



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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The Critical Role of Newborn Screening | Dec. 5, 2021 | OAS Episode 147

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.

“Newborn screening is the process of examining all infants born in the United States, so last year we had about 3.6 million kids born, for any disorders that they might have inherited from their parents.”

That was Peter Kyriacopoulos, the Director for Public Policy at the Association of Public Health Laboratories. He’s one of my guests on the podcast.

Newborn screening in the U.S. is the practice of testing every child in the country for a number of disorders, many of which can be addressed if caught early. States are in charge of newborn screening and receive advice from federal agencies.

Kyriacopoulos discusses how the screening works, how it differs from state to state, the role public health laboratories play, and the challenges they face. He also explains how the recommended uniform screening panel, or the RUSP, helps guide states in deciding which screenings to include.

My second guest is Kelsie George from NCSL, who tracks legislation related to newborn screening. She fills us in on the legislative landscape on the topic. Here’s our discussion.

Peter, welcome to the podcast.

Peter: Well, I’m delighted to be here. Thank you for having me.

Time Marker (TM): 01:44

Ed: It's great to have you on the show. I wonder if you first could tell the listeners a little bit about your background and about the Association of Public Health Laboratories.

Peter: Thank you for that question. I'd be happy to do that. So, the Association of Public Health Laboratories is the only organization that represents state and local governmental public health laboratories. I am the chief policy officer for APHL and that means that I spend an awful lot of my time understanding the challenges and opportunities that our member laboratories are experiencing, and then communicating those details to folks who are policymakers.

It is a job I've been at for over 17 years now, so I like it a lot, and it is a job that I came to from being an advocate both for state government, working for a number of governors in their Washington offices, and then prior to that I was actually on Capitol Hill working for a member of the Senate.

TM: 02:57

Ed: So, we're here to talk about newborn screenings, but I think even as a dad whose infant son had screenings, I'm not sure I was ever clear on exactly why this was done. Let's start there with some history on newborn screening and why we screen newborns for certain diseases.

Peter: Well, that's an excellent question. Newborn screening is the process of examining all infants born in the United States, so last year we had about 3.6 million kids born, for any disorders that they might have inherited from their parents. And what is especially important about doing this work is that these disorders do not present. These kids look like any other infant that you would see in the nursery. But they have these disorders that need treatment, and in some cases, they need treatment almost immediately to prevent very serious negative health impacts from developing.

The states have been at this--I should have started with that actually--it's a state-run program with some important guidance provided by the federal government. But the first states to begin newborn screening started it in 1963, looking for one disorder, and the reason that we were looking for that disorder was because a terrific scientist named Bob Guthrie had a niece who was diagnosed with a disorder and that disorder was going to seriously affect her life. And he got very frustrated that this wasn't found earlier in her life so that she could avoid some of these problems, and he decided that he was going to change things very much for the good.

TM: 04:44

Ed: For our listeners who are new to this topic, and I think that includes most of us, can you tell us what the different components of a newborn screening program are and what role states play?

Peter: Again, these are state-run programs and so what that means is that the states basically from the beginning, they determine which disorders their programs are going to screen for, and then they go through the implementation process, which is going to involve a laboratory portion. That is the process of the screening, and a follow-up portion, so that's when you do get a positive screen, what happens next.

Let me back up just a little bit and tell you how newborn screening occurs, what the mechanics are if you will. Every kid, again, born in the United States will have a small drop of blood taken from their heel and that drop of blood is put onto a special card that's made of filtered paper, and then it is taken to the state laboratory where the screening occurs.

Then the screenings results, again, if you have a positive result, will move that kid into the follow-up portion and the follow-up portion is where a different group of state employees makes certain that the parents and the medical care providers for that family know about this disorder and they get connected to treatment because it's very important.

In fact, I would say that newborn screening is probably the most time-sensitive function of state government. The one exception might be if your state runs a hospital, the emergency department of the hospital, could be as time sensitive. But this is very, very important to get these kids very early in their lives and to get them onto a path to a very productive and healthy life.

TM: 06:47

Ed: I've seen references to the recommended uniform screening panel, or the RUSP. Can you tell us what this is and how it might affect newborn screening in states?

Peter: Sure. So, the recommended uniform screening panel is an activity that occurs at the federal government level. There is an advisory committee that advises the secretary of health and human services at the federal level. It receives information from key federal agencies, the Centers for Disease Control and Prevention, the National Institutes of Health, and the Health Resources and Services Administration, so CDC, NIH and HRSA.

HRSA actually organizes the advisory committee for the secretary. They get the information from researchers, from parents, from other organizations, and they make a determination about which disorders should be included in newborn screening. Once they make that recommendation, the secretary can either accept it or ask for more information. Ultimately, if the secretary does accept it, it forms this panel, and the disorders that you see on the recommended uniform screening panel come from that process.

The second step then is that states have their own actions that they must take, and many states have an entity that is very similar to the advisory committee to the HHS secretary. Some of them have administrative processes that they use instead, but they are all getting the same inputs from the medical experts and the scientists involved in this space, and then the states determine what to do next.

