

**WORLD HEALTH ORGANIZATION  
PATIENT SAFETY: REDUCTION OF ADVERSE EVENTS THROUGH  
COMMON UNDERSTANDING AND COMMON REPORTING TOOLS**

**TOWARDS AN INTERNATIONAL PATIENT SAFETY TAXONOMY:**

- 1) A REVIEW OF THE LITERATURE ON EXISTING  
CLASSIFICATION SCHEMES FOR ADVERSE EVENTS AND NEAR  
MISSES**
- 2) A DRAFT FRAMEWORK TO ANALYZE PATIENT SAFETY  
CLASSIFICATIONS**

*Assignment Report: Number 1 & 2, 30 June 2003*

*Prepared by*

*Jerod M. Loeb, PhD and Andrew Chang, JD, MPH  
Joint Commission on Accreditation of Healthcare Organizations  
WHO Short-term Consultants*

WHO Project Officer: S. Yunkap Kwankam, Ph.D.  
Scientist  
Department of Health Service Provision (OSD)  
World Health Organization  
Avenue Appia 20, CH-1211 Geneva 27  
Switzerland

## CONTENTS

<b>I. Executive Summary</b> .....	<b>2</b>
<b>II. Terms of Reference</b> .....	<b>3</b>
<b>III. Introduction</b> .....	<b>4</b>
<b>IV. Methods</b> .....	<b>6</b>
<b>1. Literature Search Strategy</b> .....	<b>6</b>
<b>2. Literature Search Results</b> .....	<b>7</b>
<b>V. Results</b> .....	<b>9</b>
<b>VI. Format for the Classification Summary</b> .....	<b>12</b>
<b>VII. Summary of Classifications</b> .....	<b>15</b>
<b>VIII. Conclusions Concerning Existing Patient Safety Classification Systems</b> .....	<b>31</b>
<b>IX. Framework to Analyze Patient Safety Classifications</b> .....	<b>32</b>
<b>X. Recommendations for an International Taxonomy on Patient Safety</b> .....	<b>34</b>
<b>XI. Appendix</b> .....	<b>38</b>
<b>XII. References</b> .....	<b>51</b>

## I. EXECUTIVE SUMMARY

Worldwide concerns about safety in patient care have stressed the need to coordinate the monitoring, reporting, and understanding of adverse events and “near misses.” Clearly, better information on the number, types, severity, causes and consequences of adverse events is needed in countries to inform the development of strategies to reduce the risk of medical incidents and to ameliorate the devastating effects of medical errors. However, 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 schemes for coding and analyzing adverse events, making comparisons between schemes onerous. Consequently, the lack of standardized nomenclature and universal taxonomy for medical errors can complicate (and stifle) the development of viable and sustainable solutions to the many patient safety related problems, since the choice of terms or data to capture and analyze has implications for how these problems are addressed. In order to facilitate the global exchange and dissemination of information among incident monitoring and reporting systems it is necessary to adopt common terminology and to classify the information in a way that is conducive to making comparisons among different studies and reports.

The aims of this report – in fulfillment of the main items for the *terms of reference* covered in the first part (June 9-30, 2003) of the current consultancy for the World Health Organization (WHO) – are 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 [item 1 in the terms of reference covered in this first period]; 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 [also item 1]; 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 [item 2]. An overarching goal is to try and persuade developers not to invent their own

unique classification schema until they have carefully reviewed the methods that are already available. The report is not intended, however, to be an in-depth review of the science of patient safety or medical error classification; citations are included for illustrative purposes primarily. The object is not to suggest which components of a classification instrument (whether existing or proposed) ought to be included or excluded in any particular taxonomy, until further consultation with WHO and other relevant stakeholders. Instead, this report and the companion draft manuscript entitled, “Towards an International Patient Safety Taxonomy: A Comparative Glossary of Patient Safety Terms”<sup>i</sup> [item 3] have been prepared by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to assist WHO’s working group on Patient Safety 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.

## **II. TERMS OF REFERENCE**

The following items of the first consultancy period are reported here.

