Evaluation of the Newton Pen-Pad as a Tool for Collecting Clinical Research Data at the Bed-side*

Andrew M Grant, Elisabeth Delisle, Sylvain Champagne
Project FAMUS, Clinical Research Center
Sherbrooke University Hospital (CUSE)
Sherbrooke, Quebec

Pierre Théroux
Montreal Cardiology Institute
Montreal, Quebec

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A protocol for the study of practice variation between Quebec Intensive Care Units in the treatment of myocardial infarction by thrombolysis was coded into the Newton Pen-Pad. This tool for the direct recording of clinical data was tested in the working environment by research nurses of 4 different teaching hospitals. Data was sent directly from the pen-pad by telecommunication to the information coordinating center. The results of this evaluation confirm the reliabilty and robustness of this approach which promises to be an important tool for applied clinical research.

INTRODUCTION

Multicenter clinical trials are increasing in number given the complexity of research questions and the need to have access to sufficient patients within a reasonable period of time.[1] However collecting data for subsequent computer entry can be time consuming and subject to error. If use is made of photocopies or faxes additional errors can ensue.[2] Furthermore missing or inappropriate data discovered when entering data into the computer can be very difficult to correct given the distance that might separate a participant from the data recording center. Important time might lapse because of the delays between collection, recording at a center and subsequent feedback for corrections.

Of interest therefore is the use of new technologies to accelerate the process of data collection, improving data quality whilst respecting confidentiality. The pen-pad technology offers numerous potential advantages being user friendly and portable.[3,4] Data can be recorded directly into the pad and sent by telecommunication to the coordinating center as illustrated in figure 1.

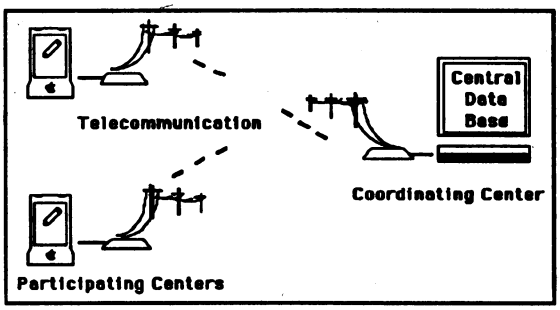

Figure 1- Electronic Multicenter Clinical Trial

This article describes a pilot project which evaluated the use of the Newton pen-pad from Apple Computer Inc. for the collection of clinical research data in the cardiology intensive care unit by a research nurse, data being subsequently transferred by telecommunication to a coordinating center. The investigation is part of a collaborative project between the Informatics and Acute Coronary Care Research groups of the Quebec Cardiology Network of the Fonds de recherche en santé du Québec (FRSQ).

METHODS

In a two phase pilot project we wished to demonstrate the feasibility of using the Newton for collecting data without interrupting the daily work flow of the nurse. It was intended to replace a paper questionnaire developed by the Acute Coronary Care Research group for the evaluation of thrombolytic therapy in the treatment of myocardial infarction in 156 clinical units distributed throughout the province of Quebec. The questionnaire was composed of a first part completed on patient arrival including hospital and patient identification, clinical presentation, admission EKG, treatment or not with thrombolysis, and specific questions concerning prior treatment and patient history. The second part was completed

during the hospital stay with information on interventions, patient outcome (discharge, transfer or death) and final diagnosis. Observer signature was also required. The completed paper questionnaire recorded over different days of the patient's admission was being transmitted by fax for manual computer entry at the coordinating center in Montreal.

The user interface which reproduced the integral structure of the clinical trial questionnaire was developed on the Newton using the Newton Toolkit 1.0.1 on a Macintosh Quadra 950 with constant attention to convivial design and accuracy of data collection. Navigation between screens was organized so that the data recording could be as simple and natural as possible. An example of screen design is given in figure 2. This shows several different features that assist data collection.

