Project to Develop the
International Classification for Patient Safety

Report of the WHO World Alliance for Patient Safety Drafting Group

6-7 December 2007
Geneva, Switzerland
Background and Overview

In 2005, the World Alliance for Patient Safety (World Alliance) assembled a panel of experts in the fields of patient safety, classification theory and development, health informatics, consumer advocacy, law and medicine to build the conceptual framework for a classification which could be used to compare patient safety information and data at an international level. The panel, known as the Drafting Group, recognized that while many patient safety classifications exist, no one classification was fit for global use. Therefore, a decision was made to use as points of origin the work of The Joint Commission in the United States (Patient Safety Event Taxonomy endorsed by the National Quality Forum)\(^1\), the National Health Service National Patient Safety Agency in the United Kingdom (National Reporting and Learning System)\(^2\), the Australian Patient Safety Foundation (Advanced Incident Management System)\(^3\), the Eindhoven University of Technology and Leiden University Medical Center in the Netherlands (Eindhoven/PRISMA-Medical Classification Model)\(^4\), and several classifications within the WHO-Family of International Classifications\(^5\), specifically the International Statistical Classification of Diseases and Related Health Problems\(^6\), the International Classification of Functioning, Disability and Health\(^7\), the preliminary elements of a future International Classification of Health Interventions\(^8\) and WHO Drug Dictionary\(^9\).

The conceptual framework for the International Classification for Patient Safety (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. It is concept driven, and seeks to map easily to existing systems with relatively low resource expenditure, to capture both adverse events and near misses, to be inclusive of a wide range of stakeholders, to be sensitive to cultural and linguistic issues, and to be adaptable yet consistent across the continuum of healthcare. The ICPS is not a reporting system; it is a logically oriented hierarchical framework of concepts designed to translate patient safety incident data collected from a range of sources into a standardized classification.

The drafting group has met officially four times between October 2005 and June 2007.\(^{10,11,12,13}\) During this time, the drafting group defined the purpose of the ICPS and devised a strategic plan for its development. The strategic plan consisted of identifying and defining key patient safety concepts, creating a conceptual framework to organize the concepts in a meaningful manner, and testing the global relevance and acceptability of the ICPS through an international consensus building process.

---

1 Patient Safety Event Taxonomy – Version 1.0 (PSET\textsuperscript{TM}v.1.0) – Joint Commission on Accreditation of Healthcare Organizations.
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
The conceptual framework, comprised of ten high level classes, was developed; and the ICPS underwent a two-round web-based modified Delphi survey of international experts and stakeholders. The results of the Delphi survey suggested that the ICPS could be valuable and useful for translating disparate information into a common format. A subgroup of the Drafting Group was convened in December 2006 to consider the Delphi responses critically and to revise the ICPS accordingly. At its 8 June 2007 meeting, the Drafting Group approved the ICPS conceptual framework and key patient safety concepts and discussed the next phase of the project.14,15

The Drafting Group met officially for a fifth time on 6-7 December 2007 in Geneva, Switzerland to present an overview of the ICPS to World Alliance for Patient Safety Regional Focal Points and to discuss the further development and testing of the ICPS.

Participants

Ten Drafting Group members, two ex-officio Drafting Group members and 10 observers from the World Alliance for Patient Safety participated in the fifth official Drafting Group meeting. One Drafting Group member and one ex-officio Drafting Group member were absent. A complete roster of participants is attached as Appendix A.

The following individuals served as officials during the meeting:

Chairman: Mr. Pierre Lewalle
Rapporteur: Dr. Heather Sherman

Objectives

1. To discuss the development of the International Classification for Patient Safety with World Alliance for Patient Safety Regional Focal Points;

2. To explore the value of the International Classification for Patient Safety and potential applications;

3. To agree upon and finalize the field testing methodology for the International Classification for Patient Safety;

4. To agree upon and finalize the dissemination and publication strategy for the work completed on the development of the International Classification for Patient Safety; and

5. To discuss, agree upon and finalize immediate next steps.


Proceedings

Discussion of the Development and Value of the International Classification for Patient Safety with World Alliance Regional Focal Points

Members of the International Classification for Patient Safety Drafting Group briefed the Regional Focal Points on the current status and technical aspects of the ICPS. The discussion focused on the following:

1. Knowledge Building – The rationale for development and the theoretical foundation upon which the ICPS is based differs from other classifications within the WHO Family of International Classifications network. For example, the unit of count is the patient safety incident as opposed to the patient. Further, the conceptual framework for the ICPS was designed to invoke action. It focuses on the epistemology of a patient safety incident. The standardized data and information should be used for learning and predictive/proactive risk assessment in addition to epidemiologic (incidence/prevalence rates, etc.) purposes.

