Varying Communication Strategies, including Successes and Pitfalls, between NBS Programs and CF Center Clinicians

This webinar is part of a NewSTEPS 360 newborn screening, cystic fibrosis community outreach, which includes examples of communication strategies, successes and pitfalls between NBS programs and clinicians. Presentations by three states begin at 4:22:

- COLORADO -Stacey Martiniano, MD Pediatric Pulmonologist, University of Colorado and Children's Hospital Colorado & Darren Michael, PhD, Program Manager, Newborn Screening Colorado Department of Public Health and Environment (CDPHE);
- NEBRASKA - Karen Eveans, MD, Newborn Screening Coordinator, Nebraska Department of Health and Human Services; and
- ARKANSAS - Barbara Holcomb, BSN, RN, Newborn Screening Coordinator, Arkansas NBS Coordinator, UAMS, Pediatric Genetics/ACH/ADH.

Marci: So, I'm gonna give everybody another minute or two to log in and then we will get started.

Okay, I'm gonna go ahead and get started and give a few introductory words first. Welcome everyone, this is Marci Sontag. I am with NewSTEPS 360 and I am excited to present your Cystic Fibrosis, New Born Screening, Timeliness Webinar for the month of July. Thank you to our presenters.

Before we get started, I would like to ask all of you that are on the phone or on the computer please to mute yourself. We're getting a little bit of background noise. And if we continue to get that noise, Louise I might ask you to just mute everyone for us, and then the speakers can unmute themselves.

So it sounds like the noise is going, so I think we're good.

So, welcome everyone. This is the same slide I've been giving for every time we've done one of these, because it's just to remind everybody where we are. And then I'm gonna walk through a little bit of the process map of newborn screening and CF newborn screening, specifically.

But just to remind everyone that we've been doing newborn screening in the country universally since 2009. Some states have been doing it since 1982, but it's really been universally adapted just since 2009. And there are many different approaches, and those many different approaches can lead to many different outcomes for timing of Cystic Fibrosis diagnosis for perhaps the specificity and sensitivity of the newborn screening test itself, and then one would then presume those impacts of the screening process and the timing of the diagnosis could have an impact on the child. And what we really wanna do here is minimize that impact on the infant and the child that's identified by newborn screening through CF, so that all of the babies start out with a very equal playing field and really have the same opportunities for a healthy start.

So, this is a little big for the screen. So I'm just gonna ask you to be patient and read the edges with me. This is the newborn screening process model that really describes the whole overall newborn screening process. And I'm not gonna go through each of the steps, but you see each of these steps in the newborn screening process really is critical in the timely diagnosis of an infant with Cystic Fibrosis, or any of the other disorders for which we screen. And so you see, after birth the dry blood spot is collected. There's lots of steps in that collection that is [inaudible 00:06:59]. It's collected, it's shipped, it arrives at the lab and then there's data entry and confirmation of that sample. All of that happens before anyone in any official laboratory testing has happened. That's the pre-analytic phase of newborn screening.

And we've spent a lot of time in the timeliness world in newborn screening really working on this piece. Educating hospitals on the appropriate time of collection. How to collect it properly so it is a good, solid sample, and the lab can test it and it's not unacceptable. The stripping of the sample in a timely way with an appropriate courier or delivery service that will deliver it in a very timely way. To get it to the lab, and then to have the labs open so that they can most efficiently process the sample and get it tested. And then the piece of that data entry and all of that is a whole other component of newborn screening of accurate data entry, and sometimes it's hard to imagine that in 2018, for almost all of the 4 million samples that are collected, there is manual data entry that is[inaudible 00:08:01]. So even though electronic data entry is happening on both ends, that transfer of electronic data is really challenging.

Then on the bottom left of this corner I have a box for rules and regulations that kinda oversees all of this process. One of those boxes that really impacts CF newborn screening is, this is a one or two specimen state. And the timing of that diagnosis is going to differ just by that very definition, that if you can do it off of one specimen or if you're waiting for two to have a more specific test. And I know in both cases, we're all working towards a more timely CF diagnosis.

