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Challenges in Measuring Cost and Value in Oncology: Making It Personal

Peter P. Yu, MD, FACP, FASCO*

Hartford HealthCare Cancer Institute, Hartford, CT, USA

ABSTRACT

Oncology patients often find themselves facing an incurable disease with limited treatment options and increasing patient fragility. The importance of patient preferences and values increases in shared decision making especially when the cost of cancer care is continuing its steep rise. As our understanding of cancer systems biology increases, we are justifiably optimistic about therapeutic improvements but recognize that this has complicated the traditional Food and Drug Administration approval of drug indications based on organ-specific cancer for a particular drug. Dynamic and agile clinical guidelines that reflect a rapidly changing knowledge base for decision-making support are needed. The American Society of Clinical Oncology (ASCO) has been working on three initiatives to tackle these complex issues. The first initiative is ASCO's collaboration with other international organizations to create a framework to assess drugs for the World Health Organization's Essential Medicines List, including non-generics. The second initiative aims to define clinically meaningful

outcomes as precision medicine expands the definition of cancers, leading to increased demand for the use of targeted drugs as single agents or in combination. The third initiative is ASCO's value framework, published in 2015, focusing on patient-physician shared decision making. The framework incorporates three parameters: 1) the meaningfulness of the clinical benefit, 2) the toxicity of the treatment, and 3) the patient's financial out-of-pocket cost. ASCO is concerned about the rising cost of cancer care when the clinical complexity and the pace of change in oncology are accelerating, and it is committed to help improve patient outcomes and value in cancer care as well as to engage the broader health care community in a process of collaborative improvement.

Keywords: clinical practice guidelines, cost-effectiveness analysis.

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Introduction

Although two-thirds of patients with cancer will live at least 5 years after diagnosis and the number of patients who can expect to live a normal life span is increasing, many patients remain in the difficult situation of facing an incurable disease. As treatment options are exhausted, the remaining choices become increasingly problematic as to likelihood of response, duration of response and patient tolerability because of treatment-related side effects, and increasing patient fragility. The importance of patient preferences and values in shared decision making increases as the balance tips away from statistical probabilities toward careful and more nuanced discussions around the meaning and quality of life; indeed it becomes very personal.

The cost of cancer care is rising steeply: The estimated cost of cancer care in the United States was \$125 billion in 2010 and is expected to rise to \$175 billion by 2020. There are various factors underlying this. First, most common cancers increase in incidence as the population ages, and the demographic characteristics of the baby boom generation will drive much of the increase in demand for oncology services. Nevertheless, although the

demographic characteristics of the US population are predictable, the increase in health care costs attributable to new diagnostic and therapeutic technology is not, and nor is it entirely rationale from a health economics perspective. The price of oncologic agents at market introduction relative to survival benefits and adjusted for inflation has been rising. By this measure, the cost of a new drug per year of life gained rose from \$139,100 in 2005 to \$207,000 in 2013 [1]. Between 1996 and 2010, health care spending grew faster than the US gross domestic product (GDP), a trajectory that is unsustainable for both patients and employers. Significantly, as an indicator of the contribution of new technology to the rising costs of health care, the rate of growth on spending for cancer drugs—still only a minority percentage of the overall cost of care—is accelerating. Of the top 10 drugs for Medicare in 2012 measured by total spending per drug, 8 were oncology drugs.

Figure 1 illustrates the growth in what are called targeted cancer therapies, which since 2006 have accounted for a higher aggregate health cost than traditional cytotoxic chemotherapy drugs [2]. As our understanding of the science of cancer biology increases, we are justifiably and appropriately optimistic that

* Address correspondence to: Peter P. Yu, Hartford HealthCare, 1 State Street, Hartford, CT 06103.

E-mail: peter.yu@asco.org.

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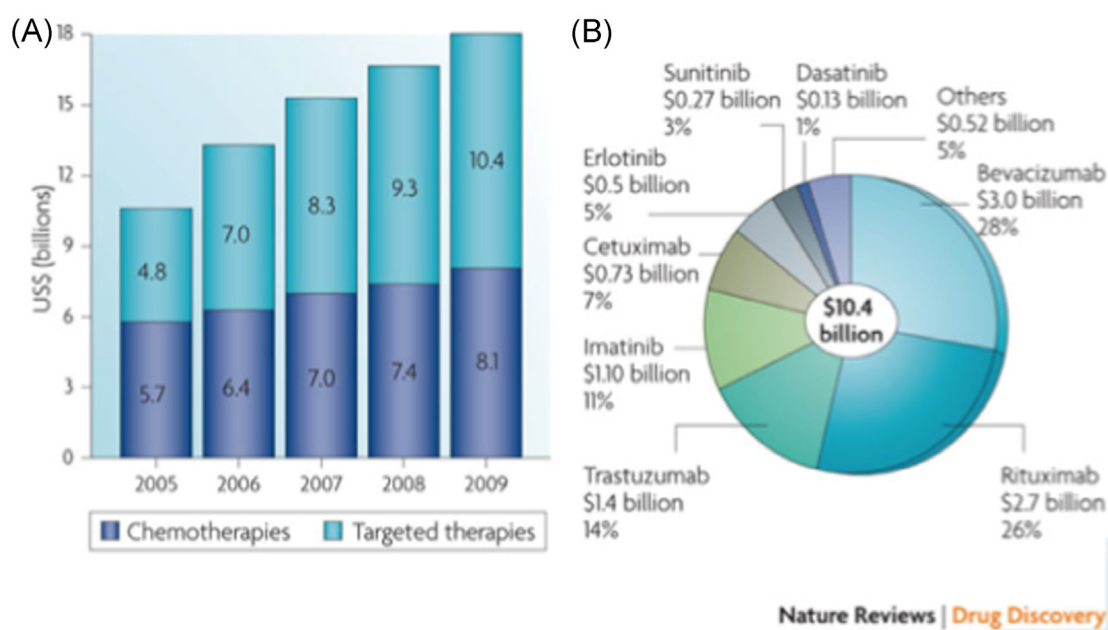
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Table 1 – Summary of recommended targets for meaningful clinical trial goals [5].

Cancer type	Patient population	Current baseline median OS (mo)	Primary end point		Secondary end point	
			Improvement over current OS that would be clinically meaningful (mo)	Target HRs	Improvement in 1-y survival rate (%) [*]	Improvement in PFS (mo)
Pancreatic cancer	FOLFIRINOX-eligible patients	10–11	4–5	0.67–0.69	48 → 63	4–5
	Gemcitabine or gemcitabine/nab-paclitaxel-eligible patients	8–9	3–4	0.6–0.75	35 → 50	3–4
Lung cancer	Nonsquamous cell carcinoma	13	3.25–4	0.76–0.8	53 → 61	4
	Squamous cell carcinoma	10	2.5–3	0.77–0.8	44 → 53	3
Breast cancer	Metastatic triple negative, previously untreated for metastatic disease	18	4.5–6	0.75–0.8	63 → 71	4
Colon cancer	Disease progression with all previous therapies (or not a candidate for standard second- or third-line options)	4–6	3–5	0.67–0.67	25 → 35	3–5

FOLFIRINOX, leucovorin, fluorouracil, irinotecan, and oxaliplatin; HR, hazard ratio; OS, overall survival; PFS, progression-free survival.
^{*} Current → target.

Expenditures on Cancer Therapies: Chemotherapy and Targeted Therapies

**Fig. 1 – Increasing role of targeted cancer therapeutics [2].**

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