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Measurement Equivalence of Patient-Reported Outcome Measure Response Scale Types Collected Using Bring Your Own Device Compared to Paper and a Provisioned Device: Results of a Randomized Equivalence Trial

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ABSTRACT

Objectives: The aim of this study was to assess the measurement equivalence of individual response scale types by using a patient reported outcome measure (PROM) collected on paper and migrated into electronic format for use on the subject's own mobile device (BYOD) and on a provisioned device (site device). **Methods:** Subjects suffering from chronic health conditions causing daily pain or discomfort were invited to participate in this single-site, single visit, three-way crossover study. Association between individual item and instrument subscale scores was assessed by using the intraclass correlation coefficient (ICC) and its CI. Participant attitudes toward the use of BYOD in a clinical trial were assessed through use of a questionnaire. **Results:** In this study, 155 subjects (females 83 [54%]; males 72 [46%]) ages 19 to 69 years (mean ± SD: 48.6 ± 13.1) were recruited. High association between the modes of administration (paper, BYOD, site device) was shown with analysis of ICCs (0.79–0.98) for each response scale type, including visual analogue scale, numeric rating scale, verbal response scale, and Likert scale. Of the subjects, 94% (146 of 155) stated that they would definitely or probably be willing to download an app onto their own mobile device for a forthcoming clinical trial. Forty-five percent of subjects felt BYOD would be more convenient compared with 15% preferring a provisioned device (40% had no preference). **Conclusions:** This study provides strong evidence supporting the use of BYOD for PROM collection in terms of the conservation of instrument measurement equivalence across the most widely used response scale types, and high patient acceptance of the approach.

Keywords: electronic patient reported outcomes (ePRO), bring your own device (BYOD), measurement equivalence, patient acceptability.

There is a drive to design more patient-centric trials that make study participation more engaging and convenient. One approach is to leverage patients' own devices to enable the collection of self-report data ("Bring Your Own Device" [BYOD]) because this eliminates the burden of carrying and maintaining a second device for the duration of the study. Migrating an instrument from a paper-and-pencil format into a screen text format qualifies as a modification of the questionnaire that requires evidence to demonstrate that the instrument's measurement properties are unaffected by the change of format [1]. Although there is a growing body of evidence showing the equivalence of patient reported outcomes measures (PROMs) when migrated from the original format to the electronic format [2,3], there is no definitive study demonstrating that variable technical specification of the mobile device used does not affect the measurement properties of the instrument. This trial in patients suffering from diseases causing chronic pain explored the measurement equivalence of a PROM delivered on paper, PROM using a standardized provisioned device, and PROM using the patient's own mobile device (smartphone or tablet).

Methods

Subjects aged 18 to 70 years suffering from a chronic health condition causing daily pain or discomfort were invited to participate. The subjects provided written informed consent to participate, and the study was approved by the Salus Institutional Review Board (Austin, TX).

Patients were requested to complete a PROM on three occasions in random order according to a William's Design balanced for first-order carryover [4]—once using a paper questionnaire,

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once electronically using a standard device provided by the study site, and a further electronic administration using an app installed on their own mobile device. The mobile app, SureSource Engage, was provided by Clinical Ink (Winston-Salem, NC). PROM administrations were conducted on the same site visit, separated by a 30- to 60-minute washout period in which subjects

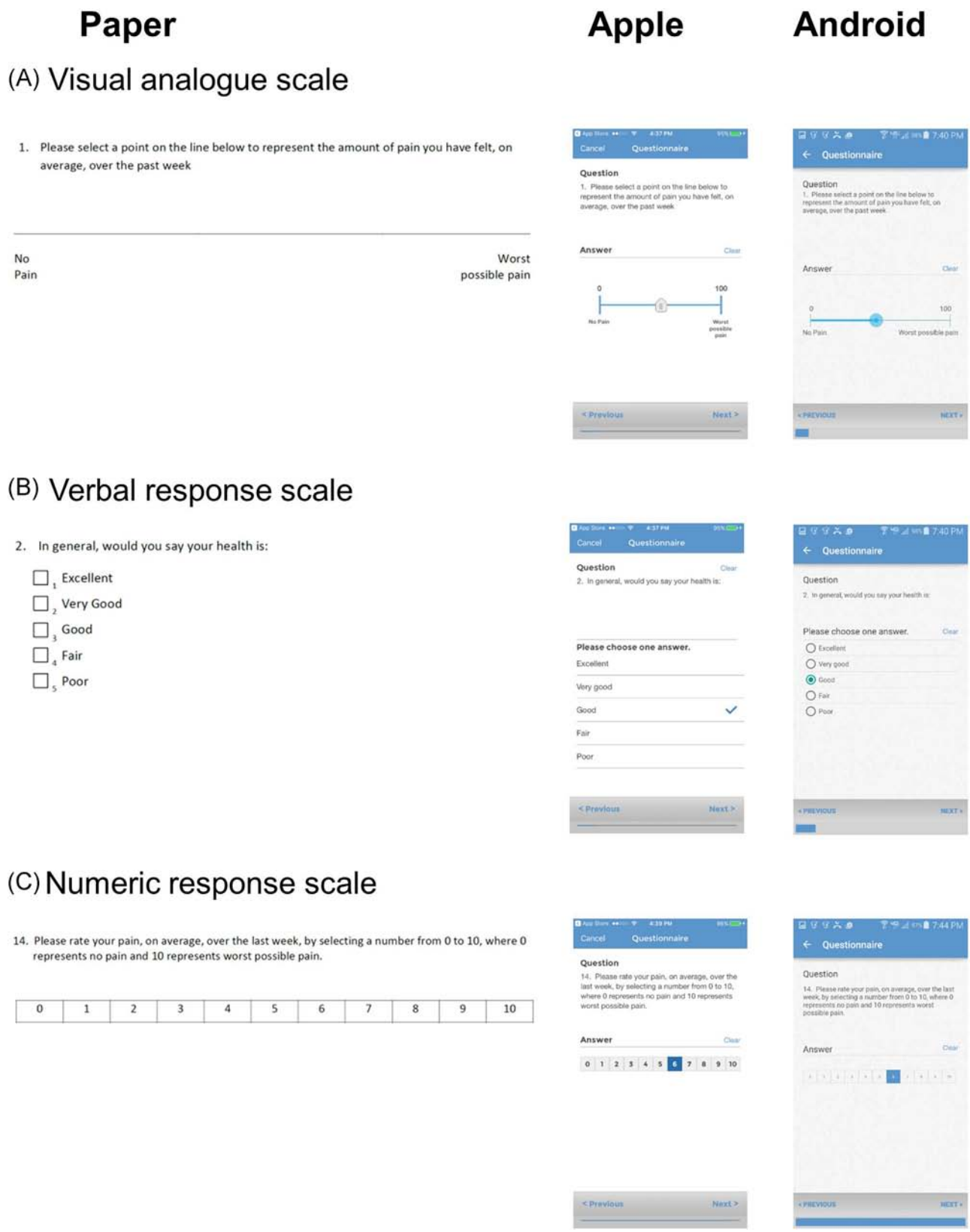

Fig. 1 – Differences in instrument display format between paper and electronic formats.