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 Inst-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

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, 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 sixth TEP meeting on September 10th, 2019. The objectives of the meeting were the following:

- Review Project Timeline; Check for Conflicts of Interest
- Review Key Findings from Alpha Testing
    - Data Quality Assurance
    - Missing Data
    - Descriptive Statistics
- Discuss and Approve Recommendations for Beta Testing

During the Sep 10th TEP meeting, no conflicts of interest were reported. The project milestones over the last 8 months were reviewed, including selection of the PROMs instruments and the iterative process of developing the Analytic Plan, Measure Specifications and Implementation Guide. The Project Team greatly appreciated the commitment and feedback from the TEP and representatives from the test sites. Feedback from the Alpha sites has been reflected in changes to the Implementation Guide and Data Dictionary to prepare for Beta testing.

DATA QUALITY ASSURANCE

Dr. Ye reviewed two tables showing aggregated data from four sites and shared a data quality assurance analysis, highlighting definitions for the following categories:

- "answer not in response options"
- "inappropriate skip"
- "inappropriate answer"

Regarding response options where the response was the inappropriate answer, e.g., '999' for questions that should be skipped based on the prior screener question or '0=No' for questions that should be skipped based on the prior screener question, one TEP member asked if the project was providing a drop down list for sites in the spreadsheet or are they building their own database? Another TEP member responded that the project is providing a spreadsheet for sites to capture data.

One TEP member asked if it is possible to differentiate whether the issue is that an abstractor is unable to locate this information (i.e., the information is not available) or if the issue is that the abstractor does not know where to look for this information. Ms. McNiff agreed that this is a good point and will make a note to provide further instructions for abstractors.

For two issues, Dr. Ye commented that project staff would discuss these with the test sites.

- One instance with the entry of '1=Yes' for 'Chemotherapy modifications – regimen changed' when the screener question indicates no modification
- Three instances with non-missing entries for 'AJCC Pathologic stage colon cancer following neoadjuvant chemo' when the screener question indicates adjuvant chemo

MISSING DATA ANALYSIS

Dr. Ye presented findings from the Missing Data Analysis. Ms. McNiff added that the project is only requesting a 'yes/no' answer in the comorbidity question and not looking for a detailed response.

One TEP member noted that missing BMI is surprising. Ms. Brodie clarified that the Data Dictionary allows the sites to submit either BMI or height and weight so that RAND can calculate BMI. Ms. McNiff noted that the Project Team will work with the test sites to confirm the reason for missing BMI.

One TEP member noted that it is hard to collect dose adjustments so the project needs to be sure that data like this is required for the end point. Ms. McNiff commented that the TEP had identified dose adjustment as an important aspect of risk adjustment but that the project would certainly monitor burden and data quality issues. Dr. Griggs noted that it is extremely difficult to get dosing information and that there may be a perverse incentive since these are accountability measures; providers may

increase dosing in order to reduce pain so that the patients feel better and the patient-reported outcome is better, but this dosing would not necessarily be guideline concordant.

Ms. McNiff commented that performance status field is collected among MOQC sites very robustly and we will discuss the clinical trial variable in upcoming slides with the group. For comorbidities, she reminded the group that the TEP decided to use a modified Elixhauser Comorbidity Index to collect comorbidities so not all comorbidities are included in the Data Dictionary. The Project Team will therefore update the response options to include 'None of the Above' so that the abstractor is not confused that certain comorbidities are not listed.

Dr. Ye continued to review the potential reasons for missing data and mitigation plans. Ms. McNiff added that it was an impressive effort to collect the data for the Alpha testing period and important to recognize that the timing is not the same as it will be for Beta testing. Therefore, some data was just not yet available during the Alpha period.

One TEP member noted that the resources to collect this data may outweigh the benefits. He asked if anyone has done a time study of how much time is required to collect the data. One TEP member replied that SCCA timed this and confirmed that they are spending 25 minutes per patient for abstraction.

Regarding missing pathological and clinical staging, Ms. Brodie noted that the Project Team will review this with the ADCC sites. Dr. Ye then proceeded to summarize the recommendations for Beta testing: develop a data quality check worksheet and provide additional training for site leaders and abstractors who will be participating in future data collection. Ms. Brodie elaborated that the Project Team will review the findings at future Friday ADCC workgroup meetings, and that the Project Team will then revise the Data Dictionary and Implementation Guide as needed. One TEP member also noted that a key purpose of the ADCC workgroup is to share detailed workflows and have a forum to share best practices for pulling patient lists and abstracting data.

DESCRIPTIVE STATISTICS

Ms. McNiff explained the color coding and column headings for the descriptive statistics table and indicated that missing data that could be an issue are highlighted in yellow. Ms. McNiff shared that demographic data such as Age, Ethnicity and Race will be abstracted from EHRs or via survey. Regarding marital status and insurance, Ms. McNiff noted that the Project Team will review the "other" variable in the insurance field to clarify if the response options are comprehensive enough. Ms. McNiff also noted that BMI field will be reviewed with sites to address the relatively high number of missing data. Lastly, Ms. McNiff reviewed the data related to clinical trial type which is being collected with a drop-down list of 3 options. The Project Team received a lot of feedback from sites that the project patient-reported outcome survey should not interfere with a clinical trial (e.g., if the project survey is redundant to a trial survey or could add burden such that a patient on the trial wouldn't want to respond to both surveys) or impact clinical trial outcomes. Ms. McNiff solicited input from the TEP about how to set up this data field to exclude the appropriate patients without excluding all patients on any clinical trial. One TEP member commented that the project should exclude patients on therapeutic trials since these all track adverse events and toxicity data, but do not exclude non-therapeutic trials. Another TEP member agreed and noted that the project would not lose many patients from the numerator or denominator as a result. Several TEP members commented that how to identify the type of clinical trial will be different for each site.

One TEP member then confirmed that all the ADCC sites have confirmed that they have access to this information.

REVIEW AND APPROVE RECOMMENDATIONS FOR BETA TESTING

Ms. Brodie reviewed the recommendations and next steps by stating that the Project Team will coordinate with ADCC sites to review the Alpha testing findings and explore the reasons for data issues. The Project Team will then revise the Data Dictionary and Implementation Guide to distribute to site leaders prior to Beta Testing. The Project Team will also incorporate improved instructions to address data quality and missing data issues for data abstractors in the Data Dictionary.

One TEP member added a quick comment that physicians on the call should reach out to the site leaders who are steeped in the data, workflow and operations if they have questions.

Ms. Brodie encouraged the group to contact the Project Team if they find any other data that should be investigated and concluded the meeting at 12:17PM.

NEXT STEPS

- The Project Team will review missing data elements with ADCC sites, including BMI, pathological and clinical staging data.
- The Project Team will review findings from Alpha Testing Analysis in a future meeting with ADCC workgroup.
- The Project Team will update Data Dictionary and Implementation Guide based on input from test sites with further instructions regarding response options.