Project to Develop the International Classification for Patient Safety

Report of the WHO World Alliance for Patient Safety Meeting with Francophone Technical Experts

Cultural and Linguistic Evaluation of the Conceptual Framework for the International Classification for Patient Safety

Drafting Group Responses to Technical Expert Comments, Suggestions and Recommendations

November 2008
Geneva, Switzerland
Background and Overview

In 2003, the World Health Organization recognized the need to standardize, aggregate and analyze patient safety incident information and data to provide comparisons for local, regional, national and international learning. In 2005, the World Alliance for Patient Safety (World Alliance) assembled a drafting group of experts in the fields of patient safety, classification theory and development, health informatics, consumer advocacy, law and medicine to develop the conceptual framework for the International Classification for Patient Safety (ICPS). Drawing upon a number of existing classifications and linked to other WHO classifications, the ICPS aims to “define, harmonize and group patient safety concepts into an internationally agreed classification in a way that is conducive to learning and improving patient safety across systems.” The World Alliance is committed to ensuring the ICPS is genuinely an international classification acceptable in the environments in which it will be utilized. Further, it is the World Alliance’s intent that the ICPS be internationally interoperable and be able to be integrated into existing classifications. To accomplish this, in 2006, the drafting group embarked on a multi-phased approach to testing the validity of the ICPS, including a two-stage, web-based Delphi survey, an in-depth examination by international experts, and cultural and linguistic evaluation. The purpose of the meeting with the Francophone technical experts was to provide a briefing on the development of the ICPS, provide an opportunity for feedback with regard to cultural and linguistic evaluations, and to explore the value of the ICPS from a particular cultural perspective. Objectives of the meeting were to:

1. Determine the cultural appropriateness of the ICPS in the Francophone patient safety environment;
2. Determine the linguistic appropriateness of the key concepts and their associated conceptual definitions and preferred terms; and
3. Identify concepts that may pose cultural difficulties and to obtain recommended suitable substitutions.

During a one-day in person meeting, the technical experts engaged in an informative and productive conversation. Following this a similar meeting with Hispanophones in Madrid, Spain, on 15 October 2008, the ICPS Drafting Group met in Geneva, Switzerland on 20-21 November 2008. The Drafting Group considered each of the comments made.

This report (Drafting Group Responses to Technical Expert Comments, Suggestions and Recommendations) specifically responds to comments, suggestions and/or recommendations made by the technical experts. In some instances the Drafting Group responses are the same or similar to those made to Challenge Group (10-11 April 2008) and Hispanophone technical experts. It is suggested that the three reports be considered together.

Responses by the Drafting Group follow the comments, recommendations and suggestions and are shown in bold italics.

1 Patient Safety Event Taxonomy – Version 1.0 (PSETM-v.1.0) – The Joint Commission
2 The National Reporting and Learning System – National Health Services, National Patient Safety Agency
3 The Australian Incident Monitoring System – Australian Patient Safety Foundation
4 The Eindhoven Classification Model for System Failure (ECM) and The Prevention and Recovery Information System for Monitoring and Analysis – Medical (PRISMA) – Eindhoven, The Netherlands: Eindhoven University of Technology
7 World Health Organization Drug Dictionary (maintained by the Uppsala Monitoring Centre), 2004.
Meeting Participants

Technical Experts:

- Rene Amalberti – HAS
- Jean Bacou – HAS
- Patrice Blondel - AFGRIS
- Charles Bruneau – HAS
- Jean Carlet – HAS
- Philippe Chevalier – HAS
- Francois Clergue – Hospital Universitaires de Geneve
- Marie Francoise Dumay – SOFGRES
- Jacques Fabry – Hospital Henry Gabrielle – HCL
- Michael Hunt – CIHI
- Philippe Michel – CCECQA
- Anne-Sophie Nyssen – University of Liege
- Tiui Ojasoo – HAS
- Michele Perrin – DHOS
- Michel Sfez – SOFGRES
- Micheline Ste-Marie – Hospital De Montreal Pour Enfants

Members of the International Classification for Patient Safety Drafting Group:

- Peter Hibbert – National Patient Safety Agency
- Jerod Loeb – The Joint Commission
- Heather Sherman – The Joint Commission
- Richard Thomson – University of Newcastle upon Tyne

Participants from the World Health Organization:

- Martin Fletcher – National Patient Safety Agency on behalf of World Alliance for Patient Safety
- Pierre Lewalle – Measurements & Health Information Systems Department
- Itziar Larizgoitia – World Alliance for Patient Safety

The following individuals served as officials during the meeting:

WHO Officer and Overall Chair: Martin Fletcher
Rapporteur: Heather Sherman
Proceedings

Charles Bruneau opened the meeting and welcomed the participants. Martin Fletcher, Peter Hibbert, Pierre Lewalle, Jerod Loeb and Richard Thomson provided an overview of the development and current status of the conceptual framework for the International Classification for Patient Safety (ICPS). Drafting group members stressed that the ICPS is not yet a classification, but is a conceptual framework for a classification which provides a reasonable understanding of the world of patient safety and patient safety concepts to which existing regional and national classifications can relate. It provides the platform for the more detailed development of the classification. Drafting group members stressed that in addition to providing a much needed method of organizing, aggregating and analyzing patient safety data and information, the conceptual framework also has intrinsic pedagogical value on its own. Participating technical experts provided an overview of the use of patient safety information in France, Belgium, Canada and Switzerland.

