



**NewSTEPS**

A Program of the Association of Public Health Laboratories™

## **Critical Congenital Heart Disease (CCHD) Technical Assistance Webinar**

**August 2013**

### **Presentations:**

- Update on status of CCHD screening in the United States—Marcie Sontag, PhD, Associate Director, NewSTEPS
- Interactive discussion on the needs of the CCHD community—Led by Marcie Sontag and Thalia Wood, MPH, NewSTEPS
- Resources available for the CCHD community—Marcie Sontag and Thalia Wood

Please direct all comments/questions pertaining to this webinar to Thalia Wood at [Thalia.wood@aphl.org](mailto:Thalia.wood@aphl.org) or 240-485-2701.

Thalia Wood: Okay, thank you everyone. Now I'm going to go over the meeting norms here. I'm going to mute your phones, so when we get into the discussion area, please push \*7 to unmute yourself to speak, and \*6 to remute yourself. Please do not place your phone on hold at any time.

The webinar is being recorded, and will be archived on the NewSTEPS website. Right now I'm going to mute everyone.

Recording: The conference has been muted.

Thalia Wood: Thank you. Marci, are you on the phone?

Marci Sontag: Yes, I am, I'm here.

Thalia Wood: Okay, I'm not sure if I have a technical issue, of getting you to be co-presenter. I'm not sure if you can see everything or not.

Marci Sontag: I can see everything. Thank you, Thalia.

Thalia Wood: Okay, you're welcome.

Marci Sontag: Since we're doing the polling, please go ahead and run the sides, because it's helpful to be able to speak into.

Thalia Wood: Okay.

Marci Sontag: Welcome, everybody. I'm Marci Sontag, I'm the Associate Director of NewSTEPS. We're excited for another CCHD webinar call. Thank you for all of you who have joined. It looks like we have about 30 people on the web, and 26 on the phone.

Today we are going to do a very interactive discussion, so I hope you all drank your coffee this morning and are ready to engage in a good discussion with us. Before we get started, I'd like to make a few announcements.

The work that NewSTEPS has done over the past two years, related to CCHD, has been guided by a work group of volunteers from the community. Also, Tom [inaudible 01:42] has not had any co-chairs of this group, and now we have two co-chairs.

We're very thankful to Lisa Holmes from Children's National Health Systems, and Amy Gaviglio from the Minnesota Department of Health, who have stepped up and agreed to lead our efforts related to CCHD technical assistance. [inaudible 00:01:59] of these technical assistance telephone calls, and then the other work that we do, related to CCHD technical assistance. We're very excited to get started with them.

We've also sent out some invitations to individuals to join the work group. If any of you would be interested in joining or becoming more involved in some of the behind-the-scenes work, to guide our efforts for CCHD technical assistance, please reach out to Thalia Wood. I think you all have her email. We'll make sure we get you connected.

Due to many competing obligations this fall for all of us in the newborn screening community, these webinars will be held on a bi-monthly basis. September is the Discretionary Advisory Committee Meeting, the DACHDNC, and that conflicts with this meeting. We will not be having a webinar in September.

We will have one in October. The end of October is the Newborn Screening Symposium, so we will have some time to talk then, so there will not be a webinar in November, and we will have one again in December. Please mark your calendars, and Thalia will be sending out reminders as well.

One of the things that we'd like to do on this call is just to catch people up with how far we've come in CCHD screening over the past couple of years. If we looked at this map just a year, 18 months ago, many of these states would have been orange. Where this is being considered and not yet approved.

This is the CCHD screening status, as we have it at NewSTEPS, as of August of 2014. You see that dark blue is universally required by law or rule and fully implemented. The light blue is universally offered, but not yet required. In some cases it may never be required, but this is offered to all babies.

We have required in the green. Required, but not yet fully implemented. It's not 100% implemented, whether it be not in all hospitals, or the data system is not implemented 100%.

The darker green is offered to select populations, or by request. Then we have those in which CCHD screening is being considered, but not yet approved in the orange. A couple of states are doing it as a part of a standard of care without a law, and no data collection.

Then, as we've heard from Pennsylvania in the past, they are reporting aggregate data only right now. The data recording is required, but the screening is not.

I'm very excited to say right now that Wisconsin, as of July 3rd, is a dark blue state. I was thinking that was coming up, but I didn't know if it had been official. Yes, we will switch Wisconsin to dark blue. Thank you, John Hokanson, for reminding us of that. That's fantastic.

If any of you see that your state is out of date, I'd like to take the next few slides to show you that updating this information, you can do it on your end, to our NewSTEPS data repository. Thalia, you can go to the next slide.

This is the NewSTEPS website, it's [www.newsteps.org](http://www.newsteps.org). Here I just clicked on the state profile information. You pull up state profiles and you get a map of the country. You can click on your favorite state and see ... any of us. You can click on any of our states and say, "Hey, what's going on in Wisconsin? I'd like to see what they are doing."

