MEETING SUMMARY

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
- ☐ Dawn Severson, MD, Henry Ford Cancer Inst-Macomb
- ☒ Sally Okun, Independent Consultant
- ☒ Susan White, PhD, RHIA, CHDA, James Cancer Hospital
- ☐ Ishwaria M. Subbiah, MD, MS, MD Anderson
- ☒ 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
- ☐ 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
- ☐ Jorge Nieva, MD, USC Norris Cancer Center

PROJECT TEAM ATTENDANCE

- ☒ Rachel Brodie, Project Director, Pacific Business Group on Health
- ☒ Emma Hoo, Director, PBGH
- ☒ Valerie Kong, Senior Manager, PBGH
- ☒ Kate Eresian Chenok, MBA, Consultant
- ☒ Kristen McNiff Landrum, MPH, Consultant
- ☒ Feifei Ye, PhD, RAND

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 eighth TEP meeting on October 28th, 2020. The objectives of the meeting were:

- Check for Conflicts of Interest
- Review Project Timeline, including Updates about COVID-19 Impact
- Review Input from Beta Midpoint Testing
- Review Plans for Burden Assessment

PROMONC Technical Expert Panel (TEP) Summary
Date: February 25, 2020

MEETING NOTES:
No members cited conflicts of interest but two members commented on the following:

- Emily Mackler has research funding from AstraZeneca but does not have a conflict of interest.
- Sally Okun has changed roles from United Health Group to independent consulting. She has some pharmaceutical clients but does not have any conflicts of interest.

MILESTONES AND ACCOMPLISHMENTS TO DATE:
Kate Chenok reviewed the project's milestones and accomplishments, to date:

- Developed measure gap analysis, landscape review of PROMs in oncology, and preliminary business case for PRO-PMs in PROMOnc
- Selected PROMs instruments
- Defined the preliminary Measure Specifications
- Developed the Analytic Plan
- Developed Implementation Guide and Data Dictionary
- Completed Alpha Testing; refined Implementation Guide and Data Dictionary based on Alpha results and input from test sites
- Began Beta Testing
- Fielded Request for Public Comment
- Conducted Feasibility and Burden Assessment
- Development of the Burden & Feasibility Assessment report is in process
- Beta Testing is in process

PROJECT TIMELINE AND IMPACTS OF COVID-19:
Rachel Brodie reviewed the project timeline and the impacts of COVID-19 pandemic on the PROMOnc project. She shared that several test sites paused survey administration and experienced reduced staffing capacity for patient engagement between March and June 2020. She also noted that some of the smaller test sites are still ramping up their testing capacity. This delayed mid-point data submission for a number of sites to August and September 2020. Baseline enrollment slowed and also some enrolled patients experienced delays in treatment and possibly also their second and third surveys. At this time, sites have agreed to extend testing to March 31, 2021 and the Project Team is in active discussions with CMS to see if there is any flexibility in the measure submission timeline which would allow submission of more robust data. The Project Team met with four ADCC sites in August 2020 and will be meeting with the rest in November 2020. The MOQC team is also meeting with MOQC sites. Rachel emphasized that the Project Team is focused on capturing best practices from workflow adaptations among test sites.

Rachel Brodie provided a brief recap of the three PRO-PMs and the objectives, which are to fully develop and test patient reported outcomes for health-related quality of life, pain and fatigue for patients with breast, colon, and non-small cell lung cancer. She reiterated that the project team will be testing the measures at the clinician and group level.

MIDPOINT ANALYSIS OF PROMONC BETA TESTING:
Kris McNiff Landrum provided an overview of the goals for midpoint analysis. She elaborated on the importance of understanding the burden and the process of implementation and data collection. She reiterated that the goals and expectations of the midpoint analysis are to provide:

- Summary statistics overall, including missing data and mitigation plan
- Patient survey completion rate at the site level

- General descriptive analytics of the test population
- Descriptive analytics of PROMIS measure scores

Kris reiterated the impact of COVID-19 pandemic on beta testing data collection which resulted in slower than expected launch for some MOQC sites. She echoed Rachel's point that the Project Team supported the sharing of best practices and the importance of taking this opportunity to make changes as needed during the testing period.

