

USER PREFERENCES FOR COMPUTER ADMINISTRATION OF QUALITY OF LIFE INSTRUMENTS*

JOSEPH A. CRAWLEY, MS

AstraZeneca LP, Wayne, Pennsylvania

LEAH KLEINMAN, DRPH

MEDTAP International, Bethesda, Maryland

JASON DOMINITZ, MD, MHS

Veterans Administration Puget Sound Health Care System, Seattle, Washington

Introduction. *While most health-related quality of life instruments are administered through paper and pencil self report or via in-person or telephone interviewer, the use of electronic data capture through a computer touch screen has unique advantages if this mode of administration is acceptable to patients and researchers.*

Methods. *A total of 134 patients with gastroesophageal reflux disease were enrolled in an age stratified cross-over design study in which they were asked to complete two quality of life instruments using paper and pencil and computer touch screen administration. Responses on preference and ease of use were solicited from both patients and research coordinators.*

Results. *Over 50% of patients found the computer to be more comfortable, faster, easier to use, and the method they would prefer to use. The majority (82%) of the research coordinators would prefer to use the computer mode of administration in a clinical trial and they thought that the computer was easier for patients to use.*

Conclusions. *The computer touch screen administration of quality of life instruments is a viable alternative for use in clinical trials. The two key user groups of patients and research coordinators strongly preferred the computer to traditional paper and pencil.*

Key Words: Health-related quality of life; Survey administration; Computer touch screen; Electronic data capture; Gastroesophageal reflux disease

INTRODUCTION

HEALTH-RELATED QUALITY of life (HRQOL) questionnaires have become an in-

creasingly important component of data collection in clinical trials. Reasons for use are varied. HRQOL outcomes can be used to support observed symptom changes where there are no objective physiological markers of disease activity such as in gastroesophageal reflux disease (GERD) without esophagitis. HRQOL can also be used to compare treatments where efficacy is similar but side-effect profiles or effects on functional abilities differ. HRQOL data provide the patient perspective of what positive or negative impact the medical therapy and any side effects

*This research was supported by a grant from AstraZeneca LP, Wayne, PA.

Results of this research were presented in part at the DIA Workshop "Electronic Data Capture: Technologies, Implications and Future Requirements," November 16-17, 1998, Baltimore, Maryland.

Reprint address: Joseph A. Crawley, Health Economics and Outcomes Research, AstraZeneca LP, 725 Chesterbrook Blvd. E-2C, Wayne, PA 19087.

may have had on their lives. When collected using validated instruments in the context of a well-controlled clinical trial, changes in HRQOL that occur between baseline and study end can be correlated to the clinical changes routinely monitored during the clinical trial, thus assisting with the translation of clinical changes into patient-based outcomes (1). Additionally, the Food and Drug Administration (FDA) has begun to allow quality of life promotional claims for pharmaceuticals that demonstrate sufficient evidence of acceptable methodology in measurement and a clear relationship between therapy and any observed change in HRQOL (1).

Although clearly important and potentially providing useful data to support scientific and promotional claims for pharmaceuticals, HRQOL data are currently not required as part of the FDA submission package for product marketing approval. Collection and analysis of data that are not central to the purpose of regulatory approval is often viewed as burdensome and may be resisted by clinical investigators. Use of HRQOL instruments in clinical studies often requires additional training of study personnel, increased time to check data reliability and completeness, and accounting for issues such as missing data in the analysis plan. Further, patients may balk at being asked to complete long, complex questionnaires at visits, leading to incomplete study data sets and frustration for the study coordinator.

While most HRQOL instruments are administered through paper and pencil self-report or via in-person or telephone interviewer, the use of electronic data capture through a computer touch-screen has labor saving features and can be cost effective compared to traditional data collection methods (2). A system implemented by Assist Technologies incorporates several features designed to enhance data quality by reducing the amount of inaccurate or unusable data. Questions and their responses are entered directly into the software program on separate screens, with one question per screen. Data edit checks can be written for each screen

and logic flow from question to question can be programmed to account for patient gender, other demographic criteria, or how previous questions were answered. Data quality assurance beyond that programmed into the software becomes minimal since edits can be programmed to prohibit out of range responses and can eliminate duplicate responses. Computers can also present appropriate prompts to minimize accidental item skipping. Data entry is automatic, and standardized data displays are part of the software. Options for data output in either SAS or ASCII files are possible to accommodate additional needs of statisticians.