- 1 A comprehensive review of the literature which identifies various approaches used in countries to define and classify adverse events, near misses and other patient safety concepts and terms.
- 2 A draft framework for assessing the strengths and weaknesses of various classification systems, to beneficially inform the process of arriving at an international taxonomy for patient safety.
- 3 A draft glossary of patient safety terms.

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<sup>i</sup> 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.”

### III. INTRODUCTION

In order to communicate, one needs a language. In patient safety, a language based on a common understanding of terminology and methods used in patient safety is of obvious importance for the purposes of developing strategies to improve global health care quality and disseminating timely, and targeted information designed to reduce the risk of medical incidents.<sup>1,2,3</sup> Standardization and uniformity in the collection and reporting of patient safety data necessary to support prevention planning by policy makers and stakeholders in general have been the focus of growing international attention in recent years.<sup>4,5,6</sup> There is also broad consensus among experts that a standardized taxonomy of health care errors and systems failures would promote improvement in error and systems failure monitoring, reporting, and analysis.<sup>7,8</sup>

It is well known that many studies have been conducted to independently establish the size and nature of the patient safety problem,<sup>9,10,11,12</sup> develop interventions to reduce errors,<sup>13,14</sup> and assess the effects of implementing approaches to reduce error at the level of a particular medical specialization or care setting<sup>15,16</sup> – with widely varying degrees of success. But much less is known about the initiatives and studies that support the generation of standardized patient safety data, which is a critical missing element that has hindered the ability to collect, analyze, report and disseminate patient safety data in a consistent fashion. There remains a need for a simple, but comprehensive, taxonomic framework for integrating the findings from disparate incident reports in various domains and for guiding the improvement process towards the common goals of any incident monitoring and reporting system.<sup>17</sup> Our best chance at understanding health care errors globally and identifying potential interventions that are useable across countries is a universal classification system for epidemiological analysis with concepts at the level of public health.<sup>18</sup>

A fairly large number of studies and initiatives undertaken by many fields of medicine and various segments of both the public and private sectors have developed their own nomenclature and classification systems during the process of designing

and implementing incident monitoring and reporting.<sup>19,20,21</sup> For each type of adverse event system, there are often several different, independently developed nomenclature and classification systems (clinical outcomes can be coded by different adverse events systems using different coding schemes<sup>ii</sup>). Each nomenclature has unique characteristics and usage, which make standardization nearly impossible, given the considerable investment to implement and apply a coding system and the resistance to changing an embedded classification system regardless of the potential benefits.

As delineated in the Glossary, patient safety nomenclature, like all language, starts with a basic set of words or terms that have a specific meaning. A term stands for some defined patient safety concept like error, iatrogenic injury or preventable adverse event. To permit flexibility, most studies allow the same patient safety concepts to be named in several different ways.<sup>22</sup> Although several terms can be used for the same concept in different studies, it is imperative in classification to define a single definition or code for every term. A number of different terms may be grouped together. The process of ascribing terms, encoding them, and then grouping them may seem complex, potentially inefficient, and to some extent ad hoc. However, the validity of a classification system depends on how carefully this process has been performed. Making sure the system is valid for the purpose to which it is being put is very important. In fact, the utility of incident monitoring and reporting systems relies heavily on how data are coded and analyzed.<sup>23,24</sup>

Clearly, there are many possible ways to classify health care errors and systems failures – however, it must be noted that medical error and adverse event classification systems are not themselves free of problems. Thus, before new development is commissioned it is important to have an understanding of the current evidence supporting patient safety classification. A systematic review of the literature on patient safety to identify the promises and shortfalls of previous classification can

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<sup>ii</sup> *Coding* is where a set of words describing some patient safety concept is translated into a single alphanumeric grouping for later analysis. Patient safety needs to contain a separate name for each distinct incident, and include any reasonable synonyms. A coding system should collect many such terms into a single code.

facilitate such understanding, and also sheds light on the challenges presented by the growing patient safety data gap. These findings in turn will provide a baseline from which recommendations can be drawn for the development of a preliminary international patient safety taxonomy model.

