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ASCO in Action Brief: Value in Cancer Care

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This ASCO in Action Brief is designed to bring members into a discussion about the complex concept of value in cancer care. In this era of heightened scrutiny of the U.S. health-care system, we believe that care for patients with cancer will increasingly be assessed on the value of that care, not just the cost. Such a significant shift in emphasis will require a collective understanding and accepted definition of what value in cancer care means. Building on our established history of tackling issues related to cost, quality, and value, the Society is engaging in a Board-level strategic initiative to define—in specific, concrete terms—value in cancer care.

Warren Buffet, the famed investor, once said, “Price is what you pay. Value is what you get.”

The ongoing U.S. debate over health-care reform has made one thing clear: The rate at which health-care costs are growing will, if unchecked, limit our country’s growth and possibly bankrupt us. Projections from the federal government indicate that health-care spending will account for nearly one-fifth of the U.S. economy in 2021.[1] Cancer drugs, in particular, are a concern because they currently comprise eight out of the top ten most expensive drugs covered by Medicare. Although cancer is in total responsible for only five percent of current health-care expenditures, cancer care costs are expected to grow from \$125 billion in 2010 to a projected \$175 billion (using 2010 dollars) in 2020—a 40 percent increase. [2]

The rising cost of cancer care impacts many stakeholders involved in our complex health-care system, including providers, payers, manufacturers, and, most importantly, patients. If the economic costs of healthcare in general, and high-quality cancer care in particular, continue to rise unchecked, it will be less and less affordable for an increasing number of Americans.

At the same time that the costs of healthcare are being scrutinized, and perhaps even as a direct result of this

scrutiny, there is a growing, widespread recognition that high-cost care does not necessarily translate into high-quality care or improved outcomes. A well-established fact is that per capita spending on healthcare in the United States far exceeds that in all other developed countries by a factor of two or more. This is juxtaposed against life expectancies for Americans as compared with citizens in developed nations, and suggests there is a great deal of wasted expense in the system.

As the demand to curb health-care costs increases, a broad societal consensus is developing that healthcare should be assessed on *value*. The American Board of Internal Medicine Foundation's Choosing Wisely campaign, for which ASCO served as a founding member, and **two-time contributor**, helped bring national attention to the fact that some of the most expensive and commonly prescribed medical tests and treatments are not evidence-based and offer very little proven value to the patient. The irony is that high-quality care—regardless of whether it is expensive or not—often turns out to be less costly in the long-term, in part because it is the most effective treatment, given at the right time, for the appropriate patient. More treatment and more testing than is needed can, on the other hand, raise costs and delay optimal therapy.

The Choosing Wisely campaign embodies the Physicians' Charter on Medical Professionalism published in 2002. [3] Developed jointly by the ABIM Foundation, ACP-ASIM Foundation, and European Federation of Internal Medicine, the Charter outlines three fundamental principles of medical professionalism in the new millennium as well as a set of 10 professional responsibilities including a "commitment to a just distribution of finite resources." Specifically, in meeting the needs of patients, the charter requires physicians "to provide health care that is based on the wise and cost-effective management of limited clinical resources."

As policymakers and those covering the costs (insurers and patients) seek ways to assure the best use of limited resources, they are turning to physician experts for a better understanding—and definition—of value. At the same time, we should recognize that best use of limited resources does not have to necessarily compromise optimal treatment of every patient. The two goals are parallel and not in opposition.

ASCO's Long-Standing Commitment

For more than two decades, ASCO has published **clinical practice guidelines** in oncology to promote high-quality, evidence-based cancer care. These guidelines provide critical guidance to practicing oncologists and represent ASCO's efforts to ensure that evidence-based medicine is the gold standard in oncology. ASCO is now in the process of incorporating cost information into the Society's guidelines to help provide additional information to clinicians when making treatment decisions with their patients. Knowledgeable patients and families increasingly demand this cost information and only a skilled oncologist can put it fully in perspective.

In the late 1990s, long before today's national focus on quality, ASCO undertook a first of its kind effort—the National Initiative on Cancer Care Quality (NICCCQ). The goal of this initiative was to identify and define the universe of measures that represent the hallmarks of high-quality oncology care. This considerable undertaking took a total of five years to complete, and by 2004, ASCO had painstakingly defined the more than 100 measures that collectively signal high-quality care in common cancers. These measures formed the basis of ASCO's **Quality Oncology Practice Initiative (QOPI)**, which launched in 2006, and to date has enrolled more than 900 practices nationwide.

Building on the success of this program, in 2010 ASCO launched the **QOPI Certification program** to formally certify those practices that achieve the highest standards of oncology care delivery to their patients. Our community's embrace of quality is reflected in the high rate of participation and certification in QOPI.

In 2007, ASCO established the Value in Cancer Care Task Force (formerly the Cost of Cancer Cost Task Force) to begin to tackle the issues of cost, quality, and value in concert. The Task Force is composed of a multidisciplinary group of physicians, payers and patient advocates dedicated to providing practical tools and resources to help physicians integrate financial considerations into their treatment discussions with patients. The Task Force published the Society's **Guidance Statement on the Cost of Cancer Care** in 2009. Designed to educate oncology professionals about the issues surrounding cost, this statement was also accompanied by a patient guide on **Managing the Cost of Cancer Care** to help patients address the issue of cost with their physicians as well.