2. Concepts – The ICPS is concept driven. Each concept contained within the conceptual framework must be defined. These definitions must be culturally appropriate. Certain definitions for the 46 key concepts should be explained further and, in some instances, a rationale for including a concept within the key concepts should be provided (i.e., the differentiation between necessary and unnecessary harm, the inclusion of side effect).

3. Applicability of the ICPS in various health care settings – Concepts contained within the ICPS refer to several areas of care (e.g., primary and secondary care). These concepts should also be applicable to patient safety issues in developing, transitional, and developed countries.

4. Cultural Shift – To achieve the full value of the ICPS, the patient safety culture should focus on systems improvement rather than individual behavior.

5. Education and Information – The Regional Focal Points for Patient Safety\(^16\) made it clear that this in person briefing was key to their understanding the purpose and intention of the ICPS. The Regional Focal Points also strongly suggested that a document containing the instructions on how to apply the ICPS, including notes and examples, should be developed to accompany the ICPS and conceptual definitions.

The Regional Focal Points indicated that they were aware of several countries from the Eastern Mediterranean (EMRO), the South-East Asia (SEARO), Europe, and the Americas (PAHO) regions that may be willing to participate in testing the validity of the conceptual framework for the ICPS.

\(^{16}\) Regional Focal Points for Patient Safety are WHO staff located in each of the six WHO regions who lead regional patient safety work in collaboration with the World Alliance Secretariat. These individuals are charged with advising senior health and other government officials regarding work undertaken at the World Alliance, implementation of WHO recommendations, and distribution of information to and from key national sectors and governmental departments.
Field Testing Methodology

The International Classification for Patient Safety is intended to become a member of the WHO – Family of International Classifications as a related classification. The Drafting Group discussed the proposed field testing methodology to achieve this goal. It was decided that the International Classification for Patient Safety was not yet a fully formed classification. It is a conceptual framework at the highest level. Standardized definitions for the concepts contained in the ICPS and a specifications manual comprised of notes and differential examples must be developed. The Drafting Group agreed that field testing should focus on validity instead of reliability and should occur in a phased manner. Development of the standardized definitions and specifications manual should occur in the first phase. Once developed, the standardized definitions and specifications manual should be translated into the languages of participating countries. Validity testing and translation and linguistic evaluation would occur in the second phase.

Three specific research questions were identified:

1. Can a range of qualified health care professionals within individual countries classify country-specific patient safety incidents using the conceptual framework for the ICPS as it current exists (Validity 1)?

2. Do a range of experts from a variety of safety related fields think the conceptual framework for the ICPS captures the essential elements of patient safety incidents collected from disparate sources (incident reporting systems, medical-legal reports, coroners’ reports and patient reports. (Validity 2)

3. Can certain existing patient safety reporting systems/classifications readily map to the conceptual framework? (Validity 3).

Publication and Dissemination Strategy

The Drafting Group discussed two components of the publication and dissemination strategy for the ICPS.

Publication: The Drafting Group supported the rapid development and submission of four manuscripts by members of the dissemination/publication subgroup: (a) an overview of the development of the ICPS to date; (b) a description of the Delphi survey process and results; (c) an explanation of the development of the conceptual framework and key patient safety concepts for the ICPS; and (d) a portrayal of the patient/consumer perspective as it relates to the ICPS. Each manuscript should reference the others. The Drafting Group decided to submit the four manuscripts to the *International Journal on Quality in Healthcare* in the hopes they would be published as a group.

