Pilot Test to Incorporate Patient Reported Outcomes into the STS Adult Cardiac Surgery Database

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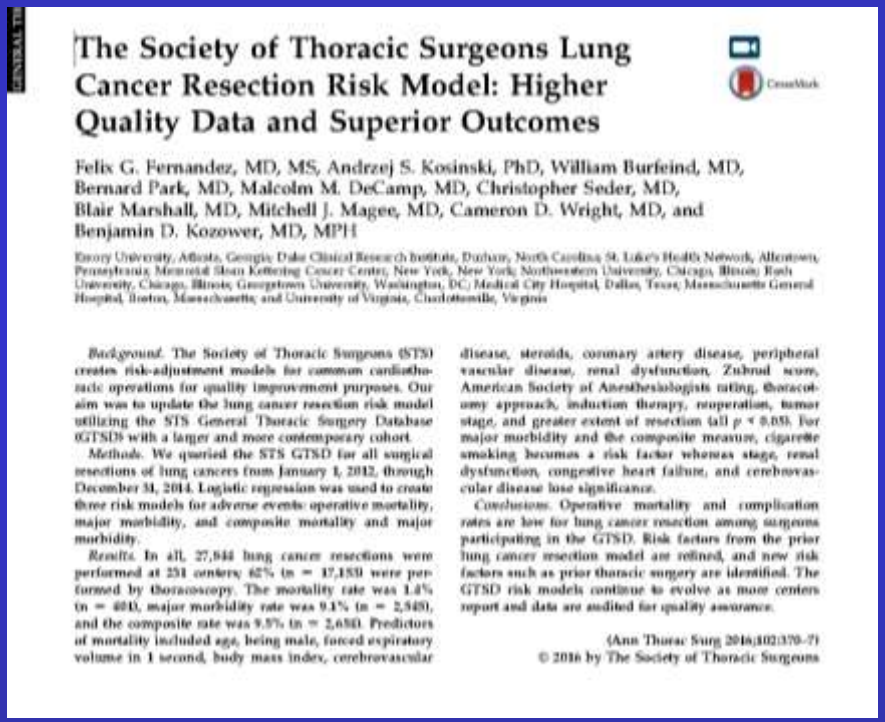
On behalf of the STS PRO Task Force

PROs in STS Database
Outline

- Rationale
- Update on preliminary work
- Description of pilot test
- Questions/discussion

- Established in 1989
- Gold standard clinical database
- Adult Cardiac, General Thoracic, Congenital
- 95% data accuracy, externally audited
- Predictive risk models for common procedures

Society of Thoracic Surgeons Lung Cancer Surgery Risk Models and Performance Measures



The Society of Thoracic Surgeons Lung Cancer Resection Risk Model: Higher Quality Data and Superior Outcomes

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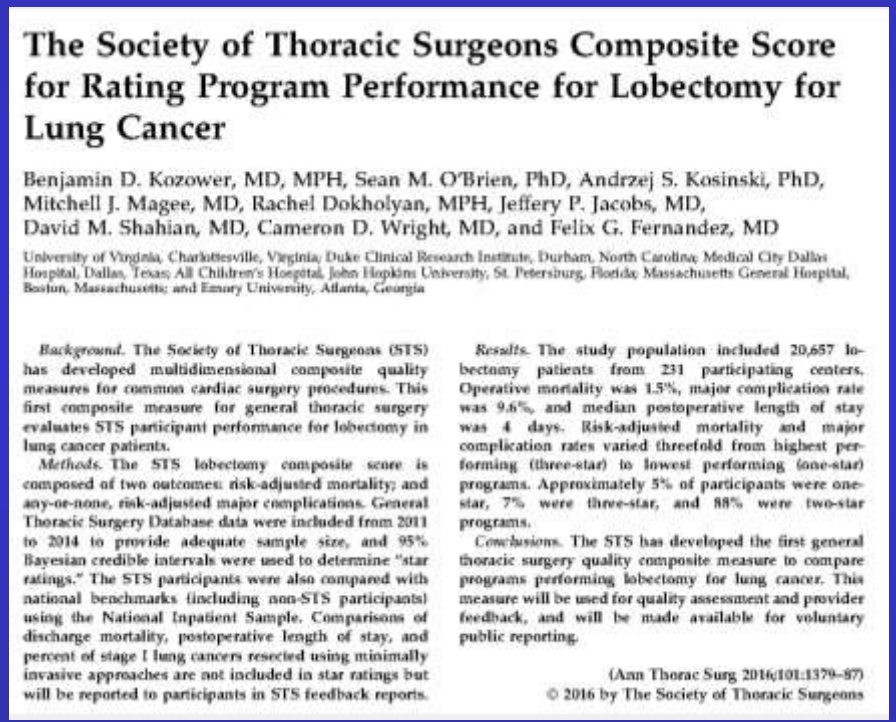
Background. The Society of Thoracic Surgeons (STS) creates risk-adjustment models for common cardiothoracic operations for quality improvement purposes. Our aim was to update the lung cancer resection risk model utilizing the STS General Thoracic Surgery Database (GTSD) with a larger and more contemporary cohort.

Methods. We queried the STS GTSD for all surgical resections of lung cancers from January 1, 2012, through December 31, 2014. Logistic regression was used to create three risk models for adverse events: operative mortality, major morbidity, and composite mortality and major morbidity.

Results. In all, 27,844 lung cancer resections were performed at 251 centers; 62% (n = 17,153) were performed by thoracoscopy. The mortality rate was 1.4% (n = 403), major morbidity rate was 9.1% (n = 2,540), and the composite rate was 9.5% (n = 2,650). Predictors of mortality included age, being male, forced expiratory volume in 1 second, body mass index, cerebrovascular disease, steroids, coronary artery disease, peripheral vascular disease, renal dysfunction, Zubrod score, American Society of Anesthesiologists rating, thoracotomy approach, induction therapy, reoperation, tumor stage, and greater extent of resection (all $p < 0.05$). For major morbidity and the composite measure, cigarette smoking becomes a risk factor whereas stage, renal dysfunction, congestive heart failure, and cerebrovascular disease lose significance.

Conclusions. Operative mortality and complication rates are low for lung cancer resection among surgeons participating in the GTSD. Risk factors from the prior lung cancer resection model are refined, and new risk factors such as prior thoracic surgery are identified. The GTSD risk models continue to evolve as more centers report and data are audited for quality assurance.

(Ann Thorac Surg 2016;102:370–7)



The Society of Thoracic Surgeons Composite Score for Rating Program Performance for Lobectomy for Lung Cancer

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Background. The Society of Thoracic Surgeons (STS) has developed multidimensional composite quality measures for common cardiac surgery procedures. This first composite measure for general thoracic surgery evaluates STS participant performance for lobectomy in lung cancer patients.

