Author's response to reviews

Title: A Computer-Based Medical Record System and Personal Digital Assistants to Assess and Follow Patients with Respiratory Tract Infections Visiting a Rural Kenyan Health Centre

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Author's response to reviews: see over
MEMORANDUM

To: BioMed Central Editorial Team
From: Lameck Diero, MBChB, and William Tierney, MD
Date: March 11, 2006
Subj: 1196552707792682 - Using Informatics Tools to Assess the Care and Outcomes of Patients with Respiratory Tract Infections Visiting a Rural Kenyan Health Centre

We greatly appreciate the referees’ comments on our above-referenced manuscript. We have responded to all of the general and specific comments, suggestions, and questions and have modified the manuscript accordingly. We hope you find the revised manuscript suitable for publication in BioMed Central Informatics and Decision Making.
1) Ethics - Experimental research that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration (http://www.wma.net/e/policy/b3.htm), and any experimental research on animals must follow internationally recognized guidelines. A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.

This project was approved by the Institutional Research Ethics Committee of Moi University and the Institutional Review Board of Indiana University. This statement has been added at the beginning of the Methods section.

2) Consent to publish - Please send us signed consent to publication of this article from the subject pictured in figure 5, their relative or their guardian.

The woman shown in Figure 5 has given her permission to include her picture in this paper. The scanned document is being sent along with this cover letter and revised manuscript.
Referee 1: Dominik Aronsky

**General Comments**

1) *It would be beneficial if the paper would have a more detailed focus on the technical feasibility aspects of using PDAs, i.e., how does informatics enable follow-up for patients in this environment; what are the advantages and disadvantages. In its current form, the paper has a combination of clinical and informatics components and lacks detail in either aspect. The goal of the study should be clearly stated, i.e., is the PDA intended to be used for daily routine to support health care professionals in providing follow-up visit or only for research purposes (data collection).*

The goal of this paper was to show that informatics tools (specifically a simple EMR and mobile computing in the form of PDAs) can enhance clinical investigations, in this case a prospective cohort study of patients with acute respiratory illness. We have clarified this in the Introduction and added a paragraph in the Introduction specifically on PDAs and their use in data collection.

2) *PDAs have advantages and disadvantages for providing care. The authors are encouraged to shortly describe these aspects in the Introduction. In the Discussion, it would be helpful to report what the experiences of the research team were with respect to these aspects. Several reviews of PDA use have been reported in the literature. In particular, the discussion section may include a paragraph about lessons learned (positive and negative) and report limitations of the study.*

The Introduction and Discussion have been edited as this Reviewer suggests.

**Specific Comments**

1) *The title is too general (e.g., “informatics tools” or “care and outcomes”) and does not describe the content of the paper.*

The title of the paper has been revised as suggested.

2) *Structure of paper: The authors may consider shortening the Introduction and moving description of the MMRS and the setting of the health center to the Methods section. A possible order may include (after the existing first paragraph) (a) general respiratory tract infections; (b) short paragraph describing the availability of MMRS and the need/desire to use the MMRS infrastructure for research purposes and/or follow-up visits using PDAs; (c) PDA characteristics (pros/cons) for clinical care and research; (d) purpose of study (define clearly whether for research/data collection purposes and/or for clinical follow-up visits). The methods section can then continue with (a) the clinical setting (“Mosoriot Rural Health Center”) and description of the served population characteristics; (b) the MMRS, and the required modifications of the MMRS to accommodate the PDA infrastructure, (c) information about the study population...*
We have rearranged the structure of the manuscript as suggested above.

3) *The recruitment process should be described in detail. Were attempts made to recruit patients on an ongoing basis, during specific days/times, when the research assistant had time, etc.?*

This has been done in the Methods section. In answer to the question, every fifth patient with acute respiratory illness was approached sequentially each day until three eligible patients per day were recruited. The research assistants were employed full time by this study. Their “having time to recruit” was not an issue. One spent full time recruiting while the other spent full time following up patients in the community.

