

## The Role of Patient-Reported Outcomes in Evaluating the Quality of Oncology Care

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### Abstract

The science of oncology care is rapidly developing, resulting in considerable variation in treatment patterns and disparity in the quality of care. Efforts are under way to evaluate and improve the quality of oncology care, because the goals of care have progressed beyond reducing morbidity and mortality to include maximizing functional and cognitive status, improving health-related quality of life, and preserving productivity. Traditional indicators of quality of care were based on survival outcomes or the processes of care. Although these remain important, they are inadequate for evaluating the multidimensional goals of care. Although not commonly included, patient-reported outcomes (PROs) would enhance the evaluation of the quality of care by including a patient perspective. A model for measuring quality of care that incorporates outcomes, structures, and processes of care as well as patient characteristics is proposed. Methodology including PROs that are valid, reliable, sensitive, and feasible, as well as rigorous risk adjustment methods, is critical to quality of care studies that appropriately inform decision makers.

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**R**apid development of the science of oncology care has resulted in variation in treatment patterns and disparity in the quality of oncology care. Recognition of these variations has led to efforts to evaluate and improve the quality

of care on the basis of scientific data. Patients and healthcare purchasers want to know more about the quality of care available to them.<sup>1,2</sup> In addition, clinicians and healthcare systems, such as hospitals and managed care organizations, need to have feedback on the quality of care that they provide to identify areas for improvement as well as to differentiate themselves from other institutions.<sup>3</sup> Cancer is the second leading cause of mortality, accounting for 1 in 4 deaths in the United States.<sup>4</sup> Furthermore, approximately 9 million Americans living today have had a diagnosis of cancer, with an estimated 1.2 million more to be diagnosed this year.<sup>4</sup> Many of these individuals are currently undergoing active treatment for the disease and the side effects of treatment. All of these patients require high-quality care to detect and treat recurrences and new cancers as well as to meet their supportive care needs. These factors greatly increase the challenges of allocating limited resources and reducing the escalating cost of oncology care while maintaining high quality to ensure improved patient outcomes.

Modern goals of medical care, including oncology, have progressed beyond reducing morbidity and mortality; they now include maximizing functional and cognitive status, improving quality of life, and preserving productivity.<sup>5,6</sup> Traditional measures of quality were based on disease status and survival outcomes or the processes of care (eg, adherence to treatment guidelines); although these remain important, they are inadequate for evalu-

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ating the multidimensional goals of care. Assessing the quality and impact of care from the patient's perspective is also essential. Assigning greater weight to the patient's perspective and values may result in an emphasis on treatments and technologies that improve lives, with less emphasis on extending life that lacks substantial quality for the individual.<sup>7</sup> The purpose of this article is to provide a model for quality measurement and to examine the role of patient-reported outcomes (PROs) in measuring the quality of oncology care.

### Quality of Oncology Care

Quality of care has been defined as the degree to which health services for individuals or populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.<sup>8</sup> A critical aspect of this definition is its emphasis on outcomes of care that are desired by the patients, which implies a need for assessment of outcomes from the patient's perspective.<sup>8</sup> In oncology, as in other therapeutic areas, patients differ in their preference for types of healthcare as well as the outcomes they expect from that care. Thus far in oncology, indicators of quality of care typically have included process indicators, such as adherence to treatment guidelines or outcome indicators of survival, with little or no consideration of patient perspective on quality of care.<sup>9</sup>

