

**Towards a Common International Understanding of Patient
Safety Concepts and Terms: Taxonomy and Terminology
Related to Medical Errors and System Failures**

Report of a WHO Working Group Meeting

8–11 October 2003

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Department of Health Service Provision

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1. Introduction

A World Health Organization (WHO) Working Group on Patient Safety Taxonomy was held in Geneva, Switzerland on the 8th to 11th October 2003. Participants reflected a wide range of expertise in the development and use of nomenclature, classification, and incident reporting in patient safety (Annex 1).

Growing concerns among a number of countries about patient safety have led WHO to call for a concerted international effort to understand and prevent adverse events in health care. The 2002 World Health Assembly resolution, WHA55.R16, confirms this and requests the Director General to initiate and oversee the development of global norms and standards, among other areas, so as to facilitate collaboration in designing and implementing systems for patient safety. The development of a common international framework for classifying, measuring, and reporting adverse events and near misses is one of the principal technical components of WHO's global strategy to improve health care delivery systems, product safety (devices, drugs, biologics, and vaccines) and safety of services (medical decision-making, diagnosis, and laboratory analysis). This framework would serve as a basis for WHO support of initiatives to address medical errors and improve patient safety. An international patient safety taxonomy not only has the potential to facilitate global monitoring and reporting of adverse events and near misses, but can also contribute to the understanding of these incidents through better information on their prevalence, types, causes, severity, and consequences.

To date, there has been a lack of methodological uniformity among the various patient safety taxonomies. Although several health care-related international taxonomies exist (such as the International Classification of Diseases and the International Drug Monitoring in Uppsala, Sweden), there is no common international framework to define and classify patient safety. Consequently, this has stifled the collective understanding among countries to inform the development of strategies to reduce the risk of medical incidents and to ameliorate the devastating effects of health care errors. The studies and incident monitoring systems that report patient safety data, with a few exceptions, differ in the way they define, count, and track adverse events. Each source of information uses different schemas for coding and analyzing adverse events, making comparisons between schemas onerous. The lack of standardized nomenclature and taxonomy for patient safety events have confounded the development of appropriate and sustainable solutions to the many patient safety related problems, since the choice of terms or data to capture and analyze had implications for how these problems were addressed. In order to facilitate the global exchange and dissemination of information among users of incident reporting systems, it is necessary to adopt a common patient safety terminology and to collect standardized patient safety data that are conducive to processing and classification.

Thus, in view of this recognition of the current limitations and future potentials of patient safety reporting in global health development, WHO considered it timely to convene a working group meeting to discuss the findings of the consultant on patient safety taxonomy, exchange ideas on the development of a common international understanding of patient safety and related terms, and agree on a process for achieving desired outcomes. Participants felt that it was important that the end products of this initiative – an international common terminology and standard taxonomy for patient safety – reflect various systems in place across the globe.

The meeting took the form of guided discussions based on background papers and presentations, of which specific conclusions and recommendations were formulated. The background papers and proceedings of the meeting formed the basis of this report.

2. Objectives of the Meeting

The purpose of the working group meeting was to lay the groundwork for the development of an international patient safety taxonomy. The major expectations of the participants were to:

- discuss the need for a common understanding of terminology and methods used in patient safety work;
- share information on how countries and organizations define patient safety and related terms;
- exchange ideas on how countries and organizations classify adverse events and near misses; and
- provide recommendations for an integrated patient safety taxonomy.

In meeting the objectives, participants recommended a more thorough understanding of the current landscape of existing reporting systems and classification schemas, especially those that are relevant and applicable to WHO members countries. Before development work is commissioned, it was important to have an understanding of the current evidence supporting patient safety taxonomy. Discussions on the promises and shortfalls of previous taxonomies facilitated such understanding, and also shed light on the challenges presented by the growing terminology gap among systems. These insights in turn provided a baseline from which preliminary recommendations were conceived to guide the development work of the international patient safety taxonomy model.

