policy". *(JCAHO, 2003b)* Sentinel event is defined as:

> "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, 'or the risk thereof'; includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called 'sentinel' because they signal the need for immediate investigation and response." *JACHO, 2003b*

These events include "unanticipated death or major permanent loss of function" (an Outcome), "suicide" (a Process), "infant abduction or discharge to the wrong family" (a Process), "hemolytic transfusion reaction involving administration of blood" (an Outcome), and "surgery on the wrong patient or wrong body part" (a Process). *JCAHO, 2003b*

None of the above should be considered to be 'incidental events' or 'stuff' that 'just happens'. Nor should any of the above be considered inevitable. There are usually a set of systemic and, sometimes, individual factors and events that contributed to their occurrence. These events are commonly tracked within health-care risk management programs as they could, or do, affect the safety of the corporate operations. The occurrence of a critical incident signals the need for immediate systematic investigation and understanding of potential contributing factors. The investigation is sometimes described as root cause analysis.

Recommended use

That **critical incident** be defined as an incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and response. The investigation is designed to identify contributing factors and the response includes actions to reduce the likelihood of recurrence.

8.0 Terms best avoided

The following terms are referenced with definitions within the body of the Dictionary. However, our recommendation is that they are not to be used when discussing patient safety.

8.1 Blame

Dictionary definition

"The action of censuring; expression of disapprobation; imputation of demerit on account of a fault or blemish; reproof; censure; reprehension. Responsibility for anything wrong, culpability; esp. in to lay the blame on, to bear the blame." *OED*

Use in the literature

"Things that are done, it is needless to speak about .... Things that are past, it is needless to blame." *Confucius. The Confucian Analects. Book3: 21, ii*

"The common reaction to an error in medical care is to blame the apparent perpetrator of the error. Blaming the person does not necessarily solve the problem; more likely, it merely changes the players in the error-conducive situation." *Bogner, 1994*

Discussion

Assigning blame to an individual for an error or adverse event does not recognize the complexity within the health-care system and the impact of latent conditions. We can only quote Senders:

"Blaming people for making errors is like blaming them for breathing. They will do both willy-nilly." *Senders, 1994*

Recommended use

Blame may help those who have suffered complications of health care, but it does little to improve patient safety. We follow others in recommending a new culture in health care that eschews labels of blame.

8.2 Fault

Dictionary definition

"Deficiency, scarcity, want thereof; default, defect, wanting in moral character; blameable imperfection." *OED*

Health-care dictionary definition

"1. Guilty of an improper act, mistake, or error; negligence; lack of care; failure to perform duty. 2. A defect or imperfection. 3. In health law or medical malpractice litigation, a wrongful act, omission, or breach of duty and the determining or fixing of blame; to blame. See also negligence." *Timmreck, 1997*

Use in the literature

"Most accidents were considered to be due to carelessness and simple fault of the workers without any significant relationship to their professional training and career." *Maeda et al, 2003*

Discussion

The term 'fault' often carries a pejorative connotation of blame or responsibility. Senders recommends that it is perhaps better not to use the term at all. Rather, fault should only be used "when referring to problems not in the actor, but in the system with which the actor interacts, as when we say 'A fault developed in the heater,' or 'there was a fault in the computer hardware'." (*Senders & Moray, 1991*) An alternative term is 'fault-line', which in geology, is a "dislocation or break in continuity of the strata or vein". *OED*

Recommended use

Fault should be avoided as a term applying to causality as it implies blame. (See above). By contrast, 'fault-lines' is a more acceptable descriptive term that pertains to hazardous environmental or systemic conditions.

8.3 Negligence

Dictionary definition

"1. Want of attention to what ought to be done or looked after; carelessness with regard to one's duty or business; lack of necessary or ordinary care in doing something." *OED*

Health-care dictionary definition

"In law, the failure to do something that a reasonable person of ordinary prudence would do in a certain situation or the doing of something that such a person would not do. Negligence may provide the basis for a lawsuit when there is a legal duty, as the duty of a physician or nurse to provide reasonable care to patients and when the negligence results in damage to the patient." *Miller, 1997*

Use in the literature

"By their own negligence and folly in their temporal affairs." *1736 Butler S. Analogy.1736; I. iv: 80*

