Patient-Reported Outcomes Core

PRO Core

Overview and Examples of System Features

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May 2017

A Comprehensive Cancer Center Designated by the National Cancer Institute

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1 Purpose

Patient surveys measuring symptoms, functioning, well-being, and health behaviors are widely used in cancer research across the continuum of care, including studies of behavioral interventions, quality of care, treatment outcomes, and comparative effectiveness. The breadth and flexibility of the **University of North Carolina Patient-Reported Outcomes Core (PRO Core)** system functionality was designed to allow simultaneous support of many studies that would not be possible or affordable using commercially available platforms or other university or hospital resources.

2 Services

2.1 Scientific Support and Project Development

PRO Core maintains a survey system for administering and managing complex survey studies. PRO Core can provide scientific support to investigators regarding issues such as study design, selection of valid and reliable measures, optimal ways to administer surveys in your study population, and guidance on data analysis. PRO Core uses a standard project development process to build each study-specific system. The invesgitator can work closely with an PRO Core Implementation Specialist throughout the design, testing, and implementation of the data collection system to gain from PRO Core's experience with primary data collection and to have assistance with managing details of the start-up process. PRO Core can provide language for grant applications, protocols, consent forms, etc.

2.2 PRO and Measurement Bibliography

The PRO Core bibliography provides references to support your study design and data collection plans, and may be useful while writing proposals, study protocols, or research papers. Topics include: 1) Introduction to PROs in Clinical Care and Research, 2) Selecting PROs for Research Studies, 3) Scale Development, Translation, and Cultural Adaptation, 4) Mode and Method of Administration, 5) Reporting PRO Results, 6) Textbooks for PRO and HRQOL Research Methods, and 7) PGHD / Activity Trackers.
https://unclineberger.org/outcomes/cores/patient-reported-outcomes-core/web-bibliography

2.3 Web-based Surveys and Custom Forms

PRO Core can administer PRO measures commonly used in cancer research including EORTC, PRO-CTCAE, MDASI, FACT and PROMIS®. We can also convert paper-based surveys to electronic format, following standard best practices. Custom forms can capture demographics, clinical information, daily diary, etc. Surveys and forms can be completed on smartphones, tablets, laptops, PCs – any device with a web browser.

2.4 Web-hosted Educational Tools and Participant Information

PRO Core can develop and host project specific websites that integrate surveys, educational materials, and online decision tools. Websites are designed with patients in mind, including clarity of information displays, usability, and the option of password protected (non-public access) to content. PRO Core contracts with UNC Graphics when graphic design services are needed.

2.5 Device Data

Data collected from wearables, e.g. fitness bands, heart rate monitors, and related devices, from brands such as Fitbit, Garmin, and Apple, can be seamlessly integrated into PRO Core study datasets.

2.6 Automated Telephone Survey

PRO Core can administer automated telephone surveys via an interactive voice response (IVR) system. IVR administration is suitable for short surveys, and enables surveys to be completed by patients without home-web access. PRO Core can provide templates for call scripts / call-flow diagrams and recommendations to make the automated survey acceptable to respondents.

2.7 Tracking, Notifications, and Custom Reports

PRO Core enables you to easily track and monitor studies in real-time. Investigators and research assistants can see progress dashboards and customized reports about metrics such as enrollment and survey response rates; survey reminders can be sent automatically to patients via email or automated phone call; and customized symptom reports can be provided in real-time to clinicians.

2.8 Sites and Languages

PRO Core is suitable for single-site and multi-site studies. Surveys can be administered in any language if investigators provide the text – English, Spanish, Arabic, French, Hindi, Korean, Portuguese, Russian, Swahili, Vietnamese, etc.

3 Data Security

Data are stored in a secure enterprise-level Oracle database managed by the ITS Research Computing group at UNC, and web servers are hosted by the UNC Center for Bioinformatics. Data transmitted between the server and end-users are encrypted using SSL, and all databases are encrypted.

4 Standard Project Development Process

PRO Core typically conducts project development using the following 10-step process:

1. Consult with investigators regarding study design and system functionality for their study, with emphasis on scientifically sound survey methods, usability, and data security;
2. Establish project task list and timeline;
3. Provide assistance to investigators with writing relevant portions of the protocol and consent form, in particular - data collection, data management, benfits and risks to human subjects;
4. Set up study-specific survey system, including survey interface, automated email reminders, survey completion tracking, task and progress dashboards, and reports for study monitoring;
5. Test study-specific survey system, including data integrity and usability;
6. Create data dictionary and annotated case report forms;
7. Train study manager and other study personnel to use PRO Core system;
8. Provide support to study personnel and investigators for use of PRO Core;
9. Make any modifications that are required after the study opens;
10. Provide complete dataset at any interim time points and at end of data collection.