As part of the ongoing work, WHO will seek to identify key stakeholders who would be invited to contribute to the taxonomy work. Participants of this working group were asked to provide recommendations on how to structure the operational framework and its development needs. They were also encouraged to define the project objectives and other task-specific issues. Because there are a number of reporting systems represented among the participants, it was necessary to be joined by a shared goal and to ecumenically work together towards a unified taxonomy. There will be no endorsement of any individual taxonomy by WHO.

3. Approach taken by the Working Group

3.1 Participants

Nineteen participants attended the working group meeting. Participants comprised of an interdisciplinary group of experts from countries and organizations who have worked on projects on taxonomy systems and or event reporting in different areas of medical safety. Specifically, attendees represented diverse professionals from the following groups:

- information management experts
- provider of health care services
- patient safety officers/managers
- researchers in patient safety and related fields

WHO staff and affiliates engaged in patient safety work were also invited to discuss their respective systems and approaches. The following individuals served as officials of the meeting:

Chairman: Mr. Clive Flashman

WHO Officer: Dr. Yunkap Kwankam

Rapporteurs: Dr. Jerod Loeb and Mr. Andrew Chang.

3.2 Background papers

The meeting was based on two background papers, prepared by Dr Jerod Loeb, PhD and Mr Andrew Chang, JD, MPH of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) under a contract with WHO, whose task was to review existing taxonomy systems and synthesize the approaches taken. The aims of the papers were to:

- 1) systematically review the current status of patient safety classification, describing its theoretical and methodological bases and indicating areas in which further development is required;
- 2) present an overview of the *leading* patient safety classification methods, with the interest of those who seek to develop and implement classification methods in mind; and
- 3) propose a preliminary assessment framework for WHO in considering the various kinds of patient safety nomenclature and classification for adverse events in health care, and an initial work plan for the development of a common international taxonomy for patient safety.

All attendees received the papers prior to the meeting with the expectation that they would review the papers prior to their arrival. One of the purposes of the meeting was to obtain feedback from the participants on the papers and to provide more details on the strengths and weaknesses of the approaches taken among existing taxonomies and the recommended framework to analyze patient safety classifications. The papers were not intended, however, to be an in-depth review of medical error classification or patient safety terminology. The objective was not to suggest which components of a classification instrument (whether existing or proposed) and definitions ought to be included or excluded in any particular taxonomy, until further consultation with WHO and other relevant stakeholders. Instead, the report and the companion draft manuscript entitled, “Towards an International Patient Safety Taxonomy: A Comparative Glossary of Patient Safety Terms”¹ have been prepared by JCAHO staff to assist this working group on patient safety taxonomy and health care leaders in structuring inquiries necessary for making decisions on salient attributes or features to adopt in the predevelopment phases of an international taxonomy on patient safety.

The background papers presented by JCAHO are available in electronic format through OSD (please address inquiries to Dr Yunkap Kwankam, Department of Health Service Provision, WHO, Geneva: kwankamy@who.int).

3.3 Exchange of ideas

JCAHO staff used the first half of day one of the meeting (the agenda is included as Annex 2) to provide the working group participants with an overview of the findings in the papers. Following the overview, participants were encouraged to discuss the topics presented and to provide their impressions of

¹ A comparative glossary of patient safety terms has been developed and submitted concurrently with this report. The terms and definitions in the glossary were obtained from a variety of sources (e.g., book glossaries, published journals), and are intended as a preliminary set for a more expansive dictionary of patient safety terms. It will be referred to herein as “the Glossary.”

the issues raised. On day two, participants were invited to present their work and experience of terminology and methods used in reporting systems. The meetings began with a summary of the previous day's discussions, including the suggestions made by participants for subsequent meetings. The working group engaged in an open exchange of ideas about the feasibility and desirability of a common approach on taxonomy for patient safety in the second half of day two and into day three. At the close of day three, participants voted on a number of key issues, future action items, and the proposed operational structure of the working groups. A mission statement of the work was also identified before the meeting adjourned.

