Implementation of the PROMIS Toolbox within an Orthopaedic Trauma Clinical Trials Consortium

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METRC
Major Extremity Trauma and Rehabilitation Consortium

BACKGROUND

The Patient-Reported Outcomes Measurement Information System (PROMIS) has developed item banks, short forms and computer-adaptive tests (CATs) to help standardize measurement for important patient reported outcome (PRO) domains. These tools have the potential to revolutionize outcome measurement in clinical research through greater assessment precision while reducing response burden. Perceived implementation challenges include the need for CAT software, mobile technology and internet access.

The overall goal of this study is to assess the performance and research utility of these new tools in injured patient populations for future comparative effectiveness research projects. The project will examine the reliability, validity and responsiveness of the PROMIS tools for clinical research following orthopaedic trauma.

Here, we present preliminary results examining the feasibility of using PROMIS tools within a large, multi-center clinical trials consortium.

MATERIALS AND METHODS

The STREAM Study (Streamlining Trauma Research Evaluation with Advanced Measurement) was an observational study of PRO data collection for 1,000 trauma patients at 43 Level 1 trauma centers participating in the Major Extremity Trauma and Rehabilitation Consortium (METRC). PROMIS short forms and CATs were incorporated into the longitudinal data collection of six ongoing orthopaedic trauma clinical trials and an expanded data collection interview conducted at the time of the last study follow up.

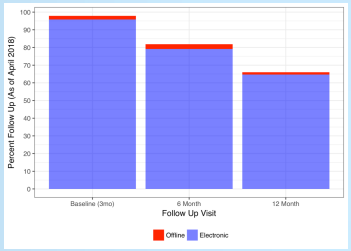
Participants were evaluated at 3, 6 and 12 months following an orthopaedic injury, which included open and closed fractures of the tibia, calcaneus, pilon, ankle and foot as well as below-the-knee amputations. Data collection specific to the STREAM study included 10 PROMIS domains (defined as traits or determinants of current or future health outcomes). These domains (6 core and 4 exploratory) are highlighted in red in the framework diagram on the far right. All 10 domains were collected at 3 and 6 months, though only the 6 core CAT domains were assessed at 12 months (these were supplemented by additional blocks of item bank questions from these domains).

RESULTS

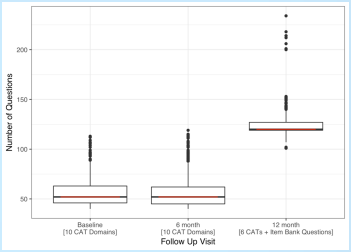
A total of 2,830 PRO assessments (a cumulative 24,740 domains) were completed across all study follow ups. Offline (back up) data collection methods occurred roughly 2% of the time and were due to occasional internet connectivity or other administrative problems at the study sites.

Among CAT assessments, 85% were recorded in person using the tablet application, 12% were completed using a survey link emailed to the participant, and 3% by phone. Across all time points, electronic data collection was used 98% of the time. The median time per full 10-domain CAT assessment was 12.3 minutes while the median number of items asked was 51.

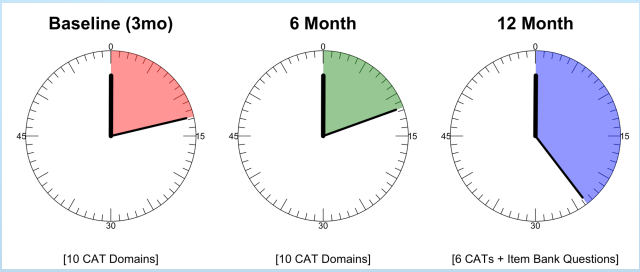
FOLLOW UP



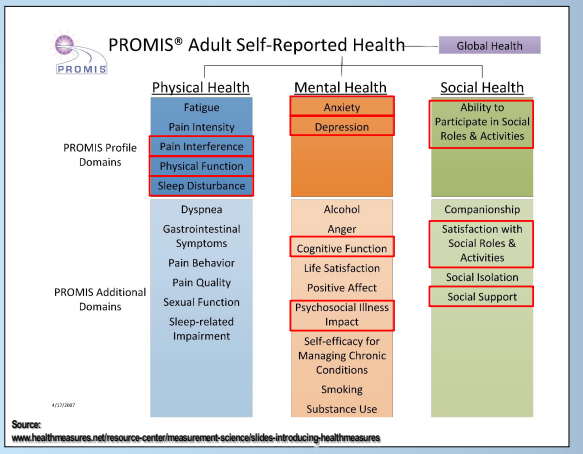
RESPONSE BURDEN: ITEMS



RESPONSE BURDEN: MEDIAN ASSESSMENT TIME (MIN)



PROMIS MEASUREMENT FRAMEWORK



THANKS TO OUR PARTICIPATING SITES

In descending order of enrollment:

- University of Maryland R Adams Cowley Shock Trauma Center
- Carolinas Medical Center
- Vanderbilt Medical Center
- University of Washington/Harborview Medical Center
- Methodist Hospital
- UT Health: The University of Texas at Houston
- Louisiana State University Health Science Center, Shreveport
- University of Mississippi Medical Center
- Rhode Island Hospital University Orthopedics
- Penn State University M.S. Hershey Medical Center
- MetroHealth Medical Center
- Hennepin County Medical Center
- Wake Forest University Baptist Medical Center
- Indiana University at Eskenazi
- San Antonio Military Medical Center
- University of Oklahoma Medical Center
- Boston Medical Center
- Miami Ryder Trauma Center
- University of Pittsburgh
- University of California, San Francisco
- Tampa General Hospital
- Allegheny Health Network
- St. Louis University Hospital
- Orthopaedic Associates of Grand Rapids Research
- Naval Medical Center Portsmouth
- University of Wisconsin
- Regional Medical Center at Memphis
- University of Texas Health Science Center, San Antonio
- Johns Hopkins University
- Walter Reed National Military Medical Center
- Jamaica Hospital Medical Center
- Ohio State University
- Regions Hospital
- University of Texas Southwestern Medical Center
- Mission Hospital
- University of Utah Orthopaedic Center
- University of Virginia
- Barnes Jewish Hospital
- Duke University Hospital
- Grant Medical Center
- Louisiana State University
- University of Pennsylvania
- Temple University Hospital

DISCLOSURES

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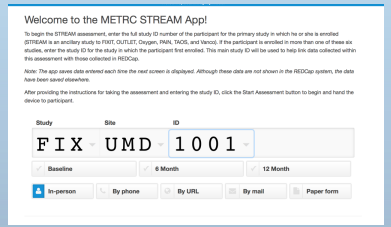
- Financial Disclosures: None

DATA COLLECTION

Data were collected using a custom-built application created for this project as well as REDCap, an open source, web-based application developed by Vanderbilt University and used by thousands of institutions across the globe. The application included an interface with our primary data capture system. It also included administrative tools to assist with study management as well as collect additional metadata regarding survey activities, including timing data and method of administration (in person, an online survey link, or by phone). Paper short-form PROMIS instruments were available as a backup.



CONCLUSIONS

It was feasible to use PROMIS tools in a large multi-center, trauma orthopaedics research setting with few barriers encountered. The ability to assess multiple PRO domains in the time typically required for a single legacy measure is appealing. This ability to ease the patient burden and diminish time required from research staff in collecting outcomes data across a wide spectrum of domains is critically important to the successful completion of future large-scale trials.