NewSTEPs

A Program of the Association of Public Health Laboratories

Short Term Follow-Up Technical Assistance Webinar

November 2016

Take Aways from the Short Term Follow Up Stakeholders Meeting

Presentations: Krystal Baumert on False Negative

Christen Crews on Co-location of Laboratory and Follow Up

Jennifer Marcy on Funding Challenges

Melody Hobert-Mellecker on the Cystic Fibrosis Quality Improvement Meeting

Please direct all comments/questions pertaining to this presentation to Thalia Wood at Thalia.wood@aphl.org or 240-485-2701

Thalia Wood: Okay, we'll still wait just a couple more minutes to get started. I'll have Carol Johnson, one of the co-chairs of the work group get us started. Welcome to the November short-term fall webinar, and I do know it's 2016. Actually, the next webinar will be in 2017. I will have that changed before we have that January webinar of course. We'll get started in just a minute. Your phones are muted. Speakers, remember to push *7 before you speak. Thank you.

Carol, it is 3:00 if you want to go ahead and introduce the topic and what we're going to talk about today.

Christen Crews: All right. Sounds good. Welcome to today's short-term follow-up webinar. We're glad you're able to join us today. On the webinar, we're going to have 3 speakers give summaries of the main topics from our first annual short-term follow-up meeting that took place a couple of weeks ago in Orlando, then we'll have another speaker talk about our participation in the CF newborn screening quality improvement meeting that many of us who were about to go to Orlando, participated in.

Without further ado, we will go ahead and start. Krystal Baumert from the Nebraska Newborn Screening Program is our first speaker for today. Krystal's going to tell us about the false negative breakout session that took place at the short-term follow-up meeting. Krystal, I will turn it over to you.

Krystal Baumert: Okay, thank you Carol. I hope you can all hear me all right.

Thalia Wood: We can. Thanks Krystal.

Krystal Baumert: Thank you Thalia. Our breakout session was related to false negative results. The discussion included ways to ascertain false negatives and strategies to reduce the number of false negatives. We kind of had a lively discussion about the issues, the challenges, and the barriers. First of all, we needed to define what false-negative is, because it means different things to everyone. It can mean different things to everyone. We started with kind of just a short list.

A true false negative may be due to a lab error, a cutoff that will not detect all disease such as in the case of CF. A true CF case may have a low IRT, however if we set the cutoff to find every low IRT, that is a burden to the lab, it's a burden to the physicians. It's a burden to the program. It's a burden to the specialist and to the parents. It may also be caused by mislabeling or wrong information, or inadequate information. Meconium ileus is not reported always on the [inaudible 00:03:04] paper. Some states may already have this on their [inaudible 00:03:09] paper, and others do not.

Sometimes it will just be a phone call that somebody's calling the lab to say, "Oh this baby has MI, can you please run the DNA?" A false negative may be a condition that is not on our screening panel, that we are not looking for. Providers may not know or understand the importance of reporting false negatives to newborn screening programs. They may be reluctant to report, concerned about HIPAA considerations, or may not know that it's a false negative.

We did hear at the meeting that 2 states require physicians to report false negatives. There are not consistent case definitions classifications. This can be true even among specialists. Endocrinologists, even in the same practice, one may call a diagnosis hypothyroidism, and another may say the baby has primary hypothyroidism. Timing is everything. Late onset for some disorders, a second screen state may be able to pick up some things that a once screen, they cannot. A second screen state may pick up a rising TSH. They could pick up a case of primary hypothyroidism, or a hypothyroidism that's not congenital. They may also be able to pick up a Tyrosinemia case because of timing.

DNA analysis may not catch every mutation. There are thousands of mutations for CF, and screening labs have a set mutation panel they are checking.

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The solutions to reduce false negatives. This was also an interesting conversation. We kind of based this around communication and education. Of course, all of us working in newborn screening know that communication is key. It's important for us to build relationships, know who to talk to. We all learn from each other. If you tell someone something, they're more likely to tell you information. Promote communication between providers, specialists, birthing facilities, labs, screening programs, parents. This will help providers and parents feel comfortable in

reporting findings.

