

# Toward a Patient Safety Upper Level Ontology

Julien SOUVIGNET<sup>a,b,1</sup> and Jean-Marie RODRIGUES<sup>a,b</sup>

<sup>a</sup>INSERM, U1142, LIMICS, F-75006, Paris, France;

Sorbonne Universités, UPMC Université Paris 06, UMR\_S 1142, LIMICS, F-75006, Paris, France;

Université Paris 13, Sorbonne Paris Cité, LIMICS, (UMR\_S 1142), F-93430, Villetaneuse, France

<sup>b</sup>Department of Public Health and Medical Informatics, University of Saint-Etienne, France

**Abstract.** Patient Safety (PS) standardization is the key to improve interoperability and expand international share of incident reporting system knowledge. By aligning the Patient Safety Categorial Structure (PS-CAST) to the Basic Formal Ontology version 2 (BFO2) upper level ontology, we aim to provide more rigor on the underlying organization on the one hand, and to share instances of concepts of categorial structure on the other hand. This alignment is a big step in the top-down approach, to build a complete and standardized domain ontology in order to facilitate the basis to a WHO accepted new information model for Patient Safety.

**Keywords.** Ontology, Alignment, Terminology, Patient Safety

## Introduction

Today, more than ever, data quality management has become a crucial and strategic topic within the health care domain [01,02]. Institutions and organizations are increasingly aware of the importance of data quality in medical databases: The more the quality of stored medical data is ensured, the better is the information for dependent applications and analytics [03].

Some risk management systems established at national or international level aspire to integrate a quality assessment phase. But these risk assessment systems are so heterogeneous that the systematic exchange of safety-relevant information is prevented, and their efficiency is clearly mitigated by their inability to interoperate [04].

A standardized representation of Patient Safety (PS) information using quality structured models is therefore essential for comparison and trend detection in reporting incidents, which often lead to adverse healthcare events.

Since 2004, the World Health Organization (WHO) Patient Safety Program, aim to accelerate and expand patient safety improvement by proposing advanced quality models [05]. In this context, in 2009, WHO published a first report presenting a conceptual basis for an International Classification for Patient Safety (ICPS) [06]. This report offered a list of terms and definitions of some patient safety notions organized in a conceptual framework showing the elements in large abstract categories called “key concepts”. When a consensus was established on definitions of PS terms, several issues were raised with the conceptual framework, e.g. that “there is no linkage at all between

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<sup>1</sup> Corresponding Author.

ICPS Key Concepts” [07]. Indeed, this model lacks a solid semantic foundation, preventing it from being computable. Other authors claimed that “further effort is required [...] following [an ontological] methodology” [08].

In 2011, taking into account these expert advices, these issues were addressed in PS-CAST, (Patient Safety - Categorial Structure) [09], an ontological representation of Patient Safety, which add a formal representation to the ICPS conceptual framework using the normalized Categorial Structure method.

The Categorial Structure from CEN/ISO (European Committee for Standardization /International Organization for Standardization) is an ontology-driven approach defined as a minimal set of constraints to represent a biomedical terminology in a given health care domain with the goal to communicate safely [10]. CAST is a model of knowledge restricted to 1) a goal, 2) a list of semantic categories, 3) the list of semantic links between semantic categories, and 4) the minimal constraints allowing the generation and the validation of well-formed terminological expressions.

In 2012, WHO contracted a (non-public) report about an International Information Model for Patient Safety (2IMPS) [05]. By using the ontological representation of PS-CAST to ensure the quality of data, IMPS also ensures validation of comparisons of PS data among countries and institutions.

In order to strengthen PS-CAST, aiming to be robust and able to integrate different PS systems in the world, even more structure and semantic explicitness is required, entailing more constraints and more standardization. Therefore, we decided to align PS-CAST to upper level ontologies (ULO).

ULO are designed to achieve better organization, integration and interoperability of biomedical data. In a first attempt, in 2012, PS-CAST was aligned with BFO (Basic Formal Ontology) [11], but this work was of little relevance because BFO’s version 1.1 did not include relationships, and as a consequence the constraints required for PS-CAST could not be expressed. As BFO version 2 includes relations, this impasse should be overcome [12].

This paper consists in three parts: 1) our material: the PS-CAST based International Information Model for Patient Safety; and 2) our alignment method between PS-CAST classes and BFO2.0 upper-level ontology; Then, 3) we share the results of ULO formalization, and finally 4) we present the perspectives of this work for international standardization of Patient Safety data.

## **1. Material**

In 2010, PS-CAST had to preserve to the largest possible extent the integrity of the conceptual framework by in terms of concept definitions and names [09]. However, PS-CAST also had to specify relationships between concepts which mostly exist intuitively in the conceptual framework and lists compulsory domain constraints that authenticate particular analytical perspectives.

