Measuring and Improving Quality of Care in an Academic Medical Center

By Douglas W. Blayney, MD

Stanford Cancer Institute, Stanford School of Medicine, Stanford, CA

The Three-Part Mission of Academic Medical Centers

The tripartite missions of an academic medical center (AMC; research, teaching, and patient care) present special challenges to measuring and improving quality cancer care, as discussed in the series overview.¹ For example, research quality, which is used for faculty evaluation and promotion, is measured by external funding and by publication. Training quality is measured by the Accrediting Council on Graduate Medical Education, feedback from trainees, and the positions trainees hold after graduation. The quality of provided patient care is usually assumed by academic physicians and leaders, but this field is the least mature in formal measurement methods.

Physicians are attracted to practice at an AMC by a desire to contribute to the mission in varying, complex, and sometimes conflicting roles. Leaders of academic medical practices need to balance the perceptions of conflict among the basic, translational, or clinical research mission, the teaching mission, and the patient care mission to deliver quality patient care. I illustrate some principles and lessons that I have developed in leadership roles in both academic and community oncology practice.

Definition of Quality Care

The construct developed by Avaris Donabedian is useful as a definition of quality of care for patients with cancer.² His paradigm includes structure, processes, and outcomes. The structure (as well as the infrastructure, particularly the informatics infrastructure) where the care is delivered should facilitate safe, quality care. There should be adherence to correct care processes. Outcomes should be appropriate and measureable.

Outcome measures: Survival and intermediate outcome measures. Survival is the most important outcome measure in cancer care. However, measuring and improving survival presents several practical problems, including the long interval between an intervention and the ability to observe its effect and reporting biases.

Cure and long-term survival is most desired by patients, and is probably the best and most valued of outcomes discussed by Donabedian²: recovery, restoration of function, and survival. However, in a chronic disease such as cancer, survival duration after a treatment intervention is usually measured in years. This long timeline makes it difficult to plan and measure quality improvement interventions on the basis of survival.

Survival data produced by single institutions are loaded with potential bias. Biases that might artificially inflate survival include differences in cancer screening methods used, the underlying health of patients referred to one center compared with another, the rigor of staging applied, and the willingness to publically release the results.³ Perioperative mortality is a commonly collected measure of intermediate outcome. Other intermediate outcomes have been proposed, but as yet, they are not widely collected nor publically shared.⁴ Adoption of social media tools by patients may facilitate patient reporting of intermediate outcomes, but this is a topic beyond the scope of this discussion.

Measures of process adherence. As applied to potentially fatal cancers, for which the outcome of major interest (cure and long-term survival) requires a long time to measure, most quality improvement efforts focus on adherence to process. Health care processes are a set of repeatable, value-creating activities subject to improvement.⁵ Measures of process adherence are useful to identify quality gaps and to measure the efficacy of a quality improvement intervention. We assume that a process of care (eg, adjuvant hormonal therapy for early-stage, hormonal responsive breast cancer)—when established by high-quality clinical trial evidence, a care guideline with a high level of evidence, or broad consensus, and applied to an individual patient—will eventually result in a good outcome for the patient.

The evidence base to guide oncology treatment choices is relatively strong. Randomized clinical trials, which test the effect on patient survival of one treatment compared with another, can guide decisions. Further, US Food and Drug Administration approval of drugs for marketing is available to guide decision making. Both sets of evidence (clinical trial results and US Food and Drug Administration approval) are often synthesized into treatment guidelines and, more recently, into clinical pathways. Measuring adherence to guidelines and adherence to treatment pathways is one of the first steps in quality improvement activities.

High-level process adherence measures. Current process adherence measures are designed to detect underuse of a treatment (Fig 1, measure 71: adjuvant chemotherapy recommended within 9 months of diagnosis for patients with American Joint Committee on Cancer stage II or III rectal cancer) or overuse of a therapy. For instance, overuse is administration of an expensive monoclonal antibody therapy in a situation in which it is not likely to be helpful (Fig 1, measure 75:

Figure 1. Adherence to processes of care at the Stanford Cancer Institute (SCI) on colon cancer measures developed by the Quality Oncology Practice Initiative (QOPI) of the American Society of Clinical Oncology.⁸ The blue bars represent performance at SCI. The gold bars represent an aggregate of QOPI-participating AMCs. The green bars represent adherence at all QOPI participating sites in spring of 2012. Measures: 66, carcinoembryonic antigen within 4 months of curative resection for colorectal cancer; 67, adjuvant chemotherapy recommended within 4 months of diagnosis for patients with American Joint Commission on Cancer (AJCC) stage III colon cancer; 68, adjuvant chemotherapy received within 4 months of diagnosis by patients with AJCC stage III colon cancer; 69, number of lymph nodes documented for resected colon cancer; 70, 12 or more lymph nodes examined for resected colon cancer; 71, adjuvant chemotherapy recommended within 9 months of diagnosis for patients with AJCC stage II or III rectal cancer; 72, adjuvant chemotherapy received within 9 months of diagnosis by patients with AJCC stage II or III rectal cancer; 73, colonoscopy before or within 6 months of curative colorectal resection or completion of primary adjuvant chemotherapy; 74, *KRAS* testing for patients with metastatic colorectal cancer who received anti-epidermal growth factor receptor (EGFR) monoclonal antibody (MoAb) therapy; 75, anti-EGFR MoAb therapy received by patients with *KRAS* mutation (lower score = better); 75a, anti-EGFR MoAb therapy not received by patients with *KRAS* mutation (inverse of measure 75).

anti-epidermal growth factor receptor monoclonal antibody therapy received by patients with *KRAS* mutation]. Early measurements of process adherence found that between 78% to 86% percent of patients received the recommended treatment for colon and breast cancer, although there was wide variation.⁶ Subsequent measurements in a voluntary program of the American Society of Clinical Oncology (ASCO), the Quality Oncology Practice Initiative (QOPI), suggest that adherence to recommended anticancer care measures is much higher, exceeding 90%. There is likely little room for improvement, either in the academic or community practice setting, in these high-level measures of treatment process adherence.^{7,8} However, adherence to processes of supportive, palliative, and end-of-life care can be improved.

Structure and infrastructure. Systems to evaluate the care infrastructure in a hospital setting (which covers most AMCs) are overseen by the joint commission or by the Centers for Medicare and Medicaid Services. These oversight bodies address safety of the physical structure, staff credentialing, and safety

procedures that apply to both inpatient and outpatient settings. A more relevant and detailed medical oncology specific program is offered by ASCO's QOPI certification program. QOPI certification addresses chemotherapy administration-specific structures and is appropriate for both hospital-based and free-standing chemotherapy administration sites.⁹

Quality Measurement and Improvement at the Physician, Practice, and Statewide Levels

Individual physician-level change. Improvement in some process adherence measures, particularly those dependent on the treatment choices made by individual physicians, are amenable to change after showing physicians their performance data. This is known as the Hawthorne effect, which is "the phenomenon in which subjects in behavioral studies change their performance in response to being observed."^{10(p9)} One example of this effect is the change in end-of-life care, particularly chemotherapy administration in the last 2 weeks of life at the University of Michigan Cancer Center.⁷ After oncologists were shown that their rate of chemotherapy administration was almost three times the rate in a benchmark group, their administration subsequently decreased to align with the external benchmark.

Practice-level-change. Because oncology care is delivered by a multidisciplinary team (eg, medical, surgery, radiation oncology, and palliative care) and providers with differing training and skillsets (eg, physicians, nurse practitioners, physician assistants, and various nursing specialties), improving quality usually requires more organized and complex interventions involving the whole team. These interventions draw upon experience in nonmedical industries, such as manufacturing and air transportation. Manufacturing analogies draw from the Toyota Production System, often known by the shorthand of "lean production."^{11,12} Air transportation, which has developed methods to achieve a focus on safety, provides lessons on standardization of practice and checklists,¹³ nonpunitive reporting of so-called near misses or other unsafe practices, and models for highly trained professionals to work together to solve unexpected problems.¹⁴

Lean methodology aims to reduce waste. Some principles include agreement on standard work (which reduces unnecessary variation), designing systems so that each participant (nurse, nurse practitioner, physician) functions at the highest level of his or her clinical skills and licensure, off-loading non-clinical or clerical tasks to clerical workers, eliminating rework, empowering frontline workers to make changes, and a relentless focus on measurement: "When you can measure what you are speaking about...you know something about it."^{15(p418)}

Many of the lessons from change management are applicable to the AMC. At both the University of Michigan and Stanford, we have embraced the practices of lean management, including establishing metrics for project success, waste reduction, and the addition of value at every step of the process. A useful start for a lean project is formulating the charter as an A3.¹¹ An example is shown in Appendix Figure A1. Typically, the A3 presents the members of the team, a statement articulating the

background and importance of the problem, a problem analysis (including an analysis of the present state), the goals of the improvement project, the measures upon which progress is judged, the desired future state, and the implementation plan with incremental goals and a timeline. Because the document is dynamic and changes as incremental goals are achieved, date and version number are included on the document.

