

PUBLIC COMMENT

Summary Report

Project Title: Patient-Reported Outcome Measures for Oncology Care (PROMOnc)

Dates:

The Call for Public Comment period ran from January 9, 2020 to January 29, 2020.

The preliminary Public Comment Summary was prepared on February 6, 2020. The final Public Comment Summary was prepared on February 28, 2020.

Project Overview

The Centers for Medicare & Medicaid Services (CMS) has awarded a [Cooperative Agreement](#) to the Pacific Business Group on Health (PBGH) to develop and test patient-reported outcome-performance measures (PRO-PMs) for oncology care. The Cooperative Agreement's goal is to develop and expand quality measures for use in the Quality Payment Program. The Cooperative Agreement grant program is MACRA/Measure Development for the Quality Payment Program, and the grant number is 1V1CMS331641. As part of its measure development process, PBGH requested interested parties to submit comments on the candidate or concept measures that may be suitable for this project.

Project Objectives:

The aims for this project are to enhance patient-centered cancer quality measurement by 1) fully developing and testing patient-reported outcome-performance measures (PRO-PMs) regarding health-related quality of life (HRQOL) and pain for patients with breast, colon and lung cancer, and 2) preparing documentation for successful submission of the measures to National Quality Forum (NQF) and CMS. We are testing two HRQOL measures and two pain measures and our objective is to develop at least one PRO-PM in each domain for submission to CMS and NQF.

Information About the Comments Received:

Request for public comment was posted on PBGH's website and public comments were solicited by email through:

- Email notifications to Alliance of Dedicated Cancer Centers (ADCC) Quality Committee;
- Email notifications to the American Society of Clinical Oncology (ASCO) and Community Oncology Alliance (COA);
- Email notifications to National Coalition of Cancer Survivorship (NCCS) and Cancer Support Community (CSC);
- Email notifications to the PROMOnc Steering Committee and PROMOnc Technical Expert Panel (TEP);
- Email notifications to PBGH partner organizations and web posts on the PBGH website (www.pbgh.org).

PBGH received 20 responses on the Measure Information Form in the following methods:

- 18 comments/comment letter received via digital submission form

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- 2 comments/comment letters received via email submission

Specifically, we received comments from 7 entities:

- 2 Specialty Societies
- 2 Provider Organizations
- 2 Individuals
- 1 Consumer Organization

Stakeholder Comments—General and Measure-Specific and Recommendations:

General Stakeholder Comments:

A total of 16 general comments were received during the Public Comment period. Topics include:

- Clarification regarding the Expected Data used in the Observed versus Expected Numerator
 - **One Commenter** requested clarification on expected data, stating they “do not understand how the Expected data will be collected, since it does not yet exist. This should be discussed further.”

Response: For the observed versus expected numerator, the expected group-level scores are predicted based on actual survey data using statistical modeling. We will predict the PROM score post-chemotherapy using baseline PROM scores, Survey 2 PROM scores, and case-mix factors. The numerator calculation will be the difference between the actual PROM score over the predicted score at post-chemotherapy.

- Survey Collection Timepoint Eligibility Window
 - **One Commenter** shared their concern regarding the timing of the survey administration at baseline: “7 days for iv and 14 days for oral drugs: I would suggest 1 month, which then would coincide within the range of a clinic visit. It would be difficult for medical oncology offices to enforce/help for out of clinic activities, even if these are online tools.”
 - **One Commenter** recommended that survey administration window for Survey 2 be extended “from 7 days to 14 days (i.e. changes in treatment, unanticipated changes in chemo end of treatment) often leave us outside the eligible window”
 - **One Commenter** noted difficulty with identifying patients within narrow survey administration windows, stating that “the administration and collection of surveys from the “right” patients at designated narrow time intervals requires significant operational and quality staff support and cannot be easily automated. Much of this stems from the narrow time windows allowed for the survey.”
 - **One Commenter** suggested that “while some detail is provided on measurement windows within section 3.18 Survey/Patient-Reported Data, it would be helpful to clarify the measurement windows by specifying a minimum and maximum amount of time for

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data collection from survey 1 to initiation of chemotherapy, from end of treatment to survey 2 and between each survey.”

Response: The survey time windows were selected based on extensive discussions among our Technical Expert Panel (TEP), input from the PROMOnc test sites, and input from patient and caregiver representatives on both the Steering Committee and TEP. Testing time windows were selected to balance ease of integration into standard clinical visit schedule/workflow with the need for meaningful, reliable and valid measurement. We appreciate your suggestion and will continuously re-evaluate the survey windows during early testing.

- Stratification of Measures by Race, Ethnicity and Stratification of Colon and Lung Cancer Measures by Gender

- **One Commenter** was concerned about the “stratification of all measures by race/ethnicity and stratification of the colon and lung cancer measures by gender. Inequitable care and outcomes by race and gender are well established, and measurement of course can be a pathway for addressing these gaps. We encourage creative solutions to resolving any barriers to addressing these concerns.”

