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Quality-Adjusted Cost Of Care: A Meaningful Way To Measure Growth In Innovation Cost Versus The Value Of Health Gains

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Abstract

Technology drives both health care spending *and* health improvement. Yet, policymakers rarely see measures of cost growth that account for both effects. To fill this gap, we present the "quality-adjusted cost of care" (QACC), illustrating cost growth net of growth in the value of health improvements, measured as survival gains multiplied by the value of survival. We apply QACC to two cases. For colorectal cancer, drug cost per patient increased by \$35,000 between 1998 and 2005 due to new drug launches, but value from offsetting health improvements netted a modest \$1,377 increase in QACC. For multiple myeloma, new therapies increased cost by \$72,900 between 2004 and 2009 but offsetting health benefits lowered overall QACC by \$67,900. However, myeloma patients on established first-line therapies saw costs rise without corresponding benefits. All three examples document rapid cost growth, but with starkly different implications for whether society "got what it paid for."

Introduction

While policymakers acknowledge that new medical technologies can improve patient care, most focus on how these new products and services put fiscal strain on government budgets. A 2013 Congressional Budget Office (CBO) report states that "a crucial factor underlying the rise in per capita spending for health care in recent decades has been the emergence, adoption, and widespread diffusion of new medical technologies and services."(1) Similarly, the Medicare Payment Advisory Commission (MedPAC) claims that "the greatest impact on spending growth is the advancement of medical technology".(2)

While medical innovations are often expensive, they may also provide health benefits that mitigate or outweigh the additional costs. One example is the discovery of new HIV treatments in the 1990s. Highly active antiretroviral therapy (HAART) substantially raised the cost of treatment for HIV patients after its introduction in the mid-1990s. However, it

also dramatically increased longevity for these patients, who previously faced bleak survival prospects. Indeed, the value of these longevity gains was about nine times larger than the cost of HAART.(3)

More generally, the relevant health policy goal is not simply to head off rising cost everywhere, but rather to identify and eliminate cases in which costs have risen without sufficient corresponding value. In other words, the biggest problem areas are those in which society is not "getting what it pays for." Identifying these areas requires the use of metrics that incorporate considerations of value into cost-measurement, alongside measurement of cost growth. Relying on established tools in the economics literature, this study presents a practical approach for assessing whether cost growth has been worth the associated value (if any) to society. As a proof of concept, we present two case studies to describe how recent treatment advances in colorectal cancer and multiple myeloma have altered both the cost of health care and its overall value to patients. Our goal is to reorient traditional cost growth calculations so that they incorporate value.

A general framework for the quality-adjusted cost of care

The traditional approach to measuring cost growth in health care is to calculate the change in health care costs. The more complete approach suggested in the health economics literature offsets the growth in costs against the corresponding gain in patient value that resulted from it.(4-6)

A simple numerical example illustrates the point. Imagine a cancer patient whose health care costs are \$100 at baseline. Now suppose that a new technology arrives, costing \$10, so health care costs rise to \$110. Conventionally, we would say that the cost of care rose by \$10. However, suppose further that this new technology provides health benefits to each patient worth \$12. Therefore, it is as if the society receives \$2 on net, or \$12 in exchange for a \$10 outlay. Thus, the net cost of health care, or what we call the "quality-adjusted cost of care" or QACC, has fallen by \$2, from \$100 to \$98.

This approach provides a straightforward procedure for incorporating value into measurements of cost growth. First, construct the conventional change in health care costs. Next, measure the growth in value to patients, in terms of monetized gains in "quality-adjusted life-years," a conventional metric that incorporates both increases in life expectancy and quality of life. The difference between the change in costs and the change in benefits then defines the net change in QACC. We operationalize this framework in two case studies below.

Colorectal Cancer Case Study

Approximately 143,000 patients were diagnosed with colorectal cancer in the United States in 2013, and 51,000 will die from the disease.(7) It is the fourth most common cancer after breast, prostate, and lung. Colorectal cancer patients usually begin treatment by having their tumor surgically removed. In the case study below, we focus on pharmaceutical treatments, which have experienced the greatest innovation in recent decades, and which are also the most important drivers of cost growth and health outcomes improvement.(8)

The cost of colorectal cancer treatments

To estimate growth in the costs of treating colorectal cancer, we use data on regimen market share, drug prices, and regimen ingredients. The average transaction price of each ingredient drug comes from IMS data. Dosage information for each drug within each regimen was collected from the National Comprehensive Cancer Network. We then constructed the weighted average market price of treatment for a representative patient. Individual regimen prices are weighted by market shares from both IntrinsiQ data and Surveillance, Epidemiology, and End Results Program Medicare (SEER-Medicare) claims data files.

