

**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**

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## 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

administrative data analysis, chart review, electronic medical record, observation of patient care, and clinical surveillance<sup>55</sup> to validate patient safety data that have complex interwoven relationships between latent errors (systems failures) and active errors. Combining data from different measurement methods using a common taxonomy has been used successfully by epidemiologists to detect nosocomial infections,<sup>56</sup> and may be useful in detecting trends and patterns in patient safety. In a number of studies, there seems to be a gradual effort to foster a science of patient safety measurement, equivalent to health measurement or psychometrics. This is important, as decisions affecting the welfare of patient and the expenditure of public funds are based on the results of patient safety measurements;<sup>57</sup> and pressure to monitor the patient safety outcomes of treatment is virtually universal.

The Generic Reference Model, a classification process conceived and used by Runciman and colleagues,<sup>58</sup> provides a structured approach to drawing out all the relevant information about an incident. With 80 categories and more than 12,000 subcategories, the classification system (the Generic Occurrence Classification), which is based on Reason's model and framework of contributory factors, can describe patient safety phenomena in terms that can be analyzed statistically.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Patient Safety Taxonomy integrates multiple, interacting classification schemes for health care errors and systems failures, and is capable of ordering complex information in a logical and reproducible fashion.<sup>59,60,61</sup> One of the unique features of the JCAHO taxonomy is that it can potentially serve as the common, back-end architecture when mapped and classified to the different front-end typologies of various patient safety data reporting systems with competing classification systems – allowing aggregated data to be combined and tracked over time, maintaining consistency across safety reporting systems, and controlling the documentation by providing consistent formatting and presentation of data that can lead to improved safety. Coded categories of adverse events of two classification systems have demonstrated acceptable comparability with incident monitoring data.<sup>62,63</sup>

Apart from the issue of how many relevant categories might be considered to be the optimum classification scheme, there will probably always be a debate over how best to classify medical errors and adverse events,<sup>64</sup> and one reason for the debate lies in the complexity and abstract nature of patient safety itself. Using a modified-Delphi process to differentiate between specific classes of medical error common to emergency medicine practice, Hobgood et al. found that cognitive errors in medical decision-making can be difficult to identify and suggested that consensus on error classification may be challenging.<sup>65</sup>

## VI. FORMAT FOR THE CLASSIFICATION SUMMARIES

Structured summaries for select classifications have been prepared and the main methods and discussions pertinent to each classification are summarized in Section VII. The underlying concepts of each included classification have been reported, although in a few cases elucidating a classification framework – when the primary aim of a study was other than to develop a classification system – was difficult as very limited information was presented in these articles. A preliminary approach to analyze present and future classifications is then discussed following the summaries.

A standard format is followed in reviewing and summarizing each classification.<sup>iii</sup>

**Title** – The title of each classification is that given by the original developer of the schema.

**Developer** – The attribution of each classification to a developer and the developer's affiliation is primarily for convenience; recognizing that most methods are developed by team effort. In certain cases additional developers are cited where they have had a continuing involvement in the development of the classification.

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<sup>iii</sup> It is essential that the reviews of each classification be checked for accuracy and completeness by the person(s) who originally developed the method, or by an acknowledged expert, to ensure that we are providing an authoritative description of each classification. In order to gain a full and accurate understanding of the existing classifications, this review process is recommended in the second part of the current consultancy.

**Year** – This is the year the classification was first published, followed by that of any major revisions.

**Country of origin** – The country where the classification was developed or last underwent a substantial change or modification.

**Purpose** – The purpose of the classification is summarized in our own words and based as far as possible on words used by the developer. We have indicated how they were used and the types of users the classification is intended for where this was stated. All too frequently the precise purpose of a classification is not made clear by its developer. Occasionally it is restated differently in different publications and we have tried to resolve such inconsistencies.

**Definition** – Where specified by the developer, this indicates the definition(s) of patient safety, medical error, systems failure and other key terms, which provide the basis for the conceptual framework in each classification scheme.

**Description** – The description indicates the important components of each classification model. We developed and used a grouping system – that allows for categorizing disparate classification models – to abstract, organize, and summarize the relevant aspects of each classification, and to present essential information in a consistent manner. Where relevant, one or more of five groups or dimensions provide the bases for describing a classification scheme. These are:

- **Impact** – categorization on the outcomes or effects of health care error or systems failure to the recipient of care, (details of the nature of the disease, injury, suffering, disability, and harm), including the economic, legal and social consequences for the health care organization, provider, and patient.
- **Type** – categorization on the perceptible, outward, or visible processes that were in error or a failure, how the incident happened, what factors lead to the outcome and consequences of the incident.
- **Domain** – categorization on where, when, and to whom a health care error or systems failure occurred, and the type of provider involved.

- **Cause** – categorization on why a health care error or systems failure happened (root causes).
- **Prevention and Mitigation** – categorization of what action was taken or proposed to reduce the occurrence of, or to ameliorate the outcomes and consequences of adverse events.

**Exhibits** – Within the Description section, we illustrate the classification scheme or categories. Occasionally, where space or unavailable information does not permit to show an entire classification system, we include sections of it and indicate where the complete version may be obtained.

**Limitations** – Where appropriate, we summarize the limitations of the classification method and outline how it compares to others with a similar focus. A more detailed analysis of the various classifications using the evaluation framework proposed in Section IX will be conducted in the second part of the current consultancy to identify strengths and weaknesses. This is intended to guide the selection of desirable attributes and/or specifications applicable to the international patient safety taxonomy, and to suggest where further developmental work may be carried.

## VII. SUMMARY OF CLASSIFICATIONS

### 1. Edinburgh Incident Classification<sup>66,67</sup> (Intensive Care Unit, Western General Hospital, Edinburgh) (1989) (United Kingdom)

**Purpose** – The Edinburgh Incident Classification (EIC) was developed to analyze and classify anesthetic mishap data collected from an incident reporting system in an Edinburgh adult intensive care unit. This reporting scheme has been used to collect data about “critical incidents” attributable to human error and equipment related failures.

**Definition** – A “critical incident” is defined by EIC as an occurrence that might have led (if not discovered in time), or did lead, to an undesirable outcome.

**Description** – The original EIC comprises 23 categories of contributing factors to critical incidents, and is grouped according to: 1) performance shaping factors (PSF), which affect task performance and produce erroneous behavior that, in turn, might lead to an incident, and 2) domain, environment, and task-specific factors, as shown in Exhibit 1.1.

**Exhibit 1.1** Edinburgh Classification of Contributing Factors (to ICU critical incidents).

#### Performance Shaping Factors

1. Inexperience with equipment
2. Shortage of trained staff
3. Night time
4. Fatigue
5. Poor equipment design
6. Unit busy
7. Agency nurse
8. Lack of suitable equipment
9. Failure to check equipment
10. Failure to perform hourly check
11. Poor communication
12. Thoughtlessness

**Domain, Environment, and Task-Specific Factors**

1. Presence of students/teaching
2. Too many people present
3. Poor visibility/position of equipment
4. Grossly obese patient
5. Turning the patient
6. Patient inadequately sedated
7. Lines not properly sutured into place
8. Intracranial Pressure Monitor not properly secured
9. Endotracheal tube not properly secured
10. Chest drain tube not properly secured
11. Nasogastric tube not properly secured

**Type, Cause:** The original EIC does not indicate the primary contributing factors, or which factors are considered proximal or distal causal factors. The classification of contributing factors has subsequently been re-classified according to Reason's accident causation and analysis model,<sup>68</sup> to address multiple levels of causation, including latent and work condition failures (distal causal factors) and active failures (proximal causal factors). There are shown in Exhibit 1.2.

**Exhibit 1.2. Failure Type Categorization of the Edinburgh Incident Classification**

**Failure Type Categorization**

**Proximal Causal Factors**

1. Failure to check equipment
2. Failure to perform hourly check
3. Thoughtlessness
4. Turning the patient
5. Patient inadequately sedated
6. Lines not properly sutured
7. ICP monitor not properly secured
8. Endotracheal tube not properly secured
9. Chest drain tube not properly secured
10. Nasogastric tube not properly secured

**Distal Causal Factors**

1. Inexperience with equipment
2. Shortage of trained staff
3. Night time

4. Fatigue
5. Poor equipment design
6. Unit busy
7. Agency nurse
8. Lack of suitable equipment
9. Presence of students/teaching
10. Too many people present
11. Poor visibility of equipment
12. Poor communication

**Limitations** – The EIC categories can provide the basis for descriptive statistics on reported incidents, but they do not facilitate the in-depth analysis of the underlying causes of incidents, since only a superficial descriptive account of the incident is given. Another limitation of the Edinburgh classification is it does not take into consideration the combined effects of multiple contributing factors, which when analyzed in relation to one another, may evince a richer data set. A single-factor classification neglects the multiple facets of human and systems failure and therefore may shed a misleading light on the aggregated incident data.

