Personal Digital Assistant Data Capture: The Future of Quality of Life Measurement in Prostate Cancer Treatment

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Abstract

Purpose: This article examines the potential use of personal digital assistant (PDA) data capture systems for real-time linear monitoring of health-related quality of life (HRQOL) in prostate cancer research and clinical care.

Methods: We discuss the benefits and potential issues of using PDA data capture in the clinical health care setting. In addition, we describe the development and potential use of a PDA data capture system specific to managing HRQOL in prostate cancer treatment.

Conclusion: Follow-up health care clinics require a practical and systematic process of HRQOL data capture and analysis. Traditional paper questionnaire data capture is problematic. Data manipulation required for clinical decision-making is impractical for patient feedback on same-day clinic visits. Furthermore, the process of transforming paper questionnaire data to analysis-quality data can compromise data integrity. In contrast, research findings confirm the acceptability, ease of use, and reliability of PDAs in capturing data across health care settings, including the collection of serial HRQOL data. The main concern for PDA capture systems is the ability to compare respondent's answers between the paper and PDA questionnaire. Other challenges included patients reporting a lack of computer literacy and/or poor eyesight, as well as initial start-up costs. If issues are successfully addressed, the use of a PDA data capture system, such as the PDA HRQOL system at Princess Margaret Hospital's Prostate Centre, allows for valid and economical data collection with the possibility of linear real-time measurement of changes in HRQOL. Accordingly, there appears to be significant potential for PDA data collection of serial HRQOL in prostate cancer clinic settings.

Introduction

In clinical and research practice linked to prostate cancer treatment, it is essential to frequently monitor a patient's health-related quality of life (HRQOL). Prostate cancer treatment regularly results in physical and emotional morbidity. Common physical adverse effects of treatment include disruption in sexual,[1,2] urinary,[3] and bowel functions.[4] Correspondingly, patients report severe distress associated with these adverse effects.[5–7] Combined, the physical and emotional correlates of prostate cancer therapy have a significant impact on patient HRQOL.[4,8] For this reason, HRQOL outcomes need to play an important role in determining prostate cancer treatment follow-up care. Likewise, comprehensive outcomes assessment of prostate cancer treatment requires analysis beyond tumor and survival measures to include patient-reported HRQOL.

To monitor patient HRQOL regularly and continually, prostate cancer treatment and follow-up health care clinics require a practical and systematic process of data capture and analysis. The traditional paper questionnaire format for data capture is problematic for both the clinician and researcher. Data manipulation required for clinical decision-making is time-consuming and impractical for patient feedback on same-day clinic visits.[9] Furthermore, the process of transforming paper questionnaire data into analysis-quality data can compromise data integrity and the validity of research outcomes.[10,11] The limitations of traditional data capture on paper raise the question of whether the use of personal digital assistant (PDA) electronic data collection systems would be a practical alternative. This article outlines the benefits and potential issues of PDA use in the clinical health care setting, and specifically discusses the potential use in prostate cancer research and clinical care.

Background

Clinicians and researchers have used PDA-administered questionnaires for patients across a number of clinical settings and disease types, including orthopedics,[12,13] anaesthesiology,[14] rheumatoid disease,[15] smoking cessation,[16] irritable bowel syndrome,[17] and allergic rhinitis.[18] PDA data collection in these studies has proven to be comparable, or superior to, paper survey methods. Agreement between paper questionnaires and PDA responses is high.[14,16] Patients report feeling more comfortable completing a PDA survey and say they prefer it to the paper questionnaire.[14,16] Likewise, research specific to HRQOL data collection also supports the use of PDA over paper surveys. Test-retest reliability is reported as similar for both modalities,[17] with no significant differences in feasibility, including time needed to complete questionnaires and patient preference.[15,17]

PDA-administered questionnaires in an oncology setting have not yet been reported in the literature. However, related research involving touch-screen and desktop administration of questionnaires has illustrated acceptability in both oncology inpatient and outpatient environments.[19–22] In essence, the research found that oncology patients report little difficulty using computer formats[21] and expressed preference for this format.[19]

Benefits of PDA Data Capture Systems

The benefits of a PDA collection system to both the clinician and researcher are potentially lower costs,[10,12] improved data quality through tailored data collection and capture,[10,23] and more efficient and effective data manipulation,[10,12] including immediate printout of data.[24]

In health care clinics serving a large volume of patients, the PDA system may be seen as clearly cost efficient when compared with paper questionnaire costs (paper and reproduction), and costs of data entry, coding and cleaning.