4. Scope of Meeting

The first objective of the meeting was to discuss the various approaches used in countries to define and classify adverse event, near misses and other patient safety concepts. Although the key deliverable will involve the development of a common international understanding of taxonomy, and an internally adopted classification system with a cross-mapped dictionary of terms, a few participants were unclear whether the creation of a new system is warranted. Several potentially significant issues relevant to the proposed work (in development, implementation, evaluation, and integration) were discussed in the following areas, but not limited to:

- 1) Types of events – What types of events should be included in the taxonomy? How should events that impact patients, including those that exist outside hospital settings, be addressed?
- 2) Level of detail – Although sufficient detail is needed in the taxonomy to be of practical use, what is the appropriate balance between greater specificity (availability and granularity of data) and ease-of-use?
- 3) Definitions – Should this initiative adopt working definitions of adverse events and near misses (such as those found in the Glossary) or create new ones based on international consensus?
- 4) Uses – How would the taxonomy be used to facilitate data sharing among WHO member countries? Does the taxonomy create a reporting framework that imposes an undue burden on health care systems, especially those that have less sophisticated information technology capabilities?
- 5) Limitations – Could a single classification be applied to the full set of things that go wrong in health care? Is it realistic to envision a system of classification that could encompass all of patient safety? Could excessive classification stifle and or constraint thorough investigation of causal factors of adverse events?
- 6) Barriers and Obstacles – What are potential setbacks to accomplishing the objectives set out here?
- 7) Implementation – Who should promulgate and maintain the use of the taxonomy for learning among countries? Should it include follow-up actions to prevent future occurrences?

It was also suggested that the involvement of taxonomists and engineers with systems background might facilitate appropriate nomenclature and information technology assessments necessary for integrating existing reporting systems. Clinicians (nurses, physicians, allied health care professionals) should also be integral in guiding the work. These 'experts' could help identify a series of targeted

recommendations for WHO action, including strategies for successful testing and implementation of the taxonomy.

Determining a solution requires collaboration with relevant national and international bodies engaged in patient safety reporting. The second objective is to identify a set of specific aims for the taxonomy that is based on broad consensus in the patient safety community about what constitutes a global taxonomy. Recognizing that classification approaches differ greatly, the workgroup suggested the involvement of other key stakeholders to help span these differences. The goal is to develop, implement, and evaluate methods for adapting a taxonomy to these diverse systems. The key deliverables will be adoption of the taxonomy initially by select WHO member countries and a consensus-based blueprint for expansion to a global wide implementation.

5. Lessons learned from event reporting systems

In meeting the goals of the meeting, participants recommended that the workgroup be aware of major patient safety and other event reporting initiatives currently operating in countries and to incorporate the best practices from these initiatives. Existing models for event reporting from the health care sector (e.g., vaccine safety, medical device safety, transfusion reactions) could serve to inform a common understanding of patient safety concepts and terms. It is important to note that even though many systems are deemed to be complete and accurate, several of these systems are either under development, in the process of being phased out, or otherwise subject to change. All of these systems were started and have evolved for different purposes. They generally exist as separate silos with no bridges between them and few mechanisms for connecting findings across them. One of the benefits to integrating such information would be better understanding of the causes of adverse events.

In addition, many reporting systems that exist outside health care were considered relevant to this work. Contributions from aviation and high-technology/high-risk industries have also been instrumental in advancing the reporting, analysis and classification of adverse events in health care. Participants agreed that it would be beneficial to examine other taxonomies and quality approaches developed in different industries. For example, classification models derived from the aeronautical and chemical industries have been adopted by developers of patient safety reporting systems.

As stated, collaboration with developers and users of reporting system is vital to this work. Participants provided a brief overview of the following reporting systems:

- NPSA National Reporting and Learning System (NRLS)¹
- PRISMA
- Medication Error Reporting Program (MER)
- Medical Dictionary for Regulatory Activity (MedDRA™)^{2,3}
- Vaccine Safety Assessment (The Brighton Collaboration)^{4,5}
- Uppsala Monitoring Center (for adverse drug events)
- ECRI Medical Device Problem Reporting Database and Medical Device Safety Reports (MDSR)^{6,7}

- Advanced Incident Monitoring System (AIMS)
- Medical Device Regulation (Medicines and Healthcare Regulatory Agency – MHRA)
- JCAHO Sentinel Events Database⁸

5.1 Reporting and Classification Schemes

The various approaches used in the health care sector to define and classify near misses, adverse events, and other patient safety concepts have generally been fragmentary and uncertain. Efforts to define and classify patient safety events had insignificant impact, and were burdened by theoretical and methodological flaws.

