Project to Develop the
International Classification for Patient Safety

Report of the WHO World Alliance for
Patient Safety Drafting Group

14-15 May 2008
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 drafting group has met officially five times between October 2005 and December 2007\(^10,11,12,13,14\). During this time, the drafting group defined the purpose of the International Classification for Patient Safety (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 developing a field testing methodology.

\(^1\) Patient Safety Event Taxonomy – Version 1.0 (PSET\(^\text{TM}\)-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
\(^7\) World Health Organization.  International Classification of Functioning, Disability and Health. (ICF).
\(^8\) World Health Organization.  International Classification of Health Interventions. (ICHI).
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. A ten class conceptual framework for the ICPS was developed; and the conceptual framework for the ICPS underwent a two-round web-based modified Delphi survey of international experts and stakeholders. 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.

The Drafting Group met officially for a sixth time on 14-15 May 2008 in Geneva, Switzerland.

Participants

Nine Drafting Group members, two ex-officio Drafting Group members and five observers from the World Alliance for Patient Safety participated in the sixth official Drafting Group meeting. Two Drafting Group members 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 (14 May 2008): Mr. Martin Fletcher
Chairman (15 May 2008): Mr. Pierre Lewalle
WHO Officer: Mr. Martin Fletcher
Rapporteur: Dr. Heather Sherman

Objectives

1. To review and discuss the results of the 10-11 April 2008 Challenge Group meeting;

2. To discuss the strategy for peer-reviewed publication; and

3. To discuss the current status of development and next steps with regard to field testing and transformation of the conceptual framework for the ICPS into a true classification.

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Proceedings

Discussion of the Results of the Challenge Group Meeting

As part of the field testing process, 12 technical experts representing the fields of patient safety, systems engineering, health policy and the law were invited to critically analyze the conceptual framework for the International Classification for Patient Safety (the “Challenge Group”). The Challenge Group met in Geneva, Switzerland on 10-11 April 2008. A complete roster of participants is attached as Appendix B. The Challenge Group participants dissected nine of the ten high level classes (Organizational Outcomes was not discussed in detail) and made valuable suggestions for revision. The Drafting Group examined each comment, suggestion, or question raised by the Challenge Group participants and made revisions to the conceptual framework for the ICPS where appropriate. These revisions will be reflected in the Conceptual Framework for the International Classification for Patient Safety V.1.1 for use in Field Testing in 2009.

Discussion of Publications

The Drafting Group reviewed the drafts of the three agreed upon manuscripts: (1) an overview paper which describes and explains the conceptual framework for the ICPS; (2) a paper discussing the Delphi process; and (3) a paper describing the process to identify and define 46 key concepts and preferred terms. The Drafting Group decided that the manuscripts should be revised in light of the input from the Challenge Group. Once finalized, the manuscripts will be submitted for publication by the WHO World Alliance for Patient Safety.

Current status of development and next steps with regard to field testing and transformation of the conceptual framework for the ICPS into a true classification

The ICPS, at the present time, is a conceptual framework comprised of a set of ten high level classes; each individual in nature but highly interconnected. The ICPS approaches patient safety from a systems perspective. It is intended to be a patient safety incident classification which allows for the retrospective categorization of salient information using concepts with agreed definitions and preferred terms so the information can be used to inform proactive risk assessment. It is not a reporting system. Further, like the International Classification of Diseases, it is evolutionary in nature.

The ICPS is to become a related member of the World Health Organization Family of International Classifications. To that end, further field testing of the conceptual framework for the ICPS should be undertaken with as many different user groups as possible. This will ensure that the ICPS emphasizes the appropriate concepts and can classify a range of incidents derived from a variety of disparate sources (e.g., reporting systems, medicolegal cases, coroners’ reports, case note review) in a variety of different locations (e.g., where healthcare is provided in developing, transitional and developed countries).

The Drafting Group also reaffirmed its decision to follow the multi-phased field testing methodology previously set forth. The methodology was designed to ensure that the ICPS meets the requirements for becoming a related classification as set forth in the World Health Organization – Family of International Classification guidelines and includes phases for developing conceptual definitions, reliability testing and linguistic and cultural evaluation.

