Problems With Public Reporting of Cancer Quality Outcomes Data

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Background: Why Are Comparative Outcome Data in Cancer Important Now?

Measuring and comparing outcomes among patients with cancer undergoing treatment in different care settings is an increasingly important component of quality of care improvement and reimbursement reform in the United States. Beginning in 1982, most hospital inpatient care for Medicare beneficiaries was paid on the basis of a Diagnosis Related Group–based Prospective Payment System (PPS). Diagnosis Related Groups are classifications of human diseases based on the affected organ system, the procedure performed on the patient, morbidity, sex of the patient, and indicated treatments. Under this system, the Centers for Medicare and Medicaid Services (CMS) pays hospitals a flat rate per case for inpatient hospital care based on facility averages. Thus, efficient hospitals are rewarded, and other hospitals have an incentive to become more efficient.¹

Many National Cancer Institute (NCI)-designated cancer centers were and remain exempt from the PPS. Facilities excluded from PPS receive payment based on a cost (rather than diagnosis) “allowable” methodology, which is meant to reflect actual operating costs. Although Congress intended the PPS exemption to be a temporary measure pending development of a more appropriate PPS for specialty hospitals, periodic considerations of alternative methods to restrain spending growth on inpatient specialty care have not altered this policy.

To retain the exemption, these PPS-exempt NCI-designated cancer centers have sought to demonstrate that they produce better patient outcomes than community centers. The National Comprehensive Cancer Network (NCCN), a coalition of free-standing NCI-designated cancer centers, sought to collect and publish cross-institutional comparative outcomes data two decades ago. However, NCCN was unable to generate data comparing outcomes for all participating institutions and all cancers. Comparison with community clinics was not feasible, either. Instead, data were generated for several cancers. Recently, NCCN’s support for this effort has ended.

Today, the need for valid, reliable and comparable outcomes data among cancer centers and outpatient oncology practices is made urgent under provisions of the Patient Protection and Affordable Care Act, the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act),² and the Taxpayer Relief Act of 2012. The Secretary for Health and Human Services is required to report the “quality measures of process, structure, outcome, patients’ perspective on care, efficiency, and costs of care” among cancer centers

via the PPS-exempt Cancer Hospital Quality Reporting (PCHQR) program. In the release of the final 2014 inpatient payment rule,³ CMS is requiring these centers to report on 14 measures starting in 2015. The Taxpayer Relief Act requires all providers practicing in the outpatient setting to report quality measures collected under the Physician Quality Reporting Initiative (PQRS) for at least 50% of patients in 2014. There are more than 100 quality metrics required under PQRS, and six focus on cancer care.

The PCHQR requirements represent a dramatic shift in paradigm for cancer centers.^{4,5} The expansion of required measures in the PCHQR program is significant because CMS is thought to be using the PPS-exempt cancer hospital cohort as a pilot group.^{6,7} The expectation is that these measures will eventually be rolled out to all cancer centers and tied to payment using PPS methodology.

The PQRS requirements also represent a substantial shift in incentives for oncologists. Failure to meet the reporting requirements or minimum performance criteria entails 1.5% to 2% penalties on outpatient physician reimbursement. Public reporting of all PQRS metrics for comparative purposes commences in 2015.

Efforts are underway by the ASCO Costs of Cancer Care Task Force⁸ and US Oncology’s Innovent Pathways program,⁹ among others, to expand metrics for assessing outpatient cancer treatment quality delivered in the outpatient setting across many more cancers.

Comparative Quality Metrics and Their Discontents

This recent activity belies a simple fact: in cancer there are lots of metrics, but no settled-on methodology for measuring treatment performance and comparing treatment outcomes between institutions, care settings, or providers. To illustrate, we consider the use of the “hard” measure, survival conditional on treatment initiation for a cancer diagnosis. This metric is considered by many to be the gold standard for comparing outcomes in phase III randomized clinical trials required for drug approval.