The PDA provides for improved data quality by tailoring data collection and capture to meet the requirements of both clinical and research tasks. PDA data collections allow for making complicated branching and skip patterns that remain invisible to interviewees.[10,23] The device can be programmed to time stamp data collection,[23] to automatically record time to complete questionnaires,[10] and to secure data through password protection.[25] The questionnaire format can be customized for different font sizes, number of questions per screen, and number of lines allotted to question and response text.[10,23] Additionally, PDA use can reduce the frequency of unintentionally missed questions by recalling the missed question at the end of the survey, or by preventing continuation if a question has not been answered. The format of the PDA precludes multiple responses for a single question, and it ensures answers are clearly indicated.

Furthermore, with PDA administration, data can be downloaded directly, thereby eliminating the error-prone step of data entry and potential for bias. This results in faster data manipulation and analysis turnaround times. An explicit advantage of the effective and efficient data manipulation is that results can be immediately scored, displayed, and printed.[16] This instant access to outcomes allows the researcher to retrieve and report on up-to-the-minute findings. Similarly, the immediate printout of data enables the clinician to review and interpret a patient profile in the company of the patient and discuss possible treatment decisions.[24]

Previous research has shown that real-time feedback results in an enhanced clinical interview for both the patient and physician.[24,26] One recent study found that oncology patients receiving immediate feedback of HRQOL information reported that their physicians inquired about daily activity and emotional problems more often than without computerized results. The physicians of these patients indicated that HRQOL information improved communication and assisted in disease management decisions.[24] This enrichment of the clinical interview appears to have a direct and positive impact on overall clinical outcomes. A recent study demonstrated that cancer patients exhibited clinically meaningful improvements in HRQOL after three sessions of using immediate feedback printouts.[27] Furthermore, real-time review of HRQOL information helped physicians identify patients experiencing significant reductions in their quality of life, allowing for rapid assessment of patient health and the promotion of timely intervention.[20]

Potential Issues Confronting PDA Data Capture Systems

The main concern for PDA capture systems is the ability to compare respondents' answers across paper and PDA administration of various questionnaires. Responses may vary as a result of the direct transfer of an existing paper questionnaire to a PDA administration format.[28] There are a number of potential moderators of mode of administration effects. First, the quality of paper and PDA surveys may differ in terms of completion pace and forced sequencing (eg, patients might experience a difference in how easily they can return and change previous responses).[28] Second, social desirability may affect comparability. Using the Marlowe-Crowne Social Desirability Scale to compare paper and computerized surveys, studies found lower social desirability scores associated with computerized administration.[29–31] Third, comparability of PDA and paper questionnaires may be affected by the nature of the subject matter being assessed. Research has shown that patients may be more comfortable disclosing sensitive and personal information on computerized versus paper surveys.[31–33] Finally, mode of administration may also be affected by respondents' beliefs and attitudes. In a trial examining substance abuse, it was found that respondents with a low "general trust in others" had a tendency to report lower substance use on a computer-assisted survey compared with a paper survey.[31] Overall, these findings warn that mode effects can exist and that the magnitude of them may vary due to a number of factors, including differences in functional responding patterns, area of study, and respondent characteristics.

Although studies examining the comparability of computerized and paper surveys typically find equivalent scores,[15,17,22] it is essential that any response differences be identified. Mode of administration effects may lead to differential responses that do not correspond to the response profiles of the reliability and validity studies defining the psychometric properties of the original paper survey.[28] Consequently, the generalizability of computerized survey responses may be compromised. To protect against this limitation, the psychometric properties of PDA administrations of surveys need to be confirmed or established on a measure-by-measure basis.

Other concerns regarding PDA data capture systems center on feasibility issues, including when patients report a lack of computer literacy as a reason for preferring and/or being more comfortable with paper forms over computerized versions.[16] There also is concern that in older patient populations participants are more likely to have problems such as poor eyesight and, consequently, have difficulty with a PDA's relatively small display screen.[13,22,23] Finally, the initial start-up costs associated with PDA data collections systems can be imposing. This cost may be offset by the practical/functional costs of

paper survey collection and the benefits of PDA systems for research and patient care.

Overall, research findings support the several benefits of using PDA devices in collecting questionnaire data from patients, provided that additional validation of the PDA-administered surveys is performed and that feasibility issues are assessed. Accordingly, there appears to be considerable potential for PDA data collection of serial HRQOL in prostate cancer clinic settings.