Comments related to the conceptual framework

Overall, the technical experts felt the ICPS conceptual framework, with some explanation, could be culturally appropriate in their environments. The main issues focused on the following:

- The relationship between incidents and contributing factors (i.e., an incident could be considered a contributing factor and vice versa). It was agreed that the ICPS should be used to organize information. The conceptual definitions for incident and contributing factor did not preclude an incident being a contributing factor to another incident or a contributing factor being an incident. It was proposed that determining whether an incident is a contributing factor or contributing factor is an incident is an issue that can be addressed by design of information systems and data analysis.

The Drafting Group reviewed the definition for patient safety incident and contributing factors/hazards and found them to be acceptable. The Drafting Group acknowledged the complex relationship between incident and contributing factors/hazards. An incident can be either a contributing factor to another incident or an incident in its own right, depending on context, circumstances and outcomes. An incident has a set of contributing factors. Although an incident can be a contributing factor to another incident, some contributing factors can not be incidents in their own right. An incident type can therefore be designated as a principal incident type depending on context specific business rules (e.g., the incident most proximal to the identified patient outcome), design of the information system or type of data analysis. For example, if a patient with atrial fibrillation on warfarin got up at night to go to the bathroom, and slipped and fell resulting in no discernable harm, the patient safety incident would be considered a no harm incident and the incident type would be categorized as a “patient accident - fall”. If this patient had been found the following morning unrousable on the floor, then it is likely that the patient safety incident would be considered a harmful incident (adverse event) and the incident type would be regarded as “clinical management”. The fall would be considered a contributing factor involving “staff factors”, “work environment factors”, and “organizational/service factors”.


• **Error recovery.** The technical experts requests further explanation of the error recovery process and questioned whether the concept of detection included the diagnosis of the problem (i.e., understanding what has happened such that mitigating or ameliorating actions are appropriately selected and applied). A suggestion was made for the drafting group to consider adding the concept of “diagnosis” as a high level class within the classification. Drafting group members felt this issue deserved further attention but may not require the addition of a new high level class.

    The Drafting Group considered the proposal to add a high level class to represent the notion of identifying (or diagnosing) what has been detected before initiating mitigating factors or ameliorating actions. The Drafting Group determined a greater explanation of the incident recovery process rather than the creation of a new class was more appropriate.

• **A communication strategy for presenting the ICPS to the general public.** This was considered essential to understand the ICPS could be used both for data collection, aggregation and analysis and for proactive pedagogical endeavors focusing specifically on patient safety. An executive summary and mission statement should be added to the ICPS document. Some suggested the possibility of splitting the conceptual framework for the ICPS into two documents: (1) the conceptual framework consisting of the 10 high level classes; and (2) the concepts falling under each of the 10 high level classes. Other proposals included means of displaying the dynamic and inter-relational elements of the framework. Graphical design and technical support for this will be helpful.

    The Drafting Group will prepare a technical report for the conceptual framework for the ICPS to ensure the rationale for the decisions made during the development of the conceptual framework and selection of key concepts/preferred terms are transparent and understandable by the general public. The technical report will also include an explanation of the conceptual framework (diagram, expanded narrative, step-by-step description), a glossary of key concepts, a description of practical applications (use of the ICPS for pedagogical and analytic purposes) and appendices (history of the project, granular concepts, bibliography and acknowledgements).

• **Testing the conceptual framework under “real world” conditions.** The current depiction of the conceptual framework is satisfactory for technical and further developmental use. If, however, the conceptual framework is to be used for pedagogical purposes, it must be redesigned so as not to be perceived as a flow chart and to more effectively describe the interdependencies and relationships between and across the classes.

    The Drafting Group will commission the services of a professional graphic designer to produce a visual representation that better reflects the dynamics and complexities of the conceptual framework.
Comments related to the key concepts (definitions and preferred terms)

** words in quotation marks are key concepts within the ICPS

The discussion on the cultural and linguistic appropriateness of the ICPS focused on the need to capture the nuances of the conceptual definitions in French and identify difficulties in compatibility with current work being undertaken. The technical experts identified several real and potential issues with the French translation of the key concepts and agreed to review the French translation to ensure it is an accurate interpretation of the conceptual definitions and preferred terms for the key concepts. All agreed that a glossary is needed to determine the origins of the definitions, as well as the semantic categories instantiated in the definition and the relationships between them.

Technical experts identified the following as key issues for further consideration by the drafting group:

- The definition of “detection” may be too narrow. It should encompass aspects of understanding the causal features of what has been detected (identified, diagnosed) so that the appropriate mitigating and ameliorating actions can be applied.