Report diagnoses, and findings to screening laboratory. Screening laboratory will not know they had a false negative unless it's reported to them. We all only know what we know. We don't know what we don't know. Education. Be clear what conditions disorder your state is screening for. In Nebraska, we try to be very clear that we're screening for congenital primary hypothyroidism and not hypothyroidism. We know we cannot detect every case of hypothyroidism.

Need to remind professionals, parents, public, that screening is not diagnostic. Many states use a disclaimer on their newborn screening report such as: the above screening result are meant to identify infants at risk, in need of additional testing, a normal result does not rule out the possibility of disease, or some other statement to this affect because we all know that not all forms of a disease will be picked up such as various forms of galactosemia, Tyrosinemia. We may miss partial by [inaudible 00:06:31] cases if a lab sets their cutoff higher because they're trying to look for profile. They may not even be trying to look for partial biotinidase deficiency.

Require meconium ileus information to be reported on filter paper. Of course, you run the risk of this being over-reported, but it is good information for the lab to have so that they can run the DNA. Inform birthing facility staff to report MI, and contact lab and ask the, to run DNA. Sometime we receive phone calls from physicians, nurse practitioners, and they say ... It could be the baby's 5 days old, 7 days old and they said, "This baby has Meconium Ileus. I know you have the screening results all done, but now we know the baby has Meconium ileus. Could you please run the DNA," so we will call and ask our lab to do that.

Produce an annual report. Report data, and conditions detected. Use this for an education tool as well. Make newborn screening diagnoses reportable to birth defects registry. Some states already so this, and have a long-running birth defects registry that gathers this information. Establish long-term follow-up programs. Evaluating cases, and finding out where there are problems, discrepancies with diagnosis and classifications. We can all learn a lot from that.

Add legislative language to rules and regs regarding reporting results negative. As I mentioned before, we heard at the meeting in Florida, that 2 states are already doing this. They already require physicians to report false negatives. Ensure sweat testing is done at a credited CF center. Of course this does not cause a false negative, however it can cause in this case. This was important thing, I thought, brought up at our meeting.

Thank you.

Thalia Wood: Thank you so much Krystal. That was great.

Carol Johnson: Yes, thank you Krystal. That was very good, and I actually, even though I was there, I learned more from your presentation, so that's great. I appreciate that.

Krystal Baumert: Thank you.

Carol Johnson: Our next speaker is Christen Crews from the Virginia Newborn Screening Program. Christen's going to talk to us about the discussions that we had at the short-term follow-up meeting on the co-location of lab and follow-up. Christen, if you'd like to go ahead, that would be wonderful.

Christen Crews: Thank you. Good afternoon. First, I'd like to start off with defining what we define as co-location. We define co-location as follow-up being in the same building as the lab. We had pretty equal representation, I think, in the focus group. We had some follow-up who work actually co-located. We had some follow-up teams who may be a few blocks away. We had some states [who 00:09:27] follow-ups might be up to 3 hours away, and then we also had some states who the follow-up and the lab weren't even in the same state. We had a lot of different scenarios, and a lot of different strengths and challenges and solutions that were discussed.

First, I'd like to start off by discussing the co-location strengths that were viewed. If lab and follow-up were co-located, you would have more face-to-face interaction opportunities. You would see each other. You might share the same buildings. This would result in improved informal communication. You would have a greater relationship building. You [inaudible 00:10:10] being able to place spaces with names, being able to start building a relationship with the personnel.

It would be easier to implement changes. Sometimes when have a change coming around, you might go back and forth with 5, 6, 8 emails before a decision is made, where if you were about to have the face-to-face time, then a decision could be easier reached. You would also have an improved understanding or linkage of the greater, or the broader public health system. This was the assumption that if we were co-located, then the laboratory would have a better understanding of what follow-up does. Then the follow-up team would have a better understanding of what the lab does as far as different processes and what is in place to make these actions go forth.

When you are educating or informing providers, you will have better understanding of what happens on all sides of newborn screening. You would also have physical ability to bridge the gap between lab and follow up. This is related to the previous screens that were discussed by improving teamwork and have increased learning opportunities. Whether you're learning about the lab side or the follow-up side when you have a new disorder come out. You have both the lab and the follow-up personnel who could work together on both sides as far as evaluating adding disorders to the panel.

You also would be able to share the same [LEM 00:11:46] system. This is an item that for some states, they weren't able to see what the lab was seeing because they weren't in the same facility. Some states who are not co-located are able to log in remotely and view the LEM system, so that's a possible solution for that.

