More than words

Conceptual Framework for the International Classification for Patient Safety

Version 1.1

Final Technical Report January 2009





Patient Safety

A World Alliance for Safer Health Care

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Executive Summary

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

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

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

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

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

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

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

48 key concepts have been defined and assigned preferred terms to facilitate understanding and transfer of information relevant to patient safety. These concepts represent the start of an on-going process of progressively improving a common international understanding of terms and concepts relevant to patient safety.

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

The conceptual framework for the ICPS was designed to provide a much needed method of organizing patient safety data and information so that it can be aggregated and analyzed to:

- Compare patient safety data across disciplines, between organizations, and across time and borders:
- Examine the roles of system and human factors in patient safety;
- Identify potential patient safety issues; and
- Develop priorities and safety solutions.

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

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Chapter 1 Background

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

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

What is a classification?

A classification comprises a set of concepts linked by semantic relationships. It provides a structure for organizing information to be used for a variety of other purposes, including national statistics, descriptive studies and evaluative research. It is important to distinguish a classification from a reporting system, which provides an interface to enable users to collect, store and retrieve data in a reliable and organized fashion.

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

Drafting Group

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

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

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

http://www.who.int/medicines/services/medicines_etools/en/

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² Fifty-Fifth World Health Assembly. Res. WHA55.18. 18 May 2002

³ Perneger, T. Borges on classification. *Int J for Qual in Health Care* 2006;28(4):264-265.

⁴ World Health Organization, Family of International Classifications Overview (2004, June). http://www.who.int/classifications/en/

⁵ World Health Organization. International Statistical Classification of Diseases and Related Health Problems. 10th Revision.

Version for 2006 (ICD-10). http://www.who.int/classifications/icd/en/index.html
⁶ World Health Organization Drug Dictionary (maintained by *the* Uppsala Monitoring Centre), 2004.

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

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

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

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

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

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⁷ Chang, A, Schyve P, Croteau R, O'Leary D, Loeb J. The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events. *Int J Qual Health Care* 2005;17:95-105. http://www.who.int/patientsafety/taxonomy/NQF Standardizing Patient Safety Taxonomy Jan202006.pdf

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

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

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

World Health Organization, Alliance for Patient Safety (2007, May) Report on the Results of the Web-Based Modified Delphi Survey of the International Classification for Patient Safety. Geneva, Switzerland.
 World Health Organization, Alliance for Patient Safety (2008, April). Report of the WHO World Alliance for Patient Safety

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

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

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

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

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

Introduction

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

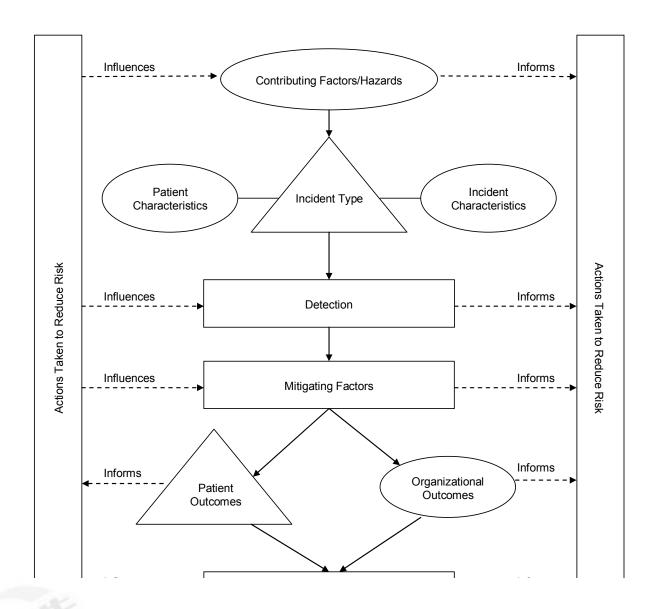
The 10 high level classes are:

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

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

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The Conceptual Framework for the International Classification for Patient Safety



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