Author's response to reviews

Title: A study of diverse clinical decision support rule authoring environments and requirements for integration

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Author's response to reviews: see over
September 2, 2012

BMC Medical Informatics & Decision Making

Dear Editors,

We are resubmitting our revised manuscript, entitled “A study of diverse clinical decision support rule authoring environments and requirements for integration” (MS: 4911017107484), for possible publication in the BMC Medical Informatics & Decision Making. This manuscript has not been submitted for publication nor has it been published in whole or in part elsewhere.

Thank you for your review of our manuscript. We appreciate the four reviewers’ valuable comments and revised the manuscript based on their suggestions. We addressed each specific item of each reviewer’s comments, point-by-point. We also mentioned the corresponding changes made in the revised text.

Thank you very much for considering our work. We look forward to your review of our revised manuscript.

Sincerely,

Li Zhou
Reviewer's report
Title: A study of diverse clinical decision support rule authoring environments and requirements for integration

Version: 3 Date: 22 July 2012
Reviewer: Beatriz Pérez

Reviewer's report:
Overall evaluation and recommendation
1. The manuscript targets somehow an interesting topic of relevance to the field of the journal. In general, the paper is well written but I personally think that it could have been better organized. From my point of view, authors would need to structure the paper in such a way that the Results section would present major findings including the limitations of the RAEs, and the Discussion section would be devoted to place the results in context, presenting their proposed set of requirements and key functions needed to be supported for a successful integrated RAE. Additionally it would address, as they do in the current version, study limitations.

Response: We agree with this assessment of the paper structure and reorganized our manuscript along these lines. The Results section includes our review of current RAEs and findings regarding their limitations based on commentary from end users, and the Discussion section now includes our analysis of key functions and requirements for an integrated system.

2. Additionally, although the considered RAEs are particular to Partners Healthcare, it would be of great interest that the authors would generalize such findings comparing them at least with some standardized approach.

Response: We added a review of existing guideline modeling languages and tools. These tools are primarily developed for capturing the knowledge from guidelines to create a structured recommendation represented in a specific modeling language. None of these existing tools facilitate the entire process flow of transforming free-text content into formal representations and then further into executable rules designed for deployment in a clinical environment.

My personal recommendation is that authors should prepare a major revision for a second review, structuring and distinguishing, in a clear way, results from discussion and contribution.

Response: we have revised the Results and Discussion based on the reviewer’s comments.

Major Compulsory Revisions
3. Related work.
   The authors present related work about computer-interpretable models for the management of guidelines (such as GLIF, Asbru, PROforma, GLARE, etc.) and note Arden rule-authoring environment as an attempt to standardize rule authoring tools. As they admit, a major limitation of their analysis is the
consideration of particular RAEs used across the Partners Healthcare and, continue saying that they cannot give a generalization of their results to other institutions because of the wide variety of systems. Nevertheless, I consider that it would be of interest for the reader to identify the similarities and differences between the considered Partners’ RAEs and, at least, the proposed standardization.

Response: It would be difficult for us to compare Partners’ experiences with local tools to any standard RAE because there is no generally accepted standard tool as of now. Most tools are developed to help capture the knowledge from guidelines to create a structured recommendation represented in a specific modeling language. Arden is a proposed standard knowledge model but there is no standard authoring environment for Arden. Many institutions that use Arden use commercial tools to author rules, and we have insufficient information about these tools to make meaningful comparisons to our experience. We mention the Columbia MLM tool as an attempt to provide a standard Arden authoring environment, but as far as we are aware this tool is not widely used. Our aim is to gather requirements from our experience with local systems which should hold true for other institutions, tools, knowledge representations and data models.

4 Description of the RAEs considered in the analysis

On the other hand, I also think that the paper should be enhanced by including in Subsection “Diversity and Unique Features of the Rule Authoring Environments” a description of the Medication Rule Editors, as they do with the Reminder Rule Editors, so that the reader can have a general idea of the main characteristics of such RAEs.

Response: The manuscript includes a description of the DDI editor, one of several editors that deals with medication rules that we have in production. We have added a screenshot and description of the Medication Rule editor as well, to show the contrast between the two.