Existing systems that were developed to meet the needs in multiple health care settings, such as those presented here by participants – have focused on more rigorous classification schemes and given greater consideration to related validity and reliability issues. However, the process and outcome “root causes” of adverse events in some of these systems were rarely described, and if they did, only described when a significant impact was recorded. The overall validity and reliability of these event reporting systems therefore remain open to challenge and may raise substantive questions about potential oversimplification of the anatomy of adverse events and misses. Also worthy of note, is the overwhelming majority of systems have been designed primarily for use in settings found in developed and industrialized countries.

This work must not neglect this systematic and broad-based approach to taxonomy in patient safety. The international taxonomy should exemplify a theory-driven analytic framework that integrates, functionally and technically, with incident reporting systems. It must focus on in-depth analysis and a search for multiple levels of causation and contributing factors, including the identification of active and latent failures. In addition, it is essential to develop a structured approach based on recognized models and frameworks of contributory and causative factors to draw out all of the relevant information about an incident and to describe patient safety phenomena in terms that can be analyzed statistically. For example, quantification of harm to patients as a result of an error is particularly important in developing countries, given the paucity of reliable data.

Several participants felt that a more rigorous system could present a steep learning curve for end-users. There was general agreement that the WHO taxonomy ought to be simple enough so that only limited training would be required. This point was substantiated by an example given in the frequent miscoding of diseases with ICD-9 by untrained personnel.

Finally, participants agreed on the need to address other related issues, such as protecting against security breaches to reporting systems, preventing future harm, and how best to address the informational needs of patients, families, caregivers, provider organizations and other entities such as research institutions.

6. Implications for integration

Potential implications of an international taxonomy must be better understood. Every system has a bona fide reason to exist. In some cases these reasons are directly related to patient safety whereas other systems would exist whether or not patient safety was a concern. Unanimity on classification systems will be difficult to resolve because of groups invested in promoting individual systems. The most efficient

approach is likely one that identifies those systems, that fulfill similar missions, and that examine integration options and possibilities for those sets of systems.

Participants were advised to focus on making reporting and classification a useful activity where data would be of unquestionable value to the entities collecting and analyzing data as well as accessible to users. Participants continually reiterated the need to produce a practical and easy-to-maintain taxonomy that would not go underutilized. It would almost certainly be more useful to combine various aspects of patient safety information for patients, clinicians, and health care organizations. However, this work should be accomplished with a minimal negative impact on current systems, which, in some cases, have developed elaborate processes to meet present reporting requirements. In order to promote acceptance or buy-in of the taxonomy from new and existing users of other systems, this work must demonstrate that the new tool has a comparative advantage, e.g., addresses more issues; more efficient; or permits international comparisons.

7. Level of detail

A successful data-driven patient safety program requires a common taxonomy with sufficient detail and scope to provide insight into specific events and situations to which this vast body of knowledge can be applied. The level of granularity appears to necessitate further discussion and refinement. A taxonomy should not be confused with a reporting system – the latter may capture only data pertinent to conventional practitioners but not errors that result from alternative therapies or traditional healers. It would of great interest in many countries, could pass unnoticed.

The potential applications for patient safety event information vary widely depending on the identity of the user – e.g., internal evaluations, oversight bodies; patient safety managers, patients, and public health officers, among others. In order to meet the needs of these diverse audiences it is essential to identify a common language that is widely applicable, simple, and straightforward. The vocabulary adopted for the taxonomy should closely resemble the language commonly used among various front-line care providers today, and avoids pejorative terms.