Random assignment of patients across care settings to measure comparative survival is generally infeasible. It is when comparative survival measures are constructed using clinical data derived from observational data that problems can arise. Consider a single-arm study completed by William Peters,¹⁰ suggesting that survival was significantly higher among patients with breast cancer who received bone marrow transplantation

(BMT) than among other similar patients treated in three Cancer and Leukemia Group B (CALGB) adjuvant trials. We quote the trial's results: "Actuarial event-free survival for the study patients at a median follow-up of 2.5 years is 72%. Comparison to three historical or concurrent CALGB adjuvant chemotherapy trials selected for similar patients showed event-free survival at 2.5 years to be between 38% and 52%." Furthermore, "quality-of-life evaluations indicate that patients are functioning well without major impairments." Likely, these findings induced many women to choose BMT over standard chemotherapy. Yet, when randomized trials were completed, none demonstrated survival advantages for subjects assigned to the BMT arm.

For many years, researchers have worried about biases in comparative outcome studies across settings using observational data. The worry centers on two related concerns. Outcomes of interest between settings can vary considerably as a result of initial subject selection and treatment intensity conditional on selection. Donald Berry, a biostatistician at MD Anderson Cancer Center, wrote a guest editorial for *The Cancer Letter* that explained the problem with comparing outcomes in cancer related to selection biases¹¹: Academic cancer centers typically treat more advanced cases. This should drive down their survival statistics. On the other hand, academic centers get better-insured patients who are more likely to have primary care physicians back home. This should result in them being diagnosed with cancer earlier, driving up survival statistics. Plus, patients have to be healthy enough to travel.

Revisiting the Peters article, higher survival for patients who received BMT was likely seen because transplanters were more thorough in staging candidates. Patients who were candidates for BMT were subjected to pretreatment bone marrow biopsies, a procedure which is not part of non-BMT clinical trial eligibility. A positive bone marrow biopsy containing occult cancer—which portends a worse survival—would exclude the patient from the treatment cohort, and consequently bias the BMT treatment cohort toward better survival.

Analytic Methods for Addressing Patient Selection and Treatment Intensity Biases

To mitigate patient selection and treatment intensity biases, most well-developed comparative "report cards" apply risk adjustment methods based on observable patient and clinical criteria, and the availability of certain technology or expertise to treat specific conditions.¹² For example, risk adjustment methods are used to construct New York and other state efforts to compare mortality rates after coronary artery bypass graft surgery across hospitals and surgeons.¹³ Others have noted that subtle unmeasured factors undoubtedly influence how patients are matched with providers.¹⁴ Instrumental variable techniques have been developed to "induce" randomization in the selection of patients into providers related to unobserved rationales.¹⁵⁻¹⁹ For cancers treated in the inpatient setting, the construction of risk-adjusted outcomes has been aided by the availability of data linking Medicare claims with other clinical data, including that provided by the SEER program.²⁰⁻²³

Yet, patient selection into outpatient-based treatment on the basis of cancer stage, line of therapy, and comorbidities may not be completely observed by an analyst when constructing comparative outcome measurements from claims data. Existing data availability limitations may simply inhibit progress on risk-adjusted comparative outcome development among nonelderly patients with cancer absent from Medicare claims.^{24,25}

Furthermore, modeling prognostic outcome correlates requires consensus on treatment for a given patient, inclusive of stage and possible line of therapy. Thus, progress on risk-adjusted outcome measurement in the near future will likely center on cancers for which treatment and patient selection follow established guidelines. Conversely, progress on risk-adjusted measurement may be slow or nonexistent among cancers for which adequate treatment and patient selection remain a topic of substantial experimentation.

A Big Problem: Identifying Unique Providers

The construction of comparative outcome measures also presumes identifiable and unique providers. Yet, the task of defining unique providers is increasingly and particularly problematic in the delivery of cancer care where consolidation has rapidly occurred.²⁶⁻²⁸ A recent report by Towle et al (2012) suggests that the share of physician-owned private practices in oncology declined 10% between 2010 and 2011, and that merger and acquisition activities between community oncology groups, hospitals, and large provider groups have increased substantially. There is also a flurry of cancer care center "affiliations" occurring nationwide. In 2013, *The Cancer Letter* reported that Memorial Sloan-Kettering Cancer Center was forming an affiliation with Hartford HealthCare and intends to seek additional affiliations.³¹ Georgetown Lombardi Comprehensive Cancer Center and Hackensack University Medical Center John Theurer Cancer Center also recently announced plans to affiliate, aiming to create a single NCI-designated consortium cancer center.³²