5 Contributions of the paper

In addition to present the RAEs and their limitations, authors give their own proposal for the requirements a successful integrated RAE would have to include. Such requirements are useful and intuitive, but it seems that they are presented only by means of Table 2, for which they do not include any explanation. Later, in the Discussion Section, some of the identified key functions are related to some aspects identified in the previous Table 2 (reporting, terminology integration, testing…). Are the requirements related to the key functions that need to be supported by RAEs? If it is the case, why do the authors not present such requirements and functions together? Perhaps they could present them together as an only approach. I think that there is a bit of mess among the identified requirements and functions. Authors would have to rewrite it.

Response: We attempted to reorganize the manuscript to better tie our assessment of critical function to the requirements table in the Discussion section.
On the other hand, Figure 4 seems to be out of place. I was expecting to found a description of the key functions leaning on this figure all along the section. If authors want to use such a figure, it would have to be used to support their key functions’ proposal.

Response: We agree that figure 4 did not add to the discussion and removed it.

Minor Essential Revisions
7 Figures
I think that the explanation of Figures 2 and 3 would have to be included within the corresponding section, or in an appendix. As I have said previously, Figure 4 needs further explanation.

Response: We intended for the descriptions of Figures 2 and 3 to be included in the figure captions, rather than the text, because we refer to parts of the user interface in detail. Figure 4 removed.

8 Language.
I have found spelling errors the authors would have to correct. For example, “Shahar et al [5]” instead of “Sharhar et al [5]”, or “GLIF [8]” instead of “GLIF,[8]”, definitely, they have to take care of the written.

Response: Spelling errors were noted and corrected.

9 Bibliography.
I have missed a RxNorm and HL7 reference, excluding this, the manuscript contains sufficient and appropriate references.

Response: We have added references for HL7 and RxNorm.

Level of interest: An article whose findings are important to those with closely related research interests
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.
Reviewer's report
Title: A study of diverse clinical decision support rule authoring environments and requirements for integration
Version: 3 Date: 1 August 2012
Reviewer: Claudio Eccher

Reviewer's report:
The manuscript reports the analysis of RAES at Partners in order to define requirements for a scalable and comprehensive tool to manage enterprise level rules for CDSs.
The problem of designing efficient, user friendly, collaborative and reliable tools for knowledge acquisition for CDSs is well known and a relevant topic in current medical informatics research.
The results, however, are interesting but not new, most of them confirm results well known by the medical informatics community
Some comments to improve the clarity of the paper in Discretionary revision.

-Major Compulsory Revisions

-Minor Essential Revisions
Missing Journal name in reference 21

Response: we added the journal name to the reference.

-Discretionary Revisions
Section Background
1) Sentence: “Guideline modelling tools such as Asbru, EON, GLIF.. etc.“ Actually, the cited acronym refer to modelling languages and/or complex methodologies to guideline modelling, authoring, and execution, possibly complemented with modelling tools (e.g., DELTA for Asbru, Protégé for EON), the sentence should be modified to:
“Guidelines modelling tools such as those for Asbru, EON, GLIF,ecc.”

Response: we revised the text to differentiate modeling languages vs. tools for these languages. Changes can be found in the 1st paragraph of Background.

2) Sentence: “They served to isolate knowledge base form execution…” The sentence seems to suggest that rule editors allow the separation between knowledge bases and the software to execute them (information model). Actually, the isolation of knowledge bases from the execution system is precisely the aim of developing formal guideline languages, since this approach allows building a general execution engine maintaining and updating only the knowledge base. Moreover, this is the approach that should be adopted in building a decision support system. The building of rule editors that operate only on knowledge bases is a consequence of this approach. If the knowledge bases were not separated from the execution engine when designing the CDS, it can hardly be
done by a rule editor.

Response: we revised the text to reduce the confusion. Early design was often hard-coded rules in EHR systems. Recent efforts have been made to design rule editors that isolate knowledge base from execution. Regier et al present a tool that allowed the separation between knowledge bases and the codes to execute them, but no formal information model was clearly defined. Changes have been made in the 3rd paragraph of Background.

3) Sentence: “Efforts have been made at other institutions to design standardized rule authoring tools…”
To my knowledge, the efforts are towards the design of tools for specific guideline modelling languages. The design of a standard tool that can build knowledge bases in every language is a very difficult task due to the peculiar features of each language. Even though, as studied by Peleg et al., Task-Network Models CIGs (Computer Interpretable Guidelines) have in common many components, they differ in the underlying decision models, goal representation, use of scenarios, and structured medical actions.

