Clinical Trial Information As a Measure of Quality Cancer Care

By Wei Chua, MBBS, and Stephen J. Clarke, MBBS, PhD

Department of Medical Oncology, Sydney Cancer Centre, Concord Repatriation General Hospital, Sydney, New South Wales, Australia

There is an increasing need to develop and improve quality indicators in oncology. Recent initiatives to improve the quality of care of patients with cancer have included the National Initiative on Cancer Care Quality promoted by ASCO and the Quality Oncology Practice Initiative, a practice-based system of quality self-assessment sponsored by the participants and ASCO, the results of which have been presented in *Journal of Oncology Practice*.¹⁻³ In colorectal cancer (CRC), the Duke Evidence-Based Practice Center (Duke University School of Medicine, Durham, NC) prepared a comprehensive report to identify measures currently available to assess the quality of care provided to patients with CRC and the extent to which these measures had been developed and tested.⁴ Examples of well-developed measures included the percentage of patients who underwent appropriate evaluation for a positive fecal occult blood test and adequate lymph node retrieval at surgery. Quality measures in medical oncology were lacking, particularly those used to assess use of palliative chemotherapy for patients with stage IV CRC.

Clinical trial units should be an integral part of cancer centers. Participation in clinical trials enables patients to access new treatment options; there is increasing evidence of improved patient outcomes from participation in clinical trials compared with noninvolved patients in non-small-cell lung, breast, colorectal, and testicular cancers.⁵⁻⁹ Recently, ASCO described both minimum requirements for a site conducting quality clinical trials and attributes of exemplary sites as a guide to oncologists wishing to conduct high-quality research programs that comply with the International Conference and Harmonisation Good Clinical Practice Guidelines.¹⁰ Consensus statements by ASCO, the American Federation of Oncological Services, and the European Society for Medical Oncology have listed patient access and opportunity to participate in relevant clinical trials as basic requirements of quality cancer care.^{11,12} In Australia, the National Health and Medical Research Council guidelines for the prevention, early detection, and management of CRC recommend that eligible patients consider participation in appropriate clinical trials.¹³ However, a survey on chemotherapy management in Australia found that 46% of patients treated by medical oncologists were not taking part in any trial, 12% were considered to be eligible for a trial, and only 8% were participating in one.¹⁴ High accrual activity to clinical trials has been used as an example of a goal of an exemplary clinical research site, with the recommendation to accrue at least 10% of patients to clinical trials.¹⁴

The recognition of the importance of clinical trial participation coupled with the need for appropriate quality indicators in medical oncology makes clinical trial activity an attractive option as a performance indicator. We propose that information from a clinical trial unit in an individual cancer center may be used in a manner that is useful to reflect the quality of care available. Response rates and survival are often the main efficacy end points in cancer chemotherapy trials; however, their use as quality indicators would be problematic because of heterogeneity and variability in clinical trials.

Appropriate measures that may allow for some degree of comparison among units include the quality measure domains of (1) number and type of clinical trials available, (2) patient enrollment onto clinical trials, (3) initial therapeutic management, (4) patient preference and inclusion in decision making, and (5) management of treatment toxicity. These have been previously identified by the National Initiative on Cancer Care Quality.² As an example, the type of clinical trials available may be categorized as biomarker, early- or late-phase drug development, or nonpharmaceutical quality-of-life trials and subclassified according to tumor type. It is not feasible for each cancer site to have active clinical trials in each of these categories, and differences in practice site, patient mix, and demographics should be taken into account. However, it would not be unreasonable to compare the number of first-line phase III randomized clinical trials available to patients in two cancer centers serving similar population sizes with similar resources. Other measure domains, such as the number of patients enrolled onto clinical trials against the total number of new patients in a specified period, may provide a crude estimate of the functioning of a clinical trial unit. However, not all patients meet the strict inclusion criteria of clinical trials, and more sophisticated measures may be necessary. As an example, the number of patients enrolled onto clinical trials (numerator) against those eligible for participation in one (denominator) may provide a better indicator of the activity of a clinical trial unit. In addition, documentation of toxicity management for patients enrolled onto clinical trials, including grade 3 or 4 severe toxicities, and number and length of hospitalizations secondary to toxicity for similar phase III trials may be other examples.

In summary, we propose use of clinical trial information and suggest aspects of this that may serve as quality indicators in medical oncology. The quality measures proposed are not exhaustive and require refinement; some of them may be inappropriate depending on local practices and health service delivery.

However, the concept presented is hypothesis generating. We are optimistic that this novel concept may stimulate healthy and open debate toward using clinical trial information for standard comparisons among cancer units to improve cancer care delivery. There is an increasing need for greater accountability and improvement of care in medical oncology, and development of such quality indicators is necessary. More controversially, it may be argued that public reporting of such performance indicators will be of even greater importance in the future as both public and private payment systems continue to develop.

Accepted for publication on March 24, 2010.

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Authors' Disclosures of Potential Conflicts of Interest

The authors indicated no potential conflicts of interest.

Author Contributions

Conception and design: Wei Chua, Stephen J. Clarke

Collection and assembly of data: Wei Chua, Stephen J. Clarke

Data analysis and interpretation: Wei Chua, Stephen J. Clarke

Manuscript writing: Wei Chua, Stephen J. Clarke

Final approval of manuscript: Wei Chua, Stephen J. Clarke

DOI: 10.1200/JOP.091099

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