4) *Also, characteristics about the PDA technical infrastructure may be beneficial, such as battery issues, readability of PDA screen in sunlight, downloading and uploading of patients, backup, any free text data entries, etc.). Why were the PDA data uploaded only once a week?*

We have added some discussion of the PDAs in the Methods section. The PDAs were uploaded once a week on the one day per week that the Principal Investigator (Dr. Diero) practiced in the TB clinic at Mosoriot.

5) *The “subject enrollment” and “data collection” from the result section should be moved into the Methods section.*

We respectfully disagree with this suggestion. Details on actual subjects enrolled and data collected belong in the Results section (the results of the recruitment and data collection methods described in the Methods section). This change was not made.

6) *The outcomes of the follow-up visit included data collection about drugs taken, hospitalization, and time away from work (page 9); results from these outcome variables, however, are not reported and should be included.*

While we fully intend to report the clinical outcomes of this study, that belongs in a clinical journal targeting a clinical audience. This paper described the informatics tools required by this prospective cohort study, and we have stuck to the description of these tools for the informatics audience. We have added only enough clinical data to show that we actually were successful in collecting these data. We appreciate the fact that this Reviewer is tantalized by those data. This is not the paper to describe them.

7) *It would be helpful to describe the regular workflow for patients with respiratory complaints and then describe what is different with the PDA. For example it is*
unclear whether the clinic usually follow-up with patients after their initial visit or was this a unique feature of the study?

Patients with respiratory complaints present to the check-in window, register for that visit, receive an encounter form, and are directed to the appropriate clinic for evaluation and treatment. Data are entered onto the paper encounter form which is presented to the clerk at the checkout window, who then enters the data into the Mosoriot Medical Record System. There are no PDAs used in this process. Hence, the PDAs did not change the regular workflow of the patients at all. The PDAs were only used to follow up patients in their homes, something the clinic does not do on a routine basis. Hence, this follow up activity and use of PDAs to facilitate it was a unique feature of the study. We made no changes in the manuscript in response to this question.

8) Results:
   a. The study period in the abstract reports Aug 2002 to Nov 2003, whereas the result sections reports the study period being Aug 2002 to Jan 2005. This error has been corrected. The Abstract and Results now report the same dates.

   b. Descriptive statistics should include standard deviation and ranges, where applicable. Drop-out patients (12%) should be described in more detail: at what interval (7 or 30 days) did the patients drop out? It would be good to describe the basic demographic characteristics of drop-out patients (average age, gender, etc.). When did the 4 patients die during the follow-up period?

We agree with this Reviewer that these are important clinical questions that the manuscript describing the clinical results of this study (for a clinical audience) will contain. These data would be distracting and not relevant to the goals of this paper or the audience of this journal.

   c. Table 1 should only list study patients, i.e., the diagnosis of 433 patients. As an alternative the Table can list both the underlying population (n=2986) and the study population. Tables need to report the total sample size. Table 2 should include sample size for days 1, 7 and 30. Percentages should be reported consistently (one or no digit after colon). What kind of “further care” did the 11% patients seek?

Again, these are important questions to understand the clinical outcomes of the study. They are not relevant to this manuscript. Hence, we have made no changes in the manuscript in response to these questions and suggestions.

9) Discussion: As mentioned earlier, a description about pros/cons of using PDA in this setting and lessons learned would be helpful.

Done.
10) **Figure 2: screen shot should be de-identified.**

We do not believe this is necessary because this is not a real patient but rather one of the authors, the EMR developer who always uses his own record (he is not a patient at Mosoriot) in all MMRS demonstrations.
Referee 2: Stephen Lapinsky

General
The precise research question is not clear, ie. whether this relates to the implementation of a mobile data collection system or the question of outcomes of patients with acute respiratory illness.

The original goal of the study was to assess the longitudinal outcomes of patients presenting at a rural Kenyan primary care clinic with acute respiratory illnesses. The goal of this paper is to describe the informatics tools (an EMR linked with mobile computing via PDA) that facilitated this prospective clinical study. We have tried to clarify this in the last paragraph of the Introduction.

Minor Essential Revisions
1) ABSTRACT - Results: I believe the dates should be "August 2002 and January 2005" according to the body of the text

The Reviewer is correct, and these dates have been corrected in the Abstract.