## **IV. METHODS**

### **1. Literature Search Strategy**

A comprehensive literature search was done in Medline (PubMed) and Excerpta Medica (Embase). The databases were searched for articles addressing classification in patient safety and incident reporting with publication dates between January 1993 and June 2003. In addition to database searches, the Internet sites of Departments, Ministries of Health and Patient Safety Organizations and Groups in Africa, Asia, Australia, Europe, and North America were searched. The reference lists of major reports were also scanned for relevant publications that date from the 1980s.

A comprehensive search strategy based on the Medline approach was used to retrieve literature that addresses various approaches used in countries to define medical errors, adverse events, near misses and other patient safety concepts and terms, including existing classification schemes on patient safety. A variety of available “mesh” terms relating to patient safety and classification and a combination of free text terms were used. The searches were not limited to articles published in the English language or within a particular geographical area. Details of the search strategies are given below.

#### Medline (PubMed)

- 1) Publication date was limited to 1993 through 2003 for all searches
- 2) Medical errors/classification [mesh]
- 3) Medical errors [mesh] AND classification [mesh]
- 4) Medical errors [mesh] AND nomenclature [mesh]
- 5) Medical errors [mesh] AND glossary [ti,ab]
- 6) #2 OR #3 OR #4 OR #5
- 7) Medication errors/classification [mesh]
- 8) Medication errors [mesh] AND classification [mesh]
- 9) Medication errors [mesh] AND nomenclature [mesh]
- 10) Medication errors [mesh] AND glossary [ti,ab]

- 11) #7 OR #8 OR #9 OR #10
- 12) Patient safety [ti,ab] AND classification [mesh]
- 13) Patient safety [ti,ab] AND nomenclature [mesh]
- 14) Patient safety [ti,ab] AND glossary [ti,ab]
- 15) #12 OR #13 OR #14
- 16) Accidents/classification [mesh]
- 17) Accidents [mesh] AND classification [mesh]
- 18) Accidents [mesh] AND nomenclature [mesh]
- 19) Accidents [mesh] AND glossary [ti,ab]
- 20) #16 OR #17 OR #18 OR #19
- 21) Safety/classification [mesh]
- 22) Safety [mesh] AND classification [mesh]
- 23) Safety [mesh] AND nomenclature [mesh]
- 24) Safety [mesh] AND glossary [ti,ab]
- 25) #21 OR #22 OR #23 OR #24
- 26) #6 OR #11 OR #15 OR #20 OR #25

#### Excerpta Medica (Embase)

- 1) Patient safety [ti,ab]
- 2) Medical error? [ti,ab]
- 3) Medication error? [ti,ab]
- 4) Classification [de]
- 5) #1 OR #2 OR #3
- 6) #4 AND #5

The initial yield of items was restricted to a topical set, including only articles concerned with medical errors, medication errors, patient safety, accidents and safety. The following keywords were used to generate a cross listing of articles: classification, nomenclature, and glossary. The two search yields were cross-referenced.

## **2. Literature Search Results**

A total of 512 distinct references were identified from the Medline search. The Embase search resulted in 15 additional unique references. The titles and/or abstracts of these articles were initially scanned, and inclusion/exclusion decisions made. Based on the review of the abstracts, we eliminated 429 articles on the following criteria:

- Not relevant to the field of patient safety/medical error/adverse event classification (e.g., studies investigating issues unrelated to iatrogenic causes)

of injuries or death, such as non-error, adverse reactions to medications (drug adverse events), and unintentional (accidental) injuries or death).

- Relevant to the field of patient safety/medical error/adverse event classification but did not provide adequate description of the components needed to define a coherent classification scheme.
- Classifications that are in the early stages of development, since any description would rapidly become outdated.
- Unpublished classifications. The very few exceptions to this are classifications that hold particular conceptual or methodological interest in the development of the field.
- Methodological concerns.

Of the 96 full articles that were reviewed, 73 were eliminated according to the above criteria. Eleven formal classification schemes identified in the remaining 23 articles that address the frequencies, types, causes and contributing factors, consequences, and prevention of medical/medication errors are summarized here.

