A comparative study of mobile electronic data entry systems for clinical trials data collection

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ABSTRACT

Purpose: To determine the speed, accuracy, ease of use, and user satisfaction of various electronic data entry platforms for use in the collection of mammography clinical trials data.

Method and materials: Four electronic data entry platforms were tested: standalone personal digital assistant (PDA), Tablet PC, digitizer Tablet/PDA Hybrid (DTP Hybrid), and digital pen (d-pen). Standard paper data entry was used as control. Each of five radiologist readers was assigned to enter interpretations for 20 screening mammograms using three out of the five data entry methods. Assistants recorded both start and stop data entry times of the radiologists and the number of help requests made. Data were checked for handwriting recognition accuracy for the d-pen platform using handwriting verification software. A user satisfaction survey was administered at the end of each platform reading session.

Results: Tablet PC and d-pen were statistically equivalent to conventional pen and paper in initial data entry speed. Average verification time for d-pen was significantly less than secondary electronic data entry of paper forms (p-value <0.001). The number of errors in handwriting recognition for d-pen was less than secondary electronic data entry of the paper forms data. Users were most satisfied with Tablet PC, d-pen, and conventional pen and paper for data entry.

Conclusions: Tablet PC and d-pen are equally fast and easy-to-use data entry methods that are well tolerated by radiologist users. Handwriting recognition review and correction for the d-pen is significantly faster and more accurate than secondary manual keyboard and mouse data entry.

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1. Introduction

Clinical trials data collection has not changed much since computers became an integral component in conducting data analysis of clinical trials. Primary data collection is largely done on paper first with electronic computer entry taking place later, generally by data entry personnel either at a centralized coordinating center for or by onsite research associates. This added data entry step can be used to validate data prior to submission to a central database, but it can also introduce data entry errors. The adoption of web-based data entry systems, which introduced real-time verification and submission, has not resulted in significant gains in terms of data accuracy or efficiency. There are a number of reasons for this
including the limited mobility of computer hardware and the lack of availability of on-line data accuracy checks (i.e. desktop personal computers far removed from location where data is initially acquired) [1]. Today there are a number of mobile devices that are used in other data collection applications that could readily be used for clinical trials data collection. The personal digital assistant (PDA), Tablet personal computer (Tablet PC), digital pen (d-pen), and digitizer Tablet/PDA Hybrid (DTP Hybrid) have all shown usefulness for mobile computing purposes [2-5] in the medical field. The PDA has been extensively tested and has shown mixed results as a data collection tool by physicians users [6,7] and patient users [8] based on the application. The large-scale implementation of any of these data collection devices for a clinical trial without some evidence of their reliability in the field could prove disastrous both monetarily and in subsequent poor quality of patient care that could result.

The purpose of this project was to determine which of four mobile electronic devices are most suitable for clinical trials data collection in our mammography clinic by assessing the speed, accuracy, ease of use, and satisfaction by radiologists, who are one group of potential users of these devices for primary data collection in medical imaging clinical trials.

2. Methods and materials

Four different mobile electronic devices were tested – a Tablet PC (Mi300, Motion Computing Inc., Austin, TX) (Fig. 1), an d-pen (Logitech io, Logitech, Fremont, CA) (Fig. 2), a DTP hybrid (Mi-Forms Pad, Mi-Co, RTP, NC/Dell Axim, Dell Inc. Round Rock, TX) (Fig. 3), and a DTP Hybrid (Mi-Forms Pad, Mi-Co, Round Rock, TX) (Fig. 4). Forms software (Mi-Forms, Mi-Co, Research Triangle Park, NC) was installed on each device allowing for data transmission to a centralized server via standard communications protocols. Conventional pen and paper completion of a form by the radiologist with secondary electronic data entry by an administrative assistant was the control condition. Five radiologists participated in this study using a standard research form created in our clinic for the collection of mammography interpretation information. The large-scale implementation of any of these data collection devices for clinical trials data collection in our mammography clinic by assessing the speed, accuracy, ease of use, and satisfaction by radiologists, who are one group of potential users of these devices for primary data collection in medical imaging clinical trials.

2.1. Statistical methods

2.1.1. Speed Analysis

A research assistant recorded the time of completion of each form during the reading sessions. Analysis of variance was used to determine if the initial data entry speed differed between each of the devices tested. The Shapiro-Wilk test indicates that the time spent in reading is skew-distributed. However, the log transformed time appears to satisfy the normality assumption. The first analysis was to fit a generalized linear model to the data, where the response used in the model is the log-transformed time spent in reading and the design matrix includes the factors of 5 devices, 5 readers, and 20 cases. The R-squared was 0.69, which shows that the generalized linear model fits the data very well. The residual analysis from the fitted model further shows that the model used for analyzing data is valid.