Some challenges of being co-located is the assumption factor. Just because you're there and you're close doesn't necessarily mean that you're aware of what is going on. Efforts of communication still have to improve. You could still be in the same building and may not have face-to-face interaction unless you make an effort to do so. Co-location may also result in a loss of resources. Some states are directly funded from the lab for their follow-up program, and if you were co-located within the laboratory, then your budget may change. As well as outside the monetary component, you may have other resources. Say like in Virginia, we're within department of health, so we're able to access a wealth of resources [inaudible 00:12:56] there whether it's at the genealogy, or we're able to network with the maternal child-health programs. There's a lot of other resources that are available.

The laboratory agenda could take precedence. You may not have as much of the opportunity to have your own agenda if you are located within the lab. Then we also have the issue of being pulled in to labs is a big issue. 1 state shared a scenario where sometimes she was pulled into meetings to discuss lab inventory, which really isn't related to follow-up.

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Carol Johnson: That is the next slide. Can you see it?

Christen Crews: Oh okay there it is. Now I see it.

Carol Johnson: [inaudible 00:13:48].

Christen Crews: Okay, so that was the co-locations. Now we're going to look at the non-co-location. Since [inaudible 00:13:55] of not being co-located with a laboratory is better stratification of projects. When you have assignments come out, then the follow-up does their part and the lab does their part, and may be able to better assign out the different components and then bring it together. With not being co-located, then you may be able to make more of an effort of focusing on improving your communication. 1 of the challenges of being co-located was you still have to make an effort of communicating. Well, if you're not co-located, it still has to occur but you may have a better idea or awareness that is does need to occur.

Some non-co-located challenges is that there are different chains of command. The lab has their own supervision, and the follow-up has their own supervision. The agendas may not align. Out stakeholders may not understand the organizational structure, so they may not be sure who to call if a certain problem occurs. Whether they need to call the lab or the follow-up team, so definitely better communication with the stakeholders as far as who to contact with different issues. Some changes in laboratory staff can restart the relationship building. It is difficult to form relationships with those who you may not see every day or every week. If you do have changes in staff, then you would have to restart that. It would be more difficult to have that same relationship as you're not going to be seeing that person

on a daily basis.

There's also the issue of increased shipping cost. If you are not within close proximity to the lab, if you do need to send materials back and forth, then you have additional cost with that.

Some non-co-location solutions that we were thinking of ... These ideas came from labs who are not co-locate, but they have some work-arounds and some measures in place to try to improve practices and communication. One of those is to ensure having monthly or quarterly meetings to improve communication between the lab and follow-up. Participation on the reciprocal advisory board so you have representation from all sides. The utilization on instant messaging platforms or video screen-sharing tools, and then here in Virginia, we kind of have a hybrid situation where we are not co-located with our laboratory, but we are within a few blocks. Follow-up makes an effort once a week to go over to the laboratory so that we do have our face-to-face interaction and we can attend the meetings in person to try to help improve some of the communication in that scenario.

Our big take-away for whether you're co-located or you're not co-located, communication is really key, and you need to make an effort and have improved communication whether you are sharing the same building or not, and I think that's pretty much the summary of that focus group.

Carol Johnson: Thank you Christen. That was a great presentation, and I love how you laid out the information in the table format. That was very easy to read.

Next we have ... we had a really vigorous and heartfelt discussion. I guess that's how my role characterizes about funding issues in newborn screening, and Jennie Marcy from Iowa is going to highlight some of the key points from that discussion. Jennie.

Jennifer Marcy: All right, did I unmute myself okay?

Carol Johnson: You did.

Jennifer Marcy: Okay, great.

I do have to preface this with: I went back to look at my notes and found I have all of 3 lines written down for this session, so I'm sure I left things out. If anybody has anything to add, I believe there's going to be opportunities for comments, so please fill in what I forgot to include here.

We started out this breakout session with the question of, "Are current resources adequate for the jobs we need or want to do?" With kind of the idea of if it was a perfect world, do you have the funding for what you want to be doing to be the program that you want to be. A couple of states reported that they're doing okay. A couple of states indicated that they really are in crisis as far as funding goes, but most of the participants felt that they were somewhere between. It could be

better, but not in a crisis situation.

