**ABSTRACT**

**Purpose**

The European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life-Core Questionnaire (QLQ-C30) is a widely used generic self-report measure of health-related quality of life (HRQOL) for cancer patients. However, no validated voice script for interviewer-led telephone administration was available. The aim of this study was to develop a voice script for interviewer administration viatelephone.

**Methods**

Following guidelines from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) PRO Mixed Modes Good Research Practices Task Force, a randomised cross-over equivalence study, including cognitive debriefing, was conducted to assess equivalence between paper and telephone administration modes. Assuming an expected intraclass correlation coefficient (ICC) of 0.70 and a minimally acceptable level of 0.50, a sample size of 63 was required.

**Results**

Cognitive interviews with five cancer patients found the voice script to be clear and understandable. Due to a protocol deviation in the first wave of testing, only 26 patients were available for analyses. A second wave of recruitment was conducted, adding 37 patients (n=63; mean age 55.48; 65.1% female). Total ICCs for mode comparison ranged from 0.72 (nausea and vomiting, 95% CI 0.48-0.86) to 0.90 (global health status/QoL, 95% CI 0.80-0.95; pain, 95% CI 0.79-0.95; constipation, 95% CI 0.80-0.95). For paper first administration, all ICCs were above 0.70, except nausea and vomiting (ICC 0.55; 95% CI 0.24-0.76) and financial difficulties (ICC 0.60; 95% CI 0.31-0.79). For phone first administration, all ICCs were above 0.70.

**Conclusions**

The equivalence testing results support the voice script’s validity for administration of the QLQ-C30 via telephone.

**Keywords:** EORTC QLQ-C30; health-related quality of life; patient-reported outcomes; core cancer symptoms; equivalence testing; voice script; administration mode; remote questionnaire administration