In the early 1990s, almost all colorectal cancer patients received a regimen consisting of low-cost fluorouracil and leucovorin (5-FU/LV). The price of a 24-week 5-FU/LV regimen in 1993 was only \$121.

In the late 1990s and 2000s, the cost of colorectal cancer medications rose dramatically due to new drug introductions. Exhibit 1 presents the growth in average colorectal cancer treatment cost. In 1998, mean per-patient cost of colorectal cancer drug treatment increased to \$688 as a new regimen with irinotecan gained market share. In the early 2000s, four new treatments (i.e., capecitabine, oxaliplatin, bevacizumab and cetuximab) were approved. By 2005, the average cost of a treatment cycle was over \$35,000; 86 percent of patients were treated with expensive products launched after 1996.

Effect of colorectal cancer drugs on the quality-adjusted cost of care

Although colorectal cancer drug treatment cost rose, these treatments also improved patient health outcomes. In 1991, patients using 5 FU/LV could expect to survive for 12.5 months on average based on data from randomized trials. By 2004, however, patients using a regimen of bevacizumab and oxaliplatin could expect to live 23.2 months. These estimates are based on randomized trials conducted on stage IV patients, who experience worse outcomes than patients with less advanced cancer. For each regimen, we conservatively assumed that patients with less advanced cancer received the same gain in quality adjusted life years as more advanced stage IV patients.

To determine the extent to which the average health improvement offset the added cost, we computed the change in the QACC, defined as the increase in health care costs, net of the value of improved health outcomes. Mechanically, the change in cost is computed as the difference between the cost of the market basket of new therapies (i.e., all therapies excluding the baseline 5-FU/LV therapy) and the cost of 5 FU/LV. The value of improved health outcomes consists of the gain in quality-adjusted life-years (QALYs) that would result from the use of this market basket, multiplied by the value of a QALY, which we take to be \$100,000. Commonly cited reviews of the literature on the value of life-years typically settle on values between \$100,000 and \$300,000 (9-11), and we employ the lower end of this range. The difference between the growth in cost and the growth in value is the change in QACC.

Average treatment cost rose almost \$35,000 between 1998 and 2005, but QACC remained largely flat due to roughly offsetting gains in health. Exhibit 2 compares the change in health care costs (bars) with the change in QACC (line). Whereas health care costs increased by

\$34,492 as a result of the new products, health improved by 0.33115 QALYs. The value of these additional life years is \$33,115 per person. Thus, QACC increased by only \$1,377 (\$34,492-\$33,115) over this time period. In this case, society got roughly what it paid for.

Multiple Myeloma Case Study

In this second case study, we illustrate how to measure the quality-adjusted cost of care when innovations have heterogeneous effects across patient populations. We compare effects for multiple myeloma patients who vary in their response to the first-line use of established drugs. To determine the impact of new pharmaceutical innovations, we separately calculate QACC for multiple myeloma patients who require second-line therapy — i.e., those who benefitted from new second-line innovation — and those who continued to use older therapies – i.e., those who did not use or benefit from these innovations during this time period. The change in QACC is quite different across these two groups.

Background on multiple myeloma and treatments

Multiple myeloma results from the abnormal proliferation of plasma cells in bone marrow, adversely affecting blood cell production.(12) In 2014, there were 24,000 projected new cases.(13) In the early 2000s, multiple myeloma pharmaceutical treatments typically relied on drug combinations using dexamethasone, melphalan, prednisone or thalidomide.

