In Search of Value in Cancer Care: What Resources Are Available to Practicing Oncologists?

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One of the more difficult topics to discuss concerning the ethics of healthcare is distributive justice—the fair distribution of benefits, risks, and costs. This moral principle is becoming one of the more important issues in oncology care because of the rising cost of cancer therapies and the significant financial toxicities that are being inflicted on patients, taxpayers, and the health system at large. As higher numbers of cancer patients are filing for bankruptcy secondary to medical costs, many oncologists are wondering whether there is a way to reconcile quality care and affordability.

The market for anticancer drugs is considerable and has been growing at a rapid rate. Global market spending for anticancer pharmaceuticals alone increased from $71 billion in 2008 to $91 billion in 2013.[1] In the United States, approximately 5% of the nation's gross domestic product was spent on healthcare in 1965. By 2004, that percentage had increased to 16%, and today it is nearing 20%.[2] However, despite the growing price of and the increased spending on anticancer pharmaceuticals, the progression-free survival (PFS) and overall survival (OS) benefits for patients have been minimal. The median improvement in PFS for new drugs between 2002 and 2014 was found to be 2.5 months, and the median improvement in OS was 2.1 months.[3] One of the reasons stated for such a large price tag on cancer therapeutics is that this is a direct consequence of the cost of developing new cancer therapies. However, studies have found that, of the new cancer therapeutics brought to market between 2002 and 2014, "74% of them had an overlapping mechanism of action with others yet approved or still in clinical development."[4] It would seem logical that developing a "me-too"[3] drug with a mechanism similar to that of an already approved drug decreases the risk of drug failure while adding the benefit of less developmental cost and the potential to get the drug to market quicker, thus allowing for increased profits.

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However, it does not increase the variability of anticancer agents, and does little to further our ability to make a more significant impact on cancer overall. Because healthcare does not fall under the influence of free market forces,[5] the competition of similar products flooding the market has done nothing to drop the prices of these agents. In fact, drug prices have been found to be dependent only on what the markets will sustain,[1] and as long as the market continues to sustain inflated drug pricing, pharmaceutical companies continue to increase the prices by approximately 10% each year.[1]

The healthcare system finds itself in a crisis of value: increased spending for less efficacious cancer therapies. But how does one define and measure value? Value has been defined in many ways. Ramsey et al[6] defined value as giving equal weight to the opinions of patients, families, physicians, and health insurers on whether the benefits of treatment outweigh the total sum of the resources expended. Others have defined value more simply as "health outcomes achieved per dollar spent,"[7] meaning total cost not only to the individual, but to society overall. Some take a more patient-centered approach and define value according to the ratio of benefits vs risks; however, there is concern that "because individual consumers are largely protected from the costs of healthcare goods and services, value equations in healthcare are not based on considerations of the total cost of goods and services but on the portion of costs borne by the individual consumers."[2] Given that value is so hard to define, developing tools to measure value has been even more difficult: Should measurements be based on societal costs or out-of-pocket costs? Does one define efficacy in terms of PFS, OS, quality of life, or something else? How does one account for patient autonomy and personal value systems? Taking these multiple variables associated with value (ie, total cost of cancer therapy, clinical efficacy, toxicity, patient preference, etc) into consideration has proven challenging. In response, both the American Society of Clinical Oncology (ASCO) and the European Society for Medical Oncology (ESMO) have released tools to help oncologists measure value.

This is not the first time that institutions have made attempts to define and measure value. Indeed, these efforts have been attempted on a global level for decades. Australia led the charge with the development of the Pharmaceutical Benefits Scheme in the early 1990s.[8] The United Kingdom followed

with the National Institute for Health and Care Excellence in 1999.[8] France has the Haute Autorité de Santé, and Germany has the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen.[8] Although the objectives of the organizations are very different, the underlying principle of using evidence-based medicine to utilize healthcare resources to their fullest potential are largely shared.[8] These organizations contracted with academic and professional external organizations to help them undertake their comparative effectiveness research, as well as performing some of the research internally. All of these organizations incorporated cost concerns into their studies. In all cases, these organizations were met with "intense controversy" and "negative press."[8] Developing such an organization in the United States has been extremely difficult, and many that were developed over the years are no longer operational. With the American Recovery and Reinvestment Act of 2009, funds were established for the development of comparative effectiveness research, but these were restricted in studies of cost because of largely politically driven publicity concerning so-called "death panels" and fear of healthcare rationing. Thus, in the United States, implementing changes through health policy channels has been slow and therefore unsuccessful in reducing the prices of cancer drugs thus far.

