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
- ☒ RAND: Feifei Ye, PhD

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 fifth TEP meeting on May 21, 2019. The objectives of the meeting were the following:

- Review Project Timeline and Check for Conflicts
- Discuss Updated Measure Specifications
- Discuss Reliability and Validity Testing
- Discuss Plans to Assess Burden & Feasibility
- Review Risk Adjustment Variables

During the May 21 TEP meeting, no conflicts of interest were reported. The project timeline and progress to date were reviewed. The Project Team provided an overview of input from the Clinician

Workgroup and reviewed the measure specifications. The TEP was asked to give feedback on the survey administration timepoints and four numerator options. Details are provided below. The analytic plan was reviewed, which included an overview of the plan for reliability testing and approaches to testing inter-unit reliability, missing data analysis, face validity, convergent and discriminant validity of performance measures, and potential data sources for validity analysis. The TEP then discussed what elements should be included in the design of the burden and feasibility analysis, with a focus on patient burden, provider burden, data collection burden, and burden during measure development versus future implementation. Results from a survey of TEP members that ranked the case-mix factors by clinical priority and also burden to collect was presented, with stratification by low/medium/high.

DISCUSSION OF UPDATED MEASURE SPECIFICATIONS

Ms. McNiff reviewed the proposed survey administration timepoints which were suggested by the Clinician Workgroup.

The TEP agreed on the following survey administration timepoints, which the project team will include in the measure specifications (also reflected in Next Steps below):

- Baseline: Survey administered on the first chemotherapy administration. For oral chemotherapy, survey administered on the date the oral chemotherapy prescription is written.
- Interim: Survey administered on the last day of chemotherapy administration. For oral chemotherapy, survey administered on the first day of the last chemotherapy cycle.
- Post-chemotherapy: Survey administered 3 months after the last chemotherapy administration. For oral chemotherapy, survey administered 3 months after the oral chemotherapy completion date.

Ms. McNiff mentioned the Project Team will reach out to TEP members to gather additional input on the allowable windows for administering each survey as well as additional comments and feedback on the measure specifications. She also noted that the Project Team will review details related to clinical data elements and treatment data elements with the Clinician Workgroup on June 7, 2019

DISCUSS RELIABILITY AND VALIDITY TESTING

Dr. Ye reviewed the current plans for reliability testing. She stated that performance measure level reliability and validity testing will be conducted for each of four numerator approaches. The four numerators approved by the TEP at the April 16, 2019 TEP meeting are:

Four Numerators for Testing
Raw/absolute change in pain intensity/pain interference/overall physical health/overall mental health following chemotherapy
Meaningful change in pain intensity/pain interference/overall physical health/overall mental health following chemotherapy • Validated or empirically derived minimally important difference in each outcome
Favorable scores of pain intensity/pain interference/overall physical health/overall mental health following chemotherapy • No pain or mild pain • No pain interference or mild pain interference • More favorable overall physical health • More favorable overall mental health
Observed vs expected scores of pain intensity/pain interference/overall physical health/overall mental health following chemotherapy • Predicted based on baseline and survey 2 data, as well as clinical/demographic characteristics

Full details of the numerators and the testing approach are contained in the Measure Specifications Document and the Analytic Plan.

She reviewed approaches to testing inter-unit reliability: a) assessing a measure's ability to distinguish performance among providers (i.e., signal to noise ratio), b) calculating intra-class correlation using random effect model for continuous measure score, and a R package (iccbin) for binary measure score, with risk adjustment variables included as covariates in these models, c) using Spearman-Brown prediction formula to calculate reliability of the measure at the provider level (also at the physician level if sample size is sufficient), and d) calculating minimum sample size needed to achieve acceptable reliability. A reliability threshold of 0.7 is recommended in the NQF-commissioned paper on PRO-PMs (NQF, 2013).

She reviewed plans for validity testing. To handle missing data analysis, we will compare eligible patients that respond and do not respond to the survey at baseline, survey 2 and survey 3. Missing data would be handled in a way that minimizes bias, and different imputation methods and estimation methods will be explored. For face validity, we will implement a structured survey across testing sites at the conclusion of testing.

To handle convergent and discriminant validity of performance measures, she described scenarios where differences or positive associations are expected at the PRO-PM score level. For example, one may be able to predict differences in the PRO-PM scores for patients with specific cancer diagnoses, stage, ages, or chemotherapy regimen. These will be identified prior to analysis and included in the testing analytic plan. She explained that the project would examine association between PRO-PM scores and other quality measures. For example, items such as patient's overall rating of the group, overall recommendation of the group, as well as patients' rating of different aspects of communications with the group (doctors and staff), are candidates to include in the survey for validity purpose.

