Author's response to reviews

Title: Prospective, randomized evaluation of a personal digital assistant-based research tool in the emergency department

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Author's response to reviews: see over
Referee #1

1. If the study were not in play would it be necessary to transcribe the paper record? In other words does the difference in time reflect only the necessity of the study or some critical aspect of patient care?

Response:
No, the paper record being compared to the PDA in this study was limited to data points being collected for an observational research study that did not impact patient care. Records written for patient care were not a part of this study. As such, this study directly compared two forms (paper and PDA) that were identical in terms of content.

2. The PDA was uploaded into the information system. The term “hot-sync” and “hot-synch” are both used. Select one for consistency.

Response:
We have replaced all appropriate occurrences with the proprietary term “HotSync®”.

3. The physicians were “interviewed” before the patients and asked 7 questions while the patients were queried for 62 data points. I am not sure what that means. Is this interview outside the clinical encounter? What were the questions asked? It seems all data reported are gleaned from the records and data from the “interviews” is absent. I am sure I am just missing something but a clarification is needed.

Response:
It seems that the term “interview” is somewhat confusing. By “physician interview” we are referring to the encounter in which the study investigator queries the physician for answers to six multiple-choice questions. Similarly, during the “patient interview” the investigator queried the patient directly for specific elements of the present and past medical histories. Answering these questions was entirely a research endeavor, not a part of usual patient care. The specific questions can be found on the screens color-coded blue in figure 1.

For clarification, we have modified the methods as follows (latter half of second paragraph under subheading “Patient enrollment”):

Five study investigators (MR, JD, BAP, AD, CK) enrolled patients. Research data were gathered in a series of two interviews during which an investigator directly queried first the patient’s physician and then the patient. Patients were each queried for 62 variables, while their physicians were queried for seven. The remaining variables (patient name, medical record number, social security number and vital signs) were collected in an un-timed step. For a given patient-physician encounter, one investigator gathered all research data. Enrollment was considered complete when all data for a patient were collected.
4. Do you believe the results might be affected by training the physicians immediately prior to the study in the proper use of the paper form as you did the proper use of the PDA?

Response:

If data were directly entered by the evaluating physicians it would be reasonable to assume that a learning bias would influence data collection times. As it were, data were entered by research investigators while interviewing physicians in real time. The investigators were given ample time to familiarize themselves with both the paper and PDA instruments prior to the timing of data collection.

Referee #2

1. The term "enrollment" is used throughout the manuscript. I noted with interest that this is the U.S. spelling, "enrolment" is used elsewhere. However, I believe that what the authors are referring to is "research data collection". Enrollment implies entering the patient into the study.

Response:

We have modified the manuscript to limit use of the term “enrollment”. When present, we have used the U.S. spelling. For further clarification we have substituted the terms “data collection” and “information gathering” when appropriate.

2. Sample sizes were based on detecting a 60 second difference in data entry times (based on ref 5). Surely this would depend on the total data entry time? (ie. 6 minutes versus 60 minutes). No mention is made of baseline times for paper or PDA being assessed.

Response:

True power determination requires a normally distributed sample set. We recognize, however that it is common practice to predict necessary sample sizes even for non-normally distributed data, and when only preliminary findings are available. As such, we calculated necessary sample sizes using approximated total data gathering time of 9 minutes for the paper method and 8 minutes (the 60 second difference) for PDA, yielding a value of 46 patients.

We have made the following change to the methods (subheading “Patient enrollment and data collection”) in order to clarify our method of sample size determination:
Sample sizes were powered to detect a difference in data collection times of 60 seconds, using an estimated data collection time of nine minutes for paper (alpha=0.05, beta=0.8).

3. Was the consent obtained (under section "Patient Enrollment") for this PDA/paper study, or for the larger pulmonary embolism study?

Response:

Patients gave consent for participation in the larger study. For the smaller study, IRB approval extended permission to include the data collectors (whose performance would be measured) as human subjects in the study. We have changed the following sentences for clarification.