If you are one of the people who has access to edit this information in your state, there is at least one person in every state who has the ability to edit this information, and there are multiple user roles. You can find

out who that person is in your state and contact them, if you feel that you should have the ability to edit some of this information as well. Let's go to the next slide.

I picked my favorite state. Being from Colorado, I picked Colorado. Here is our Colorado state profile. The first page just gives us the very basic information about Colorado. I then click on Disorders. That's the next slide; I guess I can advance these slides, Thalia.

This is just a screenshot of the top of the page. We have it divided up into the core, or the 31 disorders recommended by the Secretary of Health and Human Services, those that are on the RUSP. Secondary, those secondary conditions that are included with the RUSP Panel. Then other conditions that are screened. That are not on the RUSP, but other conditions.

Right now we're going to focus on the core. You can see in Colorado, 30 of 31 conditions listed on the RUSP are universally required by law or rule and fully implemented. The one that we have not yet required in Colorado is CCHD, as we're still working out some of the altitude issues. Next slide, I think.

When I scroll down, further down that page, I can see under Other Disorders. I see critical congenital heart disease, and it says being considered but not yet approved. Now I could log into this, and I could change that. Once we are ready to go, we could say yes, it is required and fully implemented. If you saw that your state was out of date, please go in and change that.

Earlier this summer, I've also heard, because this is a great way to get updates from those of you out in the community. I just want to also let you know that from Pennsylvania, we've just heard that their state is now dark blue too. It's not just requiring just the data collection, it is requiring all babies in the state are now mandated.

This is fantastic. And it really is, I think, impressive and a testament to all of you, how hard people have worked to get CCHD screening mandated and implemented across the United States. Thank you. I know there are many of those of you who aren't quite the blue yet, have dark blue states. I think you will be shortly. This is very exciting.

Now we're going to move on to a choose your own adventure call. Many of you may have been on a similar call that we did last winter, a choose your own adventure.

Just to refresh your memories, for those of you who did not read the childhood books of choose your own adventure, they're chapter books meant for elementary school kids. In which the hero or heroine has a choice to make. You can say if you would like the hero to walk into the lion's den, turn to page 45. If you would like the hero to climb the waterfall, turn to page 32. Then kids can choose their own adventure throughout that space.

We did this last winter, and had good success and a good discussion. We're going to do the same thing here, where we're going to give you some questions of what are the concerns that you have right now. You know, we can talk in our work groups and decide what we think those concerns are. But I think hearing from you helps us to guide not only this discussion today, but also to guide what we're doing for use at CCHD technical assistance as we move forward.

I now see there are over 40 people who have joined us, so we're going to be leaning on you to really engage in this conversation. Let us know what are the challenges that you're facing, and what are the successes you've had and how can you share those with us? Next slide, Thalia.

Thalia Wood: Thank you, and this is going to be the first question. Each time I show the question, I'm going to have to go back and find it, so bear with me. Now I'm going to bring up the poll. The first couple questions are just asking for some general information about you. If you could go ahead and fill this in, that would be great. Describe the area of CCHD in which you work.

Marci Sontag: I know for some of you, there might not be a perfect answer. This is definitely not a scientific poll. This is just to give us an idea of who is on the call with us, so you know who else is joining in our discussion today.

Overwhelmingly, it looks like our group is state public health. We have some people from the clinic setting, some of our clinical friends. We have some from advocacy, some parent advocates or other advocates. Then we have a few people who are working in academics.

Our first few slides here are really going to be trying to get a feel for who is on the call with us. Next slide, Thalia.

Does your state have a mandate for CCHD screening? Now we're breaking this down a little bit. We say yes, no exception. I guess it really should be yes, out of hospital births are excluded. Yes, special populations are excluded. Then there's no mandate at this time.

This also helps us to know, do we have a lot of those dark blue states who are on there? Or do we have some of the states who are still working to implement, and we can learn from some of the dark blue states?

Okay, it looks like most people who are on the call, it represents our map very well. But most people say yes, no exceptions, our state is screening for all babies. Some places are out of hospital births excluded. Then there are a few of us who still have no mandate at this time, and we're still looking for advice from the rest of you.

Thalia Wood: Okay, we have one more kind of general question before we get into the choose your own adventure. This is that question now.

Marci Sontag: This is kind of similar to that last question. I had thought maybe we had deleted this one, and then maybe we did not. This is especially for those of you who don't necessarily have a mandate. Everybody go ahead and answer. Many of most hospitals are screening, but it's voluntary, even if there is no mandate. What do we know about the rest of us who are not in the dark blue, our states are not dark blue yet?

All right, again that top line makes sense. Since most states are screening, and mandated for screening. In some cases it looks like most hospitals are screening, and it's mandated. But maybe not all hospitals are screening yet, so it's not yet fully implemented.

There are a lot of states who many or most hospitals are screening, but it's voluntary. I think a lot of hospitals have read these guidelines, know they need to be screening. Are screening while waiting to see what guidance they get from their state.

Thalia Wood: The next slide will actually start the choose your own adventure. Depending on your answer on this slide will depend on the questions and the discussion that follow.

