Project to Develop the
International Patient Safety Event Classification

Report of the WHO World Alliance for
Patient Safety Drafting Group

13-14 December 2006
Geneva, Switzerland
Background and Overview

The ability to accurately classify, aggregate, and compare patient safety related information across international reporting and data collection systems is almost non-existent posing a significant barrier to improving patient safety. Better classification of information related to adverse events and near misses requires clear understanding and agreement on key terms and concepts. To accomplish this, in late 2005, the WHO World Alliance for Patient Safety initiated work on the International Patient Safety Event Classification (IPSEC). The IPSEC aims to define, harmonize and group patient safety concepts into an internationally agreed upon classification in a way that is conducive to learning and improving patient safety across systems. It is intended to be adaptable yet consistent across the entire spectrum of health care and across cultures and languages.

Under the guidance of a drafting group comprised of experts in the fields of patient safety, information management and classification, the IPSEC was designed to link closely with the WHO Family of International Classifications, specifically the International Statistical Classification of Diseases and Related Health Problems, the International Classification of Functioning, Disability and Health, the International Classification of Health Interventions and WHO Drug Dictionary. The drafting group drew upon the work of the Joint Commission on Accreditation of Healthcare Organizations’ Patient Safety Event Taxonomy endorsed by the National Quality Forum in the United States, the National Health Service National Patient Safety Agency’s National Reporting and Learning System in the United Kingdom, the Australian Patient Safety Foundation’s Advanced Information Management System in Australia, and the Eindhoven University of Technology’s Eindhoven Classification Model from the Netherlands. Effort was made to ensure that the IPSEC would add value to systems currently in use in various countries, map easily to existing systems with relatively low resource expenditure, capture both adverse event and near miss data; and be sensitive to cultural and linguistic issues.

The first meeting of the Drafting Group was held on 24-25 October in Vancouver, British Columbia. The meeting took the form of a guided discussion based on background papers and presentations. During the meeting, the Drafting Group adopted the mission statement developed by the 2003 Working Group – to “develop a comprehensive standard taxonomy on patient safety, useable by all WHO Member States to facilitate improved information sharing, learning and system change in order to reduce health

5 World Health Organization Drug Dictionary (maintained by the Uppsala Monitoring Centre), 2004.
6 Patient Safety Event Taxonomy – Version 1.0 (PSETTM-v.1.0) – Joint Commission on Accreditation of Healthcare Organizations.
7 The National Reporting and Learning System – National Health Services, National Patient Safety Agency
8 The Australian Incident Monitoring System – Australian Patient Safety Foundation
9 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
care-related harm.” The purpose for The Project to Develop the International Patient Safety Event Classification as defined by the Drafting Group was to “define, harmonize and group patient safety concepts into a classification that will elicit, capture and analyze factors relevant to patient safety in a manner conducive to learning and system improvement in an adaptable yet consistent way across the entire spectrum of health care and across cultures and languages”. In addition, the Drafting Group developed a strategic plan to achieve the project’s purpose and goal.

The Drafting Group adhered to certain criteria when designing the strategic plan. The classification should (1) follow the WHO Family of International Classification specifications, (2) be concept driven, (3) add value to the current classifications and reporting systems in use in various countries, (4) be inclusive of a wide range of stakeholders, (5) map easily to existing classifications with relatively low resource expenditure, (6) capture adverse event and near miss data, and (7) be sensitive to cultural and language issues. The Drafting Group also emphasized the need to strive for maximum comparability of patient safety information on an international level while at the same time recognized that this may not be fully achievable. Global health care systems are at varying stages of development and adoption of the International Patient Safety Event Classification will be voluntary.

The strategic plan involved a stepwise process. The first step was to identify the critical concepts related to patient safety and to develop a conceptual framework within which to place the concepts. Once the concepts and conceptual framework were complete, the utility and meaningfulness of the classification would be tested through a modified Delphi approach to build consensus amongst various stakeholders and Member States. Three working groups, comprised of members of the Drafting Group, were established to undertake this work. The Concept Identification Working Group was charged with identifying critical concepts to include in the International Patient Safety Event Classification through a review of patient safety taxonomies in use internationally. The Conceptual Framework Working Group was charged with creating a logical infrastructure into which the concepts would be organized. Finally, the Delphi Planning Working Group was charged with developing the methodology to determine the extent to which the concepts, conceptual framework and scope of the classification addressed the needs of international constituents.

A joint meeting of the working groups was held on 21 March 2006 in Geneva, Switzerland to further articulate and refine the conceptual framework in preparation for the second meeting of the Drafting Group. The conceptual framework was designed to organize high level classes and underlying concepts into a transparent, theoretical and logical architecture which allowed for the translation of patient safety information and data into a common language which could then be aggregated, compared and analyzed for the purpose of learning.

The Drafting Group officially met for a second time on 4 May 2006 in Geneva, Switzerland. During the meeting, each working group provided an overview of its work. The Conceptual Framework Working Group presented the conceptual framework finalized during the 21 March 2006 meeting. The Drafting Group felt the proposed conceptual framework was an appropriate logic model to capture the salient details of all events which could have (near miss) or did (adverse event) lead to harm to a person receiving health care. The Conceptual Identification Working Group provided an overview of the approximately 500 terms and concepts to be contained within ten (10) high level classes identified in the conceptual framework. The Drafting Group believed it was essential that the term and definition for each concept be generic, neutral and fit for purpose. The Delphi Planning Working Group summarized the

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15 Minutes from the 21 March 2006 meeting of the WHO World Alliance for Patient Safety Project to Develop the International Patient Safety Event Classification Drafting Group Working Groups.
purpose for a proposed methodology to gain international consensus for the IPSEC from experts in fields of patient safety, health policy legislation, reporting systems, safety and quality control, classification theory and development, health informatics, consumer advocacy, law and medicine (the Delphi survey). The two round web-based Delphi survey would solicit input to determine global acceptability and applicability of the IPSEC and to ensure the relevance of the terms and concepts contained therein. At the conclusion of the meeting, the Drafting Group endorsed the conceptual framework and approved the implementation of the Delphi survey.16

The background material and proceedings of the prior meetings form the basis of this report.

