

PINPOINT: Gaming Technology to
Engage Adolescent Sickle Cell
Patients in Precision Pain
Management

Data Analysis Plan

NCT03291613

July 2018

PINPOINT PHASE I DATA ANALYSIS PLAN

All data will be uploaded in real-time using KB's secured network and be de-identified and stored in KB's secured database. Established protocols for quality assurance will ensure high quality data, and SAS will be used for analyses. Cognitive interviews, FGs, and Usability Testing sessions will be recorded and transcribed, and analyzed using Atlas.ti™ software. Emerging codes will be assigned to phrases and text passages that categorize views, themes, and opinions. The thematic analysis will use constant comparative analysis using grounded theory methodology and a phenomenological approach. An iterative process of summarizing data will be used to ensure saturation. Mixed-methods design research suggests that thematic saturation occurs at approximately 6-10 cases.

Adolescent Cognitive Interviews: Emerging themes will be used to better understand the clarity and exactness of the PAT questions via the patient perspective. If the analysis reveals dissention between the EAB's PAT items and the SCD youths' understanding or agreement of the items, the PAT items will be revised and interviews will be repeated until there is thematic agreement.

Focus Group: Two rounds of iterative FGs will be conducted. After FG 1, feedback will be evaluated using similar thematic approaches used in the cognitive interviews, and an initial prototype will be created. FG 2 will evaluate Prototype 1, and provide input on design, contents and features, and overall engagement. FG2 feedback will influence app modifications and then be programmed into Prototype 2.

Usability Testing and Medical Provider Interviews: Means of the Likert-response items will be calculated; an average of 67% or higher will be considered acceptable. The SUS will serve as the primary outcome variable for usability testing. A SUS score of 68 is considered above average and will serve as the criterion for measuring *Pinpoint's* usability. A summary of responses will be prepared including frequency of responses to each question. Proportions and means will be calculated. A reliability score of 0.70 or higher (Cronbach's alpha) will suggest PAT reliability. A significant correlation coefficient ($p < .05$ level) between the PAT and APPT will suggest preliminary convergent validity.