Marci Sontag: What is the CCHD newborn screening topic most important to you? You might say there's another one that's not on here that's most important to me, but of these five, pick which one is most important to you. Are you struggling most with babies born in outlying hospitals? With data collection and surveillance? With education? With legislation and mandate, getting things mandated? Or working with the birth defects registry?

We still have some votes coming in, but it looks overwhelmingly that data collection and surveillance is the biggest challenge. At this point of care

testing being implemented, we know that that is a big challenge for all of us. Thalia, if you can go up to that next question then.

Thalia Wood: Yes, there is actually two parts. This is one question about data requirements in your state. Then we'll go into what some of your challenges might be.

Marci Sontag: This, we just want to know who again, who is on our call? Is there a data reporting requirement in your state? If you're not screening at all, you can just check that last box of no reporting done or required.

Thalia and I have been working closely to gather data from the states, and this very closely matches what we have seen as we've done a more scientific evaluation of what's going on in the states. But specific data is required in many of the states requesting information about the exact screen, the pulse oximetry results, the timing of it.

Then many states are getting aggregate data from the hospitals. To say, yes, we screened this many babies, we have this many failures.

Now let's go on. We have one more choose your own adventure question, then we'll open it up for discussion. What are the biggest challenges that you face in data collection and surveillance? Getting buy-in from nursing staff? Identifying the right system to collect the data?

Developing that IT system within your state public health system? Having the public health authority to collect the data? Interpreting the data and knowing what to do with it once you have it? Money, which I guess sits for all of those above, probably also. Or is there something else that you would like to talk about?

All right, it looks like there are two questions that are leading the pack, I think at this point. Kind of tie-in to each other. How do you identify the right system? Then once you've identified it, do you need to either develop something, or using something that's canned and off the shelf. Something that's already developed within your own state?

Now we're going to put these questions back to you. For those of you who say my biggest concern is identifying and developing the right system to be able to collect the data. If you have a recent success and would like to share that with us. Or if you have a question that, here's where we are in our state, and here's where we're struggling? Please use this time to reach out to us as a community, and we'll see if people can have answers for those questions.

Thalia Wood: Remember to press \*7 to unmute, join.

Marci Sontag: Lisa, I see that you're on now, can I hand this for you for a minute? To talk a little bit about the system that you have worked with in the DC area?

Lisa: Hello? Marci, are you able to hear me?

Marci Sontag: I can hear you.

Lisa: Okay, sorry, I unmuted it on my phone, but it didn't seem to work the first time. Sure, I actually was one of the people to select developing IT system, the 33%. I think part of the challenge is interoperability in DC.

We only have seven hospitals with newborn nurseries, and yet I would say there are three to five variations of IT systems. With some hospitals using Cerner, some using Epic, some using newborn screening IT systems. Or a combination of paper and electronic, depending on what the actual data is.

That creates a hard system to really streamline a process and standardize? That's one of the challenges that I've seen, just in DC.

Then also getting the different systems to talk to each other. I think in my mind, there are a couple different levels of people who need CCHD screening results. Including families and pediatricians? There needs to be a record of it in the hospital patient charts. Then aggregate reporting or pulse-ox individual reporting, in terms of screening to public health.

It's hard, I think, to get all of those ducks in a row, and to have a low-cost uniform solution for even just seven hospitals. I would be curious to see what other people's thoughts are on that issue. On developing IT systems.

Does that make sense?

Marci Sontag: It does make sense. Those of you who are on the call, who has had either similar challenges or have you had some solutions to those challenges?

I'm looking to see if [Janice 00:20:06] is on the phone. [Janice Stock 00:20:09] from Michigan, and I don't see here. Is there anyone else from Michigan on?

For those of you who were at our in person meeting last February, the group from Michigan presented a really nice overview of their system. In which they're giving hospitals the options of how to report it back to the state. They're giving [inaudible 00:20:39] options, or letting people ... They've kind of developed that system.

They are letting people transfer data via Excel spreadsheets that have been uploaded into their system. And if I remember correctly, they're using PerkinElmer as their vendor on the back end. They've developed a module within the PerkinElmer [money 00:20:57] system to collect this data on their end.

They're allowing hospitals to kind of pick their own solution to data transfer options. That takes more work on our end to be able to do that, yet it's kind of a nice solution to have those different options. Because some of the points, Lisa, you just made of how do we collect these data, and how do we make it uniform across different hospitals?

Lisa: We've actually been very successful too, in working with OZ Systems, which I know does a lot of the public health level reporting. Working with them to try to populate it back into a hospital EMR. I know it can be done, it's just that developing that and customizing it.

Because each of the hospitals have a different electronic health record or combination of electronic health record and paper systems, that makes it somewhat challenging. Because you have to be able to work with the hospital system and really tailor the solutions. Rather than having a plug-and-play solution.

Marci Sontag: Do you mind just spending one or two minutes talking about what that OZ System does? I see there are some new people on the call who may not know what that system does. I'll say in advance ... I mentioned PerkinElmer, when we mention OZ, this is to give you options. This is by no means an endorsement of any of these options. But it's good to know what is out there.

