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SPECIAL ARTICLE

Delivering High-Quality and Affordable Care Throughout the Cancer Care Continuum

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ABSTRACT

The national cost of cancer care is projected to reach $173 billion by 2020, increasing from $125 billion in 2010. This steep upward cost trajectory has placed enormous an financial burden on patients, their families, and society as a whole and raised major concern about the ability of the health care system to provide and sustain high-quality cancer care. To better understand the cost drivers of cancer care and explore approaches that will mitigate the problem, the National Cancer Policy Forum of the Institute of Medicine held a workshop entitled "Delivering Affordable Cancer Care in the 21st Century" in October 2012. Workshop participants included bioethicists, health economists, primary care physicians, and medical, surgical, and radiation oncologists, from both academic and community settings. All speakers expressed a sense of urgency about the affordability of cancer care resulting from the future demographic trend as well as the high cost of emerging cancer therapies and rapid diffusion of new technologies in the absence to evidence indicating improved outcomes for patients. This article is our summary of presentations at the workshop that highlighted the overuse and underuse of screening, treatments, and technologies throughout the cancer care continuum in oncology practice in the United States.

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INTRODUCTION

Success in basic, translational, and clinical research has led to significant progress in diminishing the burden of malignant disease. This progress notwithstanding, cancer remains an unsolved problem of enormous magnitude. Its human dimensions are clear, and equally apparent is the enormity of the financial burden that the disease places on society and individuals. A crescendo of voices is expressing concern about the cost of health care in the United States. It is projected that 20% of the gross domestic product will be allocated to health care by 2020.[1] The national cost of cancer care is estimated to reach $173 billion in 2020, increasing from $125 billion in 2010.[2] The steep upward trajectory of cancer-related expenses has resulted from numerous factors, including costly new drugs, expensive innovations in radiation therapy and the operating room, high costs of hospital care, overuse of diagnostic tests and therapeutic interventions that have little or no value, and an aging population.

Motivated by a report commissioned by *Lancet Oncology* on the delivery of affordable cancer care in high-income countries[3] and an article expressing the urgency to bend the cost curve in cancer care,[4] the National Cancer Policy Forum of the Institute of Medicine convened a workshop entitled "Delivering Affordable Cancer Care in the 21st Century" in October 2012.[5] This article summarizes presentations by thought leaders in the field regarding the overuse and underuse of technologies throughout the cancer care continuum.

CANCER SCREENING

Current cancer screening practices provide important examples of practice patterns that offer little or no value, resulting in misallocation of limited resources. These include overuse or inappropriate use of prostate-specific antigen (PSA) –based prostate cancer screening,[6] colonoscopy,[7] and mammography.[8,9] At the same time, underuse of mammography, Pap smear, and colonoscopy has been documented in some populations.[6,8,10]

The culture of US medicine favors intervention. The public and clinicians have a positive attitude toward screening. This, coupled with low price sensitivity for patients with insurance coverage and inattention to the level of evidence underpinning an intervention, has formed a mindset that assumes more interventions will maximize the reduction in mortality from cancer. Inappropriate use of screening tests may lead to overdiagnosis and overtreatment, which not only increases health care

spending, but also causes patients more harm than good. Prostate cancer screening with PSA represents a classic example. Two large randomized controlled trials (RCTs) and several carefully controlled observational studies have found that PSA testing has a small impact on prostate cancer mortality, while nearly doubling the number of men diagnosed with and treated for prostate cancer. This has led the US Preventive Services Task Force, the American College of Physicians, and other organizations to recommend against routine PSA screening.[11,12] Nevertheless, the publication of the negative trials and recommendations have had only a moderate impact on the rate of PSA screening.[13] Analysis of the 2010 National Health Interview Survey showed that > 50% of men age ≥ 50 years with a college education reported having had a PSA test in the past year.[6]

Screening mammography can also lead to overdiagnosis,[14] and its use among women with limited life expectancy deserves special consideration. Several RCTs found routine screening mammography in women age 50 to 69 years reduced breast cancer mortality by 20% to 30%.[15] In the RCTs, there was no reduction in the number of deaths resulting from breast cancer until 7 years after mammography. Thus, screening for women with a life expectancy < 7 years will not affect their chance of dying as a result of breast cancer but will increase the number of women diagnosed with and treated for breast cancer. Nevertheless, substantial numbers of women with low life expectancy still receive routine screening mammography.[8,9]