In the mid 2000s, two new multiple myeloma treatments came on the market that provided health benefits: bortezomib in 2003 and lenalidomide in 2006. (14, 15) Both treatments originally were approved as second-line treatments. Clinical trials demonstrated that lenalidomide, for example, increased expected QALYs from 1.5 to 3.7 for patients requiring second-line treatment.(16)

Effect of multiple myeloma drugs on the quality-adjusted cost of care

We investigated trends in QACC after the introduction of these new treatments. We calculated the change in market shares of multiple myeloma treatment regimens between 2004 and 2009 using data from the Optum Touchstone claims database. These data contain de-identified administrative claims and benefit information from employees and their dependents of 33 large employers. Multiple myeloma patients were required to have one inpatient or two outpatient claims with a multiple myeloma diagnosis. Among these patients, we identified all drug molecules used that had a multiple myeloma indication based on information synthesized from the Citeline Trialtrove© database (2013). Individual molecules were combined into drug regimens if: (i) the medications were administered within 30 days of one another, and (ii) a multiple myeloma randomized controlled trial for the combination appeared in the Citeline trial data. Once drug regimens were identified, the regimen market shares were calculated based on total days supplied from associated claims. We calculated the expected health benefit as a market share-weighted average of expected QALYs and the expected cost as the market share-weighted average pharmaceutical cost.

Using the methodology described above, a majority of first-line myeloma treatments in 2004 used drug combinations that included thalidomide. In 2004, patients requiring second-line therapies often used dexamethasone or a combination of thalidomide and dexamethasone as

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a second-line treatment.(16) Once lenalidomide and bortezomib came onto the market, however, almost all non-responders received one of these therapies within a few years. By 2009, 67% of all multiple myeloma prescriptions written were for drug regimens using lenalidomide or bortezomib. Since 64% of multiple myeloma patients do not respond to first-line thalidomide therapy, we assumed that by 2009 all patients who required second-line therapy received lenalidomide or bortezomib as a second-line treatment.

Shifting second-line treatment patterns toward these innovations resulted in a large increase in treatment costs for multiple myeloma patients. The average annual cost of pharmaceuticals to treat multiple myeloma increased from \$36,607 in 2004 to \$109,544 in 2009, a net increase of about \$72,937. Prices are adjusted for inflation using the consumer price index (2014 USD).(17) Exhibit 3 displays these results.

To measure the impact of these new treatments, we calculated QACC. To be conservative about the health benefits of these treatments, we assumed that expected health outcomes for patients who respond to first-line treatment did not change after the introduction of these second-line treatments. We measured the value of health benefits as the market share weighted expected gain in QALYs times the value of a QALY (\$100,000).

In Exhibit 3, the quality-adjusted cost of care for multiple myeloma patients fell by \$67,900 between 2004 and 2009. The improvement in QACC is driven largely by the new therapies (i.e., bortezomib and lenalidomide) used as second-line treatments. These second-line treatment advances resulted in health gains valued at \$220,000, which more than offset the increased treatment cost.

The story for patients receiving only established first-line therapies, on the other hand, is quite different. Because the innovations introduced over this time period were only indicated for second-line patients, patients receiving only established first-line treatment did not receive any benefit from these innovations, at least according to labeled usage. QACC for this group rose by \$49,000, largely due to increasing thalidomide prices.

If innovative therapies had been FDA-approved for first-line treatment or if there had been off-label use, however, QACC would have fallen for first-line patients. Recent clinical trials have demonstrated that some innovative therapies currently indicated for second line treatment also benefit first-line patients. Using evidence from these trials, we estimate that the quality-adjusted cost of care would have fallen by \$82,500 if the diffusion of bortezomib and lenalidomide in first-line treatment occurred at the same rate it did in second-line treatment.

In sum, for patients who responded to established first-line treatment, society got less than it paid for, while for patients responding to new second-line treatment, society got more. There is also some evidence that first-line patients may have gotten more value if they had been able to access the innovative therapies earlier.

Discussion

The myeloma second-line, myeloma first-line, and colorectal cancer case studies above respectively provide examples in which society got more than, less than, and just about what it paid for in terms of higher health care costs. In all cases, health care costs grew dramatically over time, but this pattern obscured widely differing trends in overall value for patients. A stated goal of health policy is to ensure that society gets at least what it pays for. Pursuing this goal will require careful measurement of not just health care costs, but also the quality-adjusted cost of care, which accounts for value alongside direct financial costs. In fact, a recent Institute of Medicine report underlined that Medicare payment systems should focus on promoting high-value care.(18)

Although the Affordable Care Act (ACA) has already taken steps to incorporate quality adjustments into existing provider reimbursement systems, most existing quality metrics provide an imprecise measure of patient health. Many of these measures focus on the processes of care (e.g., administration of influenza vaccines)(19) and the few metrics that ostensibly incorporate health outcomes cover a short time frame (e.g., 30-day mortality rates (20)) or rely on surrogate endpoints (e.g., hemoglobin A1c levels for diabetics).(19) Further, existing metrics are typically confined to the limited set of diseases where clear best practices are agreed upon. Disease areas, such as cancer, where optimal practice patterns frequently shift have few if any such metrics. Using more comprehensive metrics of value, such as QACC, to assess whether society is getting what it pays for provides policymakers with critical tools for gauging success and failure in health care markets.