In methods under “Study setting and population”:

Both studies were approved by the human research committee of Partners Health Care. For the sub-study, permission was extended to include the study investigators as study subjects.

Under subheading “Patient enrollment and data collection”:

After informed consent was obtained from patients, but prior to data collection, patients were randomized using a random number generator to have their data collected using either paper forms or PDA.

4. How were data errors identified? Was this a manual check, single, duplicate?

Response:

We have included the following sentence to clarify the method of error rate determination under “Patient enrollment and data collection”.

Error rate determination was performed by a single researcher who manually examined/compared all data collected.

5. The sentence in Results, "Hence the reported mean total data-gathering time ." does not appear to be very relevant.

Response:

The sentence was meant to acknowledge that non-matched (raw mean) values for data collection times would have yielded results different from those reported. We agree with reviewer that the same conclusion can be reached from the immediately preceding sentence, and have made the appropriate deletion.

6. Ref (4) "Parsonal" should be "Personal"
Response:
The typographical error has been corrected.

7. Figure 3 adds nothing to the paper and should be deleted.

Response:
Figure 3 has been omitted from the final draft. Figure 4 has been renumbered.

Discretionary Revisions (which the author can choose to ignore)

1. Little mention is made of software development, usability testing, piloting and training. Optimization of the software would obviously have a significant impact on the timing of data entry, the major study outcome measure. For example, with more sophisticated software "nonsense" values and missing data could be eliminated.

Response:
We agree. One of the main advantages of using a PDA based system is that nonsense values can be dis-allowed in real time. This can be done by defining the type of entry that is acceptable (e.g. numerical versus alphabetical), the magnitude of allowable values (e.g. maximum weight) as well as the allowable character length of entries. We designed our PDA forms to include the first feature (acceptable data type). It is not clear if the decision not to further restrict acceptable values directly resulted in the duplication errors that were identified. Examples of these included a weight entry of 168 lbs that appeared as “168..168” and a social security number that also appeared to have been written twice. Alternatively, duplication may have occurred during data transfer. Fortunately, the intended values were interpretable – sense could be made of them. However, because the values did not conform to their intended formats we counted them as nonsense errors. As noted in the manuscript, we created a missing data program to identify missing values for certain data points. Our paper forms were also ultimately uploaded to a secure web server, which also contained programming dis-allowing nonsense or missing data. However, by the time paper forms were transcribed, the patient was typically not in the emergency department, and nonsensical or missing data could not be obtained. As the reviewer points out, this highlights one clear advantage of the PDA, i.e. real time error detection.

With regards to training and usability testing: Prior to initiation of the PDA study, study investigators had been enrolling patients using the paper form for several months. They were very familiar with the process. Similarly, when the PDA was brought online, we allowed each investigator to enroll patients using the PDA for several months prior to timing their enrollment. This way, investigators were equally familiar with the process of enrolling patients using both paper forms and the PDA.
In addition to what was previously included within the discussion, we have added the following sentence to the methods to reflect this point:

Investigators already familiar with data collection using the paper form were able to familiarize themselves with data collection using the PDA over a period of about three months prior to initiation of the sub-study.

2. Did any technical malfunctions occur, e.g. Hot-Sync problems, battery failure, loss of PDA, etc?

Response:

There were no technical problems that occurred during the study, however subsequent to the conclusion of the study one PDA free of study data was lost. We have made the following additions to reflect these points.

Within results:

There were no technical/electrical problems during the study, such as Hot Sync® malfunction or battery failures.

Within discussion:

The ever-present risk of misplacing study data is highlighted by the loss of two paper forms during this study. After study completion, one PDA was lost. It was password protected, and did not contain any study data at the time, but the potential for this problem is worth noting. While PDAs are more expensive to replace than paper, we believe the risk of lost data and patient privacy favor electronic data collection. In addition, wireless networks can be used to securely transfer PDA data from the bedside to a secure database, which can minimize the risk of lost data (10,11).