PDA Data Collection in a Prostate Cancer Clinical and Research Setting

The Prostate Centre at Princess Margaret Hospital receives approximately 200 prostate cancer patient visits per week. The patient population includes high-risk, newly diagnosed, recently treated, and long-term follow-up patients. Currently, patients complete a HRQOL paper questionnaire package at each visit. The questionnaire packages are handed out and collected by the clinic clerk. Following the clinic, a research assistant enters the questionnaire responses into the Prostate Centre database. It takes approximately 3 minutes to enter each questionnaire package, which averages to 2 hours of data entry per clinic day. The data are analyzed aggregately on a semiannual basis to determine quality of care indices for the Prostate Centre. The data are not used for individual patient-physician feedback due to the time-consuming process of data collection, entry, and manipulation. Given that follow-up visits are generally a minimum of 3 months apart, patient-physician feedback and decision-making based on previous visit data collection may be inappropriate. Therefore, for immediate care, physicians include HRQOL questions as part of their clinic visit interview. This lengthens visits and does not allow for standardized procedures/guidelines of physician practice. Consequently, the Prostate Centre developed and is piloting a PDA-administered data collection system to increase efficiency of serial HRQOL data capture and to support a real-time mechanism for individual physician-patient feedback. The following describes the development of a PDA data collection system specific to HRQOL measures in the Prostate Centre.

Prostate Centre PDA HRQOL Data Capture System

The Prostate Centre PDA HRQOL data capture system software was developed in C++ for the Palm Vx PDA series (Palm Inc, Sunnyvale, California). The software development process incorporated industry-standard quality-assurance activities, including the creation of automated unit test suites, design and code reviews, mockup and review of user interface models, system integration testing, and end-user testing. The software developed for the PDA allows a single participant to enter demographics and survey response information (Fig 1). Participants enter data into the PDA using a touch-screen stylus and are able to select only one response per question, but they have the option of changing answers if an error is made. If the participant fails to respond to a question, this question is repeated at the end of the survey. At this time, the participant has the option to provide a response, or confirm that he would like to skip the question.

On completion of the survey, the participant returns the PDA to research staff for data synchronization with a personal computer (PC). During the synchronization, demographics information is checked against that of known patients stored in Microsoft Access (Microsoft Corp, Redmond, Washington), a relational database on the PC. If no demographics match is

Figure 1. Sample questionnaire on a Prostate Centre PDA.