2.1.2. Accuracy

Three radiologists read 20 cases using both the d-pen and conventional pen and paper. One additional radiologist read 20 cases using conventional pen and paper. A data entry operator entered the data forms from these 80 cases manually via mouse and keyboard into a desktop computer. Comparison of manual data entry was made to Mi-Forms verification and correction, where a verifier/corrector checks to make sure that the handwriting recognition captured matches the information recorded on the paper source. The number of data entry errors was determined by cross checking the source paper document to the information entered into the electronic database by the data entry operator (or the verifier/corrector in the case of Mi-Forms verification). The accuracy was recorded and expressed as the percentage of cases for which one error, two errors, or more than two errors were made for each of the two data entry methods.

2.1.3. Ease of use analysis

The number of help attempts was assumed to follow a Poisson distribution with rate varying from device to device, reader to reader, and even case by case. Since conventional pen and paper required no technical usage help, it was necessary to compare the performance of the remaining four devices. The observations associated with conventional pen and paper was excluded from the data and a generalized linear model with log-link function was fitted for this Poisson data with the normality assumption. The first analysis was to fit a generalized linear model to the data, where the response used in the model is the log-transformed time spent in reading and the design matrix includes the factors of 5 devices, 5 readers, and 20 cases. The R-squared was 0.69, which shows that the generalized linear model fits the data very well. The residual analysis from the fitted model further shows that the model used for analyzing data is valid.
3. Results

3.1. Speed

The analysis of variance indicated that the times spent entering data were significantly different among the five devices (p-value <0.001), among five readers (p-value <0.001), and among
Fig. 2 – d-pen: paper pre-printed with a fine, unique dot patterned background for each page of every form must be used. The tip of the pen has a little camera that records images of the dot pattern which is uniquely arranged across the page. The result is an exact electronic replica of the handwritten page.

Fig. 3 – PDA screen-shot: stylus data entry able to fit into the palm of your hand. This device is extremely portable and lightweight. Small screen makes it unsuitable for wordy data elements. Although there is scroll capability, it can be a little cumbersome.

20 cases (p-value < 0.001). The Tukey test with significance level 0.05 showed that after controlling the confounding effects due to readers and cases, the time spent using the DTP hybrid was significantly longer than the time spent using the d-pen, conventional pen and paper, and Tablet PC (all p-values < 0.01) (Fig. 6). There was no significant difference between the time spent using the DTP hybrid and the time spent using the PDA only (p-value = 0.17). The data entry methods from fastest to slowest were conventional pen and paper entry, Tablet PC, d-pen, DTP hybrid and PDA. The speed difference between conventional pen and paper, d-pen, and Tablet PC was not significant (all pairwise p-values are larger than 0.85).

3.2. Ease of use

The ease of use of the data entry systems was determined based on the percentage of cases with at least one request for help. The PDA was the hardest to use with 70% (14/20) of the cases reviewed requiring the user to seek assistance in getting the data into the electronic device. The percentage of cases with help requests were 42% (42/100) for the DTP hybrid, 14% (14/100) for the Tablet PC, and 8.3% (4.98/60) for the d-pen. There was no significant difference in the number of help attempts observed between the d-pen and the Tablet PC (p-value = 0.26).

3.3. Accuracy

Handwriting recognition verification software (Mi-Forms, Mi-Co) was used to verify quality of computer interpretation of data collected by the d-pen. The average time spent by a data entry operator for verification of captured electronic data for the d-pen was significantly less than secondary electronic data entry and verification of paper forms (p-value < 0.001). The number of errors in handwriting recognition for the d-pen was less than the number of transcription errors based on secondary data entry of the conventional pen and paper forms data. A total of 27.5% of cases had at least one data entry error for secondary entry of paper forms. About 10% of cases had at least two errors and 6.25% had at least three errors. With the d-pen, 13.33% of the cases had at least one handwriting recognition error, 3.33% of the cases had at least two errors, and none of the cases had more than two errors.

3.4. User satisfaction

There were no significant differences in user satisfaction among the DTP hybrid, PDA, and conventional pen and paper (Fig. 7). However, the DTP hybrid, and PDA alone had significantly lower scores than either Tablet PC or d-pen (p-value < 0.003). The Tablet PC and d-pen were not significantly different from each other (p-value = 0.96).

4. Discussion

Conversion from paper primary data entry to electronic data entry will not result in error free data collection but minimizing data entry errors resulting from an extra data entry step will certainly help in the data clean-up stage of clinical tri-
Fig. 4 – DTP Hybrid: standard paper forms are positioned on a special tablet. Each form has an electronic XML definition to which data is stored upon entry of check box, option box or text. A PDA acts as the computing engine, performing real-time logic checks of the data that is entered.