This next piece is the analytic to post analytic phase of newborn screening, starting with the lab processing and testing, and then once that testing is complete, how do we communicate the results? And so communicating those results, whether they are the critical results, and critical we'd be meaning by this, they are presumptive positive diagnoses, they are those that really need a time critical response. We have the non-type critical results and then we have all results, making sure that everyone knows a baby may have had completely normal newborn screening.

And then we finally get to that stage of intervention, initiative and diagnosis confirmed. So pulling this out just a little bit, specifically related to CF, I wanna talk about this section right here. And when we dive into that a little deeper, really what we're talking about and what we're focusing on today is that relationship between the CF center and the newborn screening program. So that communication of results, how does that communication of results happen? And how is that connection, I actually had wrote here the connection between PCP and CF center, and I actually also mean, should have added, the connection between the newborn screening program and the CF center. And the newborn screening program and the PCP. There's

a lot of connections there that have to be in place in order for this to happen successfully.

And then we have the confirmation through a sweat test and availability of sweat test appointments. When they happen, how they happen, and how that communication gets communicated back to the newborn screening program. And then the opportunities for clinic visits.

In addition to this piece of this, of communicating the results, there's that feedback piece that happens that goes all the way back to the lab processing and testing. Because we know how many babies are being called out as positive, how many babies might be being missed, that communication between the CF center and the newborn screening program is critical in order to get that information back to the lab and follow up programs at the newborn screening programs to say, "Hey, you missed a couple kids. What's going on? Is there something we can do to improve?" Or, "My God, we're seeing a lot of kids that are falsely positives. Is this an opportunity for us to further make a more specific newborn screening algorithm?"

So with that [inaudible 00:10:57] we have a working group that talks about, how can we best serve the CF newborn screening community? And on our last call it was these conversations kept coming up, and we have different solutions across these different states that we'll be presenting today. And how they've approached the challenges they have faced, and then solutions they've seen.

So with that, I'm going to introduce our speaker for today with the topic of varying communication strategies, including suppressive [inaudible 00:11:24] between newborn screening programs and CF [inaudible 00:11:28]. And so we're gonna have three groups presenting. The Colorado group, the Nebraska group, and Arkansas. And first will be Dr. Stacy Martiniano and Dr. Darren Michael from the Colorado newborns, well Stacy is from the CF center at Children's Hospital, Colorado and Darren Michael is from the Colorado State newborn screening. With that, Stacy and Darren I will hand it off to you.

Stacy: Alright. Can you guys ... can you see that, those slides yet?

Marci: Yes, now we see them.

Stacy: Alright, good. Thank you Marci. So as she said, we will be talking a little bit about the Colorado program. And so just to orient you in Colorado we, if you remember, we used IRT IRT DNA algorithm for CF newborn screening. And our first cut off is fixed at 60, and then our second cutoff form IRT is again 60. If you have two elevated IRT's we move to DNA off that second sample. Currently we're using a Luminex 39 mutation panel, with the volume of samples we receive we're just performing that weekly at this point. We also added a piece to our algorithm in the last few years where if we have a first high IRT or ultra-high level of greater than 140, those samples get pulled and DNA is extracted to be directly referred for CFD off the first sample.

Additionally, in terms of an extra layer of personalizing this test, which takes some communication between the providers and the lab, we have the ability as a CF team or as [inaudible 00:13:41] that CF DNA be sent off the first sample, also. So for example, if we have a CF sibling born we put in a request to have DNA run off the first sample. Additionally, for example, if you have a baby [inaudible 00:13:56], even if that first IRT is low you can request CF DNA as an additional screen for CF. This is just an example of the form that we use that we request CF DNA off a first sample. We put the infant's name, the indication. As a medical provider we sign off and request it and fax it into the lab. Typically we're communicating with the newborn screen supervisor. [inaudible 00:14:27] and then keep an eye out for that sample to run that DNA.

This is our post-test communication that we developed and fine tuned over the last few years. In Colorado, we have the luxury of just having a single CF center. And so there's just a one point for referral for all babies with CF and PCP's. And so because of that, internally we have created an internal CF on-call system. We have a calendar. And this is either a CF provider, doctor, pulmonologist, or one of our nurse practitioners. And so we're on call for a week at a time to take any calls related to CF newborn screening. And this calendar is posted internally within the hospital, but then also sent to the State lab so they have a copy of who's on call every week.

