



ELSEVIER

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/jval

The Role of Economic Evaluation in Meeting IOM's Recommendations on Delivering High-Quality Cancer Care

Ya-Chen Tina Shih, PhD^{1,2}, C. Mullins Daniel, PhD³, Michael Drummond, PhD⁴

¹Section of Hospital Medicine, Department of Medicine, University of Chicago, Chicago, IL, USA; ²Program in the Economics of Cancer, Center for Health and the Social Sciences, Chicago, IL, USA; ³Department of Pharmaceutical Health Services Research, School of Pharmacy, University of Maryland, Baltimore, MD, USA; ⁴The University of York, Heslington, York, UK

Economic evaluation, defined as “the comparative analysis of alternative courses of action in terms of both their costs and consequences,” consists of various analytical methods to assist decision makers in achieving allocation efficiency [1]. It has been used in many industrialized countries as one of the essential criteria for coverage decisions. Use of economic evaluation, in particular cost-effectiveness analysis, to set priorities for coverage has gained little support in the United States because of the American public's fear of rationing [2,3]. This distaste for considering cost when evaluating comparative benefits and harms of health care technologies was heightened by the FY 2013 Labor, Health and Human Services, and Education Appropriations Bill drafted by a House Appropriations subcommittee on July 18, 2012, to ban any economic research from the National Institutes of Health funding [4,5]; fortunately, the Bill was not enacted. Averting economic evaluation is like ignoring the elephant in the room considering that the skyrocketing health care cost is threatening the fiscal health of the United States, with health care spending accounting for approximately 18% of the nation's gross domestic product in 2011 and projected to reach 25% by 2037 [6]. Allocation efficiency and priority settings are especially important for diseases with fast diffusions of expensive new technologies, most noticeably cancer. The number of cancer incidence cases and survivors in the United States in 2013 was 1.6 million and 14 million, respectively [7], with the cost of cancer care reaching \$125 billion in 2010 [8]. Many have expressed a serious concern that the high costs of oncology products could jeopardize the quality of cancer care [9–12]. In this Commentary, we discuss the potential of economic evaluation to assist the cancer care community, on both the research and practice sides, in meeting the recently released recommendations from the Institute of Medicine (IOM) on delivering high-quality cancer care [6].

The IOM released a report titled, “Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis,” on September 10, 2013. Although this report updates and revisits the recommendations prescribed in the 1999 report, “Ensuring Quality of Cancer Care,” the new report expresses a sense of urgency in delivering high-quality oncology care that is affordable to all cancer patients in the United States [13]. High-quality cancer care

envisioned by the IOM Quality of Cancer Care Committee is care that is patient-centered, accessible, coordinated, and evidence-based [6]. The urgency is due to several factors that have emerged in the past decade and have been magnified over time, including an aging population, which is leading to a rapid increase in cancer incidence, the rising costs of cancer care, the growing complexity in cancer treatment, and an increasing health care workforce shortage. Conversely, recent events are providing unique opportunities to improve the delivery of high-quality cancer care, such as advancements in information technology, patient empowerment, and the passage of the Affordable Care Act [14].

The recommendations in the 1999 IOM report on cancer care quality and those in the 2013 IOM report are summarized in Table 1. Three distinct features in the 2013 recommendations are as follows: 1) the emphasis on patient-centeredness (Recommendation 1 [R1, R2]); 2) the importance of the financial aspects of cancer care (R1, R10); and 3) the opportunity associated with establishing a learning health care system (R7, R8). Patient-centeredness is accomplished by understanding patient preferences and communicating information and presenting evidence, including the costs and disease burden of treatment options, in ways that are meaningful to patients. Economic evaluation provides costs, outcomes, and cost-effectiveness information that are highly relevant to achieving R1 and R10; generates patient-preferences data that are inherent within patient-centered decision making; and all the above information contributes to a learning health care system that continuously collects and updates clinical and economic information. Below we discuss the role of economic evaluation in meeting three important aspects of the recommendations stated above: value discussions, allocation efficiency and affordability, and patient centeredness.

Value Discussions

When affordability of cancer care is a potential barrier, discussions about the value of treatment options between patients and their health care providers should increase. The first recommendation from the IOM Quality of Cancer Care Committee advocates understanding the preferences of patients and their families and

Source of financial support: The authors have no other financial relationships to disclose.

1098-3015/\$36.00 – see front matter Copyright © 2014, International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

Published by Elsevier Inc.

<http://dx.doi.org/10.1016/j.jval.2014.04.003>

Table 1 – Comparisons of recommendations from the 1999 and 2013 IOM Quality of Cancer Care Report.