So, just because a disorder is added at the federal level doesn't mean that a state adds it for its state panel, because it is a recommended uniform screening panel.

TM: 08:56

Ed: That's really what I wanted to follow up on. One thing I know for sure about states is that every state has its own way of doing things, and it sounds as though that's true with newborn screening. So, how different are the approaches they take?

Peter: Most states are very similar, I think, is the easiest way to think of it. I will be sharing a link that your listeners can use to track where their state is with respect to all of the other states in the country on the number of disorders and which of the recently added disorders they have also added.

This link I'll share is part of the work that we do with HRSA under a project that is called New Steps, which is to both measure the quality of newborn screening activities and share information with all of the participants.

States, again, one of the main reasons that this is a state program is that it's funded at the state level. So, the states by and large have a fee that is associated with this newborn screening activity that helps the operations of the program.

TM: 10:12

Ed: Yes, I wanted to ask you about the cost. Do parents pay for this or is this covered by the state?

Peter: For the most part, because there are some exceptions, for the most part the fee for newborn screening is included in the charges that a hospital will assess for delivery, so that part of it happens kind of separately from state government, but the fee part then goes back into the state programs for the most part, if you will, so that they can run the programs.

I'm sure your listeners are aware that public health in general is always chronically underfunded and the work that's being done on newborn screening is no exception to that. There are always challenges related to staffing numbers and levels. The current fees are basically helping keep the wheels on; that might be the easiest way to think of it.

TM: 11:12

Ed: So, it's not buying a new Lexus. It's more like keeping that used vehicle running.

Peter: That's exactly right and that's especially important because it goes back to this conversation we had earlier, about how you add a disorder once the federal recommendation comes out. There are not people today in any state newborn screening program sitting around thinking about adding new disorders, because they're all consumed with just running the program that they currently have.

So, that's where we look to our federal partners, again CDC and HRSA primarily, to help states with the consideration of how to successfully add a new disorder. We do that in a couple of different ways. One of them is by advocating for increased federal funding for CDC and HRSA to perform that task, and then getting CDC and HRSA directly engaged with states to, again, perform that task.

TM: 12:17

Ed: Are there success stories out there? Are states making efforts to improve their newborn screening?

Peter: Oh yes. Well, I think all of newborn screening is a huge success story because of the benefits that the infants and their families have by being successfully screened and successfully treated.

One of the challenges, and this goes back to adding new disorders, that has developed recently, and by recently I'm going to say in the last decade, is how to get these more complex disorders successfully added.

Back in 2010, severe combined immune deficiency was added to the federal panel. Sadly, because the funding support for CDC and HRSA was so low, it took us a decade to get all 50 states screening for this very significant disorder. That doesn't mean that there weren't kids born with SCID in those states that weren't screened. I wish that we had captured all of those kids and gotten them all treated, but we didn't.

More recently we have an addition of spinal muscular atrophy, or SMA, and today we have many states that are screening for spinal muscular atrophy, but it's been several years since it was added to the recommend panel and, again, in those states where there is no screening for that disorder, there is a strong likelihood that kids are being born with it and being missed by the system.

So, we need to do a much better job of shortening that time window from when a disorder is recommended by the federal government and states are trying to adopt it and bring it into their programs so that we don't have this disparity where kids in some states are definitely going to get picked up and treated, and kids in other states are not.

TM: 14:15

Ed: You've noted some of the issues at public health labs. I think many of us, as a result of the pandemic, have become more familiar with how stretched our public health labs are. Can you talk specifically about some of the challenges these labs face, and are they primarily financial or staff?

Peter: It is all of those things, and let me go into a little bit more detail on that. With the addition of disorders, oftentimes there is a requirement to have another piece of testing equipment brought into the laboratory. Most of our laboratories are out of space, so one of the things in another area that we've been advocating for is federal support for construction, so that we can either renovate an existing facility or, in some cases, maybe even build an entire new facility. So, it's one more piece that makes adding a new disorder more complicated. If you don't have anyplace to put that piece of machinery, it becomes a huge challenge.

In terms of the staffing, yes, again, we've talked a little bit about public health being chronically underfunded. The salaries that our members are able to offer the scientists who are doing the work are out of balance with what the salaries are that they could receive if they were working someplace else.

The electronic movement of data is another big challenge, and we are doing a lot of work on that by supporting an effort at CDC called the data modernization initiative to make improvements for all public health data, including newborn screening data. We've got some

instances, I'm sorry to say, but today we have instances where screening test results are being transmitted by a fax machine.

That's not the most efficient, not the most effective way of handling this extremely time-sensitive information.

TM: 16:27

Ed: Okay, fax machines. That sort of captures the problem right there. Our audience, of course, is largely state legislators and legislative staff. As we wrap up, what's the key message you want to leave with them?

Peter: The key message is the newborn screening programs in the states are fantastic.

You know, one of the best things to do I think is to go and actually visit the public health laboratory. So, I encourage all of your listeners to make arrangements to visit the public health laboratory and look at the newborn screening work that is being done, because I think that experience just really helps illuminate the importance and the complexity and the commitment.

