

## Response to reviewers of Manuscript ID: ME10-02-0016<sup>1</sup>

Title: An Evolutionary Approach to Realism-Based Adverse Event Representations  
Author(s): Ceusters, Werner; Smith, Barry; Capolupo, Maria; De Moor, Georges; Devlies, Jos

**18-Jun-2010**

**Dear Prof. Ceusters:**

**The above mentioned manuscript which you submitted to the special topic “MIE 2009” of Methods of Information in Medicine has been reviewed. We would like to congratulate you that it has been selected for the special topic on MIE2009 after successful revision. The comments of the reviewers are included at the bottom of this letter. The reviewers have suggested "minor revision" of your paper.**

**Please resubmit your manuscript to Methods of Information in Medicine, and please consider carefully the suggestions of each of the reviewers.**

**[...]**

**Once again, thank you for submitting your manuscript to Methods of Information in Medicine and we look forward to receiving your revision.**

**Sincerely,  
György Surján Reinhold Haux  
Guest Editor Editor-in-Chief**

**All correspondence to:  
ed@MethodsInfMed.org**

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### **Reviewer(s)' Comments:**

#### **Reviewer: 1**

**Backed by good evidence (broad range of contradicting and shallow authoritative definitions), the authors advocate the need of standardized adverse event definitions. To this end they propose an ontological framework and provide anecdotic evidence that this framework may be appropriate.**

**Although there is no evaluation of the usability of the framework, this is reportable and important work, and the paper should be accepted with some modifications (see below).**

**[R1] One concern of the reviewer refers to the distinction between universals and defined classes, which brings in additional complexity without any obvious benefit for the construction, maintenance, and use of the ontology. More convincing arguments why this distinction is necessary would be appreciated.**

We added a paragraph clarifying the distinction and the relevance

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<sup>1</sup> Editor's and reviewers' comments are printed in **bold blue**. Authors' responses in black.

**[R2] A weak point of this paper is the discussion of related work: the most significant work that should be cited (as it claims to use ontological principle) is the International Classification for Patient Safety (ICPS) with several publications in 2009.**

We have done and added a new section on ICPS

**Detailed comments.**

**Abstract:**

**[R3] Spell out “RAPS”**

This has been done.

**4.1. and tables 2-6**

**- [R4] “Disease diagnosis” is defined using “clinical picture”, which is a quite shallow concept and not further defined.**

we added the definition from the feeder ontology OGMS in table 2

**- [R5] Some acronyms are in bold face. Is this accidental?**

no, as was (and still is) explained in section 4.1 together with all the other typographical conventions used

**- [R6] The indentation should be better visible, e.g. by using hyphens?**

I believe that typesetting of the final paper will be done by the journal staff. Tables will look different.

**- [R7] Crucial concepts are not defined, e.g. “Mental”**

the appearance of ‘MENTAL’ in table 3 was the result of a cut and paste error. The corresponding row has been removed.

**- [R8] I miss the category “quality”, which would be helpful for a better understanding of “Anatomical Structure Integrity”**

We added it

**- [R9] An important concept is “change”, which also lacks a definition**

“change” has not been introduced anywhere as a universal or defined class. A classical non-technical, everyday meaning of “change” is used in the paper.

**- [R10] is the distinction between universal and defined classes really practically useful? In DL there are only classes, anyway. Whether a class extends a universal or a concept or whether it is built from other classes using logic constructors (e.g. “not Disease”) has a minor relevance. There are domain terms that denote what may be universally accepted as universals and other ones which denote concepts or “fiat universals” (e.g. hypertension) and other ones somewhere in between. These boundary discussions may be philosophically interesting but of minor relevance for the construction of representational artifacts in a formalism that does not make any distinction between universals and non-universals. In the same vein, the distinction between member\_of and instance\_of is useless if we don’t go beyond what is expressible with DL.**

see [R1].

But note in passing that I can rephrase the argument of the reviewer as follows: why would I make the distinction between France and Germany since I personally don't speak German or French anyhow?

**[R11] - what about terms in the 3rd column which are not preceded by any feeder ontology acronym?**

as was (and still is) explained in section 4.1, those terms are introduced specifically for the ReMINE ontology.

#### 5.4.

- [R12] **CHECK: There is no #17 in Table 7. Revise your example.**

there should not be one. We are describing here an *alternative* position the clinician could have taken. We made it however more clear that it is an alternative.