Although the problem of healthcare costs is typically viewed only on the national level, the dramatic rise in the cost of healthcare has become a global issue. To truly control costs and provide value in cancer care and healthcare overall, an international institutional collaboration may be needed to work together in designing and funding comparative effectiveness trials that can obtain the data needed to make informed decisions.

As opposed to health policy, another approach to the value crisis has been to focus on the patient-physician relationship and the communication of value to patients. The medical community, through such organizations as ASCO and ESMO, are taking leadership roles in the efforts to increase the value of cancer care.[9,10] ASCO released a paper in 2014 calling on the oncology community to "raise the bar" in defining clinically meaningful outcomes in trials.[11] With larger trials, smaller statistically significant benefits of therapies were able to be detected. The drugs tested in such trials were being approved and incorporated into guidelines while bearing hefty price tags for minimal therapeutic benefit. By the

summer of 2015, both ESMO and ASCO had released tools to help oncologists assess value of cancer therapy regimens.[9,10] Although these tools are in their infancy, they have started the conversation among oncologists on how best to discuss and provide value in cancer care. One challenge that has arisen is that the tools are only as strong as the data supporting them. The possibility of weak or uneven data raises concerning questions about the comparison of regimens across trials in order to assign value to cancer treatments. However, developing these tools and starting the discussion on how oncologists can help protect patients and families from the financial toxicity of cancer therapy are sorely needed first steps.

Until the value tools can be refined and until health policy organizations are able to better guide physicians and patients through effective care, how are physicians to navigate the communication of value to their patients? One possible way to help decrease patient out-of-pocket costs is to use a multidisciplinary team that includes a financial counselor who can obtain out-of-pocket cost information for patients prior to administration of chemotherapy. This will allow the healthcare team to have a more informed value conversation with the patient concerning both out-of-pocket costs and the efficacy of therapy, and will provide time to seek out financial aid for patients and families who are in need. In addition, physicians should be mindful of expensive imaging modalities, and should use less expensive imaging modalities when appropriate and decrease the frequency of imaging when possible. Another suggestion, which may be one of the most important things a physician can do to help in providing value care to patients, is to ask patients how they are coping financially. It is important to keep the lines of communication open with regard to the patient's out-of-pocket costs. Although these conversations are challenging, and may be foreign to many physicians, framing the conversation so that patients understand that the physician is concerned about all facets of their well-being may help open the discussion in a nonthreatening way. In addition, physicians should try to reduce the use of therapies that have little to no evidence to support their use, but instead look to find appropriate clinical trials for patients.[12] If oncologists can be mindful of the cost concerns of their patients, they may be able to mitigate, albeit in a small way, the value crisis in cancer therapy.

Ethics discussions concerning value in cancer care are key to helping resolve this crisis in distributive justice and in rationing limited resources in ethical ways. Solutions will require many stakeholders coming to the table to discuss value and allocation. Greater emphasis will need to be placed on comparative effectiveness data. Until significant strides can be made in health policy, oncologists can play a small role in being good stewards of resources and having open discussions with patients concerning out-of-pocket costs and expected benefits of therapies.

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Key Points:

- The rising cost of cancer therapies is bringing the issue of financial toxicity to the forefront of oncology, particularly how it affects patients, taxpayers, and the health system in general.
- The definition of value in cancer care is still ambiguous; ASCO and ESMO have recently released tools that have initiated the conversation on how to provide the best value in cancer care.
- Involving a multidisciplinary team in the care of cancer patients can help keep them informed and aware of the value issues surrounding every aspect of their treatment; in addition, oncologists need to keep the lines of communication open about out-of-pocket costs.

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