Author's response to reviews

**Title:** People, Organizational, and Leadership Factors Influencing Access to Informatics Expertise and Resources in the Academic Clinical and Translational Research Environment

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**Version:** 4  **Date:** 28 July 2012

**Author's response to reviews:** see over
RE: MS 5178116027036207 - People, Organizational, and Leadership Factors Influencing Access to Informatics Expertise and Resources in the Academic Clinical and Translational Research Environment (formerly entitled: “Informatics Leadership Models in the Academic Clinical and Translational Research Enterprise”)

Dear Sir or Madam:

Please find attached to this cover letter a revision to our manuscript entitled “People, Organizational, and Leadership Factors Influencing Access to Informatics Expertise and Resources in the Academic Clinical and Translational Research Environment” (formerly entitled: “Informatics Leadership Models in the Academic Clinical and Translational Research Enterprise”). At a high level, we would like to thank the referees for their comprehensive, thoughtful, and highly constructive critique of our submission. We believe that as a whole, the revisions we have made to the manuscript, as outlined below, serve to greatly enhance its readability, impact, and overall quality:

**Referee 1:**

**Major Compulsory Revisions**
According to the authors, the aim of the paper is to describe a systematic survey and evaluation of such organizational and leadership models. I find clear that the paper is addressing organizational models, but I find weak the treatment of leadership models. This might be due to a difference in the understanding of leadership model. For example, the paper says, when discussing "enabling successful biomedical informatics leadership in the academic clinical and translational research enterprise", that "the results of the survey indicate that when there is a formal BMI academic unit in place, there is a distinct difference in the perceived access to both BMI and IT services and expertise as well as perceived coordination between BMI and IT leaders". I find this claim is more related to the organizational model than to how leadership is carried out. Hence, I think the authors should make more explicit which are their goals in terms of organizational and leadership models.

**Response:** We have revised the title of the manuscript, as well as our introductory definitions of the objectives motivating our manuscript to more accurately reflect the emphasis on people, organizational, and leadership factors that collectively influence access to informatics expertise and resources in the academic clinical and translational science environment. In doing so, we believe we have been able to clarify the overarching purpose and focus areas of our work, thus addressing the potential confusion noted by the referee’s critique to which this particular revision is responding.

Regarding the questionnaire itself, I have noticed that the respondents were given the following options:

- Very good
- Good
Fair3
Poor
Other (no answer, not available, etc.)

This means that they have two positive options, one neutral and one negative option. Why not including a very poor or removing the very good? This might cause distortion in the results, since the categories are unbalanced. Have you taken this into account?

Response: While we recognize that there is a potential for confusion surrounding the design of the survey's categorical response labels, our intent was for the categories of "Very Good" and "Good" to represent the positive end of the response spectrum, with the categories of "Fair" and "Poor" representing the negative end of the response spectrum. This design was subject to validity checking by a convenience sample of Subject Matter Experts in the CTS domain, who did not express concern over the understandability, expressiveness, or potential for bias associated with the preceding design. As such, we felt that there was a minimal risk of distortion in our survey results and corresponding analyses.

In the discussion section, I also think that the authors should make more clear the relation of both "differentiating the role of CS, BI and IT in the research enterprise" and "informatics workforce development is a central and supporting endeavor in well-integrated environments" with the survey and the data of the paper. The users mention that they are using some qualitative responses provided to their survey instrument, but such responses are not available.

Response: We have significantly revised and enhanced the Discussion section of the manuscript in order to further elaborate upon on the results of the structured survey and
thematic analyses, especially as they related to the subsequent author-generated perspectives concerning critical people, organizational, and leadership issues influencing access to BMI, CS, IS, and IT resources and expertise in the academic CTS enterprise. In this manner, we believe that the relationships between these two components of our narrative are much better defined and presented, thus addressing this particular critique. With regard to the qualitative results of our study, such statement refer to our thematic analysis of public-domain information resources – the actual survey, due to the need to maintain the anonymity, did not allow for such qualitative response types.

Minor Essential Revisions

It would be nice to know to how many different institutions the 31 respondents belong.

Response: Given the anonymous nature of the survey, unless respondents chose to self report their institutional affiliation (as is reflected in the partial list provided in the Results section of the manuscript), such a metric is not possible to derive.

It would be also interesting to describe which institutions were used for the "thematic evaluation of exemplary organizational structures at major AHCs". I do not mean to provide a detailed list, but it is not clear if you have analyzed the institutions of the respondents or other ones. In such case, describing them or the selection criteria would be of interest for the readers.