She asked the TEP several questions:

- As we compare our testing results to other PRO results, are there relevant data from test sites that could be used?
- One TEP member mentioned that her organization uses other PRO tools that could be used for comparison, such as the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO CTCAE), Edmonton Symptom Assessment Scale (ESAS), MD Anderson symptom inventory, and others. One could also use an item bank for pain, which would be preferable over clinician assessments. Other TEP members noted that other ADCC sites also collect these PROMs but the timeframe may not align with the project period.
- Are there services or resources that are associated with high quality care and improved outcomes that we can evaluate to compare these providers' performance scores with the other providers? What variables can be used to assess discriminant and convergent validity? Clinician observation on pain, fatigue, physical function?
    - One TEP member mentioned that for convergent validity regarding pain, there is literature showing that doctors underestimate symptoms, and reports can be uncorrelated. Therefore, she recommended against using pain for convergent validity.
    - A TEP member clarified that the project will be using reliability to assess the four different numerator approaches. The project should look at the differences in the scores between each numerator approach, to see which approach truly captures the variation of performance between providers.

- Another TEP member recommended looking at a quality measure used by the COC - stressor screening for new patients with an annual follow-up. The time points will not align, but one can look at the site-level data to see what is reported and get data by disease type.
- Another TEP member suggested adding an overall question on patient satisfaction ("overall, how would you rate the quality of the care you have received from your cancer care doctors and their team") to the pilot survey, as a comparison point. Dr. Griggs suggested looking at recent article (T.G. Smith, Perceptions of Patients with Breast and Colon Cancer of the Management of Cancer-Related Pain, Fatigue and Emotional Distress in Community Oncology, Journal of Clinical Oncology, May 17, 2019).
- Another TEP members stated that there is publicly available data on Hospital Compare.com https://www.medicare.gov/hospitalcompare/cancer-measures.html on pain plan of care in place and pain quantified for all ADCC hospitals.
- One TEP member shared that MOQC collects these pain measures. They are modifying their measures to be the same as the NQF measures. The QOPI measure is pain plan of care documented for moderate to severe pain, but they just modified it to be pain plan of care for any pain.

DISCUSSION OF PLANS TO ASSESS BURDEN & FEASIBILITY

Ms. Brodie mentioned a key aspect of the measure development process is to conduct a burden and feasibility analysis in order to prepare the business case for these measures by documenting the anticipated benefits of the measures compared to the burden associated with implementation. The plan is to collect the information by surveying patients and site leaders at the test sites and then follow up with interviews for both quantitative and qualitative feedback. For patient burden, she explained that this could include the time to complete the survey, how easy it is to interpret and complete the questions, and whether surveys are answered completely or if there is missing data.

She explained that the project will also look at provider burden. In this category, the items are mostly related to the time and resources needed by staff to work with the patients and track and follow-up to ensure that the surveys are completed. She also noted that collecting these surveys may create some redundancy in clinical workflows. Also, for provider burden, she noted that data collection burden will be assessed since many data elements may not be captured electronically or easily extracted. The plan is to work with the ADCC and MOQC Project Managers to determine what to assess and how to conduct the assessment. She noted that is it also important to note the distinction between burden associated with measure testing and with measure implementation. Within the testing context, test sites will be required to collect data (especially clinical data) to enable full specification, risk adjustment analyses, reliability testing, and validity testing. It is anticipated that the data requirements will decrease for implementation of the fully validated measure.

TEP members provided positive feedback on this plan and agreed that the project team should proceed.

CONFIRM RISK ADJUSTMENT VARIABLES

Ms. Brodie shared that 16 TEP members responded to the survey ranking the clinical importance of each potential risk adjustment variable and also the burden to collect each variable. The Project Team refined the list of risk adjustment variables based on this input. She stated that the Project Team also plans to

circulate the data dictionary to the ADCC and MOQC Project Managers to obtain any additional feedback on the list of variables.

PROJECT UPDATES

Ms. Brodie updated the TEP that the test sites are reviewing both the Implementation Guide and the Data Dictionary. She also mentioned that she is working with Western IRB on a protocol; she will provide an update about whether the project is exempt from IRB review.

NEXT STEPS

- The Project Team will update Implementation Guide and Data Dictionary based on input from test sites.
- The Project Team will update the Measure Specifications to include the survey administration timepoints recommend by the TEP at this meeting.
- The Project Team will update the Analytic Plan to reflect the survey administration timepoints recommend by the TEP at this meeting.
- To complete the Data Dictionary, the Project Team will review details related to clinical data elements and treatment data elements with the Clinician Workgroup on June 7, 2019.