These activities can shift patterns of cancer care quite dramatically and in a limited time frame, making it hard to assign treatment to a given provider. For example, according to one estimate, between 2005 and 2011, the amount of chemotherapy infused in community doctor offices decreased from 87% to 67%, even as the share of Medicare fee-for-service payments for chemotherapy administered in hospitals (as opposed to outpatient oncology practices) increased from 16.2% to 41.0%.³³ According to another report, the hospital outpatient department proportion of Medicare fee-for-service chemotherapy drug payments increased from 26% in 2005% to 37% in 2011.³⁴

Affiliation and consolidation activities among oncology providers can also compound selection and treatment biases in the construction of comparative cancer measures. The extent of the potential biases such activities introduce into these metrics is intimately related to the underlying economic and scientific rationales driving these activities. For example, according to news reports, the Memorial Sloan-Kettering alliance with Hartford is intended to syndicate treatment pathways and expand

patients' access to targeted therapy development. The University of Texas MD Anderson Cancer Center is pursuing an affiliation strategy that is intended to generate revenues by altering patient flows.³⁵ More generally, we can presume that these arrangements provide participants with several advantages, all affecting patient selection into treatment and/or the treatment patients receive, including the syndication of treatment pathways for the care of specific cancers, the creation of closer ties between institutions for patient referrals, access to shared physician time and expertise, improved bargaining power with insurers, and more control over intra-institutional prices.^{36,37}

We are unaware of efforts underway by CMS to systematically track and characterize provider relationships for quality measurement and reimbursement under the current PQRS and PCHQR requirements. Yet, current PQRS requirements do allow outpatient quality metrics to be reported by provider groups. Tracking the number and nature of groups choosing this reporting mechanism over the option to report metrics as an individual provider might be revealing. In addition, new data collection efforts are likely required to systematically track consolidation and affiliation activity between specialty provider groups primarily providing care in the outpatient setting and between hospitals and these providers and the impact of this activity on patient flow across settings. The approach used by Welch et al²⁹ exploits trends in provider's Medicare tax identification data. This might be one cost-effective way of quantifying various trends in the changing organization of oncology treatment. ASCO's National Census of Oncology Practices effort, launched in June 2012, may also be an important source of these data in the future.³⁸

Does Quality of Care Improve When Comparative Cancer Outcomes Are Publicly Reported?

Finally, we note that the construction of comparative cancer outcome measures by cancer centers and provider groups is in part intended to influence patients' and physicians' treatment decisions. Comparative metrics may be more convincing to patients and their families than standard advertising methods used by cancer centers to attract patients, including ads featuring fictional vignettes or celebrity spokespersons. Even without expertise, most adults will note these ads are misleading because they exclusively feature patients who are alive.

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Yet, in oncology, only a handful of studies have documented the impact of emerging safety and/or effectiveness evidence on chemotherapy choice in the outpatient setting without concomitant changes in guideline recommendations or insurance coverage.^{39,40} Another small set of studies has directly examined the impact of clinical pathway programs on clinical outcomes, treatment complications, and cost of care.^{41,42} Taken together, the data do suggest that the public report of empirical data can produce improvements in some areas of cancer treatment.

However, no study we are aware of has examined these outcomes in response to comparative provider metrics; the former studies focus on national patterns of medication usage, and the latter studies are restricted to specific sets of networked providers. Recent studies on coronary artery bypass graft surgery report cards do suggest that patient flow across providers might be altered in response to comparative outcomes when reports contain "news" not otherwise available.^{43,44} Others suggest there might be limited impact of the public availability of comparative outcomes on patient flow, because patients or their caregivers may not have the capacity to choose their provider, as a result of health plan restrictions or emergent medical need for treatment.⁴⁵

Thus, it remains an open, but critical, empirical question whether and how the nascent national movement to publicly report comparative cancer outcomes will alter patient flow and improve quality of care.

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