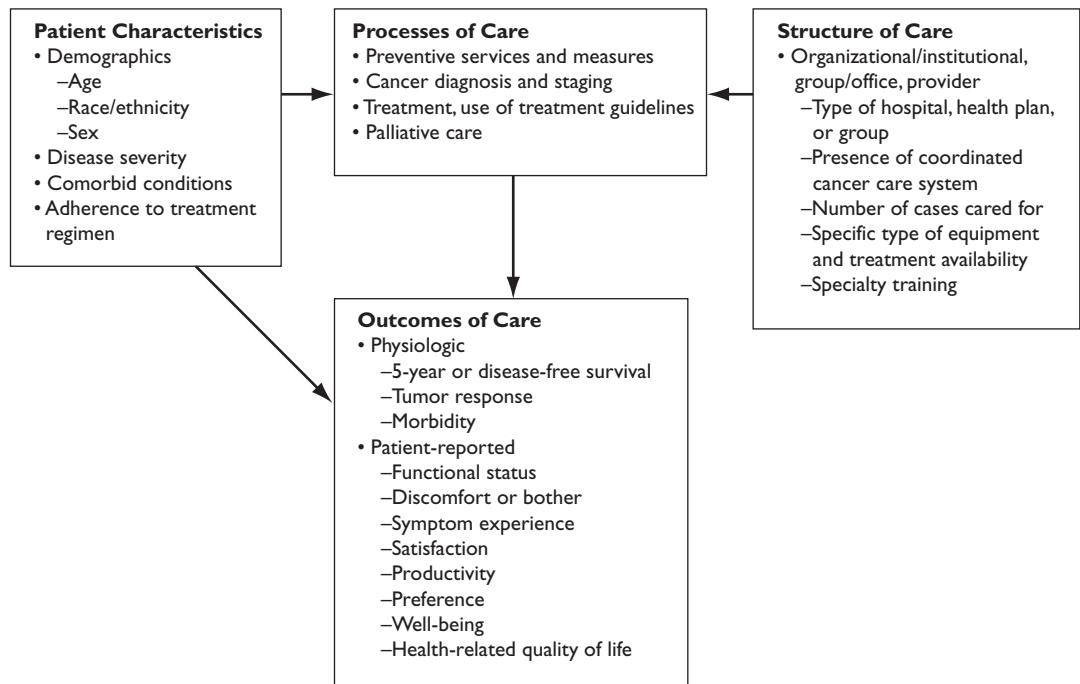
Concerns regarding inconsistency in quality of medical care recently have reached a priority level on the nation's agenda.<sup>10</sup> Moreover, the quality of oncology care as a specific national concern has been emphasized by more than a decade of National Cancer Institute (NCI)-supported research showing substantial variations in the use of proven interventions.<sup>11</sup> Many organizations have identified evaluation and improvement of the quality of oncology care as a goal, although most of these efforts are preliminary.<sup>9,12,13</sup> These organizations may choose to examine quality of care in comparison to evidence-based standards of care or variation across patient groups (eg, geographic, racial or

ethnic, and socioeconomic factors), systems of care (eg, fee-for-service versus managed care), groups of providers, individual providers, or treatment regimens.<sup>9</sup>

### Model for Measuring Quality of Care

Quality of care models are beneficial in guiding quality of care assessment and improvement efforts. In an early quality of care model, 3 major elements were characterized to link components of medical care with health outcomes: structure, process, and outcome.<sup>14</sup> This conceptual framework has provided the basis for the vast majority of efforts to assess quality of care.<sup>7,9,15</sup> An adaptation of this model, used to examine the relative importance of the burden of the patient's illness, processes of care, and structures of care in predicting outcomes in oncology, is shown in the **Figure**.<sup>9,16,17</sup> Outcomes are the end results of care, such as the changes in patient or population health status, and include both physiologic measures (eg, tumor response, treatment toxicities, 5-year survival, and disease-free survival) and patient-reported measures (eg, functional status, discomfort or bother, symptom experience, satisfaction, productivity, preference, well-being, and health-related quality of life [HRQL]). Process of care measurements encompass all that is done to and for a population of consumers and patients, such as preventive services and measures, diagnosis, treatment, and palliative end-of-life care. The structure of care involves characteristics of the healthcare system, such as the individuals and institutions providing services, as well as resources used to organize and deliver care. Within this framework, patient characteristics that are likely to influence outcomes and are independent of processes or structures of care are included for risk adjustment. Measures of risk adjustment may include severity of cancer (such as cancer stage, tumor markers, or severity of comorbidity), measures of patient adherence to treatment regimen, and demographic characteristics. Given the multitude of factors that potentially influence quality of care, identifying hypotheses that are well-grounded in a quality care model is essential. Hypotheses

**Figure.** A Model for Measurement in Quality of Oncology Care



Sources: References 9, 16, 17.

must be predefined and based on an understanding of expected response to care in terms of relationships among structures, processes, and outcomes of care. Further, the model serves to delineate structures and processes of care, which may potentially be modified to improve patient outcomes.

