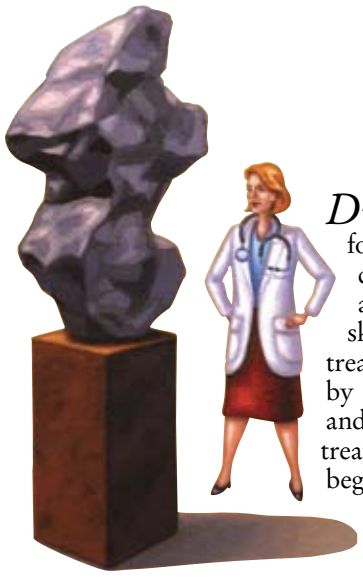
The Physician's Perspective (with Some Health Policy Thrown in)

by Barbara McAneny, MD



Dr. Newcomer's goal for Americans with cancer is, of course, one with which we can all agree—equitable access to skilled physicians and therapists, treatment with therapies proven by well-designed clinical trials, and benefit coverage to pay for the treatment. The difference of opinion begins with *how* we achieve these goals. Dr. Newcomer provides us with a number of anecdotes to support the opinions expressed within his article; however, we do not receive any information about the prevalence of these anecdotal scenarios or data showing whether or not the majority of oncologists are practicing according to guidelines and making treatment decisions based on current clinical trials. Anecdotes are often powerful stories, but they do not provide the basis for evidence-based decision-making—either in cancer therapy or in health policy.

Let's take, for example, Dr. Newcomer's anecdote of the woman treated for metastatic breast cancer. This patient was started on trastuzumab, which continued through her treatment regimens with the addition rather than substitution of therapies. The NCCN guideline for treatment of recurrent stage IV breast cancer (Version 1:2007) does comment that ER/PR negative, HER2/neu positive, symptomatic visceral or hormone refractory disease should be treated with trastuzumab plus/minus chemotherapy and then, if there is no response to sequential regimens or ECOG performance status, that consideration should be given to no further therapies. This particular physician continued the trastuzumab through several chemotherapy regimens—one of which included the addition of Avastin.

Yes, there are potential problems with this treatment scenario. On the other hand, it is easy to read the NCCN guidelines as suggesting that trastuzumab be continued through other regimens—even though there is minimal outcomes data at this point in time. Given the remarkable response rate in the adjuvant trials and the significant improvement in some patients treated with trastuzumab, an oncologist might be forgiven the assumption that the standard of care is to continue the trastuzumab. After all, every practicing physician's primary job is to be the advocate for each patient who seeks his or her help. Rather than focusing solely on cost, the "value" of individual therapies must also be considered. A regimen of morphine and sympathy is the least expensive of all treatment options, but it does not prolong life. Instead, all of our current options for prolongation of life involve expensive therapies.

In the end, the cost of this expensive regimen caused the employer to lose health insurance for the entire employee group—an unfortunate situation for everyone. To me, however, this anecdote clearly demonstrates the inability of an employer-based insurance system to handle catastrophic healthcare costs. If the insurance market were geared to selling individual insurance plans that were guaranteed to be portable and renewable, with premiums subsidized according to income so that everyone would be able to purchase insurance and have insurance throughout their lives, the other innocent bystanders (the employer and the other employees) in this scenario would not have come to any harm. Bottom line: payers should be able to use actuarial science to calculate how many people will develop metastatic breast cancer, which require expensive therapies, and then price premiums on a modified community rating with risk equalization. Instead, the incentives of the current market leave insurers little choice but to raise premiums during these catastrophic situations.

Limitations with Evidence-based Medicine

Dr. Newcomer is absolutely correct when he writes that evidence-based medicine is not routinely applied in medical care. While evidence-based medicine is ideal, those of us who practice medicine on real patients in the real world are acutely aware of its limitations.

As a specialty, oncology has perhaps done better than most in developing randomized, controlled, double-blinded clinical trials. Unfortunately, these clinical trials do not cover many of the situations that we see in clinical practice. Nor can these clinical trials be easily extrapolated from the limited study population to the general population. Part of the art of medicine is—and always will be—to take the evidence from controlled clinical trials and apply it as well as possible to the individual patient seated in the exam room. To put it in another perspective: should a person with cancer be denied treatment because of a lack of evidence-based medical data? Of course not! Instead providers do the best we can with the data that we have.

In one specific example, Dr. Newcomer writes about the inadequate documentation of HER2/neu over-expression in patients treated with trastuzumab. Ideally, targeted therapy should be used for patients who have the "target." However, as we have learned with other targeted therapies, sometimes the possession of the target does not imply a response to therapy, and sometimes the response to therapy occurs without our ability to measure the target. Until we have perfect markers that accurately predict which patient is going to respond, there will be patients who receive targeted therapy and who do not have the target. Perhaps UnitedHealthcare or another payer would fund a clinical trial to clarify the false positive and false negative rates of determination of HER2/neu and other

targets, and then correlate these findings with therapy.