And so, if we have a situation where a baby has two CF mutations detected, we now have a case of a presumed CF positive diagnosis. In this case we have asked that the lab, Greg in particular, or the newborn screen supervisor, or whoever's covering for him, call the CF provider on call directly. This most commonly occurs on a Wednesday. And the newborn screen result report is also faxed, obviously, to the baby's PCP and the CF provider so we have a copy in hand. But then at this point, that's where the hand off for this case is complete and that CF provider, that doctor or nurse practitioner then takes that case to make sure we get the appointments scheduled. So what we have been doing is, as a CF provider, we make the call with the new diagnosis to the PCP. Explain a little bit about CF and what the follow up will be. We ask the PCP to give the information and break the news to the family, but then really immediately let us know that they need communication with the family. So then that same day, the CF provider by phone calls the family and arranges an appointment to get them into clinic within 24 hours.

We see that baby actually before doing the sweat test. We start treatment, we talk about CF as a presumed diagnosis, then arrange for sweat test and DNA testing if appropriate at that point.

So if we have the other scenario, where we have one CF mutation detected or in a rare case where we have zero mutations but two very high IRT's. In this situation CF has not yet been ruled out and then we have a sweat test indicated. Again, we have a luxury that only Children's Hospital performs a sweats test in the state of Colorado, so that can be hard for families but good for us, 'cause we are able to be tracking those sweat test results and can see if a sweat test has been ordered and scheduled.

So in this situation, we have the newborn screen supervisor call the PCP to pass along the information, the results from the newborn screen, as well as our recommendations to perform the sweat test. The newborn screen supervisor also calls us as a CF provider on call and sends us the results so we can be tracking and waiting for that sweat test to occur. And then on the back end, the CF provider now takes that hand off is to us. We take on the case and we perform the follow up. So we are monitoring in the computer system if the sweat test is done and performed. As a CF on call provider for the week, we carry a folder with all the pending cases that we check several times a week. And if by the end of the week we haven't seen a sweat test done or ordered, we reach out the PCP. Remind them why the sweat test is indicated. Occasionally, rarely, we will reach out directly to a family. But typically we're moving between CF provider and PCP until that sweat test is done. Then obviously if it's positive, then we're getting them in to clinic.

And part of the reason, I think we have a fairly unique situation where we have this hand off and the CF providers are providing the follow up. And the reason that is, is because the Colorado Department of Public Health and Environment currently has a contract with CU Medicine, who is the entity that represent all university providers, including pediatric pulmonary. And so we have a contract that we provide the newborn screen both consultation and any questions, and any follow up that's needed.

This is just our internal tool. We use a piece of paper, it's very low tech. We put it in a paper folder, believe it or not. But this is how we track the baby's information and then any follow up conversations that we've had. We're also tracking times that in effort that we put into this follow up. And then at every quarter we summarize all the follow up that we've done, any cases we've diagnosed, and any data related to that. We provide that back to the lab and also we enter that into NewSTEPS.

So this is our current algorithm, this is our current worksheets for example, and the way that our conversations go. We've also instituted a few additional regular meetings in place. Part of this came up of being more formal with our meetings when we had some personnel changes and we needed to make sure. We were having some break downs in communication so we needed to make sure everybody was on the same page with how we wanted the work flow to go. So just internally with our CF provider newborn screen program we've been having meetings with the state lab, in particular with Greg. We've had two back-to-back this summer and our goal is to continue these quarterly to make sure our communication has not changed. And then this also gives us an opportunity to talk about any changes we might wanna make to the CF newborn screening program and algorithm. Analyzing our data, seeing if our cutoffs need to be changed, for example.

Additionally, this has been an existing meeting for many years. It's kinda changed formats a bit but there's always been these regular meetings with the lab and the Colorado newborn screening stakeholders, so this includes lab, clinical partners, including the contracted specialists and PCP's, as well as parents affected by newborn screen. These meetings take place quarterly. And then a new addition to some

meetings that the state lab's been holding are four regional meetings planned for the summer. This is to establish a newborn screen peer to peer network that the CDPHE, the Colorado Department of Public Health and Environment, is organizing with presentations to our clinical partners in the community and a lot of the stakeholders, the clinical specialists are gonna be presenting at these meetings as part of outreach to establish an ongoing network with the community. And this is supported by NewSTEPS 360 grant.