A clearly defined goal that is achievable and is identified by gaps in key quality measures is an important next step. ASCO's QOPI, as well as those programs provided by the University Health Consortium, are useful measurement and benchmarking tools. When setting goals for process adherence, it is important to remember that we are dealing with biologic systems and normal biologic variation. When dealing with decision making with patients with cancer, it is unrealistic to set a process adherence goal of 100%.

Nex, a project assembles a team of people who actually do the work. The team should have an administrative sponsor (often a senior physician or administrative leader) and be facilitated by a process excellence-, performance improvement-, or other dedicated facilitator with lean training. A useful first step is construction of a value stream map, in which every step of a process, the contributors to the process, the process times, and the waiting times are mapped out by the team. This map often takes 1 to 2 days of dedicated time for a team to create.

Constructing countermeasures and assigning responsibility to small teams for each improvement step is dictated by the barriers identified in the construction of the A3 document. Deadlines for when each step is to be completed, for development of success measures, for eliminating unnecessary process steps, and for reducing unnecessary variation and waste at each process step are the focus of each process improvement team.

The team should use a pilot site for initial changes. Implementation at small pilot sites usually uncovers unanticipated problems. Data that measure the impact of these changes should be reflected on the project's A3 and the countermeasures modified to address the problems. Pilot studies are useful to reduce unanticipated risks before a center- or institution-wide roll out of the change.

Information technology challenges often emerge as unanticipated barriers. It is important to recognize that our supporting information technology tools—including patient appointment and scheduling, physician record keeping tools (ie, the electronic health record), and the reporting and analytic tools—are inter-related and often complex to modify. Paper-based workarounds may be necessary during the pilot phase of the project to move forward. The team should anticipate the complexity of modifying the electronic health record and plan for it.

Finally, understand that measures to sustain the improvements brought about by pilot changes should be incorporated from the outset. The pilot project teams should develop a plan for rolling changes out across the organization. A successful pilot project that is allowed to persist only in isolation within a larger organization is a failure. A necessary countermeasure for this step is engagement of senior organizational leadership from

the outset. Many senior leaders or managers either establish performance bonus or other financial incentives, and these can be partially tied to successful organizational roll-outs and maintenance of measureable performance targets. Again, measurements can signal when the invariable deviations occur and when existing countermeasures need to be activated or new countermeasures devised.

Statewide or network-wide quality improvement programs. AMCs are acquiring existing medical practices or are establishing satellite patient care sites. There are a variety of reasons for these expansions, including furtherance of the academic missions of extending clinical research sites, exposure for trainees to alternative practice venues, and expansion or growth of the business. Monitoring the quality of care provided at these remote sites and protecting the carefully nurtured AMC brand will be a challenge. Others have described their approaches, and my colleagues at the University of Michigan describe our approach to a more loosely affiliated statewide quality consortium, which uses QOPI as measurement.¹⁶

Summary

The Donabedian² definition of quality—structure, process, and outcome—provides a useful framework. A relentless focus on measuring process adherence and outcome is critical. Systemic improvements usually require teams to plan and to implement them. The lean or Toyota production system for process improvement is one useful method of organizing work, although different approaches are often necessary at the physician, practice unit, and statewide level. Challenges include scalability of the change (ie, rolling them out across the institution or system), tailoring the information technology tools, and building systems for sustainability.

Acknowledgment

Supported by the Ann and John Doerr endowment of the Stanford Cancer Center Medical Director at the Stanford Cancer Institute, Stanford University School of Medicine.

Presented in part at the ASCO Quality Care Symposium, San Diego, CA, November 30-December 1, 2012.

