

SUMMARY MINUTES

TEP MEMBER ATTENDANCE (*alphabetical by affiliation*)

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|--|--|
| <input type="checkbox"/> Finly Zachariah, MD, City of Hope | <input checked="" type="checkbox"/> Louise Bedard, MSN, MBA, Michigan Oncology Quality Consortium (MOQC) |
| <input type="checkbox"/> Vincent Chung, MD, City of Hope (<i>Alternate</i>) | <input checked="" type="checkbox"/> Jennifer Griggs, MD, MPH, FACP, FASCO, MOQC |
| <input checked="" type="checkbox"/> Bryce Reeve, PhD, Duke School of Medicine | <input checked="" type="checkbox"/> Emily Mackler, PharmD, MOQC |
| <input checked="" type="checkbox"/> Kevin Weinfurt, PhD, Duke School of Medicine | <input checked="" type="checkbox"/> Karen K. Fields, MD, Moffitt Cancer Center |
| <input checked="" type="checkbox"/> Dawn Severson, MD, Henry Ford Cancer Institute-Macomb | <input checked="" type="checkbox"/> Stephen B. Edge, MD, Roswell Park Cancer Institute |
| <input type="checkbox"/> Susan White, PhD, RHIA, CHDA, James Cancer Hospital | <input checked="" type="checkbox"/> Sally Okun, Patients Like Me |
| <input type="checkbox"/> Victoria Blinder, MD, MSc, Memorial Sloan Kettering Cancer Center | <input checked="" type="checkbox"/> Tracy Wong, MBA, Seattle Cancer Care Alliance |
| <input type="checkbox"/> Robert Daly, MD, MBA, Memorial Sloan Kettering Cancer Center (<i>Alternate</i>) | <input type="checkbox"/> Angela Stover, PhD, University of North Carolina at Chapel Hill Gillings School of Global Public Health |
| <input checked="" type="checkbox"/> Ishwaria M. Subbiah, MD, MS, MD Anderson* | <input checked="" type="checkbox"/> Afsaneh Barzi, MD, PhD, USC Norris Comprehensive Cancer Center* |
- *Added to TEP

PROJECT TEAM ATTENDANCE

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| <input checked="" type="checkbox"/> Rachel Brodie, Project Director, Pacific Business Group on Health | <input checked="" type="checkbox"/> Emily London, Senior Manager, PBGH |
| <input checked="" type="checkbox"/> Emma Hoo, Director, PBGH | <input checked="" type="checkbox"/> Kate Eresian Chenok, MBA, Consultant |
| | <input checked="" type="checkbox"/> Kristen McNiff, MPH, Consultant |

TEP PURPOSE AND OBJECTIVES

The purpose of the TEP is to provide input on measure development; provide expertise in survey tool selection, data definitions, analytic plans, measure implementation, risk adjustment, and other methodologic issues. The TEP will meet monthly, or as needed, to advise PROMOnc project staff.

MEETING OBJECTIVES

TEP meetings follow a structured format focused on the measure development process. Summaries of each issue are presented along with key questions, followed by an open discussion of the issues by TEP members. TEP members receive a detailed pre-reading packet prior to each meeting. PROMOnc held its third TEP meeting on February 19, 2019. Meeting objectives were the following:

- Review Project Timeline and Check for Conflicts
 - Review project timeline
 - Check for any new conflicts of interest
- Review landscape of potential PROM survey instruments
 - Review potential PROMs and approach for this PRO-PM project
- Review and discuss ranking of potential PROM questions and subscales
 - Get TEP input about approach to PROM selection, and if possible, finalize the approach

During the February 19 TEP meeting, no conflicts of interest were disclosed.

PROJECT AIMS

Dr. Jennifer Griggs recapped the project aims and the measure calculation factors. She mentioned that the survey timepoints, the numerator, and the denominator will be discussed during a future call. She explained the hypothesis is that patients seen in patient-centered practices may experience pain and decreases in HRQOL during chemotherapy treatment, but should have more improvement, less incidence of symptoms or less decrement following treatment. Dr. Griggs confirmed we are only looking at colon cancer, and not colon plus rectal.

CHOOSING PROMS FOR PROMONC

Dr. Bryce Reeve, a consultant to the Project Team, provided an overview of classical test theory and item response test (IRT) theory. Both are used for evaluating items that measure a specific domain (pain, nausea, etc.). For all of the candidate PROMs, the instruments all perform well and are relevant for what we are measuring. PROMIS was built on the IRT framework; the other instruments were developed using classical test theory. IRT helps investigators to know how each item performs in terms of capturing the construct of interest, and it informs us about how well each item performs. All the candidate instruments perform well, but PROMIS is the only one built on IRT.

Ms. Kate Chenok recapped the feedback from two efforts to collect input and rate the PROM survey questions about pain and HRQOL: a survey of TEP members and also a focus-group style webinar with the Patient and Caregiver Council Members (POQC).

- Pain: The POQC felt the “interference with household chores” and “doing things around the house” questions were duplicative.
- Pain: The PROMIS pain scale and pain interference questions were highly ranked, and the Short Form PROMIS was the most preferred.
- HRQOL: Patients liked FACT G7 the best although they also liked the PROMIS-10 Global Health questions which cover both physical and mental health. The TEP members ranked the PROMIS physical and mental health questions the highest.

Multiple TEP members expressed support and preference for the item bank approach and particularly the PROMIS instrument. They liked the brevity of the instrument, felt it addressed the data that should be collected, addressed function status, provided actionable data, and could be easily customized to add other domains from the item bank. Several ADCC sites already collect PROMIS measures, and sites that use EPIC will have an easier time implementing PROMIS compared to other PROMs.

One TEP member mentioned that she preferred the PRO-CTCAE for pain as a couple of the PROMIS pain questions are redundant. And, for HRQOL, she preferred the FACT G since it might be more widely used in cancer care and therefore more easily adopted.

One TEP member recommended that we seek questions about decisional conflict or regret. Staff offered to review the PROMIS item bank to see if there are more questions about decision regret, conflict, and return to functional status. However, the PROMIS-10 Global Health questions already include an item about functional role/status.

Staff concluded pain does not need further discussion but recommended continued discussion about HRQOL.

Recommendation: Use PROMIS Pain Intensity Scale and Pain Interference Short Form 4 for the pain PRO-PM.

NEXT STEPS

- Continue to discuss the survey timepoints, the numerator(s), and the denominator.
- Review the PROMIS item bank to see if there are more questions around decision regret, conflict, and return to functional status.
- Continue the discussion about which survey questions to use to assess HRQOL.