Author's response to reviews

Title: Adaptation of a web-based, open source electronic medical record system platform to support a large study of tuberculosis epidemiology

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Author's response to reviews: see over
To the Editor

Re: Adaptation of a web-based, open source electronic medical record system platform to support a large study of tuberculosis epidemiology

We would like to thank the reviewers for their helpful comments. Responses to the comments have been added below *in-line in italics*, with the first words highlighted in yellow.

Consent to use the photo will be sent separately.

Regards

Hamish Fraser

Reviewer 1

Minor Essential Revisions:

The manuscript represents a valuable "how to" contribution in tailoring systems based on open MRS to special studies such as TB epidemiology. It will benefit greatly if the authors can share more of their evaluation criteria for success in the work they have done.

*The system* was evaluated on it’s ability to meet the requirements for this large and complex on time and within budget and to perform in a stable fashion without technical problems. There wasn’t a comparison system to act as a control. As noted OpenMRS has many new functions and capabilities compared to the start of the project and new studies considering which system to use need to assess it on that basis. This also makes assessment of the costs of supporting new projects difficult though it is clearly lower than reported here. As noted in the paper we also used the criteria from Leroux to assess the capabilities of OpenMRS.

*We have revised the text on page 14, para 2*

Reviewer 2: Jose Conde

Reviewer's report:

Article (for BMC Medical Informatics and Decision Making): ADAPTATION OF A WEB-BASED, OPEN SOURCE ELECTRONIC MEDICAL RECORD SYSTEM PLATFORM TO SUPPORT A LARGE STUDY OF TUBERCULOSIS EPIDEMIOLOGY Hamish SF Fraser MBChB, MSc; David Thomas MS; Juan Tomaylla BS; Nadia Garcia RN; Leonid Lecca MD; Megan Murray MD, DrPH; Mercedes C. Becerra ScD.
Reviewer: José G. Conde

Purpose: “In this paper we describe the customization and use of an open source EMR system platform called “OpenMRS” to support this large epidemiological study. We also describe the steps required to adapt and tailor the OpenMRS framework for this study, and our experience using the system for more than two years.”

Review:

Introduction: This paper by Hamish Fraser et al describes the customization and use of the Open Medical Record System (OpenMRS, http://openmrs.org) to support data collection and management during a tuberculosis epidemiology study in Peru. In my view, the main question to be answered by this paper is why is it necessary to modify software designed originally to support health care functions, instead of using software specifically designed to support data collection and management in clinical research environments. Does the tool outperform other applications in terms of speed, reliability, efficiency, or breadth of application? I think the question is answered only partially in this article, and applicability of OpenMRS to support research applications, though important in some instances, might be limited. On the other hand, I think the role of OpenMRS for secondary data analysis in outcomes, which is not mentioned in the paper, deserves exploration.

Comments (all 1 thru 8 Major Compulsory Revisions):

1. Cost was an important factor for selection of the application in the tuberculosis study, so open source solutions were considered, including OpenClinica, REDCap and OpenCDMS.

“Recently, a number of clinical data management tools have become available in developed countries to standardize the management of clinical research data collection. Research studies in developing countries face additional challenges in infrastructure, staffing and expertise, and are usually dependent on outside technical expertise and/or expensive software licenses for data collection systems.” However, the three options considered in the paper are already in use in developing countries. They have become international collaborations as OpenMRS has become in the EHR field. The authors mention reasons for deciding to customize OpenMRS instead of using other options. Some of them might have been valid at the time of the initial database design, but not currently.

*The decision* to use OpenMRS came before the three alternative systems listed were well established. All the systems including OpenMRS have progressed a great deal since then. Key issues driving the decision making were:

- The unusual and complex nature of some of the data that must be collected for managing or researching MDR-TB. In particular it has been our experience since 2000 that few clinical or research systems do an effective job of representing culture and drug sensitivity test (DST) data. We had established experience in that field and also the expertise to modify OpenMRS to ensure such data was correctly handled. This includes multiple hierarchies of concepts. A flat file data model such as RedCAP had in the earlier versions (personal communication, Jonathan Payne, former RedCAP developer) would likely not have handled this as well.
- We were expecting to rely on the clinical laboratory systems for collecting this culture and DST data and therefore clinical data management tools were/are very relevant. We would argue that
research data management systems should support clinical standards such as HL7, LOINC and others particularly for these circumstances, and we knew that OpenMRS had that capability although it was not ultimately necessary in the Peru study.