"The critical care unit is most vulnerable because the intensity of illness is so great. Conscious or unconscious, the patient needs human touch and consolation, which transcends technology. Indifference to this is all but negligence on the part of the nurse." *Nussbaum, 2003*

Discussion

The legal definition of negligence is:

> "the omitting to do something that a reasonable man would do or the doing of something which a reasonable man would not do so. It is the omission to do something which a reasonable man, guided upon those considerations which ordinarily regulate the conduct of human affairs, would do; or doing something which a prudent and reasonable man would not do." *Yogis & Gifis, 1998*

Yet, many health-care professionals, patients and the media use the term loosely, meaning that they think that there was a want of attention to what ought to have been done or looked after; or carelessness with regards to someone's duty or business. They may use the term in this way to describe care associated with adverse outcomes when they think that there is a basis for successful civil litigation.

> "The failure of a professional with a duty to act to provide the standard of care, which results in harm to a patient. See also: duty to act, malpractice, standard of care." *Goldfarb, 1997*

However, such use of the term is not correct because only the Courts can make a finding of negligence, on a case-by-case basis. To be successful, an action for negligence must meet four requirements:

i. the defendant must owe the plaintiff a duty of care;
ii. the defendant must breach the standard of care established by expert evidence;
iii. the plaintiff must suffer an injury or loss; and
iv. the defendant's breach of the standard of care must have been the actual and legal cause of the plaintiff's injury.

> "Thus, the common misapprehension amongst the public, that most undesirable complications must somehow be the fault of the doctor, is quite unfounded. Even if the doctor makes, what in retrospect, was an error of judgement, that is not necessarily negligent. If he was diligent, employed the correct diagnostic procedures, but in good faith drew the wrong conclusion from a set of alternatives or did not employ the optimum treatment, he may still have made only an error of clinical judgement, rather than been negligent." *Knight, 1991*

Recommended use

Negligence should be limited to use as a term in legal proceedings and the decisions of the Courts.

8.4 Recklessness

Dictionary definition

> "Of persons: Careless, heedless. Careless in respect of one's conduct, reputation, or the consequences of one's actions; lacking in prudence or caution." *OED*

Health-care dictionary definition

> "In health law, this is negligent; careless; not heeding the consequences of one's actions." *Timmreck, 1997*

Use in the literature

> "I am one, my liege, whom the vile blows and buffets of the world have so incens'd that I am reckless what I do to spite the world." *Shakespeare. Macbeth III, i,108*

> "The factors which contributed most frequently to injury were recklessness on the part of the injured party and foul or illegal play by another player. Lack of fitness and defects in sports gear, playing area, and equipment were other common causes." *Watson, 1984*

Discussion

Assigning the terms of reckless recklessness to a health-care professional or team is only applicable within very narrow circumstances, such as professional regulatory reviews or other legal proceedings.

The legal definition of reckless is being "marked by a lack of proper caution". *Yogis & Gifis, 1998*

Furthermore,

> "A person is reckless if, knowing that there is a risk, that an event may result from his or her conduct, or that a circumstance may exist, he or she takes that risk even though it is unreasonable to take it having regard to the degree and nature of the risk he or she knows to be present. The risk must be of such a type and extent that the person's failure to appreciate it, taking into account the object of his or her conduct and the circumstances known by him or her, includes a gross deviation from the level of care that a reasonable and prudent individual would have undertaken in that person's circumstance." *Yogis & Gifis, 1998*

A related term is that of 'reckless disregard', which is defined as:

> "In relation to behaviour, lack of heed, or regard for the results; especially foolishly ignoring danger, rash, heedlessly neglectful or inattentive to consequences. This involves a realization of danger and a willingness to undertake the risk." *Yogis & Gifis, 1998*

Unfortunately, many individuals are tempted to use the term reckless to explain or attribute blame when there has been an adverse outcome.

Recommended use

Recklessness, like negligence, should be limited to use as a term in legal proceedings and the decisions of the Courts.

9.0 Research Methodology

The research methodology targeted three critical domains of references for each patient-safety term.

1. Dictionary definitions, both in standard English language dictionaries, as well as in medical and health-care dictionaries;
2. Patient-safety glossaries in a national context, particularly from Australia, Canada, the United Kingdom, and the United States; and
3. Medical literature, both in standard patient-safety texts and in the periodical literature.

The steps taken to identify and cite the appropriate references within each of the three domains are outlined to provide a clear understanding of how the research process unfolded.

