Confirming Equivalence: Converting Established Diabetes Questionnaire (ADDQoL-19) from Paper to Touchscreen

myPROpad™ by writeresult®

Background - The Audit of Diabetes-Dependent Quality of Life (ADDQoL-19) was developed by Prof. Clare Bradley in the early 1990s and is well-established through academic and pharmaceutical clinical trials to provide an individualized measure of the impact of diabetes on quality of life in an adult population. The conversion from paper to electronic format was undertaken by ePRO developer WriteResult, LLC and researchers from Rutgers University, with the authorization of Health Psychology Research (HPR) as the licensor of the ADDQoL.

Form Conversion – The key concerns when moving from paper to eFormat are the time to start-up and the risk of an assessment becoming non-equivalent as a result of the conversion. myPROpad avoids the equivalency issue by using a unique approach that converts original paper forms into touchscreens with low/no change to the document so that it retains its exact structure, layout, and function once in eFormat. This qualifies as a minor change as defined in the 2009 landmark paper issued by the International Society for Patient Reported Outcomes (ISPOR) on paper to electronic PRO conversion. Trial startup is very rapid because forms do not need to be developed - whether assessments are self-generated or well-established and licensed, if they exist on paper they can be converted to myPROpad forms in a matter of days. Many different data entry controls including check boxes, VAS scales, graphics, Likert scales, and so on are available. The ADDQoL was well suited to the conversion as it was designed with simple checkbox responses and moderate branching logic.

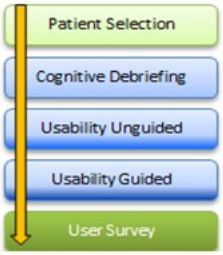
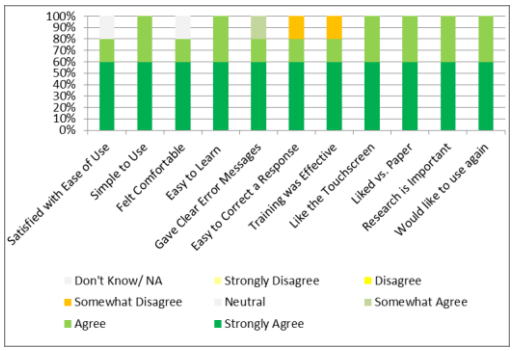


Fig 1. Testing for Conversion

Test Methodology - The migration process consisted of four steps - the creation of an electronic version of the ADDQoL for myPROpad, review of the eVersion by the author, cognitive debriefing interviews with 5 patients from the target population of English speaking adults being treated for Diabetes, and usability testing through both individual and guided monitored completion of the ADDQoL on myPROpad (see Figure 1). The assessments were completed under the observation of an interviewer, and the results of that interaction documented with any difficulties being noted. Participants were then surveyed about their experience.

Results - In converting for use on some devices, assessments and completion instructions require significant revision due to the nature of the ePRO device which warrants careful testing to ensure the revisions do not detrimentally affect the validity and therefore the equivalency of the eVersion. In this case the assessments were well-suited for the automation method that myPROpad leverages and no changes were made to the original so cognitive debriefing was less of a critical step. The equivalence was so clear that participants expressed confusion with why they were even being tested for comprehension and so the cognitive portion was suspended for the ADDQoL for three patients with researchers concerned about the burden without value. During the Usability portions, the most common comments were regarding general iPad functions such as turning pages, selecting boxes, and enlarging the screen for viewing. Once instructed, the participants were able to replicate these actions without difficulty.



Survey - The distribution of experienced iPad users was good within this small group with two who use an iPad regularly, one who uses one infrequently, and two who stated Don't Know or N/A indicating no previous iPad use. All five subjects want to use myPROpad again. Overall patients liked using myPROpad, were comfortable using it, and preferred using it instead of paper. Interestingly patients also reported strongly positive perception of the value of the research due to the iPad use – scoring the research highly important. This attribution of value may indicate an opportunity for better engagement leading to retention and/or better compliance if the research is seen as more critical.

Benefits - Employing myPROpad for data collection of Patient Outcomes research improves data completeness and data quality as the application controls for errors immediately and before the patient leaves the site - something that requires significant human intervention in a paper environment. Double data entry is eliminated along with all of the inherent costs, risks, and management issues in that process. The ADDQoL is a substantial assessment with 22 fields of entry, 19 of which have multiple levels of questioning and branching logic on each question that could result in errors of omission or over-responding in a paper setting. Setting field requirements and using automated branching to prevent subjects from answering questions irrelevant to them optimizes data quality. In addition data are available as soon as the patient completes a form so research team members can proactively monitor their data flow, and take action on that information – whether formally through interim data analysis or informally with quality and progress monitoring.

Conclusions - Using myPROpad to collect data from patient outcomes assessments like the ADDQoL-19 is a time and quality effective alternative to paper that retains the same attributes as the original paper form while adding benefits to support better data quality and completeness. The cognitive debriefing and usability tests assured the team that the assessment was functioning well and that participants once given some basic training on how to navigate the device were able to use myPROpad successfully to complete the assessment. The collaborators concurred that the myPROpad and paper versions of the ADDQoL are equivalent.

To inquire about myPROpad, email info@writeresult.com or visit www.writeresult.com.
Further information about the ADDQoL-19 is available on the website www.healthpsychologyresearch.com.