Previous studies have demonstrated the acceptability of using computers to administer HRQOL instruments (3, 4, 5). Patients expressed a preference for using the computer to complete questionnaires and authors (6, 7) stated that data collection was more complete with the computer method. There have been mixed findings in the literature regarding an association of respondent age, familiarity with computers, and the ability to easily complete computer-administered HRQOL instruments. Thus, we made the decision, a priori, to control for respondent age with stratification.

In this study, we evaluated the preferences and burdens of the clinical team and patients for mode of administration on the Quality of Life in Reflux and Dyspepsia instrument (QOLRAD), a GERD-specific health-related quality of life instrument, and the Medical Outcomes Study Short-Form 36 (SF-36), a generic HRQOL measure. Respondent and site coordinator burden, ease of use, and preference for mode of administration were assessed, with particular attention to patients over the age of 60. We hypothesized that preference for computer administration over traditional paper and pencil might vary by respondent age due to less familiarity with computers among the elderly and the possible influence of reduced visual acuity. The comparative psychometric characteristics of the QOLRAD and SF-36 by mode of administration are reported elsewhere.

METHODS

Design

The study was a cross-over design in which participants were randomly assigned to one of two groups. Subjects in Group 1 were assigned to complete questionnaires using the paper and pencil method at Visit 1 and the computer touch-screen at Visit 2. Subjects in Group 2 completed the process in reverse order. A third group comprising a subset of Group 1 subjects was asked to return for a third visit to evaluate the test-retest reliability of the touch-screen. Assessments were separated by three to five days to minimize the likelihood that respondent fatigue or learning effects influenced the results. Randomization was stratified by age so that 50% of the patients were under 60 and 50% were 60 or older to assess the impact of age on the study outcome.

Subjects

One hundred thirty four patients with chronic stable GERD were recruited from four clinical sites across the United States. Patients had to have had a diagnosis of GERD for at least six months and be currently receiving treatment (either over-the-counter or prescription medications, with or without counseling for lifestyle changes). Patients who could not read English or who had disabling psychiatric or dementia conditions were excluded from the study. Site coordinators were trained to recruit and enroll patients and administer the HRQOL questionnaires and other study instruments using both the paper and pencil and computer touch-screen methods.

Computer Technology

The computer software (Touch Outcomes Collector™) used in this study was designed by Assist Technologies of Scottsdale, AZ and featured a touch-screen monitor that could be used either with finger pressure or with a light pen. The hardware was a network ready, fully integrated LCD touch-screen worksta-

tion. The use of a touch sensitive monitor rather than a keyboard decreased the likelihood of confusion and of entering an inappropriate or invalid response. Participants simply touched the large on-screen "buttons" with their finger or a light pen. One question was displayed per screen and once a response was entered the next item automatically appeared. The participant had the option of skipping a question or returning and reviewing previous questions. After reaching the end of the questions, participants could review responses or touch a button indicating that they were done. Automatic immediate scoring was available and the data were transmitted via modem to a central location.

Assessments

The objective of the study was to evaluate the preference for administering the QOLRAD via computer touch-screen. The QOLRAD and SF-36, as well as preference and ease of use questionnaires, were utilized to fulfill this objective. Demographic and background clinical data were gathered as well. The QOLRAD is a 25-item instrument that covers the frequency and intensity of discomfort/distress induced by gastrointestinal symptoms, for example, how often the patient avoids certain foods or beverages due to pain or discomfort in the upper abdomen (8). The SF-36 is a 36-item generic health status instrument often used in validating disease-specific instruments (9, 10).

Elapsed Time. Site coordinators used stopwatches and direct observation to time the number of minutes each patient needed to complete the QOLRAD and SF-36. Timing was performed in the same way for the paper and pencil and computer modes of administration.

Ease of Use. Eight ease-of-use questions were asked after completing the QOLRAD and the SF-36. The first three questions asked if the questionnaire was easy to read (scored

as yes/no), how easy it was to change answers (1: not very easy; 5: very easy), and how difficult the method was to use (1: not difficult; 4: very difficult).

The next five questions asked patients to respond to semantic differential questions which require participants to indicate their reactions to the mode of administration on a bipolar continuum described by word pairs. The word pairs serving as anchors on the continuum were: easy to difficult, quick to slow, good to bad, short to long, and simple to confusing. Each word pair was scored on a five-point response scale and ranges to indicate extremes. For example, easy to difficult is scored as follows: 1: extremely easy, 2: moderately easy, 3: neutral, 4: moderately difficult, and 5: extremely difficult. This ease of use questionnaire was administered at Visit 1 and Visit 2.

