Is the “International Classification for Patient Safety” a Classification?

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Abstract. The WHO has developed and is currently testing a classification for patient safety (ICPS). Analyzing the ICPS in the light of classificatory and ontological principles as well as international standards we conclude that its qualification as a classification or taxonomy is misleading. Acknowledging its merits as a standard reporting instrument for change management and process improvements we propose formal improvements.

Keywords. WHO classification, ontologies, information models

1. Introduction

Patient safety issues have attracted an increasing awareness in the past decade. Several patient safety classifications exist with a limited geographical, linguistic, and cultural scope. This has prompted the WHO to develop the International Classification for Patient Safety (ICPS) [1], with the objective to represent patient safety workflows in order to facilitate international reporting, data exchange and research collaboration. ICPS v1.0 is currently undergoing field testing. In this paper, we want to give a typological account of ICPS, analyzing its architecture under the scrutiny of terminological and ontological standards. In contrast to other WHO classifications, ICPS is unique as its development has been centered on a conceptual framework (CF) (Figure 1), which is strongly oriented toward change management and process improvements. It introduces fundamental notions of patient safety, focusing on Incident Type (1) and Patient Outcome (2), specified by Patient Characteristics (3) and

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Incident Characteristics\(^4\). Incidents are triggered by Contributing Factors / Hazards\(^5\). Their effects can be alleviated by Mitigating Factors\(^6\). Incidents are perceived by Detection\(^7\). Organizational Outcomes\(^8\) are the impacts upon the organization where the incident occurs. Ameliorating Actions\(^9\) are taken to compensate the harm after an incident. Finally, contributing factors, detection and mitigating factors are influenced by Actions Taken to Reduce Risk\(^{10}\). These ten so-called major classes form the uppermost layer of ICPS, just as the chapters in ICD. They organize nearly 500 concepts in a classificatory tree with up to four hierarchical levels. Table 1 provides examples for the ICPS major classes, their subdivisions and the leaf concepts. In the following we will generically refer to ICPS classes, class subdivisions, and concepts as ICPS categories.

<table>
<thead>
<tr>
<th>ICPS Major Class</th>
<th>Subdivisions</th>
<th>Example Leaf Concepts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident Type</td>
<td>Medication/IV Fluids Problem:</td>
<td>Wrong Drug</td>
</tr>
<tr>
<td>Patient Outcome</td>
<td>Type of Harm: Pathophysiology:</td>
<td>Diseases of the Nervous System</td>
</tr>
<tr>
<td></td>
<td>Degree of harm:</td>
<td>Severe</td>
</tr>
<tr>
<td>Patient Characteristics</td>
<td>Reason for encounter: Procedure:</td>
<td>Surgical Procedure</td>
</tr>
<tr>
<td></td>
<td>Demographics:</td>
<td>Age</td>
</tr>
<tr>
<td>Incident Characteristics</td>
<td>Treatment status: Inpatient:</td>
<td>Immediate Post-OP or ICU/HDU Care</td>
</tr>
<tr>
<td></td>
<td>Discipline Involved:</td>
<td>Intensive Care</td>
</tr>
<tr>
<td></td>
<td>People Involved: Healthcare Professional:</td>
<td>Nurse Practitioner</td>
</tr>
<tr>
<td></td>
<td>Person Reporting: Healthcare Professional:</td>
<td>Doctor</td>
</tr>
<tr>
<td></td>
<td>Staff Factors: Performance Factors:</td>
<td>Distraction/Inattention</td>
</tr>
<tr>
<td></td>
<td>Patient Factors: Communication Factors:</td>
<td>With Staff</td>
</tr>
<tr>
<td>Contributing Factors /</td>
<td>Directed to Patient:</td>
<td>Patient Referred</td>
</tr>
<tr>
<td>Hazards</td>
<td>Directed to Staff:</td>
<td>Relevant Persons Educated</td>
</tr>
<tr>
<td>Detection</td>
<td>Healthcare Professional:</td>
<td>Doctor</td>
</tr>
<tr>
<td>Patient Related:</td>
<td>Increase in Required Resource Allocation:</td>
<td>Increased Length of Stay</td>
</tr>
<tr>
<td></td>
<td>Legal Ramifications</td>
<td></td>
</tr>
<tr>
<td>Ameliorating Actions</td>
<td>Patient Related:</td>
<td>Compensation</td>
</tr>
<tr>
<td></td>
<td>Patient Related:</td>
<td>Management of Disability</td>
</tr>
<tr>
<td>Actions Taken to</td>
<td>Staff Factors:</td>
<td>Staff Supervision/Assistance</td>
</tr>
<tr>
<td>Reduce Risk</td>
<td>Organizational Factors:</td>
<td>Matching of Staff to Tasks/Skills</td>
</tr>
</tbody>
</table>