Overuse of tests is also found in cancers with limited or no scientific evidence to support screening, such as transvaginal ultrasonography for ovarian cancer or chest x-ray for lung cancer. The landscape of lung cancer screening is likely to change with recent evidence from the National Lung Screening Trial (NLST).[16] The trial reported a 20% relative reduction in lung cancer mortality for high-risk patients undergoing three annual rounds of low-dose computed tomography screening compared with chest x-ray. Although findings from the NLST are uplifting for a devastating disease like lung cancer, providers should screen individuals having the same risk profiles included in the NLST until better evidence for other risk cohorts are validated. This will ensure the clinical translation of trial findings while minimizing the harms of screening, including excessive radiation exposure and surgery after false positives.[17,18]

Both overuse and underuse of colonoscopy are found among the elderly. One study examined the time interval between a negative screening and the next screening colonoscopy and found approximately 23% of the study cohort received a repeat colonoscopy within 7 years without any clinical indication, despite the fact that almost every guideline recommended a 10-year screening interval for colonoscopy.[7] Another study explored the proportion of potentially inappropriate colonoscopies performed by providers and reported the percentage was highest for those age 76 to 85 years, averaging > 30% among providers seeing patients within this age range (Table 1).[19]

This evidence of overuse or inappropriate use of screening in no way undermines the importance of screening for some cancers. The benefit of screening for breast, cervical, and colorectal cancers is well established. Despite the US public's distaste for rationing health care, rationing already exists in the current health care system in a not-so-subtle fashion, leading to a substantial proportion of people who do not receive basic care. Underuse of mammography, Pap smear, and colonoscopy has been found among the uninsured, the less educated, individuals at lower socioeconomic levels, and those without primary care physicians.[6,10] Disparities in screening and receipt of timely treatment then translate into disparities in cancer mortality, as is evident from studies documenting significant differences in survival between the insured and uninsured.[20-24]

Table 1. Inappropriate Colonoscopies in Texas by Age

Age of Recipient (years)	Possibly Inappropriate (%)	Probably Inappropriate (%)
70 to 75	9.9	7.9
76 to 85	38.8	31.7
≥ 85	24.9	17.3

Data adapted.[19]

CANCER TREATMENT

Workshop speakers expressed a sense of urgency about the affordability of cancer care as a result of the high cost of emerging therapies and rapid diffusion of new technologies in the absence of evidence indicating improved outcomes for patients.

Chemotherapy and Biologics

Advances in cancer biology have led to novel targeted therapies that are changing cancer care. Although some agents have been associated with enormous benefits, such as human epidermal growth factor receptor 2–directed therapies in breast cancer and tyrosine kinase inhibitors in chronic myelocytic leukemia, many new agents add modest incremental benefits at a substantial cost. Interestingly, regardless of the magnitude of clinical benefit of these new drugs, most of them cost approximately $10,000 per month. Pharmaceutical companies have been able to set the price for oncology drugs in the US market, often at a price much higher than that in the rest of the world. A frequently cited justification for higher prices is that the United States is cross-subsidizing the global market to preserve the incentive for pharmaceutical innovations. However, a number of regulatory factors also contribute to the steep pricing of oncology drugs in the United States. The Centers for Medicare and Medicaid Services (CMS), the largest payer for oncology drugs, is prohibited by statute from price negotiation. Additionally, federal regulations and many state laws mandate that insurance plans cover oncology drugs. Historically, drug companies were able to enjoy monopoly pricing, given the small number of oncology drugs in the pipeline. That situation is beginning to change. For example, seven drugs have been approved by the US Food and Drug Administration (FDA) to treat renal cell cancer since 2005. An important unanswered question is whether market competition will drive down the prices of these drugs as the number of drugs available to treat the same type of cancer increases.

