SUMMARY MINUTES

TEP MEMBER ATTENDANCE (*alphabetical by affiliation*)

- ☒ Linda Bosserman, MD, FACP, FASCO on behalf of 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
- ☒ Stephen B. Edge, MD, Roswell Park Cancer Institute
- ☒ Sally Okun, BSN, RN, MMHS, 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
- ☒ Other: Keith Eaton, MD, PhD, Seattle Cancer Care Alliance

PROJECT TEAM ATTENDANCE

- ☒ Rachel Brodie, Project Director, Pacific Business Group on Health (PBGH)
- ☒ Emma Hoo, Director, PBGH
- ☒ David Lansky, PhD, President & CEO, PBGH
- ☒ Emily London, Senior Manager, 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

PROMOnc held its first TEP meeting on December 20, 2018. 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. Meeting objectives were the following:

- Provide a project overview and review of project objectives
- Provide an overview of the Steering Committee and TEP
- Introduce the Project Team and each TEP member
- Provide a measure overview
- Review the measure development project plan and timeline
- Review TEP meeting schedule

During the December 20 TEP meeting, the project team recapped the project overview and objectives, and introduced the Steering Committee (SC) and the Technical Expert Panel (TEP). The

project team then reviewed the measures, went through the measure development project plan and timeline, and discussed the future meeting schedule.

PROMONC BACKGROUND

Kate Chenok provided an overview of the CMS MACRA measure development initiative and the objectives and aims of the PROMOnc project. The goal is to fully develop and test patient-reported outcome-performance measures (PRO-PMs) of health-related quality of life (HRQOL) and pain for patients with breast, colon and non-small cell lung cancer (NSCLC). The project will culminate with the preparation of documentation for successful submission of the measures to NQF and CMS.

The participating organizations were introduced – The Pacific Business Group on Health, Michigan Oncology Quality Consortium (MOQC), and the Alliance of Dedicated Cancer Centers (ADCC). 8 ADCC centers are participating across 6 states so we are testing the measures in a total of 7 states. The role of the SC and TEP were reviewed; the SC will set strategic and policy objectives for the measures, and the TEP will provide more detailed technical and clinical input on measure development.

MEASURE OVERVIEW

Kristen McNiff explained that the PRO-PMs will assess change in health-related quality of life and pain following completion of chemotherapy administered to adult patients with breast cancer, colon cancer, and NSCLC. The patient population will be patients over age 18 with stages I-III female breast cancer, OR stage II-III colon cancer, OR stage I-IIIA NSCLC, AND receiving an initial chemotherapy regimen. A single, validated PROM instrument (e.g., EORTC QLQ c30, FACT-G or PROMIS) that measures HRQOL and pain will be implemented. The measure concept is to have two survey administration intervals, which are proposed to be at baseline survey (within 3 weeks of first chemo) and post-chemo (3 mo after +/-1 mo). The survey administration timepoints will be discussed with the TEP.

Ms. McNiff outlined the stages of the measure development process:

- Measure conceptualization/specification will include selection of PROM instruments, development of initial measure specifications, creation of the analytic plan, development of a data dictionary, and creation of the testing implementation plan.
- Alpha testing will refine the implementation plan, model workflows, and the data collection plan to address issues. This will include 2-3 MOQC practices, initial data (baseline PRO only), and descriptive statistics.
- Beta testing includes an initial analysis after 6 months. Data will be submitted for all patients who meet eligibility; this will include PRO data (baseline and after chemotherapy) and clinical and demographic data. Burden assessments will be conducted for the participating sites during Beta testing.
- The final analysis will be a full data analysis. This will involve descriptive statistics, performance calculations, exclusion analyses, risk adjustment analyses, feasibility/burden analysis, and reliability and validity testing.
- Measure implementation will involve finalizing the implementation plan, preparing NQF submission materials, and writing and submitting a manuscript to a peer-reviewed journal.

DISCUSSION

One TEP member mentioned that Health-Related Quality of Life (HRQOL) is very different than discreet symptoms like pain. He was concerned that the construct is ambiguous and would be hard to measure change. He mentioned that HRQOL can't be treated on its own as it includes multiple dimensions; it's important to capture the most important and actionable components of HRQOL. Rachel Brodie responded that the project team has discussed this internally. One instrument will be selected to get a holistic view of the patient that includes multiple dimensions. She stated that the next TEP meeting will include a discussion about the HRQOL measure and how best to assess HRQOL since it is multi-dimensional. Another TEP member agreed that HRQOL is a complicated construct. She mentioned that a previous study that she was involved in showed that only vitality on the SF-36 instrument showed movable change. She agreed that we should think about this more.

One TEP member asked what treatment will be included in the measurement - adjuvant vs. metastatic treatment. She said that with adjuvant treatment patients are just beginning to recover at 3 months and you may not see improvement until 6 months. With metastatic treatment, it is ongoing. She wanted to clarify that these are different populations, and also question whether the follow-up period is too short. Kris McNiff replied that the project will only measure curative chemotherapy. She agreed we should discuss the measurement time period further as 3 months might be too soon. Another TEP member agreed that some measures and symptoms last a long time and some symptoms can take a year for recovery. She also said we should think carefully about what is really feasible. In her practice, she looks at "return to work" at 4 months, plus or minus a month – at that time, most people have gone back to work if they are going to go back to work. She thinks 3 months is reasonable as it provides a measure of recovery and an idea of where things are probably going to stay for the next year. Rachel Brodie clarified that the measure specifications presented today are in draft form and can be modified based on TEP feedback. She also agreed that some patients may not be fully recovered at 3 months post-treatment so we may need to look at different numerator options to include improvement or less decrement.

One TEP member wanted the team to think about what we are trying to demonstrate with the chosen timeframes. The worst experience is during treatment, while our measurement plan is to survey patients before chemo and then afterwards. He questioned whether the project should also survey patients during treatment. Rachel Brodie replied that these issues will be worked through during subsequent TEP calls.

Staff thanked the TEP for their input and invited members to submit questions or comments in advance of the January meeting.

NEXT STEPS

- Develop draft measure specifications for review, including survey administration timepoints for discussion
- Refine landscape review of PROM instruments and criteria for selection of the PROM
- Discuss how best to assess HRQOL which is a multi-dimensional construct