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)*
- ☒ Ishwaria M. Subbiah, MD, MS, MD Anderson*
- ☒ 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
- ☒ Afsaneh Barzi, MD, PhD, USC Norris Comprehensive Cancer Center*

**Added to TEP*

PROJECT TEAM ATTENDANCE

- ☒ Rachel Brodie, Project Director, Pacific Business Group on Health
- ☒ Emma Hoo, Director, 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 fourth TEP meeting on March 19, 2019. The objectives of the meeting were the following:

- Review Project Timeline and Check for Conflicts
  - Review project timeline and progress to date
  - Check for any new conflicts of interest
- Confirm selection of PROMs
  - Confirm selection of PROMs for this PRO-PM project
- Discuss measure rationale and refine measure specifications
  - Review rationale for PRO-PMs for pain and HRQOL; discuss how these measures address quality concerns and goals for improvement
  - Refine measure specifications
  - Brainstorm about risk adjustment variables

During the March 19 TEP meeting, no conflicts of interest were reported. The project team recapped the aims of the project, responded to some questions that had been raised between meetings about the history of the project, and presented a final recommendation about the PROMs for assessing outcomes in this project. The project team then shared drafts of the rationales/business cases for each performance measure in this project. Finally, the project team presented a preliminary draft of the measure specifications and solicited input from TEP members about the measure numerator and denominator, as well as exclusions and timing of survey administration.

CONFIRMING SELECTION OF PROMS FOR PROMONC MEASURES

The TEP reviewed and confirmed the recommendations from the last meeting and follow-up discussions to select the following PROMs for this project: PROMIS Pain Intensity, PROMIS Pain Interference Short Form 4, and PROMIS-10 Global Health. There were no objections to the choice of PROMs.

Bryce Reeve, PhD provided an overview of the psychometric evidence for these PROMs and available minimally important difference (MID) information for these measures. Two TEP members raised a question about whether the Cella et al article from 2014 that described how clinicians went through a process to validate severity thresholds ("mild, moderate, high") for patient symptoms are appropriate for this project. One concern was that these thresholds were determined by clinicians which is contrary to the concept of PROs, which are based on patient information without clinician interpretation; this TEP member felt that the Cella article might imply that clinicians were interpreting PRO data. In response, another TEP member pointed out that this concern can be addressed during the analysis phase by using other statistical measures to analyze the data collected during this process, and that we wouldn't need to rely on the Cella article findings. It was also suggested that the Project Team review the severity thresholds with the Patient and Caregiver Council. However, Dr. Reeve explained that the severity thresholds are not required for the calculation of the performance measures and are only used for reference data or to understand potential cutpoints. Another TEP member questioned whether the MIDs for the PROMIS measures would be appropriate for patients receiving curative treatment since the research was based on patients with advanced cancer. Dr. Reeve responded that the MIDs have been tested with multiple patient populations, that they tend to be very consistent and usually fall between .25 and .5 of a standard deviation, and therefore these MIDs would be appropriate for the project patient population. Dr. Reeve also indicated that there are many other studies that we can use, and that many are listed on the PROMIS website. The Project Team has collected these studies.

Recommendation: Use the following PROMIS questions to assess pain and HRQOL: PROMIS Pain Intensity, PROMIS Pain Interference Short Form 4, and PROMIS-10 Global Health (which includes scores for mental and physical health).

MEASURE RATIONALES

Emily Mackler, PharmD presented work that has been done by the project team to develop vignettes about fictitious patients to illustrate how, in each scenario, higher quality care and different interventions might result in different changes in PROM scores. Using pain as an example, she explained that there is increasing evidence in oncology that survival is linked to symptom reporting and control, and that pain management in particular contributes to improved quality-of-life. Since patients with cancer report that pain interferes with their mood, work, relationships with other people, sleep and overall enjoyment of life, PRO-PMs that look at pain intensity and also pain interference are also

important. Since management of pain is consistently identified as a priority by clinicians, health services researchers and patients, these measures address important quality concerns. Ms. Mackler also stated that patient-reported outcomes are the best approach to measuring pain since it is often underestimated by physicians and only patients can report on how much pain interferes with their daily activities.

One TEP member said that this was very helpful in making the case for how clinical teams might manage patients with pain and the relevance of the performance measures.
When Ms. Mackler reviewed the rationale for the HRQOL measures, she explained that HRQOL is generally a broader, multi-dimensional view of a cancer patients' symptoms, including physical, emotional, social, and cognitive functions as well as side effects of treatment. Like pain, research has shown that patient self-reported HRQOL is more accurate than clinician assessment. While HRQOL is now included in evaluations of new cancer treatments by the US Food and Drug Administration, there are no PRO-PMs for HRQOL that have been developed and approved for accountability measurement so our PRO-PM will address that quality measure gap as well as a aspect of quality that should be addressed in quality improvement.

Several TEP members agreed that the rationales explained why these measures address quality gaps and important quality concerns that need to be tackled, as well as how these measures can be used in clinical care for quality improvement.

One TEP member suggested that the Project Team obtain more clinical input to further substantiate the rationales, possibly after the measure specifications are more refined. He commented that it is hard to refine these without more details about the survey timing and expected trajectories of the outcomes. Another TEP member also emphasized that determining the timing of PRO collection will be important for accountability measures.

MEASURE SPECIFICATIONS

The TEP began to discuss the specifications about the numerator(s) and denominator of the proposed measures.

One TEP member asked whether patients receiving oral chemotherapy should be excluded. Other TEP members noted that it will be possible during this testing project to get information about patients who fill their prescriptions and have fairly good information about the start of therapy. Another TEP member said that she manages all patients regardless of whether they receive IV or oral chemotherapy in the same way; she explained that she did not believe there is any reason to exclude patients receiving oral chemotherapy. Other TEP members suggested that it is very important to clarify in the data dictionary which regimens are included.

The TEP discussed testing both absolute change and meaningful change in PROM measures. Several members of the TEP noted that whichever numerator is chosen needed to be meaningful to patients and physicians.

One TEP member noted that it's unlikely that a patient's pain score would decrease during treatment and questioned whether it would be meaningful to look at decrement in pain as a performance measure.

Another TEP member stated that part of what is actionable is educating patients to manage their expectations. This should correlate well with HRQOL measure and should also be relevant to the pain measure.

One TEP member asked whether we could collect and analyze additional time points. The Project

Director responded that participants were welcome to do so for use in clinical care, but for purposes of this analysis, we are going to look at baseline and post scores at time intervals that will be recommended and approved by the TEP at a future meeting.

One TEP member wondered whether the Hawthorne Effect might occur, i.e., that sites that hadn't collected PROs in the past and began to do so during this project would find a bump in performance.

NEXT STEPS

- Continue to refine the measure specifications, particularly the survey administration timepoints and the numerator options