Response: we agree with reviewer. We added a review of tools for guideline languages in the background section (including specific graphical and markup tools for these reviewed guideline models). We also pointed out that standards and mechanisms are still needed to allow these diverse guideline models and tools to be shared between different institutions and software platforms and to be used to encode guidelines as part of real CDS systems.

Subsection Goal Analysis
4) Sentence: “This step is critical to help us identify possible solutions to achieve our goal of developing common CDS rules as…well as centralized rule execution services.”
In my opinion, the use of a common knowledge representation language is the necessary condition to develop common CDS rules.
In the paragraph above, however, the authors state that “diverse RAEs have been developed at different time periods for different purposes and implemented on different platforms.” The authors should specify which CIGs the CDSs use and if there is a common formalism. In my opinion, the impossibility of developing common CDS rules is not due to the plurality of RAEs at Partners, which is the consequence and not the cause of this problem.

Response: based on the reviewer’s suggestion, we specified that there are no common knowledge representation formalisms or computer-interpretable guideline models that have been used to develop these CDS rules.

Section Methods:
5) For the sake of clarity, the authors should specify which kind of rules the clinical reminder CDS(s) and the medication management CDS use. Simple if-then conditions? More sophisticated task network languages? Again, to they
use the same formalism?
Response: They don’t use the same formalism and don’t employ a computer-interpretable guideline language. We have added a statement in the “Goal of Analysis” to clarify this. In the results section, we present detailed information about what the rules look like. Under the “Major Limitations – Nonstandardized” section, we specified that “most rules are expressed using local dictionaries and using non-standardized knowledge representations”.

Section Results
Subsection Overview of the Rule Authoring Environments
See comment under Result section.
Subsection Major Limitations of Current Systems
6) Sentence: “However, it is unclear to what degree these limitations are due to the diversity of authoring environments, […], rather than the lack of shared knowledge repository, execution engine, or underlying knowledge representation.”
This sentence seems to be in contradiction with the following paragraphs (Isolated, Nonsharable, Nonstandardized) where the authors correctly recognize that the common source of problems is the lack of a standardized language and shared knowledge based. In fact, in my opinion the diversity of RAEs environments are not limitations of the RAES, but a consequence of the fact that currently a common rule language and a common knowledge repository have not yet defined at Partners.

Response: we have revised this sentence as following “While some of these current limitations could be addressed by consolidating the diverse authoring environments, other critical limitations are a result of the lack of a shared knowledge repository, an integrated rule execution engine, and a common knowledge representation.”

Paragraph Nonextensible
7) Sentence: “The current RAES are not well-structured to accommodate the future complexity of knowledge representation needs due to the content diversity.”
The authors should elaborate on this. The sentence is not clear because they do not detail what kind of representation language CDSs use. If the CDSs are based on if-then rules, they can accommodate all the knowledge expressible with if-then rules. If new knowledge is not expressible in rules, the adoption of a different knowledge representation language, and the consequent modification of RAES, is needed.
In general, the effort of the guideline community has been to define CIGs that can accommodate all the present and future knowledge expressible in guidelines. RAES are tools to put the medical knowledge in the chosen format.

Response: we further elaborated the “Nonextensible” section. We explained that the existing RAES were built to support the current state of the rule content, which is primarily if-then logic and some of the user interfaces were customized to match Partners’ local terminology. Rules
with complicated logics (such as chaining and inferencing) are not supported. Having a flexible, integrated authoring environment that is not content specific would require an underlying extensible knowledge representation model that is able to accommodate the present and future knowledge.

Section Discussion
Subsection Critical Success Factors
Sub-subsection Collaboration Support
The following sentence, however, puzzles me: “In the current system, most rule specifications are stored in Microsoft Word or Excel documents.”
Are these rules machine executable? Are they written in Visual Basic Application or as text? Are your CDSs based on engines for VBA? If rules are stored as text, how can CDSs at Partners use them for giving support? And do RAES maintain textual CIGs?

Response: we cited the article provided by the reviewer. These specifications that are stored in MS words and Excel are not machine executable. They are documents and specifications used or generated from the collaborative processes (e.g., intermediate representation of rule logic). A robust RAE should allow KEs to create free-text or intermediate semi-structured representations of rule logic, allow SMEs to comment on and adjust the logic, convert them to a formal, executable representation, and then submit it to developers to integrate into the receiving application for execution, all in an ordered and standardized method.