Methods. The STS lobectomy composite score is composed of two outcomes: risk-adjusted mortality; and any-or-none, risk-adjusted major complications. General Thoracic Surgery Database data were included from 2011 to 2014 to provide adequate sample size, and 95% Bayesian credible intervals were used to determine "star ratings." The STS participants were also compared with national benchmarks (including non-STS participants) using the National Inpatient Sample. Comparisons of discharge mortality, postoperative length of stay, and percent of stage I lung cancers resected using minimally invasive approaches are not included in star ratings but will be reported to participants in STS feedback reports.

Results. The study population included 20,657 lobectomy patients from 231 participating centers. Operative mortality was 1.5%, major complication rate was 9.6%, and median postoperative length of stay was 4 days. Risk-adjusted mortality and major complication rates varied threefold from highest performing (three-star) to lowest performing (one-star) programs. Approximately 5% of participants were one-star, 7% were three-star, and 88% were two-star programs.

Conclusions. The STS has developed the first general thoracic surgery quality composite measure to compare programs performing lobectomy for lung cancer. This measure will be used for quality assessment and provider feedback, and will be made available for voluntary public reporting.

(Ann Thorac Surg 2016;101:1379–87)

Currently, thoracic surgery outcomes in the STS database are assessed by morbidity and mortality.

Patient-Reported Outcomes (PROs)

- Symptom management – a cornerstone of clinical practice
- Symptoms and quality of life are high priorities for patients and caregivers "How will I feel and function?"
- Patients are in the best position to report on their symptoms and quality of life
- PROs – measures of physical, mental and emotional well being obtained by patient self report

Increased Demand for PRO

- Organizations Promoting Use of PRO Measures:
  - Centers for Medicare and Medicaid Services
  - National Quality Forum
  - National Committee for Quality Assurance

- Medical specialty society guidelines
  - ACCP recommends that a validated HRQL instrument be administered to lung cancer surgery patients at baseline and subsequent follow-up *(Colt. Chest. 2013)*

The absence of PROs represents a critical gap in the STS Database and our current approach to quality measurement

Pilot Study to Integrate Patient Reported Outcomes After Lung Cancer Operations Into The Society of Thoracic Surgeons Database

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GENERAL THORACIC

Background. A critical gap in The Society of Thoracic Surgeons (STS) Database is the absence of patient-reported outcomes (PRO), which are of increasing importance in outcomes and performance measurement. Our aim was to demonstrate the feasibility of integrating PRO into the STS Database for patients undergoing lung cancer operations.

Methods. The National Institutes of Health Patient Reported Outcome Measurement Information System (PROMIS) includes reliable, precise measures of PRO. We used validated item banks within PROMIS to develop a survey for patients undergoing lung cancer resection. PRO data were prospectively collected electronically on tablet devices and merged with our institutional STS data. Patients were enrolled over 18 months (November 2014 to May 2016). The survey was administered preoperatively and at 1 and 6 months after lung cancer resection.

Results. The study included 127 patients. All patients completed the initial postoperative survey, and 108 reached the 6-month follow-up. The most common procedure was video-assisted thoracic lobectomy (55%). At the first postoperative visit, there was a significant increase in pain, fatigue, and sleep impairment and a decrease in physical function. By 6 months, these PRO measures had generally improved toward baseline.

Conclusions. Collecting PRO data from lung cancer surgical patients and integrating the results into an institutional database is feasible. This pilot serves as a model for widespread incorporation of PRO data into the STS Database. Future integration of such data will continue to position the STS National Database as the gold standard for clinical registries. This will be necessary for assessing overall patient responses to different surgical therapies.

(Ann Thorac Surg 2017;104:245–53)

AATS Graham Foundation Cardiothoracic Surgical Investigators Program

Emory Pilot Study: Objectives

Primary: To demonstrate the feasibility of integrating PRO into our institutional STS database for patients undergoing lung cancer surgery.

Secondary: To describe the longitudinal pattern and variance of PRO following lung cancer surgery.

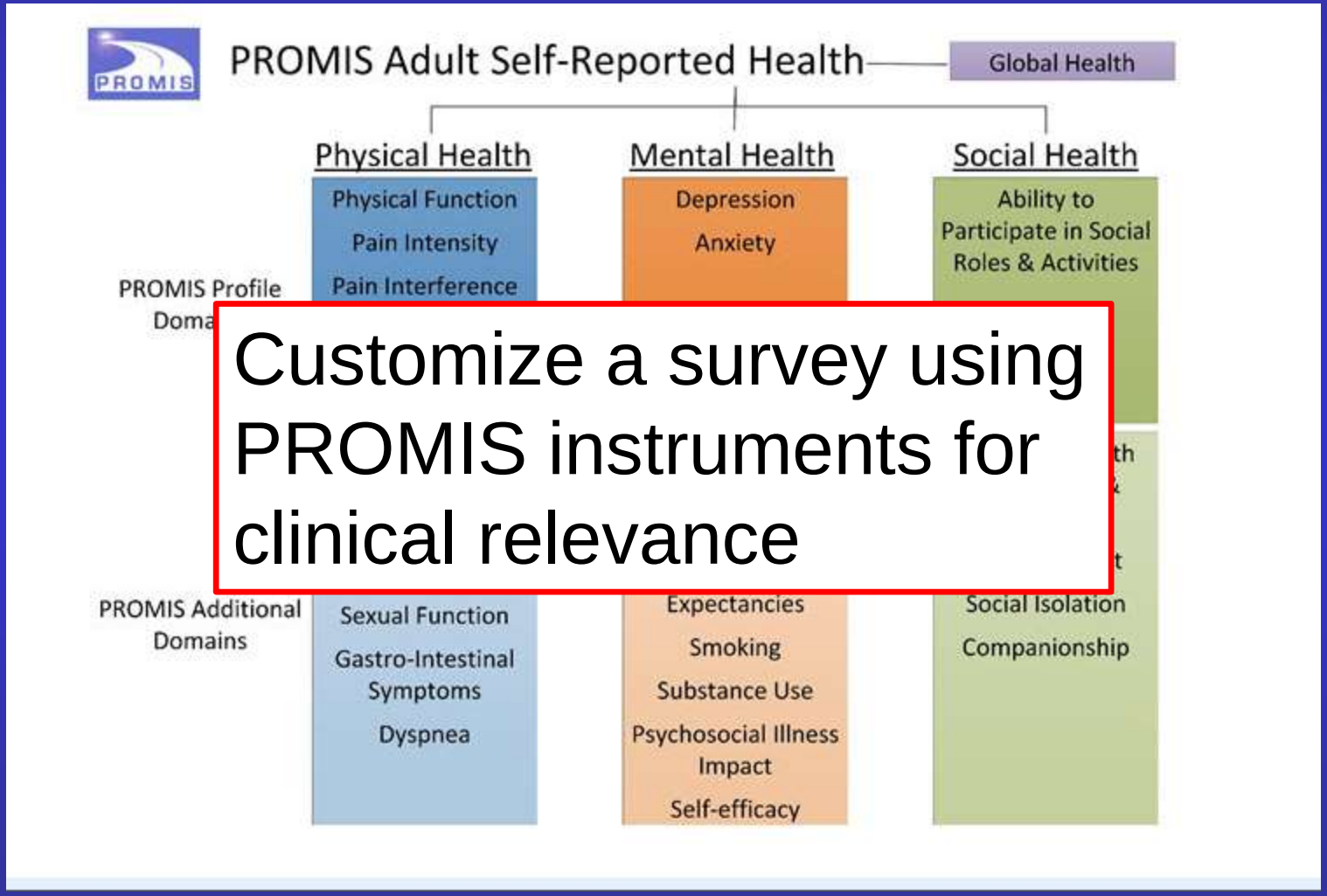
Methods

- Prospective, cohort study
  - Patients enrolled from Nov, 2014 through May, 2016
- Inclusion Criteria:
  - All patients who were candidates for resection of a known or presumed lung cancer
  - Patients with final path diagnosis other than primary lung cancer were excluded from subsequent analysis

