



Getting Past No in Cancer Care

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Disclosures of potential conflicts of interest may be found at the end of this article.

The rising cost of cancer care, and especially the rising cost of cancer drugs, is widely held to be unsustainable. At the heart of this debate is the belief that the benefit society is receiving is out of register with the cost—that we are not getting good value—and there is evidence to support that view [1]. This is not a debate about the amazing progress that has been made in the fundamental understanding of cancer or on the breathtaking outcomes achieved with some of the new targeted therapies or immuno-oncologic agents. Rather, it is the concern that many of the new therapies being brought to market are priced at a premium irrespective of clinical impact, resulting in a fundamental misalignment between cost and benefit. In his payer perspective, Dr. Newcomer [2] proposes solutions to the frequently discussed challenge of controlling the rapidly increasing costs of cancer care. He reviews why the free market has failed (i.e., because it is not really a free market). He goes on to delineate four specific “simple” steps: (a) eliminate coverage mandates; (b) allow for true comparative effectiveness and cost-effectiveness research; (c) eliminate site of service differentials; and (d) build a rapid learning system, apply it initially to personalized medicine, and empower it to be a major tool of clinical research. Each of these has merits, but each has shortcomings, particularly when considering the pragmatic perspective of “how to get it done.” It is not merely, as the author suggests, a matter of “commitment, rigor, and courage.” Most of the proposals impact the cost of cancer care but only indirectly address the cost of cancer drugs. It behooves us to consider each in turn, as well as in the context of numerous other proposed solutions.

REMOVE COVERAGE MANDATES FROM STATE AND FEDERAL INSURANCE LAW

Mandated coverage is in fact law. To undo it would require a law, and that law would need to empower someone to be able to draw the line at what is good enough for coverage. Given past experience, it is unlikely that such discretion would easily be granted to a payer. In fact, the opposition from manufacturers and patients would be fierce, for all the same reasons that the law was passed in the first place. In a health care market that is increasingly viewed as consumer-focused, I am not optimistic that this would ever come to pass. In addition, it is unclear that such an approach would really ever be implementable. An instructive example is to consider the

fate of the Independent Payment Advisory Board as proposed by the Affordable Care Act (ACA), which, although technically still alive, has met such stiff political opposition that few expect it ever to be operational. Removing coverage mandates would have an impact on the cost of care, but it is uncertain whether it would have substantial impact on the cost of drugs, unless manufacturers are willing to discount their products to facilitate access. This is, in fact, a common methodology to obtain provisional coverage in the U.K. via patient access schemes negotiated with the National Institute for Health and Care Excellence (NICE) [3].

CREATE PERFORMANCE TRANSPARENCY FOR DRUG REGIMENS

The recommendation for comparative effectiveness and cost-effectiveness faces some of the same challenges. It is not that this cannot be done; it certainly can, and the attempts by the American Society of Clinical Oncology (ASCO) [4], the National Comprehensive Cancer Center Network [5], and others to develop value constructs are early attempts. The question is how to use the results. Many have said that it is unlikely that the U.S. would ever embrace health technology assessment similar to that adopted by our European neighbors (e.g., NICE in the U.K.). Any attempt to limit access based on the results of comparative-effectiveness research would meet the same obstacles noted above. Again, remember that the Patient-Centered Outcomes Research Institute, the entity created by the ACA to perform comparative effectiveness research, is prohibited from considering cost by statute. However, a “solution” based on these principles is currently available, and this solution is a clinical pathways programs [6]. It is not the goal here to review all the controversy surrounding these programs, nor is it worth describing their shortcomings and how these might be solved [7]. Rather, this is offered as a solution regarding how to implement comparative effectiveness and cost-effectiveness at the point of care. As the methodology becomes more refined, including real-world evidence and patient-reported outcomes, the tools can only improve. This is adoption of comparative effectiveness without mandate. Again, although this might control total cost, whether it would reduce the cost of new drugs is arguable, unless manufacturers are willing to provide discounts in exchange for favorable pathway placement.

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PROFIT MARGINS FOR ADMINISTERING THESE DRUGS SHOULD BE CAPPED AT 18%

Site of service, including the evolution of cancer care as a revenue center for hospital-based programs, is a real problem. To be clear, it is not so much of a problem for Medicare but is a huge problem for commercial payers. This is because Medicare has leveled the Part B playing field with the Hospital Outpatient Prospective Payment System. Hospitals will argue that they cannot survive without this cost shift borne by commercial payers, but these charges have become egregious. Again, either a law could cap profitability or a contracting mandate could fix this. However, hospitals are viewed as a community resource, and any attempt to legislate or impose this would be difficult, because the hospital lobby and their allies would aggressively oppose such a policy. In addition, although this would reduce the amount paid for cancer therapy, it would likely have no impact on the cost of new agents and could induce a perverse incentive to prescribe the most expensive therapeutic alternative to maintain margin (as many have felt the Medicare Modernization Act has done). This seduction by margin is exacerbated by 340B pricing, the government-mandated and -administered program by which chemotherapy drugs are sold to qualifying providers (usually hospitals) at an approximately 30% discount, putatively to ensure that these providers who care for a high percentage of indigent patients can do so without incurring major financial loss. However, this program, as currently constituted, extends these discounts to all patients cared for by any individual provider, not just indigent patients, and thus makes use of these expensive drugs irresistible (particularly because there is no 340B pricing for generic agents). The 340B reform will go a long way to impact this equation, but it needs to be done with surgical precision to ensure the survival of this program for those who really need the safety net [8]. The ultimate solution here may well be health care reform such that these institutions become risk-bearing entities and fee-for-service cancer care is no longer a profit center. In the short run, courage in contracting with a walkaway option may be the only solution, and often no such option exists.