Preference for Method. The questionnaires contained four close-ended questions asking which method was more comfortable, faster, and easier, and which method the participant preferred.

All patient-based preference and burden questions were asked after the HRQOL assessments were completed for each visit. Preference and burden questions were administered via paper and pencil.

Site Coordinator Questionnaire. The site coordinator questionnaire contained questions regarding the implementation of the study, difficulty with implementing the two modes of administration, and preference for modes of administration. Questions about difficulty in implementing the two modes of administration were scored on a Likert-type response scale where one represents “not at all difficult” and five represents “extremely difficult.” Site coordinators were also asked which mode of administration they preferred overall. Site coordinators completed the questionnaire when their site had completed patient enrollment for the study. These questionnaires were administered via paper and pencil.

Statistical Analysis

The analysis presented here focuses on an evaluation of preference and ease of use for respondents and site coordinators. Two-sided t-tests were used when appropriate with a p-value of 0.05. No adjustments were made for multiple comparisons. Patient and site coordinator ease of use and preferences were assessed using t-tests for continuous data, and chi-squares were used for categorical data.

RESULTS

Demographic Characteristics

The majority of patient participants were male and white with an overall average age of 59.3 years (Table 1). The average age of the 60 and over group was 71.3 (SD = 6.4), the average age of the under 60 group was 47.6 (SD = 8.9). Only 57% of the 60 and over age group had previous experience with computers compared with 90% of the under 60 age group. One hundred and thirty four patients completed the study. Results for each assessment were as follows.

Elapsed Time

There were no statistically significant differences in the time it took for patients to complete the HRQOL instruments by mode of administration either overall or within a specific visit, although patients needed less time

TABLE 1
Socio-Demographic Characteristics

Characteristic	Total
	(n = 134)
Male, n (%)	76 (56.7%)
White, n (%)	115 (86.5%)
Age ≥ 60, n (%)	65 (49%)
Age < 60, n (%)	69 (51%)
Education—high school or less, n (%)	38 (28.6%)
Employment—Full time, n (%)	49 (36.8%)
Computer ever used, n (%)	98 (73.7%)
ATM ever used, n (%)	103(77.4%)

during Visit 1 for the paper and pencil method. There were, however, significant differences in time to complete the HRQOL instruments by age. Overall, those 60 and over took significantly longer to complete the HRQOL instruments using the computer touch-screen method than did those under 60 (15.52 minutes versus 12.34 minutes, $p < 0.005$). A similar difference by age was observed for the paper and pencil method where those 60 and older took an average of 14.08 minutes to complete the HRQOL instruments while those under 60 took 11.75 minutes ($p = 0.03$).

Ease of Use

Patients responded that both modes of administration were in the high range for ease of use, that is, “very easy” or “not difficult.” Statistically significant differences favoring computer administration were observed in two instances, both of which only occurred within a specific visit (Table 2). Analysis by age showed no significant differences in ease of use for computer or paper and pencil.

Semantic Differential

Results from the semantic differential questionnaire demonstrated very little difference between mode of administration. When age of the patient was accounted for in the analysis, patients age 60 and over scored use of the computer touch screen as slower than the

mean score of patients under the age of 60. Similar expected differences by age were seen in evaluating the short-long semantic pairing.

Preference for Method

Patient preference for method was examined by age and overall (Table 3). There were no significant differences by age in terms of the comfort level with method, speed of use by method, ease of use by method, and overall preference for choice of a method. In general, patients either preferred the computer or thought there was no difference between the computer and paper and pencil. Over 50% of participants found the computer to be more comfortable, faster, easier to use, and the method they would prefer to use.

Site Coordinator Results

The low sample size ($n = 11$) did not allow for statistical analysis. Therefore, the data presented here are descriptive. In general, site coordinators had very little difficulty implementing the paper and pencil mode of administration. The task related to paper and pencil administration that elicited the highest difficulty response (median = 2.0) was that of conducting the data transfer: copying and mailing the forms. All other tasks had median responses of 1.0. Similarly, there was very little difficulty with implementing the computer mode of administration. Median re-