Patient Reported Outcomes Measurement Information System (PROMIS)

- NIH funded initiative
- Comprehensive set of person-centered measures that evaluate physical, social, and emotional health
- PROMIS measures can be used with the general population and in patients with chronic conditions
- Specific to health domains rather than a specific disease
  - Created to be relevant across all conditions for the assessment of symptoms and functions

PROMIS Measures



Methods

Ten PROMIS instruments assessing several health domains were selected:

1. Physical Function
2. Pain Intensity
3. Pain interference
4. Depression
5. Anxiety
6. Sleep related impairment
7. Fatigue
8. Emotional support
9. Informational Support
10. Ability to participate in social roles and activities

Methods

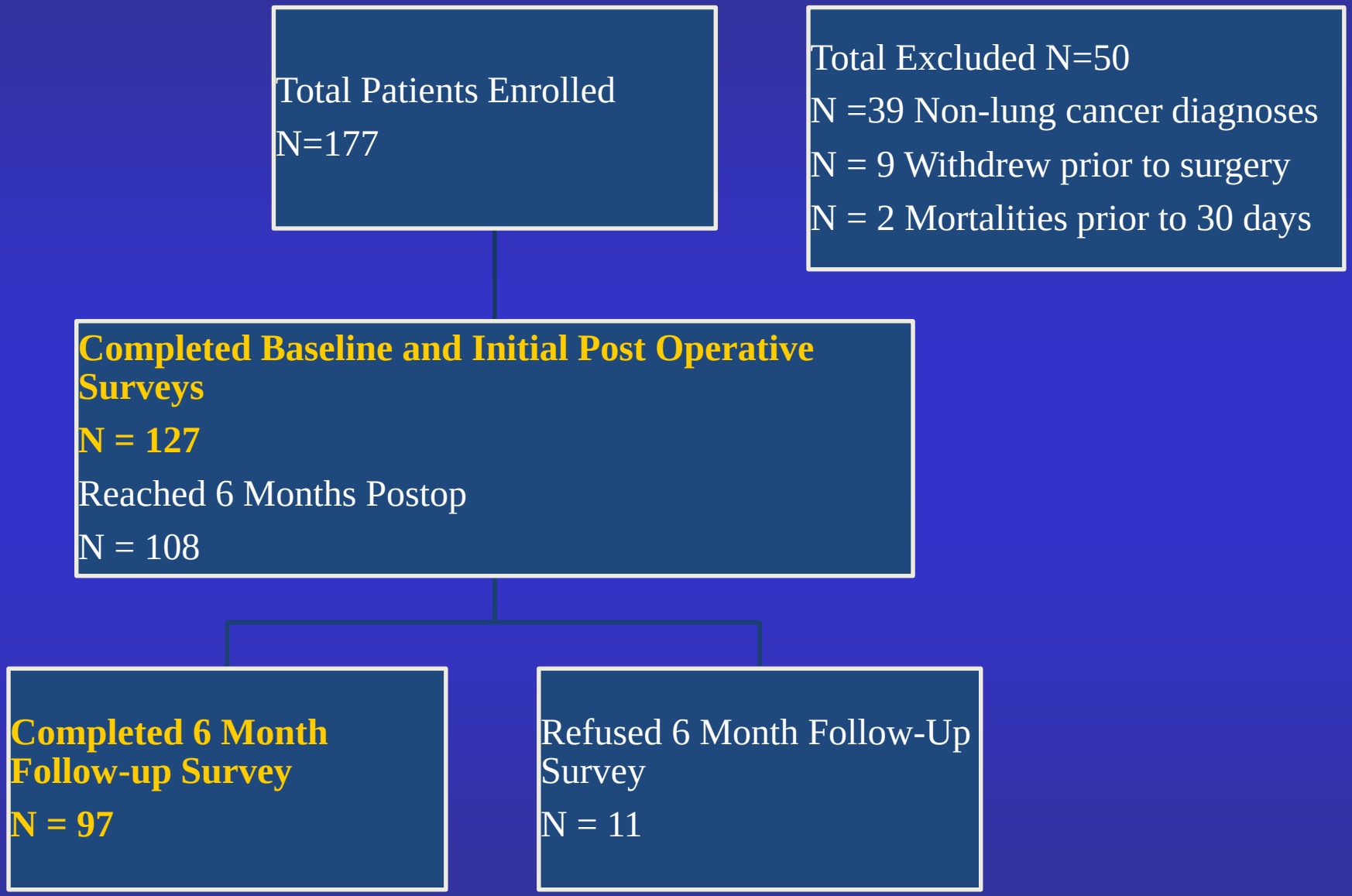
- Assessment Center website used to administer survey, score and store PRO data
- Survey was administered via a tablet device in the clinic at 3 time points
  - preoperatively
  - initial postoperative visit
  - 6 months postop
- Linkage of the PRO data and STS-GTSD was accomplished with unique identifiers

Scoring PROMIS Instruments

- T-score (1-100):
  - Standardized score, like z-scores and IQ scores
  - Compared to a mean score representative of a **reference population**
  - Population mean is 50 for T-scores (SD ± 10)

- For many PROMIS measures, the reference population was the 2000 General US Census.