Response: Thank you for your comments. We agree that evaluation of disparities is critical to any testing project. Testing analysis will include evaluating performance differences per patient characteristics prior to any adjustment, including race, ethnicity, and gender. We currently have identified these variables as potential statistical risk adjustment covariates, and agree completely that we should explore stratification as an alternative, especially if variations in care are found in testing data.

- Consideration of Measures of Dose Intensity

- **One Commenter** stated that “It is well established that chemotherapy toxicity is the primary driver of quality of life and negative PROs in the tumor types referenced in these measures (breast, colorectal, and non-small cell lung). Reduced exposure to chemotherapy is subsequently associated with better toxicity profiles compared to higher doses. To avoid rewarding practices for unindicated dose reductions and delays, [we] recommends including measures of dose intensity to monitor for dose modifications.”

Response: We agree that maintaining dose intensity is critical. Thus, multiple attributes of chemotherapy, including initial dose selection, dose modifications, delays between cycles, and the composite measure of dose intensity, are all being collected via detailed medical record review. These data are included in our collection of clinical data and are identified for analytic/adjustment purposes in our analytic plan.

- General Feedback on the Three Approaches to Evaluating Numerators

- Approach 1) Meaningful change following chemotherapy
 - **One Commenter** cautions that “change-score metrics may not yield clinically meaningful results. An unfavorable change in outcomes between survey 2 and 3 may not truly indicate worse quality of care and/or performance of a provider of practice, even when controlling for baseline scores.”

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- Approach 2) Favorable scores of global physical health/global mental health/pain intensity/pain interference following chemotherapy
 - **One Commenter** supports “the use of absolute score metrics to evaluate symptoms. Evaluating the prevalence of specific levels of symptoms at standardized timepoints is meaningful and likely does reflect overall management. A composite of multiple symptoms compared to a single symptom assessment is likely to yield a more clinically meaningful and accurate assessment of management.”
- Approach 3) Observed vs expected score following chemotherapy
 - **One Commenter** expressed concern with “the use of observed vs expected evaluations. Functional status and symptoms are highly variable between and within patients receiving chemotherapy. Direct comparisons may not be appropriate, particularly when considering differences in dose intensity if not accounted for”.

Response: Because PRO-PM development is in its infancy, our project is designed to test multiple numerator approaches to help contribute to learning/literature for measure developers. With guidance from the project TEP, clinical workgroup, and Steering Committee, PROMOnc selected three numerator analyses that are expected to provide the most clinically relevant and meaningful performance data. Testing results and expert feedback will determine which is the preferred numerator measure for each outcome. Specifically, the three approaches will be evaluated and compared based on analyses related to validity and reliability described in the later sections. Final decisions regarding which approach is optimal will depend on the results of the validity and reliability assessment and feedback from the TEP. We appreciate you providing your recommendations and will review your input with the TEP.

- General Feedback on the Denominator
 - **One Commenter** noted that they “understand the decision to limit the population to patients receiving chemotherapy and that the inclusion of additional types of therapies would complicate these measures. However, with great advances in immunotherapy underway, particularly in the treatment of lung cancer, we feel these measures would be more current and meaningful if immunotherapy regimens were included. We also recommend the inclusion of biologics. The management of symptoms and monitoring for toxicities in patients receiving immunotherapy or biologics is critical, regardless of whether the patient is concurrently receiving chemotherapy. These regimens may have adverse implications for quality of life, and it is necessary for physicians to be mindful of the patient experience when administering immunotherapies and biologics. Because of the potential negative outcomes and quality of life associated with immunotherapy, ASCO is currently developing new guidelines to address the management of symptoms and toxicities in this setting.”

Response: Thank you for this comment. Please note that patients receiving chemotherapy + immunotherapy/biologics are included in the measure. Our measure includes only participants receiving adjuvant therapy, and there are few immunotherapies/biologics that are administered without accompanying chemotherapy in the adjuvant setting at this time. We strongly agree

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that this will be an important population for measure expansion in the future. ASCO's guidelines will provide a critical resource to justify this expansion.

- Incorporating Additional Treatments such as Radiation Therapy in Measure Calculations
 - **One Commenter** noted "it would be beneficial to elucidate how these other treatments are incorporated in the measure calculations. For example, treatments such as radiation therapy or ovarian suppression that are started during or after chemotherapy and within the measurement window will have impacts on quality of life. Patients with localized disease are not excluded from the denominator via the exception for patients with recurrence/disease progression/metastatic cancer, and this population commonly receives more treatments. The treatment received and the timeframe of the treatment and where it falls within the measurement periods should be considered when assessing performance rates."

Response: We agree. A comprehensive set of treatments received will be collected from the medical records of the study participants. The analytic plan will account for these additional treatments for the reasons you describe.

