SUMMARY MINUTES

TEP MEMBER ATTENDANCE (*alphabetical by affiliation*)

- ☒ Finly Zachariah, MD, City of Hope
- ☐ Vincent Chung, MD, City of Hope *(Alternate)*
- ☒ Bryce Reeve, PhD, Duke School of Medicine
- ☐ Kevin Weinfurt, PhD, Duke School of Medicine
- ☐ Dawn Severson, MD, Henry Ford Cancer Institute-Macomb
- ☒ Susan White, PhD, RHIA, CHDA, James Cancer Hospital
- ☒ Victoria Blinder, MD, MSc, Memorial Sloan Kettering Cancer Center
- ☐ Robert Daly, MD, MBA, Memorial Sloan Kettering Cancer Center *(Alternate)*
- ☐ Louise Bedard, MSN, MBA, Michigan Oncology Quality Consortium (MOQC)
- ☐ Jennifer Griggs, MD, MPH, FACP, FASCO, MOQC
- ☒ Emily Mackler, PharmD, MOQC
- ☐ Karen K. Fields, MD, Moffitt Cancer Center*
- ☐ Stephen B. Edge, MD, Roswell Park Cancer Institute
- ☒ Sally Okun, Patients Like Me
- ☒ Tracy Wong, MBA, Seattle Cancer Care Alliance
- ☒ Angela Stover, PhD, University of North Carolina at Chapel Hill Gilling School of Global Public Health

**Added to TEP*

PROJECT TEAM ATTENDANCE

- ☒ Rachel Brodie, Project Director, Pacific Business Group on Health (PBGH)
- ☒ Emma Hoo, Director, PBGH
- ☒ David Lansky, PhD, President & CEO, PBGH
- ☒ Kate Eresian Chenok, MBA, Consultant
- ☒ 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 second TEP meeting on January 8, 2019. Meeting objectives were the following:

- Review and Approve the TEP Charter; Review the Project Timeline and Check for Conflicts
  - Check for any conflicts of interest
  - Review and approve the TEP Charter
  - Provide an overview of the project timeline
  - Review TEP Decision Schedule
- Measure Background and Work in Progress
  - Continue discussion from orientation webinar about measure specification
- Review PROM instrument landscape and discuss criteria for selection
  - Discuss how to conceptualize the outcomes that we are measuring
  - Review draft criteria for instrument selection

- Identify follow up information needed to select the PROM

During the January 8 TEP meeting, no conflicts of interest were declared, the TEP charter was reviewed and approved, and the project timeline and TEP decision schedule was reviewed. A discussion was continued from the orientation webinar around the measure background and work in progress. Staff then reviewed the PROM instrument landscape and discussed the criteria for selection. This included a discussion about how best to measure the outcomes and the draft criteria for instrument selection.

FEEDBACK ABOUT MEASURING PAIN – HOW TO MEASURE AND SCORE

Some TEP members noted that pain may not be a critical symptom for patients with the disease states that we are considering who are undergoing adjuvant therapy with curative intent. Related to this, some TEP members questioned whether measurable changes in pain would be detectable if there is little to no pain at any point. Other TEP members countered these points to state that clinicians often underestimate the pain.

Several TEP members noted the importance of being able to determine the causes of pain (i.e., did the patient have pain at the beginning of chemotherapy, either from another comorbidity or from surgery) and being able to exclude pain that is unrelated to chemo treatment. However, another TEP member stated that medical oncologists need to treat the whole patient and should be accountable for treating pain regardless of the origin.

Some TEP members noted that the post-chemotherapy survey timing may need to be more than 3 months post-treatment in order to detect improvement.

Most TEP members felt that measuring pain interference with activities of daily living is more meaningful and actionable from a treatment perspective than pain severity. Members also noted that pain severity is more subjective and harder to use as a performance measure. Some TEP members noted that they are discouraged from treating pain in patients with curative intent (vs. palliative care) with opioids and at least one intervention for neuropathy is now a Schedule V drug. Some members recommended that pain should be defined for the patient as some patients will experience neuropathy as tingling while others will experience it as pain. Ideally, the project would measure pain intensity and interference, and possibly also frequency.

There is a strong correlation between mental health status, pain, and other symptoms so measuring mental health status (anxiety, depression) is key.

FEEDBACK ON HRQOL – HOW TO MEASURE AND SCORE

Some TEP members noted differences in how the instruments measure and score HRQOL. Several TEP members discussed the desire to choose survey instruments that phrased questions in a positive rather than negative manner since the negative framing can be depressing for patients. It was noted that EORTC questions can be perceived as negative by some patients and patient advocates. Suggestion was made to have questions that focus on “living the best life that I can during this difficult experience of my life”. Clinicians can help patients understand what that means in the context of their treatment course. Suggestion was made to ask questions like “how much of a problem is it for you? How can we best help you with this, e.g., talk to someone, get medication, etc.?”

Some TEP members voiced concern about redundancy in questions since many ADCC sites already administer other patient symptom and patient experience surveys. Request is to be concise and only add questions that are new so as not to increase patient burden. One TEP members explained that the ability to use the measure in clinical care is important, and that patients want to see that the clinician uses the survey information in the office visit. It was also noted that the timing of the post-survey administration was important since HRQOL diminishes significantly during chemotherapy.

Several TEP members noted that it's important to get to an agreed upon HRQOL definition since the impact of treatment and disease on a patient's life includes physical, social, and mental health. Within physical health, there are elements of pain, sleep, etc.; Some tools ask component elements which roll up to a summary value. HRQOL will be a challenging domain since it is multi-dimensional. It may also be difficult to see change from baseline since one could see a reduction in pain and nausea (components of HRQOL) but not address a patient's mental health, for example.

FEEDBACK ON ADDITIONAL CRITERIA FOR SELECTING A PROM SURVEY INSTRUMENT

One TEP member suggested that it was important to choose tools that were developed with input of patients, and for scoring that considered patient's viewpoints about minimally important differences. Two TEP members suggested looking at City of Hope's tools. One member suggested the PRO-CTCAE which has 2 questions for pain but no question sets for HRQOL. Several TEP members noted the potential benefit of using an item bank to address the issues listed in each area and also reduce survey length and duplicity within the clinical workflow.

NEXT STEPS

- Survey TEP members to rank candidate PROM survey question items
- Obtain patient input about which candidate PROM survey questions best represent how they experience pain and HRQOL; obtain patient input about whether any of the candidate questions are offputting or hard to interpret
- Review revised landscape of PROM survey instruments
- Continue discussing survey administration timepoints, especially post-treatment
- Consider how best to incorporate mental health status in selection of PROM instrument