2. ICPS: What It Is Not

Is ICPS a classification? To answer this question we refer to existing desiderata, standards and evaluation frameworks for clinical terminologies and classifications [2–7]. For instance, [2] requires that every representational unit must have a unique identifier. It is therefore remarkable that ICPS, compared to other WHO classifications, completely lacks identifiers or codes, although numerous ICPS categories have identical names. So are there eight different categories with the name “Problem”, each of which inserted in a different hierarchic context. ICPS categories do not carry definitions either. Instead, ICPS provides a glossary of 46 Key Concepts with short textual definitions and uniquely identified by ordinal numbers. Most of these definitions are quite precise, although the choice of words is occasionally sloppy and unfortunate: So is Disability introduced as a “type of impairment (…)”, whereas Incident Type is introduced as a “descriptive term of a category (…)”. Surprisingly there is no linkage at all between ICPS Key Concepts and the classification itself,
although most of the names of ICPS Key Concepts are substrings of ICPS labels (e.g., *Violations*, *Error*, *Risk*, *Hazard*). Only seven of these concepts exactly match with ICPS categories (*Injury*, *Patient*). Finally there are numerous ICPS Key Concept names that do not occur even as substrings in any ICPS category label (e.g., *Preventable*, *Adverse Event*, *Near Miss*, *Resilience*).

Some of the 46 ICPS Key Concepts describe the representation itself: So is *Classification* introduced as an “arrangement of concepts into classes”. A *Concept* is defined as “embodiment of meaning”, and a *Class* is a “group or set of like things”. It is not clear which ICPS categories are classes and which are concepts. Furthermore, the documentation also contains terms like *taxonomy*, *thing*, *term*, *descriptor* in an unsystematic way. We also miss an account of the nature of hierarchical links in ICPS, in light of the quite universally accepted view that classifications and taxonomies are characterized by generic (*is-a*) hierarchies [5, 8]. The ICPS definitions furthermore conflict with the notion that the members of classes in classification system are particular objects [6] and not abstract concepts, just as the ICD classifies concrete diseases and other health problems and not concepts. Unfortunately, the distinction between particular objects on the one hand and classes or concepts on the other hand has been obfuscated by the promiscuous use of words like “class”, “concept”, “category” in authoritative documents such as [5, 9], criticized by [10]. The turn toward formal ontologies [11] has helped illuminate the distinction between classes, concepts and particulars. So are concepts abstractions of the inherent properties of particulars, and the relation between a particular and the corresponding concept is called instantiation. Concepts extend to classes of particulars which share certain properties. The close relation between a concept and the class it extends to explains why these terms are often mixed up. Formally, a class $B$ is a subclass of a class $A$ if all members of $B$ are also members of $A$. We express this relationship by the symbol *is-a*. It equals to what has been standardized as *generic relation* [5] or *subtype relation* in OWL [12].

An *is-a* hierarchy is also called a taxonomic order [5]. Classifications, according to [3, 6] (endorsed by [9] for the WHO-FIC classifications) carry an additional restriction that comes from the need to avoid duplicate attributions, viz. that the classes are mutually exclusive and exhaustive.

It is easy to demonstrate that the strict stipulations on hierarchical links do not hold for ICPS. So it is unclear, e.g., what the referent of the class *With Staff* is and whether it stands in an *is-a* hierarchy with the class *With Whom*. The same applies to the pair *Directed to Patient* and *Patient Referred*, as well as to *Patient Related* and *Compensation*. One could, however, regard the intermediate class *Patient Related* as a shortcut for “patient related ameliorating action” and *With Staff* could be an abbreviation of “communication with staff factor” (and *With Whom* a meaningless organization node).