This literature review and synthesis may have missed some studies that merited inclusion. Prospective studies of design and/or implementation of incident monitoring/reporting systems (though limited to a few countries that are heavily engaged in national patient safety efforts – Australia, Denmark, France, Hong Kong, New Zealand, Netherlands, Norway, Sweden, United Kingdom, United States) are too numerous to mention in this report and since they do not directly address the purpose of this review, they were excluded. Moreover, the studies on existing incident monitoring and reporting systems have already been well-documented elsewhere.<sup>25,26</sup>

We have been selective in the classifications we present – despite the paucity of information – because there is little benefit in reviewing a mediocre method when a superior one is available. Naturally, a different selection could have been made if there were better choices, but the areas of disagreement would apply mainly to the less rigorous methods of classification. The classification instruments summarized in

this report represent the current state of this field and whose inclusion cannot reasonably be disputed.

## V. RESULTS

Information on various approaches used in countries to define and classify adverse events, near misses and other patient safety concepts has generally been fragmentary,<sup>27,28</sup> There are a number of methods of classification available in patient safety, but they tend to be, with some notable exceptions, underdeveloped and mostly concentrated in the field of medication errors,<sup>29,30,31</sup> and more generally in the realms of primary care/specialty care<sup>32,33,34,35</sup> and nursing care.<sup>36,37</sup> Early efforts to classify “error” or “mistakes” showed insignificant impact, and were flawed by theoretical and methodological shortfalls. A model of medical error was largely unspecified, if not absent. Where classification instruments were described, their validity was below standard, and their reliability not reported upon. Most classification systems of medical errors and preventable adverse events do not provide sufficient detail to allow analysis and comparisons of these problems. A systematic review of the classification schemes in primary care by Elder and Dovey,<sup>38</sup> found a limited number of studies that attempted to categorize medical errors, near misses and adverse events.<sup>39,40,41,42,43,44</sup> Most of these studies were not designed with the development of a functional classification scheme in mind; thus they did offer a conceptual explanation of what they classify or to the value judgments they incorporate.

Busse and Wright proposed a more promising classification methodology and an enhanced evaluation approach for the Edinburgh Incident Classification.<sup>45</sup> Focusing on in-depth analysis and a search for multiple levels of causation and contributing factors, including the identification of active and latent failures, this classification model exemplifies a theory-driven categorization and analysis framework that integrates functionally and technically with a corresponding incident reporting scheme. This systematic approach to classification in patient safety did not become the de facto standard for quite sometime, and is still often neglected. In fact, the classificatory framework and theoretical and technical foundation for in-depth

analysis and root causes of adverse events did not materialize until shortly after the publication of the seminal works by Reason,<sup>46</sup> Rasmussen,<sup>47</sup> and Hale<sup>48</sup> on classification of error types. Contributions from aviation<sup>49</sup> and high-technology/high-risk industries have also been instrumental in advancing the reporting, analysis and classification of adverse events in health care.

In comparison to the early efforts, a few studies of recent vintage (such as those reported by Makeham,<sup>3</sup> Battles,<sup>45</sup> Victoroff<sup>50</sup>) focused on more rigorous classification schemes and an increased consideration of related validity and reliability issues. In these classifications, however, the “root causes” of the process and outcome of adverse events were only described where a significant impact was recorded, which may not reveal gaps and inadequacies in the health care system.<sup>51</sup> The overall validity and reliability of these classification schemes therefore remain open to challenge, with questions about the oversimplification of the causes of an adverse event. Furthermore, there is no conclusive evidence (and no published studies) on the effectiveness of preventive and corrective strategies that may have been derived from analysis using these classification schemes.

For a classification system to be truly effective, the data collected and analyzed must be used to inform the development of strategies for reducing the occurrence of adverse events or minimizing the harm when they occur. Two studies reported the development and evaluation of strategies this way, but contained no information on the impact of the system.<sup>52,53</sup> One of the studies by Brixey et al. evaluated a taxonomy of medication errors developed by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) – which spawned from the Medication Error Reporting (MER) Program – and found it was limited in its ability to map information from a national medication monitoring system.

In the development stages of an incident monitoring system, classification has been used in a heuristic approach designed to identify the required data elements needed to prospectively measure errors and adverse events.<sup>54</sup> Apart from error-reporting systems, classifications are commonly employed in other error measurement methods such as