Lisa: Sure, so we had a unique opportunity, and we actually applied for a grant through Masimo Foundation, where we were able to get some funding to be able to implement in DC. OZ Systems already collects data for genetic and hearing screens for the DC Department of Health. It was kind of a natural fit, because they have a very nice CCHD module as well.

We were able to work with them to have hospitals send data through the OZ System, to be able to report I guess at the population. Sort of state level results from all seven of the hospitals.

Some of those hospitals needed to do manual data entry? Where they would enter the result, the screening date, age at time of screen. We were able to do some chelate projects off of it as well.

The OZ also has another tool which we were able to pilot at one of our hospitals. Where the screening results actually go from the pulse-oximetry device itself, and that data is captured. Where if the nurse or technician is performing the screen chooses the pre- and postductal set, that gets sent automatically to a state level reporting tool or report.

Then there is the potential also to work with the folks at the hospital EMR. To be able to auto-populate it into the baby's electronic medical record, if the hospital is using that.

We have two out of the seven hospitals that are still using paper charts, so there would be no way to automatically populate it into a paper chart. For other hospitals that do have an EMR, that certainly is a nice possibility.

Thalia Wood: Thank you, Lisa. Just for those that are on the call, that was Hom from Children's National here in Washington, DC. We ask for all the speakers to be identified?

Marci, we do have a couple of questions over in the chat box. Did you want to read those out loud, or you want me to?

Marci Sontag: Sure, I can read those.

Thalia Wood: Okay.

Marci Sontag: One question from Sharon [inaudible 00:24:47] from Wisconsin is are the HO7 standards for reporting CCHD final? They are not final. [00:24:56] was working very hard on those when she was at NLM, and she has recently left.

Oh, yes they are final. They are public. Hey Laura. Laura, can you unmute yourself and talk about that? This is Laura [DeSots 00:25:14] from OZ Systems.

Laura: OZ Systems.

Marci Sontag: Are you able to ...? Everyone is still muted. If you press \*7, you can unmute. We can't hear you, Laura.

Laura: Can you hear me now?

Marci Sontag: Now we can hear you.

Laura: All right. No, they are published. I don't know if they're publicly out on the web. But if you are an Ho7 member, you should be able to access them. They have been sent in and they are finalized, so it is done. Finally it is done.

Marci Sontag: Yeah, I was thinking they were still going through the process. That is fabulous.

Laura: No, they're done. They were voted on, they've been sent to publication, and it is done. They're done. It's a long process. It's a lot of collaboration, but they are available out there. Or they should be available out there.

Marci Sontag: Excellent. Thank you very much.

Laura: Sure.

Marci Sontag: Then, once you have the guides, it's the implementation of the guides and making sure you have that data collect. Those guides get us part of the way there, thenj there's still a lot of work that has to happen. But that's a really monumental undertaking. I'm glad to hear that those are final.

Laura: Yeah, and just as an aside. I'll just add that Michigan did do a one-off implementation guide for their CCHD implementation? They've kind of constrained it, and it's a little bit different than the HO7 draft standards for trial and use [inaudible 00:26:40] out there for CCHD. In case anybody wants to reference that as well. But the actual standard should be available on HO7.

Marci Sontag: Perfect. That's great to know.

That's something that, to kind of plug another APHO work group, we have an HIT work group in which we are trying to address some of these various issues. Of data transfer, and interoperability across the newborn screening system. We will, on an upcoming call.

In this coming month, we're going to be talking about CCHD and newborn hearing loss and hearing screening, the technical side of this and data transfer. When that comes out and that webinar is announced, we'll make sure that it also gets sent to this group, so you can hear what those people talking on that call have to say about CCHD screening as well.

Any other comments or thoughts about HO7 messaging, before I move on to the next question?

HO7 messaging, or any of those types of ... Go ahead.

Bob: This is Bob [Chico 00:27:53]. I guess the question I have for people is when you set up ... We've talked about this with hearing screening in Pennsylvania. Trying to figure out electronic ways to get the data from the hospital point of testing to the Department of Health. Every time I bring it up, the question comes up, "But who is going to be responsible for creating the linkages between the hospital," in terms of paying for the linkages between the hospital.

It has always been my contention that if the hospital is mandated to report, then they're mandated to report. They're going to put in resources to do that reporting one way or the other. Those resources are probably less to do it electronically than it is to do it via some sort of paper system that I think is always problematic.

In states that have done electronic reporting, I'd be curious to see how they are winding up paying for this. Is Department of Health paying for the whole thing, or are the hospitals paying for the linkages? I'm not sure how that's working.

Debbie: Hi, this is Debbie from Maryland. Bob, are you talking about the telepathic download of the pulse-ox?

Bob: Yeah.

Debbie: In Maryland, we have worked with OZ to offer that. They're directly asking hospitals if they would like to purchase that. We just did not have the funds. Not only the funds to buy it, but then there is a maintenance cost, every year?