Classification of data elements below codified data fields will require the use of free text, at least until new terms and categories can be included, if needed. Narrative data (free text) add the benefits of storytelling⁹ to the advantages derived from capturing events-related data in code form – i.e., being able to aggregate and analyze the data more effectively and efficiently, without losing the nuances (and valuable nuggets of information) obtained from narratives. However, narrative data may be more difficult to consistently and objectively analyze. Conversely, codified data fields must have sufficient detail to be meaningful.

8. Definitions

The 2003 Institute of Medicine (IOM) report, *Patient Safety: Achieving a New Standard of Care*, recommends that better definitions on patient safety – including near misses and adverse events – is needed to inform the development of standardized data on medical incidents.¹⁰ However, current incident monitoring systems that report patient safety data differ in the way they define these events. Within each reporting system, there are often differences in definitions, which can make standardization across systems difficult. Given the considerable investment to design and implement a reporting system there is natural resistance from an organization to change its terminology and coding system (clinical terms and concepts can be coded by different systems using dissimilar coding schemes), regardless of the perceived benefits.

Shared concepts and standard definitions are, however, a necessary foundation for the field of patient safety. Because this work involves individuals with diverse cultural and linguistic backgrounds, common terms may share different definitions. While terms can have variable meanings in different languages, concepts are defined by the underlying idea. And since terminology is about concepts – not terms – definitions need to be constructed into a certain framework or system of concepts. Besides, concepts are more consistently understood and less subject to misinterpretation despite cultural and linguistic influences at which they are applied. The structure of a taxonomy is about concepts of safety – concepts that could define what is minimally needed to be “safe.” Conducting a survey to determine if concepts of safety differ across the world might be informative.

Since various factors influence opinions given by experts, it is important to utilize appropriate methods to obtain reliable consensus opinion on definitions from such experts. The Delphi approach to identifying key terms and data elements might be a viable solution to achieve international consensus.

Clearly, international acceptance and usability of the taxonomy must be ensured, both from a linguistic and technological perspective. The taxonomy must meet the requirements of easy, open, secure and seamless exchange of information among countries and organizations. Exchangeability of data (using complementary data standards such as HL-7, E2B, etc.) will ultimately determine the success or failure of the system. If the data remains in a “national information island,” it will not help to promote or enhance learning elsewhere. It will also be of little use if data obtained from research using this taxonomy are not comparable to the data acquired from participating member countries.

9. Uses

Presenting a unified and coherent structure for event reporting through a working taxonomy conveys the message that WHO will maintain a singular focus on the detection, capture, analysis and reporting of all aspects of medical events. Structuring patient safety information and sharing it in a structured way can support a deeper understanding of things that go wrong in health care, which could lead to implementation of positive actions. It provides an infrastructure that will support the development of specific modules to address emerging patient safety concerns, and facility-specific or regional interests.

Patient safety is a fundamental right of people who seek medical care and as such, there needs to be incentives, created by the taxonomy, to provide equitable access to critical patient safety information across the globe. At the same time, the taxonomy could serve as a ‘tipping point’ for developing countries that may lag behind to join the patient safety movement.

Although quite a bit is known about the uses of taxonomy and data capture, there is little or no information on how safety can be improved through its use. More research is needed to understand how it influences pathways to increase safety. Standardized definitions are also required to develop better quantitative and qualitative measures in patient safety.

10. Limitations

Taxonomy should not be expected to “fix” incident reporting. We may need multiple, discipline-sensitive taxonomies that map to a higher level of an overarching scheme. The variety of inputs and outputs should be identified early in the work, as together they will determine the complexity needed. Practicality is important but must be balanced with specificity. Desirable attributes also include prevention, detection and mitigation.

11. Barriers and obstacles

Despite the availability of a common taxonomy, many clinicians, policy-makers, and health care organizations may not readily accept the new system or relinquish their established systems, especially if the proposed taxonomy does not offer a clear comparative advantage.

Several participants acknowledged that existing classification systems are not practical for global use. However, they felt that unless the new taxonomy is available at little or no cost and designed to address country-specific issues it will not gain widespread acceptance and adoption. The same participants also noted that many countries have not implemented systems because of ownership (copyright) and royalty issues.