1999 Recommendations	2013 Recommendations
1. Ensure patients undergoing procedures that are technically difficult to perform and have been associated with higher mortality in lower volume settings receive care at facilities with extensive experience	1. Provide patients and their families with understandable information about cancer prognosis, treatment benefits and harms, palliative care, psychosocial support, and estimates of the total and out-of-pocket costs
2. Use systematically developed guidelines based on the best available evidence for prevention, diagnosis, treatment, and palliative care	2. Provide patients with end-of-life care consistent with their needs, values, and preferences
3. Measure and monitor the quality of care using a core set of quality measures	3. Ensure coordinated and comprehensive patient-centered care
4. Ensure the following elements of quality care for each individual with cancer: experienced professionals who make recommendations about initial cancer management, an agreed-upon cancer plan that outlines goals of care, access to the full complement of resources necessary to implement the care plan, access to high-quality clinical trials, policies to ensure full disclosure of information about appropriate treatment options, a mechanism to coordinate services, and psychosocial support services and compassionate care	4. Ensure that all individuals caring for cancer patients have appropriate core competencies
5. Ensure quality of care at the end of life, particularly the management of cancer-related pain and timely referral to palliative and hospice care	5. Expand the breadth of data collected in cancer research for older adults and patients with multiple comorbid conditions
6. Federal and private research sponsors should invest in clinical trials to address questions about cancer care management	6. Expand the depth of data collected in cancer research through a common set of data elements that capture patient-reported outcomes, relevant patient characteristics, and health behaviors
7. A cancer data system that can provide quality benchmarks for use by systems of care (e.g., hospitals, provider groups, and managed care systems) is needed	7. Develop a learning health care information technology system for cancer that enables real-time analysis of data from cancer patients in various care settings
8. Research sponsors should support national studies of recently diagnosed individuals with cancer, using information sources with sufficient detail to assess patterns of cancer care and factors associated with the receipt of good care, and also training for cancer care providers interested in health services research	8. Develop a national quality reporting program for cancer care as part of a learning health care system
9. Services for the uninsured and underinsured should be enhanced to ensure entry to, and equitable treatment within, the cancer care system	9. Implement a national strategy to reduce disparities in access to cancer care for underserved populations by leveraging community interventions
10. Studies are needed to examine why specific segments of the population (e.g., members of certain racial or ethnic groups, older patients) do not receive appropriate cancer care	10. Improve the affordability of cancer care by leveraging existing efforts to reform payment and eliminate waste

IOM, Institute of Medicine.

providing them with comprehensible clinical and economic information, including estimates of the total and out-of-pocket costs. The IOM report defined out-of-pocket costs as expenses for medical care that are paid for by the patient and can include deductibles, coinsurance, and co-payments for covered services, and services that are not covered by insurance [15]. Although oncologists are comfortable discussing clinical information with their patients, many expressed discomfort in incorporating costs into such discussions [16]—although a national survey indicated that patients' out-of-pocket spending does influence treatment decisions [17]. Recognizing cost discussions as an important component of high-quality cancer care, the American Society of Clinical Oncology established a Cost of Care Task Force in 2007, which published a Guidance Statement on the Cost of Cancer Care in 2009 to provide an overview of the economic issues facing stakeholders in the cancer community [18].

How can cancer-related economic evaluations generate understandable information for patients and their clinicians (R1)? To determine the full financial impact of cancer treatment, patients need to know their out-of-pocket expenses associated

with a complete course of treatment. These should include treatment possibly needed for complications, not just the difference in treatment costs between the therapeutic alternatives because supportive care can be costly—a study estimated that the average cost for hospitalizations to treat common complication of cancer treatments exceeded \$7000 [19]. It is not realistic to expect studies of economic evaluation to provide precise, patient-specific estimates of out-of-pocket expenses for each treatment option because the amount differs by patients' treatment pathway and insurance. Nevertheless, studies that present a detailed cost table that itemizes every relevant cost element and the associated unit cost will serve as a useful starting point. Using the unit cost information as the national averages, clinicians can aggregate over cost elements deemed to be relevant to the patient's treatment plan to arrive at an estimate of the total costs and then apply the specific cost-sharing requirement in the patient's insurance to estimate the out-of-pocket costs. Although estimates from the above approach may not be as accurate as those obtained from financial consultants or navigators at providers' facilities, not all facilities have the resource to employ financial consultants—oftentimes a back-of-the-envelope

calculation from the literature is the only resource that clinicians and patients can access in a timely manner.