Bob: Right.

Debbie: We just did not have the funds to do that.

Bob: Okay, so the hospitals are paying for it.

Debbie: Yes, we're asking the hospitals if they want ... I think it depends. Some hospitals may only have 10 births a month, and for them it may not be worth it. Whereas the ones that have thousands a month, it would be worth their while.

Bob: Yeah, okay.

Marci Sontag: Bob, this is Marci Sontag. Just going to tell you a little bit of our Colorado experience. We are still ... I reach out to you actually about how you mandated reporting before screening. Because we're looking at that. We need to collect data in order to really refine our cut-off. The [inaudible 00:30:19] are trying to collect data from the hospitals who are already screening.

But it's just a process of that cost in itself, of getting people to enter the data in a way that can be transferred over to us so we can analyze the data. Even granted that it's not human subject research, we don't need that kind of approval. But who is funding the port for the ... even the IT people within the hospitals, to gather the reports from the EHR to send to us in a usable form so we can analyze the data.

Then the next step is, there are some hospitals not even entering it into an EHR now, they're still doing it on paper form.

Bob: Right.

Marci Sontag: They said we'd be happy to share, but we don't have the funds to enter the data, so how are we going to get there? It's a little bit of building that infrastructure so we have the funds to get the data to report back, so we can use the data.

Bob: Yeah. I mean it's clearly a problem. You can't just talk about the problem in DC of doing seven hospitals. I've been charged with trying to put together ... Now that it's mandated in Pennsylvania. Even though we were reporting, it was very haphazard. Probably they were only getting half the reports, and I know darn well more of the hospitals are screening and not sending in the reports. Even though they were supposed to.

Now that it's mandated, I've been charged to get a sub-committee together to re-look at the whole reporting system and how it is that we're doing it. Pennsylvania is so behind in terms of electronic reporting and everything, it's all been paper.

If it's hard for seven hospitals in terms of all the different systems and the way they do things and everything, think about it for 100. I have 100 birthing hospitals in Pennsylvania that I'm trying to figure out how to do this with. It's a challenge.

Lisa:

This is Lisa again from Children's National. Bob, I think you make an excellent report about the linkages between the hospitals and the transfers? It's no easy undertaking. I was curious too, just based off of a comment you made, Marci. Where you said about building infrastructure.

I am sort of CCHD centric, but I'm curious to know what kind of infrastructure exists for reporting older newborn screens to public health. Is that automated, largely? Or are there any other lessons that we could steal in terms of electronic solutions? Or even just any solutions? And apply those?

What kind of infrastructure's already in existence that could maybe be used for CCHD screening reporting?

Marci Sontag:

Some of the lessons I think we can learn can come from hearing screening. Because the rest of the screening tends to be run by the public health system, and they're pushing information out. Rather than the screenings happening at the point of care of the child, and the results need to come back to public health.

There are some lessons that we can learn from data transfer in hearing screening. Again, OZ Systems has worked with that. There's actually a paper coming from the Secretary's Advisory Committee that should be out pretty soon. That Chris Kus has led, and I'm not sure if he's on the call today or not.

They have taken some of those lessons learned from hearing screening and talked about how we can share that with the CCHD community. Anybody else have thoughts on this issue?

Debbie:

This is Debbie again from Maryland. That's essentially what we did. We took advantage of some of our infant hearing program funding and expanded our database. We're collecting CCHD birth defects and infant hearing data in the same database.

It is helpful, although what we have found is that it's not as seamless as we would have thought. There are often different staff that are entering the different data? There are very different levels of compliance.

It's often the hearing screeners, the audiologists who come in who enter the infant hearing data? This was completely brand new to the nursing staff who are entering the CCHD results or the birth defects.

Bob: And the hospitals are doing that along the lines, am I right about that?

Debbie: Yes, the hospitals are entering the data. Yeah. But different staff within each hospital.

Bob: Yeah.

Thalia Wood: Marci, did you want to go to the other question that was asked earlier?

Marci Sontag: I sure will. This question is coming from [Debra Watson-Doyle 00:35:07] in Washington. She says, "Our state health director recently commented that she would support a mandate for CCHD to be added to the newborn screening panel. But only if there was no requirement for the health department to do any data collection or surveillance.

"She believes that CCHD screening is a good public health policy. But failing to screen or follow-up accordingly, is a medical malpractice issue, not a public health issue." This is a great question, Debra. So Debra would like to know our thoughts on this.

If you all remember, Washington was one of the light blue states in which screening is really being done universally in all hospitals, and not mandated. So there is no data reporting requirement.

Bob: This is Bob Chico again. I'd be happy to chime in on my thoughts about that, since I've had 180 degree turn on that? This whole issue? I always thought it was a good medical thing to do, but wasn't sure that we needed to do it as a public health initiative.

Again, the same, I mean we screen everyone for hyperbilirubinemia and it's certainly not done as a public health diameter. We don't report bilirubin results to the state or track it and things like this. That was my first thing. I wasn't sure that it needed to be reported.