It is evident that some systems are orders of magnitude more sophisticated than other systems. Although this may seem problematic, it actually helps narrow the field of candidate systems. Clearly, the taxonomy cannot serve the needs of every user and such attempts to achieve otherwise impossible aims are not necessarily the path of greatest value. It should be a means to an end, not an end in itself, and its real value emerges from the use of consistent terminology as a basis for improving understanding of things that go wrong and identifying strategies to improve patient safety,

12. Implementation

Countries must be given the option to implement the taxonomy using a paper-based approach or by integrating it into a computerized/online system, depending on the availability of information technology resources.

A taxonomy based on a broad and flexible infrastructure requires ongoing support, maintenance and updating. To ensure ease of support and maintenance, a computerized approach was recommended. Responsibility for maintenance, support and updating will have to be clearly defined prior to its development.

13. Other Areas of Discussion

13.1 Conflict of interest

Conflict of interest was also seen as a major issue to be considered. While initiatives are growing, reporting on medical error is not without peril. One of many problems concerns the absence of global privacy protection for information assembled on medical errors, leaving many reporting systems exposed to legal and ethical concerns. Unresolved conflicts of interest have the potential to create disincentives that may discourage reporting by individuals and/or organizations. Many legal scholars in the US have recommended national legislation to protect medical error data and to encourage reporting and learning from adverse events. The extent of similar initiatives in other countries was not evident. This remains a contentious matter but it could be partly overcome by uncovering and disclosing the potential risks to would be reporters, and allowing them to weigh the cost-benefits of reporting. Issues such as user accountability and disclosure of reports could significantly influence the open adoption and acceptance of a new system.

13.2 Data sources

Many large – and as yet untapped – repositories exist; these data sources should be used as secondary sources for the proposed taxonomy. Mortality data, patient complaints and medico-legal proceedings are among the sources of adverse event data. However, these data may not be widely accessible or readily available to all interested parties. In particular, preparatory investigations will be necessary to ensure that efforts to collect and use such data are amenable to local privacy laws, since such laws may present a formidable barrier to the use of unpublished hospital data in the taxonomy.

14. Resolutions and Recommendations

14.1 Mission Statement

A preliminary mission statement was developed as an important first step to accurately explain why the project exists and what it hopes to achieve in the future. The mission statement is subject to revision pending further review by members of this consultation. As drafted, the mission of the project is:

“To propose 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 care-related harm”

14.2 Operational Structure

In order to fulfill the mission of this project, an operational structure, comprised of a steering committee, secretariat, and three workgroups (Figure 1), was created to provide oversight and ensure coordination of work among participants.

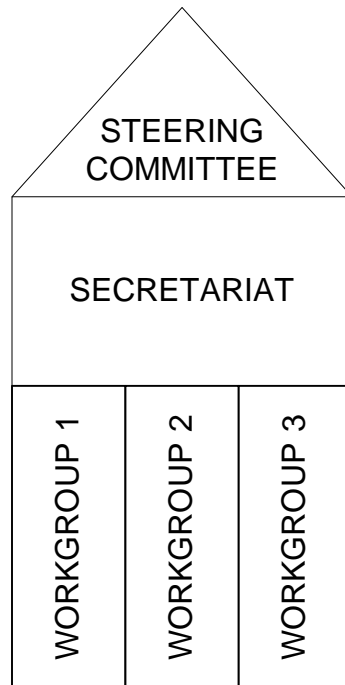


Figure 1. Proposed Operational Structure

14.2.1 Steering Committee

The Steering Committee will oversee the overall mission, set policies, determine the process, strategic goals and objectives, and monitor the growth of the project. This participation and decision-making ability will enable Committee members to own the process since they will have invested time and energy into it.

14.2.2 Secretariat

The Secretariat is expected to coordinate and manage the work of the project to meet its objectives. It may consist of a coordinator and/or a project manager. Depending on the workload, additional staff may be required in the Secretariat.