A first pilot phase was undertaken with nurse participants from 4 different Quebec hospitals with the aim of evaluating the acceptability of data entry and to compare the work associated with an electronic recording approach to the traditional paper based approach. This phase, which lasted a month, commenced with a three hour training meeting involving designers and trial participants. It included a description of the use of the pen-pad as well as the structure of the electronic questionnaire. Each participant received an English version of the Newton model 120 with the 1.3 operating system as well as a set of rechargeable batteries. Technical support by a 1-800 telephone line was offered throughout the pilot phase.

During the pilot phase the nurse was asked to record 20 patient records in the pen-pad as well as simultaneously completing the paper version of the same questionnaire. An evaluation questionnaire was completed by the participants. This evaluation questionnaire was based on a previous questionnaire used in another project[5] and had 4 sections, identification and clinical research experience (6 questions), previous computer experience (6 questions), software for data collection (11 questions which covered individual screen and feature acceptance, technical problems, time taken, where and at what moment data entry was carried out, and overall appreciation) and the use of the Newton pen-pad itself (4 questions). At the end of the phase a plenary meeting was held to discuss the participants' experience of using the Newton.

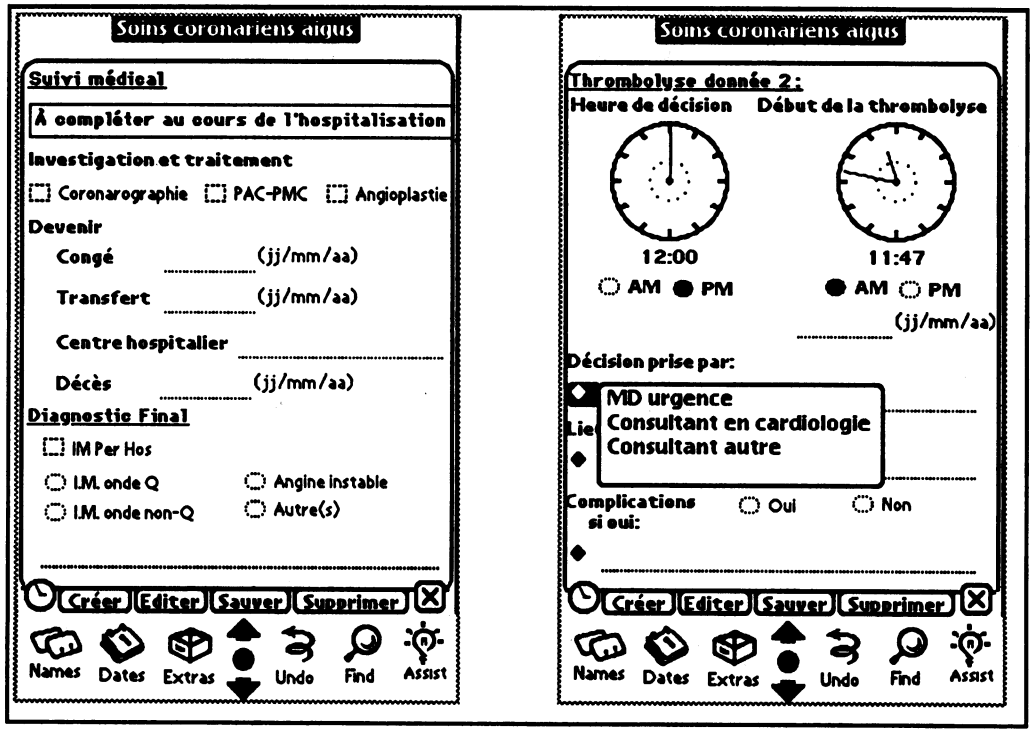

Figure 2- Example of screen design

The results of this evaluation were a number of modifications to interface design. The telecommunication module was also subsequently developed. As no protocol was readily available for the Newton, we developed our own using the cyclic redundancy check (CRC) of the Kermit Protocol from Columbia University for data integrity.[6] The data is received on an IBM personal DX4-100 computer with a script written with Procomm Plus 2.1 software.

The same participants took part in a second evaluation study to examine the use of the Newton in the working environment. To test the telecommunication module, each participant received an external modem attachment for the Newton. A second evaluation questionnaire was completed consisting of 5 questions assessing overall performance and acceptance.