I'll let Darren talk a little bit about some more of the internal processes.

Darren: Sure, thanks Stacy. So, I'm Darren Michael. I'm the program manager for newborn screening. Greg Bonn is on vacation so I'm trying to represent a lot of the work load that he covers. I thought I'd give the picture in terms of what happens within the lab. I first wanted to show the parallel accountability tool that we use on our side. We use PerkinElmer's Specimen Gate as our limb system and we have a custom written view from Sequel Server that we enter all of our contact information regarding which specialist we talked to, when we talked to them, as we try to document this transfer of information over to the specialist. Can I have the next slide, please?

As Stacy mentioned, we have a formal contract in place and I think of this as a way to outline rules and responsibilities formally. We also have a contract monitoring process in place. The CF contract is part of a larger contract with a single entity that covers multiple conditions for each of our conditions on our panel we have a similar contract in place. We use the statement of work to define rules and expectations as well as the general and specific provisions of the contract. In terms of contract monitoring we have a post award meeting where representatives from both sides read through the contract together to make sure that we're all in agreement on who's roles are covered for each activity, as well as expectations in terms of pro dramatic reporting and fiscal reporting, as Stacy mentioned. And then we also go over the operational responsibilities. Every quarter I receive invoices, and the key linkage for me is the [inaudible 00:24:39] number that we use here at the labratory that allows me to gather clinical outcome, asking around true positive or false positive. As well as to document the activity that's being completed. So that will, over time, hopefully let us adjust our cutoffs, as Marci was alluding to as we gather data.

And then the final slide is just to talk about what Stacy hinted towards in terms of succession planning, or going through a change around a primary contact within a program. We're trying to make sure this sort of work flow is captured in a standard operating procedure for post analytical processes, knowing the contact information, communication expectations, making sure that our contracted specialists know when we're open. I'm talking more broadly around all of the conditions we test for and ensure that on our side we have redundancy in terms of capabilities and knowledge among staff. We're making sure all of this information is stored centrally within the program and then making sure there's a shared email account that can reach all members of the newborn screening program, should there be a case where a specialist is unable to interact with the person that they normally contact. And I'll stop there.

Marci: Great! Thank you so much to the Colorado team. And we're gonna hold questions until the end, but I want to just highlight the growth that I've seen in this Colorado team and the sense the CF meeting that we had a couple years ago and the plans they have made. So that CF meeting we've been plotting improvement meeting we had here in Denver that really, I think, pulled the group together with the common goal of saying, "Hey, how can we really make this?" And they have, as Stacy said, they have had regular meetings. They have worked really closely together. Darren's joined the crew and we've just had a lot of progress in Colorado. So, thank you for all of you doing that.

And then we'll come back if the rest of you have specific questions for them, momentarily. But for our next slide I would like to introduce the Nebraska team. And we have Karen Evans, who is representing the Nebraska newborn screening program, and Dee Acquazzino who I'm hoping was able to sneak out of clinic for a little bit this morning. And she is representing the Nebraska regional CF center in Omaha. And Karen, I think you're first. You just let me know and I will forward your slides.

Karen: Okay. You can hear me?

Marci: I can hear you.

Karen: Good. Yeah, the way we're planning to do this is I'll start with doing the talking and Dee's gonna chime in as she sees fit in case I miss anything. Which is kinda how we do ...

Marci: Karen? ... Karen, I'm not hearing you. Are you hearing Karen? No, no one's hearing Karen. Karen, we lost you somehow ...

Karen: Okay, I think I got it. Am I good?

Marci: There we go! Now we can hear you.

Karen: Okay, sorry. Anyway, if we go to the next slide. Before the Cystic Fibrosis screening actually started happening in Nebraska, there were meetings that happened between the CF center and the newborn screening team to basically come up with how we were gonna handle the situation. What the policies and procedures would be. And then as the years have gone by, which that started in 2006 is when we started screening, we have intermittently had other meetings that would be to address whatever came up along the way. These have been to deal with things like changes in the algorithm, dealing with specific problems where they seem to be ongoing, we needed brainstorming sessions to try to come up with plans to deal with. And it's been helpful when we can get together to do so, and really bounce ideas off of each other and see it from each side's point of view.

