**PRM173**

**MODIFICATION OF PATIENT REPORTED OUTCOMES MEASURES OF COMPLIANCE, GASTROINTESTINAL SYMPTOMS, PALATABILITY AND EATING SATISFACTION FOR PATIENTS NEEDING ION CHOLERATION THERAPY**


**Objective:** In patients requiring frequent blood transfusions due to transfusion dependent anemia (TDA) (e.g., sickle cell disease [SCD]) and myelodysplastic syndromes (MDS), life expectancy is directly related to the quality of chelation therapy, and poor adherence to treatment increases the risk of complications and shortens survival1. Improved palatability ratings and gastrointestinal (GI) tolerability could have a positive impact on adherence with iron chelation therapy (ICT). Therefore, patient-reported outcomes (PROs) measuring compliance, GI symptoms, and palatability were developed and the Satisfaction with Iron Chelation Therapy (SICT) questionnaire was modified, as electronic PROs (ePROs) specific to a new formulation of ITLC are needed. METHODS: Eleven patients were provided with consent and were included in this qualitative study. Two sets of face-to-face cognitive interviews were conducted iteratively, modifications to items were debriefed in the second set. A single version open-endedly elicited patients’ spontaneous experiences with ICT. Interviews were audio recorded and transcribed. An item tracking matrix documented the changes made for each item. Data analysis used ATLAS.ti software. This study was conducted according to best practices for development of Cost and modification of ePROs in an ePRO format. RESULTS: Patients were 73% (n=8) male and 27% (n=3) female with a mean age of 43 (range 14-81 years); 45% (n=5) had SCD, and 27% (n=3) had MDS. Patient spontaneous reports and cognitive debriefing responses to the ICT were comprehensible, clear, and gave insight into the multidimensional impact of ICT. Changes made after cognitive debriefing ensured the comprehensibility, lack of redundancy, and appropriate instructions and response options. The resultant PRO included the compliance (2 items), GI Symptom Diary (6 items), Palatability (6 items), and modified SICT (13 items). CONCLUSIONS: Results support the content validity of PRO measures of compliance, GI symptoms, palatability, and satisfaction with ICT. These measures require psychometric validation of psychometric validity, reliability, and responsiveness before recommending their use in future clinical research.

**PRM174**

**THE IMPORTANCE OF MIGRATION ASSESSMENTS: ECOA TRANSLATIONS AND LINGUISTIC VALIDATION**

Sweeney E, Kelley T

**Objective:** As the use of cultural outcomes assessments (COAs) in global studies continues to increase, early collaboration between eCOA and linguistic validation providers becomes critical to the success of global initiatives. Early involvement of a linguistic partner in the eCOA project can avoid the implementation of migration issues that may not be present in the English version of the instrument, but if not identified, can lead to study delays as well as increased costs for the sponsor. METHODS: An eCOA translation was conducted previously using linguistic validation project best practices for a German version of an eCOA instrument, and the translated version included either newly developed eCOAs or pen/paper to eCOA migration. A comparison of various eCOA platforms, the corresponding issues, and details relating to migration solutions were assessed. RESULTS: Frequently, a line of text that is present in an eCOA platform (proprietary software, Excel, etc.) is coded such that it populates into the eCOA device in multiple locations. These segments are sometimes referred to as “computed text” and are commonly used for response options that repeat for multiple items of a questionnaire. While this may work adequately in English, many languages require a variance in the translation used based on the context of the item and/or response choice. While a pen/paper version may allow for these variances, the initial eCOA programming may not. The variance is only determined further into the linguistic validation process and presents challenges if the device requires re-programming. CONCLUSIONS: A migration assessment, separate from equivalency testing, allows for the eCOA and linguistic validation providers to assess the impact of the language used in the eCOA software. This assessment can determine whether system modifications are necessary to allow for the translations to properly be mapped and displayed. This additional step will also prevent study delays as well as quality issues as it allows issues to be addressed early and avoid later difficulties.

**PRM175**

**PATIENT-DRIVEN QUESTIONNAIRE DEVELOPMENT, ITEM FEEDBACK FROM USERS OF A PATIENT NETWORK**

Castagnet N1, Harrington M2, Campillo-Alvarez A1, Rebollo P1

1LASER ANALYTICA, Oviedo, Spain; 2PatientsLikeMe, Cambridge, MA, USA

**Objective:** C4T-Health is a general health related quality of life computer adaptive test developed and validated in Spain. Based on its 96 item pool, a new instrument is being developed in English. The objective of the present study was to obtain subjective feedback from patients on the C4T-Health platform, that centralizes FROM research and is integrated with PatientsLikeMe and an online community. METHODS: The item pool was split in four sets of 24 items each and then a random sample of patients, with 65 conditions, answered an e-mail that included link to a survey open for 7 days. They were asked to answer one of the sets and give feedback on a 4 point scale for applicability, comprehensibility and appropriateness of response options. They were also encouraged to leave free-text feedback. RESULTS: A total of 218 subjects provided feedback, 61.47% female. Mean age was 55.78 years, with patients from 18-80 years, 40.37% between 55-65 years. The most represented conditions were Parkinson’s (27), Fibromyalgia (23), Multiple Sclerosis (19), Depression (18) and Rheumatoid Arthritis (16). The evaluation of effectiveness results between these two measures following the introduction of validated independent value sets for EQ-5D-5L is encouraged.