It should be noted that economic evaluation often emphasizes the differences between the study comparators (e.g., incremental costs and incremental effectiveness) to assist decision makers in understanding the trade-offs between new and existing interventions. The focus on the “increments” sometimes prompts researchers to neglect certain cost elements (e.g., costs of complications or follow-ups) and justify such choice by claiming that these elements are similar between interventions and thus would be a “wash” under the calculation of increments. This approach, although reduces the complexity of data collection and is theoretically justifiable, compromises the usefulness of cost information in the financial discussions during patient-clinician communications. In addition, many economic evaluations are conducted from the perspective of a third-party payer and thus do not collect information on out-of-pocket costs. To help achieve R1 in the 2013 IOM report, future cancer-related economic evaluation research should be mindful of the type of cost information that may be helpful to the discussions of costs between patients and clinicians and present study findings in a format that is transparent, easily understandable, and adoptable. Studies using the patient perspective will meet such information need.

Allocation Efficiency and Affordability

Economic evaluation provides decision makers with analytical tools to improve allocation efficiency and assess the affordability of health care; these analyses offer invaluable insights into interventions or payment mechanisms designed to improve the affordability of cancer care (R10). Although there is no commonly accepted threshold of the incremental cost-effectiveness ratio (ICER) in the United States, an excessively high ICER (e.g., over \$150,000 per quality-adjusted life-year [QALY] for studies using a societal perspective) should prompt clinicians to initiate a conversation with their patients on the “value” of new therapy by discussing the trade-off between costs and QALYs because a high ICER is often an indication that the new therapy is much more expensive than its therapeutic alternative(s) but may bring only a small improvement in QALY. Another important analysis under economic evaluation is budget impact analysis (BIA), which incorporates the uptake and diffusion of technologies from a system perspective and therefore provides information on the affordability of a new technology [20]. Depending on the disease prevalence and the standard of care in current practice, it is possible that a new drug considered not to be cost-effective can be affordable (e.g., orphan drugs) and vice versa. BIA is especially helpful in evaluating the financial impact of new payment policies because changes in reimbursement can hinder or boost the uptake and diffusion of new technologies. Collectively, CEA and BIA generate critical information to achieve R10, with CEA helping decision makers to identify possible waste in the system and BIA guiding the direction of payment reforms to improve the affordability of cancer care.

Patient Centeredness

Patient centeredness reflects responsiveness to expressed needs and desires of patients to obtain information relevant to their values and the medical decisions that they make. Economic evaluations in cancer can provide meaningful information on the entire burden of cancer and associated care. This can be accomplished by describing the patient cost sharing components as well as broadening the scope of costs beyond the narrow

definition of direct medical costs by incorporating a broader definition of cost that includes indirect and intangible costs. In addition, economic evaluation research provides an opportunity for patients to engage in research to better understand those broader patient-centered cost considerations. Patient engagement across the continuum of research would identify patient burden and cost outcomes that influence patient treatment choice and decision making [21]. In clinical practice, improved communication surrounding the costs and patient burden would facilitate a higher quality of cancer care. By banning funding for economic research, the government will create large gaps in evidence surrounding one of the most patient-centered aspects of high-quality, affordable cancer care—the cost.

American Exceptionism?

Is the cancer care crisis depicted in the recent IOM report a phenomenon unique to the United States? The attempt to ban economic research symbolized a shortsighted decision based on an unfounded fear of rationing. If succeeded, it can severely limit our ability to meet IOM recommendations and deliver high-quality cancer care. Several jurisdictions, including Australia, Canada, The Netherlands, and the United Kingdom, have used economic evaluation in making drug coverage decisions. Mason et al. [22] compared the decisions in the United States (by the Centers for Medicare & Medicaid Services, the Veterans Administration, and a Blues plan) with those in the United Kingdom (by the National Institute for Health and Social Care and Scottish Medicines Consortium) for cancer drugs approved by the Food and Drug Administration since 2004 [22]. Although they found that there was more restricted coverage in the United Kingdom than in the United States, this restriction was not universal and allowed coverage for patients who would benefit the most. In addition, it is becoming common for pharmaceutical companies to offer “patient access schemes” in the United Kingdom, whereby discounts or subsidies are offered to secure a recommendation for broader use of the drug. In commenting on the article by Mason et al. [22], Malin [23] noted, “We have a choice: do we use science to help us reach consensus on what we are willing to pay for new therapies and innovation, or do we leave individual patients to wrestle with the skyrocketing costs of cancer care and treatment determined by their ability to pay?” The IOM Quality of Cancer Care Committee calls for collective efforts from all participants and stakeholders to address the challenges that impede the delivery of high-quality care in the US cancer care system—a system in crisis. To accomplish this mission, let’s talk about the elephant in the room.