My rationale for that is that most kids with CCHD, they don't pass the screen, you deal with it right away. This is not like hearing, where kids need to be tracked for a long period of time. [inaudible 00:36:46] before the time of screening, the time of diagnosis. CCHD, between the time between a positive screen and the time of diagnosis is usually ... It shouldn't be more than days or hours.

Then I came around to thinking that we really do, as we implement a universal screening technique. That has been studied in studies, but has not been universally implemented at every hospital. It really becomes important to track what the impact of this is on the overall public health of people.

In tracking things like how many false positives do you have out there? How many kids are getting transferred to a diagnostic center for an echo and then finding that they didn't have any heart disease? You know, I think it does become a public ... If you don't report it, you're not going to get any of that information.

I believe that it does need to be reported. I think it need to be reported as a public health initiative that allows us to determine what is nthe public health impact of this new screening technique? Are we picking up disease? What's the cost of picking up that disease? How many echoes are being done, that are not necessary?

I think all that falls under public health. I don't see any way to get around it without reporting it.

Marci Sontag:

Bob, that was very well said. This is Marci. As an epidemiologist, you couldn't have said it better. We need the data to be able to see how it's going. These cut-offs were really determined ... The cut-offs that we are using based on Anne Granelli's work in Sweden, that Alex [Tepper 00:38:35] then wrote up, have really been determined on a relatively small number of babies.

To have data on a large number of babies, implemented in local settings at local hospitals, will help us to inform what those cut-offs should be. Hopefully most of you have heard about Matt Oster's work, from Emory. That he is trying to pull together existing data from around the country. To say, "Hey, what are the cut-offs? How well are they working?" We're only going to be able to do that if we really have data.

Then that public health surveillance piece of it is can we follow those babies and are we really doing a good thing here? Are there different hospitals that are doing better than others? How is the failure rate working? True positives, false positives, false negatives?

We need the data to be able to collect it. The only place that really can collect that data is the public health system.

Anybody else have any ...? I guess Bob and I have spoken pretty strongly now, but is there a contradictory voice out there? That would like to say, "You know what, I don't think we need to collect this data, and here's why."

Deb: This is Deb in Washington. I don't want to be perceived as being anti-CCHD or contrary, but I'm stirring the pot a little bit. Because I absolutely agree that we need that information. From an epidemiologic standpoint, it makes perfect sense.

But if you are a state, and you have limited resources, and those limited resources have to cover all your public health activities. Is this appropriate to begin a new surveillance and tracking system, collecting data, etc. Versus is that more appropriate for academia?

Marci Sontag: I love the pot stirring, Deb. Anybody have thoughts on that?

Bob: I guess my comment to you is is it appropriate for academic? Absolutely it's appropriate for academia. But academia is never going to be able to do the amount of data collection, the kind of data collection you need when it's a universal screen.

Let me tell you why I think there's some wiggle room in this whole thing. Because I think that the NICU population is a real mess right now. It actually worries me in Pennsylvania, because like I said, we just passed a mandate that it includes everybody. I'm just not sure how we're going to handle the NICU population.

Because it's just a whole ... I mean, we all know this and probably everyone that is on this call understands the can of worms that the NICU population presents. They've had a screening echo before, they're still on oxygen. They still have [inaudible 00:41:32], what are the cut-offs and everything.

I actually would have been happier, when we passed our mandate, if it would have excluded NICU babies? Because I don't know how to collect the data and everything there. I think it's a big mess to try to do that.

But as far as the rest, I'm just not sure how the academic ... And I'm an academician, by the way, just so you know. I don't know how they would do this in an academic way that is going to now figure out the variation between hospitals that are not involved in academics.

If the academicians get involved with doing this tracking and screening, they are basically going to do it in primarily those institutions where there is an academic presence. My worry about where you're going to get variation and potentially false positive and negatives, is going to be in a lot of the community hospitals. Especially in the rural areas.

I don't think putting this on the academic community is going to necessarily reach those areas, in terms of how well they're doing things.

Marci Sontag:

Just to add to that, I worry a little about academics. I do work in academics, and we're trying to collect the data. Yet without a mandate to report the data, so they report it. Then the hospitals who are more interested in research tend to be the larger hospitals that are going to report.

That gives us a very good view of what's happening in those hospitals, but we have no idea of what's happening in the outlying hospitals. The smaller rural hospitals, all of those. Then it's not doing a service to public health. It's doing a service for the larger academic, more research-oriented hospitals.

If we are going to collect the data in the name of public health, we need to be looking out ... That's the beauty of newborn screening, is it doesn't discriminate across where you are born, or the size of the hospital, or any of that.

Lisa:

This is Lisa from Children's National. I really appreciate your comment, Deb, I think it's really interesting. This is a problem that we ran into with resource allocation with the reporting. Is that the nursing [inaudible 00:43:39] in the hospitals, they're telling me things like, "Oh, I'm literally being pulled into staffing. I cannot report this data because I can't even assess and cover my nursing staff."