PLACE EVERY PATIENT WITH A GENETIC MUTATION IN A CLINICAL TRIAL

The call for reform of the clinical trial apparatus as a tool to collect real-world evidence in a format that can guide coverage policy can certainly be embraced. To be clear, this does not mean thousands of clinical trials built in the fashion that trials have traditionally been built. That would be cost-prohibitive, and the current regulatory gauntlet would pose near-insurmountable challenges. Rather, the formation of high-quality registries to, at the minimum, collect data and identify signals of what might be useful and what is certainly not useful could be profoundly beneficial to patients. Yes, these would require informed consent. Yes, these trials would result in savings because the expectation would be that the pharmaceutical company would provide the drug free of charge. ASCO's Targeted Agent and Profiling Utilization Registry is a wonderful example of an initial foray in the personalized medicine space [9], and it should be supported by all stakeholders. In addition, this model could easily be adapted to any

number of new promising technologies. It is prudent to remember, however, that maintaining a high-quality registry costs money. In addition, as potential therapeutic options are identified and adopted, any savings realized by elimination of the intuitive n of 1 trial will likely disappear, because this approach does nothing to control the cost of drug. Unless the therapy is curative or treatments are eliminated from consideration because a biomarker excludes a nonresponding population, the novel therapy will simply be added to the queue, for better or worse. However, for all stakeholders to embrace this option, there will need to be a good-faith assurance that the results obtained by these registries will have an impact on the regulatory path as well as on coverage policy. There needs to be agreement that some evidence, even if imperfect, is better than anecdotal or no evidence at all.

These four solutions all merit consideration, as do several others. Indication-specific and reference pricing are attempts to more directly link price to the specific benefit derived for particular disease states [10]. For example, many chemotherapy agents are used in several diseases but do not contribute the same clinical benefit across the board. In indication-specific pricing, the cost would be tied to the specific benefit in a particular disease and, in reference pricing, to a "reference price" for agents (in the same therapeutic class) used to treat the same clinical condition. These two approaches face two major hurdles. The first is that someone needs to be empowered to assign benefit and a fair cost. The second is related to current reimbursement for medical injectables that is based (again by statute for Medicare) on average sales price (ASP), and there is only one ASP for a given agent. However, this impediment does not exist for oral agents, and it is likely that we will see initial pilots in the oral cancer drug space very soon. Of note, both of these have been called out by the Center for Medicare and Medicaid Innovation in their recent Part B reimbursement reform pilot proposal. Other options might include attempting to control drug costs through risk-shifting arrangements. One possible arrangement would be to shift risk to the providers through episode-based reimbursement [11]. In this model, the cost of drugs would be included in the amount a provider is paid to manage a patient with a given condition, thereby incentivizing the provider to make value-driven clinical choices. However, this has caused concern among patient groups that care will be rationed by physicians so that they might optimize profit, so safeguards that guarantee quality reporting to protect patients are desperately needed. In addition, in this model, really effective innovative therapies that enter the market at a premium might face stiff obstacles to adoption because they put the financial viability of the episode (and thus the provider) at risk. An alternative is to place manufacturers at risk through performance-based contracting. In this model, a percentage of the reimbursement must be earned (and so it is at risk) by meeting quality or financial thresholds. The challenge here is defining how much is at risk and what those thresholds might be, but there has been a lot of discussion about this model.

As these options are considered, three facts need to be kept front and center. First, solutions are not likely to come by fiat. Cooperation will be necessary, and every stakeholder will need to give a little (or maybe even a lot). Second, we need to

promote innovation and reward real breakthroughs. The challenge we face now is that we have become accustomed to paying a premium for mediocrity under the guise of incremental progress. Intellectual honesty coupled with less hype will go a long way. Third, considering cost in the absence of considering outcome is a mistake. This has led, in the hepatitis C space, to arguments and even litigation regarding access to life-saving therapies. Given the advances in oncology, we need to be prepared for success, because it may not be very long before

patients are really being cured. If that can be done at a one-time cost of \$72,000 as it can be done in hepatitis C, there will be cause for celebration. In the interim, we need to demand value and embrace common sense.

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EDITOR'S NOTE: See the related article, "Those Who Pay Have a Say: A View on Oncology Drug Pricing and Reimbursement," by Lee N. Newcomer, on page 779 of this issue.