Response: We have revised the manuscript to reflect that the thematic analysis was performed based upon institutions included in the set of such organizations included in the criteria for our survey efforts.
Referee 2:

Minor Essential Revisions

Conclusion (in the Abstract) should more clearly reflect the recommendations from the Discussion, and the conclusions. Currently the conclusions are essentially that 1) leadership influences organizational effectiveness, and 2) better understanding of organizational structures would be helpful, which are not very compelling conclusions.

Response: We have extended both or Discussion and Conclusions to more fully explain and emphasize our findings and their implications, in order to better convey the critical messages incumbent to our report.

The Thematic Evaluation Of Exemplary Organizational Structures At Major AHCs is orphaned – authors mention they did it and say the results are in Table 4, but do not interpret the findings in the Results, or discuss them in the Discussion.

Some discussion of how this thematic evaluation influenced the recommendations and conclusions is needed.

Response: We have extended and enhanced the Discussion section of the manuscript to further elaborate upon and contextualize the results of our thematic analyses.

What was the response rate of the survey?
Response: *Per our prior response to Referee 2, this metric cannot be derived due to the anonymous nature of the survey and the recruitment mechanisms utilized (e.g., the broadcast of an invitation to participate in the survey sent to the two constituencies indicated via an email list service).*

p -9-

- risk ratio of 0.061 (0.08, 1.06): what is the interval given in brackets? It does not contain the stated estimate of 0.061.

Response: *The risk ratio as included in the manuscript was erroneously indicates ad .061, and should in fact be reports as 0.61 (this error has been corrected)*

Discretionary Revisions

P -2-

- priority (in the United States), -> priority in the United States,

- we describe an effort intended to address -> we describe an effort to address

p -3-

- research and ultimately, improvements -> research and ultimately, to improvements
Response: All three of the preceding suggested revisions have been made.

Referee 3:

Major Compulsory Revisions

1. The Methods part (page 7-8): In the last paragraph of this section, on page 8 (“Additionally, to provide... for programmatic success.”), it would be better if these approaches can be described in more details, e.g., with a list of the resources used.

Response: This section of the manuscript has been extended to more fully explain the types of resources used for the indicated thematic analyses.

2. The Discussion part (page 10-15): More references can be used to support the suggested “critical strategies that are essential to the successful leadership and organizational delivery...”.

Response: Given that these statements reflect the perspectives of the authors, and per the revised manuscript, have been explicitly situated so as to derive support from our study findings, we respectively disagree that additional external references are needed to support such statements.

Minor Essential Revisions

1. The Background part (page 3-7): The authors defined some of the terms such as biomedical informatics (BMI) clearly. It would be better if the concept of clinical and
translational science (CTS) can be explained in more details with examples. In addition, the roles of CS, IS, BMI, and IT in translational research can be discussed with a more thorough review of the current status.

Response: Given the stated scope of this report, and the space constraints associated with the provision of a concise research report, we have chosen to include a number of references to seminal reports describing the definitions, case studies, and examples requests in this particular critique. We believe this is an appropriate mechanism of providing readers that require further information concerning the nature and practice of the indicated disciplines with pertinent background materials.

2. The Methods part (page 7-8): It seems the study was done mostly based on subjective surveys. Is it possible to provide some more objective analyses? For example, the application rates of certain programs, cost-effectiveness analysis, etc. These can also be discussed in the Discussion section.

Response: Such data and research questions extend well beyond the stated scope of this manuscript, which is focused on people, organizational, and leadership issues, and not resource utilization and/or economic analyses of CS, IS, BMI, and/or IT resources supporting the CTS domain.

Discretionary Revisions

1. The Results part (page 8-10): A more detailed discussion can be provided for each table.
Response: We have significantly extended and enhanced the Discussion section of the manuscript to provide a more full description of the survey results, as summarized in the major Tables associated with the Results section.

2. As the authors pointed out in the discussion part, more data with statistical meanings would be very helpful.

Response: As was described in the manuscript, due to the number of survey responses and the nature of the convenience sample of CTS thought leaders engaged in this particular study, such statistical analyses are not feasible. Instead, per precedent from numerous other, analogous studies, we have chose to triangulate our findings using a mixed-methods approach including descriptive statistics and thematic analyses.

Referee 4:

i) While the survey and the results are for US based institutions, translational science is a global enterprise. For a publication in an international journal it will be most appropriate if in both the abstract and in the introduction the authors provide a broader international context of the organizational challenges associated with translational science data infrastructure. Certainly there are numerous publications in international journals that will be important to cite here.

Response: While we agree that the CTS domain is much broader than activities underway within the United States, given the scope of the survey respondents and associated institutions included in this specific study, which are all based in the US, we respectively disagree with this
referee, in that a broader treatment of the CTS domain at the international level would in fact represent a significant and potentially confusing expansion of the scope of the report.

ii) Perhaps the authors should discuss in pg. 4 that the required data infrastructure for translational research is very similar to the infrastructure required for other important research agendas based in reusing clinical data. Among them it is worth citing: drug repositioning, comparative effectiveness research, post market drug safety surveillance, etc. This may be obvious to informatitians, but not to leaders of many academic health science centers.