Researching dictionary definitions

A key objective was to understand, where possible, how terms were first used in the English language. Although several patient-safety terms were only developed in and/or gained common acceptance in the 20th century, the origins of many terms are centuries old. The *Oxford English Dictionary (OED)* is the standard text for this kind of research. It provides not only the etymology of the word, but places the various meanings of the word in context, using the earliest examples available in the English language.

While certain patient-safety terms do appear in the *OED*, given that the *Canadian Patient Safety Dictionary* is targeted primarily for a health-care audience, it became imperative to consider how medical and health-care dictionaries defined and described these terms. Given the wide range of available references, both general medical dictionaries and those applicable to health care were consulted. *Stedman's Medical Dictionary (Stedman, 2000)* is the standard medical dictionary used in most medical libraries. However, its medical focus meant that many terms identified in the Canadian Patient Safety Dictionary were not listed. Therefore, a number of dictionaries, with an emphasis on health care generally, were of greater use.

Researching patient safety glossaries in a national context

The search for patient-safety glossaries was aided primarily by the amount of information available on the Internet. Basic search engines and the keywords, 'patient safety' and 'glossary', were used in conjunction with the country of interest. Glossaries from these countries were then identified and accessed. As with any research done using the Internet, credibility is key: glossaries attributed to accredited and/or professional health-care associations carried a high degree of authority. While a number of patient-safety glossaries are available in Canada and the United States, it was also necessary to understand how patient-safety terms were defined beyond North America. In particular, glossaries from Australia and the United Kingdom were of greatest interest as these are countries with English as an official language and with health-care environments comparable to those in Canada and the United States.

Researching the use of the term in the health-care literature

Within the discourse on patient safety there are a number of authoritative works recognized as estab-

lished and seminal texts. To determine the key literature in the field, *Patient Safety and Healthcare Error in the Canadian Healthcare System*, a Report to Health Canada by G. R. Baker and P. Norton, (*Baker & Norton, 2002*) provided the initial direction. Notable names listed in their section on general texts and overviews of safety and error include MS Bogner, L. Leape, J Reason, and JW Senders. The abundance of citations to their work, and the prevalence of their publications on human error and patient safety, have resulted in these authors being consistently cited within the patient-safety literature. These works were starting points to determine how the classic texts have used the patient-safety terms included in this Dictionary.

In addition to referring to classic texts, given the importance of periodical literature to the health-care community, it was also crucial to understand how patient safety terms were used in this literature. The major medical information databases, including *MEDLINE*, *CINAHL* and *PubMed*, allowed subject and keyword searching of various patient-safety terms. Given the common usage of many of these terms (not solely from a patient-safety perspective), the options to 'limit' and retrieve articles with a particular subject focus or 'subset', for example, Bioethics, helped in finding the most applicable and relevant articles.

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11.0 Alphabetical summary of recommended usage of terms

S*P*O **Accident** (p. 33)

That accident be defined as an adverse outcome that was NOT caused by chance or fate. Most accidents and their contributing factors are predictable and the probability of their occurrence may be reduced through system improvements.

S***P***O** **Active failure** (p. 25)

That active failure be defined as an event/action/process that is undertaken or takes place during the provision of direct patient care and fails to achieve its expected aims. While active failures may contribute to patient injury, not all do.

S***P***O** **Adverse event** (p. 39)

That adverse event be defined in one of three ways.

1. An unexpected and undesired incident directly associated with the care or services provided to the patient;
2. An incident that occurs during the process of providing health care and results in patient injury or death;
3. An adverse outcome for a patient, including an injury or complication.

In view of the three different options, it is essential that the context be described whenever the term adverse event is used. A preferable option would be to use an alternate term with a better-defined meaning.

S*P***O** **Cause** (p. 36)

That cause be defined as an antecedent set of actions, circumstances or conditions that produce an event, effect, or phenomenon. A cause may be proximate (immediately precede) or remote (a factor in predisposing to) the event, effect, or phenomenon.

S*P*O **Complication** (p. 34)

That complication be defined as a disease or injury that arises subsequent to another disease and/or health-care intervention.

S*P*O Contributing factors (p. 36)

That contributing factors be defined as the reason(s), situational factor(s), or latent condition(s) that played a role in the genesis of an adverse outcome.