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The next general point that we looked at was just what does funding look like currently. We didn't really pool everyone sitting there, but there was a general discussion. People were offering up some bits and pieces of their different funding in different programs. Some places do a lab fee. Some places have their funding all through public health department general funds. 1 state participant indicated that they charge for each newborn screening filter paper card that is sent out from the lab, and the charge for that filter paper then covers the testing and the follow up that they don't charge when the sample actually gets to the lab, so a little bit different than a fee for a service funding model. Then there's places that have a combination of funding resources.

I'm guessing that there may be other people who either didn't speak up specifically or maybe who were just not at the meeting, but there could be even other funding sources out there that are even different. Then kind of the general question was thrown out of, "Should we be part of the public health funding as a whole, or should newborn screening be included in the strategic plan, and how does that all fit together? How does newborn screening fit into the greater structure of funding and planning within public health?"

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The challenges that were identified is that as far as being able to collect information and identify what is being covered, what's not being covered, what works well, what doesn't work well ... Each program has grown up independently and exists in its own little world of state public health and it's very hard to compare and contrast. There are many different funding mechanisms and systems which makes it difficult to move forward as a group, I'm thinking. It was also brought up that funding for newborn screening specifically was removed from title 5, and I was indicated that APHL and NewSTEPs and others lobbied to keep newborn screening as part of title 5 funding, but it didn't work unfortunately. That's hit some states hard.

Then it seems like newborn screening staff, follow-up staff aren't always the individuals who have authority to share information or even have many of the details about funding sources, and so trying to identify who, within each program, would need to contribute that information may be hard.

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It also seemed like there was an atmosphere of reluctance. Here I wasn't sure if I was just picking up on what a few people were feeling or if this is more widespread than that, but that there's a hesitancy to share information and that people are afraid of being compared to the next state over where the newborn screening scene may be very low or maybe doesn't even exist. In asking for additional funding

or to increase funding, if you say, "Look at what this other state is doing," and then the health department comes back and says, "Yeah, but that state over there, they don't charge anything so why are we charging anything at all?" Just kind of a hesitance to share or put too much out there for fear of being compared or contrasted when we're not comparing apples to apples.

Let's see, and then in general, we all know that funding sources in all of healthcare are drying up. They're shrinking. They're already spread thin, so asking for additional funding in that atmosphere is difficult. We also have the issues of increased newborn screening costs with vendor costs for lab supplies and things. The stress that adding new conditions to the screening program adds. Paying for things like couriers or extending lab hours or days of the week that they're open to meet the demand and expectation of faster turnaround times with the recent push for that quality control measure. All of those things are contributing to an increased cost of newborn screening in this era of loss of funding and shrinking resources.

It's also very difficult to quantify non-lab activities of newborn screening. It's very easy to say, "Oh, we need so many machines to run [TNDMS 00:24:35], we need so many lab staff to run so many tests in a given day." It's a lot harder to quantify how many follow-up staff you need to get ahold of the right primary care provider or to keep education resources up to date. Also the idea of what exactly is included in the activities of a newborn screening program? There may not be consistency in what every state puts under that umbrella of newborn screening activities. Again, what are we comparing and contrasting if we're trying to problem solve all of this together?

We spent quite a bit of time, and I think this was brought up more than once, talking about ... We've kind of gotten ourselves into a little bit of a pickle, just because we've done such a good job of getting everything done with limited funding already. It seems like we're all pretty dedicated to newborn screening and really feel like it's important, and so have gone above and beyond as an industry. As a group, to provide good services, even when the finding hasn't been there for overtime or whatever. We kind of put ourselves in a position where we've done it for so long, and now to ask for more.

Replacing staff with people who aren't capable or able to do all of the things that people had done before. You may have to replace a seasoned talented person who's retiring with 2 new nurses, or 2 new staff in order to cover everything that 1 person was doing. That has put is in a difficult situation of we've done such a good job and we've cared so much that now we may be in a little bit of trouble because of that.

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We did come up with some ideas for possible solutions. The idea of partnering with other groups in developing a newborn screening message to use in asking for more money, changing funding programs. It was highlighted that we need to speak the same language as the people we are talking with and asking this of. We need to

make newborn screening understandable in that group's terms, so whether we're talking to public health or we're talking to legislators, or we're talking to ... we need to be mindful of who our audience is, and make sure that we are expressing the importance of newborn screening in terms that they understand so they will be more willing to work with us and perhaps provide some more funding.