Als. No matter how sophisticated the central data collection system database, ultimately a clinical trial’s data quality rests in the hands of the individual sites so it becomes imperative that an understanding of the practical usage of the prospective data collection system take into consideration system features (Table 1) and the user requirements.

4.1. The data entry platforms

4.1.1. Tablet PC

A Tablet PC has the functionality of a laptop with the added benefit of a screen with stylus data entry like that of a PDA. Tablet PCs at the moment are the most expensive laptop computers on the market. A large screen that is roughly the size of a piece of paper makes it visually appealing. Normally around 3-4 pounds in weight, it is easily portable from one room to another. The interface can be made to emulate a paper form and logic checks can be built in to prevent some common data entry problems. For example, this system can prevent input of a number that is outside an acceptable range of values. The Tablet PC is handwriting recognition capable and allows for handwritten signature capture. A source document is generated and can be printed, if needed, or permanently stored electronically. All of the handwriting is converted to computer text in a separate file, where the data can be verified for accuracy prior to uploading to the study database, which can be done immediately or following verification at some set time in the future as a batch process. Tablet PCs today can be wireless-enabled or blue-tooth-enabled for communications to and from the study database server. Cross-outs are traceable and electronically time stamped and maintained with the source handwritten form electronic form.

4.1.2. Personal digital assistant (PDA)

This electronic data entry system also has touch screen stylus data entry. This device is extremely portable and lightweight. The small screen makes it poorly suited for lengthy data elements, and although there is scroll capability, it can be somewhat difficult to navigate. Logic checks can be built in and data can be instantly uploaded to a study database with wireless functionality or by docking to a cradle. This is a relatively inexpensive system, even with wireless capability. Handwriting recognition is built in. There is, however, immediate conversion to typed text with no handwritten source document stored. The verification step takes place usually after uploading the forms to a computer with a larger screen, although it can be done on the small screen. This device is most useful when there are a limited number of data elements with few text box entries. This system is impractical for forms with any number of data elements over 20 or 30. However, the PDA could
Fig. 5 – Mi-Forms verification software. Useful for verifying that handwritten fields (like case number) are correctly interpreted by the handwriting recognition software. Also can be used to verify data entry completion and logic prior to submission to a backend database.

Fig. 6 – The average time spent by radiologist entering data for each data entry method.

Fig. 7 – Average satisfaction rating of each data entry method.
easily be used for a checklist or short form such as those used by research associates to determine eligibility criteria and to retrieve pre-generated study identification numbers from a centralized database.

4.1.3. Digitizer Tablet/PDA Hybrid (DTP Hybrid)
If a paper trail is desired, the DTP Hybrid electronic data entry system will provide one. Standard paper forms are positioned on a special tablet. Each form has an electronic match to which data is dumped upon entry of a check box, option box, or text. A PDA performs real-time logic checks of the data after it is entered into the PDA but before upload to the study database. Data verification can similarly be done using the PDA screen or after transferring data to another computer. The digitizer tablet itself is roughly 10 × 13in. with a tethered pen that is to be used to complete the forms, which are readily printed as needed.

4.1.4. Digital pen (d-pen)
This is yet another mobile device with the ability to produce a paper-based source trail if required. Paper with unique dot patterns for each page of every form is initially created. This special dot-patterned paper can be printed out from specific types of laser jet printers or pre-printed forms can be ordered from a printing house for high volume applications. There are additional costs associated with printing the forms but the d-pen itself is really inexpensive. The tip of the d-pen contains a tiny camera that records images of the dot pattern, which is uniquely arranged across the page. From the uniquely arranged dot patterns, the d-pen computes a sequence of positions corresponding to the handwriting trace. The result is an exact electronic replica of the handwritten page. The d-pen has a docking station to upload all data collected, but this does not have to be done after each and every case. The d-pen can store over 100 forms at one time. To the user, it is like using conventional pen and paper but with an electronic replica that can be electronically stored so that handwriting recognition software can be used to verify information without typing all of it with immediate upload to a study database. There is no learning curve since using this device is intuitive and like using a regular pen. However, there are no real-time logic checks of the data. The d-pen is ideal for patient data entry, especially for consent and history forms.