The financial burden these new cancer drugs impose on the health care system is compounded by off-label use. The percentage of off-label use was estimated to be approximately 33% of all drug administrations to patients with cancer in the late 1980s[25] and rose to 60% to 70% in mid 2000s.[26] The reasons behind off-label prescribing can reflect physicians acting on the clinical urgency and biologic plausibility of a particular disease or regulatory decisions lagging behind the scientific evidence, or it may be a product of misalignment of financial incentives in our fee-for-service payment system. Regarding the latter point, once a decision is made by CMS to reimburse a drug

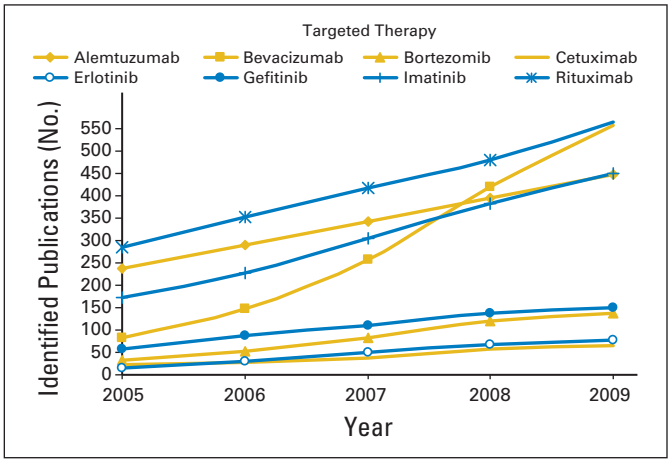

Fig 1. Number of publications supporting off-label indications, 2005 to 2009. Data adapted.[28]

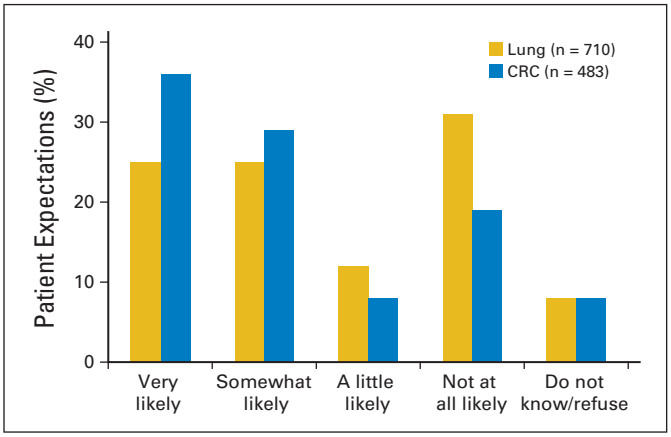

Fig 2. Patient expectations of likelihood that chemotherapy will cure cancer (from the CanCORS [Cancer Care Outcomes Research and Surveillance] study). CRC, colorectal cancer. Reprinted with permission.[30]

for off-label use, most other payers will usually follow the Medicare reimbursement policy. Regardless of the motivation, rising off-label use increases the cost of cancer care, especially if the prescription involves high-priced anticancer drugs.

Drug compendia are used to help guide reimbursement decisions on off-label prescriptions. However, most compendia consider their purpose to be providing guidance on the use of a drug after it has been prescribed (eg, toxicity), not determining whether one drug is better than the other.[27] Because the review criteria and quality standards vary across compendia, the number of reimbursable off-label indications is likely to increase as CMS expands the sources of compendia. This approach to reimbursing off-label prescriptions creates a perverse incentive to produce as many studies as possible to fill the evidence gap as quickly as possible. Figure 1 illustrates the number of publications on off-label indications of eight targeted therapy agents, totaling 442 publications in a 5-year period (2005 to 2009).[28] Another study showed that although oncology trials accounted for the largest proportion of studies on clinicaltrials.gov, 88% of them were not blinded, 64% were not randomized, and 84% were in early phases.[29] The proliferation of small studies raises important questions about the validity of evidence supporting use of oncologics, which has implications for the cost and more importantly the quality of cancer care.

The payment mechanism for oncology drugs contributes to the upward spiral of cancer care costs. Many cancer drugs are parenteral and must be administered in the oncologist's office or hospital clinic; therefore, they are covered by insurance plans under medical benefit. For infused chemotherapy agents, community-based oncologists are paid at the average sale price plus a 6% markup under Medicare Part B. This payment system creates a perverse financial incentive for providers to choose more expensive, but not necessarily better, drugs. Well-insured patients (eg, Medicare beneficiaries with Medigap) are unlikely to object to their oncologists' choice of a more expensive drug, because their insurance coverage makes them less cost sensitive. The end result is that the high cost of cancer care is borne by taxpayers nationwide. Currently, we do not have a payment system that aligns incentives to promote high-value care, although patients and the public would benefit from such a system that need not necessarily cost more. Increasing use of oral cancer drugs may mitigate some of the pressure on the health care system as costs shift from medical to pharmacy benefits. In this situation, payers have had more success at containing cost without compromising quality through the use of tools like tiered formularies and prior authorization.