Dissemination: It was agreed that a plan to communicate the intricacies of the ICPS to the stakeholders was necessary and that in person educational sessions which provide the background, rationale, and technical aspects of the ICPS would be the preferred method for disseminating the information. This approach (1) conveys the current status of the ICPS; (2) explains how the ICPS is intended to be used once testing is completed; (3) describes the tools that will accompany the implementation of the ICPS; and (4) illustrates how the ICPS can be mapped to existing systems or used as the foundation for new reporting systems. This approach also provides the Drafting Group with the opportunity to obtain guidance, support and acceptance from key stakeholders, as well as to identify and address content and validity issues not easily accessible through non-interactive formats.
Immediate Next Steps

The field testing subgroup, led by Tjerk van der Schaaf, will revise the testing methodology based upon the discussions. The testing methodology will be a phased approach with milestones, specifically highlighting what can be accomplished by June 2008.

In conjunction with the World Alliance, the field testing subgroup will formalize the details (attendance, location, etc.) for the educational sessions. The Drafting Group agreed that sessions should at least be held with the Latin American community, the experts in the World Alliance Research strand, and the French and the Spanish patient safety community. The conceptual Framework for the ICPS and the 46 key patient safety concepts have already been translated into French and Spanish. The French and the Spanish educational sessions will be conducted in French and Spanish respectively and will serve two purposes: first, to inform and educate the patient safety experts about the ICPS and second, to evaluate the current translation.

The publication/dissemination subgroup will prepare and submit the four manuscripts for publication.

Recommendations

The Drafting Group recommends the following:

1. The World Alliance undertake the necessary additional development work to prepare the ICPS for field testing.

2. The World Alliance focus initial field testing on assessing the validity of the ICPS.

3. The World Alliance promote the adoption of the ICPS internationally through publication and in-person educational sessions.

4. The World Alliance and the Drafting Group foster further collaboration with the Regional Focal Points and with the World Alliance Research strand.

5. Once appropriate, the World Alliance publish the field testing strategy on the WHO World Alliance for Patient Safety Taxonomy website.

It is envisaged that the above recommendations will be completed in a reasonably expedient but scientifically sound manner.

The sixth official meeting of Drafting Group is scheduled for 14-15 May 2008.

APPENDIX A

World Health Organization  Organisation Mondiale de la Sante

Project to Develop the
International Classification for Patient Safety
Geneva, Switzerland, 6-7 December 2007

List of Participants

Mr. Martin Fletcher
National Patient Safety Agency on behalf of the World Alliance for Patient Safety, World Health Organization

Dr. Robert Jakob
Measurements & Health Information Systems Department, Information, Evidence and Research
World Health Organization

Mr. Richard Koss
Department of Health Services Research, Division of Quality Measurement and Research
The Joint Commission

Mr. Pierre Lewalle
Measurements & Health Information Systems Department, Information, Evidence and Research
World Health Organization

Dr. Jerod Loeb
Division of Quality Measurement and Research, The Joint Commission

Professor Thomas V. Perneger
Department of Anaesthesia and Intensive Care, Royal Adelaide Hospital, North Terrace, Adelaide

Dr. Heather Sherman
Center for Patient Safety Research, Department of Health Services Research
Division of Quality Measurement and Research, The Joint Commission

Professor Richard Thomson
Professor of Epidemiology and Public Health, Newcastle University Medical School

Dr. Tjerk W. van der Schaaf
Associate Professor of Patient Safety Research
Eindhoven University of Technology and Leiden University Medical Center
Appendix A cont. – List of Participants

**Ex-Officio Drafting Group Members**

Mr. Peter Hibbert  
Australian Patient Safety Foundation

Mr. Martin Hatlie  
Partnership for Patient Safety

**Absent**

Mr. Gerry Castro (Ex-Officio Drafting Group Member)  
International Center for Patient Safety, The Joint Commission

**Observers**

Dr. Ahmed Ali Abdullatif  
World Alliance for Patient Safety, EMRO Regional Focal Point

Dr. Jonas Gonseth Garcia  
World Alliance for Patient Safety, PAHO Regional Focal Point

Ms. Margaret Hercules  
World Alliance for Patient Safety, SEARO Regional Focal Point

Ms. Valentina Hafner  
World Alliance for Patient Safety, EURO Regional Focal Point

Ms. Helen Hughes  
World Health Organization Office for Patient Safety, London, UK

Dr. Edward Kelley  
World Alliance for Patient Safety

Itziar Larizgoitia  
World Alliance for Patient Safety

Ms. Julia Panayiotou  
World Health Organization

Dr. Sara Scobie  
National Patient Safety Agency, National Health Services, UK