Ohio's Statewide Trial: Accessing Free Genomic Testing in Lung Cancer

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Dr. Carbone:
Over the last decade or so, we've learned that certain targeted therapies when matched to patients with certain genetic lesions have dramatic efficacy. Patients' tumors shrink most of the time, and that shrinkage lasts a long time, and these therapies are typically oral and minimally toxic.

But to find those patients, they need to have their molecular profiling of their tumors. And even today, a decade after the introduction of some of these therapies and the discovery of the earliest drivers, many patients don't get this testing. In fact, about a third of patients don't get even the basic EGFR, ALK gene testing, and now the NCCN guidelines have recommendations to screen for seven different gene mutations, and there are very few patients in this country who are screened for all of those.

So the statewide initiative in Ohio is an effort to prove the value of this kind of advanced molecular profiling as well as to educate patients and their physicians about its value.

And the way we're doing that is in a statewide network—about 50 hospitals—we are trying to capture every new diagnosis of advanced non-small cell lung cancer. We are in the first period of the study just trying to learn what the practices are of the physicians taking care of those patients.

So we'll just record what the doctor orders on their tumors and what they do with that information. After we get a feel of what the standard, the usual care is in those practices, we will start randomizing patients. In half the patients, we will give them free, advanced genetic profiling and PD-L1 immuno-biomarker testing, and the other half we'll continue to provide the patients with information.

We will—but we will not provide the free up-front test. The doctor can order what they normally order, and they do with it as they would like to do.

Along with the advanced genetic testing, we also will provide expert decision support. So if the doctor doesn't know what to do with a BRAF mutation, they can call a number, and we can discuss with them their options for treating patients with that mutation.

We hope to enroll about 2,500 patients in this randomized study, and the point, the primary point of the study is to show that provision determining these molecular features up front in these patients will improve their survival. So it's a survival

end-point study, and there's never been a population-based, randomized prospective study that proves that doing this testing up front improves survival in these patients.

But on top of that after this period of randomization, we're doing another observation phase to see if our intervention of giving these tests to these doctors in rural communities throughout the state of Ohio, whether their practice will change. And we would have educated the patients in that practice and the doctors to increase their uptake of molecular testing.

And we will also be doing things such as a quality-of-life assessment. From—instead of just during a particular treatment, the quality of life will be assessed for the entire life span of the patient, through all of the different treatments they receive throughout their course of their life with lung cancer. We have a smoking-cessation aspect to this.

We have a cost-effectiveness aspect. And so I think there's a huge potential, not just for helping the patients that are enrolled in the study but for educating the physicians, for educating the—the practices to do the right thing, and for obtaining data that will help payers, convince payers and insurance companies to pay for this up-front molecular profiling.

And so I'm very excited about this project, that it will be both an interesting research project but also in a very real sense help the patients with lung cancer in my state of Ohio.