Also our medical director of the CF center, Dr. Colombo, serves on the advisory committee that we have, which is very actively involved in newborn screening follow

up. And they meet on a quarterly basis. We do review data a those meetings for all the diseases, including Cystic Fibrosis. Particularly data that is about how quickly we get people diagnosed and how quickly interventions or treatments actually happen. Can we go to the next slide?

This is our algorithm in general. It's somewhat simplified. It leaves off a lot of particular, unusual situations like the [inaudible 00:30:17], et cetera. But in general, the algorithm starts with an elevated IRT. The lab looks for Delta F508, which is the most common mutation we see. And if it's not present, it goes down the left hand side of the algorithm. If it is present in one copy, then the newborn screening lab goes to the Luminex panel of 39 mutations looking for others. If it's just one copy Delta F508 that's inconclusive, if we get two that goes over into the positive. If right after the first screen there's two Delta F508's, that's considered a positive. And we receive the information, the results from the screening lab via phone and fax, as well as the PCP getting a phone call and fax, and the house administer of the hospital as well. And then, further contact with the CF center is usually initiated by the program calling them. Simultaneously, sometimes before of after we talk to the PCP, to get them on board that we have this baby there is a positive. This baby's gonna need a follow up. And by talking with them right away it gets the process going as fast as possible. And so that they're prepared for when the PCP actually calls after they've talked to the parents and called to get them into the CF center.

On the opposite side, the left side is the algorithm when there are no copies of Delta F508. If the IRT is greater than 130 we ask for a repeat. If the repeat is elevated then we go to the further panel of DNA mutations, and regardless of whether there is zero, one, or two, they're gonna have to be seen at the CF center. If there's two mutations that put them in the positive range and more urgent, if there's zero or one mutation that's still inconclusive that they still need to be seen.

Previously the CF center was alerted for every screen that we had that was abnormal, so we were sending them copies of all the elevated IRT's and it just got to be too burdensome at some point for them and of not any value for them to see all the one's that then repeated normal. So, if it's just elevated IRT we don't communicate with them about it unless there's some specific concern. And so we discontinued that to try to smooth along the process, not overwhelm them, and keep things going. We have, by tweaking the algorithm, however really cut down on the number of babies who do need repeats and they probably actually could handle it if I sent them every screen that was abnormal. We just don't bother 'cause it doesn't seem of any value at this point.

Most of the problems that we encounter with timeliness, I would have to say are related to inconclusive screens on babies that are in NICU's. And those babies can be very small, not ready for a sweat test in any way and often have other medical issues going on, which seems to inhibit a referral to the CF center or a consultation with the CF center physicians. That's an ongoing problem that we're having, seems that some of the [inaudible 00:33:42] just really wanna make a diagnosis prior to calling in the CF center team. And that we see as a problem that's ongoing and we're continuing to

work on. We're not gonna solve the problem of not being able to do the sweat test, but we do see value in the CF center physicians involved at an earlier time than they sometimes are.

Our system is created, in part, to be a redundant system. We do use both paper as well as computerized tracking for our babies at the program. And so some of our communication means that we ask for things in writing and stuff is to put into the paper file, as well as having the information duplicated in the electronic file. We do anticipate that at some point we'll be switching to completely electronic, but at this point we are doing both and keeping the written record for 29 years, I understand. And so we do make an effort to make sure that we have systems in place that accommodate both parts of the record.

And let's see, I think that there's distinct instructions given at the step of the follow up program speaking with the PCP's nurse or the doctor themselves. Very specific instructions given about how to facilitate that equipment with CF center. I talked to them about where to call, what to say, how to get this accomplished quickly and not just schedule an outpatient sweat test themselves, or not send them to an inappropriate place to get a sweat test that isn't really an accredited CF center, and those sort of things. And that information is repeated both in the letter that they're sent, in the ad sheets that we use, and like I said what I tell them over the phone. And so we make every attempt to make sure that they easily know how it is to get their patient to the CF center promptly. And by communicating with the CF center promptly, they're ready for the calls that they get from the PCP or from parents who may need some calming down and who need to get that appointment facilitated as soon as possible. And we do continue to communicate with the PCP if it isn't happening quickly, to make sure that we understand exactly what is going on with the family and why it's not happening quickly. And if the family needs more urging so the PCP knows that they haven't followed through and they need to be urged to do that.