5 Examples of Current Projects

PRO Core is currently hosting a variety of single site and multi-site studies of treatment outcomes, mHealth tools, and observational studies with complex data collection protocols, which are funded by agencies including PCORI, NIAMS and NCI.

- Electronic Patient Reporting of Symptoms During Outpatient Cancer Treatment: A U.S. National Randomized Controlled Trial (PI: Basch, Univ North Carolina; Alliance for Clinical Trials in Oncology; Funding: PCORI; multi-site study)
- Patient-Reported Outcomes-Based Performance Management (PI: Basch, Univ North Carolina; Funding: PCORI; multi-site study)
- Comparison of Operative to Medical Endocrine Therapy (COMET) for Low-Risk DCIS. Large Pragmatic Studies to Evaluate Patient-Centered Outcomes (PCORI). (PI: Hwang, Duke Univ., Alliance for Clinical Trials in Oncology; Funding: PCORI; multi-site study)

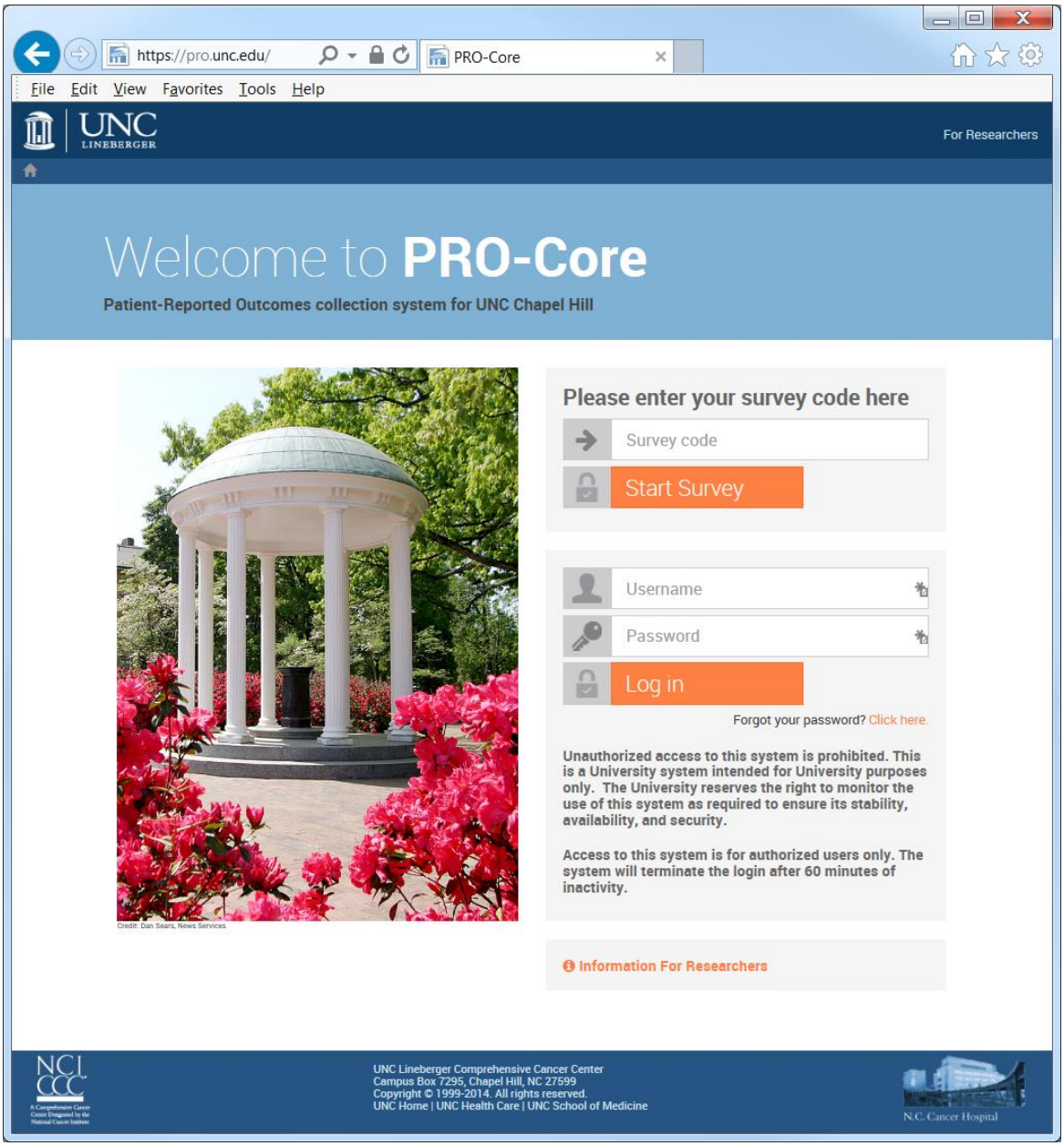
- Enhancing Clinical Meaningfulness and Usefulness of PROMIS Pediatric Measures via Validation in Children and Adolescents with Rheumatic Disease, Cancer, or Inflammatory Bowel Disease. Validation of Pediatric Patient Reported Outcomes in Chronic Diseases (PEPR) Consortium. (PI: Reeve, Univ North Carolina; Funding: NIAMS; multi-site studies)
- Developing an Interactive, Patient-Centered mHealth Tool to Enhance Post-Cystectomy Care: Identifying High-Priority Patient-Centered Outcomes in the Postoperative Cystectomy Period. (PI: Smith, Univ North Carolina; Funding: American Cancer Society)
- Access to and Value of Treatment Innovation Study. Objective: To survey a large population of adults receiving treatment for leukemia regarding cost of care, financial burden, and preferences. Role: Investigator (PI: Conti, Univ Chicago; Funding: Leukemia and Lymphoma Society; multi-site NCORP study)