Author's Disclosures of Potential Conflicts of Interest

Although all authors completed the disclosure declaration, the following author(s) and/or an author's immediate family member(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a "U" are those for which no compensation was received; those relationships marked with a "C" were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

Employment or Leadership Position: Douglas W. Blayney, Stanford Cancer Center (C) **Consultant or Advisory Role:** Douglas W. Blayney, United Healthcare (C), National Oncology Consultants (C), Bristol-Myers Squibb (C), Astellus Pharmaceuticals (C), Celgene (C), Xcenda Pharmaceuticals (C) **Stock Ownership:** Douglas W. Blayney, Abbvie, Abbott Laboratories, Autodesk, Citrix Systems, EMC Corp, Google, International Business Machine, Oracle Corporation, QUALCOMM, Amgen, Bristol-Myers Squibb, Covidien, Express Scripts Hldg,

Johnson & Johnson, UnitedHealth Group, Apple, Automatic Data Processing **Honoraria:** Douglas W. Blayney, American Society of Clinical Oncology, University of Michigan, Saudi Cancer Foundation **Research Funding:** Douglas W. Blayney, Blue Cross Blue Shield of Michigan **Expert Testimony:** None **Other Remuneration:** None

Corresponding author: Douglas W. Blayney, MD, Ann and John Doerr Medical Director, Stanford Cancer Institute, Professor of Medicine,

Stanford School of Medicine, Associate Division Chief of Medical Oncology, 875 Blake Wilbur Dr, CC 2213, MC 5827, Stanford, CA 94305-5827; e-mail: dblayney@stanford.edu.

DOI: 10.1200/JOP.2013.000991

References

1. Krzyzanowska MK: Models that work: Incorporating quality principles in different clinical settings. *J Oncol Pract* 9:135-137, 2013
2. Donabedian A: The quality of care: How can it be assessed? *JAMA* 260:1743-1748, 1988
3. Berry DA: Comparing survival outcomes across centers: Biases galore. *Cancer Lett* 37:7-10, 2011
4. Porter ME: What is value in health care? *New Engl J Med* 363:2477-2481, 2010
5. Bergman B, Neuhauser D, Provost L: Five main processes in healthcare: A citizen perspective. *BMJ Qual Saf* 20:140-142, 2010 (suppl 1)
6. Malin JL, Schneider EC, Epstein AM, et al: Results of the National Initiative for Cancer Care Quality: How can we improve the quality of cancer care in the United States? *J Clin Oncol* 24:626-634, 2006
7. Blayney DW, McNiff K, Hanauer D, et al: Implementation of the Quality Oncology Practice Initiative at a university comprehensive cancer center. *J Clin Oncol* 27:3802-3807, 2009
8. Neuss MN, Malin JL, Chan S, et al: Measuring the improving quality of outpatient care in medical oncology practices in the United States. *J Clin Oncol* 31:1471-1477, 2013
9. McNiff KK, Bonelli KR, Jacobson JO: Quality Oncology Practice Initiative certification program: Overview, measure scoring methodology, and site assessment standards. *J Oncol Pract* 5:270-276, 2009
10. The Human Relations Movement: Harvard Business School and the Hawthorne experiments. <http://www.library.hbs.edu/hc/hawthorne/>
11. Liker JK, Meier D: *The Toyota Way: Management Principles and Fieldbook*. New York, NY, McGraw-Hill, 2004, pp 27-34, 244-248, 2004
12. Toussaint J, Gerard RA: Action plan, in Toussaint J, Gerard RA: *On the Mend: Revolutionizing Healthcare to Save Lives and Transform the Industry*. Cambridge, MA, Lean Enterprise Institute, 2012, pp 138-155
13. Pronovost P, Needham D, Berenholtz S, et al: An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med* 355:2725-2732, 2006
14. Helmreich RL: On error management: Lessons from aviation. *BMJ* 320:781-785, 2000
15. Kelvin LWT: Electrical units of measurement, in Shapiro FR (ed): *The Yale Book of Quotations*. New Haven, CT, Yale University Press, 2006, p 418
16. Smerage JB, Abtoss K, Severson J, et al: Effect of intervention on quality measures of symptom management in the Michigan Oncology Quality Consortium (MOQC). *J Clin Oncol* 30, 2012 (abstr 70). <http://meetinglibrary.asco.org/content/104221-126>

Appendix