- We were able to develop a training system for staff and be certain that the source code of the system was fully under the control of the project.
- Many partner organizations around the world have established expertise in the deployment and modification of OpenMRS which reduces the bar to using that system.

2. "Due to the focus on safe collection, storage, and management of clinical data, it includes auditing of data changes in the main database tables. This feature allows tracking of the history of changes in data items linked to the login of the user (although the original version of OpenMRS did not provide auditing of all required items for the study). There is a strong security system to ensure that only the authorized users have access to the clinical data, with the use of encryption of data transmitted over the web using Secure Socket Layer (SSL) Protocol [13]."

At least OpenClinica, REDCap and OpenCDMS (all developed as research applications) support these features. Some of these software applications had these features from the start. OpenMRS was also modified to include tools such as encoding of foreign languages, reconciliation of data entry discrepancies, role-based security tools and applications, reporting tools and data export already. These are also available in open source research-focused data management solutions.

The point here is particularly addressed to the many projects which build their own research data management systems from scratch rather than relying on existing systems. It is hoped to foster discussion about these requirements and why well established systems like OpenMRS, Redcap or OpenClinica are typically better options.

3. “OpenMRS is designed around a flexible data dictionary, called the concept dictionary, which allows new data items to be added without changing the underlying database structure. The dictionary simplifies the translation and maintenance of items in additional languages like Spanish.”

The three open source alternatives mentioned in the paper also allow for this flexibility. Actually, the use of the concept dictionary (https://wiki.openmrs.org/display/docs/Data+Model) as implemented in OpenMRS, while providing for some degree of flexibility in modifying and dealing with the requirements of an electronic health record system, might provide less flexibility in a research environment compared to other options. The authors recognize this issue in the discussion section: The biggest technical challenge in adapting and using OpenMRS relates to the data model based on the concept dictionary.

This is also a disadvantage presented in Table 1. Looking at the The philosophy behind OpenMRS as originally designed is to provide a modular approach to EHR systems, so institutions can build their systems from a set of robust modules requiring minimal or no modification (OpenMRS Guide version2, available at https://wiki.openmrs.org/display/docs/User+Guide). It is a very different scenario compared to requirements of clinical research data collection and management systems, which must be able to
support the creation of complex databases from scratch in support of a wide range of types of studies, including cross-sectional studies, case-control studies, cohort studies and clinical trials within and outside health care scenarios. Researchers demand systems that are easily but robustly configured to deal with a wide variety of data collection, data management and data export requirements necessary to successfully implement their studies. In this sense, this paper does not show evidence that OpenMRS provides the necessary level of flexibility and ease of use to serve as an all-purpose clinical research database management system. It would have been useful to know the amount of time and/or person-time units required to make all modifications necessary for this study, as well as the expertise and amount of familiarity with the software of technical staff.

The issue noted here we would argue is not a lack of flexibility of the OpenMRS data model, which has proved highly adaptable and expressive for a wide range of projects around the world. This is complemented by a unique modular software architecture which allows enormous flexibility and power for projects with programming expertise. The gap identified by the reviewer is more a case of structuring the data collection scenarios to match various study designs and therefore providing guidance and standardized tools. OpenMRS requires more examples of customization for specific study types but has the flexibility to support that. The main challenge identified in the paper is the need for a wider range of data export tools in OpenMRS which has been addressed to a large extent since the study commenced.

4. "OpenMRS is supported by a community of developers and implementers in many countries who communicate by email, regular conference calls, and periodic face-to-face meetings." This is also valid for OpenClinica and REDCap. I am not that familiar with OpenCDMS.

OpenMRS has a large and rapidly growing open source community, it is the second most downloaded medical record system on the open source site Sourceforge for example. In addition while we recognize that Redcap has a large impact world wide, the fact that it is not a true open source project is a concern for many developers who are not certain that they will always own or control their contributions. Open source software is clearly defined to ensure maximum collaboration opportunities:
http://opensource.org/

5. "Most core features had already been built and tested, and new technical issues could be discussed with the community. The programming done for this project is being shared back with the OpenMRS community, a particularly important benefit in resource poor environments."

