

# ADVANCES IN DRUG DEVELOPMENT

Current Developments in Oncology Drug Research

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## The Value in Cancer Care Consortium: Addressing Financial Toxicity



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### H&O What is the Value in Cancer Care Consortium?

**AL** The Value in Cancer Care Consortium is a group of physicians who have come together to create, design, and implement clinical trials with the goal of increasing the value of cancer therapeutics. Many drugs today are not being used in the ideal dose. They may be given in too large a dose, for example, or too frequently. They may be given in schedules or durations that are not ideal. A patient may receive a drug for longer than needed. If clinical trials can show that patients do just as well with lower doses, less frequent doses, or shorter lengths of treatment, then the cost comes down, and consequently the value goes up.

I should emphasize that we are not seeking to change the price of the drug. Pricing is a complicated issue, and beyond the scope of the Value in Cancer Care Consortium. We are trying to show how to use drugs more intelligently and more wisely, in order to create more value.

### H&O What type of trial design will you follow?

**AL** Studies will follow the design of classic phase 3 clinical trials. One arm is the standard, labeled dose of the drug, and the other arm is a different dose, schedule, and/or duration. The trial will be powered statistically to show whether the 2 arms are equivalent. Data should illuminate the clinical science and show whether the different treatment regimens are the same or if one is superior to the other.

### H&O Have any trials confirmed the validity of this approach?

**AL** To show proof of principle for our concept, a small

pilot trial by Szmulewitz and colleagues evaluated how food impacts the pharmacokinetics and pharmacodynamics of abiraterone acetate. According to the label, abiraterone acetate should be administered at 1000 mg in a fasting state. It is well-known, however, that this drug is absorbed much better with food. In this study of 72 patients, half received the labeled dose, given without food. The other half received one-fourth of the labeled dose, 250 mg, given with food. The results were tantalizing. They showed a similar response, as indicated by levels of prostate-specific antigen. The drug levels were a little higher with the larger dose, but still adequate with the smaller dose. The symptom relief appeared to be the same.

These results cannot be viewed with certainty because the trial was small and had a 12-week endpoint. When graphing the data, the error bars around the results were wide because of the small numbers. It will be necessary to repeat the trial with a larger number of patients and for a longer duration to increase confidence in the results. However, the trial showed that these types of studies are feasible. Doctors will inform patients about them, patients will enroll, and the results can be satisfactory.

### H&O Do the results from your studies have the potential to change the labeled dosage?

**AL** We are not seeking to change the label, which is owned by the manufacturer. A change to the label can be instituted only by the manufacturer, working with the US Food and Drug Administration (FDA). What the manufacturers choose to do based on the results of our trials is up to them. We have had informal discussions with the FDA about our work.

### H&O What is the financial burden faced by people with cancer?

**AL** The financial burden is a huge problem today. Obviously, the prices of new drugs entering the market have escalated to extraordinary levels. Patients, even when well-insured, have copays and other expenses that put a huge strain on their financial well-being. The phrase “financial toxicity” has a lot of truth to it. Trials showing that decreased doses of a drug produce equivalent results can relieve some of this financial toxicity.

In addition, a lower dosage can reduce the biologic toxicity of the drug. The side effects of the drug should decrease with lower doses. We expect to see some relief in both the financial toxicity and in organ-specific toxicity.

### H&O Should physicians consider cost when selecting treatment?

**AL** That is a complicated issue. In medical school, I was taught that our job is to evaluate and treat patients. To a large extent, some of this philosophy has continued. The first thing we must do as physicians is to identify the problem, and then determine the patient’s best option, regardless of cost. In the past, this approach worked because the cost of therapies was not very high. But now it is almost impossible to not pay at least some attention to what a treatment can cost and what the patient’s burden will be. Doctors should not prescribe a treatment if a patient cannot afford to fill the prescription. To reduce costs, a patient might also take the drug every other day or cut tablets in half to stretch out the prescription, therefore getting doses that are not ideal. I believe that paying attention to the cost of therapy is an essential part of management today. However, physicians are not well-trained to do so, and it is not easy.

### H&O Are there estimates of how much money could be saved with different prescribing strategies, and where is the savings likely to manifest?

**AL** The cost of abiraterone acetate is approximately \$10,000 a month. Using one-fourth of the dose reduces that to \$2500, an impressive reduction. Many current cancer drugs reach billions of dollars in worldwide sales. The Value in Cancer Care Consortium intends to perform studies in which the hypothesis posits that a lower dose of a treatment would save at least 50% of the cost. Hundreds of millions of dollars could be saved.

These savings can lower health expenditures for Medicare, insurance companies, and large corporations that self-insure. Patients with substantial insurance copays or who pay out-of-pocket could see a direct benefit. It is unlikely that our work will cause the cost of health insurance to plummet. But it is necessary to begin to slow the cost of care and reduce the rate of increases in health insurance premiums. Ways to reduce the cost of care should be explored throughout all specialties in medicine, not just oncology.

### H&O What signals indicate that a drug might benefit from a different prescribing strategy and therefore be suitable for one of your studies?

**AL** We have experts working with us in the field of clinical pharmacology and therapeutics to identify candidate drugs. There are drugs that can be absorbed more effectively when taken with food. In drugs with long half-lives in the body, it may be possible to stretch the interval between doses. These are the types of signals that we are looking for to direct us toward the trials that need to be done.

We will also perform some trials that involve direct substitution of a lower-cost drug for a higher-cost drug. There are cases where the mechanism of action of a generic drug is similar, if not identical, to that of a higher-price branded drug, and those 2 drugs should be compared with one another.

### H&O What are the next steps for the Value in Cancer Care Consortium?

**AL** We are laying the infrastructure. We have funding that will allow us to hire staff and begin to design clinical trials. We are starting to sign up study sites. There is a great deal of enthusiasm from practices to join in this effort. The big step, however, is to raise the funding to perform the studies. We are actively pursuing interaction with a host of organizations around the country and around the world that believe in what we are doing, where the message resonates. We hope to begin enrolling patients in studies in the first half of 2018.

#### Disclosure

*Dr Lichter has no real or apparent conflicts of interest to report.*

#### Suggested Readings

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