Patients' high expectations of cancer therapy may be another cost driver. A study surveyed > 1,000 patients with metastatic lung or metastatic colorectal cancer on their expectations about the benefits of chemotherapy.[30] Even in the case of incurable disease, > 80% of patients with metastatic colorectal cancer and 69% of those with metastatic lung cancer believed that they were very or somewhat likely to be cured with chemotherapy (Fig 2). The study concluded that "physicians may be able to improve patients' understanding, but this may come at the cost of patents' satisfaction."[30(p1616)] This conclusion highlights the challenges oncologists face: In a culture that favors treatment and has an overly optimistic view of what medicine can offer, it is an uphill battle for cost-conscious oncologists to communicate the true value of various forms of therapies, particularly when curative treatment options are lacking.

Radiotherapy and Surgery

Innovative technologies in radiation therapy are subject to different approvals than the FDA requires for pharmaceuticals. Many new radiotherapies hit the market soon after obtaining safety clearance from the FDA and are diffused quickly into practice despite limited comparative evidence on their benefits and harms.[31-34] Under the fee-for-service payment system, highly reimbursed technologies create an incentive for adoption. Studies using population-based data have shown rapid diffusion of brachytherapy and intensity-modulated radiotherapy in prostate and breast cancers.[31-34] It has been estimated that intensity-modulated radiotherapy alone accounted for an additional $1 billion in Medicare spending on prostate cancer between 2002 and 2005.[32] As in other specialties of medicine, it is also challenging to change practice patterns toward more value-oriented care in radiotherapy. For example, although multiple-fraction radiotherapy for bone metastases has been commonly employed, a randomized trial published in 2006 concluded that single-fraction radiotherapy was as effective in pain reduction.[35] Yet a recent SEER-Medicare analysis demonstrated that multiple-fraction radiotherapy remains common, even in the last 30 days of life.[36]

Robotic-assisted surgeries have been the focal point of surgical innovation in oncology in the last decade. As in the case of new

radiotherapies, FDA approval of surgical devices does not require clinical trials. The da Vinci Surgical System received FDA approval in 2000, and rapid diffusion of robotic-assisted surgeries in oncology practice has followed. The novelty associated with the term robotic has struck the fancy of the US public, attracting massive media attention and leading to a medical arms race among hospitals. Some of the media coverage and materials in direct-to-consumer advertisements have contained promotional language that is not evidence based, raising high hopes among the public for what this new technology can deliver. By 2009, > 1,400 machines had been installed in hospitals across the United States. It is estimated that robotic surgery adds 13% to the cost of surgery.[37]

The success of marketing robotic surgery to oncology is exemplified by the surgical treatment of prostate cancer; several studies have shown that by 2007, close to 50% of radical prostatectomies (RPs) had been performed as laparoscopic procedures.[38-40] On the basis of practice patterns in the mid 2000s, it is believed that a majority of laparoscopic cases documented in these studies were robotic assisted.[41] Whether robotic surgery adds value to the surgical treatment of cancer remains debatable. As a tool, the design of the robot system facilitates procedures that are traditionally considered to be technically challenging. Patients who undergo robotic-assisted procedures often have smaller excisions, less blood loss, and shorter lengths of stay in the hospital. Observational studies (not prospective randomized trials) have shown that compared with open surgeries, robotic surgeries in general have fewer postoperative complications in RP[38] and lower inpatient mortality in RP and cystectomy.[42] However, robotic-assisted RP was associated with more genitourinary complications than open surgery.[38] Additionally, the shorter length of stay does not imply cost saving. A systematic review concluded that the cost of robotic-assisted RP was $2,000 to $4,000 greater than that of open surgery.[43] The higher inpatient costs involved in robotic surgeries have been attributed to operative times. Given the high level of heterogeneity in surgical outcomes and the expansive learning curve associated with robotic surgeries,[44] the fast diffusion of robotic surgery raises concern about the cost and quality of cancer surgeries, especially for patients treated by low-volume surgeons and in low-volume hospitals.