  The Drafting Group reviewed the definition for detection in light of discussion regarding understanding the features of what has been detected before initiating mitigating and ameliorating actions, and determined the definition does not require revision; an expanded explanation of the incident recovery process will be provided in the technical report.

- “Healthcare associated harm” may be redundant with “adverse event”. An explanation as to why “healthcare associated harm” was used in place of iatrogenic and nosocomial harm should be provided.

  The Drafting Group reviewed the definitions for healthcare associated harm and adverse event. These definitions are not redundant. The definition for healthcare associated harm refers to the harm that arises from or is associated with plans or actions taken during the provision of care; the definition for harmful incident (adverse event) refers specifically to a patient safety incident that resulted in harm to a patient. The distinction is the occurrence of a patient safety incident, as opposed to the provision of healthcare.

  The reason the Drafting Group selected the key concept “healthcare associated harm” instead of “iatrogenic” or “nosocomial” harm is because the Drafting Group felt iatrogenic and nosocomial harm was no longer appropriate for the way healthcare is provided, who provides the care and where it is provided. Iatrogenic harm, defined as (1) an ‘injury originating from or caused by a physician…, including unintended or unnecessary harm or suffering arising from any aspect of health care management, including problems arising from acts of commission or omission’ (Reference: Aspden P, Corrigan J, Wolcott J, Erickson S, editors. Institute of Medicine, Committee on Data Standards for Patient Safety, Board on Health Care Services. Patient Safety: Achieving a New Standard for Care. Washington DC: National Academies of Sciences, 2004); or (2) ‘induced unintentionally by a physician through his diagnosis, manner, or treatment; of or pertaining to the induction of (mental or bodily) disorders, symptoms, etc., in this way’ (Reference: Oxford English Dictionary), focuses only on the physician. Nosocomial harm, defined as ‘pertaining to or originating in a health care facility’ (Reference: Committee of Experts on Management of Safety and Quality in Health Care, Glossary of terms related to patient and medication safety – approved terms. Council of Europe. 2005); or (2) ‘of or relating to a hospital; spec. (of a disease) originating or acquired in hospital’ (Reference: Oxford English Dictionary), applies only to the inpatient setting. Healthcare associated harm (‘harm arising from or associated with plans or actions taken
during the provision of healthcare, rather than an underlying disease or injury’), therefore acknowledges that healthcare is provided by a number of different individuals (including patients) in a variety of care settings (community settings, home, etc.).

- The definition of “preventable” was discussed. Technical experts ultimately determined that the definition was suitable and did not require revision.

  The Drafting Group is in full agreement.

- The definition for “violation” is satisfactory. The French preferred term should be “violation” rather than “infraction”. In the French environment, “infraction” implies law and regulation.

  Issues regarding translation and interpretation will be resolved by consultation with WHO official translators and identified technical experts from this meeting. This will involve ongoing discussion and reverse translation.

- A difference may exist between “patient safety” and patient security; specifically the difference concerns what the concept of “healthcare” includes (the provision of care itself, access to care, etc) in English and in French. This needs further consideration.

  Issues regarding translation and interpretation will be resolved by consultation with WHO official translators and identified technical experts from this meeting. This will involve ongoing discussion and reverse translation.

- The discussion explored whether the conceptual definition of “hazard” is interpreted differently in French than in English or whether it is a matter relating to the preferred term. From the discussion, the conceptual definition of “hazard” was more aligned with the French term “danger”.

  Issues regarding translation and interpretation will be resolved by consultation with WHO official translators and identified technical experts from this meeting. This will involve ongoing discussion and reverse translation.

- The use of the word freedom in the definition of “safety” should be reconsidered. It was argued that because risk is an inherent part of the provision of health care, it is inappropriate to give the impression that one is truly free from hazard.

  The Drafting Group reviewed the definition of “safety” and the use of the word freedom within the definition. The Drafting Group agreed that a definition for “safety” that is reflective of reality (i.e., risk is a component of receiving healthcare) is necessary. The revised definition for “safety” is ‘the reduction of risk of unnecessary harm to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment. The revised definition for “patient safety” is ‘the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum again refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment’.
• The concepts of informed consent, disclosure, apology and patient information should be added as key concepts.

An explanation for inclusion/exclusion of key concepts (definitions and preferred terms) will be included in the technical report.

The addition of certain key concepts (those concepts which facilitate understanding and transfer of information relevant to patient safety) is being considered for a future version of the ICPS.

Next Steps

The conceptual framework for the ICPS will be finalized at the November 2008 drafting group meeting. The WHO intends to respond to the needs of its Member States, but must be pragmatic in its approach. Therefore all input received until that point will be integrated to the largest extent possible. This includes a review of the French translation of the key concepts to ensure the intent of the conceptual definitions is accurately captured.

The ICPS should be tested in real world situations; specifically the HAS should consider testing version 1.1 of the ICPS (to be released by January 2009) in the French national survey.

Further collaboration will be fostered with participants from this meeting following the release of the next version of the ICPS.