- "Doc, what will I go through after my surgery?" Understanding Symptom Issues and Functional Recovery after Major Gastrointestinal Surgery within a Tertiary DC Hospital (PI: Jensen, Georgetown Univ; Funding: Foundation; multi-site study)
- Assessing Physical Fitness in Cancer Patients with Cardiopulmonary Exercise Testing and Wearable Data Generation (PI: Wood, Univ North Carolina; Funding: Alliance for Clinical Trials in Oncology; multi-site Alliance study)
- Evaluating the Ability of Electronic Patient Symptom Reporting to Reduce Symptom Burden During Hospitalization for Intensive Chemotherapy. (PI: Leak, Univ North Carolina)
- Impact of a Physical Activity Program on Biomarkers of Aging during Adjuvant or Neoadjuvant Chemotherapy for Breast Cancer (PI: Muss, Univ North Carolina)
- Creating and Validating Child Adverse Event Reporting in Oncology Trials (PI: Reeve, Univ North Carolina; Funding: NCI; multi-site study)
- GENIC, A Genotype-Directed Phase II Study of Higher Dose of Irinotecan in First-Line Metastatic Colorectal Cancer Patients Treated With FOLFIRI Plus Bevacizumab (PI: Sanoff, Univ North Carolina; multi-site study)

6 Visual Examples of PRO Core

These are examples of the PRO Core interface, which is tailored to each project.

6.1 Example of PRO Core front page typically seen by project coordinators

This is the login screen typically used by project coordinators and research staff to access the study management interface. Study participants are able to login to complete surveys via this page, but most often, studies are set up so that participants are emailed a link which takes them directly to their survey. This login can also be embedded within a project specific website.