SUPPORTIVE CARE

End-of-life care in the United States needs great improvement. All too often, patients with incurable advanced cancer are receiving active antineoplastic therapies in the last weeks of life. There is ample documentation that patients who received aggressive interventions near the end of life had worse quality of life.[45] Greater use of palliative care can improve quality of life and even lengthen survival.[46] In the aggregate, Medicare payments in the last year of life accounted for > 25% of Medicare spending.[47] Overtreatment of patients with cancer with incurable disease is an important contributor to the high cost of cancer care, and yet many studies have documented overly aggressive care for patients with cancer in the last month or even week of their lives.[36,48-50]

An innovative care delivery model that integrates palliative and oncology care around the time of diagnosis for patients with advanced cancer was developed with the goal of initiating conversation about prognosis earlier in the course of illness.[46] This early palliative care model was evaluated in a randomized trial of patients with newly diagnosed metastatic non–small-cell lung cancer. The trial demonstrated that the early palliative care model was associated with lower resource use; thus, it has the potential to alleviate some of the cost pressure observed in the last few months of life. Patients randomly assigned to the early palliative care model were less likely to receive chemotherapy at the end of life, had longer lengths of stay in hospice, and incurred fewer hospitalizations and emergency room visits. Comparisons of total cost in the last 30 days of life showed that the average cost difference was $2,000.[51]

Table 2. Comparison of Quality-of-Life Outcomes Between Standard Care and Early Palliative Care

Scale	Standard Care (n = 47)	Early Palliative Care (n = 60)	Difference Between Early and Standard Care	95% CI	*P*
FACT-L	91.5	98.0	6.5	0.5 to 12.4	.03
LCS	19.3	21.0	1.7	0.1 to 3.2	.03
TOI	53.0	59.0	6.0	1.5 to 10.4	.009

NOTE. Quality of life was assessed using three scales: the FACT-L scale, in which scores range from 0 to 136, with higher scores indicating better quality of life; the LCS of the FACT-L scale, in which scores range from 0 to 28, with higher scores indicating fewer symptoms; and the TOI, which is the sum of the scores of the LCS and the physical and functional well-being subscales of the FACT-L scale (scores range from 0 to 84, with higher scores indicating better quality of life). Reprinted with permission.[46]

Abbreviations: FACT-L, Functional Assessment of Cancer Therapy–Lung; LCS, Lung Cancer Subscale; TOI, Trial Outcome Index.

The quality of care that patients with cancer experience is even more important than concerns about cost. To ensure the delivery of high-quality cancer care, patients and their families must be knowledgeable about their illnesses and prognoses so they can make informed decisions about their care. Data suggest that patients with advanced cancer and their families prefer to receive accurate and truthful information about their illnesses.[52] The trial of early palliative care[46] also showed that the early palliative care model improved patients' quality of life (Table 2), lowered the rate of depression, and was more likely to alter patients' perception of their disease to reach a more accurate projection of their prognosis over time.[46,53] Yet many physicians are hesitant to fully disclose prognostic information to their patients. Poor communication at this critical juncture leads patients to hold an overly optimistic perception of their disease, which contributes to patients choice of more intensive therapy and hesitance to engage in discussions about palliative and hospice care.[54,55]

DISCUSSION

Cancer care in the United States is at a crossroads. Medical innovations have enabled the best and most novel treatments for citizens in this country; however, the rapid diffusion of costly new therapies coupled with an aging demographic trend has stimulated a growing public need that is increasingly becoming unaffordable for many. The aging of the US population is a key driver of the growing cost of cancer. Other cost drivers include overuse and inappropriate use of technologies, the rising cost of innovations, public demand for non–evidence-based services, and unrealistic expectations. Although the aging trend is irreversible, understanding the overuse or inappropriate use of new technologies provides opportunities to reduce costs by designing policies targeted at modifiable

factors. The Institute of Medicine Workshop convened bioethicists, economists, primary care physicians, and medical, surgical, and radiation oncologists to discuss the cost drivers of cancer care resulting from factors other than the demographic trend and explore approaches that would mitigate the problem.