**2. Taxonomy for Error Reporting, Root Cause Analysis and Analysis of Practice Responsibility (TERCAP)<sup>69,70</sup>** (Patricia Benner, PhD, RN, FAAN, University of California, San Francisco, School of Nursing, Box 0612. San Francisco, CA 94143) (2002) (USA)

**Purpose** – TERCAP was originally developed as a systematic error-reporting tool to analyze and compare nursing errors and disciplinary actions taken across states in America. The TERCAP Instrument – The TERCAP Error Audit Tool – has been used as a proactive reporting system to promote improvement both at the individual level, and at the levels of educational and healthcare delivery and regulatory organizations. By analyzing nursing errors reported to the State Boards of Nursing, TERCAP can be used to develop strategies for error prevention in practice settings and for nursing education.

**Definition** – Healthcare errors are defined here as a “mistake, inadvertent occurrence, or unintended event in health care delivery which may, or may not, result in patient injury.”<sup>71</sup>

**Description** – TERCAP is an error taxonomy and survey instrument that classifies nursing errors, their causes, patient outcomes, and disciplinary actions. **Impact:** The medication errors discovered and categories of patient harm are captured in TERCAP using the NCC MERP Medication Errors Taxonomy. **Type:** It covers nursing errors representing a broad range of possible errors and contributive or causative factors in eight categories: 1) lack of attentiveness; 2) lack of agency/fiduciary concern; 3) inappropriate judgment; 4) medication errors, 5) lack of intervention on the patient’s behalf; 6) lack of prevention, 7) missed or mistaken physician/healthcare provider’s orders; and 8) documentation errors. Within each category there are between one and eight subcategories, each of which is in turn divided into broader categories that are coded, including an “other” category for free-text entry (c.f. Appendix A). **Domain:** Nurses who monitor and manage the quality of health care delivered in hospitals, outpatient departments, long-term care facilities, and other relevant nursing practice settings have a role to detect and intervene in practice breakdown to reduce adverse events for patients. **Cause:** In each of the categories listed above, the causes of errors at the individual and practice responsibility level could be identified. Also included in the TERCAP Instrument are the following categories of blunt-end factors (system issues) that contribute to the nurse’s practice breakdown: environmental factors; communication factors; employee safety/support factors; leadership/management factors; backup and support factors; and other factors. **Prevention & Mitigation:** TERCAP was designed to identify errors in such a way that the multiple causes of the error could be deduced from the way the error was defined. Events with similar patient outcomes but different causes for the error could be tied to a category to capture causes that could be tied to remediation or prevention.

**Limitations** – This taxonomy provides an interpretive guide for analyzing and reporting nursing errors, and can facilitate communication about types of adverse events and preventive efforts but it does not adhere to a common patient safety

terminology that conforms to the best available scientific evidence. It offers a brief classification suitable for education and system (organization) redesign when the goal is to improve individual and professional practice responsibility among nurses, rather than to provide a detailed assessment of the nature of adverse events that occur in nursing practice. While no information on validity is yet available, the method seems potentially suitable as a classification module (on nursing errors) in a more comprehensive error taxonomy. If the taxonomy is to gain acceptance, it will have to be compared with other similar classifications and be tested for feasibility across multiple settings (i.e., inpatient, outpatient).

**3. International Taxonomy for Errors in General Practice<sup>72</sup>** (Meredith AB Makeham, BMed (Hons), Department of General Practice, University of Sydney, Sydney, NSW. (2002) (Australia)

**Purpose** – This taxonomy was designed to classify the types of errors that occur in general practice and could be applied in multiple countries with similar primary health care standards.

**Definition** – Adopting the definition of “medical errors” promulgated by a study at the American Academy of Family Physicians,<sup>73</sup> this taxonomy defines errors as “events in your practice that make you conclude: ‘that was a threat to patient well-being and should not happen. I don’t want it to happen again’. Such an event affects or could affect the quality of the care you give your patients. Errors may be large or small, administrative or clinical, or actions taken or not taken. Errors may or may not have discernable effects. Errors in this study are anything that you identify as something wrong, to be avoided in the future.”

**Description** – This taxonomy was initially based on a preliminary taxonomy designed in the United States (c.f. Taxonomy of Medical Errors in Family Practice) but was further developed and refined in a pilot study to capture a broader range of error types reported from Australia, Canada, the Netherlands, New Zealand and the

United Kingdom. The taxonomy has a five-level classification system comprising of 171 error types. At the highest level, errors are classified according to two primary groups: 1) process errors; and 2) knowledge and skills errors, as shown in Exhibit 3. In the pilot study, the ratio of process errors to errors in knowledge and skills involved in general practice was approximately 4:1.

**Exhibit 3.** The first three levels of the five-level International Taxonomy for Errors in General Practice.

## **1. Process Errors**

### **1.1. Errors in office administration**

- 1.1.1. Filing system errors
- 1.1.2. Chart completeness errors
- 1.1.3. Patient flow (through the health care system)
- 1.1.4. Message handling errors
- 1.1.5. Appointment errors
- 1.1.6. Errors in maintenance of a safe physical environment

### **1.2. Investigation errors**

- 1.2.1. Laboratory errors
- 1.2.2. Diagnostic imaging errors
- 1.2.3. Errors in the processes of other investigations

### **1.3. Treatment errors**

- 1.3.1. Medication errors
- 1.3.2. Errors in other treatments

### **1.4. Communication errors**

- 1.4.1. Errors in communication with patients
- 1.4.2. Errors in communication with other health care professional (non-medical)
- 1.4.3. Errors in communication with other doctors
- 1.4.4. Errors in communication amongst the whole health care team

### **1.5. Payment errors**

- 1.5.1. Errors in processing insurance claims
- 1.5.2. Errors in electronic payments
- 1.5.3. Wrongly charged for care not received

### **1.6. Errors on health care workforce management**

- 1.6.1. Absent staff not covered
- 1.6.2. Dysfunctional referral procedures
- 1.6.3. Errors in appointing after-hours workforce

## **2. Knowledge and Skills Errors**

### **2.1. Error in the execution of a clinical task**

- 2.1.1. Non-clinical staff made the wrong clinical decision
- 2.1.2. Failed to follow standard practice

- 2.1.3. Lacked needed experience or expertise in a clinical task
- 2.2. Errors in diagnosis
  - 2.2.1. Error in diagnosis by a nurse
  - 2.2.2. Delay in diagnosis
  - 2.2.3. Wrong or delayed diagnosis attributable to misinterpretation of investigations
  - 2.2.4. Wrong or delayed diagnosis attributable to misinterpretation of examination
  - 2.2.5. Wrong diagnosis by a pharmacist
  - 2.2.6. Wrong diagnosis by a hospital-based doctor
- 2.3. Wrong treatment decision with right diagnosis
  - 2.3.1. Wrong treatment decision, influenced by patient preferences
  - 2.3.2. Wrong treatment decision by doctor

**4. NCC MERP Taxonomy of Medication Error<sup>74</sup>** (National Coordinating Council for Medication Error Reporting and Prevention, c/o USP, 12601 Twinbrook Parkway, Rockville, MD 20852) (1998) (USA)

**Purpose** –The NCC MERP Taxonomy of Medication Error provides a standard language and structure of medication-error related data that address these events, and can be used to record, track, analyze, and benchmark medication error data in a standardized format for U.S. hospitals,<sup>75</sup> and has been adopted by the U.S. Pharmacopeia (USP) and U.S. Food Drug and Administration (FDA). provide a nationally projected measure of errors grouped according to categories established by the NCC MERP.