6.2 Example survey item (one item per screen)

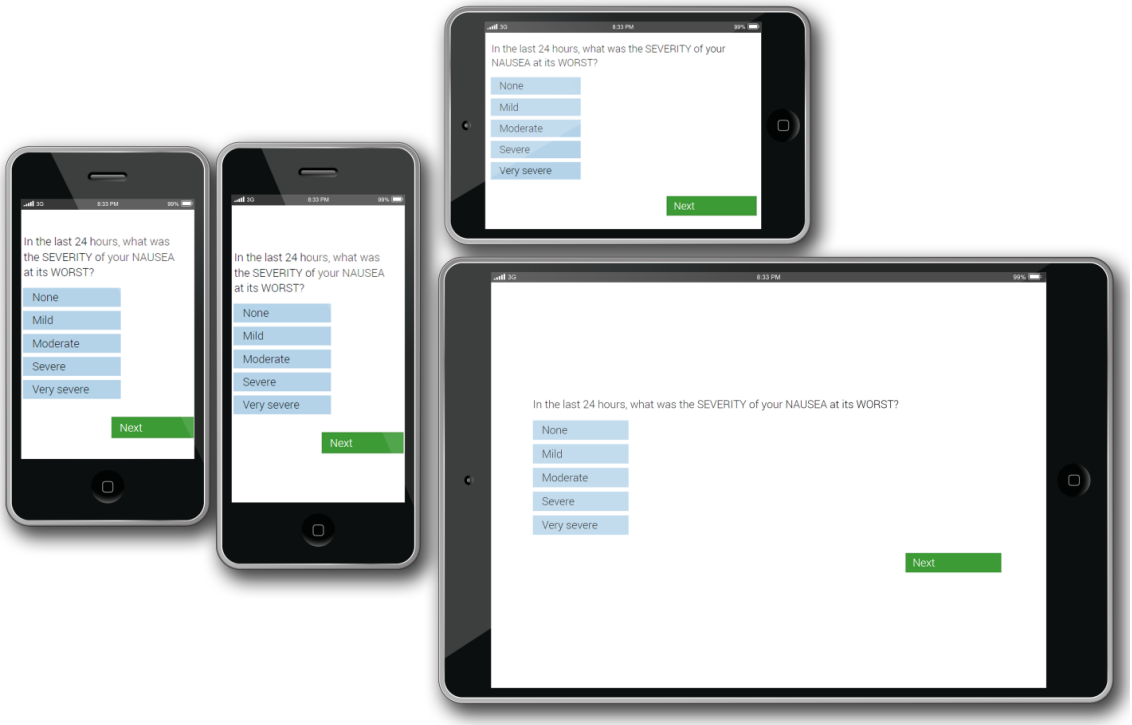
The display of this symptom item from the NCI PRO-CTCAE is an example of the format typically used for items when they are displayed one per screen. (The capitalized text is specific to the PRO-CTCAE)

In the last 24 hours, what was the SEVERITY of your NAUSEA at its WORST?

- None
- Mild
- Moderate
- Severe
- Very severe

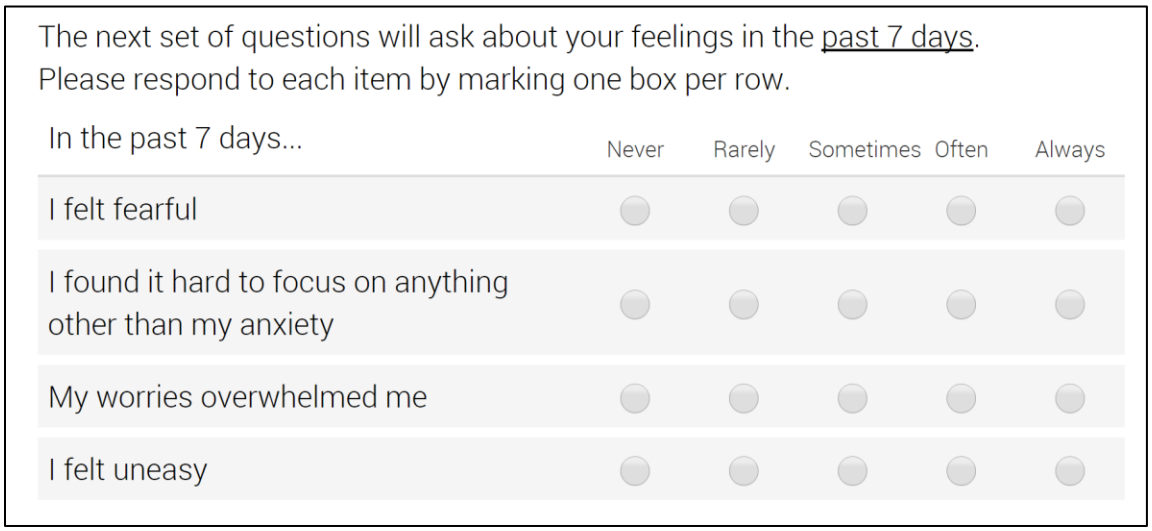
6.3 Survey items can automatically resize to fit the device screen size

Because participants use a variety of devices to access the internet, the formatting of PRO Core interfaces can be set to automatically adjust to the device screen size.