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#### Reviewer: 2

##### 1 general comments

**[R13] 11 the international context of patient safety is not comprehensively assessed by the multitude of definitions and their terminological wilderness with a main reference to a report in one country and in 2000**

Since then an International initiative by WHO and world alliance has contributed to this field trying to harmonize the terminological knowledge with an ontology approach some references are

[3] Department of Health. **An Organisation with a Memory - Report of an Expert Group on Learning from Adverse Events in the NHS** Chaired by the Chief Medical Officer. London: The Stationery Office, 2000.

[4] Runciman WB, Moller J. **Iatrogenic Injury in Australia**. Adelaide: Australian Patient Safety Foundation, 2001. Available at <http://www.apsf.net.au>

[5] World Alliance for Patient Safety. **International Classification for Patient Safety**. <http://www.who.int/patientsafety/taxonomy/en/>

[6] Runciman WB, Williamson JA, Deakin A, et al. **An integrated framework for safety, quality and risk management: an information and incident management system based on a universal patient safety classification**. *Qual Saf Health Care* 2006;15 Suppl 1:i82-90.

[7] ICPS (2008). **The Conceptual Framework for the International Classification for Patient Safety Version 1.0 for Use in Field Testing**, Geneva, WHO, <http://www.who.int/patientsafety/taxonomy/en/>

We studied these papers in 2008 and the results were published in Ceusters W, Capolupo M, De Moor G, Devlies J. **Introducing Realist Ontology for the Representation of Adverse Events**. In: Eschenbach C, Gruninger M. (eds.) *Formal Ontology in Information Systems*, IOS Press, Amsterdam, 2008;:237-250

**[R14] 12 Following this point assessing patient safety risk ONLY through the data of the Electronic Health Records (EHR) shall be restricted to a part of the issue for the semantic interoperability between EHR and other forms of already existing Patient Safety reporting systems can be more difficult and need more the use of the ontology based tools proposed by the paper**

We agree

**[R15] 13 The realism based ontology which is developed is well expressed by the authors who are the international reference of this approach in bio-informatics but it does not show the specificity of the approach for patient safety**

This comment is not clear. On the one hand, ontological realism is a generally applicable doctrine and not supposed to be specific. On the other hand, we applied it

here specifically to adverse events by describing the entities that are relevant in this context

**[R16] nor the evolutionary character mentioned in the title**

This was addressed in section 5.4, quote: “This approach, which in contrast to related work reported in [ref] provides an evolutionary view on reality, allows us to track in detail and with various kinds of subtleties how the relevant portions of reality and the stakeholders’ beliefs therein evolve over time.”

**[R17] 14 The discussion is interesting with the proposal of the 3 levels of reality filter and pointing the lack of clarity of definitions :It is less convincing when managing the subtleties in an unambiguous RAPS**

The point is that the RAPS system *is made* unambiguous by applying this analysis.

**2 specific comments**

**[R18] 21 The acronyms shall be defined the first time they appear in the text**

This has been taken care of

**[R19] 22 The choice to explain the content of the tables in the annexes within the chapters results and discussion makes the understanding more difficult**

We leave the layout of the paper to the Journal editor

**[R20] 23 The different definitions shall be extended to the ones of the WHO World alliance initiative named ICPS (International Classification of Patient Safety)**

The ICPS provides definitions for terms under a concept-based view and is as a consequence full of ambiguities. We do not define terms, but describe entities in reality that might be referred to when talking about adverse events, for instance by using ICPS terms. We added a section making these issues clear.

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**Reviewer: 3**

**Good paper which presents an interesting implementation of an ontology.  
Too concise and sometimes cryptic in some parts (especially section 4).  
Good bibliographic section, but a little bit self-referent.**

**[R21] In the summary, make explicit the meaning of the acronyms RAPS and OBO.**

This has been done

**page 3, line -6**

**[R22] Please explain why the common sense definition given for "adverse event" is referred as "cognitive engineering position". It is not clear the role of cognitivism in such a definition.**

We removed the adjective ‘cognitive’

**section 3**

**[R23] The methodological approach is clear, but how is the ontology implemented? Was OWL-DL used or other formalisms. Please, make it clear.**

A paragraph covering this has been added to section 5.4

**section 4**

**[R24] Without reading papers quoted as n. 12 and 30, it is difficult to understand clearly the ontology implemented. Some more details of the work previously done should be given**

We added some more definitions as also requested by another reviewer

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**Editorial Comments:**

**[R25] As is well-known, references to the relevant literature are a requirement for publication in a scientific journal. We suggest that authors be especially aware of, and refer to recent articles in Methods of Information in Medicine, that are relevant to their work, since this will allow Methods readers to better follow topics of special interest to them.**

We did a Pubmed search on “ontology” or “adverse event”, restricted to this journal, and found one relevant paper. We added the reference.

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