



The Our American States podcast—produced by the National Conference of State Legislatures—is where you hear compelling conversations that tell the story of America’s state legislatures, the people in them, and the policies, process and politics that shape them.

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A New Era of Cancer Diagnosis and Treatment | Aug. 8, 2021 | OAS Episode 138

Ed: Hello and welcome to “Our American States,” a podcast from the National Conference of State Legislatures. This podcast is all about legislatures: the people in them, the policies, process and politics that shape them. I’m your host, Ed Smith.

“We can develop a specific biomarker that exactly targets which places that drug is going to work in, and in those therapies, we refer to those in a general concept as targeted therapies.”

That was Dr. Carl Morrison, a molecular biologist and pathologist. He’s the senior vice president of scientific development in integrative medicine at the Roswell Park Comprehensive Cancer Center in Buffalo, New York. He’s one of the nation’s leading researchers in the area of personalized or targeted medicine. He’s one of my guests on the podcast.

The field of precision medicine uses specific information about a person’s cancer to create therapies targeted at just that specific cancer. Dr. Morrison explains how biomarkers are used in this effort, the benefits of such a diagnostic and treatment approach, and the challenge of high cost for many of the treatments.

My second guest is Karmen Hansen, a policy expert at NCSL. She explains why these new treatments are important for legislators to understand, both so they can aid their constituents and because of the cost to the healthcare system.

Let’s start with Dr. Morrison. Welcome to the podcast.

Dr. M: Thank you for having me here today, sir. I really appreciate it.

Time Marker (TM): 01:44

Ed: Dr. Morrison, thanks for taking the time from what I know is a demanding schedule to talk today. Our audience is largely legislators, legislative staff and other state policymakers. Since many of them may be unfamiliar with the work of a molecular biologist researcher such as

yourself, I wondered if you could provide a brief explanation of biomarkers and why they're important to your research.

Dr. M: I think it all starts with patient treatments, biomarkers do, and FDA approval of drugs. One of the important components before a drug can ever be given to a patient is you have to understand the mechanism of action. The mechanism of action is one of the principles of research, of drug development, and in regard to the mechanism of action of a drug really unfolds what is the biomarker because if you understand the mechanism of action, you know what the biomarkers are.

In my area of application, once the mechanism of action is understood and the research is completed and the drug goes into development and gets approved for patients, you have to say: well, how do we measure that biomarker? How do we best understand that mechanism of action? Because if we can understand and accurately measure that biomarker, we can more accurately measure what patient that drug is most appropriate for through the biomarker.

TM: 03:13

Ed: I've heard this expression, personalized medicine, to describe advanced diagnostic and treatment options. How does this research personalize the experience for people with cancer or other conditions?

Dr. M: I think when you really look at how drugs work in patients, some drugs work through kind of a general mechanism of action and therefore they're not really personalized; it's just that there is a general mechanism of action for that drug. But then there are certain drugs, and this is really where medicine is evolving to, that we better understand more specifically, more precisely what the mechanism of action is.

And therefore, we can develop a specific biomarker that exactly targets which patients that drug is going to work in. And in those therapies, we refer to those in a general concept as targeted therapies. It is a very evolving field, particularly in oncology more than any other field of medicine. I would say today that almost half of our patient therapies are driven around targeted therapies and biomarkers.

One reason why this has been so important to patients is when you treat a patient through just kind of a general mechanism of action, there are a lot of side effects. That's kind of the way chemotherapies always work. Patients get very serious side effects because you're affecting a general process in their body.

But when you can be much, much more specific and you can just attack one little component of a pathway, one little gene in a pathway, then what happens is if you can identify those genes or biomarkers that are specific only for cancer and not for all the other activities in your body, then what happens is the patient will get a therapy that's not toxic. It's only toxic to the cancer and it's not toxic to them. So, no longer are they sick and having nausea and vomiting and their hair is falling out. They can take this drug that attacks their cancer and for the most part, it has about the same side effects of perhaps taking an aspirin.

So, it's really remarkable the decrease in the side effects. And efficacy, the treatment, how effective the drug is, is often remarkably better than it was before. And one reason why that is, is because if you go back to something like chemotherapy and mechanism of action, any time we treat a cancer, it doesn't just die overnight. It takes months to years to die. And many patients when you're treating them with a general mechanism of action, they can't stay on the drug long enough to kill all the cancer cells. But with targeted therapy, since you don't have that toxicity, these patients often go on a targeted therapy and will stay on it for years.

At some point, people will start discussing this concept of the cost. Some people can afford that drug for years and some people can't afford that drug for years. That is a huge issue and I think even outside of cancers becoming like some big issues we've seen recently like an Alzheimer's disease and so forth, who can afford a drug and who can't afford a drug. It's an important component of how we move forward with the treatment of patients.