Acknowledgments

We thank Dr. Patricia Ganz, Dr. Thomas Feeley, and Ms. Laura Levit for their helpful reviews and comments. The responsibility for the content of this article rests with the authors and does not necessarily represent the views of the IOM, its committees, or its convening activities.

REFERENCES

- [1] Drummond MF, Sculpher MJ, Torrance GW, et al. *Methods for the Economic Evaluation of Health Care Programmes*. (3rd ed.). New York: Oxford University Press, 2005.
- [2] Gold MR, Sofaer S, Siegelberg T. Medicare and cost-effectiveness analysis: time to ask the taxpayers. *Health Aff (Millwood)* 2007; 26:1399–406.

- [3] Botta MD, Blendon RJ, Benson JM. Cost-effectiveness decision making and US public opinion. *JAMA Intern Med* 2014;174(1):141–3.
- [4] FY 2013 Labor, Health and Human Services, and Education Appropriations Bill. Available from: <http://appropriations.house.gov/uploadedfiles/bills-112hr-sc-ap-fy13-laborhhsed.pdf>. [Accessed February 8, 2014].
- [5] Kaiser J. House Bill targets health economics, evidence-based medicine 2012: Available from: <http://news.sciencemag.org/funding/2012/07/house-bill-targets-health-economics-evidence-based-medicine>. [Accessed March 20, 2014].
- [6] Institute of Medicine. *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*. Washington, DC: Institute of Medicine, 2013.
- [7] American Cancer Society. *Cancer Facts & Figures 2013*. Atlanta: American Cancer Society, 2013.
- [8] Mariotto AB, Yabroff KR, Shao Y, et al. Projections of the cost of cancer care in the United States: 2010–2020. *J Natl Cancer Inst* 2011;103:117–28.
- [9] Institute of Medicine. *Delivering Affordable Cancer Care in the 21st Century: Workshop Summary*. Washington, DC: Institute of Medicine, 2013.
- [10] Shih YC, Ganz PA, Aberle D, et al. Delivering high-quality and affordable care throughout the cancer care continuum. *J Clin Oncol* 2013;31:4151–7.
- [11] Smith TJ, Hillner BE. Bending the cost curve in cancer care. *N Engl J Med* 2011;364:2060–5.
- [12] Sullivan R, Peppercorn J, Sikora K, et al. Delivering affordable cancer care in high-income countries. *Lancet Oncol* 2011;12:933–80.
- [13] Institute of Medicine. *Ensuring Quality Cancer Care*. Washington, DC: Institute of Medicine, 1999.
- [14] PUBLIC LAW 111–148—MAR. 23, 2010. Available from: <http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>. [Accessed March 20, 2014].
- [15] HealthCare.gov. Out-of-pocket costs. 2013. Available from: <http://www.healthcare.gov/glossary/O/ooop-costs.html>. [Accessed February 10, 2014].
- [16] Ubel PA. Beyond costs and benefits: understanding how patients make health care decisions. *Oncologist* 2010;15(Suppl. 1):5–10.
- [17] Neumann PJ, Palmer JA, Nadler E, et al. Cancer therapy costs influence treatment: a national survey of oncologists. *Health Aff (Millwood)* 2010;29:196–202.
- [18] Meropol NJ, Schrag D, Smith TJ, et al. American Society of Clinical Oncology guidance statement: the cost of cancer care. *J Clin Oncol* 2009;27:3868–74.
- [19] Elting LS, Shih YC. The economic burden of supportive care of cancer patients. *Support Care Cancer* 2004;12:219–26.
- [20] Mayskopf JA, Sullivan SD, Annemans L, et al. Principles of good practice for budget impact analysis: report of the ISPOR Task Force on good research practices—budget impact analysis. *Value Health* 2007;10:336–47.
- [21] Mullins CD, Abdulhalim AM, Lavalley DC. Continuous patient engagement in comparative effectiveness research. *JAMA* 2012;307:1587–8.
- [22] Mason A, Drummond M, Ramsey S, et al. Comparison of anticancer drug coverage decisions in the United States and United Kingdom: does the evidence support the rhetoric? *J Clin Oncol* 2010;28:3234–8.
- [23] Malin JL. Wrestling with the high price of cancer care: should we control costs by individuals' ability to pay or society's willingness to pay? *J Clin Oncol* 2010;28:3212–4.