Sub-subsection User-interface
9) Sentence: “Some commercial or open-source products mainly use traditional rule logic representations and artefacts such as if-then rules, decision tables, and decision trees.” What do the CDSs at Partners use? I understood that CDSs were rule based. Are they hard-coded in Java component? How are they related to rules in Excel or Word?

Response: CDS at Partners are rule based. SME and KEs use existing rule editors to author CDS rules. Programmers code these rules (or convert these rules from rule editors) in JAVA or Cache. CDS documents and specifications that cannot be shared using existing RAE are shared via Excel or Word.
The problem is that some commercial or open-source products mainly use traditional rule logic representations and artifacts such as if-then rules (with specific syntax), decision tables, and decision trees. These artifacts are easy to understand and manipulate by programmers but not
intuitive for KEs who usually have limited technical background and programming skills. An intuitive UI can streamline rule development for KEs through the use of well-defined templates for managing meta-data and defining rule logic (e.g., risk group, overdue conditions, physicians’ coded responses, and message) in a way that divorces the user interface from the underlying semantics and structures.

We revised this section to make it much clear.

Sub-subsection Terminology integration
10) Sentence: “However, these subsets are defined by mixed use of local and standard terminology...” Why the use of local terminologies, once codified, does constitute a problem for RAEs? An effort of mapping local terminologies to some reference terminology can be made if you need the interoperability with external systems.

Response: we have explained the reason in this section. These subsets are defined by mixed-use of local and standard terminology, largely because no suitable standard codes fully meet our needs. In addition, the problem subsets are not initially designed to support automated updates, so the subsets have to be continually reviewed, refined and vetted.

Level of interest: An article of limited interest

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
Reviewer's report
Title: A study of diverse clinical decision support rule authoring environments and requirements for integration

Version: 3 Date: 29 July 2012
Reviewer: David Isern

Reviewer's report:
Rule authoring systems are a type of DSS quite popular in the 90’s. In my opinion, these Systems have been embedded by clinical guideline-based Systems due to the time consuming task of maintenance and interoperability. As authors of the paper noticed at the end of the paper, most of the RAE systems analysed lack of openness and standardization.

Major compulsory revisions
My major doubt is about the bias of the study. On page 16, the authors summarise the list of limitations of the study, which are quite restrictive. Usually, these tools are localized in a healthcare organization without connection with other information systems and without interfaces to exchange information between them. This is a traditional drawback on computer science where providers of software usually create ad hoc tools/solutions according to the on-site conditions. Change this situation is a challenging task that begins with the creation of open protocols and tools to use them. This discussion should be improved in the paper.

Response: we accepted the reviewer’s suggestion. We added this discussion in the “Formal Knowledge Representation and Standards” section.

Isern and Moreno [1] analysed the use of clinical guidelines in healthcare from different perspectives. Several points are the same such as the analysis of the knowledge representation, the necessity of accurate interfaces, and the adoption of widely-used terminologies. Following the conclusions of this study, one of the most important requirements is the connection of these tools (patient-centred) with electronic health records. I recommend discuss this issue separately using information provided in Table 1. For instance, the 2nd edition of Reminder, Nephros, Gerios, and MRE offer this facility. Another perspective that has not been addressed is the analysis of the kernel of these systems: the rules. It could be interesting to know the level of expressivity on each case, analyse common and distinct actions, and devise the possibility to adopt a standard in a near future.

Response: we have cited the article by Isern and Moreno. We also have added a section to discuss the integration of RAEs with EHR systems (see “Integration with EHR systems” in the Discussion). We have described diverse reminder rules and medication rules in the methods and results section, including the diversity and unique features for each type. We also added some discussion - the adopted knowledge models should be capable of expressing different types of
clinical knowledge and conveying the complexities and nuances of clinical knowledge at different levels of granularity.

Minor essential revisions
Introduction could be improved with the discussion of recent works as [2] and [3]. The first one performs a deep study of the development of a rule-based system. Particularly interesting is the analysis with clinical guidelines. The second work analyses the rules from a qualitative perspective. This is an interesting issue: how good and reliable are rules? Validation measures should be included during the creation of rules in order to assure a level of quality and avoid ambiguities. Additionally, Shiffman et al. [4] proposes a methodology to acquire and represent medical knowledge in clinical guidelines. These general patterns could be used to improve authoring rules.