I think this might be the main contribution of the paper. OpenMRS has a wide user base as an EHR system. This paper reports the changes that were necessary to take advantage of OpenMRS within the context of a very specific study, and it demonstrates that under specific circumstances, if OpenMRS already contains a module or set of modules that can be minimally modified, and the research support team has expertise in the use of the system, it might be more convenient to modify OpenMRS. When planning began for this study, the team had extensive experience in developing information systems to support the clinical care of MDR-TB in Peru, including management of laboratory data, and one of the authors is a co-founder of the OpenMRS project. This might not be the case in other scenarios, so applicability seems limited. The authors mention interoperability with i2b2, which is also a welcome
addition. However, a major contribution could be the potential for Open MRS to be used in outcomes research by facilitating data selection and export from OpenMRS-based EHR’s for analysis of data generated by regular health care activities. To realize this potential, a robust OpenMRS data export module should be built. Does any other open source application for EHR development and management have this capability?

We agree that a key area where OpenMRS has value is in the secondary use of clinical data for research purposes. In addition sites that are already proficient in installing and extending OpenMRS have seen benefit in leveraging the system rather than installing a parallel research data management system. The correct decision under those circumstances will depend on how closely related the research study is to the clinical care at a site and therefore how much data might be common to both. There other EMR systems in use in developing countries but we believe OpenMRS is the most widely used in low income countries and has some of the best data extraction tools. We have added the following:

Page 20, para 3

“The data warehouse system Pentaho [32] is also being integrated with OpenMRS to allow a wide range of analyses and data exports.”

Page 21, para 1

“Research on data collected for clinical purposes in EMR systems is an important priority for many organizations, and OpenMRS is uniquely positioned to support such work especially in resource poor environments.”

6. "The statistical analysis of the study data set required a full extraction of the data. The main tool for this purpose was written in SQL (a database language) and SAS (SAS Inc., Cary, NC) by the study staff." It seems this is a tool written separately from the OpenMRS framework, and so not an OpenMRS native feature (also suggested by Table 1). This type of tool has been available in open source research database management solutions from several years. As stated above, a native OpenMRS module to support this function might be an important contribution for EHR applications.

We agree that this is an important requirement. As noted in the paper there is a new module in OpenMRS for research data extraction that has been developed over the last 2 years as well as the links to i2b2 and Pentaho. However some research teams with strong statistical programming skills prefer to build their own tools in SAS or R as was the case here.

7. “The system was required to meet US Food and Drug Administration (FDA) requirements for certification of software development processes, security of data, and auditing of any changes to data already entered (21 CFR 11[8]). It also had to meet Good Clinical Practice requirements [9]”. As mentioned in the paper, compliance with 21 CFR Part 11 is usually an FDA requirement. The paper is not clear about the circumstances leading to the requirement for 21 CFR Part 11 compliance in this epidemiologic study.

We have added the following statement to the paper:
“The national TB guidelines in Peru called for the use of tuberculin skin testing in household contacts younger than 15 years old[8]. Because the study aimed to assess new infections in all the household contacts, our study protocol required the use the tuberculin skin test in all these subjects regardless of age. Because of this discrepancy between the national TB guidelines and our study protocol, the NIH classified the study as an interventional trial.”

8. “Auditing of changes in data entered was mainly achieved using the built in tools in OpenMRS. Some additional tables had to be added to the database (using the study module) to track data items like patient encounters and some demographic data. This ensured that the system was compliant with FDA 21 CFR Part 11[8].” OpenClinical, REDCap and OpenCDMS support audit trails. Actually, section 11 applies to Electronic Records; Electronic Signatures, so its application includes, but is not limited to software. Compliance with 21 CFR Part 11 has 5 components: software validation, audit trails, legacy systems (applicable only to systems that otherwise were operational prior to August 20, 1997), copies of records and records retention.

(http://www.fda.gov/regulatoryinformation/guidances/ucm125067.htm).