Wanna go to the next slide? This is a copy of the actually sheet that we use for inconclusive results where we're asking them to see somebody at the CF center and get a sweat test done. We put the things that the PCP needs to do in the left hand corner of the sheet in a box, with the idea that focus on this, this is what you need to do. In addition, then, following is information that we consider an educational component in order to alow them to be able to explain to the families exactly what has happened and what will be happening. And also just general background if they need a refresher on Cystic Fibrosis. And then in the bottom right hand corner there is some information about websites they could go to if they feel like they need more information, and also the contact information for the CF centers. Now most of our patients do go to the CF center in Omaha. Two thirds of the babies are born in the Eastern half of the state where Omaha is, and so because of the numbers they actually see most of our patients. Occasionally we will have somebody who is far West and they will go to Denver.

Next slide. This is the actually sheet for a positive Cystic Fibrosis screen. Again, there is the box at the top telling the PCP what you need to do now. Again this is similar

education and contact information in the bottom right. We try to use this format with the actually sheets in general, with the idea being that the physicians then, are familiar. Where do I look first? What do I need to do first? And where is the information? And as I said, it's also in the letter that they receive. And we have letters tailored for a positive result, an inconclusive result, a repeat inconclusive result, et cetera.

Next slide. The CF center has done a lot of things to try to improve or increase the timeliness of the diagnosis of CF. And so as soon as they are notified that an appointment needs to take place, the CF center coordinator, or Dee, starts to arrange for an appointment that involves getting a physician who could be available and getting a proper room that's gonna be available at a time when the family can actually attend. And so that coordination can sometimes take a bit of extra time, and so by giving them the heads up just as soon as we know that they're gonna need to do that, Dee can start to get things ready. And she's also then ready if a PCP calls with questions or a family calls with questions.

The second thing that they do is that the CF center staff does the sweat test and gets the results within an hour. And then the CF's physician can provide the results and the counseling the family needs as well as any plans for further evaluation and treatment if necessary. They have a genetic counselors that are available and they generally see the families at the second visit unless it is a situation where the sweat test is negative. There isn't going to be second visit, that they will still follow up with those families who have children that had at least one mutation and are thought to be carriers. Next slide.

Recently, we tried to improve awareness on part of CF center physicians as to what the newborn screening program or who the newborn screening program was continuing to follow. So all the babies that are currently followed are put on this registry and you can see the things across. The baby's name on the birth certificate or the baby's name on the newborn screen, because they're sometimes known by different names. I have a column for my questions. Let's say the baby's been on the list for a couple weeks and I wanna know specifically do they need a sweat test? Or is the repeat okay? Or because it's an unusual situation, I can put my questions directly in there. We have the birth date and the current age and days, so everybody is aware how long this is taking. The way it comes into play particularly with the NICU babies, as they have to be big enough to sweat, and by keeping current with that we'll know how close they're getting to that point. The current location helps people to understand whether we're dealing with a hospital or whether we're dealing with a baby who's at home and the PCP. I put the newborn screens as we have them and sometimes if our newborn screens for the NICU baby, that can be multiple screens because they're exteriorly screened, even if it's not just for an elevated IRT.

And the clinical information I just put very brief clinical information here, but in general the babies who are on this list for some period of time have a lot of clinical information. If they had surgery for meconium ileus or their NPO or they're not or they're on a vent or they're not, and that kind of ongoing information I try to update

as I can. And so that they're aware too of what's happening with the baby, even if they haven't been consulted yet. And then if they are consulted, I usually put the doctor's name in there to keep everybody aware of who it is that has been consulting on the baby. And sweat test results, you know, usually that kind of ends things in terms of whether we're getting a diagnosis at that point, but sometimes the sweat test results are Q and F. Or they're Q and F on one side and a number of value on the other side. And so I try to put all those down there so everybody's aware of how many sweat tests might have been detected and what the results would be. Any more DNA results also.