- Higher score represents more of measured domain (i.e. more pain or better physical function)


Total Patients Enrolled
N=177
Total Excluded N=50
N =39 Non-lung cancer diagnoses
N = 9 Withdrew prior to surgery
N = 2 Mortalities prior to 30 days
Completed Baseline and Initial Post Operative Surveys
N = 127
Reached 6 Months Postop
N = 108
Completed 6 Month Follow-up Survey
N = 97
Refused 6 Month Follow-Up Survey
N = 11

Overall Cohort

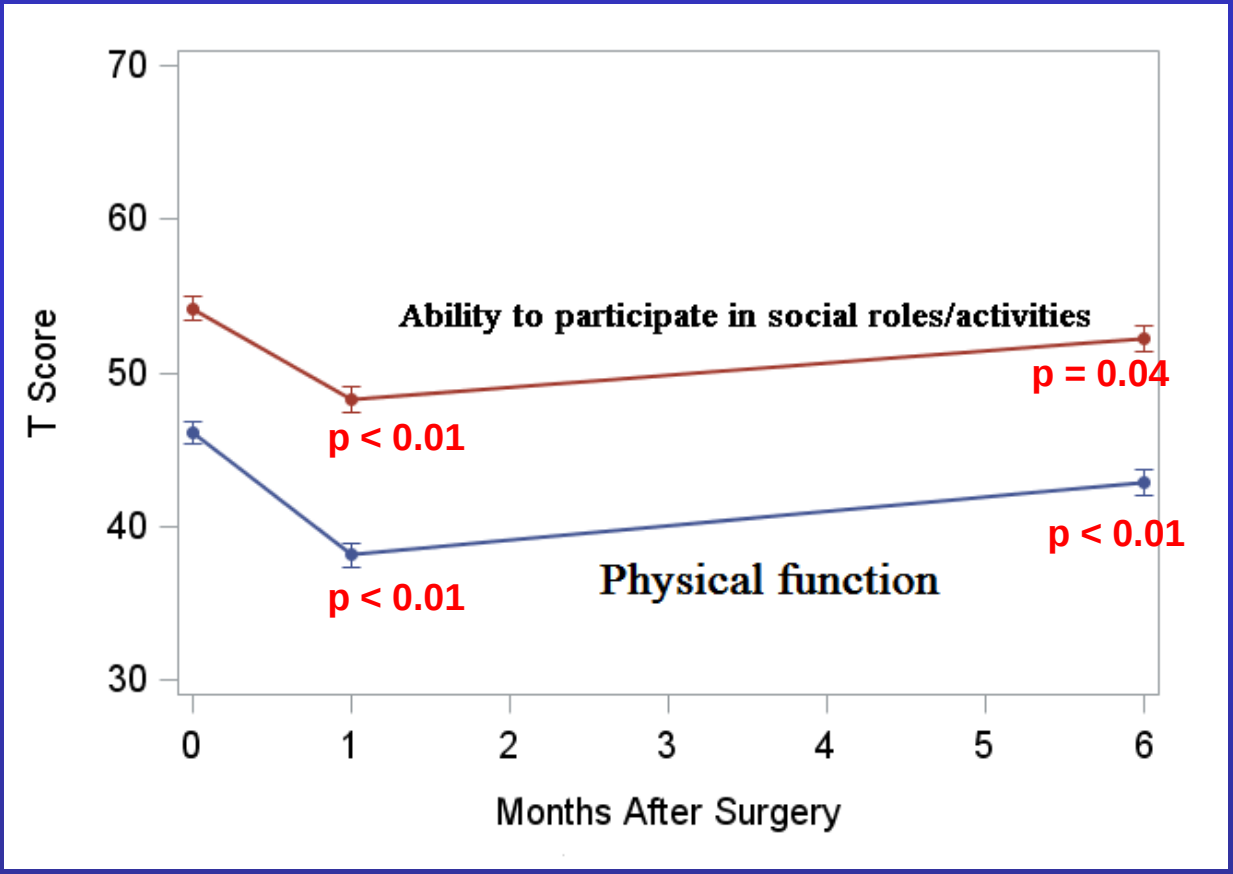
	n = 127
Mean Age (SD)	66.3 (9.4)
Male (%)	50 (39.4%)
Race: White (%)	79(62.2%)
Mean BMI (SD)	27.1 (5.9)
Smoking Status:	
Current smoker (%)	24 (18.9%)
Former smoker* (%)	81 (63.8%)
Non-smoker (%)	22 (17.3%)
Zubrod Score=1	70 (55.1%)
Neoadjuvant Chemotherapy (%)	7 (5.5%)
Neoadjuvant Radiation (%)	11 (8.7%)

Pathologic Stage:	
IA	56 (44.1%)
IB	29 (22.8%)
IIA	16 (12.6%)
IIB	15 (11.8%)
IIIA	10 (7.9%)
IV	1 (0.8%)
Surgery Performed	
VATS: Wedge Resection	18 (14.2%)
Lobectomy	70 (55.1%)
Segmentectomy	14 (11.0%)
Pneumonectomy	1 (0.8%)
Thoracotomy: Lobectomy	13 (10.2%)
Bilobectomy	3 (2.4%)
Pneumonectomy	8 (6.3%)