The coordinator and/or project manager and staff will develop and implement procedures and strategic plans. They will enable the Steering Committee to fulfill its function, and the workgroups to work together efficiently towards the achievement of the mission of the project, and its goals and objectives. The coordinator and/or project manager will be assigned by the Steering Committee and have the appropriate expertise and backgrounds.

14.2.3 Workgroups

Each of the three workgroups will be assigned a well-defined set of tasks. The tasks of the three workgroups are:

Group 1: Definitions, terms, concepts and requirements: Examine shared concepts and standard definitions are a necessary foundation for the field of patient safety classification.

Group 2: Fact-finding on existing taxonomies: Research and document those characteristics for each system identified (including non-medical taxonomies) and expand the set of classification systems already identified by JCAHO. A preliminary approach to analyze present and future classifications is discussed in the JCAHO report.

Group 3: Functional requirements, including outcomes: Identify the purpose for which the user intends to use the taxonomy.

14.2.4 Small group

Among the participants, a team of four members (Clive Fishman, NPSA; Jerod Loeb, JCAHO; Tjerk Van Der Schaaf, Eindhoven University; Tomas Perneger, Geneva University Hospitals) was picked and charged with the responsibility to review the US Institute of Medicine (IOM) Report, 'Patient Safety: Achieving a New Standard of Care,' and the draft mission statement. This team had an initial assignment to review the proposed operational structure, chart a plan of action to advance the development process of this initiative, and identify the membership of the workgroups and the tasks they should address.

There was a vote on the time frame within which the overarching taxonomy and the development of the modules should be completed. The participants thought it was expedient to begin the development of taxonomy and then with the glossary. Participants also agreed that it would be reasonable to expect the small group to report their deliberations around February 2004 and to begin the transition to the Steering Committee shortly thereafter.

Annex 1: List of Participants

1. Ms Cecilia Biriell
Head of Internal Affairs Uppsala Monitoring Centre
WHO Collaborating Centre for International Drug Monitoring
Stora Torget No. 3
75320 Uppsala , Sweden
Tel: +46 18 65 60 73
Fax: +46 18 65 60 80
E-mail: cecilia.biriell@.who-umc-org

2. Dr Jan Bonhoeffer
The Brighton Collaboration EUSAFEVAC Project
Universitäts-Kinderspital Beider Basel (UKBB)
Basel, Switzerland
Tel:
Fax: +4161685 6012

3. Mr Andrew Chang
Director, Center for Patient Safety Research
Division of Research
Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
One Renaissance Boulevard
Oakbrook Terrace, IL 60181, USA
Tel: +1630 792 5967
Fax: +1630 792 4967
[E-mail: anchang@jcaho.org](mailto:anchang@jcaho.org)

4. Mr Clive Flashman (Chair)
Information Management
National Patient Safety Agency 4, Maple Street
London W1T 5 HD, United Kingdom
Tel: +44 207 927 9544
Fax: +44 207 927 9501
[E-mail: helen.hughes@.npsa.nhs.uk](mailto:helen.hughes@.npsa.nhs.uk)

5. Ms Frances Griffin
Director of Patient Safety
Institute for Healthcare Improvement
1375 Longwood Ave., 4th floor
Boston, MA 02215, USA
Fax: +1732-869-0533
[E-mail: Griffin@ihi.org](mailto:Griffin@ihi.org)