In 2014, PS-CAST has evolved to a degree that it is now fully compliant with multiple reporting systems in the world, and is thus paving the way for advanced (and hopefully efficient) processing of Patient Safety information (see Figure 1).



**Figure 1.** Representation of the Incident Model in current PS-CAST ontology.

Basic Formal Ontology (BFO) [11] is a philosophically inspired upper ontological framework, which provides universal categories as a basis for domain ontologies. BFO 2.0 was presented in 2012 [12]. In the paragraphs below, we will use “BFO” to specify properties that apply to all versions of BFO, if necessary, the exact version of BFO is indicated (BFO 1.X or BFO2.0).

BFO relies on a central organizing axis: the dichotomy between continuant and occurrent. Continuants are entities that persist, endure, or continue to exist through time while maintaining their identities and occurrents are entities which exist in full in a single instant of time. An entity is anything that exists or has existed or will exist, and entities are linked together in relations.

One of the main changes in BFO2.0 compared to BFO1.X is the inclusion of relations. Before, it was suggested that relations had to be taken apart, for instance using the Relation Ontology (RO). The BFO2.0 version includes most of RO but with changes to relations (exists\_at relation added, parthood disambiguated, contained\_in deprecated, etc.) [12].

BFO provides a coherent and unified understanding of fundamental ontological entities to describe a science-based reality, and aims at integrating domain terminologies such as biomedical ones.

## 2. Methods

The BFO 2.0 Reference Guide [12] describes the conditions which must be satisfied by entities to be categorized as instantiating the different BFO 2.0 types. Based on this guide, a manual alignment was performed by two experts; their aim was to align concepts of PS-CAST with BFO and indicates the type of relation describing this alignment. The first expert validated the coherence of the propositions in term of patient safety, while the second expert validated the ontological coherence.

The alignment method involved three steps. First, we performed an analysis of the concept definitions and elucidations proposed in BFO2.0. Then a search for alignments between PS-CAST and these concepts was performed. Then alignment proposed was then reviewed the experts. If concepts definitions were unclear or inaccurate, or if a relation was questionable, new proposals were made.

In addition to ontological constraints, the experts had to follow the monohierarchy principle, a strategy for ontology building recommended by BFO users. It involves the creation of *is\_a* hierarchies so that each concept should have at most one *is\_a* parent.

The mapping was based on the OWL-DL versions of both ULOs, using taxonomic subsumption (“is-a”) (A subClassOf B or A subPropertyOf B), equivalence (A equivalentClass B or A equivalentProperty B) or instances relations (A instanceOf B).

The mappings were considered complete when a consensus was achieved between experts. The logical consistency mappings was checked by a reasoner (HerMiT OWL-DL reasoner [13]) that check if no violation of domains and ranges were made and ensures that the merged structure does not imply any incompatible inferences.

### 3. Results

We produced a new version for PS-CAST ontology linked to BFO2.0. We created, 52 concept mappings with BFO2.0 (32 for concepts and 20 for relations), we failed to create 2 mappings of relations (for “hasCause” and “hasConsequence”), see Discussion. An excerpt of alignments is presented in table 1.

**Table 1.** Excerpt of main alignments between PS-CAST and BFO2.0

PS-CAST Concepts	(link) BFO2.0
Incident	(subClassOf) Process
Incident_Type	(subClassOf) Generically Dependant Continuant
Outcome	(subClassOf) Disposition
Action	(subClassOf) Process
Circumstance	(subClassOf) Disposition
Detection	(subClassOf) Process
Care_Setting	(subClassOf) Site
Agent	(subClassOf) Material Entity
Role	(subClassOf) Role
hasType	(subRelationOf) hasContinuantPartAtAllTime
hasConsequence	-
hasSituation	(subRelationOf) hasOccurentPart
hasCause	-
hasDetection	(subRelationOf) hasOccurentPart
hasLocation	(equivalentTo) HasLocationAtSomeTime
hasAgentInvolved	(equivalentTo) HasContinuantPartAtSomeTime
hasRole	(equivalentTo) HasRoleAtSomeTime

### 4. Discussion

In PS-CAST, “hasCause” and “hasConsequence” relationships involve causality. This refers to a trigger-and-realization process pair. However, BFO does not incorporate any theory of causality [12]. We could have used the accommodative relation “hasDisposition” but, to respect strictly BFO2.0 guidelines, we did not create any alignment with these relations.

We have reported the use of CAST and ULO informatics methods to develop and enhance the International Information Model for Patient Safety. By adding constraints e.g.; providing more rigors on the underlying organization on the one hand, and to share instances of concepts of categorial structure on the other hand. This alignment is

a big step in the top-down approach, to build a complete and standardized domain ontology.

Thanks to this consistent architecture we plan to facilitate the basis to a WHO accepted new information model and its associated value sets that will allow the comparisons of incident reports to support the whole process from identification of the incidents to correcting and preventing actions and permanent control of the security of patients.

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