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Participants

Eleven (11) Drafting Group members and three (3) ex-officio Drafting Group members participated the third Drafting Group meeting. Participants represented an interdisciplinary group of classification and patient safety experts with considerable experience with patient safety taxonomies, event reporting systems and/or organizations committed to patient safety. A complete roster of participants is attached as Appendix A.

The following individuals served as officials during the meeting:

Chairman: Mr. Pierre Lewalle
WHO Officer: Mr. Martin Fletcher
Rapporteur: Mr. Gerry Castro

Objectives

The objectives of the third meeting of the Drafting Group were to:

1. Review the outcomes of the Delphi consultation process (Delphi survey) and finalize the concepts and conceptual framework for the International Patient Safety Event Classification; and

2. Recommend the scope of the next phase of work.

Proceedings

The Delphi Planning Working Group provided an overview of the Delphi consultation process, summarized the outcomes and presented areas for further discussion by the Drafting Group.

Members of the drafting group had previously identified over 300 experts in the fields of patient safety, health policy legislation, reporting systems, safety and quality control, classification theory and development, health informatics, consumer advocacy, law and medicine. Each received a personalized invitation to participate in the Delphi process containing a unique link to the electronic surveys. Input had also been sought from a wider stakeholder constituency. Open invitations to take part in the Delphi process were placed in an article published in the International Journal for Quality in Health Care17 and on the websites of the World Health Organization’s World Alliance for Patient Safety, the Australian Patient Safety Foundation, the Joint Commission on Accreditation of Healthcare Organizations and the National Patient Safety Agency.

Delphi participants had been asked to complete two rounds of surveys. Only those who provided input during the first round were asked to participate in the second round. Respondents were promised confidentiality but not anonymity.

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The first round of the web-based Delphi survey was from 18 August to 22 September 2006. Following analysis of the results, the IPSEC was modified and feedback was provided to the Delphi participants. The second round of the Delphi survey took place from 1 November to 27 November 2006. Feedback from both rounds was presented to the Drafting Group for consideration and discussion. As a result of the Drafting Group discussions, an overview was written to explain the purpose and structure of the IPSEC and demonstrate its ability to serve as a model to classify patient safety events (adverse events and near misses); definitions for the ten (10) high level classes were refined; and the conceptual framework was revised to clarify the purpose of each high level class and to explicitly show the relationships among and between them.

**Next Steps**

A sub-group of the Drafting Group will oversee the process to accomplish the following by the end of the first quarter in 2007:

1. A report of the Delphi process to be provided to all Delphi participants;
2. Refinement of the terms and concepts contained within the IPSEC and technical editing to ensure clarity;
3. Translation of the IPSEC into other official languages of the United Nations, notably French and Spanish; and
4. Wide dissemination of the IPSEC under the aegis of the WHO in a variety of formats including the WHO website, conference presentations, and submission of articles to peer reviewed journals.

Pierre Lewalle, William Runciman, Richard Thomson, Tjerk van der Schaaf and the Joint Commission will serve on the sub-group.

The above items will form the basis for discussion at the next full Drafting Group meeting scheduled for the beginning of 2007. The envisioned outcome of this meeting will be version 1 of the IC4PS for pilot testing (see Recommendations below).
Recommendations

The Drafting Group recommends to the WHO World Alliance for Patient Safety that:

1. The IPSEC be renamed to the International Classification for Patient Safety (IC4PS).

2. The WHO commission a second phase of work which actively builds upon the work already undertaken to develop the IPSEC. Specifically:
   a. Develop a set of implementation tools to accompany the IPSEC;
   b. Test the IPSEC internationally in conjunction with the implementation tools in order to refine its validity, reliability, usability and applicability;
      i. Pilot test (alpha test) the IPSEC with a target number of sites recruited from developed and developing countries in each of the six (6) WHO regions representing a range of potential end users and data sources;
      ii. Review and revise the IPSEC in light of the pilot test;
   iii. Conduct wider field testing (beta testing); and
   iv. Review and revise the IPSEC in light of the wider field testing.

   The Drafting Group recommends the WHO World Alliance for Patient Safety accept the previous recommendation made at the first meeting of the Drafting Group in Vancouver 2005 that the pilot (alpha) testing and wider field (beta) testing be designed and overseen by a task force of the Drafting Group led by Tjerk van der Schaaf.

3. Continued development of the IPSEC should be guided by the existing Drafting Group to ensure continuity with the addition of one or two experts from developing countries and a smaller project Steering Group drawn from the Drafting Group should be formally constituted.

4. The WHO leverage and promote the adoption of the IPSEC internationally.

5. The WHO initiate a process through which “owners” of existing large scale patient safety data collection systems are invited to map their classification systems to the IPSEC and report on the results, with a view of developing a common mapping tool for wider use.

It is envisioned that the above recommendations be completed by the end of the fourth quarter 2008.

Respectfully submitted for approval on 28 December 2006.
APPENDIX A

World Health Organization Organization Mondiale de la Sante

Project to Develop the International Patient Safety Event Classification

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