**Definition** – NCC MERP defines medication error as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.”

**Description** – The NCC MERP Taxonomy of Medication Errors is organized into eight major categories: 1) patient information, 2) medication error event, 3) patient outcome, 4) product information, 5) personnel involved, 6) type of medication error, 7) causes, 8) contributing factors (c.f. Appendix B). Each category has numerous attributes to be selected or completed about the error. In Category 1, patient demographic information is requested. Category 2 is concerned with the specifics of the medication error event. The description of the event is a free text entry field. Category 3 requests information about the patient’s outcome. Information about the product that was actually or potentially given is classified in Category 4. The personnel involved in the error are classified under Category 5. In this category, information about who made the initial error is identified as well as who perpetuated the error. In Category 6, the type of medication error is categorized by such occurrences as dose omission, improper dose, and wrong route of administration, wrong rate, and monitoring. Category 7 identifies communication, name confusion, labeling, and human factors that contributed to the error. Category 8 focuses on the contributing factors to errors.

**Limitations:** The NCC MERP taxonomy is comprehensive and it is good for certain data collection and archiving purposes. However, it is not based on a systematic approach, a theory of errors, or an approach that can categorize errors not only for archiving and statistics but also for generating interventions of error reduction. One good feature of NCC MERP is its explicit inclusion of human factors. However, its treatment and presentation of human factors – one of the most fundamental causes of medical errors – are far from sufficient. A systematic treatment of human factors is essential for a useful taxonomy that has values for interventions. The NCC MERP taxonomy is also limited in coding specific details of medical device errors.

**5. Taxonomy of Medical Errors in Family Practice**<sup>76</sup> (Susan M. Dovey, MPH, PhD The Robert Graham Center, Policy studies in Family Practice and Primary Care, American Academy of Family Physicians, 2023 Massachusetts Ave NW, Washington, DC 20036) (2002) (USA).

**Purpose** – This preliminary taxonomy was designed to organize error reports made by family physicians in both inpatient and outpatient settings and in the transition between care settings. It provides a tool for understanding opportunities to improve patient care and suggests priority areas for remedial attention.

**Definitions** – In this taxonomy, “safety” is defined according to the US Institute of Medicine’s definition as freedom from accidental injury. “Error” is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

**Description** – The taxonomy comprises two primary categories which distinguish between errors attributable to aspects of care delivery systems (process errors) and errors that could only be averted by improving providers’ clinical skills and/or knowledge or diverting clinical tasks to clinically trained providers (knowledge and skills errors). The “process errors” category contains 34 items in five broad subcategories: office administration; investigations; treatments; communication; payment; and the “knowledge and skills errors” category has three subcategories: execution of a clinical task; misdiagnosis; wrong treatment decision (c.f. Appendix C).

**Limitations** – This medical error taxonomy may be limited in its scope since it was developed from self-reports of errors observed by family physicians during their routine clinical practice. However, this approach allowed the taxonomy to be derived from “real world” data relevant to family practice and not from prior knowledge of other characterizations of medical error. The single error classification code assigned to each adverse event using the first error in the chronology of the event neglects the multifaceted nature of medical errors and may shed a misleading light on the collected incident data.

**6. Classification of medical errors and preventable adverse events in primary care** (Nancy C. Elder, MD, MSPH, Cincinnati, Ohio) (2002) (USA)

**Purpose** – This classification was designed to assist family physicians and other primary care researchers in understanding how process errors and preventable adverse events happen during the practice of primary care.

**Definition** – none

**Description** – This classification categorizes adverse event and near miss data from primary care practice. **Type:** It defines the three main categories of preventable adverse events related by primary care physicians: diagnosis, treatment, and preventive errors, which are presented in a hierarchical order as shown in Exhibit 6.1.

**Exhibit 6.1.** Classification of preventable adverse events in primary care

<b>Diagnosis</b>
Related to symptoms
Misdiagnosis
Missed diagnosis
Delayed diagnosis
Related to prevention
Misdiagnosis
Missed diagnosis
Delayed diagnosis
<b>Treatment</b>
Drug
Incorrect drug
Incorrect dose
Delayed administration
Omitted administration
Non-drug
Inappropriate
Delayed
Omitted
Procedural complication
<b>Preventive services</b>
Inappropriate
Delayed
Omitted
Procedural complication

**Cause:** The contributing factors or “process errors” are categorized into 4 factors: clinician factors, communication factors, administration factors, and blunt end factors, and is shown in Exhibit 6.2. These factors, according to the published literature on the classification, represent the holes in the “Swiss Cheese” model,<sup>77</sup> which postulates that barriers (patient safety factors) exist to prevent adverse events until the holes in many layers line up. The proposed model of interaction between the different factors of the classification is also based, in part, on theoretical assumptions about multiple contributing factors to incidents.

**Exhibit 6.2.** Classification of process errors in primary care

**Clinician factors**

Clinical judgment  
Procedural skills error

**Communication factors**

Clinician-patient  
Clinician-clinician or health care system personnel

**Administration factors**

Clinician  
Pharmacy  
Ancillary providers (physical therapy, occupational therapy, etc.)  
Office setting

**Blunt end factors**

Personal and family issues of clinicians and staff  
Insurance company regulations  
Funding and employers  
Physical size and location of practice  
General health care system

**7. Eindhoven Classification Model for Medical Domain** (Tjerk W. Van der Schaaf, Eindhoven University of Technology) (1995) (Netherlands)

**Purpose** – The Eindhoven Classification was originally developed to classify adverse events in the chemical industry but has been adapted for medicine (c.f. MERS-TM).

**Definition** – c.f. Glossary

**Description** – The Eindhoven Classification uses nineteen codes to classify events based upon the results of a root cause analysis and categorized into three major groups: 1) technical; 2) organizational; and 3) human causes, consistent with latent and active error theory and with the classification of human behavior into skill-, rule-, and knowledge-based behavior, including 1) failure in the correct and complete assessment of a situation; 2) failure during monitoring of a process; and 3) failure in task planning. (c.f. Appendix D)

**Limitations** – Use of this classification system requires training, especially for those with non-quality assurance background. It may require monitoring and guidance to ensure consistency of coding between systems.

**8. Classification in Medical-Event Reporting System for Transfusion Medicine (MERS-TM)<sup>78,79</sup>** (Harold S. Kaplan, MD, Columbia University, Harkness 4-418, 622 West 168 St., NY, NY 10032, and James B. Battles, PhD, AHRQ, Rockville, MD) (1998) (USA)

**Purpose** – MERS-TM is an event reporting system developed for transfusion services and blood centers to collect, classify, and analyze events that could potentially compromise transfusion safety. MERS-TM provides the opportunity to study and monitor both actual and near-miss events to facilitate process improvement efforts.

**Definition** – A medical event refers to any error, incident, deviation, variance, or sentinel/adverse event related to blood components and transfusion procedures.

**Description** – The MERS-TM classification process assigns standardized codes to describe the event and root causes. Events are classified by using preset event codes and 20 possible causal codes. Causal codes are subdivided into latent failures (organizational and technical), active failures (human-related errors), and patient-

related factors. A technical error occurs when there are problems with equipment, software, materials, labels, or forms. Organizational errors occur when there are problems with protocols, procedures, transfer of knowledge, management priorities, and culture. Near miss events – events for which a recovery step (planned or unplanned) allows for interruption and correction of the error – are included in the classification. They occur more frequently, and are a valuable source of data because they share many of the characteristics and causes of actual events. Near miss data present opportunities to learn from mistakes and improve the overall safety of the transfusion service.

**9a. Generic Occurrence Classification (GOC) for Incidents and Accidents in the Health Care System<sup>80</sup>** (William B. Runciman, MBBCh, PhD, Australian Patient Safety Foundation, GPO Box 400, Adelaide, SA 5005) (1998) (Australia)

**Purpose** – The GOC was developed to code salient features and contributing factors of things that go wrong in patient care, including incidents from near misses to sentinel events.

**Definition** – Iatrogenic harm is defined as “harm from things that go wrong in health care.”

**Description** – The GOC employs various types of “natural categories” that may be linked together using “natural mapping.” A natural category is a descriptor that is brief, easily and commonly understood, which captures the essence of an adverse event, and is not limited to any class or property. Using the dominant natural categories, one could code patient safety data from any source much faster than using key words. In 1998, Runciman reported that there were over 20,000 incidents and adverse events coded. Today, over 100,000 incidents have been analyzed and classified. The GOC allows incidents and accidents to be analyzed at the level of detail required to understand and learn about their causes and to develop preventive strategies to reduce their occurrence. A classification process (known as The Generic

Reference Model) “de-constructs” the relevant information about an incident. This process is designed to place the extracted information in context and record the underlying causes, including both system-based and human factors. Some of the contributing factors include: 1) environmental factors, 2) organization factors, 3) human factors, 3) subject of incident factors, and 4) agents and agent factors

#### **9b. Generic Occurrence Classification (GOC) for Adverse Drug Events<sup>81</sup>**

(William B. Runciman, MBBCh, PhD, Australian Patient Safety Foundation, GPO Box 400, Adelaide, SA 5005) (1999) (Australia)

**Purpose** – This “sub-branch” of the GOC is designed to specifically classify or code medication incidents in a way that allows the frequencies, causes and contributing factors to be analyzed.