As with everything else, there's always opportunities for looking for cost saving efficiencies within programs. Just because we've done something 1 way forever and a day, doesn't mean that there might not be a better way of doing it now. Easy example is some places mailing things, we've moved to faxing. You save yourself the postage, et cetera.

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The group seemed very interested in developing resources on a national level, like through NewSTEPs. Resources that individual state programs could use to improve funding, so not just helping create the message of what newborn screening is, but also best practices on how to be a good advocate for your program. Then maybe compiling models of funding programs or systems that have been successful and sustainable. Just because you can successfully fund something in a current situation, what if adding the next condition is what tips the scales and now it's not sustainable? Look at how funding is set up so that it can grow and change with the needs of the program.

Then also coming up with a good comprehensive description of what newborn screening is. [inaudible 00:29:33] being short-term follow-up, we're all well aware that it's not just a lab. It's not just a blood-test, but this is a process. It integrates everybody from the birthing centers to local providers to state health departments and lab staff, follow-up staff. We are aware of that, but maybe putting together some kind of comprehensive resource that states can then use to help spread that message and help advocate for themselves.

That was everything that I could remember.

Carol Johnson: Well thank you Jennie. That was an excellent summary of what is a difficult and actually somewhat emotional topic for many of us. NewSTEPs and my coach chair John Thompson and I heard you all load and clear at the end of our meeting, that you definitely want some resources to be an advocate for yourself as well as for your program. Stay tuned for that, and I will day here ... I was going to save it until the end, but I'll mention it here. We are very lucky in that NewSTEPs has agreed to support a second annual short-term follow-up meeting which will take place sometime in the spring of 2018. Stay tuned for that, and in the meantime, we will continue to work on trying to help each other with some of these very interesting topics.

Last, but certainly not least, we wanted to talk a little bit about the CF quality improvement meeting that we all attended along with our CF colleagues whether they were MDs or CF center coordinators. I think it was a wonderful meeting that

we had, and Melody Hobert-Mellecker from the Iowa short-term [follow it 00:31:36] program is going to give you a summary of what was discussed at that meeting. Melody.

Melody Hobert: Hi Carol. Thanks. I just wanted to start with ... we actually had to take shuttle buses over to a different hotel, so that was a feat in and of itself logistically speaking. Thank you to APHL for arranging all of that. Then after the welcome, we really kind of just dug right in to the meat of what we were there to talk about. We started with several presentations that were centered on Cystic Fibrosis newborn screening update. What are the progresses and what are the new challenges that we've been making. Marcy Sontag gave a presentation of the new CLSI guidelines with new data on IRT cutoff values.

The initial guidelines were written back on 2011, and they have a goal to get those updated and simplified. Marcy wanted to let us know that this is a consensus process through the entire group, so that they will have balanced results. It is still in the conferencing stage, and by spring of 2017 they are hoping to have a document out and available for comment.

Then we moved into a presentation from Marty Kharrazi on the initial observations from a national survey on false-negative results with low IRT and CF cases. Previous studies around the country had indicated that there is an approximately 5% false negative rate with Cystic Fibrosis. It is well known that non-cystic fibrosis factors do impact the IRT. Some of these in particular are heat and humidity, storage conditions. If a baby is older at the time of collection, if a baby has a meconium ileus, if the baby is of African American descent, and if you're talking about a stressed or an ill baby. All of those things combine to affect the IRT. The study that Dr. Kharrazi did involved 13 states, 4 newborn screening algorithms, and accounted for approximately 46% of all US births.

Interestingly enough, false-negative babies were more likely to have had a red blood cell transfusion. They were more likely to find that they had mutations of varying consequences. They were twice as likely to have had a meconium ileus at birth, and interestingly enough, and we're not quite sure the significance of this ... They were more likely to have been born on a Saturday and to have been born sometime in November. The study actually concludes that false-negatives cannot be eliminated entirely by decreasing IRT cutoffs in the various programs. There are just too many different reasons for abnormal IRTs.