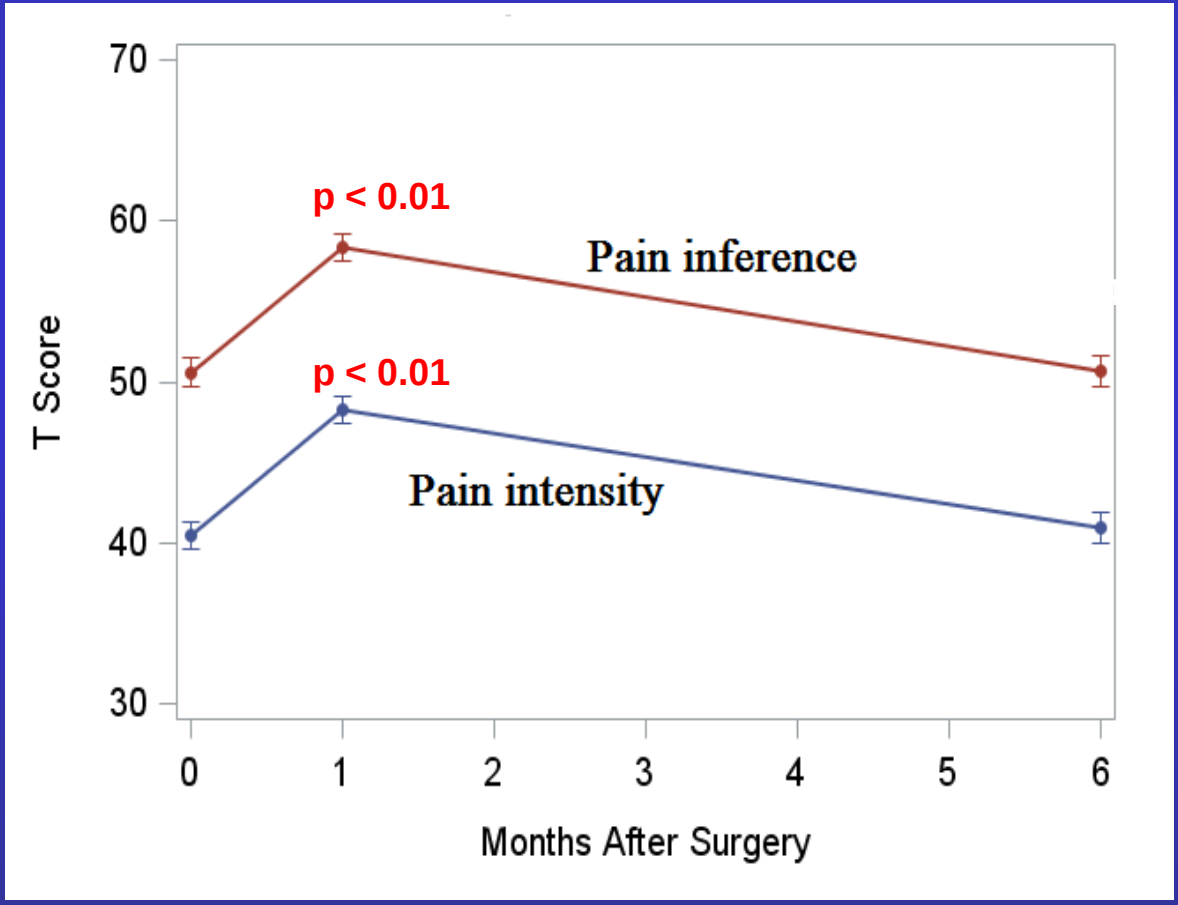
Survey Characteristics

	Median Date of Survey (IQR)	Time to Complete Survey (IQR)
Baseline	12 days prior to surgery (5-21)	13 minutes (10 - 16)
1st Postoperative	22 days after surgery (18-29)	14 minutes (11 - 20)
6-Month F/U	208 days after surgery (196-235)	15 minutes (12 - 19)

Patient Reported Outcomes



Patient Reported Outcomes



Summary

1. Demonstrate the feasibility of collecting PRO data in a lung cancer surgery cohort.

2. The median time required for patients to complete the survey ranged from 13-15 minutes per encounter.

3. Pain and physical function worsened at 1 month, returning to near-baseline levels by 6 months.

Conclusions

- Serves as a model for widespread incorporation of PRO data into the STS National Database
- Generalizable and can be applied to other disease processes and procedures allowing for:
  - Improved risk stratification & performance measurement
  - Comparative analyses
  - Enhanced preoperative patient counseling
- Next step: measure PRO as routine clinic operations rather than as research

Pilot Test to Incorporate PRO Measurement into the STS Adult Cardiac Surgery Database

Incorporating PRO into STS ND

- 5-10 MSTCVS cardiac surgery programs
- Operations:
  - Coronary artery bypass grafting
  - Aortic valve replacement
- Data collection time points:
  - Pre-operative
  - 30 days post-operative (early recovery)
  - 6 months post-operative (late recovery)

Incorporating PRO into STS ND

- PRO will be collected from patients in a variety of clinical settings:
  - Pre-operative clinic visit
  - Acute inpatient consultation (preoperative)
  - Post-operative clinic visit
  - Hospital readmission
  - Longitudinal follow-up clinic visit
  - Email or phone call?
  - Web based portal

Incorporating PRO into STS ND

- Patients can be provided access to PRO surveys by the following individuals:
  - Clinic front desk staff
  - Clinic medical assistant
  - Clinic/hospital midlevel provider
  - Clinical practice care coordinator

- We do not want to pay a study coordinator to facilitate PRO collection because that is not representative of clinical practice

Incorporating PRO into STS ND

- PRO survey based on PROMIS instruments will be created in Assessment Center

- Suggested domains for PRO measurement:
  - Global health measure v1.2
  - Physical function measure (CAT) v2.0
  - Pain interference measure (CAT) v1.1
  - Dyspnea severity measure (CAT) v1.0

- <5 minutes to complete

Assessment Center

- Online data collection tool that enables creation of study-specific websites for capturing PRO data securely online.

- Assessment Center enables:
  - Customization of items or instruments
  - Real-time scoring of instruments
  - Storage of PHI in a separate, secure database
  - Automated accrual reports
  - Real-time data export

Incorporating PRO into STS ND

- Assessment Center account license to be obtained from Northwestern University
- Participating sites will have administrative access to Assessment Center Account
- PRO surveys administered on electronic tablets with internet access or hospital/clinic computers
  - 1-2 tablets provided to each site

Incorporating PRO into STS ND

- At registration, patients enter name and date of birth
  - Used to link patient PRO data to STS data by site data manager
- Institutional IRBs have uniformly approved waiver of all elements of informed consent and complete waiver of HIPAA authorization for patients to have their data entered into the STS database

Assessment Center℠

Login
Password
Continue
Register New User
Forgot Password

Resources

- Instrument Library
- Scoring Manuals
- Workshops
- Publications
- Presentations
- User Manuals
- Glossary
- Terms and Conditions
- FAQ
- Release History
- About Us
- Video Tutorials

Contact Us: Email
Help Line: 877-283-6596

Support Hours:
9:00am - 5:00pm CST
Monday - Friday

WHAT IS ASSESSMENT CENTER℠

Assessment Center℠ is a online data collection tool that enables researchers to create study-specific websites for capturing participant data securely online.

Studies can include measures within the Assessment Center library as well as custom instruments entered by the researcher. The instrument library includes self- and proxy-report short forms, computerized adaptive tests (CATs), and batteries or profiles from:

- Patient-Reported Outcomes Measurement Information System (PROMIS)
- Quality of Life in Neurological Diseases (Neuro-QoL)
- NIH Toolbox
- Health LITT

Among other important features, Assessment Center also enables:

- Downloading library instruments for administration on paper
- Customization of items or instruments (e.g., format, randomization, skip patterns)
- Real-time scoring of CATs and short forms
- Storage of protected health information (PHI) in a separate, secure database
- Automated accrual reports
- Real-time data export
- Ability to capture endorsement of online consent forms

ANNOUNCEMENTS

Learn how to use the Assessment Center Scoring Service in this brief tutorial.