**Definition** – An incident is defined as “any event or circumstance which could have, or did harm anyone, or could result in a complaint.”

**Description** – The GOC has 827 branches of code specific to medication problems and further separated unto sub-branches to the depth of over 12 levels. The detailed medication problems sub-branch enables medication incidents to be coded in depth, and is structured to allow ‘cross-mapping’ to ICD-10. **Types:** The first sub-branch is for identifying the specific medication(s) associated with the incident. A list of generic medication names is provided as ‘additional keywords’ from which the coder selects the relevant name. If the name of the medication is not provided on the report form, the class of medication can be coded, if known. The second sub-branch is for coding ‘problems with therapeutic use’, where an incident has occurred following the administration of the correct, intended drug, at the correct dosage and time, by the correct route, to the patient for whom it was intended. Under the third sub-branch, ‘intentional self harm’ involving medications (ICD-10 codes X60-64) can be coded. The fourth sub-branch, ‘Non administration, under dose, delayed administration or premature cessation of indicated and/or intended medication’, provides codes for

incidents in which the error was a sub-optimum medication modality. The largest sub-branch is the ‘premature, excessive, inappropriate or wrong medication, formulation or route’ sub-branch for poisoning arising from the use of medications, which is further subdivided into the following: premature administration of indicated and/or intended medication; administration of contraindicated medication; administration of an excessive dose of a medication; medications administered via the wrong route, or in the wrong formulation; and administration of unintended (wrong) medication. The final sub-branch in the ‘medication problems’ section is for incidents that involve problems with the ‘requisition, storage and wastage of medications’. This includes problems with ordering and dispensing medications, special storage requirements not being fulfilled, and incidents arising from the incorrect audit of controlled medications. **Impact, Domain, Causes:** Details of contributing factors, outcomes and other features of the incident (such as inappropriate staff, equipment problems or documentation problems) can be coded into other branches of the GOC to allow detailed analysis of similar incidents.

**10. JCAHO Patient Safety Taxonomy** (Andrew Chang, JD, MPH and Jerod Loeb, PhD, Division of Research, Joint Commission on Accreditation of Healthcare Organizations, One Renaissance Boulevard, Oakbrook Terrace, IL 60062) (2001) (USA)

**Purpose** – The JCAHO *Taxonomy* was developed to assist health care leaders in a balanced and broadened approach to assessing and improving patient safety within any defined service delivery setting. Its purpose is to support the generation of standardized patient safety data, which can facilitate the understanding of what variables or interactions of variables cause health care errors and systems failures.

**Definition** – The JCAHO definitions of terms are given in the Glossary.

**Description** – The JCAHO *Taxonomy* is a classification scheme for health care errors and systems failures. It integrates several highly regarded error/failure modeling

frameworks and human factors and error type classifications – by Reason, Rasmussen, Weigmann and Shappell,<sup>82</sup> Eindhoven, and NCC MERP. The *Taxonomy* has 4 root nodes (primary classifications) that are segmented into corresponding priority patient safety concepts – 15 secondary classifications – that are key to understanding what variables or interaction of variables affect patient safety. These classifications are branched into 140 coded categories with the flexibility to include unlimited free text below the coded categories. Its variable-level classification framework and the shared language of the taxonomy can be adapted to match the patient safety needs of any international health care setting through individual modules. **Impact:** The taxonomy identifies the severity or degree of physical and psychological harm, ranging from the least harm to the most harm, resulting from adverse events. It also categorizes other potential consequences due to error and systems failure that are related to legal, social, and economic issues. **Type:** There are three priority areas: 1) Communication failures that exist between patient and provider, patient’s proxy and practitioner, practitioner and non-medical staff, and among practitioners; 2) Patient management issues that involves improper delegation, failure in tracking or follow-up, wrong referral or consultation, and wrong use of resources; and 3) Clinical performance issues. **Domain:** The taxonomy is not limited to a specific healthcare setting or type of adverse events. It is intended to be broadly applicable to any incident resulting from patient care. **Cause:** The causal framework of the taxonomy addresses the entire spectrum of latent and active failures. Categorization of causes and contributing factors reflects the multilevel nature of incident causation. **Prevention & Mitigation:** Patient safety data obtained from reporting systems and other pertinent data sources can be “de-constructed” using the analytical framework of the taxonomy, to identify trends, make comparisons, and discern whether there are patterns that indicate recurring problems. These, in turn, can inform the development of preventive and corrective strategies.

## **VIII. CONCLUSIONS CONCERNING EXISTING PATIENT SAFETY CLASSIFICATION SYSTEMS**

There is considerable variation in the quality and sophistication of the patient safety classifications reviewed here. This may reflect the relative newness of the field – the development of patient safety nomenclature and taxonomy is a recent endeavor compared with classifying diseases, diagnoses or treatments. Nonetheless, it's an emerging field that has advanced rapidly in a relatively brief period of time, though the current state of the art in this area suggests direction for collaborative work.

Developers of patient safety classification have benefited from the theoretical and technical advances in human error and systems failure research already achieved in the behavioral and engineering sciences, but the application of this knowledge to patient safety has been uneven. In recent years the number of studies on the development of nomenclature and classification systems to complement incident monitoring and reporting systems has markedly increase, although there is still a need to refine and further test existing instruments.

As patient safety becomes an increasingly important focus in the health care industry worldwide and the reporting of adverse events and medical errors becomes a more critical part of quality management, there will be closer scrutiny on classifications and nomenclature schemes and pressure to adopt standards. Monitoring of events between different adverse events systems and the sharing of best practices within and across countries will create the need for systems with interoperability and commonality. The maintenance and use of diverse classification systems will be a barrier to effective sharing and implementation of best practices for improving the quality of care. The use of a more universal system that allows for input from a wide range of stakeholders and adequately classifies all significant components of patient safety monitoring and reporting will be instrumental in wholesale improvement in patient safety.

The knowledge gleaned from the current review of the published and grey literature on classification systems for adverse events and near misses in countries has led to specific recommendations presented in Section X. It will also be used in the second part of the consultancy to inform processes and strategies for formulation of a model international patient safety taxonomy. A thorough analysis of the existing patient safety classification systems, including results of past classification developments, is needed to gain a full understanding of the technical issues related to building a new taxonomy or integrating existing ones. This evaluation process must also take into consideration the particular features that are broadly applicable to diverse patient safety issues. To that end, we have developed a priority-based framework to analyze the identified classification schemes, as outlined in the next section.

## **IX. FRAMEWORK TO ANALYZE PATIENT SAFETY CLASSIFICATIONS**

Patient safety classification systems consist of three components – elements, structures, and rules. Elements are comprised of terms, categories, and cross-references between common terms that make up the building blocks of a classification system. Structures consist of the elements themselves and the relationships that link them together. Rules are the criteria and instructions for users to assign and categorize data. Each classification system represents a sampling of these components from a larger number that could have been included. The selection of a particular classification instrument is a choice among alternative components. Naturally, it would be sensible to analyze the strengths and weaknesses of a classification system at the component level. A difficulty is commonly encountered in comparing two classification systems – one with excellent theoretical and technical foundations but may be untested in the “real world” and another that is more widely implemented but shows somewhat less adequate validity.

Recommending the “best” classification is, therefore, difficult to make without knowing about the purpose for which the user intends to use the classification. Several indications of the relative merits of the various schemes have been given, but all of the classifications reviewed here have different strengths and weaknesses.

WHO must decide exactly what is required of the classification. For example, will it be used to organize error reports or to understand opportunities to improve patient care and suggests priority areas for remedial attention? What type of errors will be classified and assessed (medical, medication, human factors, systems failure)? How broad a classification must be made, and how detailed does the information (layers of categories) need to be? For example, a classification system for epidemiological analysis will have concepts at the level of public health, rather than at the level of a particular medical specialization. Would a single classification of the causative and contributing factors of errors suffice, or are more extensive multi-dimensional classifications of the consequences as well as the types of error – including near misses – needed? In short, the appropriate balance to strike between the detail and accuracy required and the effort of collecting it must be clearly delineated.