Even here at the hospital level it's a different concern. But in terms of resource allocation and being between a rock and a hard place. Thinking CCHD surveillance is an awesome idea, and implementing it. Knowing that another very worthy public health goal might be not as well funded.

I think there is a very compelling case to be made for CCHD screening, given that it is the most common birth defect. The implications of not understanding or not decreasing the number of false negatives that occur? The results being death or permanent neurological damage, I think, are very compelling. For that reason I think it should be pushed to the top of the list, in terms of resource allocation for surveillance.

Marci Sontag: Along these same lines, there is a comment from [Lois Taylor 00:44:49] that says, "I agree that we are collecting data, and not really doing follow-up of CCHD." This is different, even different than hearing screening. In that hearing screening, still that follow-up still happens on the public health side, or much of that follow-up does.

That was my commentary, sorry. Lois continues to say, "Newborn screening is gathering the limited data sooner. But in most states, the birth defects registry does a more detailed analysis."

Thalia Wood: Marci, this is Thalia. I want to go ahead and ask that birth defects registry question at this point, just to see what people say about that. The screen mentioned [inaudible 00:45:24].

Marci Sontag: Okay. Here is a survey question to ans- ... I think there is a comment that is going to come too, but feel free to answer the survey question. Are you working with your state birth defects registry, or BDR, to collect or compare data?

Yes, the system is working well. Yes, we are collecting very specific data. No, it is volunteer reporting. Or No reporting done or required.

Debbie G: Marci, I'm not certain if you can hear me if I'm on muted? When I tried to unmute myself, I hung up the phone. This is Debbie [Greenenberg 00:45:56].

Marci Sontag: Yes, Debbie, I can hear you.

Debbie G: Okay, great. I just wanted to point out something about birth defects registry. The birth defects registries are not in real-time, so to speak, the way newborn screening is. You're only going to see your data a couple of years down the road. Even with those birth defect registries that are doing active surveillance.

I personally think that a couple of years is too long to assess the system, to see if it's meeting its goals. Or whether it is actually improving in detecting kids. To decide whether it is really doing what we think it was designed to do.

In our state, we have a really ... We are implementing as of September 1. We have an odd little I guess law, in that the law says they only report confirmed cases to us. So we won't be able to know about false negatives or positives.

But then that information, after we get it, goes over to the birth registry. Then they will reconcile what we are sending them with what their active surveillance has detected. I just think you need to realize that birth defects registries are not going to give you answers quickly.

Marci Sontag: There is a good point. Although the beauty of the birth defects registry is it will give us information on babies that aren't picked up on screening. Whether they were picked up prenatally, then treated, then they'll get reported to the birth defects registry. Or they were picked up and they were a missed case on newborn screening.

That helps us, but you're absolutely right that it's not real time. It's down the road, for quality improvement, quality assurance activities for the CCHD system.

Debbie G: Then the other thing that we just recently discovered is that ... For the birth defects registry to consider it a case? The mother has to be a resident of the state of Texas. For instance, our state, we have a lot of undocumented moms? Those would not be found in the birth defects registry.

I'm not certain if all birth defects registries work that way. I was led to believe that's part of the case definition for birth defects registry. But mom has to be a state resident. You're automatically losing a proportion of your population if mom is not a state resident.

I just became away of this within the last month, that that was one of the limitations of the birth defects registry.

Marci Sontag: Well that, and ... You have a unique situation, where you have a lot of people who are not residents of the US. But all states share borders. Well, I guess almost all states share borders with other states, with the exception of Hawaii and Alaska. Share borders with other states and there are babies who transfer across those borders for care.

I know New Jersey has had some challenges with that. I think [Jean's 00:48:54] on. Jean, I don't know if you would like to speak to this. Babies who are born in certain parts of New Jersey are automatically transferred to hospitals ... Or they might even be born in a hospital in another state, because of their high risk birth. Or transferred shortly after birth, and that's where they receive all their care. Then they come home and live in New Jersey.

There are the challenges of getting those records across state lines. I know that some of our birth defects friends are trying to think of systems to help us do that. On the national level, to be able to share data between the birth defects registries.

Anyone else have any thoughts on data collection? I love the counter argument from Washington. I think that has given us a good point of discussion to be able to think about what is our role.

That gets back to the public health mandates to collect the data. I know there are some states who are saying, "Well we can collect the newborn screening information, because we are the ones who are performing the testing. We may not have the authority to collect the data."

Just by adding this information to the screening panel, we may not have the authority. We have to really look carefully into how to change that legislatively, or through other mechanisms. In order to have the authority to collect the data.

All right. My time zone, it's 11:51, so we have 10 minutes left until the hour. I don't know that we are going to have time to start another choose your own adventure question. We have had a really good discussion today, and we hoped to get to a couple more of these questions. But I think we're not going to have time to do another question justice.

We will keep some of these in our back pocket. I'd like to thank all of you really for engaging in this great discussion.

Thalia Wood: Wait, wait. We have some more information. We have some more slides, Marci. [crosstalk 00:51:02].

Marci Sontag: I was going to get there.