- Choice of Patient-Reported Outcome Measurement Survey Instrument
 - **One Commenter** pointed out that "While the Patient-Reported Outcomes Measurement Information System (PROMIS) is an appropriate instrument to capture symptoms, we recommend also testing Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) items to increase the applicability and promote implementation of these measures across providers participating in the Quality Payment Program. An expansion to include PRO-CTCAE items provides practices with a choice of measure to use for the specifications, easing administrative costs and burden in capturing these measures. Many health systems are integrating PROMIS and/or PRO-CTCAE measurement systems; including both in testing promotes the future use of these measures.

Furthermore, they "recommend using only a single item per domain. For example, a single item for pain. Current evidence demonstrates minimal additional information is obtained by asking multiple questions within a domain. Additional questions contribute to unnecessary burden on patients, who may also be facing questionnaires and surveys from various other sources. It is our viewpoint that a parsimonious approach to survey questions as reflected by single item metrics is the best approach to successful implementation and adoption. As such, we also support the use of the short pain form over the long form."

Response: For instrument selection, PROMOnc conducted a landscape assessment of 13 PROM survey instruments and evaluated the PROMs using criteria based on EMPRO and ISOQOL recommendations. PRO-CTCAE was one of the instruments considered. After a rigorous evaluation and rating process by clinicians, methodologists, patients and caregivers, PROMIS was selected. One reason is that our measure seeks target symptom outcomes of cancer diagnosis and treatment that persist and impact patient re-entry into cancer survivorship, with follow-up survey implementation at 3 months after completion of chemotherapy.

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Testing multiple surveys would have been ideal; however, burden to patients and test sites, testing timelines, and standard measurement challenges prevented that option. Measure testing does not replace research, and additional research is needed in this area.

We agree that minimizing the number of survey questions and questionnaire completion time is important in order to reduce patient burden and optimize likelihood of survey completion. The length of each PROMIS survey was considered carefully by our TEP and a focus group of patients and caregivers that we convened for the purpose of selecting the PROMOnc instruments.

- Concern regarding Other Treatments prior to Chemotherapy Not Addressed in Analytic Plan
 - **One commenter** expressed that “It is important that an analytic plan control for other treatments such as surgery before chemotherapy as compared to primary systemic therapy. Hospitalizations or surgery during or just before a survey measurement period may or may not be attributable to chemotherapy. For example, a breast reconstruction surgery could occur around the time survey 3 is completed. While this consideration may already be accounted for within the analytic plan, we felt it prudent to highlight this consideration.”

Response: Thank you for your additional comments; as you note, the analytic plan was not posted because the planned analyses are beyond the scope requested at this point and thus the posted documentation. PROMOnc will test a statistical risk adjustment model including covariates such as patient demographic characteristics, baseline clinical factors and treatments administered.

- Omission of Liver Cancer Patients from Eligible Cancer Type
 - **One Commenter** noted that “there is a critical omission from the current pre-testing measure information form. It is disappointing to see that PBGH is developing and testing patient-reported outcome-performance measures (PRO-PMs) regarding health-related quality of life (HRQOL) and pain for patients without considering liver cancer. Omission of liver cancer undermines the representativeness of the project and generalizability of any results.”

Response: Thank you for your comment. At this time, the measure denominator is limited to patients with breast, colon, and non-small cell lung cancer. We take into advisement your compelling recommendation for expanding the measures to liver cancer in future testing. We would be very interested in discussing future opportunities with you.

- Comments Regarding Feasibility and Workflow:
 - Manual processes related to survey administration, survey fatigue for patients at time of diagnosis, and challenges related to inclusion of oral chemotherapy patients
 - **One Commenter** noted several concerns, first “prospectively identifying both clinical and pathologic staging in advance of initial survey requires a manual process”; and secondly “identifying appropriate survey windows to receive second and third surveys is a manual process. Relying on the EMR alone doesn’t account for daily changes in treatment regimens that can influence the timeframes for survey eligibility”

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- **One Commenter** recommends using “second and third surveys to measure % change. Patients are often overwhelmed at the time of diagnosis and if possible, eliminating a survey at that timeframe could benefit the patient. There is a general survey fatigue we also would like to be sensitive to where multiple ongoing initiatives are also active at our center”
- **One Commenter** noted that “surveying and identifying oral chemotherapy patients is a challenge and recommend excluding these patients from the survey process”

Response: Thank you for your comments. You have identified the critical feasibility and workflow issues that are being evaluated early in our testing process. We know that one of the major challenges of reliable, valid PRO-PM implementation is integration of PROs into oncology practice workflows. We will share your specific recommendations with our TEP and will continue to learn from our test sites.

○ Burden of Collecting Survey Refusal reasons

- **One Commenter** raised the concern that “collecting survey refusal reasons is burdensome and recommend excluding this data element”

Response: Your feedback regarding survey refusal burden is appreciated; granular data is required for testing purposes and we will evaluate the need to maintain this level of detail for implementation.

○ Use of Alternate Tool to Collect and Respond to PRO Data for Pain Measurement

- **One Commenter** expressed that “of the three survey tools used for measurement, our center has chosen an alternate tool to collect and respond to PRO data for pain (DVPRS) and will not implement Pain Intensity Scale 1a or Pain Interference Short Form 4a beyond the scope of the ADCC PROMOnc project. We will continue to utilize the PROMIS Global Health v1.2”

Response: Thank you for your feedback. We will be collecting evaluation information from all test sites during the measure testing phase.

● Difficulty of Determining “End of Chemotherapy” for Survey Administration

- **One commenter** discussed their difficulty administering surveys during specific timepoints, noting that “requiring surveys on a more regular basis during chemotherapy (instead of at narrow windows around the start and end of chemotherapy) would make it easier to administer the surveys, as it is often difficult to determine the “end of chemotherapy,” which may not be regularly captured in oncology workflows or may change based on the patient’s clinical course.”
- **One Commenter** expressed that “even with appropriate clinical intervention, merely surveying the patients at the start and end of chemotherapy is insufficient if the goal is to improve patient care stemming from symptoms that arise in the course of receiving chemotherapy. We would submit surveying patients more frequently during the course of their chemotherapy and looking for meaningful intervention during surveys taken while in chemotherapy would be more clinically appropriate.”

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Response: Test sites (and sites implementing the final measure) may find that more frequent administration of the surveys creates a more efficient and reliable workflow. We support this approach for both quality and workflow reasons, and it is allowed under the testing protocol. To ensure valid and reliable measurement, however, it is necessary that the survey data used for measure calculation are administered within the defined windows.

- Clinical Relevance of Measuring Patient-Reported Outcomes
 - **One Commenter** pointed out that “Goals of improvement are focused on improvement between surveys 2 and 3. Additional clinical benefit could be gained by addressing patient symptoms during chemotherapy (between surveys 1 and 2)”

Response: We agree and support use of surveys 1 and 2 for clinical intervention. For quality measurement via PRO-PM, the TEP identified that the measurement target is for patients completing treatment and entering survivorship.

- **One Commenter** noted that “there is no requirement for clinical intervention in response to patient surveys. The goal of measuring patient-reported outcomes is to improve patient care, but that only happens with appropriate clinical intervention”

Response: We absolutely agree that the goal of measuring PROs is to act on the information and improve patient care. If this is done, PRO-PM scores should reflect this in high/positive performance compared to other clinicians/groups. This project is not measuring processes of care, but sites may choose to measure process (e.g., action taken) to support improvement efforts.

- **One Commenter** suggested that “educational handouts or videos may be appropriate depending on the urgency of the identified symptoms” to “reduce provider burden for interventions”

Response: As noted, we completely support more frequent survey administration and interventions to address issues identified in real time. Evidence-based interventions that reduce burden on oncologists (e.g., handouts or videos) may be important tools and are beyond the scope of this testing project.

Measure-Specific Stakeholder Comments:

A total of 4 measure-specific comments were received during Public Comment Period. Topics include:

- Comments regarding Health-Related Quality of Life Measures: (Patient-Reported Overall Mental Health and Physical Health Following Chemotherapy):
 - Limited resources due to shortage of mental health providers to treat and respond to patients needing referrals
 - **One commenter** is concerned that “There is a national shortage of mental health providers. There is well documented effects from cancer therapy on patients; 1 in 5 breast cancer patients develops PTSD. However, tying reimbursement to mental health essentially ties reimbursement of oncologists at a time when resources aren't available for them to help patients. This is likely to create a backlash and frustration among treating clinicians.”

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Response: Thank you for reiterating the importance of inclusion of global mental health as a component of HRQOL in PROMOnc. As you note, performance gaps identified in this measure may include a shortage of mental health providers to whom medical oncologists may refer; however, national guidelines provide recommendations for actions which medical oncologists can take to impact patients' mental health (e.g., NCCN Distress Management guideline; ASCO Patient-Clinician Communication guideline).

- Approach to hold providers accountable for functional status
 - **One commenter** expressed that "While we appreciate the use of a validated tool, specifically the PROMIS Global Health for HRQOL, we have concerns regarding the approach to hold providers accountable for functional status. Physical function is not always actionable and the variables impacting performance status are largely beyond therapeutic control. An alternative approach, though complex, is to include measurement of inappropriately aggressive treatment for patients with poor performance status or a lack of palliative care consults for patients who are frail. If PBGH does pursue a physical function assessment, [our organization] suggests consideration of the patient-reported Eastern Cooperative Oncology Group (ECOG) performance status, developed by Cancer Care Ontario (CCO), as it is akin to the criteria oncologists use (i.e., clinician-reported ECOG performance status)."

Response: PROMOnc is testing the overall assessment of physical health, which is a component of HRQOL. Physical health and HRQOL are among the outcomes prioritized in the International Consortium for Health Outcomes Measurement (ICHOM) standard sets for breast, lung and colon cancers, and the literature in this field suggests that detriments to physical health are common in this population.

For instrument selection, PROMOnc conducted a landscape assessment of 13 PROM survey instruments and evaluated the PROMs using criteria based on EMPRO and ISOQOL recommendations. After a rigorous evaluation and rating process by clinicians, methodologists, and patients and caregivers, PROMIS was selected. One reason is that our measure targets symptoms related to cancer and its treatment that persist and impact patient re-entry into cancer survivorship, with follow-up survey implementation at 3 months after completion of chemotherapy.

We believe there are actionable interventions medical oncologists can take to impact their patients' physical health, which will in turn impact performance on this measure. For instance, there are relevant guideline recommendations, such as NCCN's Adult Cancer Pain, Cancer-Related Fatigue, and Survivorship guidelines.

- Comments Regarding Patient-Reported Pain Intensity and Pain Interference Following Chemotherapy Measures:
 - Implications of tying reimbursement with pain treatment given opioid crisis
 - **One commenter** noted that "In the past, there was a nationwide push to aggressively treat pain and treat it "as the 5th vital sign". We now have a national opioid crisis and some of that is tied to this philosophy. Tying reimbursement to self reported pain is likely to have the consequence of once again igniting this debate and causing massive frustration among physicians and patients."

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Response: Thank you for raising this concern which must be considered for any measure regarding pain. However, pain remains a frequent and distressing symptom among patients with cancer. Medical oncologists have increased access to evidence and recommendations regarding alternative pharmacologic and non-pharmacologic methods to treat pain, e.g., as recommended in the NCCN Adult Cancer Pain guideline.

It is possible that pain intensity may not be the best target for a PRO-PM and that the pain interference measure may be more suitable for accountability purposes. To address this, our Analytic Plan is designed to test both the pain intensity and pain interference measures and ultimately determine whether each is reliable, valid and responsive, and also to assess suitability for payment and other accountability uses.

- Use of single-item per domain for pain to reduce unnecessary burden on patients
 - **One commenter** supports the use of short pain form and further recommends “using only a single item per domain for pain. Current evidence demonstrates minimal additional information is obtained by asking multiple questions within a domain. Additional questions contribute to unnecessary burden on patients, who may also be facing questionnaires and surveys from various other sources. It is our viewpoint that a parsimonious approach to survey questions as reflected by single item metrics is the best approach to successful implementation and adoption.”

Response: PROMOnc agrees that minimizing the number of survey questions and questionnaire completion time is important in order to reduce patient burden and optimize likelihood of survey completion. The PROMOnc TEP and a separate focus group of patients and caregivers convened to evaluate domain and item selection both emphasized that it was important to assess both pain intensity and pain interference. Due to recognized concerns regarding PRO-PMs of pain intensity, it is possible that pain intensity may not be the best target for a PRO-PM and that the pain interference measure may be more suitable for accountability purposes. To address this, our Analytic Plan is designed to test both the pain intensity and pain interference measures and ultimately determine whether each is reliable, valid and responsive, and also to assess suitability for payment and other accountability uses.

At this time, the validated PROMIS pain interference scales are 4, 6 and 8 items.

- Comment Regarding both HRQOL and Pain Measures:
 - **One commenter** is concerned about “being measured for % change in pain, and potential questions addressing mental health with common misconceptions about treating pain (and measurement of pain) with the opioid crisis. For mental health issues, many centers are faced with limited resources to treat and respond to patients in need of referral services. Concern for used in a value-based program.”

Response: Thank you for your comments regarding the measurement of pain and mental health. As you note, performance gaps identified in the mental health measure may include a shortage of referral resources; national guidelines provide recommendations for actions which medical oncologists can take to impact patients’ mental health (e.g., NCCN Distress Management guideline; ASCO Patient-Clinician Communication guideline).

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Thank you for raising this concern which must be considered for any measure regarding pain; however, pain remains a frequent and distressing symptom among cancer patients. Medical oncologists have increased access to evidence and recommendations regarding alternative pharmacologic and non-pharmacologic methods to treat pain, e.g., as recommended in the NCCN Adult Cancer Pain guideline.

It is possible that pain intensity may not be the best target a PRO-PM and that the pain interference measure may be more suitable for accountability purposes. To address this, our Analytic Plan is designed to test both the pain intensity and pain interference measures and ultimately determine whether each is reliable, valid and responsive, and also assess whether suitable for payment and other accountability uses.

Overall Analysis of the Comments and Recommendations

The PROMOnc Project Team appreciates the commenters' thoughtful input, recommendations and requests for clarifications about the measures. All comments and responses were reviewed with the Technical Expert Panel (TEP) on February 25, 2020. Comments from the public were consistent with issues that have been raised during TEP and Steering Committee discussions in prior meetings. Moreover, many of the issues there were raised align with what we expect to be key learnings from measure testing. After review of the preliminary summary report, the TEP did not recommend any changes to the Measure Information Form, Analytic Plan or implementation plan at this time. The Project Team intends to continue to discuss many of these important issues during upcoming TEP and Steering Committee meetings along with data that is collected during testing.

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Comment Number*	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Measure Set or Measure	Text of Comments
1	January 12, 2020	Claire Verschraegen, MD Individual - Clinician	General Comments	I have 2 comments: I do not understand how the Expected data will be collected, since it does not yet exists. This should be discussed further.
2	January 12, 2020	Same As Above	General Comments	The timing of the collection: 7 days for iv and 14 days for oral drugs: I would suggest 1 month, which then would coincide within the range of a clinic visit. It would be difficult for medical oncology offices to enforce/help for out of clinic activities, even if these are online tools.
3	January 12, 2020	Jeffrey Vandeusen, MD PhD Individual – Medical Oncologist	HRQOL: Patient-Reported Overall Mental Health Following Chemotherapy	There is a national shortage of mental health providers. There is well documented effects from cancer therapy on patients; 1 in 5 breast cancer patients develops PTSD. However, tying reimbursement to mental health essentially ties reimbursement of oncologists at a time when resources aren't available for them to help patients. This is likely to create a backlash and frustration among treating clinicians.
4	January 12, 2020	Same As Above	Patient-Reported Pain Intensity Following Chemotherapy Patient-Reported Pain Interference Following Chemotherapy	In the past, there was a nationwide push to aggressively treat pain and treat it "as the 5th vital sign". We now have a national opioid crisis and some of that is tied to this philosophy. Tying reimbursement to self reported pain is likely to have the consequence of once again igniting this debate and causing massive frustration among physicians and patients.
5	January 28, 2020	Carol Sakala National Partnership for Women & Families	General Comments	Thank you for reaching out, and thank you for carrying out the important work of developing PRO-PMs for several common conditions. As you likely know, we are ardent advocates for person-reported measures. Unfortunately, we no longer have funding to support work in this area, and are stretched thin, especially given the tight turnaround and our wish to provide thoughtful and thorough feedback. We would like to offer one strong recommendation: stratification of all measures by race/ethnicity and stratification of the colon and lung cancer measures by gender. Inequitable care and outcomes by race and gender are well established, and measurement of course can be a pathway for addressing these gaps. We encourage creative solutions to resolving any barriers to addressing these concerns.

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				<p>This work is so important to us! Perhaps we could be more helpful in the future, especially if brought in earlier in the process.</p> <p>Best wishes, Carol</p>
6	January 29, 2020	Angela Kennedy, DC MBA American Society of Clinical Oncology (ASCO)	HRQOL: Patient-Reported Overall Physical Health Following Chemotherapy	<p>3.18 Survey/Patient-Reported Data (NQF Submission Form S.16.)</p> <p>While we appreciate the use of a validated tool, specifically the PROMIS Global Health for HRQOL, we have concerns regarding the approach to hold providers accountable for functional status. Physical function is not always actionable and the variables impacting performance status are largely beyond therapeutic control. An alternative approach, though complex, is to include measurement of inappropriately aggressive treatment for patients with poor performance status or a lack of palliative care consults for patients who are frail. If PBGH does pursue a physical function assessment, ASCO suggests consideration of the patient-reported Eastern Cooperative Oncology Group (ECOG) performance status, developed by Cancer Care Ontario (CCO), as it is akin to the criteria oncologists use (i.e., clinician-reported ECOG performance status).</p>
7	January 29, 2020	Same As Above	<p>Patient-Reported Pain Intensity Following Chemotherapy</p> <p>Patient-Reported Pain Interference Following Chemotherapy</p>	<p>3.20 Data Source or Collection Instrument (NQF Submission Form S.18.)</p> <p>As mentioned above, we support the use of the short pain form and further recommend using only a single item per domain for pain. Current evidence demonstrates minimal additional information is obtained by asking multiple questions within a domain. Additional questions contribute to unnecessary burden on patients, who may also be facing questionnaires and surveys from various other sources. It is our viewpoint that a parsimonious approach to survey questions as reflected by single item metrics is the best approach to successful implementation and adoption.</p>
8-14	January 29, 2020	Same As Above	General Comments	<p>Dear PBGH PROMonc Project Team,</p> <p>The American Society of Clinical Oncology (ASCO) appreciates the opportunity to comment on the Patient-Reported Outcome Measures for Oncology Care (PROMonc) pre-testing measure specifications.</p> <p>ASCO is the national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans, including Medicare beneficiaries.</p>

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(8)			<p>ASCO recognizes the vital importance of including the patient voice in quality measurement. We applaud the effort undertaken by PBGH to develop and test patient-reported outcome-performance measures (PRO-PMs) for oncology care for intended use in the Quality Payment Program.</p> <p>General Comments</p> <p>It is well established that chemotherapy toxicity is the primary driver of quality of life and negative PROs in the tumor types referenced in these measures (breast, colorectal, and non-small cell lung). Reduced exposure to chemotherapy is subsequently associated with better toxicity profiles compared to higher doses. To avoid rewarding practices for unindicated dose reductions and delays, ASCO recommends including measures of dose intensity to monitor for dose modifications.</p>
(9)			<p>3.7 Numerator Details (NQF Submission Form S.5.)</p> <p>PBGH notes that for each of the PRO-PMs, three approaches to the numerator calculations will be taken. General feedback on each approach is provided below and applies across all four numerators.</p> <p>1) Meaningful change following chemotherapy</p> <p>ASCO cautions PBGH that change-score metrics may not yield clinically meaningful results. An unfavorable change in outcomes between survey 2 and 3 may not truly indicate worse quality of care and/or performance of a provider of practice, even when controlling for baseline scores.</p> <p>2) Favorable scores of global physical health/global mental health/pain intensity/pain interference following chemotherapy</p> <p>ASCO supports the use of absolute score metrics to evaluate symptoms. Evaluating the prevalence of specific levels of symptoms at standardized timepoints is meaningful and likely does reflect overall management. A composite of multiple symptoms compared to a single symptom assessment is likely to yield a more clinically meaningful and accurate assessment of management.</p> <p>3) Observed vs expected score following chemotherapy</p> <p>ASCO also cautions PBGH in the use of observed vs expected evaluations. Functional status and symptoms are highly variable between and within patients receiving chemotherapy. Direct comparisons may not be appropriate, particularly when considering differences in dose intensity if not accounted for.</p>
(10)			<p>3.9 Denominator Details (NQF Submission Form S.7.)</p> <p>We understand the decision to limit the population to patients receiving chemotherapy and that the inclusion of additional types of therapies would complicate these measures. However, with great advances in immunotherapy underway, particularly in the treatment of lung cancer, we feel these</p>

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(11)			<p>measures would be more current and meaningful if immunotherapy regimens were included. We also recommend the inclusion of biologics. The management of symptoms and monitoring for toxicities in patients receiving immunotherapy or biologics is critical, regardless of whether the patient is concurrently receiving chemotherapy. These regimens may have adverse implications for quality of life, and it is necessary for physicians to be mindful of the patient experience when administering immunotherapies and biologics. Because of the potential negative outcomes and quality of life associated with immunotherapy, ASCO is currently developing new guidelines to address the management of symptoms and toxicities in this setting. As treatment advances, the comparability of data within and across tumor types will become increasingly limited if these newer forms of therapy are not considered. In the absence of an ability to include a broader denominator inclusive of other therapies, a plan and timeline to address additional therapies in the future is advised.</p> <p>We also understand the rationale to include chemotherapy administered to a patient with any other treatment modality and in any sequence; however, it would be beneficial to elucidate how these other treatments are incorporated in the measure calculations. For example, treatments such as radiation therapy or ovarian suppression that are started during or after chemotherapy and within the measurement window will have impacts on quality of life. Patients with localized disease are not excluded from the denominator via the exception for patients with recurrence/disease progression/metastatic cancer, and this population commonly receives more treatments. The treatment received and the timeframe of the treatment and where it falls within the measurement periods should be considered when assessing performance rates.</p>
(12)			<p>3.20 Data Source or Collection Instrument (NQF Submission Form S.18.)</p> <p>While the Patient-Reported Outcomes Measurement Information System (PROMIS) is an appropriate instrument to capture symptoms, we recommend also testing Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) items to increase the applicability and promote implementation of these measures across providers participating in the Quality Payment Program. An expansion to include PRO-CTCAE items provides practices with a choice of measure to use for the specifications, easing administrative costs and burden in capturing these measures. Many health systems are integrating PROMIS and/or PRO-CTCAE measurement systems; including both in testing promotes the future use of these measures.</p> <p>For any PROMIS items across the measures, we recommend using only a single item per domain. For example, a single item for pain. Current evidence demonstrates minimal additional information is obtained by asking multiple questions within a domain. Additional questions contribute to unnecessary burden on patients, who may also be facing questionnaires and surveys from various other sources. It is our viewpoint that a parsimonious approach to survey questions as reflected by single item metrics is the best approach to successful implementation and adoption. As such, we also support the use of the short pain form over the long form.</p> <p>Analytic Plan</p> <p>Though the public comment period is focused on providing feedback on the measure numerator, denominator and exclusions, our review of the full measure information form (MIF) identified additional</p>

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				<p>Globally, liver cancer is the second most common cause of death from cancer (World Cancer research Fund, 2019). In 2018 worldwide, 841,000 new cases of liver cancer were diagnosed and more than 780,000 deaths reported (WHO International Agency for Research on Cancer, 2019). In the United States this year, more than 42,000 people will be diagnosed with liver cancer and more than 31,000 people will die from this disease (American Cancer Society, 2019). The National Cancer Institute estimates that there were more than 83,000 people living with liver cancer in the United States in 2016 (National Cancer Institute, 2019).</p> <p>Unlike other cancer rates that have been on the decline, liver cancer rates for new liver and intrahepatic bile duct cancer cases have been rising, and rates have more than tripled since 1980. Even worse, death rates have more than doubled since 1980 despite treatment advances and promising research (American Cancer Society, 2019). Given these increasing rates for new cases and deaths the five-year survival rate for liver cancer is only 18% (American Cancer Society, 2019). This survival rate is among the lowest for cancers in the US.</p> <p>Liver cancer impacts all racial, ethnic, gender and socioeconomic groups, but certain communities like Asian or Pacific Islander, Hispanic, Native American and African American are disproportionately affected. Additionally, conditions like obesity, hepatitis B and C, fatty liver disease and nonalcoholic steatohepatitis (NASH) are currently uncontrolled and driving greater incidence of liver cancer. All liver diseases can lead to liver cancer. Unlike most other cancers for which the causes are unknown, the cause of liver cancer is well known, is identifiable, and thus highly preventable with regular screenings, vaccinations, and treatments.</p> <p>It is liver cancer's continuous rise, health disparities, and intrinsic link to a wide range of diseases with equally valuable PROs that underline its' needed inclusion in PBGH's report. According to the American Cancer Society, 70% of liver cancer cases could be prevented. It is critical to understand the health-related quality of life (HRQOL) and pain that these patients experience to better develop response strategies and slow the rise of this life threatening cancer.</p> <p>As patients for whom a targeted response to this disease is literally a life- and-death issue, we could not be more appreciative of the opportunity to comment on this critical report. We appreciate PBGH's consideration of our request, and look forward to continuing to work together to prevent and address this life threatening disease.</p> <p>If you have any questions please don't hesitate to reach out to our Director of Policy, Andrew Scott, at ascott@globabliver.org or 831-246-1586.</p> <p>With appreciation and respect,</p> <p>Global Liver Institute</p>
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				<p>Citations</p> <ul style="list-style-type: none"> American Cancer Society . (2019). Cancer Facts and Figures 2019 . Retrieved from American Cancer Society: https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf National Cancer Institute. (2019). Cancer Stat Facts: Liver and Intrahepatic Bile Duct Cancer . Retrieved from National Cancer Institute: https://seer.cancer.gov/statfacts/html/livibd.html WHO International Agency for Research on Cancer. (2019). Cancer Today . Retrieved from World Health Organization International Agency for Research on Cancer: https://gco.iarc.fr/today/online-analysis-multi-bars?v=2018&mode=cancer&mode_population=countries&population=900&populations=900&key=total&sex=0&cancer=39&type=0&statistic=5&prevalence=0&population_group=0&ages_group%5B%5D=0&ages_group%5B%5D=17&nb_items=1 World Cancer Research Fund. (2019). Retrieved from World Cancer Research Fund: https://www.wcrf.org/dietandcancer/liver-cancer
16	January 29, 2020	Laura Thacker The James Cancer Hospital	General Comments	<p>Survey administration time points and eligibility criteria</p> <ul style="list-style-type: none"> Prospectively identifying both clinical and pathologic staging in advance of initial survey requires a manual process Identifying appropriate survey windows to receive second and third surveys is a manual process. Relying on the EMR alone doesn't account for daily changes in treatment regimens that can influence the timeframes for survey eligibility Recommend survey 2, lengthen eligibility window from 7 days to 14 days (i.e. changes in treatment, unanticipated changes in chemo end of treatment) often leave us outside the eligible window Recommend second and third surveys to measure % change. Patients are often overwhelmed at the time of diagnosis and if possible, eliminating a survey at that timeframe could benefit the patient. There is a general survey fatigue we also would like to be sensitive to where multiple ongoing initiatives are also active at our center Surveying and identifying oral chemotherapy patients is a challenge and recommend excluding these patients from the survey process
17	January 29, 2020	Same As Above	General Comments	<p>Measurement</p> <ul style="list-style-type: none"> Concern for being measured for % change in pain, and potential questions addressing mental health with common misconceptions about treating pain (and measurement of pain) with the opioid crisis. For mental health issues, many centers are faced with limited resources to treat and respond to patients in need of referral services. Concern for used in a value-based program. Collecting survey refusal reasons is burdensome and recommend excluding this data element

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