In analyzing the technical merit of the various extant classification methods, the following characteristics or attributes of a classification should be considered:

- Is the purpose of the classification fully explained and is it appropriate for the intended use? Preferably, the classification should have been tested on the types of incidents and adverse events to which it will be applied.
- Is the classification broad enough for the application, neither capturing too many nor too few data elements? Is it capable of identifying preventive and corrective strategies where this is relevant?
- What is the conceptual approach to the classification framework? In other words, which theory in the science of human factors and error and systems failure does it reflect, if any, and is this approach consonant with the orientation of the purpose? Is the theory well established (e.g., Reason's human error) or is it an idiosyncratic notion that may not correspond to a broader body of knowledge?
- How feasible is the classification to implement? Can it be implemented as a paper-based and electronic on-line incident monitoring system or mapped to data collected from existing reporting systems? Is professional expertise required to apply or interpret the classification instrument? Does it use readily

available data (e.g., information already contained in medical records, medicolegal files, complaints, morbidity and mortality data) and will it be readily acceptable to patient safety stakeholders? What useful purposes have been achieved using the classification? Is the classification instrument readily available and is there a cost involved? Above all, are there clear instructions that specify how the data elements are codified?

- Is it clear how data derived from the classification are analyzed?
- Is it sufficiently sensitive to differentiate similar adverse events with different contributing factors, and is this adequate for the purpose? Is it suitable for recording and tracking errors only, or can it provide detailed information to inform the development of preventive and corrective strategies?
- How strong is the available evidence for reliability and validity of the classification instrument? Has it been field tested in the “real world?” How many different incident-reporting systems has it been compared with? How many different users have tested the classification instrument, and did they obtain similar results?

## **X. RECOMMENDATIONS FOR AN INTERNATIONAL TAXONOMY ON PATIENT SAFETY**

We endeavored to stay strictly within the focused charge defined in the terms of reference of this consultancy. In the course of the work, however, we identified many important issues in addition to the objectives of the activity that should be considered if a viable and sustainable international patient safety taxonomy were to be developed. Based on the review of the identified research and existing classification systems on adverse events, near misses and other events associated with patient safety, the following recommendations can be made.

- An international patient safety taxonomy should use an unambiguous, common vocabulary of patient safety that conforms to the best available

scientific evidence. It should be based on an established body of theory derived exclusively from the epidemiologic science of error and systems failure, and show how the information obtained may be interpreted in light of that theory.

- An international patient safety taxonomy should address a broad and diverse range of patient safety issues and concerns across multiple health care settings of different countries. To meet the requirements of this wide audience it is essential that the common nomenclature selected is simple and complexity kept to a minimum.
- An international patient safety taxonomy should be compatible with major adverse event classification systems and suited to meet the need for seamless integration of patient safety data acquired from disparate sources. Since there are many possible ways to classify health care errors and systems failures – and each has strengths and weaknesses – it may be prudent to combine more than one classification approach, where feasible. This has the advantage of ensuring wider acceptance and broader deployment of the classification instrument when the data elements from ostensibly similar classifications are in agreement, and it also serves to increase our general understanding of the comparability of the classifications.
- An international patient safety taxonomy should 1) avoid or reject the use of terms that might cause misunderstandings or confusion, 2) avoid the unnecessary creation of terms, and 3) aim for stability.
- An international patient safety taxonomy should identify high-priority patient safety data elements that are important to health care systems internationally. These data elements should be cross-walked or mapped to existing classification systems used by countries to collect these elements.
- An international patient safety taxonomy should classify information related to what, where and how medical management go wrong, the reasons why medical incidents occur, and what preventive and corrective strategies can be developed to keep them from occurring or to ameliorate their effects in health care systems globally. It must provide a meaningful and comprehensive

linkage between the contributory factors and the errors and systems failures that lead to adverse events.

- An international patient safety taxonomy should facilitate the monitoring, reporting, and investigation of adverse events and near misses at the public health level – allowing aggregated data to be combined and tracked, maintaining consistency across reporting systems, and providing consistent analysis and presentation of data.
- An international patient safety taxonomy should be validated with independent data from the “real world” to ensure its validity and reliability.
- An international patient safety taxonomy should mitigate the under-reporting of adverse event and near miss data and underutilization of those data that are reported. By codifying patient safety data and devising common rules for presenting and ordering information in a digestible fashion, the end user of a reporting system could more rapidly achieve a deeper understanding of the reported data.
- An international patient safety taxonomy should lessen the burden on patient safety organizations that operate in multiple jurisdictions or are subject to reporting requirements of ministries of health, multiple government agencies, and private oversight bodies, without requiring expensive reengineering of existing incident monitoring and reporting systems to a standardized format.

Lastly, while one may complain about the weakness and lack of coordinated development work in the areas of patient safety classification and incident monitoring, it is also true that the universal, perfect system may never exist. It is quite incorrect (and unrealistic) to imagine a *single* classification scheme suited to all countries, all health care systems, and all incidents. Such a taxonomy would have to make so many compromises or to be so unwieldy it would probably not be suitable for any particular application. What is required in an international patient safety taxonomy are multidimensional classification modules with the flexibility to meet the diverse patient safety needs worldwide but also has fundamentally different and specific classification modules for countries with similar health care challenges and

for high technology healthcare systems, as an example. In addition, the taxonomy will have generic or common components – primary classification modules – that can be applied in any country and health delivery setting, and toward any adverse event.

There are several possible avenues along which the development of an international taxonomy may proceed. *First*, many methodological advances simply have not been applied, making patient safety classification instruments less superior than their potential. Our review of existing classifications are intended to give an initial stimulus to further work in consolidating the field of classifying, measuring and reporting adverse events, and the assessment framework given in Section IX suggests how this may be done. *Second*, more formal channels of recognition for this collaborative work are required. A recognized body could be asked to take on a coordinating role in formalizing the taxonomy, making recommendations on choices among key patient stakeholders from multiple countries. *Finally*, the recommendations on how to develop, test, and implement a taxonomy, if successful, should lead to generally applicable technical standards for the broader discipline to promote an international common understanding in patient safety.

## **XI. APPENDIX**

### **Appendix A - Taxonomy for Error Reporting, Root Cause Analysis and Analysis of Practice Responsibility (TERCAP)**

- 1) Lack of attentiveness or surveillance**
  - a. Lack of attentiveness or surveillance related to patient's:
    - i. Reaction to medications or treatment
    - ii. Need for ventilatory assistance
    - iii. Dangerous cardiac arrhythmias
    - iv. Compromised patient airway
    - v. Postoperative complications
    - vi. Potency of IV
    - vii. Need for suicide precautions
    - viii. Newly developing conditions
    - ix. Missed dangerous signs and symptoms
    - x. Need for care tailored to history and anticipated needs
  - b. Nurse(s)' lack of attentiveness and surveillance related to:
    - i. Directing substandard care
    - ii. Not detecting substandard care
    - iii. Not recognizing error
    - iv. Lack of effective monitoring of patients for an unsafe period of time
    - v. Other type of lack of attentiveness or surveillance
  - c. Patient characteristics
    - i. Infant or child
    - ii. Elderly
    - iii. Cultural misunderstandings/conflict
    - iv. Language difficulties
    - v. Cognitive impairment
    - vi. Diminished functional ability or specific disability due to illness or therapies
    - vii. Post-anesthesia
    - viii. Post-surgical
    - ix. Other
- 2) Lack of agency/fiduciary concern**
  - a. Did not notify physician or other provider of patient conditions
  - b. Lack of insight regarding patient needs so that focus on other task demands while not recognizing needs of patients
  - c. Specific patient requests or concern unattended
  - d. Inappropriate withholding of treatment without patient or family consent
  - e. Missed or diminished sense of patient safety
  - f. Lack of respect for patient/family concerns and dignity
  - g. Patient abandonment
  - h. Deliberately covering up error
  - i. Boundary violations
  - j. Breach of confidentiality
    - i. Unintentional
    - ii. Intentional
  - k. Nurse attributes responsibility to others
  - l. Failure to act on behalf of patient due to lack of reimbursement
  - m. Other
- 3) Lack of intervention**
  - a. Endangerment of patients due to lack of intervention by nurse
  - b. Error in performance of procedure/intervention
  - c. Delay in procedure or treatment
  - d. Other