2) RESULTS - Subject Enrollment: "..were due to acute respiratory tract infection" should be ".. were due to upper respiratory tract infection"

This statement has been changed as suggested.

3) DISCUSSION: p11 - the last paragraph repeats information given previously.

This error has been corrected.

Discretionary Revisions
Although the methodology for the study is described in great detail, little information is provided on the implementation and management over the 2.5 year period. Questions which may be of interest include:
- how many handheld devices were used?
- how many research assistants were trained to use the Palm?
- was hardware/battery/software failure encountered? Were data ever lost?
- was any resistance encountered to the use of the handheld?

There were 2 handheld devises. We had 2 research assistants. There was no hardware failure or data lost and no resistance encountered to the use of handheld devises. We have added this information to the end of the Results section.
Referee 3: Ronald C. C Merrell.

Major Essential Revisions

1) **The most important outcome would be the effect of the EHR on the management of the patients. This should be clearly stated and in any way possible quantified. You conclude that the EMR’s and PDA were "useful tools" and I agree. However, the case is not made in the MS.**

This has been addressed and paragraph added under the section on MMRS stating and quantifying the effect of MMRS on workflow and patient care at Mosoriot.

2) **How were the 433 patients chosen? Could there have been a control group where the PDA was not applied? How would the outcomes have been affected by the use of the EHR and the extension of the EHR with PDA?**

The 433 patients were chosen by systematic sampling. It was only feasible to enroll three patients with acute respiratory illness presenting each day given the difficulties our research assistant had in following up patients in their homes (most of which were only accessible by bicycle). We estimated that every clinic day 20 patients visited with respiratory infections, so every fifth patient with a diagnosis of acute respiratory infection was recruited sequentially as they presented for care until three agreed to participate. We did not include a group where we did not use a PDA for follow up data collection because this was primarily a prospective cohort study of patients with acute respiratory illnesses, not a randomized controlled trial of the PDA as a data collection tool.

3) **What treatments were applied and how do you explain the refractory nature of symptoms in so many patients?**

Of the 433 patients recruited for follow up 40% did not receive any medications at the health center (due to financial constraints and not being eligible for free medicines), and of those who got medications the majority were oral penicillins and cough syrups. Very limited investigations were available to find the causes of respiratory illnesses among these patients. Fewer than 5% had either chest x rays or sputum smears done to rule out any chronic lung diseases or tuberculosis. The refractory nature of the symptoms could be due to inadequate treatments and diagnostic workups of these patients, or the patients with persistent symptoms could be having severe respiratory disorders that can not be diagnosed in a small rural health center such as Mosoriot. We did not modify the text of the manuscript in response to this question because it is clinical and beyond the scope of this informatics methods paper.

4) **The question posed by the authors is clear to me but may not be to a reader not familiar with the subject.**

We are not clear what the reviewer wants us to do in response to this criticism. We have gone through the manuscript carefully and tried to make it clearer wherever possible that
our goal was to show how an existing EHR could be combined with mobile computing via PDA to do prospective clinical cohort studies.

5) *The methods are appropriate but there could be some improvement in the objectives to evaluate the outcome of the application of the EMR.*

The aim of this paper was to describe the methods used to develop the database from the EMR and to assemble the informatics tools for assessing care among patients with respiratory diseases. We appreciate that this Reviewer wants to know more about the clinical aspects of our study. A second paper (under construction) will describe these clinical outcomes in more detail.

6) *The discussion would benefit by expansion to discuss the situation when proper electronic data management are not applied to rural care. For example, the electronic system moves from incident care to longitudinal care or disease management. That is a crucial extension in the developing world and the work of the authors makes it possible.*

We have described this in earlier publications that looked at the implementation of the MMRS and the impact it has made on reports to the ministry of health, identification of high risk patients, and workflow.¹ We have added some text to the Conclusion describing the degree to which even simple EMRs, which gather data for clinical purposes during each patient visit, can be used to enhance longitudinal care and disease management, both at the level of the individual patient through the health center and even to higher levels of health system management.

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