While payers are making a huge push to ensure that providers are practicing evidence-based medicine, payers themselves are not always taking science into account when making their coverage decisions. For example, Medicare has issued a national coverage decision (NCD) about erythropoiesis-stimulating agents (ESAs) that does not follow ASCO or NCCN guidelines for treating cancer therapy induced anemia. These guidelines suggest a hemoglobin level of 12g/dL or less before a patient should be treated with an ESA; Medicare made an arbitrary decision that 10g/dL should be sufficient—regardless of patient situation, comorbid conditions, or altitude.

Payers would probably prefer to develop policies that do not require frequent modification, but this is rarely possible—particularly in cancer treatment. With every therapy that is introduced to the marketplace, indications change as the physician community learns more about its use, side effects, and toxicities. Sometimes providers feel as if certain payers use selective literature to support the development of policies that fit a preconceived determination, rather than allowing pharmacology and clinical science to guide policy development. To its credit, I believe that UnitedHealthcare has not adopted the CMS NCD on ESAs.

In his example of a patient with pancreatic cancer, Dr. Newcomer does indeed demonstrate that oncologists are treating patients with drugs of limited efficacy—where no better options exist. However, Dr. Newcomer does not say whether the 188 combinations of therapy in his 248-patient study used variations of the 7 drugs recommended in the NCCN guidelines or other drugs. And in all fairness, physicians might try combinations of drugs with some degree of efficacy in situations as desperate as pancreatic cancer.

Clearly, therapies whose effectiveness is still to be proven should be used in the context of a clinical trial; however, clinical trials limited to academic medical centers do not promote enrollment from the community—where the majority of cancer patients are receiving their cancer treatment. These programs need to remove enrollment barriers so that community physicians from across the country can easily access them. If and when that happens, we are faced with another barrier: many insurers do not pay for patients who are on clinical trials, claiming that the therapy is "experimental." One solution to this dilemma is for payers to fund the non-experimental aspects of clinical trials, including Phase I trials. If they did so, desperate cancer patients with good performance status could participate in a clinical trial for which they are eligible and be assured that the costs would not have to be borne by their families.

Treatment Cost: A Double-edged Sword

In his article, Dr. Newcomer asks that clinicians take into account the cost of the treatment when making treatment decisions. For providers, this request is a double-edged sword. On the one hand, oncologists are accused of taking treatment costs into account in order to maximize their own profit. On the other hand, oncologists are accused of *not* taking into account treatment costs when considering the healthcare system as a whole.

As managing partner of a practice of nine medical oncologists, I have learned several lessons. The first is that my physicians believe it is most ethical to treat a patient regardless of his or her ability to pay. My physicians are not interested in practicing two tiers of medicine—one with better drugs for people with resources and/or insurance and the other with cheaper, less effective drugs for uninsured, underinsured, or people with limited resources. From the amount of chemotherapy that my practice purchases and gives away to uninsured patients, I can assure you that my physicians do not have any idea of the dollar amount that they are being reimbursed for any given drug. In addition, our internal salary system links physician compensation to the amount of work done and *not* to the drugs prescribed. As I speak to the managing partners of oncology practices across the country, I know that we are not alone in using this methodology. In other words, the oncology community has already established a means for ensuring that physicians are *not* rewarded for selecting more costly regimens.

As evidence that oncologists make treatment choices based on their profit margin, Dr. Newcomer uses a SWOG and ECOG lung cancer study that compared five treatment doublets. The study did not demonstrate a survival advantage for any of the doublets, yet selected carboplatin and paclitaxel as the standard of therapy for lung cancer. Dr. Newcomer attributes this selection to the fact that this preferred regimen cost $12,000 more per month. However, I offer another perspective. First, any provider who has prescribed cisplatin knows that it is harder for a patient to tolerate than carboplatin. Rather than assuming that providers are selecting carboplatin and paclitaxel *instead* of other doublets, I suggest that we are *selecting one sequence of doublets in preference to* a different sequence of therapies. A significant percentage of lung cancer patients will respond to the first regimen and get some degree of prolongation of survival with that regimen. When they relapse, a significant percentage of patients will still have adequate performance status to go on to a second regimen and often a third. As you see, the planned use of several chemotherapies in sequence makes the cost argument for the first one much less convincing.

While Dr. Newcomer is probably correct about our lack of knowledge of the effect our prescribing habits have on the healthcare system as a whole, he over-estimates the ability of oncologists to select drug regimens to maximize profit. To his credit, Dr. Newcomer admits that some therapies are paid so poorly that they do not cover the practice costs. Hopefully payers will correct these situations by agreeing to increase payments for infusion codes, pharmacy inventory costs, and other overhead costs.