- 4) **Inappropriate judgment**
  - a. Lack of adequate assessment/information
  - b. Not detecting faulty or missing patient information
  - c. Clinical implications of signs, symptoms and/or interventions not recognized
    - i. Problem in knowledge application
    - ii. Clinical significance of patient's condition not recognized
    - iii. Lack of skillful/timely implementation of interventions
  - d. Lack of clinical grasp or sense of salience of patient's condition
  - e. Lack of appropriate priorities
  - f. Tunnel vision (quick focus on presumed cause)
  - g. Inappropriate intervention, not what is needed
  - h. Faulty logic/use of rote or convention
  - i. Lack of evaluation of patient response to therapy
  - j. Poor judgment related to medication administration
  - k. Operating new equipment – no orientation/training
  - l. Poor judgment in the supervision of others
    - i. Expectations not clearly communicated
    - ii. Staff is inadequately monitored
    - iii. Failure to evaluate effectiveness of delegation or assignment
    - iv. Lack of follow-up on problems
  - m. Inappropriate acceptance of delegation or assignment
  - n. Inappropriate (not indicated) care
  - o. Other
- 5) **Missed or mistaken physician or other health care provider order**
  - a. Missed physician's or other provider's order
  - b. Misinterpreted telephone or other verbal order
  - c. Physician error undetected resulting in execution of inappropriate order
  - d. Fails to identify inappropriate medication or treatment, gives inappropriate medication or treatment
  - e. Fails to confront physician or other health care provider, gives inappropriate medication or treatment
  - f. Confronts immediate health care provider who orders inappropriate medication or treatment but does not go further up chain of command, gives inappropriate medication or treatment
  - g. Other
- 6) **Lack of prevention**
  - a. Failure to take preventive measures
  - b. Inadequate monitoring or follow-up
  - c. Breach of infection precaution
    - i. Breach of universal precaution
    - ii. Breach of specific precautions
    - iii. Administers unsterile IV
  - d. Used contaminated equipment
  - e. Not recognizing equipment failure
  - f. Other
- 7) **Documentation errors**
  - a. Deliberate changing of documentation to cover up error
  - b. Failure to chart medications that have been administered
  - c. Pre-charting
  - d. Falsely charted medication administration
  - e. Lack of documentation of observations or actions
  - f. Other

## **Appendix B**

### **NCC MERP Taxonomy of Medication**

#### **10 PATIENT INFORMATION**

10.1 Identification Number or Initials: \_\_\_\_\_

10.2 Age - Date of Birth

10.3 Gender

10.4 Weight [may be omitted unless directly pertinent to the error (e.g., medication overdose in a pediatric patient)].

#### **20 THE EVENT**

21 DATE (mmddyyyy)

21.1 Date of event

21.1.1 Weekend

21.1.2 Holiday

21.2 Date of Initial Report

21.3 Date of Follow-up Report

22 TIME

22.1 Time of Error (24 hour clock)

23 SETTING (of initial error)

23.1 Adult Day Health Care

23.2 Assisted Living/Board and Care

23.3 Correctional Facility

23.4 Emergency Rescue Unit

23.5 Health Food Store

23.6 Hospice

23.7 Hospital

23.7.1 Cardiac Step Down

23.7.2 Central Supply

23.7.3 Emergency Room

23.7.4 Intensive Care Unit (ICU)

23.7.4.1 Cardiac ICU

23.7.4.2 Medical ICU

23.7.4.3 Neonatal ICU/Step Down (Infant Transitional)

23.7.4.4 Pediatric ICU

23.7.4.5 Surgical ICU

23.7.5 Labor/Delivery

23.7.6 Long Term Acute Care

23.7.7 Nursery

23.7.8 Nursing Unit

23.7.9 Oncology

23.7.10 Operating Room

23.7.11 Outpatient

23.7.12 Pediatrics

23.7.13 Pharmacy

23.7.13.1 Inpatient

23.7.13.2 Outpatient

23.7.13.3 Nuclear

23.7.14 Psychiatric Unit

23.7.15 Radiology

23.7.15.1 Nuclear

23.7.15.2 Special Procedures Area

23.7.16 Respiratory Therapy

- 23.7.17 Recovery Room (PACU)
- 23.7.18 Sub-acute Care
- 23.7.19 Other
- 23.8 Home Health Care
- 23.9 Mental Health Facility
- 23.10 Nursing Facility (Free Standing)
  - 23.10.1 Skilled
  - 23.10.2 Intermediate
  - 23.10.3 Pharmacy
- 23.11 Outpatient Facility
  - 23.11.1 Ambulatory Surgery
  - 23.11.2 Rehabilitation
  - 23.11.3 Urgent Care Clinic
- 23.12 Patient's Home/Work
- 23.13 Pharmacy
  - 23.13.1 Community
  - 23.13.2 Home Health Care
  - 23.13.3 Long Term Care
  - 23.13.4 Mail Service
  - 23.13.5 Managed Care
  - 23.13.6 Mental Health
  - 23.13.7 Nuclear
- 23.14 Prescriber's Office
- 23.15 School
- 23.16 Other
- 23.17 Unknown
- 24 SETTING (Where Error Perpetuated)
- 24.1 Adult Day Health Care
- 24.2 Assisted Living/Board and Care
- 24.3 Correctional Facility
- 24.4 Emergency Rescue Unit
- 24.5 Health Food Store
- 24.6 Hospice
- 24.7 Hospital
  - 24.7.1 Cardiac Step Down
  - 24.7.2 Central Supply
  - 24.7.3 Emergency Room
  - 24.7.4 Intensive Care Unit (ICU)
    - 24.7.4.1 Cardiac ICU
    - 24.7.4.2 Medical ICU
    - 24.7.4.3 Neonatal ICU/Step Down (Infant Transitional)
    - 24.7.4.4 Pediatric ICU
    - 24.7.4.5 Surgical ICU
  - 24.7.5 Labor/Delivery
  - 24.7.6 Long Term Acute Care
  - 24.7.7 Nursery
  - 24.7.8 Nursing Unit
  - 24.7.9 Oncology
  - 24.7.10 Operating Room
  - 24.7.11 Outpatient
  - 24.7.12 Pediatrics
  - 24.7.13 Pharmacy
    - 24.7.13.1 Inpatient
    - 24.7.13.2 Outpatient
    - 24.7.13.3 Nuclear
  - 24.7.14 Psychiatric Unit

- 24.7.15 Radiology
  - 24.7.15.1 Nuclear
  - 24.7.15.2 Special Procedures Area
- 24.7.16 Respiratory Therapy
- 24.7.17 Recovery Room (PACU)
- 24.7.18 Sub-acute Care
- 24.7.19 Other
- 24.8 Home Health Care
- 24.9 Mental Health Facility
- 24.10 Nursing Facility (Free Standing)
  - 24.10.1 Skilled
  - 24.10.2 Intermediate
  - 24.10.3 Pharmacy
- 24.11 Outpatient Facility
  - 24.11.1 Ambulatory Surgery
  - 24.11.2 Rehabilitation
  - 24.11.3 Urgent Care Clinic
- 24.12 Patient's Home/Work
- 24.13 Pharmacy
  - 24.13.1 Community
  - 24.13.2 Home Health Care
  - 24.13.3 Long Term Care
  - 24.13.4 Mail Service
  - 24.13.5 Managed Care
  - 24.13.6 Mental Health
  - 24.13.7 Nuclear
- 24.14 Prescriber's Office
- 24.15 School
- 24.16 Other
- 24.17 Unknown

25 DESCRIPTION OF EVENT [This is a free text entry field. The user should provide a narrative description of the event, including how the error was perpetuated and discovered. Other relevant information should be included, such as:]

- Laboratory data or tests, including dates
- Other relevant history, including preexisting medical conditions (e.g., allergies)
- Concomitant therapy
- Dates of therapy
- Indication for use (Diagnosis)
- Medical intervention(s) following the error
- Actions taken and recommendation for prevention].

### **30 PATIENT OUTCOME**

#### **31 NO ERROR**

31.1 Category A Circumstances or events that have the capacity to cause error

32 ERROR, NO HARM [Note: Harm is defined as temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting there from requiring intervention.]