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Then we finished up this initial presentation with Dennis Stokes who talked a bit about the responses of effective states to the Whole Logic Kit recall. Dennis relayed to all of us Tennessee's experience with the recall. They had initially been a state that was using IRT-IRT, but then got talked in to going ahead and using the Whole Logic Kit beginning in 2015, and just a number of months later in March of 2015, along comes the recall. Tennessee immediately began contract discussions with Luminex and started sending their samples to [Perk and Elmer 00:35:15] while their

new platform was being validated. What a heroic effort that was, because by June of 2015 they had their Luminex platform up and running again, however they did notice that their experience with their previous algorithm of using IRT-IRT had done a better job at being able to identify African American babies with cystic fibrosis.

Because of that experience, they are going to be using an IRT DNA IRT algorithm going forward. Then there was kind of an open discussion for a short period from various states about their experiences because altogether about 23 states were affected by the recall. It was interesting to hear how all the different states pulled together and got over this hump.

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Then we moved into a lovely presentation by Clement Wren, and if you haven't ever heard Dr. Wren speak, he has the most beautiful voice. He talked about the cystic fibrosis diagnosis, consensus, conference, process, products, and plans. he did start out by telling us that they have noticed that the CFF registry and the Cystic Fibrosis Foundation criteria for diagnosis are not using the same definitions. Those were in-specific definitions for cystic fibrosis, CRMS, and unknown. They have found that a certain percentage of the cases that are being entered in the registry as cystic fibrosis are actually thought to be more likely CRMS.

Then Dr. Wren talked a bit about what CRMS, which is cystic fibrosis related metabolic syndrome, and how most states have 5-7 cases of cystic fibrosis forever 1 case of identified CRMS except in California I believe. They said because they use Next Gen Sequencing, the rate of CRMS is actually higher. Then he did talk a little bit about the 10-39% rate of Pseudomonas, infections that are found in CRMS patients, so this is not a group of patients that we just want to ignore.

He then did lead us into a discussion of how CRMS is more accurately captured as something called CRMS/CFSPID. Most of us have never really heard of CFSPID, and that actually stands for CF Screen Positive Inconclusive Diagnosis. 1 of the reasons they came up with this term was because it more accurately describes what it is that we're talking about. These are kids who have had a screen that is positive for cystic fibrosis, but we don't really have a diagnostic category to put them into. By definition, CRMS/CFSPID is a newborn screening diagnosis. It has to have a positive newborn screen, and 1 or the other of the next 2 things, which would be either a [sweat chloride 00:38:22] of less than 3, which is normal, and 2 CFTR mutations. 1 of which is on certain significance or a borderline sweat chloride result of 30-59 and 1 or no CF causing mutations of the CFTR.

Then he did talk about some of the changing consensus guidelines from the 2008 consensus guidelines to the new ones that are going to be coming out and they want to emphasize that there has to be a sweat chloride test for all positive newborn screens. That is the diagnostic standard. 1 change though now, that they're making is that a normal sweat test is going to be considered less than 30 for all babies of all ages. Also, he did talk a little bit about with ongoing work of the CFTR2 project, they have now gone from classifying 23 mutations to over 272

different mutations. Then he hold us we could expect to see if these consensus guidelines would be published sometime in December of 2016.

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Then we moved into a discussion with Michael Rock on the sweat chloride testing for diagnostic confirmation in neo-nates, where Dr. Rock did again emphasize that the cystic fibrosis foundation will now be requiring that a sweat test is done before a case can be enters into their registry database, and that in almost all cases, sweat testing needs to be completed by the time baby is 4 weeks of age in all screen-positive newborns. I believe he had mentioned something about because a positive newborn screen is a newborn diagnosis, there have been some issues in some states with some pairs where they don't want to pay for sweat testing outside of the newborn period, which technically ends the day baby turns 4 weeks old.

Then Susanna McColley gave a presentation on establishing and reporting to the age of diagnosis. The goal for their project was really to kind of define 2 things. A presumptive diagnosis of cystic fibrosis as compared to a confirmed diagnosis. A presumptive diagnosis, they have decided, is really when you have a positive newborn screen with 2 disease causing mutations, or 1 mutation and clinical symptoms, or it could be an infant who has a meconium ileus with or without a positive newborn screening result, or again, prenatal testing with 2 disease causing mutations. All of those things would be an example of a presumptive diagnosis of CF. However, a confirmed diagnosis of CF is again, to be base solely on the diagnostic sweat testing.