The criterion of mutual disjointness is not fulfilled either, since more than hundred ICPS classes occur more than once in different hierarchies. E.g., *Healthcare Professional* occurs both as a child of *People Involved* and *Person Reporting*. A class that occurs in six different hierarchies is *Wrong Patient*. It is not clear whether these concepts are, in fact, different ones. Although there are good reasons for polyhierarchies, (albeit problematic in statistical classifications [2, 6]), the use of

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2 Examples of particulars: the endotracheal tube in Patient #123, his pneumonia, his current risk for ARDS, the amount of methicillin he got this morning by IV.

3 Recently, the use of the word “class” is superseding the use of “concept” (the latter has been criticized by several reasons). We therefore adhere to this convention, particularly in the context of clinical classifications.
multiple is-a links in ICPS sheds light on a phenomenon that goes beyond. So is an instance of Healthcare Professional not necessarily an instance of Person Reporting or an instance of People Involved, and nobody is by essence a Wrong Patient. Both are examples of what have been named non-rigid properties [13] or contingent is-a relations [14]. Such categories are rather roles that are played by material entities under certain circumstances. A cursory review of the ICPS reveals that most children of Problem stand for non-rigid properties or roles, e.g., Wrong *, Contraindicated, Unclean/Unsterile etc.

Concluding the typological analysis, using the criteria from [8], ICPS may qualify as terminology, but not as a vocabulary as even free-text definitions of its categories are lacking. It is not a thesaurus as synonyms are lacking. It is not a coding system as codes are lacking and it is not a classification as there is no is-a hierarchy. It cannot be seen as a nomenclature either as there is no composition mechanism.

3. What ICPS (Possibly) Is or May Become

If ICPS is neither a classification nor a taxonomy, not to mention any other kind of vocabulary, how can we nevertheless characterize it?

- The ICPS glossary is best described as an informal ontology, as it introduces concepts with textual descriptions of their generic properties. The descriptions use terms that can interpreted to denote types and relations in upper ontologies (e.g., in [15, 16]), e.g., “state”, “substance”, “event”, “agent”, “object”, “action”, “quality”.
- The ICPS CF may be seen as a complex patient safety model. Ontologically it could be interpreted as a kind of event, but it also looks like a business or workflow model. Its semantic relations like influences and informs could be specified in terms of necessary or optional attributes. Unlabelled arrows could also be made explicit.
- The ICPS tree can be described as a structured checklist of binary fields 4. The field names get their semantics from the hierarchic context. So is Delivery placed in the mixed hierarchy/attribute-value structure 5 Incident Type → Blood/Blood Products → Blood/Blood Products Use Process. It is assigned a “True” value if there is an incident as a consequence of a harmful delivery of blood or blood products.

There is some a similarity between ICPS and the HL7 Individual Case Safety Report (ICSR) standard and the Public Health Reporting Domain Information Model. Both are restricted to the reporting aspect, whereas the scope of ICPS seems to be much broader, covering information related to workflow activities related to patient safety. This may justify describing the ICPS hierarchical tree as a complex information model. However, ICPS leaves many questions unanswered, e.g., how to deal with overlapping categories such as incident types, or which items are optional etc. It is in from an information model perspective that ICPS has been implemented at the University Hospitals of Geneva in the context of the incident reporting system. The experience has shown that the information model can mostly be used by professionals in charge of managing incidents, while the report forms for users are implemented using free text.

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4 With the exception of Age, which is obviously not binary.
5 One possible interpretation is that Blood/Blood Products Use Process denotes a role and thus the entities listed below do not form a hierarchy but an attribute-value structure. E.g., one could describe an instance of a Blood/Blood Product Incident Type using the role Blood/Blood Product Involved, e.g., Cellular Products.
4. Conclusion

ICPS’s name and its closeness to the WHO-FIC [9] are misleading. ICPS is neither a classification nor a taxonomy. Its hierarchical tree could be described as an information model or reporting template. As such it is well-thought and may be suited for the purpose being devised for. The glossary may play an important role to clearly define the concepts that are addressed in the tree labels. To this end, its coverage should be increased and the Key Concepts should be bound to the fields of the tree. ICPS is being used within the European FP7 project DebugIT [17]. Here, the whole conceptual space addressed by the fields in the ICPS hierarchy is identified and remodeled in an OWL [12] ontology, in order to achieve a formal representation of patient safety relevant issues, still compatible with ICPS. Other information models covering the patient safety domain will also being analyzed as knowledge source potentially relevant for the DebugIT ontology such as Individual Case Safety Report (ICSR) standard and the HL7 Public Health Reporting Domain Information Model [18].

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References