Editor

BMC Medical Research Methodology

September 19, 2004

Re: Prospective Study of Clinician-Entered Research Data in the Emergency Department Using an Internet-Based System after the Privacy Rule

Sir:

I am pleased to have the chance to re-submit this manuscript to BMC Medical Research Methodology.

We have carefully considered the reviewer’s comments, and addressed all concerns. Please see our point-by-point responses, appended below.

I have reviewed the formatting guidelines at http://www.biomedcentral.com/info/ifora/medicine_journals and followed all instructions.

We hope that this manuscript meets with approval for publication.

On behalf of all authors, I am

Very Truly Yours,

Jeffrey A. Kline MD
Director of Research
Department of Emergency Medicine
Carolinas Medical Center
The audience for the first of these is the research community and it will be very interested in the paper.

Readers will want, however, more detail regarding a) exactly what HIPAA requires and b) how the process of getting through the data committee worked [how many iterations of the proposal were required, what were the stumbling blocks [points of dispute, compromise, etc.]]?

This is a very relevant suggestion, and we have addressed this in highlighted text on pages 4 and 5. We tried to address this in a way that would be useful to other investigators, rather than focus on the internal struggles that we believe may be unique to our hospital.

What have they learned from the experience? An extended discussion of this process would be most welcome.

Thank you for raising this question. On pages 13-14 we discuss that we could not make the PDA approach work, despite having specific funding for this purpose. We think this is contrary to what many others are reporting, or at least what they believe. However, the most important point that we learned was that this can be done, i.e., we can collect data from multiple hospitals on a hosted server, then use these data to complete follow-up later on, all while in compliance with the Privacy Rule. No PHI were disclosed to any unauthorized person, and the sky did not fall.

The second aspect may be of interest to the informatics community but in present form is insufficiently sketched out to be of use. If this is an informatics paper it needs to discuss the specific techniques that make this work notable and provide sufficient description so that others could reproduce it. If there are proprietary issues here they should be noted. The paper also needs to make a better case for the novelty of the informatics section of the work.

We would respectfully refer back to the original text on page 3 last para and top page 15 where we discuss the fact that commercially available systems are inadequate. The technical description of the system is outlined on pages 6-8. However, this paper is intended for an audience of clinical investigators, not IS experts. We assume that the savvy investigator has a reasonable level of technical knowledge, but is not interested in drilling on the incredibly complex (and boring) issues of why we chose to use .asp server side controls, our choice of middle-ware, the risks and benefits of SQL versus the Nix systems, and so forth. The issue about reproducibility is a tough one, because no two webmaster/programmers would do this exactly the same. We could write a level of detail ranging from showing scripts of source code (very detailed) to just describing the use of the system as if for a lay audience. We chose a middle ground.

The reviewer is exactly right that there are proprietary issues, and these have been fully disclosed.
The third aspect is the most troublesome as there is a lack of clarity regarding which phenomena are being measured. The current design fails to differentiate discrepancies that occurred in the data acquisition process from those introduced during the data entry process. It would appear that the focus should be the latter but this cannot be disentangled from the former. Based on my perception that researchers are very interested in how to comply with HIPAA in a way that allows them to conduct their work, I would urge the authors to amplify 1) and back off on the others. This is not a mandatory requirement however. If the authors are to focus on 2) they need to do a better job of making the paper adequately descriptive. If they are to focus on 3) they need to justify their study design and explain how the results should be interpreted. A more detailed paper on 1) would be most exciting to this reviewer.

In accordance with this recommendation, we have deleted all reference to the interobserver variability experiments. We believe that this was important data, but we respect the reviewer's point of view. Moreover, without over-repeating information that has been published by others (in our bibliography), we describe on pages 5 and 6 how the DHHS has specified methods required to collect data under waiver of authorization. This is somewhat brief, but we did not want this to turn into another review on "what HIPAA means to clinical research." Several of these have been published, and the authors are aware of several more that are in press. Our point is to say that "we did it and you can too."

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

1) Properly utilize "principal" and "principal!"

Corrected

2) The interpretation of Cohen's kappa is quite contentious and the Landis & Koch criteria that most people cite are very problematic. In certain circumstances a kappa of .6 is "good" in others it is dreadful. This should be discussed.
3) I am confused about the data checking. It appears that for continuous numeric data (e.g. pulse) the software will not permit entry of ridiculous values. How then do you report errors in these fields? It would seem that this should not happen.

The side-server will not let the form upload until a non-ridiculous value is entered. This is stated under C. data form entry structure. Two examiners also examined each of 70 fields for 1022 patients to be sure the data were valid. These results are stated on page 11 last para.