Thalia Wood: Okay. Just wanted to make sure you had not forgotten.

Marci Sontag: I was going to add that. I'm sorry. Thank you, Thalia. Don't hang up, anyone.

We did want to remind people of some of the resources that we have at NewSTEPS, and that are coming up in the coming months as well.

At NewSTEPS, [newsteps.org](http://newsteps.org), we have a CCHD resource page, in which we have information about recent activities that have gone on with CCHD.

We try to post the latest articles. Archive the articles. Archive these webinars.

We have some pointers from different states. Their success stories. What has happened. Please go on, look and see if there are things that can be helpful to you.

Also, if there are other things that you say, "You know what, I really would like ... I have something that I would like to show off." We would love for you to brag to us and say, "Hey, could you please feature X, Y, or Z from my state?" We would love to have that information.

Or if you know what someone else is doing. We're really looking at this as a comprehensive resource center, so we can all not have to look 100 different places to get our information about CCHD.

Thalia Wood: This, under News and Education, we have a ways to stay connected with NewSTEPS. It includes links on how to join some of our listeners. I'm going to show you two slides. The next slide, is the bottom of that page. Where you can join us on LinkedIn, and get information about activities that are going on.

It's very self-explanatory, when you go onto this page, to how to join us on LinkedIn. How to join the listserv. We want to make sure that you are aware of all the different ways you can stay connected with us.

Then the slide before the final slide. Here Marci, if you want to talk about the symposium?

Marci Sontag: Actually, can you back one slide real quick?

Thalia Wood: Sure.

Marci Sontag: Because I'd like to talk just for a second about ... We've got HIT listserv, that's the group who do the bi-monthly webinars on HIT Newborn Screening Issues. Join that listserv, and pay attention to the announcements as they come out for those.

This LinkedIn group, I know many of you are likely a little resistant to professional social networking. If you haven't joined LinkedIn, it really is meant to be a professional social network, where you are ... You post here is what I do in my job? Then you can help to find other people that are doing similar jobs.

We have a newborn screen group within there, that we are trying to grow. We have 81 members now. But to be able to use this as somewhat of a directory for newborn screening.

So I go, "Oh, you know what? I met Bob Chico on that call the other day," or I met him at a meeting. Now I want to reach out to him. Where was he again? What is his job? You can see his picture. You can use this as a virtual directory for newborn screening.

You're not going to be hearing posts about what people had for lunch, this is not that kind of social network. This is really meant to be professional.

It's also a great way, there are job postings that go up there. We're trying to encourage people in the newborn screening communities to post their job opportunities up there.

Great way to look for jobs and also a great way to say, "Hey, I met that great coordinator from Kansas. I would love to reach out to her. Maybe she could help find some work for me." She might see it that way, or you might be able to reach out to her directly on LinkedIn.

I would really encourage you to join that group. As you join, it's going to be come more robust.

Next slide, Thalia, and I'll get to that last slide.

Thalia Wood: Okay, and before I do that I just want to answer a couple of questions that were asked up in the chat box. The map that we showed you will be up on the NewSTEPs website. If your state is incorrect, please let me know so I can change it right away.

It looks like somebody is asking you a question directly, Marci, as well. And Laura, from OZ Systems, provided some websites to me in the chat box. I have asked her to email me those so I can get them out to everybody in an email.

Marci Sontag: The last point we'd like to bring up today is related to CCHD at the Newborn Screening and Genetic Testing Symposium. This is the APHL symposium that occurs October 27-31 in Anaheim. There are a couple of activities.

Wednesday, from 06:30-08:00, there is a special session on the current status of CCHD in the US. This is an evening session. It's informal, so it's

not part of the primary session. But we really would encourage you all to come. You can meet each other, talk in person. We're going to start with a facilitated discussion, and then some time for some questions and answers. And to get to know each other and network during that time.

On Thursday the 29th, from 04:00-05:30 ... are these the right days? We'll double check this. On session nine, Points of Care for CCHD, and that will be moderated by Julie [Lexing 00:56:08] from Nebraska, and Bev [Tharel 00:56:10] from Texas. There will be I think four or five abstracts that will be presented during that time on CCHD newborn screening.

Thalia Wood: Thank you, Marci. I think in the preliminary I was looking at the days wrong. You're right, it's Tuesday the 28th and Wednesday the 29th. Thank you for [crosstalk 00:56:31].

Marci Sontag: I was thinking, I was like I think the meeting actually ends on Thursday.

Thalia Wood: Yeah, it does, and you're correct. [crosstalk 00:56:35].

Marci Sontag: Tuesday night, and we will post this information on the NewSTEPS website as well. But Tuesday the 28th and Wednesday the 29th. If you're planning to attend the symposium, we would love to see you and connect there as well.

I think ... Is that the end of our slides, Thalia? There you go, if you have any questions, please reach out to Thalia. I would also be happy to talk with you and thank you for a great conversation today. We will see you all shortly.

Thalia Wood: Yes, thank you very much, everyone, for a great discussion.