The people who are involved in state newborn programs are tremendously committed and they will move heaven and earth to make sure that those programs function well.

Ed: Peter, thanks for walking us through this issue. Take care.

I'll be right back after this with Kelsie George from NCSL.

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Ed: Kelsie, welcome to the podcast.

Kelsie: Thanks for having me, Ed.

TM: 18:24

Ed: So, we're talking about newborn screening, and I wonder if you could tell me what's going on in terms of newborn screening legislation in state houses around the country. What types of bills have you been seeing?

Kelsie: NCSL tracks newborn screening alongside our maternal and child health legislative tracking. We've identified a few recent trends in enactive legislation which include establishing newborn screening advisory committees, adding new disorders to state screening panels, changing

financing and payment structures, and increasing access to follow-up care, which includes diagnostic testing and treatment.

TM: 18:58

Ed: Are there some specific state examples you can give us?

Kelsie: Several states establish advisory groups to bring stakeholders together including medical providers, public health professionals, laboratory experts, parents and advocates.

Advisory committees may determine which conditions to screen for or how to improve program efficiency or effectiveness. Georgia established an advisory committee in 2021 with the goal of including recommended uniform screening panel or RUST conditions in the state screening panel within one year of being recommended. The advisory committee also estimates the cost of screening for proposed conditions.

Oregon established an advisory board in 2019, which requires consensus to add conditions to the state screening panel. States also use a variety of approaches to add new conditions. Some states make changes through legislation, while others require approval from the state department of health or an advisory board.

Nebraska added spinal muscular atrophy to its panel through legislation in 2020. Louisiana enacted legislation urging its health department, which has the final say on which conditions make it onto the state screening panel, to study the costs and benefits of Mucopolysaccharidosis Type 1 and Pompe Disease to its panel in 2019.

TM: 20:11

Ed: So, one of the things I talked about in the earlier conversation with Peter was how to pay for these tests, and I wonder if states have taken action around this in trying to address the issue of cost.

Kelsie: Payment and financing models differ greatly. Some states appropriate funding, other states may charge hospitals for laboratory fees, which may be passed on to the patient, and other states may require public or private payers to cover the cost of screening.

Several states have made changes to alleviate the cost burden to consumers and improve access for follow-up services. The District of Columbia requires individual group health plans to cover the cost of newborn screenings, and Utah charges fees to hospitals to cover the cost of laboratory services to process results. Utah also requires Medicaid and its state employee health plan to cover screening.

Newborn screening results may be in range, meaning a baby likely does not have a condition, out of range, meaning a baby may have the condition, or borderline, meaning somewhere in-between. This is not a diagnosis. Instead, babies with out of range or borderline results should see a specialist for follow-up testing and potential treatment.

Several states created a more seamless transition between newborn screening and diagnosis and treatment. Colorado created a special fund in 2018 to cover the costs associated with newborn screening, follow-up care, genetic counseling, and education programs.

TM: 21:35

Ed: You mentioned the RUSP earlier and Peter did as well. I wonder if you can tell us about how states are using RUSP to make decisions about the newborn screening panels.

Kelsie: Anyone can propose a condition for consideration at the state or federal level, but decision-making processes for recommending or implementing screening are often complex.

As Peter mentioned, every state requires newborn screening for every infant, but the number of conditions that each state screens for varies. Some factors include state laws, financial costs and funding sources, the frequency of the disorder within the state, and available treatments and follow-up.

Many states consider the RUSP when adding conditions to their state panels. Several states have passed legislation to align with RUSP-recommended conditions more closely, such as Arizona which required state newborn screening programs to include all congenital disorders that are included in the RUSP by January 1st of 2022, and Virginia, which requires its department of health to review national recommendations biannually and consult with its advisory committee on changes to its screening panel.

States can also add conditions that aren't on the RUSP. For example, Krabbe Disease was considered by the federal advisory committee on heritable disorders in newborns and children in 2009 but was ultimately not added to the RUSP because there is no cure. The committee decided that additional information on diagnosis and screening methods was needed.

Even so, nearly a dozen states have added the condition to their screening panel. New York was the first to add Krabbe Disease in 2006, and South Carolina most recently began screening in 2020.

TM: 23:12

Ed: Keeping our audience of legislators and legislative staff in mind, I wonder if there's anything else as we wrap up that you'd like to share.

Kelsie: This was a lot of information and NCSL has a ton of resources on this topic. They're all available on our website and we're here to support our members with questions on newborn screening programs or to provide additional information on any of the examples mentioned today.

Ed: Well, we'll be sure to link to those resources on the web page for the podcast, and Kelsie, thanks for walking us through this. It's really interesting. Take care.

MUSIC

Ed: And that concludes this episode of our podcast. We encourage you to review and rate NCSL podcasts on Apple podcasts, Google Play, Pocket Casts, Stitcher, or Spotify. We also encourage you to check out our other podcasts: *Legislatures*, *The Inside Story*, and the special series *Building Democracy*. Thanks for listening.