Meanwhile, as Medicare and other third-party payers have been wrestling with how best to contain the escalating costs of medical care, ASCO has been working alongside the payer community to incorporate quality measures into reimbursement formulas. It is widely recognized that delivering high-quality care is itself a means to reduce costs, since consistent application of evidence-based medicine has been shown to eliminate unnecessary medical expense. ASCO has been actively promoting quality improvement programs as the right and best means to achieve cost savings while ensuring that patients continue to receive high-quality care. As part of its campaign, ASCO is applying to have the QOPI program deemed by the Centers for Medicare and Medicaid Services (CMS) as an approved means of satisfying federal quality reporting requirements under Medicare.

In 2011, ASCO published its ground-breaking report, **“Accelerating Progress Against Cancer: ASCO’s Blueprint for Transforming Clinical and Translational Cancer Research.”** This report identified three areas where change is urgently needed and provided specific recommendations to address each:

- Establish a new approach to therapeutic development
- Design smarter, faster clinical trials
- Harness information technology

In follow up to this report, ASCO is soon to publish its Clinically Meaningful Outcomes paper, the culmination of a year-long effort to provide recommendations that attempt to set a higher bar for endpoints in clinical trials, in order to improve our ability to enhance therapy. Intended for use by all involved in designing and conducting clinical trials, these recommendations define a proposed minimum improvement in overall survival that should be expected from clinical trials in order to offer patients a meaningful benefit.

And finally, over the last two years, ASCO has embarked on perhaps its most ambitious endeavor –developing a “learning health-care system” designed to improve the quality, and in turn, the value, of cancer care that is being delivered to patients. Designed to harness information technology, CancerLinQ, a cutting edge health IT platform, will use “big data” to revolutionize how we, as oncologists, care for people with cancer. Designed to aggregate and analyze an almost infinite web of real-world cancer care data, CancerLinQ will decipher patterns that can improve care, feed personalized insights to doctors, and provide real-time quality feedback. The **CancerLinQ prototype** was successfully completed in 2012, the full-build of the system began in 2013, and CancerLinQ is expected to debut to the first tier of practices in 2015.

The Value Initiative

Now, under the leadership of the Value in Cancer Care Task Force, ASCO has launched a new strategic initiative to define value in cancer care. Not only is the Society developing a working definition for value that is specific to oncology, it is also identifying opportunities to integrate value considerations into clinical decisions along the continuum of cancer care. In terms of healthcare, value has been defined by Michael Porter, a leading authority on competitive business strategy, as outcomes relative to cost.[4] In order to define value in cancer care specifically, ASCO is developing a methodology for determining the relative value of cancer treatments and interventions to help physicians make the best decisions with and for their patients.

“In oncology, we face the fascinating challenge of determining the value of today’s cancer treatments,” said ASCO President Clifford A. Hudis, MD, FACP. “What is the worth, for example, of an average of three or four more weeks of time—be it freedom from progression, or life itself—relative to the cost and side effects of the treatment? What if a few benefit greatly and many not at all? The answers to these kinds of questions may vary widely among different patients, families, health-care providers, and communities, but we must confront these difficult issues with courage, compassion, and integrity.”

Based on the work of this task force, ASCO has identified three goals for its strategic value initiative:

- Oncologists will have the skills and tools needed to assess relative value of interventions and use these in discussing treatment options with their patients.
- Patients will have ready access to information that assists them in selecting high value treatment that meets their unique needs.
- Those responsible for covering the costs of cancer care will have a useful algorithm with which to define and assess value of cancer treatment options.

Immediate Challenges

With these goals in mind, there are two major challenges that require immediate attention by the oncology community. First, oncology providers will need to adapt to growing demands to demonstrate quality, efficiency and transparency in the care they provide to their patients. To this end, ASCO’s quality measurement and improvement programs have been shown to improve measurable patient care quality for the past decade. Second, and perhaps more difficult, the oncology community will need to address the spiraling costs of new cancer therapies and tests. This may become even more urgent as novel therapies are tested and administered in combinations of two, three, or more drugs based in some cases on sequential use of novel assays and imaging tests. While there are numerous drivers of the escalating costs of cancer care—including imaging, diagnostics, new technologies, advanced delivery mechanisms, and hospital costs—for most patients, drug costs in particular represent a significant percentage of their direct expenses.

Increasingly, the price of cancer therapeutics has been the subject of intense discussion and debate within the oncology community. Since the 2009 publication of ASCO’s Guidance Statement on The Cost of Cancer Care, the discussion of drug costs has broadened to the larger medical professional community as well as the general public through professional publications and mainstream media alike. From institutional decisions to not offer certain expensive new therapies, to commentaries from leading oncologists across the country, the soaring cost of cancer drugs is under scrutiny by the very doctors who prescribe them. In a special article, “Cancer Drugs in the United States: Justum Pretium-The Just Price” published in the *Journal of Clinical Oncology*, Hagop Kantarjian, MD, and his coauthors drive right to the core of the issue.[5] They raise questions about the ethics of the current pricing model and challenge the increasing practice by drug manufacturers of charging people faced with life-threatening disease enormous sums of money for the life-saving drugs that they require. They also note the disconnect between the benefit—value—of some new drugs and their pricing. This robust discussion makes it clear that oncologists have not only a role, but indeed a responsibility to help address and manage the issue of high drug costs on behalf of our patients.

