Author's response to reviews

Title: Information Management to Enable Personalized Medicine: Stakeholder Roles in Building Clinical Decision Support

Authors:

Gregory J Downing (gregory.downing@hhs.gov)
Scott N Boyle (scott.n.boyle@gmail.com)
Kristin M Brinner (kristin.brinner@gmail.com)
Jerome A Osheroff (jerry.osheroff@thomsonreuters.com)

Version: 2 Date: 25 May 2009

Author's response to reviews:

May 19, 2009

Iratxe Puebla
Senior Editor, BMC-series journals
BioMed Central

RE: 1140311431260045 – Information Management to Support Personalized Decision-Making in Health Care: Points to Consider

To whom it may concern:

Thank you for the careful review of our manuscript addressing clinical decision support and personalized medicine. We have reviewed each of the reviewers' comments and address them in the attached revision.

We have addressed the editorial comments regarding journal style for the following areas pointed out:

1) Abstract – was modified to reflect the format required for the “Debate” style manuscripts, including the structure of the submission.
2) Author’s contributions section was added to the manuscript.

Here were detail our responses to the reviewers. We appreciate the degree of attention that the reviewers provided and acknowledge that all of the points made were important and we believe that the revisions address their concerns.

Based on comments from reviewer 2, we have made substantially rewritten sections of the manuscript. Please note that the title has been changed to reflect additional efforts to focus the manuscript and to clarify the rationale for focusing future work toward stakeholder organizations. The new title is “Information Management to Enable Personalized Medicine: Stakeholder Roles in Building Clinical Decision Support.” The abstract has been modified to comply with the “debate” type of articles requirements.
Provided here are responses to each of the reviewers' comments.

Comments from Reviewer 3.
The reviewer's comments were favorable regarding the subject matter and potential value to the readership of the Journal.

Discretionary revisions:
The reviewer suggested that the issue of quantitative impact of electronic data has yet to be demonstrated. Further, the reviewer suggested that this context be addressed in the manuscript.

Response – this point has been addressed in the rewritten introductory session and comments to the reviewer’s points have been added on page 4-5.

Comments from Reviewer 2.
Major Compulsory Revisions:
1. The paper needs a clearer focus.
Response: We agreed with the reviewer's point and as a consequence, we made major revisions to the introductory section of the manuscript. The focus was sharpened and consistently related to as the later sections of the manuscript unfold. The authors refined the major needs for clinical decision support (CDS) to support personalized medicine and lay out the requirements for meaningful application of CDS in this setting. The examples of how CDS can improve decision making were retained but strengthened (see below) as these provide current day situations that can be addressed more effectively in the future.

2. The methodology used to develop the article would be helpful. The context of the work is not clear. The role of the AHIC in the conduct of the work and or its description in the manuscript in addition to the brief sentence in the acknowledgements should be included in the paper.
Response: We agree that more clarity was needed in the original draft. The methodology for the information input to the manuscript is described beginning on page 5. Reference to AHIC and its work groups is included in the abstract, on page 6, and more detail on page 17 relative to recommendations. As AHIC is no longer a federal advisory committee, it is referred to in past tense. The AHIC received and approved general recommendations regarding CDS. Recommendations developed by the personalized health care work group were directed to broader HHS activities on clinical decision support (these are described on page 17). Further, AHIC encouraged the work group to hold forums on the topic to seek input on this future-looking application of CDS. As has been done with several of the other areas that has been developed by the personalized health care work group, efforts to disseminate this information via print media have been strongly encouraged.

3. There are a number of terms and acronyms used throughout the document and it is not clear if and when the terms are intended as synonyms. To the extent that the terms have different meanings and/or applicability the authors should be clear. These terms include: personalized health care and personalized medicine; HIT platforms; CDS tools; EHRs; HIT. At a minimum the terms as used by the
authors need to be defined.

Response: We agree with the reviewer that the use of multiple terms was confusing. We have focused further on meaning and limited the terminology to electronic health records, clinical decision support, and personalized medicine. Definitions, as addressed below, are included where needed. We believe that this effort has also been addressed by the increased focus on clinical decision support used in the context of electronic health records.

4. The goals of the paper are not clear. For example, on page two in the abstract the authors note “we consider the current and desired state of decision support for personalized medicine...” On page 4 the authors state “the paper outlines the current state of the art in information management...”

Response: We agree with the reviewer that the goal of the paper was not clear. This was one of the major areas addressed in the rewriting of the introduction of the paper. The discussion session of the abstract has been clarified to address the major goals of the paper: to develop a needs assessment of CDS to support personalized medicine, and to characterize an action plan by stakeholder organizations. The discrepancy with the text and the abstract was addressed.

5. It is not clear if the authors are referring to information management, HIT, EHRs, and/or clinical decision support tools.

Response: We agree with the comment. The paper is focused on electronic health record systems and clinical decision support tools. Other terms are not used unless in reference to related work or in other contexts were the relevance is explained.

6. It is not clear if the example of the human genome project (page 2) is the only relevant example of “personalized health care.”