Kris highlighted the key findings from the data quality assurance process and shared a table that summarized missing variables and mitigation plans being used with test sites to reduce amount of missing data. Kris shared the number eligible patients in total and by site. Overall, the survey completion rates were below expected which is reflective of impact of the COVID-19 pandemic.

Kris reviewed the denominator exclusions and rationale for each exclusion criteria. She presented key findings from survey completion among the eligible patients, including the number of patients who completed surveys at each timepoint. She reviewed patient characteristics and noted that the high ratio of females at sites may reflect the high volume of breast cancer patients and/or that sites are more successful at enrolling breast cancer patients.

One TEP member wondered whether pre-COVID and post-COVID volumes are different between academic medical centers and community practices, referring specifically to whether larger sites are affected similarly by COVID-19 pandemic as the smaller sites. Kris confirmed that this data is not yet available. Another TEP member noted that it would be interested to look at the COVID impact by week or month to evaluate the impact. The Project Team will take these suggestions under advisement.

Kris reviewed aggregate PROMIS responses to date. She noted that this data has many caveats given that early results are based on aggregate survey scores and sample patients are not matched. She also reiterated that PRO-PMs have not been calculated. The reference values are based on the general population, and the Project Team may use cancer-specific values in future analyses.

The TEP discussed interest in finding out what programs may be in place at different test sites to support patients in increasing their exercise or other activities that may moderate their level of fatigue. One TEP member suggested that the sites can provide a list of services or consults that would lead to better outcomes for fatigue and then each site could confirm whether these services are offered. The Project Team will explore surveying sites to see what programs are in place.

Kris highlighted the Project Team will seek guidance from the TEP once final data is available to maximize the use of submitted data, especially for low volume sites. One TEP member proposed pooling low-volume treatment sites.

FEASIBILITY AND BURDEN ASSESSMENT:

Rachel Brodie provided an update on the progress of the Feasibility and Burden Assessment. The Project Team started design of the process in late 2019 through early 2020, reviewing the approach with NQF staff. Clinicians, staff and patients provided feedback, and data collection was completed in September 2020. Rachel explained that there are three components of the assessment:

- Data element feasibility scorecard completed by all test sites in July 2020.
- Staff burden assessment: Three types of staff were surveyed online or interviewed.

  - Front-office staff involved in identifying patient eligibility for survey and patient engagement;
  - Management staff involved in planning, training and project management;
  - Clinical staff who use of survey responses for clinical care.
- Patient burden surveys

Analysis is being completed by the end of October 2020, and the report will be reviewed with the PROMOnc TEP in December 2020.

Rachel solicited comments from the group on the approach and the goal of understanding the burden and balancing the potential benefits that these measures can bring to clinical care. One TEP member noted that the burden to patients can be observed from the trend of fewer surveys completed over time. They suggested that the Project Team should survey patient burden at different timepoints in order to understand whether the perception of burden changes. When it was noted that some sites did not want to ask their patients to complete an additional survey about burden, a TEP member commented that this notion might be paternalistic and the patients should be able to decide for patients whether to complete a burden survey or not. One TEP member also pointed out that their quality team was calling after every survey that was electronically sent and heard from some patients that they were experiencing survey fatigue. One of their lessons learned was to make the survey responses available to the clinical team so that they can act on it, and therefore the patients see that responding to the survey is clinically important. This TEP member noted that measure testing projects should emphasize clinical use and even make it mandatory.

NEXT STEPS:

Kate Chenok reviewed next steps and the upcoming TEP meeting schedule for 2021 including continuing and completing beta testing, refining business case and looking forward to final testing analysis as well as producing final measure documentation in Year 3 of the project.

Rachel Brodie thanked the group for their time and briefly shared plans to notify the group with any important news from CMS on submission timeline before adjourning the meeting.