

ADVANCES IN DRUG DEVELOPMENT

Current Developments in Oncology Drug Research

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Cost of New Oncology Drugs

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H&O Why is the cost debate most prominent in oncology as opposed to other diseases?

LN There are a few reasons why oncology is the focus of the drug cost debate. One reason is that cancer care in general is very expensive compared to other disease states. One can have a coronary bypass for their heart disease for \$20,000, but the average lifetime cost of cancer is well over \$100,000. The other issue is that there is a considerable amount of information available in cancer; we know how many months of life are gained with a particular drug because of the extensive studies that have been done. Thus, this is an area in which we can say for X thousands of dollars, a patient gains X extra months of life. The data are available for cancer and often not available for other diseases.

H&O What is the current state of drug pricing in oncology?

LN At present, in oncology, the drugs that are being developed are all fairly unique; we do not see many me-too drugs coming to the market, and so there are no substitutions. As a result, a manufacturer can price a drug at a fairly high level. What has become apparent is that drug pricing for new agents is whatever the market will bear, and in oncology, since someone else is always paying for treatment—government or private insurers rather than patients themselves—consumers have less incentive to be price sensitive and in turn this creates incentives for manufacturers to charge higher prices. So, we see new regimens coming to market that

cost \$50,000, \$60,000, \$70,000 or even \$80,000 per regimen, and there is no economic force that keeps manufacturers from raising their prices. This occurs also because there is no competition; with patent protection, no other manufacturer can make the same drug for the duration of patent exclusivity. The real cost of the drug is hidden; insurance companies put it in their premium because they have to cover the drug, and consumers do not always make the connection between high drug costs and a higher insurance premium.

H&O Do you think that considering cost in the drug approval process is feasible in the United States?

LN At present, we as a society have not said what we are willing to pay for an extra year of life. Therefore, drugs that come to market that show only marginal therapeutic benefits are difficult to evaluate. The British, through the National Institute for Health and Clinical Excellence, have established a maximum threshold of £30,000 for 1 extra year of life. The United States does not have such a threshold for anticancer therapies, and, therefore, Americans are paying a significant amount of money for a treatment that may provide an extra month of life. This issue is something that the federal government will have to wrestle with as it undertakes the task of making cost of care more affordable. Ultimately, I think that considering cost in the drug approval process, as done in the United Kingdom, is feasible. We will have to include this consideration because we cannot sustain increasing drug costs for an unlimited amount of time.

H&O In your recent article in the *Oncologist*, you ask the question “How do we get the desired outcome at the best possible cost?” How does one achieve this?

LN In terms of determining which drug is the most cost effective, one can run a clinical trial comparing drug regimens to each other and record the costs of giving those drugs; it is just a matter of doing the math to calculate which is the least expensive approach producing the best patient response. Dr. Scott Ramsey at the University of Washington did this in 2000. A large national trial was comparing 4 drug combinations for the treatment of lung cancer. Study findings showed that all 4 combinations had the exact same response rate, but Dr. Ramsey recorded the cost of each regimen and found that there was a 3- to 4-fold difference in cost between one regimen and another.

Most new drugs simply have to prove that they have a response for cancer; they do not have to undergo any cost effectiveness studies for approval. Therefore, it is up to society to get the data and make the choice to use the most cost-effective drug.

H&O Can you discuss the 3 changes you believe need to be made in order to provide affordable care?

LN In the *Journal of Oncology Practice*, I explained the 3 changes that I think need to be made in order to have affordable care: strictly using evidence, becoming more consistent and improving care with results measurement, and developing a new payment system.

Strictly using evidence refers to adhering to evidence standards when treating patients. When a clinical trial is conducted, and even though the results show that drug A plus drug B is effective, we should not then assume that drug A plus drug C will work as well. Strictly using evidence involves not partaking in off-label experimentation. In oncology, it is not uncommon to see drugs that are approved for one indication being used for unapproved indications. The drug may or may not work in these other unapproved indications, as many studies have shown, but we need to effectively utilize the available evidence without going beyond what the evidence shows. If we think an agent is going to be effective in a particular cancer type, we need to do the study to actually show that it works rather than start treating patients with that drug off-label.

Once we are using the evidence we have to effectively treat patients, we can then create a more consistent standardized approach to treatment, which will help identify the best practices in cancer care. Some of our past research shows that in approximately 250 patients who had pancreatic cancer, 184 different treatments were being used, with only 3 drugs that were approved for pancreatic cancer. This many approaches to patient care make it impossible to accurately measure results. However, if we were to use the available data and treat patients with pancreatic cancer with only FDA-approved regimens, we would be able to measure and compare results and subsequently determine the best therapeutic option for those patients.

The third change that needs to be made for affordable healthcare is in the payment system. Currently, oncologists make most of their income from chemotherapy drugs. This has created an incentive to use more expensive drugs rather than less expensive alternatives. The current payment system does not pay oncologists to focus on patient care, and this has created some misaligned incentives. The goal should be to maintain oncologists' income by moving the focus to the patient and away from being dependent on selecting the most expensive treatment approach. Over time, if we start to change our current practices, we hope to end up with a payment method that includes cost-effectiveness and quality with more patient-focused care.

H&O What needs to be done by the government, physicians, insurance companies, etc in order to reduce the cost of oncology care?

LN A national decision will have to be made about how much we can afford to pay for medical costs, and then we will need to work within that budget. I believe it is crucial to have an open debate; insurers cannot make this decision alone, nor can healthcare providers—it will require a consensus decision by society. Ultimately, Congress will need to enforce some type of price ceiling, and manufacturers—faced with new payment structures—may decide to price their drugs entirely differently, possibly commensurate with the health benefit derived from the drug.

Suggested Readings

Newcomer L. Three changes for affordable care: one payer's wish. *J Oncology Practice*. 2009;5:219-221.

Newcomer L. The responsibility to pay for cancer treatments: a health insurer's view of value. *Oncologist*. 2010;15(suppl 1):32-35.

Danzon P, Taylor E. Drug pricing and value in oncology. *Oncologist*. 2010;15(suppl 1):24-31.