The data received by telecommunication were also downloaded directly into a FileMaker Pro 2.0 file enabling the questionnaires to be amalgamated for analysis.

RESULTS

The first evaluation phase permitted comparison of paper and electronic data aquisition. All data could be collected without problem using electronic data aquisition. A small number of random errors of data entry were noted. Of the four participants 2 were female nurses, one a male nurse and one a male doctor. They had a mean of 20 years of practice experience of which 6 years in clinical research. 3 participants made only occasional use of a computer and one used a computer daily. 2 participants also have a personal computer at home. They all generally liked computers and considered their computer experience prior to the study as positive.

Overall, the study participants enjoyed using the Newton and appreciated its portable format and its reliability. However the training requirement was longer than expected. The time taken to complete a questionnaire on the Newton was 14 minutes, longer than that taken for paper which was 11 minutes, however it was thought that this would diminish with experience.

Ticking a box, the use of radio buttons, the scrolling menus and the calendars were all viewed as efficient and useful. The clock faces for inserting the time were less appreciated. Inserting numbers with the pen was particularly useful, however adding free text was inefficient and time consuming. The availability of a small qwerty keyboard on the screen was an acceptable compromise for particular fields such as patient initials. It should be mentioned that the participants had not well understood that in the section preferences a guest mode could be selected that would learn to adapt to that user's writing, and this made the learning period more difficult.

Three participants carried out data entry at the time of patient admission or during the daily ward round. The fourth participant used the patient record in retrospect. Several suggestions were made for improvement of the software particularly for the management of the patient list, in that the questionnaire had to be accessed twice during the patient stay, and also that there was a need to indicate which questionnaires had been completed.

It also proved necessary to modify the field for the patient's initials so that there would not be an automatic search in the dictionary and to change how the birth date was entered to avoid a complication when a calculation checked the birth date against the age of the patient.

Three participants out of four believed that the Newton could replace paper. The fourth wanted opportunity for adding explanations, although this is usually to be avoided in clinical research.

The evaluation questionnaire for the second phase was answered by the same participants with one exception as the physician was replaced by a research nurse. It was evident that the navigation between sections was still not well understood and this needs to be emphasized at training. The time for completing data entry for a patient had been reduced to 9 minutes due both to participant experience and the improvements made to the software. The participants again confirmed their appreciation for the reliability of the Newton and considered that its format facilitated completing a patient protocol which required multiple times of data collection.

The telecommunications were also tested during the second phase evaluation. They do require the use of a direct telephone line such as a fax line for long distance calls in those cases where the use of the hospital switchboard system results in variable delays for the necessary tone signals.

DISCUSSION

The results of this study with its two part evaluation design were very conclusive as to the utility of the pen-pad approach in the clinical research setting, proving that it is possible to develop a clinical research tool that can satisfy the needs of research nurses who often undertake the bulk of data aquisition in clinical intervention studies.

The use of direct data recording enables the detection of certain errors at the moment of data collection which potentially could reduce the retrospective work

of error correction, a constant preoccupation of clinical trial administrators. The recording of findings in a structured way is particularly appropriate for outcomes research and research databases.[7]

The predominant criticisms at the first evaluation were the slowness of the software and the recognition of characters. The speed was much improved by the time of the second evaluation. At present, the ability of the system to recognise characters is somewhat limited and as such the need to write text should be restricted to a minimum which is in fact consistent with the requirements of clinical trials. The Newton does however permit a number of choices of data entry which were exploited in this protocol design including check boxes, selecting from a scrolling menu, easily manipulable calendars for recording the date and clocks for time selection. We found nevertheless that the three hours initial training was insufficient. Furthermore ready access to technical support proved essential to help the user over their initial experience with this new informatics support to clinical research.

The use of large computers may not be satisfactory at the time of patient interview[8] and can be less flexible than using paper and pen[9] although this may depend on the attitude of the health care giver. In eliminating the complexities of the keyboard, the Newton by its portability and interesting interface is a very promising tool for the needs of a research nurse and can be readily integrated into the daily task schedule.

CONCLUSION

Direct capture of clinical research information is both practical and acceptable by the research nurse.

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