**Case Mix/Risk Adjustment**

Systematic differences in baseline health status, processes of care, and outcomes among a cohort of oncology patients may result, depending on the method of case identification in a quality of care assessment. Important factors in case identification include diagnostic setting (eg, outpatient screening versus inpatient admission because of undiagnosed cancer) and type of service (eg, chemotherapy, radiation, surgery). For example, the estimated 5-year survival is higher (approximately 85%) among breast cancer patients with ductal carcinoma in situ diagnosed based on mammography findings com-

pared with those diagnosed based on physical findings.<sup>9</sup> Most patients with a diagnosis made after detection of an abnormal physical finding have invasive disease, often at an advanced stage, whereas detection during mammography typically occurs at an earlier disease stage. Similarly, case identification of patients receiving chemotherapy selects for patients with more advanced disease and more aggressive treatment and excludes both those with less advanced disease and those who should have received chemotherapy but were not offered this as a treatment option. Although no single way is most correct in identifying patients with cancer for quality care evaluation, considering the potential bias of the selection method and using risk adjustment analyses to avoid erroneous conclusions regarding the quality of care are essential components of this process.

In the following sections, the pertinence of PROs in oncology, the role of PROs in quality of care evaluation, and

specific methodologic issues will be examined.

### **PROs in Oncology**

PROs provide the patient's report of a health condition and its treatment through patient-centered assessment of functional status, discomfort or bother, symptom experience, satisfaction, productivity, preference, well-being, and HRQL.<sup>18</sup> PROs capture the patient's unique voice and valuable perspective that should be integral to medical decision-making and the evaluation of treatment effectiveness. This is particularly important in the oncology setting, which includes diseases for which multiple treatment options exist<sup>19</sup> as well as diseases for which survival gains of treatment are modest and treatment toxicity is considerable.<sup>20</sup>

Although often considered soft outcomes, PROs are scientific measures that evaluate change in health outcomes.<sup>21</sup> To promote clarity and scientific rigor, PROs should be conceptualized to operate within a model or framework to guide assessment, and should be measured using reliable and valid methods. Additionally, PRO measures and responses should be appropriate to the health construct and patient population of interest. In oncology, disease-specific or domain-specific measures often are used to capture the impact of cancer and its treatment on PROs. Although data provided by the patient is inherently subjective, scientific methods for assessing subjective outcomes are well developed and provide a basis for PRO assessment.<sup>22</sup>

In oncology, curative treatment is not always possible. Various treatments to prolong survival or provide palliation may be associated with different outcomes. For example, comparative treatments may be associated with similar survival but different toxicity profiles. Alternatively, one treatment may be associated with improved survival at the cost of a severe side effect profile, whereas another treatment may offer less improvement in survival but improved or stable HRQL for the patient's remaining months or years. Although the 5-year survival rate or the

interval of disease-free survival has customarily been used to evaluate the success of oncology treatments, HRQL and other PROs are increasingly included as outcomes in oncology clinical trials.<sup>23</sup> Approximately 20% of current NCI-sponsored phase II and III trials include HRQL end points.<sup>11</sup>

PRO data have influenced oncology care in a variety of ways, especially in relation to symptom control, supportive and palliative care, and cancer with poor prognosis.<sup>24</sup> PRO data have enlightened decisions about the superiority of treatment options by providing a more comprehensive view of the impact of a treatment than was afforded by safety and efficacy data alone. In addition, PRO data have clarified the effects of treatment toxicity from the patient's perspective. Moreover, HRQL data have been demonstrated to be a stronger predictor of survival than other clinical measures, such as performance status.<sup>25,26</sup> Clearly, the assessment and interpretation of PROs makes an important contribution to the care of patients with cancer.<sup>24</sup> Decisions related to oncology treatment and evaluation of the effectiveness of such treatment should be based on PRO considerations as well as expected impact on survival and disease status.

### **PROs in Quality of Oncology Care Measurement**

Outcomes measurement is central to the model of quality of oncology care. Although outcome indicators of survival commonly have been used in evaluating the quality of care, using survival as the sole outcome of care has disadvantages.<sup>27</sup> For early stage disease or curable cancer, death soon after the care episode is rare and, conversely, for advanced stage disease such as malignancy, death may be an expected outcome; both of these suggest that survival indicators may be insensitive to differences in quality of care. Although survival as a sole outcome of care is insufficient, PROs have not been commonly used as indicators of quality of oncology care.