Naturally, the QACC framework involves a few notable limitations that are illustrated by the case studies. First, QACC calculations require the presence of accurate, specific, and applicable data on patient health benefits. There are typically varying degrees of difficulty associated with obtaining such information. For example, we have relied here on clinical trial data, which is often used when evaluating newly launched therapies. However, clinical trial participants may not adequately represent the real-world patient population receiving treatment world. Policymakers can supplement clinical trial data with real-world evidence, but using real world data to attribute health benefits to treatments faces its own challenges (e.g., selection bias due to nonrandom treatment assignment).

Second, in principle QACC should consider all costs associated with treatments. These data may be challenging to obtain for at least two reasons: (i) it can be difficult to find drug cost and non-drug cost that are accurate, representative, and internally consistent; and (ii) it is often difficult to obtain long-run costs associated with therapy, even though this is highly salient to a calculation of social value.

Our two case studies provide alternative illustrations of the second challenge. The colorectal cancer case, for example, focused on drug costs only, because we had access to high-quality, nationally representative, market-based data on actual drug prices paid, but lacked corresponding access to market-based data on non-drug costs for a nationally representative population. To illustrate a potential solution to this problem, we performed a sensitivity analysis in the myeloma case study. Specifically, we used the smallest medication

monitoring and adverse event medical costs found in the literature (\$2,359 per year for dexamethasone (21)) as a measure of non-drug costs for established multiple myeloma treatments and the highest medication management and adverse event cost (\$17,246 for bortezomib(22)) for new treatments; we also added the cost of autologous stem cell transplants (\$385,642) (23) to all therapies. This approach overstates the true costs of new therapies since novel therapies may delay the need for expensive autologous stem cell transplants (24) and some innovative therapies (e.g., lenalidomide) have lower medication management and adverse event costs than others (e.g., bortezomib) (22). Even after imposing these assumed medical costs, however, QACC for myeloma patients still fell by \$57,500 overall, compared to a \$67,900 decrease in the baseline approach. In this case, incorporating information about non-drug costs does not change the qualitative conclusion for QACC, although the magnitude of QACC suffers from some uncertainty.

Our goal in this study has been to provide a simple, transparent framework based on existing economic tools that can help policymakers incorporate value into considerations of healthcare cost growth. The idea of blending cost and value is certainly not new, and indeed lies at the heart of "cost-effectiveness" analysis in health economics. For a variety of reasons, however, cost-effectiveness has rarely if ever been used to frame or contextualize discussions of aggregate healthcare cost growth in a disease area or market segment. Rather, its use has often been restricted to evaluating individual medical technologies. The quality-adjusted cost of care metric reformulates the tools of health economic and cost-effectiveness analysis to better inform policymakers seeking to understand the implications of trends in healthcare cost growth.

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EXHIBIT 1. Average Cost of 24-week Colorectal Cancer Treatment Regimen, 1993-2005 SOURCE: Authors' calculations Notes: None.

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EXHIBIT 2. Trends in Costs and Quality Adjusted Cost of Care (QACC) for Colorectal Cancer Treatment, 1998-2005

SOURCE: Authors' calculations

Notes: Cost is measured as the average price of a 24-week regimen of colorectal cancer treatment. The quality-adjusted cost of care (QACC) calculated as the increase in the price of treatment minus the increase in the patient's expected quality-adjusted life years (QALY) multiplied by the value of a QALY.

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EXHIBIT 3. Trends in Costs and Quality Adjusted Cost of Care (QACC) for Multiple Myeloma Treatment, 2004-2009

SOURCE: Authors' calculations

Notes: The quality-adjusted cost of care (QACC) calculated as the increase in the price of treatment minus the increase in the patient's expected quality-adjusted life years (QALY) multiplied by the value of a QALY. The term "innovative therapies" refers to the use of bortezomib and lenalidomide.