The following summarizes my experience while testing (relevant screenshot images are included):

I went to the OpenMRS portal and tested the OpenMRS TB Demo (available at https://mdrtbdemo.pih-emr.org/openmrs/login.htm) This system has been customized and used in the “real world” for management of drug-resistant tuberculosis. This does not seem to correspond to the OpenMRS modification for research, but I thought it could provide a feel for some of the features. I tested the system with an iMac (late 2006) running MacOSX 10.6.8 Snow Leopard with 3 GB RAM, 2.16 GHz Intel Core 2 Duo CPU running Safari 5.1.7. My institution intercampus network connections, as well as connections to both the commodity Internet and Internet2 are provided by a major US Internet Service Provider. There was intermittent latency with the system. Traceroutes from outside our firewall on three different days are shown below: raceroute to openmrs.org (205.186.173.50)

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Once I logged in, the MDR TB system interface appeared. The system supports dropdown, dates with calendar, radio buttons, text boxes and text entry fields. Data entry forms for patient data had no controls for upper or lower limits of acceptable data. For example, the system accepted (without warning) a weight of 5648 kg, temperature of 200 C, pulse 500, systolic blood pressure of 0, and respiratory rate of 567. I had similar results when a testing on a second date. I tried to get a report as indicated in the portal: The site From the home page, click MDR-TB Indicator Report to see a breakdown of patient data including drug regimen groups. Enter 2009 under “Year” and click Run. Clicking on the highlighted numbers that appear will show you summary data about each group of patients. WHO reports also work well for 2009. I obtained the following: An Internal Error has Occurred java.lang.AbstractMethodError Consult the help document.

Contact your friendly neighborhood administrator if it cannot be resolved. Show stack trace I had similar experience with other features of the demo. In the case of the resistance profile I waited for two minutes after the request, but the report had not appeared, so I stopped the browser. However, other
sections of the application worked flawlessly. For example, the Patient DashBoard and the Chart View integrate information from several sources in just one screen. Again, I think this demo module might not be exactly what the authors describe in this paper, but it is a related application. OpenMRS has been adopted widely, so I cannot say that my experience with this specific module reflects the actual capabilities of OpenMRS. I encourage potential users to validate my experience, and OpenMRS to provide a more complete version of the application online.

*We appreciate the reviewer’s thoroughness* in researching OpenMRS including studying the demonstration server for the clinical MDR-TB system, and the feedback provided. There was a technical problem with the demonstration server accessed regarding the reporting framework which we immediately corrected. As he also notes this is not the same application of OpenMRS as the one described in the paper, the data validation rules for the research study are more strict.

As regards the network connectivity and traceroute data, as a demonstration server we are not prioritizing performance and are unfortunately not able to respond as quickly to technical issues as we do with our production systems. In addition sites using OpenMRS typically support local servers and sometimes use offline/online data synchronization.

Summary: I think this paper might be published as a case study, but only after addressing major issues indicated above and focusing on the specific circumstances that led the authors to use OpenMRS. In the section titled "Conclusions and future plans" the authors conclude that "Our experience and that of other users suggests that OpenMRS is a valuable tool for research data collection in resource poor environments, especially if there is a need to collect data for both clinical and research purposes, or to link to data sources such as laboratories using coding and data exchange standards." The evidence supporting this statement is not strong. The advantages of OpenMRS as an all-purpose clinical research database management system are not evident. The added features are already available in research data management applications, and the OpenMRS data model, while valuable for EHR development, does not provide the added flexibility required by the research community. As of today, I would probably have the same reaction to a paper reporting the creation of an EHR with OpenClinica, REDCap or OpenCDMS. In my view, the research and health care communities are better served by developing focused, dedicated applications. Some overlap and interoperability might be useful, but feature creep might jeopardize the overall development of even the most advanced application.

*We have clarified the language* in the paper to address these comments as noted above. This is a rapidly evolving field and new opportunities and capabilities are emerging that will make research data management easier using a number of different systems. A variety of projects are already using OpenMRS to collect research data as noted in the paper. For example PIH is currently presenting several posters at the International Aids Conference and recently published a paper on outcomes for HIV care based on HIV patient data collected in OpenMRS in Rwanda.

In addition we would note that OpenClinica has not had good support for the medical data standard HL7 which is important for the import of laboratory data from commercial or clinical labs, see for example from August 2011: [http://blog.openclinica.com/2011/08/03/eclinical-integration/](http://blog.openclinica.com/2011/08/03/eclinical-integration/)
*We feel this emphasizes the point that research and clinical systems development communities have important lessons to learn from each other which is especially likely to happen with open source systems.*

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

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

José G. Conde, MD, MPH is Professor at the University of Puerto Rico School of Medicine; Director of the RCMI Program and Director of the Center for Information Technologies and Telecommunications at the University of Puerto Rico Medical Sciences Campus. He is a collaborator of the REDCap consortium and member of the REDCap Library Oversight Committee (REDLOC)