They also wanted to really make sure that people are reporting the date that treatment was initiated. If the baby appears symptomatic, then we should be starting treatment long before we get the results of sweat testing.

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Then our final presentation came for Marcy Sontag and other about the NewSTEPs 360 APHL/CFS partnership. Marcy and others presented an overview of the project, an update from the Denver meeting, and then the ways that New Steps and CFF are partnering to improve cystic fibrosis newborn screening. This last one kind of led to a really incredible interactive breakout session that was done by algorithm and 1 or 2 screen states. Whether you were a 1 screen state that did IRT-IRT or a 2 screen state that did IRT-DNA-IRT, or whatever your combination was. She kind of broke out into those and then we all reported on everything. That's on the next slide.

We really were asked to, as the cystic fibrosis foundation really wanted us to work on identifying what issues we saw in newborn screening with the identification of cystic fibrosis. Regardless whether you are a 1 screen state or a 2 screen state, or what algorithm, we all kind of identified similar issues. This was this ongoing need for education with providers and the cystic fibrosis centers. That is a never-ending task, in newborn screening. Then we also talked about the problems that some of

the centers have with quantity not sufficient, or QNF specimens. Some states talked about that they had no centralized courier service, and that that led to a delay in the initial results of newborn screening. Just overall problems in the newborn screening system delaying diagnosis across the board. Also impacts cystic fibrosis.

1 or 2 states also talked about that even between NICUs located within the same state, you have 1 doctor who wanted to respond to a positive newborn screen in 1 way, and a doctor in a different NICU wanting to respond to the same result in a different way and that there was really no standardized protocols, even within the same state. The 2 screen states did talk ab how sometimes they have problems getting that second screen, but then if they do, they're not always acting on those first screens when they're abnormal, and how to change that mindset. If you can't get the second screen, you should be acting on the first screen abnormal.

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Then we were asked to identify the low-hanging fruit, IE the easy fixes. What could we easily do as a newborn screening system to fix some of these things? 1 of the thing that we though ant, again, whether we were a 1 or a 2 screen state, was that we could use the CLSI guidelines to reinforce the need for timely sweat testing by day of life 28. I know that here in Iowa, we're thinking about just changing that and putting that right in our letters that go out to the docs. 1 state did bring up the fact that they actually use QNS data for non-accredited centers, to discourage providers from even sending kids to those non-accredited centers.

Then we talked about how some states have creative funding to help families pay for sweat testing. Maybe through a maternal child health plant for special needs kids or specialized funding that pays specifically for confirmatory testing. Then it was brought up that some states or some CF centers, have a habit of if they get a QNS, they wait 30 days to re-sweat the kid, and there is absolutely no medical evidence in the literature to support this practice. In fact, 1 doctor did mention that at their CF center, they have sort of the same thing. If you can't get an IV or a blood-draw after 2 pokes, you go and get another person to do it. He said they have about 90% success in if 1 tech cannot get a kid to sweat, they go and get somebody else. That second person can often times get the baby to sweat. I though that was a good idea.

The next slide please.

Then we were asked to think about all the potential partners in all of our states, that we could partner with to work to really get the word out about this emphasis on increased timeliness in newborn screening and the increased timeliness with cystic fibrosis screening in particular. We thought about our departments of health, our actual CFF accredited centers, the Cystic Fibrosis Foundation themselves, state hospitals associations, the American Academy of Pediatrics and the American Academy of Family Physicians, New Steps, [AMCHIP 00:46:36] and other organizations. The National Society for Genetic Counselors, state advisory boards.

Doing grand rounds in facilities is a great way to get providers onboard. CLSI. Obviously any discussion that has to happen about healthcare needs to include payers. We talked about our own newborn screening programs, and then the ACMG. I believe that pretty much wraps that up.

Thalia Wood: Thank you melody.

Melody Hobert: Thank you.

Thalia Wood: This is Thalia. We do have 1 comment in the comment box. It's not actually a question, but I will read it. It's regarding the funding portion of the presentation. "Regarding the funding challenges, 1 of the points that was brought up was that we, the dedicated professionals that we are, stay late without compensation, don't take vacation days, skip lunch, et cetera, otherwise things wouldn't get done. Working like this without documenting the extra time we put in or vacations we give up, makes it look like everything is running just fine with the limited resources we have. This hurts newborn screening as a whole and is not sustainable, we have to start valuing our time and taking care of ourselves, otherwise we will burn out." That was an interesting comment, I think, on the finding sections.