Most troubling to ASCO are the reports that high drug prices are limiting patient access to treatment and challenging patients’ (and their families’) financial stability and security. The overall burden on the national economy translates into enormous strain at the individual level: patients and their families affected by disease often face crippling expenses during what is already one of the most difficult and stressful times in their lives. According to the National Cancer Institute, an estimated 1.7 million Americans will be diagnosed with cancer this year—bringing the high cost of cancer drugs close to home for that many more patients and their families.[6] With many newly approved oncology drugs costing as much as \$100,000 or more for a single course of treatment,

these therapies are out of reach for many.

It is important to stress, however, that drug costs are only one of a multiplicity of causes (technological innovations in surgery and radiation therapy, hospitalizations, futile cancer care provided at the end of life) for rapid rises in the costs of cancer care and the financial burdens they collectively represent.

Overall, medical costs are the leading cause of personal bankruptcy and the costs of cancer care are an important component of this societal problem.[7] The “financial toxicity” of treatment is a growing concern.[8] While oncologists frequently discuss the toxicities of chemotherapy drugs, they are typically referring to the physical side effects of treatment. However, these financial toxicities can have a substantial impact on patients and should therefore be discussed when treatment options are presented. Patients are sometimes faced with choosing between cancer treatments and paying for food, shelter and other necessities. Two recent studies published in the *Journal of Oncology Practice* highlight these issues. In the first study, among 164 participants, 45 percent reported cost-related medication non-adherence, with 22 percent taking less medication than prescribed, 25 percent only partially filling their prescriptions, and 27 percent not filling their prescriptions at all.[9] In a second study looking specifically at patients covered by insurance, Wong et. al. found that cost concerns are common among insured patients as well.[10] Nearly one-third of covered patients reported concerns about paying for treatment. In yet a third study conducted by USA Today, the Kaiser Family Foundation, and the Harvard School of Public Health, a quarter of patients with insurance reported that they had used up all or most of their savings to deal with their cancer.[11] The issue of the high cost of cancer care for patients is cast in stark relief when one considers that people living with cancer are three times more likely to file for bankruptcy than people without cancer.[12]

“As the organization representing the nation’s cancer doctors, we have a responsibility to speak out on behalf of our patients against the unsustainable rising cost of cancer care—and to work with government agencies, insurance companies, pharmaceutical companies, patient groups and policymakers to help limit its future growth,” said Dr. Hudis.

The Value Framework

The ASCO Value in Cancer Care Task Force is working to develop an initial framework for evaluating value in oncology and to define the key components of this framework. Three key elements have emerged from the work of the Task Force:

- **Clinical benefit.** Clinical benefit is commonly accepted to mean that the treatment demonstrates an improvement in survival compared with no therapy (when appropriate) or to a known effective therapy. In some cases, however, clinical benefit may also constitute a clear improvement in time to disease progression together with an improvement in symptoms or quality of life. In other cases, clinical benefit may not translate to an increased period of disease control, but rather a markedly reduced symptom burden resulting in improved quality of life.
- **Toxicity.** Toxicity refers to side effects associated with treatment, particularly those that impact a patient’s quality of life or ability to complete their usual activities of daily living. It is important to consider the degree of toxicity as many side effects can be managed with supportive or additional treatments.
- **Cost.** Cost encompasses those expenses incurred by patients, society and insurers. In an era when co-pays are rising as a fraction of the cost for care delivered, there are increasing numbers of patients who are forced to file for bankruptcy protection, or make choices between other necessities such as food or shelter. Financial toxicity also can result in poorer outcomes as many patients do not adhere to their treatment regimens in an effort to conserve limited financial resources.

ASCO is working to further refine these core elements of value as well as develop a methodology by which to

apply these elements to ultimately determine a value “score” for various treatments.

In addition, the Society will be leading a number of national and international efforts in 2014 to engage the broader oncology community in this critical discussion including hosting a stakeholder meeting to address the issue of skyrocketing drug costs, developing standards to help define clinical meaningful outcomes for clinical cancer research, and integrating value discussions into the Society’s international scientific and educational meetings

“Through fostering a dialogue within the ASCO community of what value means to patients, providers, and the overall health-care system, we as oncologists have an opportunity to help shape the larger national debate on health-care spending,” said Lowell E. Schnipper, MD, Chair of the Value of Cancer Care Task Force.” We have an obligation to our patients to lead the way in identifying solutions that promote high-value, high-quality cancer care.”

To learn more about the Value of Cancer Care Task Force and its work, click [here](#).

ASCO is very interested in receiving feedback on its Value Initiative and the ideas presented in this AiA Brief. Please send comments, questions, and concerns to publicpolicy@asco.org.

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