TABLE 2
Ease of Use Questions—Total Sample

Question	Method	Overall Mean, (SD)	Visit 1 Mean, (SD)	Visit 2 Mean, (SD)
Were the questions easy to read?	Computer	1.00 (0.00)	1.00 (0.00)	1.00 (0.00)
	Paper and pencil	1.01 (1.21)	1.02 (1.23)	1.01 (1.21)
How easy was it to go back and change answers (1)?	Computer	4.70 (0.78)	4.80* (0.52)	4.59 (0.96)
	Paper and pencil	4.39 (0.73)	4.31 (0.74)	4.48 (0.73)
How difficult was it to use this questionnaire?	Computer	1.04 (0.26)	1.06 (0.34)	1.02 (0.12)*
	Paper and pencil	1.11 (0.40)	1.05 (0.27)	1.18 (0.49)

(1)—only those who said they tried to change their answers are included (the higher the score, the easier to change answers)

*— $p \leq 0.01$

TABLE 3
Preferences for Methods by Age (1)

Method	≥60 n (%)	<60 n (%)	Overall n (%)
Which method was more comfortable for you to use?			
Paper and pencil	7 (10.9%)	2 (3.0%)	9 (6.9%)
Computer	29 (45.3%)	39 (58.2%)	68 (51.9%)
No difference	28 (43.8%)	26 (38.8%)	54 (41.2%)
Which method seemed faster for completing the questionnaire?			
Paper and pencil	10 (15.6%)	11 (15.9%)	21 (15.8%)
Computer	38 (59.4%)	44 (63.77%)	82 (61.7%)
No difference	16 (25.0%)	14 (20.29%)	30 (22.6%)
Which method was easier to use?			
Paper and pencil	8 (12.5%)	3 (4.4%)	11 (8.3%)
Computer	34 (53.1%)	39 (29.32%)	73 (54.9%)
No difference	22 (34.4%)	27 (20.30%)	49 (36.8%)
If there were a choice, which method of completing the questionnaire would you prefer?			
Paper and pencil	8 (12.5%)	8 (11.6%)	16 (12.0%)
Computer	41 (64.1%)	47 (68.1%)	88 (66.2%)
No difference	15 (23.4%)	14 (20.3%)	29 (21.8%)

(1)—No statistical difference by age was observed for any comparison.

sponses for those items were 1.0 (data not shown). Table 4 provides information on the site coordinators preferences for mode of administration. Paper and pencil was seen as the easiest to set up (55%) while the computer was perceived by the coordinators as easier for patients to use (55%). The majority of site coordinators (82%) would prefer to use the computer mode of administration in a clinical trial while 73% of coordinators thought that most patients would prefer to use the computer.

DISCUSSION

This study evaluated site coordinator and patient burden and preferences for two different modes of HRQOL self-administration, paper and pencil and computer touch-screen, in a sample of patients with stable GERD. We found little difference in elapsed time between the two methods of administration. Both the ease of use questions and semantic differences evaluation demonstrated very little difference between the two modes of ad-

TABLE 4
Site Coordinator Descriptive Data (n = 11)

Question	Paper and Pencil	Computer	No Difference
Which method was easiest to set up?	6 (55%)	3 (27%)	2 (18%)
Which method seemed easier for patients?	2 (18%)	6 (55%)	3 (27%)
Which method would you prefer to use in a clinical trial?	1 (9%)	9 (82%)	1 (9%)
Which method do you think most patients would prefer?	0 (0%)	8 (73%)	3 (27%)

ministration. Patients and site coordinators generally preferred the computer touch-screen to the paper and pencil mode of administration.

In general, the elapsed time for completing the HRQOL administration was short regardless of mode of administration, with patients 60 years and older requiring more time to complete the questionnaires regardless of mode of administration. It is interesting to note that use of the computer method appears to have created the perception of a faster process (1.52 versus 1.35, $p \leq 0.05$) when, in fact, the quantitative assessment of elapsed time indicates that the paper and pencil method was shorter, though not significantly. No additional allowances were made to account for potential visual deficits or reduced functional abilities among the patients 60 and over. Some consideration should be given to these issues in choosing to implement either of these modes of administration if a study were to involve a geriatric patient population.

Patients reported both methods as being easy to use and results from the semantic differential demonstrated very few significant differences. When patient age group was controlled for in analysis, the 60 and over age group reported the computer method to be longer and slower. There may be a break point somewhere near 15 minutes that creates a sufficient burden on the respondent, regardless of age, where perception changes on ease of use. Since only the older age group took that long to complete the HRQOL instruments, this is showing here as an age-related difference. Longer questionnaires would need to be compared in this same manner to more fully explore this observed difference.

Patients appeared to either prefer the computer or find no difference between the two methods. Less than 20% of patients expressed a direct preference for the paper and pencil mode of administration, and this held true even when the sample was stratified by age.

