Reviewer’s report

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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Reviewer: Jose Conde

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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

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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 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. These include:

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.

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 version 2, 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.

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.

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 cold be the potential for OpenMRS 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?
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.

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.

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), 64 hops max, 52 byte packets
1 136.145.128.1 (136.145.128.1) 0.717 ms 0.270 ms 0.237 ms
2 136.145.94.10 (136.145.94.10) 0.249 ms 0.413 ms 0.237 ms
3 136.145.95.1 (136.145.95.1) 0.491 ms 0.498 ms 0.490 ms
4 hpcf2rcm.hpcf.upr.edu (136.145.215.45) 0.738 ms 0.742 ms 0.740 ms
5 76002gsr.hpcf.upr.edu (136.145.215.54) 0.986 ms 0.897 ms 0.735 ms
6 ac2hpcf.hpcf.upr.edu (136.145.215.1) 1.014 ms 0.881 ms 0.987 ms
7 181-207-38-65-static.centennialpr.net (65.38.207.181) 1.283 ms 1.249 ms 1.229 ms
9 w021.z207088246.xo.cnc.net (207.88.246.21) 27.472 ms 27.337 ms 27.729 ms
10 71.5.172.5.ptr.us.xo.net (71.5.172.5) 27.210 ms 28.082 ms 27.277 ms
11 te1-0-0d0.cir1.miami2-fl.us.xo.net (207.88.15.41) 27.433 ms 27.331 ms 27.201 ms
12 mai-b1-link.telia.net (80.239.196.185) 28.984 ms 29.046 ms 29.509 ms
13 dls-bb1-link.telia.net (80.91.252.61) 58.535 ms 58.396 ms *
14 las-bb1-link.telia.net (213.155.131.77) 101.497 ms 95.666 ms 97.187 ms
15 net2ez-ic-152338-las-bb1.c.telia.net (213.155.129.70) 94.662 ms 94.186 ms 99.446 ms
16 br01-1-2.lax4.net2ez.com (64.93.64.162) 94.377 ms 94.732 ms 94.612 ms
17 cr02-1-2.lax4.net2ez.com (64.93.64.78) 94.629 ms 94.763 ms 94.172 ms
18 mt-cr02.mediatemple.net (64.93.75.18) 94.669 ms 94.793 ms 94.462 ms
19 e1.1.as02.lax01.mtsvc.net (72.10.63.198) 94.650 ms 94.246 ms 97.892 ms
20 e1.3.as06.lax02.mtsvc.net (72.10.63.250) 104.432 ms 94.270 ms 96.426 ms

traceroute to openmrs.org (205.186.173.50), 64 hops max, 52 byte packets 1
136.145.128.1 (136.145.128.1) 0.719 ms 0.280 ms 0.232 ms 2 136.145.94.10 (136.145.94.10) 0.225 ms 0.257 ms 0.235 ms 3 136.145.95.1 (136.145.95.1) 0.728 ms 0.726 ms 0.487 ms 4 hpcf2rcm.hpcf.upr.edu (136.145.215.45) 0.731 ms 0.719 ms
0.732 ms 5 76002gsr.hpcf.upr.edu (136.145.215.54) 313.593 ms 1.029 ms 0.985 ms
6 ac2hpcf.hpcf.upr.edu (136.145.215.1) 0.981 ms 1.061 ms 0.984 ms 7
181-207-38-65-static.centennialpr.net (65.38.207.181) 1.236 ms 1.325 ms 1.181
traceroute to openmrs.org (205.186.173.50), 64 hops max, 52 byte packets

136.145.128.1 (136.145.128.1) 0.675 ms 0.289 ms 0.241 ms
136.145.94.10 (136.145.94.10) 0.227 ms 0.268 ms 0.225 ms
136.145.95.1 (136.145.95.1) 0.734

ms 0.551 ms 0.470 ms 4 hpcf2rcm.hpcf.upr.edu (136.145.215.45) 0.718 ms
0.585 ms

0.481 ms 5 76002gsr.hpcf.upr.edu (136.145.215.54) 0.735 ms 0.807 ms 0.707 ms

ac2hpcf.hpcf.upr.edu (136.145.215.1) 1.019 ms 0.851 ms 1.226 ms

181-207-38-65-static.centennialpr.net (65.38.207.181) 1.769 ms 1.272 ms 1.233 ms

27.241 ms 9 w021.z207088246.xo.cnc.net (207.88.246.21) 177.146 ms 120.963 ms

294.367 ms 10 71.5.172.5.ptr.us.xo.net (71.5.172.5) 27.642 ms 27.419 ms 27.685 ms

ms 11 te1-0-0d0.cir1.miami2-fl.us.xo.net (207.88.15.41) 27.515 ms 27.290 ms
27.456 ms 12 206.111.1.1222.ptr.us.xo.net (206.111.1.1222) 28.889 ms 29.022 ms
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.

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.

**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:**

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