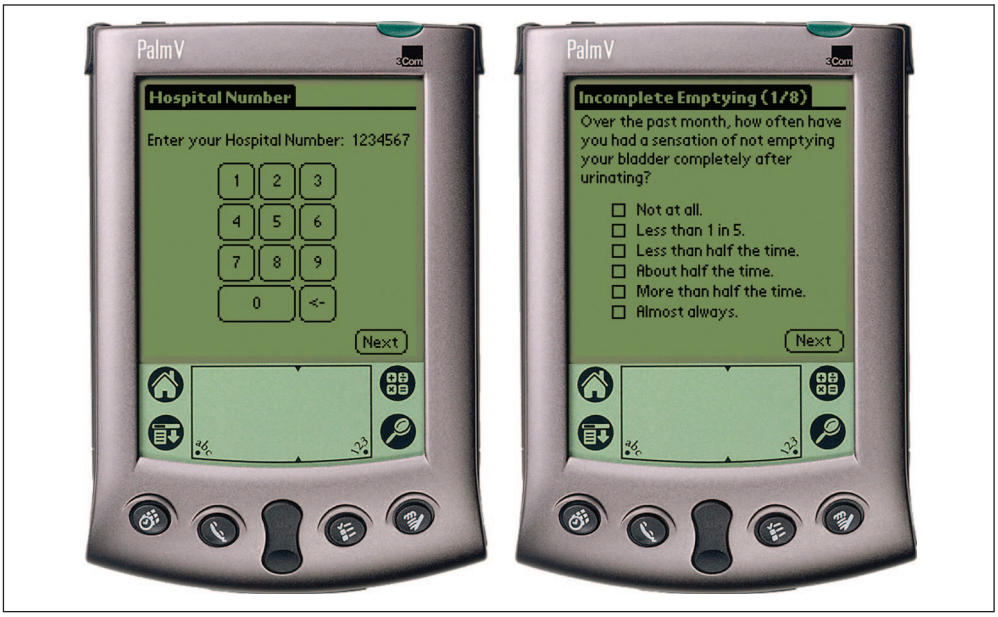
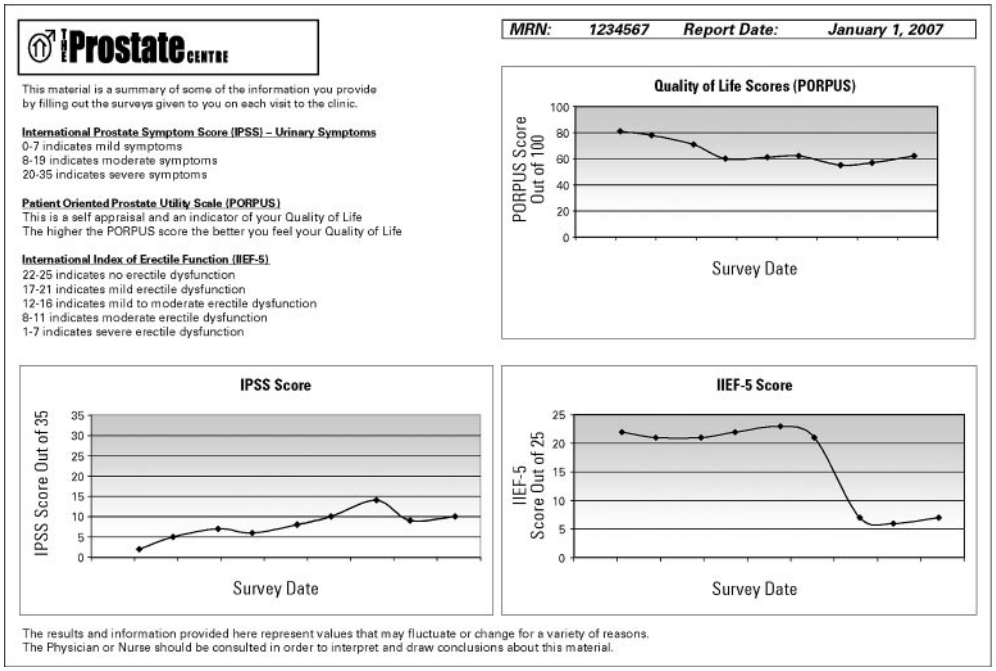


Figure 2. Feedback report from the Prostate Centre PDA HRQOL survey.



found, the participant is asked to correct his demographics information on the PDA and resynchronize (survey responses are preserved). Survey data from the PDA is transferred into the database on the PC, and a report is generated for the patient. Synchronization (Palm COM Conduit; Palm Inc) and report generation software are written in Visual Basic (Microsoft Corp).

Patients completing PDA-administered HRQOL questionnaires are identified by medical record number and date of birth. Patient data are protected through the use of multiple levels of encryption and a password access system. Once the PDA has been synchronized with the PC, the patient self-reported data are purged from the unit. These features ensure that sensitive information is only accessible to appropriate clinic staff. All other medical data are stored in the Prostate Centre's main database and are not directly accessible on either the PC or PDA. The Prostate Centre database is safeguarded through industry standard security and operational protections.

The initial development cost of the Prostate Centre PDA HRQOL platform, including Palm hardware and system research and design, was $3,000. The cost associated with implementation, real-time scoring, graphic output, and testing for three HRQOL measures was $1,400 per questionnaire, for a total of $4,200. Finally, the cost of integrating PDA data capture with the Prostate Centre database and troubleshooting was $5,300. Thus, the overall cost of the Prostate Centre HRQOL-PDA system was $12,500. These costs do not include the cost of the PC/laptop hardware and operating system.

Health-Related Quality of Life Measures

The HRQOL measures incorporated into the PDA introduced in the Prostate Centre include the International Prostate Symptom Score (IPSS),[34] the Patient Oriented-Prostate Cancer Utility Survey (PORPUS),[35] and the International Index of Erectile Function-5 (IIEF-5).[36] The IPSS is an eight-item measure of patient urinary voiding function and includes a quality of life score. The PORPUS is a prostate cancer–specific comprehensive instrument for measuring HRQOL. The 10-item psychometric instrument assesses 10 quality of life domains: pain, energy, social support, communication with physician, emotional well-being, urinary frequency, bladder control, sexual function, sexual interest, and bowel problems. The IIEF-5 is an abbreviated version of the International Index of Erectile Function[37] and was developed for use as a screening tool in clinical settings to discern men with erectile dysfunction. All measures are reliable and valid.[34,38,39]

Immediate Printout: Physician-Patient Feedback

The Prostate Centre PDA HRQOL data capture system was designed to produce an immediate feedback printout directly following the PDA data synchronization with a PC (Fig 2). The printout consists of a brief lay explanation of the IPSS, PORPUS, and IIEF-5, with a summary graph depicting outcome scores over time for each questionnaire.