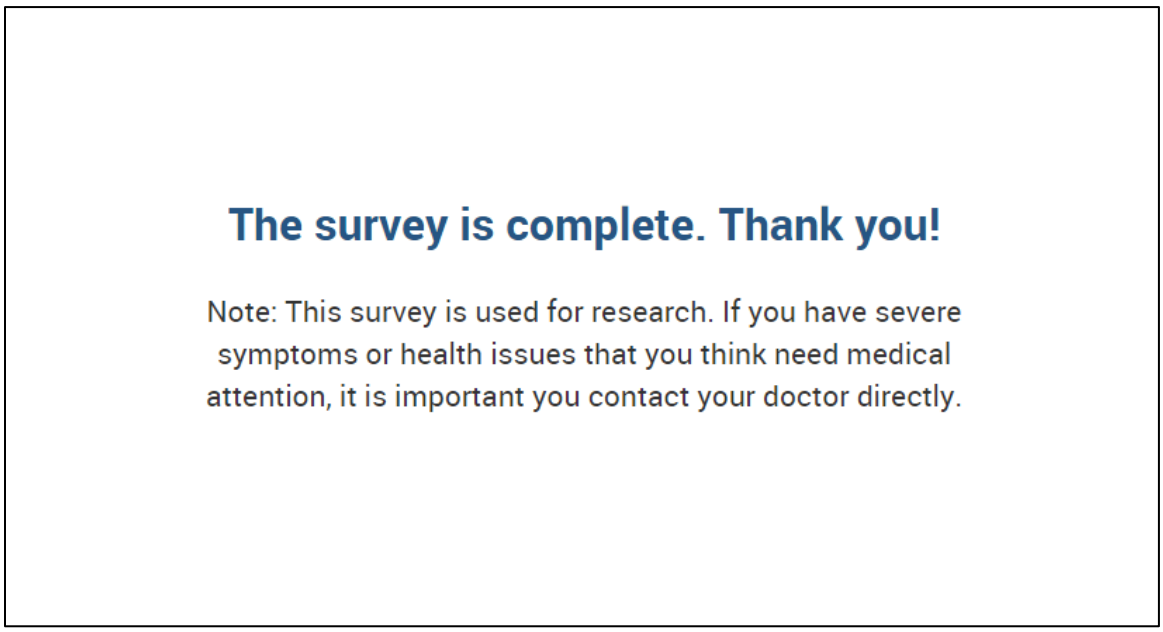
6.4 Example survey item (grid of items)

This group of PROMIS® Anxiety items is an example of a grid display. This and many other styles of survey items can be created for specific projects.



6.5 Example of introductory or closing messages specific to each study

Introductory or closing messages are typically added to surveys. This is an example of one:



6.6 Example of symptom report to show clinician the change in symptoms from prior day

This report was requested by the investigator, specific to the needs of their study.

A B MRN: 654	Date Completed: 7/22/14 Time Completed: 12:00 AM

Survey Data Reported by the Patient

Symptom	Severity or Frequency					Change
Cough	None	Mild	Moderate	Severe	Very Severe	^
Decreased Appetite	None	Mild	Moderate	Severe	Very Severe	^
Insomnia	None	Mild	Moderate	Severe	Very Severe	^
Nausea	None	Mild	Moderate	Severe	Very Severe	^
Nothing can cheer me up	None	Mild	Moderate	Severe	Very Severe	^
Diarrhea	Never	Rarely	Occasionally	Frequently	Almost Constantly	⟷
Fatigue	None	Mild	Moderate	Severe	Very Severe	⟷
Mouth or Throat Sores	None	Mild	Moderate	Severe	Very Severe	⟷
Sad/Unhappy feelings	None	Mild	Moderate	Severe	Very Severe	⟷
Heartburn	None	Mild	Moderate	Severe	Very Severe	^
Shortness of Breath	None	Mild	Moderate	Severe	Very Severe	^
Constipation	None	Mild	Moderate	Severe	Very Severe	⟷
Anxiety	None	Mild	Moderate	Severe	Very Severe	v
Vomiting	None	Mild	Moderate	Severe	Very Severe	⟷
Pain	None	Mild	Moderate	Severe	Very Severe	v
Rash	No	Yes				v

Legend

^	Symptom worsening since prior day
v	Symptom improving since prior day
⟷	Symptom unchanged since prior day
**	No prior data
Item Unanswered	Item unanswered