The widespread overuse of health care resources was a focal point for many discussants who suggested myriad strategies for potential savings. In our view, if there was a single sentiment that echoed throughout the workshop, it is that we, the stakeholders in the cancer care system (clinicians, payers, patients, and biotech or pharmaceutical companies), have met the enemy, and we are it. Speakers presented studies that documented overuse across the spectrum of cancer care, from screening and diagnosis to treatment and surveillance. Overuse has been widely recognized by the Choosing Wisely Campaign sponsored by the American Board of Internal Medicine.[56] The American Society of Clinical Oncology has spearheaded this effort in cancer care by identifying five common practices in oncology for which there is little or no evidence of benefit to the patient and urged that physicians avoid these practices and discuss the rationale with patients.[57] The thread that weaves through the overuse of medical technology is the lack of attention to high-level evidence for patient benefit. While acknowledging that every patient is unique, and exceptions are at times justifiable, there is little doubt that greater adherence to high-quality scientific evidence would improve the quality of cancer care, limit morbidity related to overuse, eliminate underuse of life-saving technologies, and increase the value of cancer care. Applying the right amount of care in the right context could save billions.

The explosion of novel cancer therapies has caused a level of enthusiasm for the possibility of long-term disease control or cure that for the most part has not yet been realized. Nonetheless, the promise of major improvements, amply supported by media, industry, and the scientific establishment, drives desperate patients with cancer and their physician advocates to explore every option. Therapies that offer modest benefit are often priced equivalently to those that engender long-term disease control. Cancer drugs represent the most expensive agents in most hospital pharmacies and are on a steep upward trajectory. The fact that drug prices in the US market are much higher than those in other countries is problematic. When an innovation is being subjected to a clinical trial, it is imperative that the trial design be unimpeachable, the emerging data be of high quality, and the conclusions drawn from the trial be meaningful. Too often, new agents are approved based on extremely modest improvements in outcome. Although the patient has every reason to want every measure of benefit, it should be the role of expert panels and patient advocates to determine what value a new innovation represents.

Robotic surgery has become a widespread reality, as indicated by the broad-based uptake of the technology across the country. Despite the rapid diffusion of this technology, it has not been subjected to rigorous comparisons with existing surgical approaches in RCTs. Nor have there been comparative trials addressing the value of radiologic innovations, such as proton beam therapy as compared with conventional delivery of high-energy photons. Subjecting surgical and device innovations to more systematic scrutiny similar to that required by the FDA for drug approval is one potential strategy, which would provide opportunities to curb widespread dissemination of high-cost, relatively low-benefit interventions.

Special attention is warranted by end-of-life care. All too often, patients for whom there are no effective therapies, and who are ineligible for clinical trials, are administered chemotherapy in the hope that it will do some good and little harm. Oncologists commonly treat patients with intensive therapy when they are only weeks away from death, a juncture at which it is highly unlikely that any such therapy will have benefit. The importance of appropriate integration of palliative care with frank, empathetic, and culturally appropriate discussion about prognosis and end-of-life care preferences should be recognized.

As cancer care evolves, we need a system that is rational and not rationed. It must be a system in which the incentives that motivate each protagonist in the care equation are aligned: here we refer to the patient, physician, hospital, biotech or pharmaceutical company, and insurer. Communication strategies that encompass patient to clinician, clinician to clinician, hospital to patient, and health care system to health system are essential. Widespread use of electronic medical record technology that is accessible across institutional barriers is urgently needed. The inadvertent incentive to do more without evidence of benefit must be discouraged. Innovative payment reforms that encourage positive health practices and efficient high-quality care are needed. Such a system would pay for services of definite value based on prevailing evidence, while discouraging use of those that fail to meet this test by creating a financial disincentive. Current medical practice entrenches financial reimbursement based on individual medical specialties, creating a distorted perspective. Coordinated multispecialty care in which providers across all relevant disciplines share resources, risks, and reimbursements can realign incentives to foster coherent, evidence-based practice. Pilot projects of this type have been undertaken, and more are sorely needed.

Perhaps the last word should focus on the patient, because it is the patient who is at the core of our concern. Educating patients of today and tomorrow so that their understanding and expectations about cancer care are informed is essential. This requires access to high-quality information that is not tainted by marketing ploys promoting excessive or low-yield interventions. Direct marketing of drugs and devices to the patients should be discouraged, and patients should be empowered to ask their physicians about therapeutic options and the financial implications of recommended treatments. The changes called for by individual speakers at this workshop are sweeping; if enacted broadly, they will revolutionize cancer medicine by improving its quality and enhancing its value. They will also bend the cost curve. The problems posed by the rising cost of cancer care are paradigmatic of those confronting the US health care system as a whole and must be addressed urgently.

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