## Collection of Multiple Patient-Reported Outcome Measures (CRAM-PROMs) in Orthopaedic Trauma: Assessment of the Impact of Quantity on Quality

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**Purpose**: Our study objective was to determine if the number of electronic patient-reported outcome measures (PROMs) questionnaires completed by fracture patients affected their psychometric properties. Our hypothesis was that there was going to be a progressive decline in PROMs reliability as we increased the number of questionnaires given to participants.

**Methods**: In this single-center, randomized trial, we included patients presenting to the fracture clinic for follow-up within 6 months of their initial injury. They were randomly assigned to one of the following 4 groups: group 1 only answered the electronic EQ-5D-5L (EuroQol-5 Dimensions-5 Levels) questionnaire, group 2 answered 1 additional questionnaire previous to the EQ-5D-5L, group 3 answered 2 additional questionnaires previous to the EQ-5D-5L, and group 4 answered 3 additional questionnaires previous to the EQ-5D-5L. The main outcome measured was the internal consistency of the virtual EQ-5D-5L as a measure of reliability. Secondary outcomes included questionnaire completeness and time to completion.

**Results**: 115 participants were enrolled in the CRAM-PROMs study. 28 participants were randomized to group 1, 29 to group 2, 29 to group 3, and 29 to group 4. All groups demonstrated an acceptable level of internal consistency and reliability, as measured by Cochran's alpha (group 1: 0.83, 95% confidence interval (CI) 0.70 to 0.91; group 2: 0.74, 95% CI 0.56 to 0.87; group 3: 0.68, 95% CI 0.44 to 0.83; group 4: 0.81, 95% CI 0.68 to 0.90). Completeness was 100% for group 1, 98.5% for group 2, 100% for group 3 and 92% for group 4.

**Conclusion**: Our results support our hypothesis that there is a progressive decline in psychometric properties in the EQ-5D-5L in terms of reliability as we increase the number of questionnaires given to participants in groups 1 to 3. Although there is an increase in Cochran's alpha for group 4 compared to group 3, it should be noted that 3 participants (10%) in group 4 did not complete the questionnaires at all, which may have affected the Cochran's alpha for this group. Therefore, this value should be interpreted with caution.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device they wish to use in clinical practice.