Response: The similarities and differences between CS, IS, BMI, and IT resources and platforms that serve to support and enable CTS, as well as numerous other research paradigms, is discussed in great detail in a number of the publications cited in our review of pertinent background materials. Again, as per the prior response to this referee, we believe that a more detailed explanation of these issues in this particular manuscript, given its stated focus on CTS, would represent a significant and potentially confusing expansion of the scope of the report.

iii) Pg. 5. “systematic survey” may be a bit too broad to describe this work.

Response: We have revised the manuscript to omit the term “systematic” in regards to our survey.

iv) Pg. 7. the authors may want to emphasize that the results primary represent the opinions of the informatitians, which may be different that the perception of users vis a vis accessibility, etc. Certainly a similar survey of users will be extremely valuable.
Response: We have included a statement to this effect in the Limitations section of our report.

v) Pg. 10. The section “Thematic Evaluation…” it is very difficult to read, the paper will be much more readable if the authors explain in more detail how they performed the grounded-theory analysis as well as if they provide a better description of the AHC included in this study.

Response: We have revised and extended our discussion of both the methods and results associated with this component of our overall study design. As is noted in the manuscript, the types of institutions included in the thematic analyses are also explained.

vi) The Discussion section has three types of materials, background comments that should be more appropriate for the introduction, comments on the specific results of the survey that are germane to the section and contextual comments that represent that authors views. While for the most part I consider that the contextual comments are correct, I also believe that they cannot be inferred directly from the survey. In my opinion these contextual comments should be clearly separated from the specific results of the survey and identified as such.

Response: The Discussion section of the manuscript has been significantly revised and extended to address the issues identified by the referee, providing greater linkage between the findings of the study and the author’s perspectives/recommendations.

vii) Pg. 13. “empirically indefensible” please provide a reference for this statement.
Response: Given that this component of the report represents the authors perspectives, we do not necessarily believe it is necessary to support all assertions with external references. However, we have modified the language in this case to read as “we believe indefensible.”

viii) Pg. 14, in Limitations. An important limitation that should be explicitly acknowledged is the lack of user representation in the survey.

Response: Per the prior responses to this referee, such a limitation has been noted in the revised manuscript.

ix) Table 4. The Axis 2 and Axis 3 have not been defined, please clarify.

Response: Further definitions of the terms used to describe these axes have been added to the table caption.

x) Figure 1, the authors may want to consider adding Biophysics and Biochemistry as supporting basic sciences. Medical Sciences may be a better term than Medicine.

Response: This figure is based upon well-established conceptual models in the Biomedical Informatics domain, which define specific disciplines and sub-disciplines that converge to enable/support the pursuit of Biomedical Informatics science and practice. While the referees suggestions are valid, extending or modifying such an established model extends well beyond the scope of this report and could lead to confusion on the part of readers familiar with this particular definition/model of BMI.
Referee 5:

The article needs a basic overhaul. It is not bad in its approach per se, but it is very "fuzzy". It appears to be more of an editorial and maybe should be in a journal such as JHIM or JAHIMA (maybe even JASIST), but needs work to present the data in a more convincing format.

Response: As is stated throughout the manuscript, this is a mixed method study designed to elicit and describe critical people, organizational, and leadership issues that influence access to informatics expertise in the modern academic clinical and translational research environment. By its very nature, this topic area generates a number of both quantitative and qualitative (e.g., “fuzzy” per the referee’s comments) findings, which must be interpreted holistically. As is the best practice in the mixed-methods research domain, attempting to “quantitate” such inherently qualitative findings is a risky endeavor that can lead to erroneous interpretations and assumptions regarding such data.

There is nothing wrong with the exploratory approach, but at the end of reading it, the general question left is "So what?" with not much in the way of new insights given to the reader.

Response: As is evidenced through the discordance between our survey findings and thematic analyses, the key conclusions and outcomes described in this manuscript appear to be far from well understood or commonly held by members of the CTS community. Therefore, we believe that describing such issues has significant value in terms of catalyzing critical conversations regarding this subject matter.
Please continue to work on this. It is an important area of work

Response: We respectfully disagree with the referee that additional/substantive work is needed to support this particular report. Any such further research would rightfully constitute future lines of complementary inquiry.

Please do not hesitate to contact me should you require any further information in order to evaluate this resubmission. We will look forward to your comments and feedback on our manuscript.

Respectfully,

Philip R.O. Payne, Ph.D.