Results from the site coordinators were similar to those from the patients. Site coordinators had the most difficulty with the data transfer element of responsibilities for both

methods of administration. Anecdotal evidence, however, indicates that the difficulty with the electronic data transfer was reduced when a phone line and number at the receiving end was dedicated to data transfer from this study. Difficulties with data transfer of the paper and pencil questionnaires included the need to find a photocopying machine and the time it took to photocopy and mail the questionnaires. This time might have been reduced with the use of multi-copy NCR forms. In general, the site coordinators preferred the computer mode of administration for use in clinical trials and thought that patients would prefer it as well.

Further areas of research are suggested by these results. This study lacked a detailed time component, making it difficult to estimate the amount of time saved by the site coordinator. This, in turn, means that the cost savings of the computer method cannot be estimated although a cost savings has been suggested by other authors (2). We also did not compare the costs of preparing the paper and pencil forms for the sites to the costs of programming and renting the computers. In addition, the vast majority of the study participants were white which means that the sample is not representative of the population as a whole. Evidence suggests that minorities with lower incomes are less likely to own a computer. Most participants were in fair to good health which may not be the case in all clinical trials; however, evidence from research done in oncology has demonstrated that those patients also prefer the computer and find it easy to use.

The authors caution the reader that when considering utilization of computer touch-screen technology for HRQOL data collection in clinical trials, investigators need to be familiar with the FDA Guidance on computerized systems used in clinical trials and ensure that whatever system is used is in compliance with all elements of the guideline.

This study attempted to mimic aspects of a clinical trial. Patients were asked to return a minimum of one time. The time between visits was short but long enough to neutralize

learning effects while answering the HRQOL questionnaires. In general, the computer mode of administration was well-accepted by the clinical investigators, site coordinators, and patients; indeed it was highly preferred in many cases. Age comparisons demonstrated that older patients had slightly more difficulty using the computer, but this did not seem to interfere with their preference for the computer. Data capture through use of a computer appears to minimize the burden on the site coordinator and has the intangible benefit of allowing "state-of-the-art" tools to be offered to sites agreeing to participate in clinical studies. As the computer becomes more and more commonplace in both home and the workplace, it will become the more "usual" way of information exchange.

Acknowledgment—The authors acknowledge the assistance of Nancy Kline Leidy, PhD, of MEDTAP International in the analysis and interpretation of the study findings.

REFERENCES

1. Leidy NK, Revicki DA, Geneste B. Recommendations for evaluating the validity of quality of life claims for labeling and promotion. *Value Health*. 1999;2:113–127.
2. Schaffer M, Lofland JH, Johnson NE. Cost comparison of computerized touch-screen technology and traditional paper systems for evaluating quality of life outcomes. *Pharmacother*. 1998; 18(2): 437.
3. Taenzer PA, Specia M, Atkinson MJ, et al. Computerized quality-of-life screening in oncology clinic. *Cancer Pract*. 1997;5:168–175.
4. Buxton J, White M, Osoba D. Patients' experiences using a computerized program with a touch-sensitive video monitor for the assessment of health-related quality of life. *Quality Life Res*. 1998;7:513–519.
5. Pouwer F, Snoek FJ, van der Ploeg HM, et al. A comparison of the standard and the computerized versions of the Well-being Questionnaire (WBQ) and the Diabetes Treatment Satisfaction Questionnaire (DTSQ). *Quality Life Res*. 1998;7:33–38.
6. Drummond HE, Ghosh S, Ferguson A. Electronic quality of life questionnaires: a comparison of pen-based electronic questionnaires with conventional paper in a gastrointestinal study. *Quality Life Res*. 1995;4:21–26.
7. Velikova G, Wright EP, Smith AB, et al. Automated collection of quality-of-life data: a comparison of paper and computer touch-screen questionnaires. *J Clin Oncol*. 1999;17:998–1007.
8. Wiklund IK, Junghard O, Grace E, et al. Quality of life in reflux and dyspepsia patients. Psychometric documentation of a new disease-specific questionnaire (QOLRAD). *Eur J Surg*. 1998;Suppl 583: 41–49.
9. Ware JE, Kosinski M, Keller SF. *SF-36 Physical and Mental Health Summary Scores: A User's Manual*. Boston, MA: The Health Institute, New England Medical Center; 1994.
10. Ware JE, Snow KK, Kosinski M, et al. *SF-36 Health Survey: Manual and Interpretation Guide*. Boston, MA: The Health Institute, New England Medical Center; 1993.