The Next Step

Before PDA data collection techniques can be fully established for clinical or research purposes in health care, the mode needs

to be adequately validated for use with specific measures and patient populations. As part of our piloting of the Prostate Centre PDA HRQOL, we are comparing the use of our Prostate Centre PDA HRQOL data capture system to paper/pencil questionnaires in a randomized control trial. Evaluation will include an assessment of feasibility (participation rates, time to completion, and preference), data quality and validity (completeness of data, response correlation, and internal consistency), and patient satisfaction. The unique relevance of this research is its focus on prostate cancer patients' responses to the PDA data collection system, as well as on the validity and reliability of the IPSS, PORPUS, and the IIEF-5 using the PDA to administer surveys. If this study and others support the use of PDA collection and feedback systems in prostate cancer settings, the potential for a beneficial impact on prostate cancer research and clinical care will be significant.

Authors' Disclosures of Potential Conflicts of Interest

Although all authors completed the disclosure declaration, the following authors or their immediate family members indicated a financial interest. No conflict existed for drugs or devices used in a study if they are not being evaluated as part of the investigation.

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Editorial: The Challenge of Electronically Captured Patient-Reported Outcomes

Barry Fortner, PhD

By Barry Fortner, PhD

As illustrated by Matthew et al[1] in this issue of the *Journal of Oncology Practice*, it is exciting to witness the expanding array of electronic tools and platforms employed to capture patient-reported outcomes data. Although "patient report" is a mainstay of the clinical process, one of the primary factors limiting the routine, clinical use of tools for collecting, standardizing, and facilitating patient reported information is assumed to be the practical limits of paper and pencil methods for capturing this type of data.

This and other recent work demonstrates the viability of collecting patient-reported outcomes through electronic methods, including personal digital assistants, personal computers, pen-based computers, Internet-based systems, and the phone (using interactive voice response or voice recognition systems). These electronic tools are stand-alone software programs or extensions of other electronic medical information systems, such as the electronic medical record. While significant progress has been made, serious challenges continue to plague the field, including those discussed below.

First, electronic capture of patient-reported outcomes does not necessarily translate directly from paper tools—clinical validity may be lost (or gained) in the translation. The practical usefulness of collecting patient-reported outcomes through electronic means has been well demonstrated. However, it should not be assumed that a given questionnaire, which may have proven reliability and validity in paper form, will have the same psychometric properties when reformatted for electronic administration, or that a scale administered in one electronic medium is reliable when deployed in a different electronic form. Alternate forms reliability and validity studies are required when scales are reformatted.

Moreover, a greater overarching challenge is to demonstrate that specific patient reported outcome measures are useful, or valid, in terms of everyday clinical practice. In contrast to the ubiquitous validation studies that compare a new measure with other established measures, studies are needed to explore the implications of patient reported outcome measures in relation to clinical screening, diagnosis, and treatment decision making. Only when these measures, electronic or not, are shown to be beneficial for the frontline clinician are they going to be adopted widely to the benefit of large numbers of patients.

The second challenge—quality control and scalability—may not be apparent to most scientists and end users who are unfamiliar with the mature software industry. Not only is the measure itself required to be reliable and valid, but the software supporting the measurement process must be reliable and valid. Extensive industry standards exist to guide and judge the programming required for this type of work. Extensive software validity testing must be completed and documented for a software program to withstand scrutiny and the inevitable external audits required when these measures find their way into the clinical charts of patients. Compounding this requirement is the fact that software may be valid when used in one context but not when used in another. For example, when moving from 10 to 1,000 users, the software may become unstable or may display unacceptable error rates. These extensive requirements directly affect the time and expense demanded to develop and validate the underlying software platform and ultimately to format and deploy a given measure.

Additionally, regulatory standards must be fulfilled. As electronic patient-reported outcomes become available in clinical settings, they face the challenge of being subject to federal and medical legal requirements. Perhaps the best known are the Health Information Portability and Accountability Act (HIPAA) and the Code of Federal Regulations (Part 11). HIPAA requires that software be constructed with demonstrated and documented characteristics ensuring the protection of personal health information and that policies and procedures surrounding the