The immediate next steps should be to publish the three manuscripts and finalize a statement describing the ICPS’ purpose, intended users and uses, classification structure, and current status of development. Simultaneously, the Drafting Group should continue to test the validity of the conceptual framework for the ICPS as described in the endorsed operational plan for field testing. The next version of the conceptual framework for the ICPS (the Conceptual Framework for the International Classification for Patient Safety Version 1.1 for use in Field Testing in 2009), will be revised based upon the content validity testing. This version should be used to complete the multi-phased field testing thus constituting the basis for transforming the conceptual framework into a true classification.

**Recommendations**

The Drafting Group recommends the following:

1. The World Alliance continue to follow the agreed operational plan for field testing the ICPS.
2. The World Alliance promote the ICPS internationally through publication.
3. The World Alliance engage in efforts to develop and grow a community of interest among stakeholders and potential end users internationally to ensure maximum acceptance and utility of the ICPS.
4. The World Alliance provide official feedback to the Challenge Group participants indicating actions taken in response to their input.

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

The seventh official meeting of Drafting Group is scheduled for 20-21 November 2008.

Respectfully submitted for approval on 9 June 2008.
APPENDIX A

World Health Organization  
Organisation Mondiale de la Sante

Project to Develop the
International Classification for Patient Safety
Geneva, Switzerland, 14-15 May 2008

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
Health Information Systems Department
World Health Organization

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

Mr. Pierre Lewalle
Health Information Systems Department
World Health Organization

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

Professor William Runciman
Department of Patient Safety & Healthcare Human Factors
University of South Australia
Joanna Briggs Institute & Royal Adelaide Hospital

Dr. Heather Sherman
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
Appendix A cont. – List of Participants

Dr. Tjerk W. van der Schaaf  
Human Factors in Risk Control  
Eindhoven University of Technology  
Economic Aspects of Patient Safety  
Hasselt University

**Ex-Officio Drafting Group Members**

Mr. Peter Hibbert  
Australian Patient Safety Foundation

Mr. Martin Hatlie  
Partnership for Patient Safety

**Absent**

Dr. Martti Virtanen  
STAKES (Nordic Centre for Classifications in Health Care)  
Dept. of Public Health and Caring Science

Professor Thomas V. Perneger  
Clinical Epidemiology Services  
Geneva University Hospitals

Mr. Gerry Castro  
International Center for Patient Safety  
The Joint Commission

**Observers**

Sir Liam Donaldson  
Helen Hughes  
Edward Kelley  
Itziar Larizgoitia  
Albert Wu
APPENDIX B

World Health Organization  
Organisation Mondiale de la Sante

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
Geneva, Switzerland, 10-11 April 2008

List of Participants

Technical Experts

Dr. Ahmed Al-Mandhari – Deputy Director General, Clinical Affairs, Sultan Qaboos University Hospital (Oman)

Dr. Mahi Al-Tehewy – Professor of Public Health, Ain Shams University (Egypt)

Dr. Rene Amalberti – HAS (France)

Mr. Brian Capstick – Senior Partner Emeritus, Capsticks Solicitors (United Kingdom)

Dr. Mark Chassin – President, The Joint Commission (United States)

Dr. Peter Goldschmidt – World Development Group (United States)

Dr. Harold Kaplan – Professor of Clinical Pathology & Director of Transfusion Medicine, Columbia University (United States)

Dr. Tebogo Kgosietsile Letlape – Immediate Past-President, World Medical Association (South Africa)

Professor James Reason – Saferhealthcare (United Kingdom)

Dr. Pedro Saturno – UD Medicina Preventiva y Salud Publica, Universidad de Murcia (Spain)

Dr. Kenichiro Taneda – Chief, Department of Health Policy Sciences, National Institute of Public Health (Japan)

Dr. Mikel Torrontegui – Avedis Donabedian Institute (Spain)
Appendix B cont. – List of Participants

**Members of the International Classification for Patient Safety Drafting Group**

Dr. Jerod Loeb – The Joint Commission (United States)

Dr. Heather Sherman – The Joint Commission (United States)

Professor Richard Thomson – University of Newcastle upon Tyne (United Kingdom)

Professor Tjerk van der Schaaf – Hasselt University (Belgium)

**Participants from the World Health Organization**

Mr. Martin Fletcher – National Patient Safety Agency (United Kingdom) on behalf of World Alliance for Patient Safety

Ms. Pauline Philip – World Alliance for Patient Safety

Dr. Agnes Leotsakos – World Alliance for Patient Safety