### Table 1 – Comparison of data entry systems – key features useful for data collection and verification

<table>
<thead>
<tr>
<th>System features</th>
<th>Handheld (&quot;PDA&quot;) system</th>
<th>&quot;Tablet PC&quot; system</th>
<th>Hybrid handheld/pen-on-paper system &quot;DTP Hybrid&quot;</th>
<th>Digital pen system &quot;d-pen&quot;</th>
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<tbody>
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<td>Pen-on-paper interface</td>
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<td>Immediate validations</td>
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<td>Offline validations</td>
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<td>Real-time handwriting recognition</td>
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<td>Deferred handwriting recognition</td>
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<td>Deferred correction of recognition errors</td>
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<td>Picklists</td>
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<tr>
<td>Real-time capture to database</td>
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<td>Store-and-forward capture to database</td>
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<td>Hardware cost (approximate)</td>
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<td>$2000</td>
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<td>$200</td>
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</table>

4.2. User requirements
When introducing new technology, a basic understanding of the user requirements can save time and money. The user group tested in this study was academic radiologists who are experts in mammography. The environment was carefully controlled reading room (outside of normal clinical environment, controlled for noise and distraction). Our results presented here are specifically for this user group within a controlled environment. The results for our radiologists may differ in their hectic clinical environment. The needs of other clinicians and medical professionals working in other types of clinical environments may differ as well.

The academic radiologists in our experiment participate in numerous clinical trials and visual perception studies so they are accustomed to filling out research forms. The key issue for our users in regards to completing research paperwork beyond normal clinically required documentation is the time it takes to complete the forms. The total time would include not only the time it takes for them to initially complete the form but also the time it takes for them to correct the form if errors are found. The four parameters we chose to look at when assessing the most suitable electronic data collection systems not only take into consideration the requirements of our radiologists but also issues that will influence the quality of the data collected.

4.2.1. Speed
Most of the time research forms are completed in the clinic during breaks or at the end of their clinical workday. Navigation through forms must be intuitive or guided through business rules based on response. In this study, the form had multiple parts, which were completed when necessary, based on the findings seen on the mammograms that the radiologists reviewed.
4.2.2. Ease of use
There is always a learning curve associated with any type of data collection. It inevitably will take the radiologist longer to complete a paper form when they first start a trial but this time should diminish as they become more familiar with order and options of the data elements on the forms. For this study, three out of the five radiologist participants had experienced with the order and options of data elements on the forms because they had used the forms for various clinical trials. In choosing to move to an electronic format, we must consider not only the learning curve for the form content but also the learning curve for the data entry system. The learning curve to use an electronic data entry system should be proportionate to the extent of use. In other words, the radiologist and research associate who will presumably complete study forms for the one or two years of data collection will have extensive training in data collection for a clinical trial. However, their efficiency with a device to capture that information will rest in the frequency of use.

4.2.3. Accuracy
The type of error that can be minimized by the introduction of direct electronic data entry is the transcription data entry error. The data entry personnel who may be the research associate on site or professional typists of the sponsor are charged with data entry and verifying the completeness of the forms. When errors are found prior to transcription of the information from a paper form into the electronic database that will be used to house the information for future analysis, the data entry personnel can request clarification from the person who is the source of the information. Otherwise, the error goes downstream to the statistical center. Either way, clarification is required which may go undetected for months or even years after the data was initially collected. Removing the secondary data entry step would ideally minimize this type of error, as the validation step could be the primary concern of the data management team as opposed to both data entry and validation. The other type of error is the logic error, which is misinterpretation of the question asked or skipping required fields. The ability to perform real-time logic checks as the data is being collected will assist in minimizing logic errors.

4.2.4. User satisfaction
The reason why paper data collection dominates in our research environment is because the radiologists have found every computer interface designed to collect information from them within the clinical environment to be cumbersome to use. There are few options in regards to the hardware used to enter data electronically for a clinical trial as the sponsor of the clinical trial dictates the data collection methods; other than complete a paper form and have someone else on your staff worry about entering the data electronically. If the radiologists are comfortable using an electronic device to enter the information they are required to for a study, they will use it so long as it does not significantly add to the amount of time it takes them to complete the form.

5. Conclusion
In this study, the Tablet PC and the d-pen were equally fast and easily to use than the FDA and DTP Hybrid alternatives. Users were equally satisfied with the d-pen and Tablet PC according to a survey, and more satisfied with those two platforms than with the FDA and DTP Hybrid alternatives. Handwriting recognition results review and correction using Mi-Forms for the d-pen was significantly faster and more accurate than secondary manual keyboard and mouse data entry.

In evaluating and selecting and electronic data entry system, the end user, their working environment, and the form design are key aspects in successful data collection. Our study was designed to test how effective various devices, when fitted with a single vendor’s commercially available software solution, would hold up in data collection of clinical trial data provided by radiologists within the context of an ongoing research project. The results presented here may differ with other forms software. While the results presented here are unique to the form design, data elements, training, and experiment environment of our tested users, we believe that the results provide important information in assessing the relevance of various electronic data capture devices for any data collection purpose given specific use requirements.

References