Response: We agree with the reviewer’s perspective. While the genome project is one of the major feats of science, it is not the only basis for the personalized medicine approach. On page 7, discussion puts in context the genomics issues along with other advances in science and medicine that are important contributors.

7. The paper would benefit from a working definition of personalized health/medicine as used by the authors.

Response: We agree with the reviewer’s comment. On page 5, we provide a definition of personalized medicine that is taken from a widely-accepted source (reference 1) which is consistent with the application of the term by us.

8. Page 3 – it is not clear how evidence-based clinical guidelines relate to the prior emphasis on EHRs and CDS.

Response: We agree with the reviewer. The basis of this point rests that many efforts are underway in personalized medicine to use an evidence base for suggesting health care interventions. Transparency of the data used to support algorithms or rules developed in CDS has been a major point of emphasis and will be crucial to user adoption. A key point is that the user of clinical decision support should be able to review the evidence or seek additional information through info-buttons. A discussion about these points is provided on page 8.
Also, the discussion regarding Figure 1 addresses these points.

9. Beginning on page 8 – are these examples hypothetical or real? The document should be clear. The ramification/implication of the examples is not clear.

Response: Both examples represent current state of the knowledge of these medical conditions and this is clarified in the introduction to the scenarios. The purpose of presenting these examples is to demonstrate how clinical decision support can be applied to improve the quality of care through improved use of clinically-relevant information.

Minor Essential Revisions

1. page 11 – “as demonstrated above, CDS tools “can “ enable – would have the “potential to” be a more accurate statement.

Response – We agree and have modified the statement (on page 5) as suggested.

2. Page 20 first sentence under paragraph “organizations that develop…” is not clear.

Response – We agree and the statement was has been modified to provide clarification (page 20) about what organizations are involved in development of evidence for decision making.

3. Stakeholders roles section – this section does not allow for a depiction of the possible collaboration that should be conducted across stakeholders. Think it would be useful to consider grouping and presenting the recommendations by topic and not by stakeholder.

Response – We appreciate the reviewer’s perspective on the organization of the recommendations and the comment regarding cross-sector collaboration. On the latter point, on page 16 in the lead in to the discussion of recommendations, the point of cross sector collaboration is now made explicitly. The first section of the recommendations addresses multisector collaboration. This organizational framework by stakeholder came out of discussions with the work group. The authors discussed reorganizing this section. The authors considered and attempted reorganization around needs and opportunities (third column of table 1) but felt that a needs representation and reorientation may detract from potential “ownership” in taking on various activities. Further, we had difficulty with reorganizing this way that did not add too numerous subsections and adding to the length of the paper. Therefore, we prefer to keep the stakeholder structure intact. In conclusion, we considered a reordering but felt that the information we wished to present remained more direct as to how the work would be done but taking this approach. The title reflects this choice as well.

4. The conclusion is somewhat weak and potentially confusing. The benefits of the specific recommendations would be especially useful.

Response – We agree with this. The conclusion was modified to provide specific examples of where early applications of CDS can make an impact on personalized medicine.
5. The flowchart/graphic that follows the chart is not clearly explained. We agree with this suggestion. A detailed description of Figure 1 is now provided on page 15.

Discretionary Revisions
1. Authors should review the use of verb tense throughout the document. It appears inconsistent.

Response – we agree with the reviewers comment and have carefully reviewed the manuscript for inconsistencies. For the bulk of the discussion on CDS, we use future tense in most cases where these define steps to be taken or recommendations and likely results. Current or past tense is used when referring to current capabilities or actions taken previous to this report.

Comments by Reviewer 1.

Detailed comments were not provided. The reviewer expressed that the manuscript did not contribute to the body of work already existing in clinical decision support and that sufficient explanations of barriers had been previously covered. There are two points that we wish to make to address this concern:

1) We believe that there is substantive value to the readership and that the current revisions take into account what differences in applications for clinical decision support are needed for personalized medicine. The types of decisions, the increased levels of biological and personal differences, and dependency of individualized care approaches on CDS tools is distinct from many areas of clinical practice today.

2) The manuscript does not focus exclusively on barriers to CDS, in fact, there is minimal amount of discussion on these points. The greater context is an effort to demonstrate added utility of CDS in complex clinical situations, and for opportunities to coordinate efforts across sector in strategies to enhance this area.

We hope that the revised manuscript will give the reviewer a better perspective on this dependency to represent value overall to health care.

In conclusion, we found the reviewers’ comments and your suggestions for revisions to be very helpful. We have addressed the mandatory comments and made our best efforts to accommodate reorganization and clarification of the recommendations sections. The structuring of the manuscript by stakeholders’ was felt by the authors to be important for organizations and individuals to understand the importance of their contributions and avoid the notion that the work should be done by others.

We appreciate the considerable time and effort that the editorial staff and the reviewers provided to the manuscript. We believe that it makes important contributions at a time when personalized medicine is becoming an increasingly applied clinical practice in need of meaningful supporting contributions from information technology.

Thank you.
Greg
Gregory J. Downing, D.O., Ph.D.
Project Director, Personalized Health Care Initiative