32.1 Category B An error occurred but the error did not reach the patient (An "error of omission" does reach the patient.)

32.2 Category C An error occurred that reached the patient, but did not cause patient harm

32.2.1 Medication reaches the patient and is administered

32.2.2 Medication reaches the patient but not administered

32.3 Category D An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm

#### **33 ERROR, HARM**

- 33.1 Category E An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.
- 33.2 Category F An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization.
- 33.3 Category G An error occurred that may have contributed to or resulted in permanent patient harm
- 33.4 Category H An error occurred that required intervention necessary to sustain life
- 34 ERROR, DEATH
- 34.1 Category I An error occurred that may have contributed to or resulted in the patient's death.

**50 PRODUCT INFORMATION - #1 [PRODUCT THAT WAS ACTUALLY (OR POTENTIALLY) GIVEN]**

**51 GENERAL**

51.1 Name of Drug (or other products, if applicable)

- 51.1.1 Proprietary (Trade) Name
- 51.1.2 Established (Generic) Name
- 51.1.3 Compounded Ingredients

51.2 Strength

51.3 Dose, Frequency & Route

51.4 Status

- 51.4.1 Prescription
- 51.4.2 Over-the-Counter
- 51.4.3 Investigational

51.5 Name of Manufacturer

51.6 Name of Labeler or Distributor

**52 DOSAGE FORM**

52.1 Tablet

- 52.1.1 Extended-release

52.2 Capsule

52.2.1 Extended-release

52.3 Oral Liquid

- 52.3.1 Concentrate

52.4 Injectable

52.5 Cream-Ointment-Gel-Paste

52.6 Aerosol (spray and metered)

52.7 Other

53 PACKAGING – CONTAINER [Note that these are some examples of packaging frequently involved in errors. The list does not include all packaging configurations available in the market place. Select one item from this section]

53.1 Unit Dose

53.2 Multiple Dose Vials (Injectable)

53.3 Single Dose Vials/Ampuls (Injectable)

53.4 Intravenous Solutions (small and large volume parenterals)

- 53.4.1 Manufacturer Prepared
- 53.4.2 Institution Prepared

53.5 Syringes

53.6 Manufacturer Samples

53.7 Other (Please specify)

54 PHARMACOLOGIC - THERAPEUTIC CLASSIFICATION The council recommends the use of the pharmacologic-therapeutic classification system defined by either the American Society of Health-Systems Pharmacists (i.e., AHFS code) or the Veterans Administration (i.e., VA codes).

**55 PRODUCT INFORMATION - #2 (PRODUCT THAT WAS INTENDED TO BE GIVEN)**

**56 GENERAL**

56.1 Name

- 56.1.1 Proprietary (Trade) Name
- 56.1.2 Established (Generic) Name
- 56.1.3 Compounded Ingredients

- 56.2 Strength
- 56.3 Dose, Frequency & Route
- 56.4 Status
  - 56.4.1 Prescription
  - 56.4.2 Over-the-Counter
  - 56.4.3 Investigational
- 56.5 Name of Manufacturer
- 56.6 Name of Labeler or Distributor
- 57 DOSAGE FORM
- 57.1 Tablet
  - 57.1.1 Extended-release
- 57.2 Capsule
  - 57.2.1 Extended-release
- 57.3 Oral Liquid
  - 57.3.1 Concentrate
- 57.4 Injectable
- 57.5 Cream-Ointment-Gel-Paste
- 57.6 Aerosol (spray and metered)
- 57.7 Other
- 58 PACKAGING – CONTAINER
- 58.1 Unit Dose
- 58.2 Multiple Dose Vials (Injectable)
- 58.3 Single Dose Vials/Ampuls (Injectable)
- 58.4 Intravenous Solutions (small and large volume parenterals)
  - 58.4.1 Manufacturer Prepared
  - 58.4.2 Institution Prepared
- 58.5 Syringes
- 58.6 Manufacturer Samples
- 58.7 Other (Please specify)
- 59 PHARMACOLOGIC - THERAPEUTIC CLASSIFICATION

**60 PERSONNEL INVOLVED**

- 61 Initial Error Made by 62 Error Perpetuated by:
  - 61.1 Physician 62.1 Physician
    - 61.1.1 Intern 62.1.1 Intern
    - 61.1.2 Resident 62.1.2 Resident
    - 61.1.3 Practicing Physician 62.1.3 Practicing Physician
    - 61.1.4 Other 62.1.4 Other
  - 61.2 Pharmacist 62.2 Pharmacist
  - 61.3 Nurse 62.3 Nurse
    - 61.3.1 Nurse Practitioner/ 62.3.1 Nurse Practitioner/Advanced Practice Advanced Practice
    - 61.3.2 Registered Nurse 62.3.2 Registered Nurse
    - 61.3.3 Licensed Practical Nurse 62.3.3 Licensed Practical Nurse
    - 61.3.4 Other \_\_\_\_\_ 62.3.4 Other \_\_\_\_\_
  - 61.4 Physician Assistant 62.4 Physician Assistant
  - 61.5 Dentist 62.5 Dentist
  - 61.6 Veterinarian 62.6 Veterinarian
  - 61.7 Optometrist 62.7 Optometrist
  - 61.8 Support Personnel 62.8 Support Personnel
    - 61.8.1 Pharmacy Technician 62.8.1 Pharmacy Technician
    - 61.8.2 Nurses Aide 62.8.2 Nurses Aide
    - 61.8.3 Medication Aide 62.8.4 Medication Aide
    - 61.8.4 Clerical 62.8.5 Clerical
  - 61.9 Health Professions Student 62.9 Health Professions Student
    - 61.9.1 Medicine 62.9.1 Medicine
    - 61.9.2 Pharmacy 62.9.2 Pharmacy

- 61.9.3 Nursing 62.9.3 Nursing
- 61.9.4 Other 62.9.4 Other
- 61.10 Patient/Caregiver 62.10 Patient/Caregiver
- 61.11 Other 62.11 Other
- 61.12 Unknown 62.12 None
- 63 Error Discovered by:
  - 63.1 Physician
    - 63.1.1 Intern
    - 63.1.2 Resident
    - 63.1.3 Practicing Physician
    - 63.1.4 Other
  - 63.2 Pharmacist
  - 63.3 Nurse
    - 63.3.1 Nurse Practitioner/Advanced Practice
    - 63.3.2 Registered Nurse
    - 63.3.3 Licensed Practical Nurse
    - 63.3.4 Other \_\_\_\_\_
  - 63.4 Physician Assistant
  - 63.5 Dentist
  - 63.6 Veterinarian
  - 63.7 Optometrist
  - 63.8 Support Personnel
    - 63.8.1 Pharmacy Technician
    - 63.8.2 Nurses Aide
    - 63.8.3 Medication Aide
    - 63.8.4 Clerical
  - 63.9 Health Professions Student
    - 63.9.1 Medicine
    - 63.9.2 Pharmacy
    - 63.9.3 Nursing
    - 63.9.4 Other
  - 63.10 Patient/Caregiver
  - 63.11 Other
  - 63.12 Unknown

**70 TYPE**

- 70.2 Improper Dose
  - 70.2.1 Resulting in Overdosage
  - 70.2.2 Resulting in Under dosage
  - 70.2.3 Extra Dose
- 70.3 Wrong Strength/Concentration
- 70.4 Wrong Drug
- 70.5 Wrong Dosage Form
- 70.6 Wrong Technique (includes inappropriate crushing of tablets)
- 70.7 Wrong Route of Administration

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Route Given Route Intended

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- 70.7.1 IV Gastric
- 70.7.2 Intrathecal IV
- 70.7.3 IV Oral
- 70.7.4 IV IM
- 70.7.5 IM IV
- 70.7.6 Other
- 70.8 Wrong Rate
  - 70.8.1 Too fast

- 70.8.2 Too slow
- 70.9 Wrong Duration
- 70.10 Wrong Time
- 70.11 Wrong Patient
- 70.12 Monitoring Error (includes Contraindicated Drugs)
  - 70.12.1 Drug-Drug Interaction
  - 70.12.2 Drug-Food/Nutrient Interaction
  - 70.12.3 Documented Allergy
  - 70.12.4 Drug-Disease Interaction
  - 70.12.5 Clinical (e.g., blood glucose, prothrombin, blood pressure,)
- 70.13 Deteriorated Drug Error (Dispensing drug which has expired)
- 70.14 Other [Any medication error that does not fall into one of the above]