S*P*O Critical incident (p. 42)

That critical incident be defined as an incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and response. The investigation is designed to identify contributing factors and the response includes actions to reduce the likelihood of recurrence.

S*P*O Disclosure (p. 17)

That disclosure be understood as the imparting, by health-care workers to patients or their significant others, of information pertaining to any health-care event affecting (or liable to affect) the patient's interests. The obligation to disclose is proportional to the degree of actual harm to the patient (or the realistic threat of such) arising from an untoward event.

S*P*O Hazard (p. 23)

That hazard be defined as a set of circumstances or a situation that could harm a person's interests, such as their health or welfare.

S*P*O Human error (p. 27)

That (human) error be defined as the failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim.

S*P*O Incident (p. 40)

That incident be defined as including events, processes, practices, or outcomes that are noteworthy by virtue of the hazards they create for, or the harms they cause, patients. Incident reporting systems are meant to capture any and all incidents that are worthy of reporting. They often fail to do so because practitioners do not know what they should report.

S*P*O Latent condition (p. 24)

That latent condition be defined as the structural flaws in the system, or 'resident pathogens', that predispose to adverse outcomes, and that it be used as a term instead of 'latent failure'.

S*P*O Medical error (p. 29)

That medical error be no different from a definition of the term 'error', where error is the failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim.

S*P*O **Medication error** (p. 30)

That medication error be defined as the failure to complete a planned action as it was intended, or when an incorrect plan is used, at any point in the process of providing medications to patients.

S*P*O **Outcome** (p. 32)

That outcome be defined as a product, result or practical effect. In health care, outcomes may be measured in a variety of ways, but tend to reflect the health and well-being of the patient and associated costs.

S*P*O **Patient safety** (p. 11)

That patient safety be defined as 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.

S*P*O **Preventable/Preventability** (p. 16)

That preventable be used with caution, and without implying either negligence or harm.

S*P*O **Process** (p. 24)

That process be defined as a course of action, or sequence of steps, including what is done and how it is done. Examples of these interrelated activities within the health-care system include decision making, problem solving and communication.

S*P*O **Risk** (p. 15)

That risk be defined as the probability of danger, loss or injury within the health-care system.

S*P*O **Risk management** (p. 16)

That risk management in health care be defined as organizational activities designed to prevent patient injury or moderate the actual financial losses following an adverse outcome.

S*P*O **Root cause analysis** (p. 37)

That root cause analysis be defined as 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.

S*P*O **Standard(s)** (p. 21)

That standard(s) be used in the sense of a level or measure, rather than a rule or policy.

S*P*O **Standard of care** (p. 22)

That standard of care be as found in a policy, or clinical guideline, or in common practice — a set of steps that would be followed or an outcome that would be expected.

S*P*O **Structure** (p. 20)

That structure be defined as a supporting framework or essential parts. It includes all elements of the health-care system that exist before any actions or activities take place.

S*P*O **System** (p. 13)

That system be reserved for use when describing the entirety of health care and be defined as a set of interdependent components interacting to achieve a common aim. Within the system, these components may be classified in various ways. One classification is based on socio-geographic factors: national, provincial, organizational/institutional, health-care provider, and patient/family. System characteristics include complexity and coupling.

S*P*O **Unsafe acts** (p. 26)

There are three types of unsafe acts: error, violation and sabotage. Error should be defined as the failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim. Violation should be defined as representing a deliberate deviation from standards, rules or safe operating procedures. Sabotage should be defined as an activity in which both the act(s) and the harm or damage are intended.

Terms best avoided

Blame (p.44)

Blame may help those who have suffered complications of health care, but it does little to improve patient safety. We follow others in recommending a new culture in health care that eschews labels of blame.

Fault (p.44)

Fault should be avoided as a term applying to causality as it implies blame. By contrast, 'fault-lines' is a more acceptable descriptive term that pertains to hazardous environmental or systemic conditions.

Negligence (p.45)

Negligence should be limited to use as a term in legal proceedings and the decisions of the Courts.

Recklessness (p. 46)

Recklessness, like negligence, should be limited to use as a term in legal proceedings and the decisions of the Courts.

Index

Terms listed in the Table of Contents are considered primary and appear in the list below in regular font. A number of other terms have been defined only within the text of the Dictionary and are therefore considered *secondary terms*. The *secondary terms* have been italicised in the list below.

Notes