

- Clinical Pharmacy Division
- Social and Administrative Sciences Division
- Pharmaceutical Sciences Division

FINAL REPORT

Assessment of Clinical Data Collection via Touch Screen

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INTRODUCTION

In clinical trials, the collection of clinician-reported data (e.g., clinical assessments) can be a cumbersome task. Traditionally, data have been collected through paper-based questionnaires and then manually entered into an electronic database for analysis. With advances in technology, those questionnaires can be converted to electronic formats, allowing the clinician to answer questions using a computer keyboard or touch-screen device. Hence, the primary purpose of this study was to explore the usefulness and acceptability of touch-screen technology for the collection of clinician-reported data.

METHODS

A total of five participants were recruited from personnel in the Department of Psychiatry at the University of Arizona. Each of the participants routinely conducts clinical assessments of patients in psychiatric clinical trials and is a research specialist or research nurse. Participants were asked to view a demonstration of the touch screen data collection device. The demonstration included touch screen versions of the Hamilton Anxiety Scale, Hamilton Depression Rating Scale (6-item), and Montgomery-Asberg Depression Rating Scale. Participants were asked to review each of the three instruments and respond to each item as if they were completing them for a patient in a clinical trial.

Upon completion of the demonstration, participants were asked to complete a 10-item questionnaire (Appendix) that assessed their perceptions of the touch screen data collection approach. In addition to the quantitative questionnaire-based data, unsolicited qualitative data were collected. Participants were provided compensation for their time.

RESULTS

The responses to the questionnaire items are provided in Table 1. For clarity, the complete wording for each of the questionnaire's items is included.

All five of the participants reported (1) that they routinely completed a paper-based form while in the presence of their patient, (2) that the touch screen device would be an acceptable way to collect clinical data, (3) that they would prefer to use a touch screen device over a paper-based collection form, and (4) that the touch screen device would take less effort to complete.

All five reported that the paper-based forms had to be scored prior to submission. Four responded that their interest in using the touch screen device would increase because the data can be recorded immediately requiring no manual entry. One reported their interest would not increase. Two responded that they felt the touch screen device would produce more accurate data, two felt there would be no difference, and one participant did not respond.

When asked if they could think of any reason why a touch screen device could not be used in place of paper-based data collection forms, four responded "No," while one responded "Yes" with the explanation that "paper based collection would have proof of errors/corrections made." Each of the five responded that a summary screen including individual items responses and overall score would be necessary at the end of each instrument.

Table 1. Questionnaire Results

In your department, who would be routinely completing these types of clinician-reported data forms in a clinical trial?
Check all that apply:

- 1 Physician/Investigator
- 2 Research Nurse
- 1 Research Assistant/Associate
- 4 Research Specialist

If the Physician/Investigator is not the respondent, does the Physician/Investigator have to review and sign the form before submitting to the Sponsor?

- 1 Yes
- 4 No

How do you obtain the data to complete clinician-reported data forms?

- 0 I take notes while interacting with a patient and later complete a paper-based form.
- 5 I complete a paper-based form while the patient is present.
- 0 I fill out a paper-based form from memory after the patient has left the office.

Do you ever have to score the forms prior to submission (perhaps for inclusion/exclusion criteria)?

- 5 Yes
- 0 No

Do you think that a touch screen device is an acceptable way to collect clinical data?

- 5 Yes
- 0 No

If Yes, would you prefer to use a touch screen device over a paper-based data collection form?

- 5 Yes
- 0 No

The touch screen method records data immediately requiring no manual data entry. Does this increase your interest in using this method?

- 4 Yes
- 1 No

Which method do you feel would produce more accurate data?

- 2 Touch screen
- 0 Paper-based
- 2 There would be no difference.

Which method do you feel would take the least effort to complete?

- 5 Touch screen
- 0 Paper-based
- 0 There would be no difference.

Can you think of any reason why a touch screen device could not be used in place of paper-based data collection forms?

- 1 Yes
- 4 No

If Yes, why? "Paper based collection would have proof of errors/corrections made."

Do you feel that a summary screen including your individual item responses and overall score would be necessary at the end of each instrument?

- 5 Yes
- 0 No

Additional comments from respondents:

- I'm the computer geek of the group and I would like to know if they use a basic Access program to load the instruments or a CC2 program.
- I know these instruments by heart. It would be much easier to use a touch screen device.
- Would need to have a hard copy of the data that was entered.
- There is no way to remember everything from a patient visit to complete the instruments after the patient has left. I complete the instruments while in front of the patient. Clients are used to seeing something that the clinician uses to record the info. Would be nice to have a print out of the data entered.
- This is so cool. I would much rather use a computer device. At a previous job, there was a computer guy that loaded all of the instruments on to my laptop. At the end of the day, I could know exactly how many people I had seen that were depressed.

CONCLUSIONS

Each participant responded enthusiastically to the touch screen device. They were eager to see the clinician-reported instruments and get a feel for completing the questions by touch screen. Based on both the quantitative and qualitative results, it is quite apparent that the touch screen device is a very acceptable data collection tool and would be welcomed as part of a clinical trial. In addition, it is evident that having a summary screen of the scored clinical assessments is essential and the ability to print out a hard copy would be useful.

Acknowledgement

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Appendix

Assessment of Clinical Data Collection via Touch Screen

Please answer the following questions regarding your experience with clinical trial data collection and your perception of the touch screen data collection method.

1. In your department, who would be routinely completing these types of clinician-reported data forms in a clinical trial? Check all that apply:

- Physician/Investigator
- Research Nurse
- Research Assistant/Associate
- Research Specialist
- Other _____

2. If the Physician/Investigator is not the respondent, does the Physician/Investigator have to review and sign the form before submitting to the Sponsor?

- Yes No

3. How do you obtain the data to complete clinician-reported data forms?

- I take notes while interacting with a patient and later complete a paper-based form.
- I complete a paper-based form while the patient is present.
- I fill out a paper-based form from memory after the patient has left the office.
- Other _____

4. Do you ever have to score the forms prior to submission (perhaps for inclusion/exclusion criteria)?

- Yes No

5. Do you think that a touch screen device is an acceptable way to collect clinical data?

- Yes
- No
- No opinion

- 5a. If Yes, would you prefer to use a touch screen device over a paper-based data collection form?

- Yes No

5b. If No, why not? _____

6. The touch screen method records data immediately requiring no manual data entry. Does this increase your interest in using this method?

___ Yes

___ No

___ No opinion

7. Which method do you feel would produce more accurate data?

___ Touch screen

___ Paper-based

___ There would be no difference.

8. Which method do you feel would take the least effort to complete?

___ Touch screen

___ Paper-based

___ There would be no difference.

9. Can you think of any reason why a touch screen device could not be used in place of paper-based data collection forms?

___ Yes

___ No

9a. If Yes, why? _____

10. Do you feel that a summary screen including your individual item responses and overall score would be necessary at the end of each instrument?

___ Yes

___ No

___ No opinion

Thank you for your participation.