Demonstration CAT

Click here to try a PROMIS Computerized Adaptive Test and receive a score report

Scoring Service

Request PDFs of PROMIS Instruments

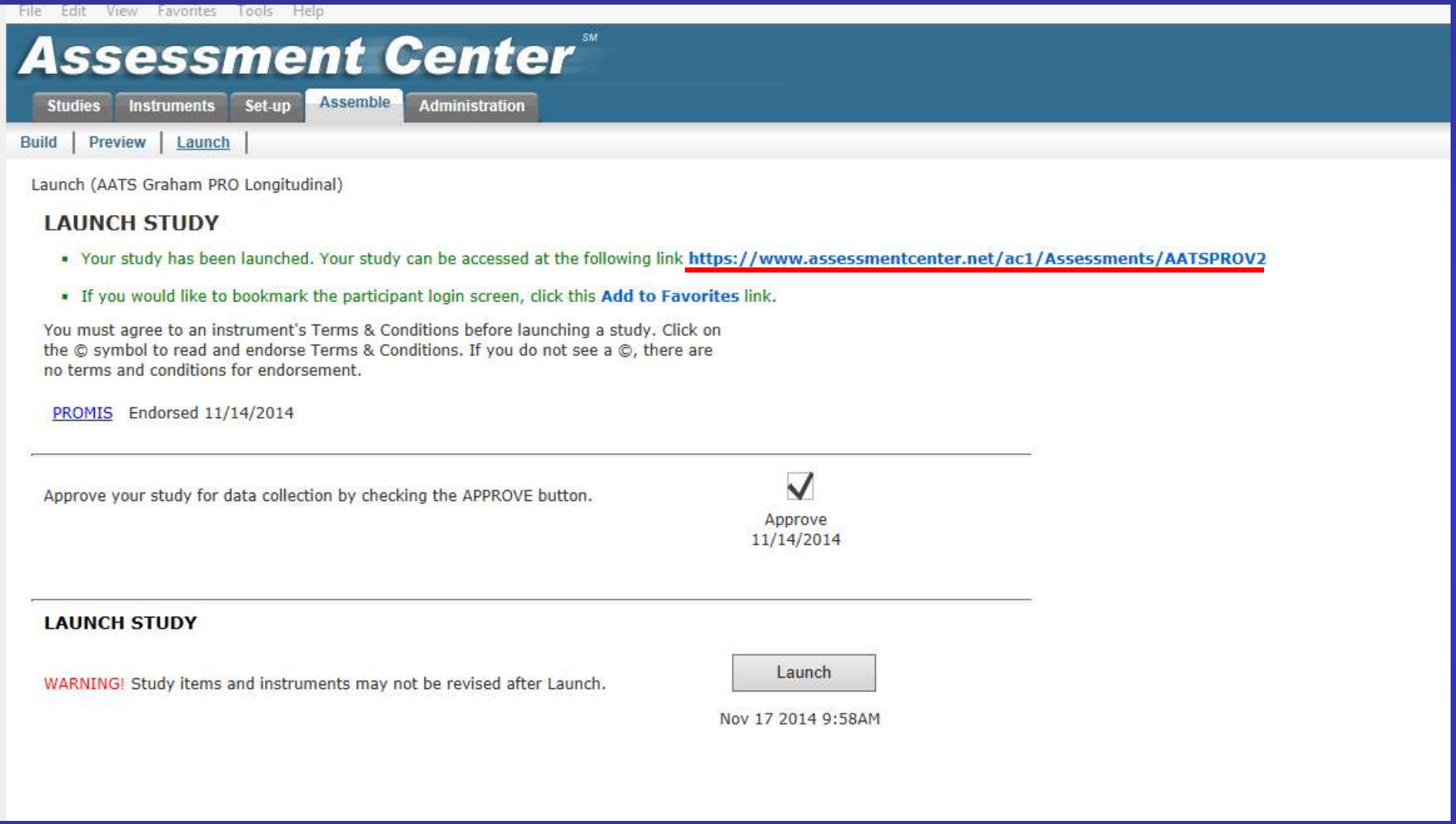
Request PDFs of Neuro-QoL Instruments

Sponsors

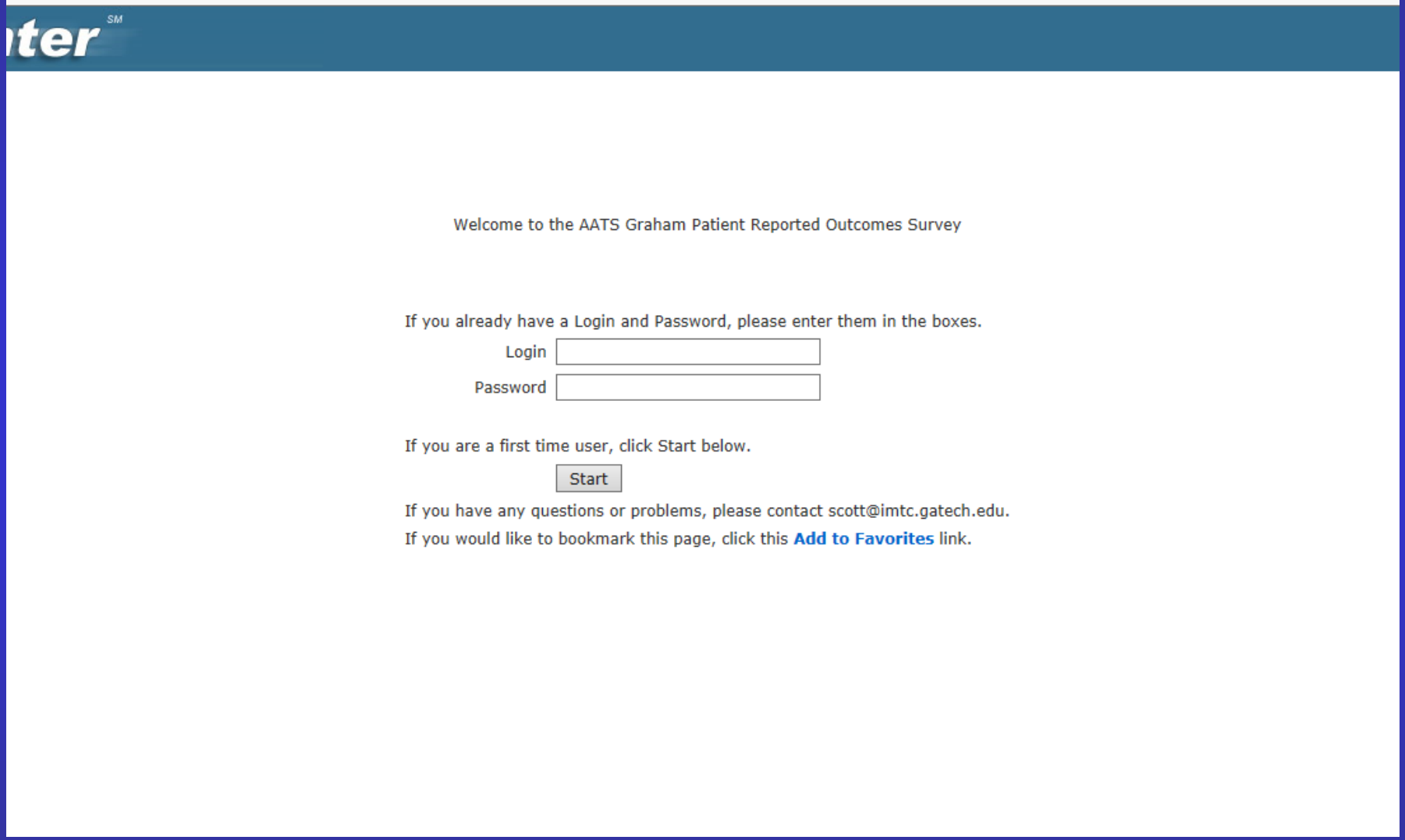
- PROMIS
- Neuro-QoL
- NIH Toolbox

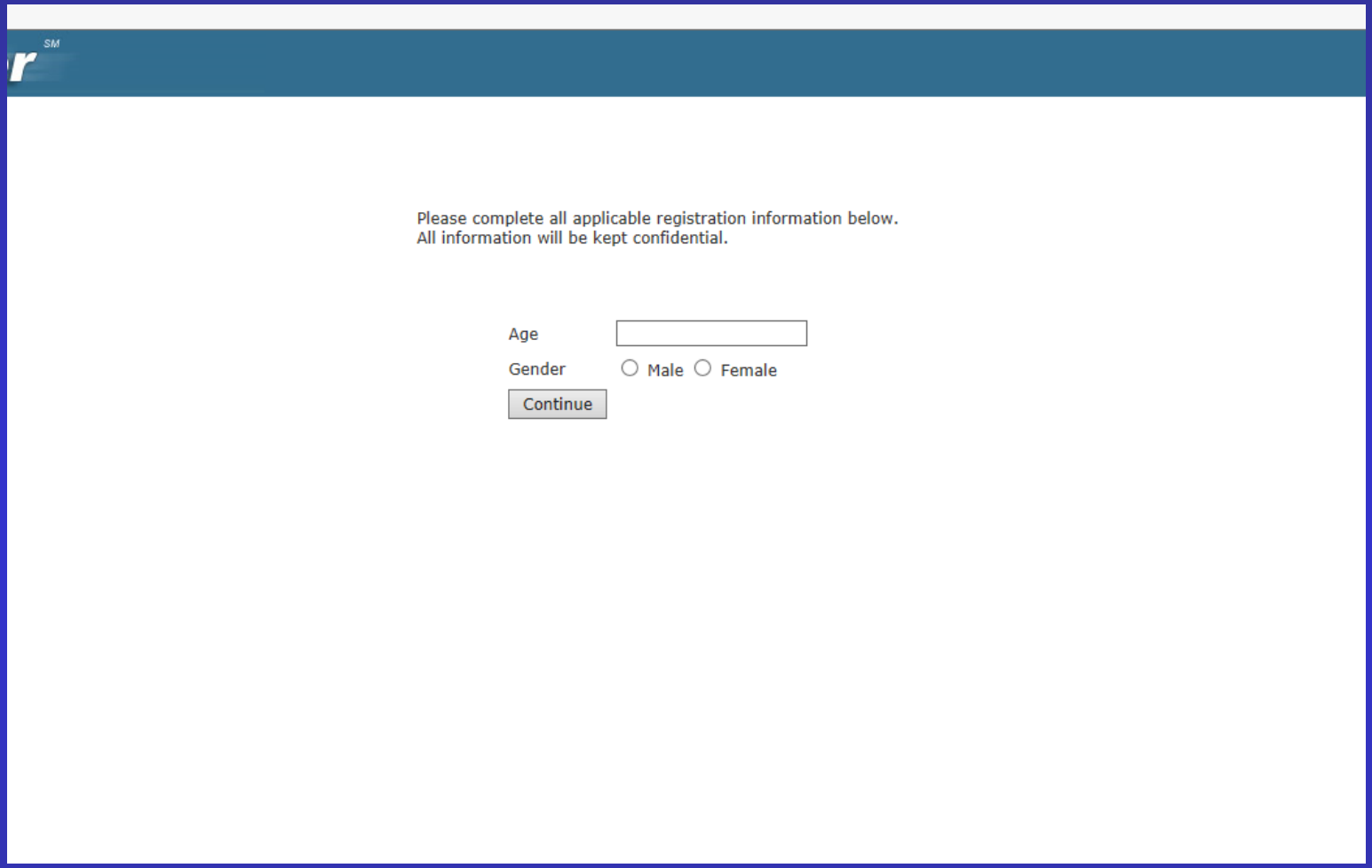
Studies of Interest

- PROsetta Stone
- Health LITT

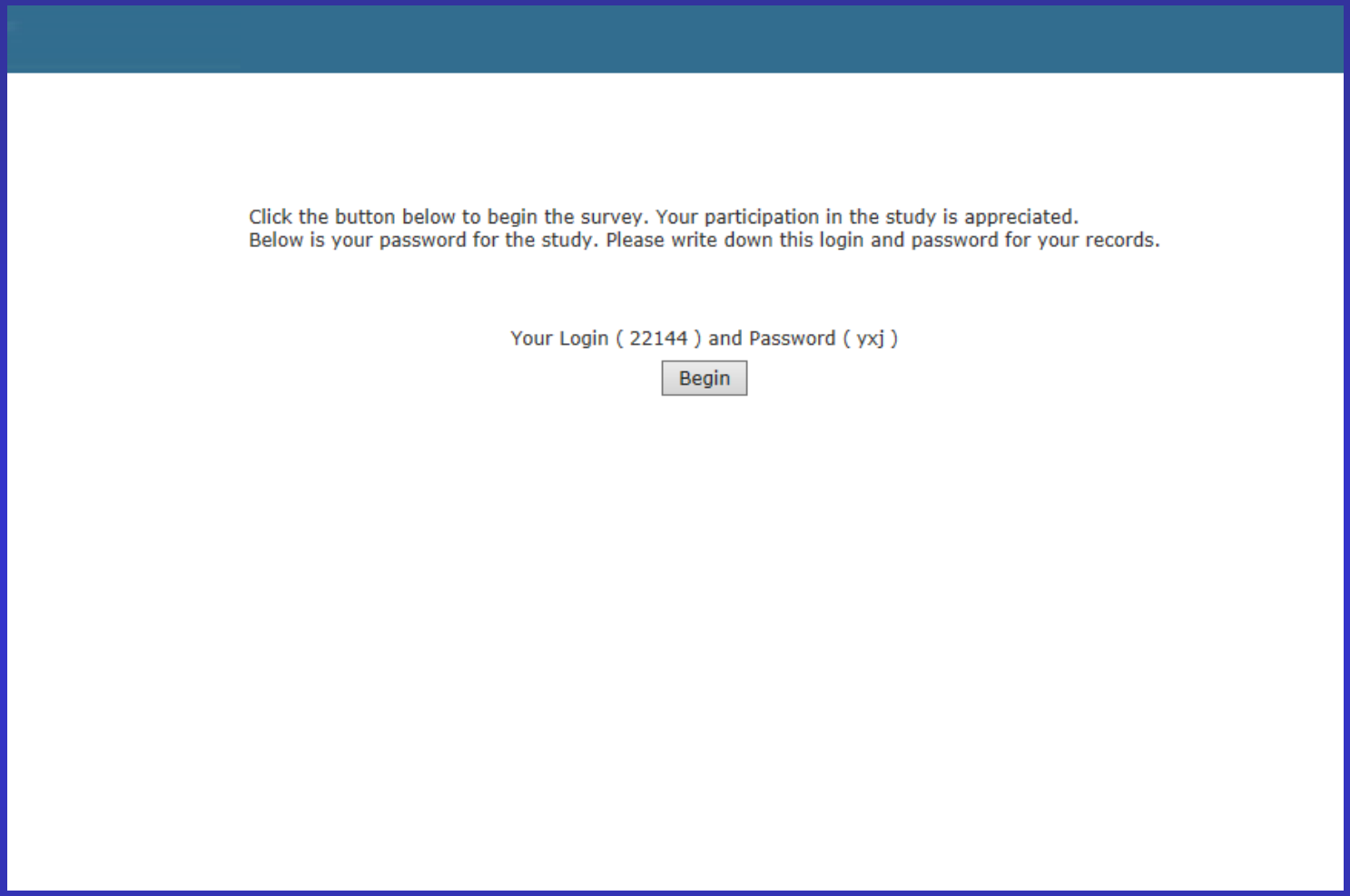


Short cut to URL can be created that appears on desktop of tablet or computer

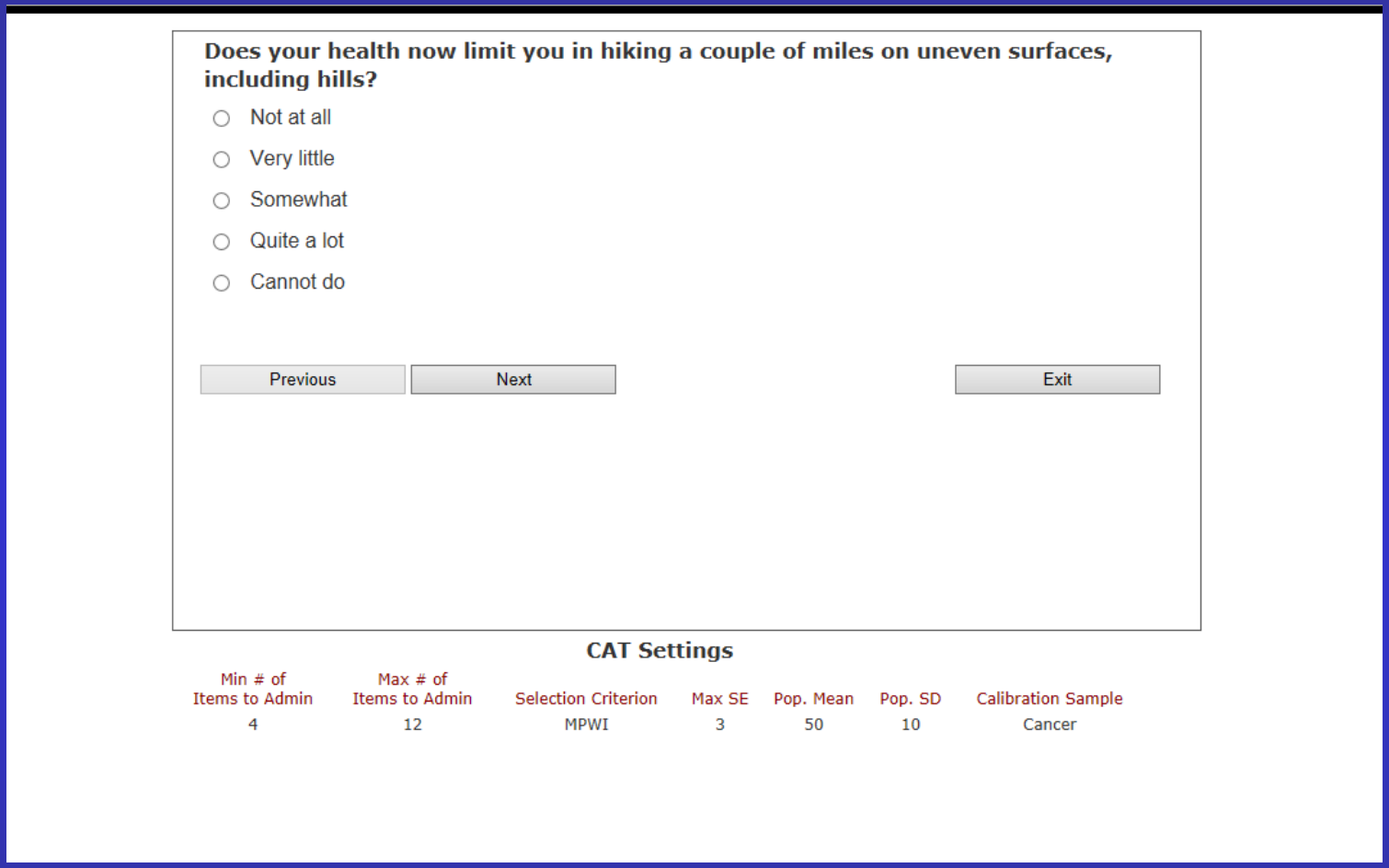

ter SM
Welcome to the AATS Graham Patient Reported Outcomes Survey
If you already have a Login and Password, please enter them in the boxes.
Login
Password
If you are a first time user, click Start below.
Start
If you have any questions or problems, please contact scott@imtc.gatech.edu.
If you would like to bookmark this page, click this Add to Favorites link.



Name and DOB (or other identifier) entered by patient at time of registration)



Remembering password will be a challenge. Individuals with administrative access to Assessment Center site can retrieve password.



Computer Adaptive Test (CAT)

File Edit View Favorites Tools Help

