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Medical Informatics in a United and Healthy Europe

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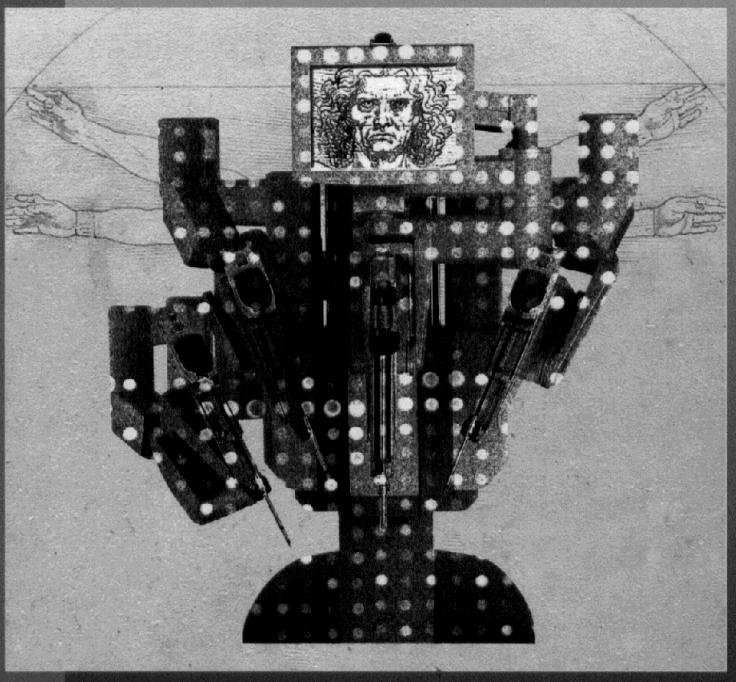

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Is the International Classification for Patient Safety (ICPS) a Classification?

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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 ontology principles 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 facilitate reporting by care providers, collaboration of researchers and international data exchange. 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.

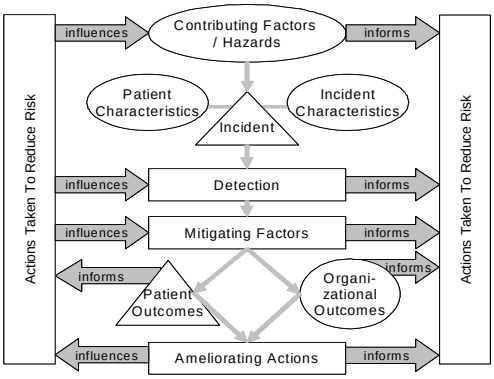

Fig. 1: ICPS conceptual framework

2. ICPS: Architecture

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 *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

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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 1: ICPS major classes with subdivisions and example concepts

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

3. ICPS: What it isn't

Is ICPS a classification? To answer this question we refer to existent desiderata, standards and evaluation frameworks for clinical terminologies and classifications [2][3][4][5][6][7]. For instance, [2] requires that every concept 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* that are provided with short textual definitions and uniquely identified by an ordinal number. Most of these definitions are relatively 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. *Violation*, *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.[2] 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.[3]

Formally, a class B is a subclass of a class A if all members of B are also members of A. For this relationship we use the symbol *is-a*. This relation 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 [6][3] (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 is it 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

[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 entities can play 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.

4. 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 further 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.

[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*.

5. 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 will be used within the European FP7 project DebugIT [17], by identifying the whole conceptual space addressed by the fields in the ICPS hierarchy and remodelling them 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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