While recommending improvements in Medicare subsidized care, some authors

advocate increased attention to broad health outcomes and PROs, including HRQL, patient satisfaction, and well-being, in the evaluation and improvement of quality of care.<sup>8</sup> Similarly, institution of a patient-centered approach to care was among 6 specific aims to improve the quality of care in a recent report that called for major restructuring of the American healthcare system.<sup>10</sup> Assessment of PROs is an essential component in the evaluation of the quality of care that is patient-centered and focused on the patient's experience of illness and healthcare as well as the systems that work or fail to meet individual patients' needs.

Significant improvements in HRQL and symptom experience have been demonstrated after palliative treatment in cancer.<sup>28</sup> After risk adjustment, aggregate level HRQL and symptom experience outcomes would be expected to be better among those receiving higher quality care compared with those receiving suboptimal care. For example, a group of patients who received optimal treatment according to the National Comprehensive Cancer Network Palliative Care Treatment Guidelines would be expected to receive higher quality care in terms of better pain and other symptom management compared with an otherwise similar group of patients who received treatment that did not focus on palliative care, even though survival rates may be similar for the 2 groups.<sup>29</sup> This hypothetical example demonstrates that inclusion of PRO measures, such as symptom experience, in addition to physiologic measures, such as survival, would enhance the evaluation of the quality of palliative oncology care by providing the patient's perspective.

#### **Methodological Issues**

Several key issues should be considered before the use of a PRO for monitoring the quality of care.<sup>30-31</sup> First, an established relationship must exist between the PRO and the process of care. PROs do not directly assess the quality of care provided but do allow an inference about the quality of the process of care. If outcomes are positive, an appropriate inference would

be that care was more likely to have been high quality than not. The degree of confidence in the inference depends on the strength of the predetermined causal relationship between process and outcome. If the relationship is strong, more confidence can be placed in the inference about quality. Such a relationship can only be shown with PRO measures that are valid, reliable, and sensitive to change over time to detect variations on the processes of care as well as being able to discriminate between groups of patients with similar disease characteristics receiving different quality of care.

Secondly, the impact of cancer, treatment, and rates of adverse events may differ by group because of variations in pathophysiology or other factors unrelated to the quality of care provided. Because the relationship between process and outcome of care is modified by factors other than healthcare, corrections must be made for the effects of these factors by risk adjustment, case-mix standardization, or other means. These modifying factors are an important reason that the use of outcomes, without concurrent assessment of process, can be very misleading as indicators of quality of care.<sup>32</sup> Confidence in inferences from outcomes improves when analyses have been adjusted for these factors. Although methodology has advanced, current methods of case-mix standardization are inadequate to allow for conclusions about quality solely on the basis of outcomes.<sup>30,32</sup>

Other methodological issues to be considered include incomplete PRO data with mortality, divergence between physiologic outcomes and PROs, and the multidimensional nature of PROs, such as HRQL. In oncology, when survival is limited, PRO data may not be available for deceased patients. Plans for dealing with missing PRO data should be established a priori. In addition, although inclusion of both physiologic and PRO measures provides a more comprehensive evaluation that incorporates the patient's perspective of the quality of care, divergence between physiologic outcomes and PROs may occur. However, this divergence may

be acceptable because the 2 types of outcomes measure different constructs. For example, care may include a treatment with toxic side effects and simultaneous deterioration in HRQL and combined with extended survival. HRQL may not always parallel survival or other physiologic outcomes, and in many cases, it does not. Finally, the multidimensional nature of PROs, such as HRQL, must be considered when measured as outcomes to evaluate the quality of care. Many factors other than quality of care may influence HRQL outcomes. Improved HRQL may reflect improved quality of care, but the reverse is not necessarily true.<sup>33</sup> HRQL may remain stable or even decline despite high-quality care. These issues should be addressed in quality of care evaluation.

### Conclusion

Evaluation and improvement of the quality of oncology care is a national priority. The traditional approach of using process indicators or survival and disease status measures to evaluate quality does not adequately address the multidimensional goals of care. A quality of care model that includes patient characteristics and processes and structures of care to predict outcomes of care is proposed. The inclusion of PROs in the model is essential to ensure the model evaluates the quality of care from a multidimensional view with value placed on the patient perspective. Methodology must include PROs that are valid, reliable, sensitive, and feasible, as well as rigorous risk adjustment methods for use in quality of care studies, if these studies are to appropriately inform decision makers.

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