TM: 06:48

Ed: These are, of course, cutting-edge treatments. Are there clinical trials available?

Dr. M: Every drug that patients get treated with at some point or another has to go through a clinical trial for approval. And there are many targeted therapy drugs that are beyond clinical trials and are standard of care. The majority of those today are in cancers like lung cancer and melanoma. But targeted therapies are evolving in many other tumor types and even continue to evolve in lung cancer and melanoma, and they're in the clinical trial stage of development.

About 60 to 80% of those therapeutic drugs that are targeted therapies in clinical trials are based upon one or more biomarkers. So, again, biomarkers are essential to this process even during the clinical trials process.

TM: 07:40

Ed: How about the costs? I know there may be upfront costs for biomarker testing, but is it likely that personalized medicine tools like this could be a cost saver for payers in the long run?

Dr. M: We need to separate the cost of the biomarker and the cost of the drug. Cost of the biomarker is typically 1% of the cost of the lifetime of the drug. So, a typical biomarker cost for a targeted therapy may range anywhere from a few hundred dollars, three or four hundred dollars, up to perhaps maybe even three or four thousand.

The cost of a targeted therapy for a year can easily be \$150,000. So, you can see that having the correct biomarker and giving the patients the right drug is a very cost-efficient process for deciding how we use our precious dollars in treatment of cancer patients and patients that are in other aspects of medical care too.

TM: 08:40

Ed: I'm wondering if something like treatment for Hepatitis C is an example of the value of upfront costs providing long-term benefits and savings.

Dr. M: Well, it's certainly not my area of expertise, but Hepatitis C, why it is such a dreadful disease is the fact that it leads to a cancer called hepatocellular carcinoma. Kind of like the statement if you smoke long enough, you'll get lung cancer, well, the other statement is if you live long enough with Hepatitis C, you will eventually get what's called hepatocellular carcinoma.

And we've always known how to identify Hepatitis C. The identification of the virus is the biomarker. But we never really had a treatment and then most recently there is a treatment and it's extremely effective but, again, it is very, very expensive. It prevents the downstream cost of a person having hepatocellular carcinoma; it extends their life. So, sometimes the cost of the drug may seem like a lot, but the savings to healthcare downstream are not accounted for.

TM: 09:42

Ed: As the COVID pandemic made clear to everyone, health issues affect populations differently, exposing inequities in access and treatment. Can advancements in biomarker research increase equity in healthcare?

Dr. M: Many of the current biomarkers for targeted therapy cannot be easily measured. They require hot technology, innovative procedures like what's called next gen sequencing, and many of these technologies are not readily available in communities that don't have high-end resources.

So, patients can go to a hospital or a physician's office where they don't have ready access to those high-end technologies and their biomarkers never get measured. So, they really don't know if they are applicable to those therapies or not. It goes without saying that in many instances, there's inequity between the delivery of care and what procedures can occur from one institution to the next in the healthcare field.

TM: 10:53

Ed: As we wrap up, I wonder if you have any final thoughts to share with the policymakers in the audience.

Dr. M: Well, I think one of the most important messages is that we should support the reimbursement of biomarkers by our payers. Our payers often are reluctant to pay for biomarkers and one of the reasons is they think they're not FDA-approved. They go under a rubric, what we refer to as laboratory developed tests, the vast majority do. And so, they don't want to pay for them.

But yet, we see the payers willing to pay for expensive drugs which often are given without a biomarker test when there is a biomarker requirement. I think we really ought to sit down and say that there ought to be a requirement for this set of biomarkers that all patients are required to be tested for and that there's payment for them, so there is not an inequity between those who are poor or disabled versus those who have wealth and access to better healthcare.

Ed: Dr. Morrison, thanks again for taking the time to walk us through this cutting-edge work. Take care.

I'll be back after this with Karmen Hansen from NCSL to discuss how states are grappling with this issue.

MUSIC and Gene VO

NCSL's Legislative Summit is back. Connect with your colleagues November 3rd through the 5th in sunny Tampa, Florida to gain unique insights and practical knowledge to drive results for your state. Early-bird pricing is available through August 31st. Register today at nctl.org.

Ed: I'm back with Karmen Hansen from NCSL. Karmen, welcome back to the podcast.

KH: Thanks, Ed. It's great to be back.

TM: 12:47

Ed: It's so nice to have you back on the podcast. We've talked before about some of the interesting issues you track for NCSL. For this podcast, we're focusing on policies related to advanced cancer screening and treatment. I just talked with Dr. Carl Morrison, and he gave us a briefing on this technology. I wonder if you could start off by explaining why it's important for state legislators to know more about biomarkers and other issues related to cancer.