## **80 CAUSES**

### **81 COMMUNICATION**

- 81.1 Verbal miscommunication
- 81.2 Written miscommunication
  - 81.2.1 Illegible handwriting
  - 81.2.2 Abbreviations
  - 81.2.3 Non-metric units of measurement (e.g., apothecary)
  - 81.2.4 Trailing Zero
  - 81.2.5 Leading Zero
  - 81.2.6 Decimal Point
  - 81.2.7 Misread or Didn't Read
- 81.3 Misinterpretation of the order

### **83 NAME CONFUSION**

- 83.1 Proprietary (Trade) Name Confusion
  - 83.1.1 Suffix confusion
  - 83.1.2 Prefix confusion
  - 83.1.3 Sound-alike to another trade name
  - 83.1.4 Sound-alike to an established (generic) name
  - 83.1.5 Look-alike to another trade name
  - 83.1.6 Look-alike to an established name
  - 83.1.7 Appears to be misleading
  - 83.1.8 Confusion with Over-the-Counter "Family Trade Names"
- 83.2 Established (Generic) Name Confusion
  - 83.2.1 Sound-alike to another established name
  - 83.2.2 Sound-alike to a trade name
  - 83.2.3 Look-alike to another established name
  - 83.2.4 Look-alike to a trade name

### **85 LABELING**

- 85.1 Immediate Container Labels of Product - Manufacturer, Distributor or Repackager
  - 85.1.1 Looks too similar to another manufacturer
  - 85.1.2 Looks too similar within the same company's product line.
  - 85.1.3 Appears to be inaccurate or incomplete
  - 85.1.4 Appears to be misleading or confusing
  - 85.1.5 Distracting Symbols or Logo
- 85.2 Labels of Dispensed Product - Practitioner
  - 85.2.1 Wrong Directions
  - 85.2.2 Incomplete Directions (including lack of ancillary labels)
  - 85.2.3 Wrong Drug Name
  - 85.2.4 Wrong Drug Strength
  - 85.2.5 Wrong Patient
  - 85.2.6 Other
- 85.3 Carton Labeling of Product - Manufacturer, Distributor or Repackager
  - 85.3.1 Looks too similar to another manufacturer

- 85.3.2 Looks too similar within the same company's product line.
- 85.3.3 Appears to be inaccurate
- 85.3.4 Appears to be misleading
- 85.3.5 Distracting Symbols or Logo
- 85.4 Package Insert
  - 85.4.1 Appears to be inaccurate
  - 85.4.2 Appears to be misleading
  - 85.4.3 Other
- 85.5 Electronic Reference Material
  - 85.5.1 Inaccurate
  - 85.5.2 Unclear or inconsistent
  - 85.5.3 Omission of data
  - 85.5.4 Outdated
  - 85.5.5 Unavailable
- 85.6 Printed Reference Material
  - 85.6.1 Inaccurate
  - 85.6.2 Unclear or inconsistent
  - 85.6.3 Omission of data
  - 85.6.4 Unavailable
- 85.7 Advertising
  - 85.7.1 Error or error potential associated with the commercial advertising of a product.
- 87 HUMAN FACTORS
  - 87.1 Knowledge Deficit
  - 87.2 Performance Deficit
  - 87.3 Miscalculation of Dosage or Infusion Rate
  - 87.4 Computer Error
    - 87.4.1 Incorrect selection from a list by computer operator
    - 87.4.2 Incorrect programming into the database.
    - 87.4.3 Inadequate screening for allergies, interactions, etc.
  - 87.5 Error in Stocking/Restocking/Cart Filling
  - 87.6 Drug Preparation Error
    - 87.6.1 Failure to activate delivery system
    - 87.6.2 Wrong Diluent
    - 87.6.3 Wrong Amount of Diluent
    - 87.6.4 Wrong amount of active ingredient added to the final product
    - 87.6.5 Wrong drug added
  - 87.7 Transcription Error
    - 87.7.1 Original to Paper/Carbon paper
    - 87.7.2 Original to Computer
    - 87.7.3 Original to Facsimile
    - 87.7.4 Recopying MAR
  - 87.8 Stress (high volume workload, etc.)
  - 87.9 Fatigue/Lack of Sleep
  - 87.10 Confrontational or intimidating behavior
- 89 PACKAGING/DESIGN
  - 89.1 Inappropriate Packaging or Design
  - 89.2 Dosage Form (Tablet/Capsule) Confusion :
    - 89.2.1 Confusion due to similarity in color, shape, and/or size to another product.
    - 89.2.2 Confusion due to similarity in color, shape, and/or size of the same product but different strength.
  - 89.3 Devices
    - 89.3.1 Malfunction
    - 89.3.2 Wrong Device Selected (e.g., TB syringe used instead of Insulin syringe)
    - 89.3.3 Adapters (e.g., Parenteral vs Enteral)
    - 89.3.4 Automated Distribution/Vending Systems
    - 89.3.5 Automated Counting Machines

- 89.3.6 Automated Compounders
- 89.3.7 Oral Measuring Devices (e.g., syringes, cups, spoons)
- 89.3.8 Infusion (PCA, Infusion pumps)

**90 CONTRIBUTING FACTORS (SYSTEMS RELATED)**

- 90.1 Lighting
- 90.2 Noise Level
- 90.3 Frequent Interruptions and distractions
- 90.4 Training
- 90.5 Staffing
- 90.6 Lack of availability of health care professional
  - 90.6.1 Medical
  - 90.6.2 Other Allied Health Care Professional
  - 90.6.3 Pharmacy
  - 90.6.4 Nursing
  - 90.6.5 Other
- 90.7 Assignment or placement of a health care provider or inexperienced personnel
- 90.8 System for Covering Patient Care (e.g., floating personnel, agency coverage)
  - 90.8.1 Medical
  - 90.8.2 Other Allied Health Care Professional
  - 90.8.3 Pharmacy
  - 90.8.4 Nursing
  - 90.8.5 Other
- 90.9 Policies and procedures
- 90.10 Communication systems between health care practitioners
- 90.11 Patient counseling
- 90.12 Floor Stock
- 90.13 Pre-printed medication orders
- 90.14 Other

## Appendix C

### **Taxonomy of Medical Errors in Family Practice**

#### **1 PROCESS ERRORS**

##### **3.1 Office Administration**

###### **3.1.1 Filing System**

###### **3.1.2 Chart completeness**

###### **3.1.2.1 Record(s) unavailable**

###### **3.1.2.2 Care given but not documented**

###### **3.1.2.3 Record not up to date or complete**

###### **3.1.3 Patient flow**

###### **3.1.4 Message handling**

###### **3.1.5 Appointments**

##### **3.2 Investigations**

###### **3.2.1 Laboratory**

###### **3.2.1.1 Ordering laboratory investigation**

###### **3.2.1.2 Implementing laboratory investigations**

###### **3.2.1.3 Reporting laboratory investigations**

###### **3.2.1.4 Responding to abnormal laboratory investigation results**

###### **3.2.2 Diagnostic imaging**

###### **3.2.2.1 Ordering diagnostic imaging**

###### **3.2.2.2 Implementing diagnostic imaging**

###### **3.2.2.3 Reporting diagnostic imaging**

###### **3.2.2.4 Responding to abnormal diagnostic imaging results**

###### **3.2.3 Other investigations**

###### **3.2.3.1 Ordering other investigations**

###### **3.2.3.2 Implementing other investigations**

###### **3.2.3.3 Reporting other investigations**

###### **3.2.3.4 Responding to abnormal results of other investigations**

##### **3.3 Treatments**

###### **3.3.1 Medications**

###### **3.3.1.1 Ordering medications**

###### **3.3.1.2 Implementing medication orders**

###### **3.3.1.3 Receiving medications**

###### **3.3.2 Other treatments**

###### **3.3.2.1 Ordering other treatments**

###### **3.3.2.2 Implementing other treatments**

##### **3.4 Communication**

###### **3.4.1 Communication with patients**

###### **3.4.1.1 Consent errors**

###### **3.4.2 Communication with non-physician colleagues**

###### **3.4.3 Communication with physician colleagues**

##### **3.5 Payment**

#### **4 KNOWLEDGE AND SKILLS ERRORS**

##### **4.1 Execution of a clinical task**

##### **4.2 Misdiagnosis**

##### **4.3 Wrong treatment decision**