Some payers are looking to use the incentive of increased reimbursement payments for providers that are directing therapy in a more cost-effective way. I would suggest that payers instead look to reward physician behavior shown to save money, such as: keeping patients out of the hospital, and adequate payment for office administration of antibiotics and fluids for neutropenic febrile patients with a reliable home situation and adequate vital signs.

Aligning Incentives and Quality Care

Dr. Newcomer describes a current study that compares physician groups that follow strict evidence-based guidelines for treatment decisions to physician groups where individual providers select therapy for individual patients. The study will compare complications, cost, and quality measures for these two cohorts. If the physician prac-

5 Suggestions for Improving Our Healthcare System

1. Reduce the amount of money pharmaceutical companies spend on marketing. A very substantial fraction of costs attributed to research and development costs are actually spent on "marketing research." Reducing the dollar amount spent on marketing research could lower the cost of therapies—ultimately reducing what patients and insurers pay.

2. Ask payers to reduce healthcare costs by reducing their profit margins and operating costs. I see the health insurance industry from three different perspectives: as an employer who purchases insurance for my group of 200 employees; as a physician who has a contract with the same insurance company to treat patients; and as a patient who pays co-pays and deductibles. As a physician, employer, and patient, I would love to see savings brought about by the adoption of new policies that would place limits on the unreasonable percentage that payers take out of the healthcare dollar as profit to be delivered to stockholders and highly-paid staff.

3. Reward provider behavior shown to save money. Consider financial compensation for physician's making treatment decisions that reduce ER visits, hospital admissions, LOS, adverse drug events, and other cost-saving efforts.

4. Reimburse for the implementation of the processes that allow quality care to be provided. These include new (and often costly) technology, support systems, electronic health records, and the development and management of a clinical trials portfolio.

5. Fix what is broken. Increase payments for therapies that are currently paid so poorly that they do not cover practice costs. Increase the payments for "under-water" drugs and treatments. Ensure that drug administration is reimbursed adequately. Pay for pharmacy handling and inventory, and other overhead costs. Eliminate access barriers by deleting co-pays for preventative measures. Pay for clinical trials and work with the oncology community to develop a more widely disseminated set of clinical trials so that more patients can be enrolled and we can determine true quality of care.

tice that followed evidence-based guidelines saves UnitedHealthcare money, the insurer is considering paying a "retainer fee" to help make up the lost profits, suggesting that this action would align the interests of the doctors in providing equivalent care when it is lower cost with the incentives of the insurance company.

It would truly be wonderful to see the incentives aligned between payers, patients, physicians, pharmaceutical companies, and all facets of the healthcare delivery system. However, I view with suspicion UnitedHealthcare's current plan to have a retainer (initial payment on the first visit) to offset the expected differences in profits with this new approach. To me, this practice sounds like capitation renamed. Capitation was a disaster in general and especially for oncology. Capitation promotes under-therapy. And in oncology, under-therapy pits the welfare of the patient against that of the physician. Patients themselves were also very skeptical of any system that paid their physician more *not* to treat them than to treat them. Rather than reinvent capitation as a retainer payment, I would instead suggest that insurers pay for the cognitive and counseling services that are required to not treat a patient. It takes oncologists far more time in the examination room helping patients decide to forgo therapy of limited benefit than it does to treat them.

And then there is the issue of quality care. I understand why insurers would want to "rate" physicians and try to direct care to those physicians they believe are most qualified. However, quality is a difficult characteristic to measure and an inexact science at best. In fact, the measurement of co-existing conditions and confounding variables is in its infancy and outcome measures are truly premature. How do you compare the outcome of a physician practicing in a major tertiary institution with all of the appropriate technological advances, support systems, electronic health records, and access to clinical trials with the quality of care practiced by an oncologist in the inner city where patients present with later stages of illness, do not have the economic support system to comply appropriately with therapy, cannot get the bus fare to make appointments for chemotherapy and follow-up, or are too afraid to go to the hospital when complications occur? And yet, the academic physician will likely be penalized simply for being more expensive.

Our healthcare system is broken and serves no one well—a point that both payers and providers can agree on. As stakeholders in the system, we are trying to make the system work better. Unfortunately, any stakeholder can only influence a small piece of the system, and we as a nation are just starting to address the entire problem.

To date, the payer's solution is to spend an increasing amount of the premium dollar setting up cost-containment programs, developing disease management programs, scrutinizing claims for denial possibilities, and paying shareholders. If this country could develop a plan of individually-owned and selected, portable insurance policies with guaranteed renewability and appropriate subsidies for people of limited means, and return insurance companies to the role of using actuarial science to develop premiums and pay claims, the savings would be considerable. Until that time comes, we will continue to argue about the various costs and benefits of band-aids on our sick healthcare system.

I welcome Dr. Newcomer's plea for physicians and payers to work together to bring about these needed changes to improve patient care and make it more affordable and accessible for all.

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References

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