Reviewer's report

Title: Physicians Perceptions of an Electronic Health Record-based Clinical Trial Alert Approach to Subject Recruitment: A Survey

Version: 2 Date: 19 November 2007

Reviewer: Lawrence Afrin

Reviewer's report:

General

This is a well-written paper about a well-conceived, well-executed study of an important topic in the emerging field of clinical research informatics. Its chief limitations are its relatively small size and clinical scope, which were necessarily constrained by the size and scope of the interventional study that preceded it. In spite of these limitations, the findings in the current study should help informaticists further improve EMR-linked clinical trial accrual assistance systems. Such improvement is quite important given (1) the huge problem that poor accrual poses to the clinical trial industry and (2) the increasing use of EMRs in the clinical community in general and particularly in the academic sector where most clinical trials are performed.

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

None.

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

There are a number of minor language errors scattered throughout the paper, as itemized below:

(1) Page 2, Abstract, "Results," line 4: "...about a trial via a CTA, including." Including what? Or should ", including" be deleted?

(2) Page 4, Background, line 6, "physician" should be "physicians".

(3) Page 6, two lines above the "Purpose for the Survey" header, delete the word "using".

(4) Page 8, Results, line 3: there is an extraneous comma after "58%".

(5) Page 10, Discussion, second paragraph, line 8, "all together" should be "altogether". Also, last line on the page, "findings" should be "finding".
(6) Page 11, first line: "were" should be "was" as the subject of the verb is the singular "proportion". Also, second paragraph on the page, second line, "...versus non-responders, it..." should be "...versus non-responders was found, it...". Finally, line 6 in the same (second) paragraph, "cautios" should be "cautious".

(7) Page 12, Authors Contributions, "Authors" should be in the possessive form ("Authors'"), and on the fourth line, "All" should be "all" since it's not the beginning of a new sentence.

(8) Table 2: There are extraneous commas following the percentage figures in the first four lines of the table.

Discretionary Revisions (which the author can choose to ignore)

(1) Page 10: The authors question whether a respondent would truly want to be made aware via the CTA system of multiple trials for which his patient might be eligible. This doubt seemingly presumes that the CTA system must generate an individual alert for each trial for which a patient might be eligible. However, it is conceivable that the system could be enhanced to deliver a single alert containing notification of potential eligibility for multiple trials. This is an area for study in its own right. On the one hand, such a multiple-eligibility notification could be seen as very convenient to the physician and thus might increase screening and accrual. On the other hand, such a multiple-eligibility notification could be seen by the receiving physician as a heightened cognitive challenge (as compared to a single-eligibility notification) that he’s simply not willing to manage in the tight timeframe of a typical office encounter, and thus multiple-eligibility notifications could lead to more notifications being dismissed without being read -- and thus lead to a lower rates of screening and accrual.

(2) Page 11: The authors discuss that some respondents desired the clinical trial alert contain a link to more information about the trial, and they note that such a link is "feasible and could lead to improved usage." Although some physicians might indeed click on such links, the criticality of keeping to one’s schedule in the ambulatory setting is paramount, and I suspect most physicians would not click on such links. Instead, I recommend the authors investigate the feasibility and utility of providing an "E-mail me more information about this trial" button/link in each alert their CTA system issues. Such an approach would allow the physician who is potentially interested in learning about trials for his patient to spend minimal time managing the alert at a point in his workflow when time-efficiency is critical, while simultaneously giving him access to a wealth of desired information for review at a more convenient point later in his workflow (e.g., after clinic).

(3) Page 11, second paragraph on limitations: The authors should consider briefly mentioning another significant limitation of the current study, namely that it surveyed attitudes about alerts given to a limited population of clinicians (internists and endocrinologists at a single institution) about a single trial (ACCORD). In my opinion, although the interesting marriage of technology and
workflow that is the CTA system holds much promise, it remains unclear whether such a system will necessarily yield similar benefits when applied to other types of physicians and other types of trials. For example, will oncologists respond as favorably as endocrinologists? Will there be an impact of the prevalence, or morbidity/mortality, of the disease being studied on the likelihood of physician response to the alert?

It also remains unclear how much work will be required to extend the CTA method to EMR environments other than the one used at the authors' institution. It is notable that the current CCHIT certification criteria for both ambulatory and inpatient EHRs do not include a requirement for CTA-like functionality; the closest CCHIT currently comes to a CTA-like functionality requirement is an expectation that the 2009 criteria will require certified products to have a method for receiving (via direct machine-to-machine communication) trial eligibility criteria from which the EHR can automatically identify potentially eligible patients and respond to the trial authority with a count of such patients and the EHR site's intent to participate in the trial or not (cf. http://www.cchit.org/files/Ambulatory_Domain/CCHIT_Ambulatory_INTEROPERABILITY_Criteria_2007_Final_16MAR07.pdf, section IA-9.01 on page 6; note this is the correct URL in spite of the misspelling of "Criteria"). Thus, without any expectation yet that CTA-like functionality will be built into EHRs as a "standard" feature, the applicability of the authors’ approach to most other EMR environments -- especially those based primarily on closed architecture -- remains an open question.

**What next?**: Accept after minor essential revisions

**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**:

I declare that I have no competing interests.