Assessment Center℠

Studies | Instruments | Set-up | Assemble | Administration

Overview | Registration Details | Participant Details | Contact Information | Custom Fields | Reports | Participant Data

Study Overview

Study: AATS Graham PRO Longitudinal

Goal Participants	Accessed Study	Registered	Started	Completed	Off Study	Refusal
5000	250	212	206	5	0	0

To create a new participant registration record,
click the Find/Create Login button.

Enter participant login then click Find/Create Login button
to view an existing participant registration.
[ ] Find/create Login

Retrieve login and password

To view a list of participants in this study, click the Participant List button below.
Participant List

NIH Inclusion Enrollment Report
Data Dictionary Report
Enrollment Report

Customize login/password
Access patient specific URL

Request and Download Data

To enable data export request buttons, navigate to Studies tab, click on the Team link
and give yourself appropriate permissions. If you do not have ability to assign permissions,
please ask study creator to make the needed permissions changes.

When your data is available, an email notification will be sent to the email below.
Click buttons to request or download data. Please make sure that you are able to accept emails from this site.

Fferna3@emory.edu

Request Assessment Data	**Assessment Data as of 8/17/2016 3:14:09 PM CST**
Request Assessment Scores	**Assessment Scores as of 6/8/2017 8:45:58 AM CST**
Request Registration Data	**Registration Data as of 8/25/2016 9:49:00 AM CST**
Request Scores and Demographics	**Scores and Demographics Data as of 7/27/2016 11:08:54 AM CST**
Request Consent Data	

Download patient data

Challenges

- Integrating PRO measurement into clinical workflow
- Capturing PRO on inpatient consults scheduled for surgery the next day
- Longitudinal follow-up
  - Change in normal follow-up pattern (6 months is not standard)
  - Lost login/password
  - Patients missing follow-up may not be missing at random
- Merging PRO data into STS data records

Future Directions

- Integration of PRO into EMR
  - Limited availability in Epic and Allscripts
  - 10 most common instruments
- Automated emails to patients at pre-specified time points
- Bar codes or QR codes to facilitate login process

Next steps

- Identification of pilot test sites
- Contracting with STS
- Obtain Assessment Center license and set up survey