Reviewer’s report

Title: Requirements for Guidelines Systems: Implementation Challenges and Lessons from Existing Software-Engineering Efforts

Version: 2 Date: 6 November 2011

Reviewer: David Isern

Reviewer’s report:

The paper has been amended accordingly with the comments made by the reviewer, but the reviewer has some additional comments.

The change of the focus of the paper is quite interesting in order to tackle the main drawback of existing guideline-based systems: fill the gap between academic and commercial systems. As the authors noted, existing CGs does not apply desirable security and tailoring techniques used in other environments.

Major Compulsory Revisions

The authors have included through the paper a lot of references and the current release of the manuscript is quite confusing merging old with new requirements. I recommend the authors to summarize those new requirements in a table grouped by main topics (knowledge representation, ambiguity, etc.).

For instance, on pages 6-7, requirements about knowledge representation (KR) are analyzed. The authors identify several sub-requirements related with KR such as modularity, reusability, use of design patterns, etc. but some of these requirements are also identified in the past, such as the latter identified in works of Peleg and Tu.

On page 7, the subsection named ‘Permitting Ambiguity: Parameterization’ is not well justified. I agree with the authors that the parameterization of CGs is interesting, but the section talks about two different types of parameterization that are not well distinguished. In one hand, the adaptation of a CG to local circumstances, and on the other hand, allowing the use of ‘fuzzy’ states inside CGs in order to represent a non-evidence-based state. I think that these two perspectives should be clearly identified.

Section ‘Complex Coordination: Relation with Business Workflow Systems’ is quite interesting and requires more details.

The section begins with the introduction of several concepts coming from the business side. Then, the authors identify a list of requirements based on their experience. Some of them should be explained in detail in order to introduce them to clinicians. Particularly, integration, robustness and scalability are not well explained. Authors can use examples of using existing medical systems such as CPOEs or EHRs in order to explain how CGs can use these systems as facilities during its enactment. Modularization and reusing existing systems have pros and
cons that also should be analyzed. Moreover, one of the items identified is particularly critical: the participation of humans during the process. In this sense, several papers talk about a general reticence of practitioners to use guideline-based systems in daily care.

On page 15, section ‘Implications of Longer Duration of Execution’ should be improved. The authors introduce the problem but the solutions proposed by business-workflow engines are not well detailed. Persistence is a technique to maintain the correct state of data. The authors should include more examples explaining how persistence could solve the described requirement. In addition, the second situation (‘A sophisticated version-aware runtime engine’) should be explained.

Conclusions should be improved drastically summarizing the main (new) requirements identified by the authors. It is important to note the step made with this paper towards the widely adoption of these type of systems in daily care, assuming the advantages provided to practitioners and patients.

Minor Essential Revisions

In (Ingenae et al, 2010) a rule-based guideline-based execution engine using Drools is introduced. It could be added to the ‘Requirements’ section because it is a good example that combines medical ontologies, standard representation languages, and a complete case study.

Concerning the ‘parameterization’ and ‘requirements -issues 4 and 5-‘ sections, in (Batet et al, 2011) we addressed the modularization and personalization of CGs to local/patient circumstances. At first, the paper distinguishes different layers of abstraction, then, it presents the concept of individual intervention plan, which are general guidelines adopted to the particular circumstances of the patient, and finally, it presents a distributed architecture to enact those sequences of medical actions over a patient during a mid or long term period.

Discretionary Revisions

I have a formal doubt about how to add references to tools or URLs. The paper combines two ways: including the URL in the text (inline), and adding a reference at the end of the document (outline). Please, revise the ‘guide for authors’ of the journal to harmonize them.

Sweidan et. al, (2011) deals with evaluation measures (safety and quality) associated with clinical software that could be adopted by guideline-based systems.

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**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests