Perspective

Patient-Reported Outcome Performance Measures in Oncology

By Ethan Basch, MD, Claire Snyder, PhD, Kristen McNiff, MPH, Rebecca Brown, Suzanne Maddux, RN, Mary Lou Smith, JD, MBA, Thomas M. Atkinson, PhD, Doris Howell, PhD, RN, Anne Chiang, MD, William Wood, MD, MPH, Nathan Levitan, MD, Albert W. Wu, MD, MPH, FACP, and Monika Krzyzanowska, MD

Lineberger Cancer Center, University of North Carolina, Chapel Hill, NC; Johns Hopkins School of Medicine, Baltimore, MD; American Society of Clinical Oncology, Alexandria, VA; Research Advocacy Network, Plano, TX; Memorial Sloan Kettering Cancer Center, New York, NY; Princess Margaret Hospital, Toronto, Ontario, Canada; Yale Cancer Center, New Haven, CT; University Hospitals Seidman Cancer Center, Cleveland, OH; and Dana-Farber/Harvard Cancer Center, Boston, MA

Patient-reported outcomes (PROs) such as symptoms, quality of life, and functional status are commonly measured in cancer clinical trials,[1,2] increasingly in comparative effectiveness research,[3,4] and in routine clinical care for symptom screening and to enhance communication.[5,6] There is emerging interest in integrating PROs into the assessment of care quality.[7] Historically, patient-reported experience measures, also called satisfaction measures, have been included in performance measurement programs, for example, using the Consumer Assessment of Healthcare Providers and Systems assessment questionnaires. These measures ask patients about their experiences with providers and care delivery processes, but do not ask patients about their symptoms, functioning, or well-being. PROs reflect how people feel, but generally have not been part of performance evaluation.

Last year, the National Quality Forum (NQF), the major US organization that reviews and endorses quality metrics, assembled an expert panel to develop standards around the development of patient-reported outcome performance measures (PRO-PMs).[8] A resulting white paper described a pathway for developing such measures toward NQF endorsement,[6] and was endorsed by the International Society for Quality of Life Research.[9] Recommended steps include:

- Start with the population or health care context of interest to identify a performance concern or knowledge gap—for example, it is not well understood how effectively patients' nausea is controlled after administration of emetogenic chemotherapy in the community.
- Determine which outcomes are meaningful to patients and are changeable/actionable by providers in that context—for example, nausea control.
- Develop or identify robust PRO measures for those outcomes—for example, nausea questions from the National Cancer Institute's Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) or from the Multinational Association of Supportive Care in Cancer.
- Determine the PRO-PM—for example, the proportion of patients receiving moderately or highly emetogenic chemotherapy who report nausea that is moderate in severity or worse during the 7 days after chemotherapy.
- Conduct pilot tests in actual clinics—for example, administration of measures to a small number of patients to assess feasibility, responsiveness, score cutoffs, case mix adjustment strategies, and/or necessary sample sizes.
- Standardize interpretation and reporting guidelines—for example, specify how to share results with providers, and what thresholds to use for categorizing providers on the basis of outcomes. Identify potential interventions to improve performance, such as site educational sessions.

Building on this model, the American Society of Clinical Oncology (ASCO) Quality of Care Committee formed a workgroup to explore the development of PRO-PMs specific to oncology for integration in ASCO quality programs.

The workgroup determined two different approaches to PRO-PMs: first, outcome measurement (eg, the proportion of patients with a particular symptomatic toxicity); and second, process measurement (eg, the proportion of patients in a clinic whose self-reported symptoms were collected and reviewed at visits). Recognizing that this is a nascent field, the workgroup suggested implementation of both types of measures, but with an initial focus on outcome measures.

Two priority areas were identified through consensus. These included pain assessment among patients with bone metastases, and postchemotherapy nausea. Consistent with the NQF approach, criteria for selection of these outcomes included prevalence of the problems, known underdetection by providers despite substantial efforts, actionability, and appropriateness for patient self-reporting. Notably, clinical practice guidelines already exist in both of these areas,[10-12] with evidence that guideline adherence improves patient outcomes.[13,14] Both areas are well recognized as priorities by cancer care providers. The workgroup conducted a review of existing instruments in both areas, cataloging their characteristics and psychometric properties.

For pain assessment, the workgroup achieved consensus that the "worst pain" item from the well-established Brief Pain Inventory is the most appropriate tool for PRO measurement.[15] This item is a simple question that asks patients to report their worst pain severity over the previous 24 hours using a numerical

rating scale ranging from 0 to 10. There was consensus that the PRO-PM should assess the proportion of patients with radiographically detected metastatic disease in a given practice with worst pain ≥ 4 (a score threshold associated with clinically meaningful pain that interferes with daily activities[16]). Recent evidence reports substantial numbers of patients with pain above this threshold in routine oncology practice who might benefit from modified analgesic regimens.[17]

The second PRO-PM is the proportion of patients receiving moderately or highly emetogenic systemic cancer treatment (on the basis of ASCO and Multinational Association of Supportive Care in Cancer guideline criteria) who experience moderate or worse nausea within a week. The workgroup selected the National Cancer Institute's PRO-CTCAE nausea items to serve as the assessment instrument.[10,11] These two items ask patients to rate their worst nausea severity and frequency of nausea during the last 7 days.

Initial pilot testing will explore the feasibility of implementing these PRO-PMs and will generate information about performance of the items, necessary sample sizes, case mix adjustment, and risk adjustment strategies to produce meaningful data. The method of collecting the patient-reported information to optimize response rates is not yet established (eg, paper surveys, automated telephone interactive voice response systems, tablet computers, Web access), and it is unknown whether medical chart information about supportive medications (eg, analgesics, antiemetics) at the patient level would add information to the PRO-PM. These issues will begin to be addressed during planned ASCO pilot testing.

Beyond these initial measures, the workgroup is interested in developing oncology-specific PRO-PMs for additional symptoms or constellations of symptoms as well as functional status. More broadly, there are opportunities to use PRO measures that assess decision quality and understanding of goals of care. Some of these areas are encompassed in the development program for the new Cancer–Consumer Assessment of Healthcare Providers and Systems measurement system, which is being tested elsewhere but is of direct pertinence to ASCO and oncology practice.[18]

Use of PROs in performance evaluation is closely related to a growing interest in integrating PROs into electronic health records systems and patient portals as a part of routine clinical care. An increasing number of practices are including PROs in the workflow for care processes, particularly those addressing chronic illnesses that impact how patients feel and function.[5] Evidence demonstrates that patient reporting can improve communication, satisfaction, and symptom management.[19,20] Several large initiatives are already using patient reporting, including a province-wide initiative in Ontario that administers electronic symptom questionnaires to outpatients with cancer[21]; a Minnesota program collecting patient-reported depression scores by primary care and psychiatric practices across the state[22]; administration of a symptom and functional status questionnaire to patients enrolled in Medicare Advantage plans[23]; and a program for universal reporting of symptoms and functional status by patients in the United Kingdom after selected elective surgeries.[24]

In summary, patient self-reporting affords the opportunity to better understand the impact of care processes on how patients feel. Optimizing how patients feel is a goal of good oncology practice, and therefore is appropriate for measurement to assess quality. Use of PRO-PMs in oncology is just beginning but is likely to become more common as PROs are increasingly integrated into electronic health records, registries, and routine practice workflow.[5,25] It is hoped that using these measures to understand and improve the patient experience will lead to more patient-centered care and to better quality overall.

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Author Contributions

Conception and design: Ethan Basch, Monika K. Krzyzanowska

Administrative support: Kristen McNiff, Rebecca Brown, Suzanne E. Maddux

Collection and assembly of data: All authors

Data analysis and interpretation: Ethan Basch, Claire F. Snyder, Thomas M. Atkinson, William Wood, Albert W. Wu, Monika K. Krzyzanowska

Manuscript writing: All authors

Final approval of manuscript: All authors

Corresponding author: Ethan Basch, MD, MSc, Cancer Outcomes Research Program, Lineberger Comprehensive Cancer Center, University of North Carolina, Chapel Hill, NC 27516; e-mail: ebasch@med.unc.edu.

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