Reviewer's report

Title: Evidence for handheld electronic medication records in improving care: a systematic review

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Reviewer: Jonathan Handler

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General

This is an article on a very important topic. Handheld EMR's are widely believed to be an important component of next generation care. Most believe that greater access to the EMR will lead to improvements in clinical care. The handheld EMR (as defined in this article) provides clinicians with an additional method for access to the benefits of an EMR. Logically then, it seems that a handheld EMR should be able to positively affect outcomes, but empirical evidence is needed to actually prove or disprove this hypothesis. This article attempts, through a systematic review of the existing literature, to clarify what is actually known about the ability of a handheld EMR to improve patient care.

The paper is well-written. The authors define the EMR clearly and broadly. The authors also clearly defined their methods, including their search strategy, in a way that would allow replication of their methodology.

The articles in this review were not only few in number (two), but very low in quality despite (and likely because of) the requirement for randomized, controlled trials. The authors do a very nice job of highlighting the many weaknesses of the two studies that they reviewed. Both studies had very small sample sizes (3 practitioner subjects in one, and 6 practitioner subjects in another). There was no diversity in the practitioner subjects in the studies, and minimal diversity in the patient subjects. Both studies were performed in an environment of orthopedic care. In one study, the 3 practitioners were anesthetists, and in the other the 6 practitioners were house officers caring for orthopedic inpatients. There was no diversity in the type of software or hardware used in these studies. The outcome measures were soft and not patient-based -- time required for documentation, documentation completeness, and documentation correctness. The studies pre-date wireless technology, and the applicability of their results to the current day is questionable. As a result, the generalizability and utility of these studies is low. The authors reach the same conclusion, and urge further research.

In this paper, the inclusion criteria required a "randomized controlled trial". Large, multi-center, double-blind, prospective, randomized controlled trials are generally considered the pinnacle of empirical medical research. Studies that do not have all of these attributes may still provide important guiding evidence to decision-makers in a field. That is fortunate, because many studies simply cannot be done if all of these attributes are required. For example, blinding is useful to remove a major source of bias, but it simply cannot be done in some instances. It might be impossible to do a study of handheld EMRs with blinding if the outcome measures related to the clinician experience, so the decision not to require blinding in this review was certainly appropriate. Other study attributes that are very important are the selection of subjects, the diversity of subjects, the number of subjects, the outcome metrics, the timing of data collection (prospective vs. retrospective) and the metric measurement methodologies.

The importance of a study attribute varies by the study topic. In this particular paper, studies that were not both randomized and controlled were specifically excluded. Even though randomization is a highly desirable method for eliminating a source of bias, there are a number of very good alternative methods for eliminating or reducing those same sources of bias. Matched controls, crossover designs, and non-random but relatively arbitrary group assignment are just some of the methods for reducing bias that can otherwise occur during the assignment of a subject to the intervention or the control group. For this particular topic, requiring study randomization may have paradoxically resulted in the inclusion of very low quality studies, and the possible exclusion of higher quality studies that would have truly added to our understanding of this topic.

The inclusion criteria for this review resulted in the exclusion of all but two of the 1773 citations that were screened, and those two articles do not significantly advance our knowledge in this area. Readers of this paper may wonder whether so few citations were found because there is no good published evidence, or because the inclusion criteria were too narrow. Given that the search criteria included "randomized
controlled trial", more citations might have been found and screened if there had not been a requirement for randomization. A slightly broader set of inclusion criteria, for instance "controlled trials not dependent upon convenience samples", would have yielded at least an equal, and probably larger set of articles for review. This would increase the likelihood that truly high quality studies were captured by the search criteria, without expanding the search criteria so broadly that an impossible number of citations would require review.

I did a brief review of PubMed using a few searches based on the authors' search terms. Based on that cursory review, it appears that dropping the requirement for randomization will be unlikely to yield much more than what the authors have already found. However, that cannot be known until a more systematic review is actually done. It is critically important for a systematic review to cast a wide net in order to provide readers with the assurance that no reasonable stone has been left unturned. Otherwise, readers cannot trust the conclusions of the review.

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

In order to assure readers that the search for quality data was truly comprehensive, the authors should do a second level search for all controlled trials, perhaps excluding those that used convenience samples. For that round, I believe it would be reasonable to search CINAHL, PubMed, etc... I think that reviewing the citations in every identified article would be nice, but not absolutely necessary, for this second round. If this were done and the results were included in the paper, then I think this would be a much stronger paper -- one that should be published.

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

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

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

Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:

To the best of my knowledge, I do not believe that I have any competing interests. However, in the full diversity of organizations with which I have interacted, I cannot be certain that the publication of this paper will have absolutely no effect on any of those organizations now or in the future.