6. Dr Jerod Loeb
Executive Vice President of Research
Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
One Renaissance Boulevard
Oakbrook Terrace, IL 60181, USA
Tel: +1630 792 5920
Fax: +1630 792 4920
[E-mail: jloeb@jcaho.org](mailto:jloeb@jcaho.org)
7. Dr Tomas Moraleda
International Medical Officer MedDRA. MSSO Cine,
43 - Esc 3 - 2D Madrid 28024, Spain
Tel & fax: +34 91 5187013
E-mail tmoraled@teline.es
8. Professor Thomas V. Perneger
Council of Europe Quality of Care Unit Geneva University Hospitals
1211 Geneva 14, Switzerland
Tel: +4122 372 9012
Fax: +4122 372 9016
[E-mail: thomas.perneger@hcuge.ch](mailto:thomas.perneger@hcuge.ch)
9. Professor Bill Runciman
Department of Anaesthesia
Royal Adelaide Hospital North Terrace,
Adelaide, South Australia 5000
Tel: +61 8 8222 5422
Fax: +61 8 83381207 or +61 8 8222 5887
E-mail: william.runciman@adelaide.edu.au
preferred e-mail: hsmith3@mail.rah.sa.gov.au; wunciman@bigpond.com
10. Mr Anthony Sant
Group Manager
Biosciences an Implants, and Adverse Incident Centre Medicines and Healthcare
products Regulatory Agency Room 906
Hannibal House
London SE1 6TQ United Kingdom
Tel: + 44 207 972 8288
Mobile: +44 786 753 7569
Fax: +44 207 972 8209
[E-mail: tony.sant@mhra.gsi.gov.uk](mailto:tony.sant@mhra.gsi.gov.uk)
11. Dr Tjerk W. van der Schaaf
Associate Professor of Human Factors in Risk Control Eindhoven Safety Management
Group Department of Technology Management Eindhoven University of Technology
Eindhoven, The Netherlands

Tel: +3140 247 4380/2493
Fax: +3140 243 7161
E-mail: T.W.v.d.schaaf@tm.tue.nl

12. Dr Elliot B. Sloane
Director of Research
Department of Decision and Information Technology
Villanova University - College of Commerce and Finance
3003 Bartley Hall
800 Lancaster Avenue
Villanova, PA 19085, USA
Tel: +1610 519-6432
Fax: +1610 519-5015
[E-mail: ebsloane@villanova.edu](mailto:ebsloane@villanova.edu)

WHO Regional Offices

13. Dr Bernard Lala
DSD/DLS
World Health Organization Regional Office for Africa PO Box N° 6
Brazzaville, Congo
Tel: + 242 83 91 00
Fax: +242 83 95 01
[E-mail: lalab@afro.who.int](mailto:lalab@afro.who.int)
14. Dr Ahmed Abdullatif
Regional Adviser Health Care Delivery
World Health Organization
Regional Office for the Eastern Mediterranean WHO Post Office
Abdul Razzak Al Sanhoury Street, opposite Children's Library
Nasr City, Cairo 11371, Egypt
Tel: +20 2 65350
Fax: +20 2 670 2492
[E-mail: ALATIFA@emro.who.int](mailto:ALATIFA@emro.who.int)
15. Dr Isuf Kalo
SCS/QHS
World Health Organization Regional Office for Europe 8, Scherfigsvej
DK- 2100 Kobenhavn 0
Denmark
Tel: +45 39 17 17 17
Fax: +45 39 17 18 18
[E-mail: IKA@who.dk](mailto:IKA@who.dk)
16. Dr T. Walia
Regional Adviser

Health Systems Development (HSD)
World Health Organization Regional Office for South-East Asia
World Health House Indraprastha Estate
Mahatma Gandhi Road
New Delhi-110002 India
Tel: +91 112
Fax: +91 112
[E-mail: waliat@whosea.org](mailto:waliat@whosea.org)

WHO Headquarters:

17. Ms. Pauline Philip
Public Health Officer
Health Facilities and Service Provision
Health Service Provision
Evidence and Information for Policy
World Health Organization HQ
Geneva, Switzerland
Tel: +41 22 13203
E-mail: philipp@who.int
18. Dr Yunkap Kwankam
Scientist
Health Facilities and Service Provision
Health Service Provision
Evidence and Information for Policy
World Health Organization HQ
Geneva, Switzerland
Tel: +41 22 12527
E-mail: kwankamy@who.int
19. Dr Ilja Borysenko
Technical Officer
Health Facilities and Service Provision
Health Service Provision
Evidence and Information for Policy
World Health Organization HQ
Geneva, Switzerland
Tel: +41 22 12581
E-mail: borysenkoi@who.int

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