Carol, do you want to see if we have any other questions or comment?

Carol Johnson: Sure, and Melody, I wanted to tell you that was a great presentation as well.

Melody Hobert: Oh thank you.

Carol Johnson: I take that comment that was given to heart. I think that goes back to what I was saying earlier about not only being an advocate for our program, but being an advocate for ourselves, right. Together this is a subject that we have to work on, and we do plan to do that.

Now we'll open it up to questions. Remember to push *7 if you want to unmute and ask a question.

Melody Hobert: This is Melody. I will say I was pleased to see that somebody submitted that comment to you Thalia, because I vividly remember when it was asked in that funding discussion group for people to raise their hands ... The number of program managers or program staff who had maxed out on their vacation because they simple could not afford to be away from their program because of funding issues. There were just so many hands that went up in that room. It was starkly real to me how much of their personal time people have been giving to these programs over the years.

Thalia Wood: Absolutely.

Melody Hobert: Mm-hmm (affirmative).

Thalia Wood: You can still send questions. If anybody on the phone was actually at the meeting in

Orlando, would like to comment on some of the takeaways that you got from the meeting, we would love to hear from you.

John: Hi this is John from Washington State. Can you hear me?

Thalia Wood: We can. Thanks John.

John: Great. I just wanted to say great job to all of the people who graciously presented on summaries of what the different breakout sessions were, and it was just a great meeting. I think what I came away from the meeting ... I loved hearing from all of you, and learning what situations you're in and trying to figure out how your experiences might be helpful for us here in Washington. I think what I came away with is that we as a community ... we've worked together over many, many years and we've taken the low-hanging fruit and figured out how to do them. The challenges that are left are really difficult and complex. I think that really highlights the theme of the meeting, which is the importance of communication in the what we're doing.

Just the past couple weeks since our meeting, I've been in a number of scenarios where I thought, "Oh, that was great. We had wonderful communication and it turned out really well because of that communication." Then there's been a couple of times where I'm like, "Oh man. We totally blew it. We missed an opportunity or we did extra work." There's just different areas on a day-to-day basis where the communication is really key to us doing good work.

That's been nice for me to move forward in that context. As the short-term follow-up group continues, we will be remembering things that were discussed in the meetings, and we're also interested in any feedback from those that weren't at the meeting to help us as we plan for future activities. What we really want to do is provide resources that will be helpful to you at the ground level, to us all really, to be able to be more productive, more effective, and to kind of release some of the tension and stress and challenges that we face so that we can focus on the real purpose of why we do what we do.

Carol Johnson: Well stated John. Thank you. Does anybody else have any questions or comments or take-homes they want to share?

Thalia Wood: This is Thalia. They have 1 question in the chat box. It asks, "Will a recording of this presentation be available?" Yes. All of these webinars are recorded and transcribed and put on the NewSTEPs website, so information about that will be coming out. All of the previous webinars are already there. This 1 will be out there within a week.

Carol Johnson: Great. Thank you Thalia. Well, last chance. If I don't hear anything, it doesn't sound like I do. Just a reminder that there will be a survey sent out after this call to get more ideas from you, and get some feedback. I guess since we don't seem to have any other questions, we'll wrap this up for today. A big huge thank you to our

speakers who presented today. You all did a wonderful job, and on behalf of John and myself and our NewSTEPs crew, we'd like to thank you for attending and wish that everyone has a great week.

Thalia Wood: Thank you.

Carol Johnson: Thank you very much.

Thalia Wood: Thank you Carol. Just 1 other reminder the next webinar will be January 9th at 3:00 pm eastern time.

Carol Johnson: Great Thalia. Thank you.

John: A big thanks to NewSTEPs and the CF foundation for sponsoring the meeting and allowing us to do the work that we did.

Carol Johnson: Absolutely.

Thalia Wood: Absolutely.

Carol Johnson: It was fantastic. Thank you all.

Thalia Wood: Yes thank you everybody. Have a good day.

Carol Johnson: Bye everyone.