Author's response to reviews

Title: Automated inter-rater reliability assessment and electronic data collection in a multi-center breast cancer study

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Version: 2 Date: 18 April 2007

Author's response to reviews: see over
Editor  
BMC Medical Research Methodology  

4/20/2007

Dear Editor,

We are submitting our revised manuscript titled, “Automated inter-rater reliability assessment and electronic data collection in a multi-center breast cancer study,” for publication in your Medical Research Methodology online journal. We have carefully considered the reviewers’ comments and provide below the point-by-point response to their concerns.

Thank you very much for your consideration.

Sincerely,

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REVIEWER 1 (Ronald Lagoe)

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

The manuscript contains a well constructed methodology and research plan concerning the process of electronic data collection. The process component of the research plan is well described. In this reviewer’s opinion, two subjects require further development.

Comment #1:
The first is the need for clarification of the differences between the control samples and the intervention samples of the study. The authors clearly describe data collection for the electronic sample and the methods of evaluating reliability between the two samples. In the opinion of this reviewer, there needs to be more specific description of the control, paper collection sample and how it differs from the electronic sample. This could include additional material describing the two samples at each of the provider sites.

Response
We apologize for the confusion. There were no control or intervention strategies. Rather, the electronic data collection was fully implemented, although sites had varying amounts of electronic data available, as now clarified in the second paragraph of the Results section. The intention of this manuscript was to report efficiencies gained from implementing an electronic data collection (EDC) instead of the originally proposed paper-based data collection. EDC allowed for a natural extension of the system for reliability testing, and the results from the reliability testing are also integrated into the findings reported in this manuscript.

Comment #2:
The second subject is the need for quantification of resources required for the paper and electronic samples. In the Background and Table 2, the authors use terms such as “cost effective”, “resources”, and “efficiency” in discussing the strengths of electronic data collection. While the focus of this study was on process and reliability, it seems logical for the authors to generate estimates of the resources required by the two data collection methods. This need not entail the use of exhaustive accounting methods. It could be carried out through budgeting the costs of paper data collection in medical record departments in one or more of the sites and budgeting the costs of electronic data collection used in the study. This exercise would help complete the process of addressing this subject.

Response
The research study was initially funded for a full paper medical record abstraction. However, upon review of available resources, the investigators chose to implement an electronic data collection. We report in the second to last paragraph of the Results section a reduction of approximately 4 months in data collection time stemming from efficiencies attributable to the electronic data collection system. This translated to an estimated savings of $72,000 in medical record abstraction costs across the six sites. To reflect this,
we have added to the Results the following sentence, “These efficiencies resulted in an estimated savings of $72,000 in medical record abstraction costs across the six sites.”

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Comment #3:
Page 6, Paragraph 3, Line 1, Add an “s” to amount

Response
An “s” has been added to the word amount as suggested.

Discretionary Revisions (which the author can choose to ignore)

Comment #4:
As previously noted, this reviewer believes that the process component of the research methodology was well done. At the same time, this evaluation resulted in only a single statistical presentation, Table 1. The authors might consider whether the evaluation generated material for additional tables involving comparisons of the control and intervention samples and the six sites.

Response
Thank you for your suggestion. We presented our findings both graphically and numerically and we felt that this combination was the most efficient and effective strategy for communicating the intentions of this manuscript, which was to report efficiencies gained from electronic data collection compared to full paper collection, including our system for reliability testing. As described above, there were no control and intervention samples.

Comment #5:
The authors have correctly pointed out that only a limited amount of research is available concerning electronic data collection. They have not indicated, however, whether any of the evaluation tools or other components of that research were used in this study. Such a brief discussion could provide some connection with other published studies.

Response
In our thorough review of the literature we found little of relevance to the topic of this manuscript. The peripherally related literature addresses electronic versus paper survey instruments, which have very different data collection challenges than our topic of collecting data from a medical record by review via a small number of abstractors. For example, collecting a survey requires locating a target sample population, distributing the survey to participants by some method (e.g., email or postal service), and collecting the survey responses by some method (e.g., email or postal service). None of these aspects apply to our topic. We face the challenge of efficiently distributing the same medical record review system (paper or database) to a small number of medical record abstractors in a limited number of sites. Moreover, post versus email was not relevant to the costs and
efficiency in our study. Our efficiency comparison derives from data quality and transfer of data back from the reviewer to the analysis center. Please see our response below to Reviewer #2, Comment #1 where we give specific examples of seemingly related literature and explain why they are merely tangentially related.

Comment #6:
An additional thought concerns the relationship between the Methods and Results sections. Because this study largely focuses on a process, it is logical that reference to methods not be limited to that section. At the same time, the authors might consider moving some of the discussion concerning the process of evaluation from the Results to the Methods section and allowing the Results section to focus only on the outcomes of the study.