KH: Sure, thanks Ed, I'd be happy to. After covering cancer and prescription drug policies here at NCSL for the last 20 years, I've learned that legislators receive a lot of requests from their constituents asking for help for problems related to healthcare that they're receiving or not receiving: things like mysterious medical bills showing up out of nowhere or accessing services or treatments that might not be covered by their healthcare coverage.

They are seen as problem solvers in their communities. So, a basic understanding of health and medical advancements may be really helpful for them as they try to assist their constituents and consider legislation in these areas as well.

Cancer has always been a complicated issue and, as Dr. Morrison mentioned, the science behind this detection and treatment can evolve very, very quickly.

TM: 13:59

Ed: Well, that makes a lot of sense. Lawmakers are in the business of constituent service after all. So, what are states doing in this area of biomarkers and personalized medicine?

KH: States are just now starting to look into these issues because they are so new and cutting-edge. NCSL has been tracking the state policies related to biomarkers and precision medicine and with any policy area, the advancements in research and technology often outpace the speed to which legislators are addressing things via legislation.

Once they start appearing on a legislator's radar, that's when they want to start looking for information. And NCSL has been responding to these questions about biomarkers and precision medicine and broadly sharing information with policymakers as best we can.

It can be really hard to work on these complicated issues, so helping legislators and legislative staff understand some of the basic science principles behind it and how this topic is related to larger health issues, even if it's a schoolhouse rock version, is very important.

Right now, at least two states including Illinois and Iowa have enacted biomarker or precision medicine awareness months, and that's where you often see states initially address a new, breaking health issue. And there is a handful of states that have introduced legislation to require healthcare coverage and screening and treatments.

TM: 15:22

Ed: So, it sounds like lawmakers are in the early stages of figuring out their role in this new technology. How about the money side of things – Are these biomarker related tests typically covered by insurance or Medicaid?

KH: Yeah, you're right. Legislators are always interested in what's the bottom line, what's it going to do to state budgets. And this is such a new issue. States have just recently started to consider this as a covered service for Medicaid or as a health insurance required coverage within their state.

So far, Louisiana and Illinois are the only states to enact legislation, and in Illinois, it passed both chambers unanimously. So, this is a largely bipartisan supported issue, and how often do you hear of that anymore?

Clinical trials are also another way that people are getting access to biomarker screening and testing, and it also may be covered by someone's health insurance on an individual level, just depending on the individual's medical situation.

TM: 16:21

Ed: How about cancer screenings? I understand that during the pandemic, those decreased as many people missed medical appointments. Is there a renewed effort to encourage people to receive cancer screenings?

KH: Yeah, you're definitely right. Public attention on cancer screening and prevention measures definitely did decrease during COVID, early 2020 in particular. Individuals were very distracted and healthcare systems were pretty much completely focused on COVID-related issues. And many healthcare facilities temporarily closed for non-emergency procedures.

There is some research that recently came out from a Boston cancer center that showed screenings dipped around 70% from June through September of last year and, as a result, doctors are reporting an increase in suspicious nodules and tumors in lung cancer screenings in particular. And they're saying that is likely related back to those delays in the regular screenings during early COVID.

But during the last three months of 2020, they started to see a dramatic rebound, which is good news, and at this time we're back to almost pre-COVID numbers. So, we're catching up pretty quickly, which sounds like good news.

And in a related note, the use of at-home cancer screening tests for things like colorectal cancer, which are often referred to as FIT tests, F-I-T for fecal immunochemical tests, they're using those as a way to at least get people screened. It's not the full colonoscopy, but it's one way to have an initial screening to see if they can then follow up with someone with another screening or if that home test screening is going to be enough to use when appropriate.

TM: 18:03

Ed: I think a lot of people are familiar with those home tests to screen for colon cancer. I'm sure most people prefer it to a colonoscopy.

As we wrap up, is there anything else you'd like to share or resources you'd like to direct people to so they can learn more about this issue?

KH: Yes, thanks. NCSL does have a few resources on cancer in the 21st century, and those are available on our website at ncsl.org. We will have additional resources on the subject coming out later in 2021. In addition to this podcast, we'll have a legis brief and some blogs about topics, so we do have a lot of stuff coming out on this very important issue.

Ed: Well, Karmen, I'll be sure to link to those resources on the podcast page on ncsl.org. Thanks again and take care.

MUSIC

Ed: And that concludes this edition of our podcast. We encourage you to review and rate our episodes on iTunes, Google Play or Spotify. You may also go to Google Play, iTunes or Spotify to have these episodes downloaded directly to your mobile device when a new episode is ready. For the National Conference of State Legislatures, this is Ed Smith. Thanks for listening and being part of "Our American States."