Response:
We’ve cited Isern’s paper on “computer-based execution of clinical guidelines.”
We’ve cited the paper by Medlock et al in the testing section.
We’ve also cited Shiffman’s paper in the background section.
Seto et al reported detailed steps for developing and evaluating a rule-based system for a heart failure mobile phone-based telemonitoring system. They discussed that guidelines need to be tailored to take into consideration of clinical settings and individual patients. Although their methods are interesting, they are domain-specific and the review of diverse rule based systems is out of the scope of this study.

Discretionary revisions
It could be interesting to provide more details about the analysed tools, more statistical information as well as screenshots. I assume that it depends on the copyrights.

Response: we added another example- the Medication Rule Editor in an Ambulatory EHR, with a screenshot.


Level of interest: An article of limited interest
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
Reviewer's report:
The paper is well-executed. In some ways I find the results very unsurprising - naturally it's a mess having 10 different rule authoring environments, and it would be messy just as indicated, and consolidation would be helpful (again, just as indicated). The context at Partners would be one of the most matured in this regard, and thus the results are interesting to set the requirement that better management is needed as institutions race headlong into CDSS for HIMSS EMR level 7 maturity and Meaningful Use. On balance, it's a useful paper to have out there, and I'll cite it to justify some of my own grant proposals.

I have only one major area where I believe there should be more clarification, if not considerable expansion of the material. In the middle of the first paragraph of the Background, in one paragraph, with citation of references 5-14, the entire 'guideline modeling tools' literature is brought to our attention; and with just the following sentence it is summarily dismissed. As a minor aspect of my dissatisfaction with this, I note that this is the first time the word 'guideline' is used in the paper, and it's never defined. I'm not sure that it must be (probably does), but the relationship between rule authoring environments and guideline modeling needs to be drawn out more carefully. More importantly, I believe that some of the work from this genre should be brought back in for the Discussion for consideration in how it might play roles in at least informing the solution for Partners. In particular, I saw a tool at Silvia Miksch's lab about 8 years ago, that was very relevant. I believe it's the one described in:

http://dl.acm.org/citation.cfm?id=1567114

Similarly, on the authoring side, isn't this what GEM Cutter was all about?

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3243287/

And also much of the work from Raza Abidi's lab would seem aimed at executable guideline engines and associated tools covering much of the desired space, e.g.:

http://www.springerlink.com/content/g7524337244k8nr7/

Thus, in summary, I think the relationship of past literature under the 'guideline modeling' label to RAEs should be made clearer; and relevant work should be cited as part of the Discussion of the possibilities for the way ahead for Partners.

Response:

We have cited the references as suggested by the reviewer (Miksch et al, Hajizadeh et al on GEM, and Jafarpour’s OWL-based approach). We have also defined “clinical guideline” in the beginning of the Background as text-based, unstructured medical knowledge.

In the background, we provided more detailed review about guideline representation languages and tools for these models. Even though these computer-interpretable guideline
models have many components in common, they differ in the underlying representation formalisms, decision models, goal representation, use of scenarios, and structured medical actions, and have different intended users and applications. Standards and mechanisms are still needed to allow these diverse guideline models and tools to be shared between different institutions and software platforms, and to be used to encode guidelines as part of real CDS systems. We further clarify that this study focuses on rule authoring environments (RAEs) used primarily to create and maintain rules for common CDS interventions (such as alerts and reminders) implemented in diverse EHR systems. RAEs include rule editors and other ancillary tools that span the steps of the rule authoring process as described in Figure 1: creating knowledge specifications, integrating with terminology, authoring rules, testing rules, publishing rules and reporting.

In the “Major Limitation” of current system section, we highlighted the lack of a standard knowledge representation model. In the discussion section, we pointed out that future work needs to be done to validate existing guideline representation languages and frameworks, as reviewed in the background section, and integrate them in working EHRs. We also reported that recently, we have developed a multi-layered knowledge representation framework for structuring guideline recommendations for implementation in a variety of CDS contexts.

Minor points: 'Shahar' is written once as 'Sharhar'; DDI isn't defined.

Response: we have fixed the typo and defined DDI.

Level of interest: An article whose findings are important to those with closely related research interests

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