Response
Thank you for your suggestion. Please see the revised manuscript. We have shifted some of the discussion concerning the process of evaluation as follows:

- Revised Results paragraph 5: moved from Discussion beginning “We developed… agreement was over 83%.”
- Revised Results paragraph 7: moved from Discussion beginning “These efficiencies… the six sites.”
- Revised Discussion paragraph 1: moved from Results beginning “EDC allowed… paper data collection.”
- Revised Discussion paragraph 5: moved from Results beginning “This is a logical… of abstract completion.”
REVIEWER 2 (Elizabeth Staton)

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

Comment #1:
The authors should revisit their claim that few published reports have compared electronic data collection with paper data collection. A quick search provided these references (which may not be right on, but which illustrate that the topic has been discussed in the literature):
Ann Epidemiol. 2000 Oct 1;10(7):457
Occupational Medicine 1999;49:556-558
Literature outside the biomedical field may also be good sources.

Response
Thank you for the references. We have carefully reviewed the recommended literature. Unfortunately, we believe none of the papers are applicable to the topic of this manuscript due to methodological differences in data collection and type of data.

The Annals of Epidemiology paper compares handheld collection of menstrual symptoms to diary collection of these symptoms. Respondents are the participants themselves (one respondent for each record), whereas our respondents are reviewers of medical records (one reviewer responsible for review of multiple medical records). The comparison of data quality and data collection efficiency is quite different when the data collection method applies to the respondent, not to a medical record reviewer, because of the economies of scale pertain to very different aspects of the data collection. Similarly, the Journal of Operations Management paper compares data collection of consumer surveys (not medical endpoints) by electronic and paper response methods. Once again, the users of the two systems are respondents themselves, not medical record reviewers. Last, the Occupational Medicine paper compares paper, email, and internet collection of health surveys in the workplaces. The users of these data collection methods are the respondents themselves, not a medical record reviewer of multiple records.

We appreciate the reviewer’s effort in conducting this “quick search.” Our thorough review of the papers, as explained, found them to be methodologically off topic and we have therefore not revised the manuscript with any reference to these papers.

Comment #2:
The authors should refer to other studies in the discussion section. Although there may be little research in this area, it is difficult to determine how this study advances the field when there is no comment in the discussion on how it compares with previous work.

Response
Ascertaining accuracy of available electronic data and usability of EDC systems for medical research have been discussed in previous studies. We have expanded our Discussion section to integrate these topics.
Comment #3:
References are needed for some statements in the intro ("some of the documented advantages of EDS," and "The disadvantages are" -p.1)

Response
References have been added.

Comment #4:
The results section appears to have methods-type information in it (such as data cleaning). Please separate results from methods.

Response
See Reviewer #1, Response to Comment #6.

Comment #5:
The guidelines for designing an EDC for research (p.9) are good ideas, but the authors need to provide support for these statements, either from the results reported here or by referring back to other literature.

Response
We have modified the paragraph in the Discussion section by removing the 3rd and 5th guidelines with support of the remaining guidelines as stated.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Comment #6:
Some mention of HIPAA agreements/arrangements seems appropriate.

Response
We have modified the last sentence of the first paragraph in the Methods section, under ‘EDC System,’ which highlights the removal of identifying information before exporting data into the “back end” database in compliance with the data use agreement among sites. The sentence now reads, “Consistent with data use agreements between Boston Medical Center and the data collection sites, and per HIPAA agreements, personal identifiers such as surgeons’ names and patients’ day of birth were deleted before exporting into the ‘back-end’ database.”

Comment #7:
Please clarify the differences between "automated EDC" and "EDC."

Response
EDC is an abbreviation for ‘Electronic Data Collection.’ This is the computer program developed for data collection either through manual data entry or by automation, hence the prefix automated ECD. By automation of the data entry process, all data elements
previously available in electronic format are merged into the program allowing for additional data elements, not available electronically, to be collected and entered manually.

Discretionary Revisions (which the author can choose to ignore)

**Comment #8:**
It would be great to see more details on how data were preloaded into the EDC. What were the electronic data sources? Any roadblocks you faced? Were the data sources different for each site?

**Response**
We have modified the 2nd paragraph of the Results section to reflect the sources and formats of data elements electronically available for preloading. The paragraph reads as follows.

“There were varying amounts of electronic data available from cancer registry and administrative databases for preloading. Two non-registry sites had 5 data items available (age, birth-month, birth-year, potential diagnosis date, end of follow-up date), whereas four registry sites had 32 to 37 data items available. All electronically available data were sent in Microsoft Excel, Access, or SAS format and merged to the backend database of the EDC system.”