And then in the last column there the most recent information to get is in terms of communication. So if I know that Dee called the family on such and such date, I will record it. If I sent letters or I make phone calls, I will record the dates on that. So everybody's aware of when things are happening. The CF center staff has a meeting every Friday, so I send this report to Dee on Thursday so she can circulate it among the physicians and then they can, if need be, discuss it at our weekly meeting as to who's doing what and what the status is and what yet needs to be done. And this way, we're hoping that everybody stays on the same page. Everybody's aware of what we're waiting on from whom. And it seems like my list is getting shorter, so I think it's actually making progress in sort of getting us to have babies, maybe even some of the more chronic babies, move along into the system and get past the point where we know where the diagnosis is in terms of CF.

And so far Dee hasn't said anything! Next slide. This is a form that we use that's part of the paper system. It's a form that we use to have communication between the Cystic Fibrosis physicians and the program. Once there is a sweat test diagnosis, et cetera, Dee will have one of these filled out and she'll fax it back to me, and then I can make it part of the paper record. And it makes sure too, that we're on the same page about what day treatment was started. Because it may be different than what day the diagnosis was made, and the sweat test that gave us a diagnosis will be recorded on there along with the values to make sure that we get the correct information. And then this is included in the baby's paper file, as well as the information I add electronically to our system.

So, these are the tactics we have of trying to communicate as much as possible. Dee and I communicate via phone, via fax, and encrypted email. Encrypted email helps a lot, especially when she's in clinic or when I'm not exactly right here, so that as soon as we both are able we get the messages and understand what's going on and what the questions are from each other. Sometimes the question comes from Dee, it may be a sibling of a baby they're seeing and they wanna know what the screen results were for the sibling, and that kind of thing. Or otherwise, the stuff is usually initiated from the program going to the CF center we're saying, "We have a baby, these are the results. This is what I know about the baby's clinical situation. This is the PCP's name. And I've spoken to them and they're gonna be calling you within the next couple of hours, or they're gonna be calling you tomorrow morning." And that's the kind of information. And so we go back and forth a lot and just keep in touch a lot so that

we're always knowing where the status is of any of the babies who have an abnormal newborn screen.

And let's see the last slide. These are all the people who I would wanna thank, the members of our program. Julie, Crystal and Sara. Dee as a clinical coordinator. Dr. Colombo is the medical director. Dr. Samut, Dr. Thomas are the other pulmonologists, and I think there's more now but they have been the ones involved previously in our meetings to try to resolve any problems or issues. And of course, the unnamed but very appreciated CF center staff.

Dee: This is Dee, can you guys hear me?

Karen: I can, yeah.

Dee: Okay, so Karen is very articulate so I didn't really think I was gonna need to add anything and I don't. But one of the things that I do wanna add is the success of our program, I think is because of Karen being a bulldog and really aggressive at contacting families, contacting PCP's, really staying on top of every single case and trying to get these patients in and evaluated. And as she had alluded to, our communication is frequent and effective, and it really does help. As soon as I know there is a patient that needs to be evaluated, whether the PCP has talked to the family or not, I can start looking for an appointment. And we do have this unique appointment where we do the sweat test actually up in our clinic and then we can get it run by the lab within an hour. And so all in one day we can see the family, see the patient, get the sweat test done, hopefully have enough sweat, and the doctor can talk to the family. So that's worked really well for us, but truly it's a key to have a follow up coordinator that's as aggressive as she is. She's been the follow up coordinator for us since the program started in 2006. So we have to give her a lot of credit.

Karen: I have the help. When I'm not here the other people cover for me, so we all work on these things together.

Marci: Yeah, I think it absolutely takes a team and Dee thank you for pointing out the importance of a strong follow up coordinator on the newborn screening side. And then I would just put it right back to you that it's really important also to have a receptive staff on the CF center side that are listening and reacting to what's happening from the newborn screening having good communication. And it sounds like you guys definitely have that in Nebraska, so great job!

Karen: Thank you, yeah.

Marci: Thank you guys very much for presenting, and I'm gonna move us on in the interest of time to Barbara Holkham who is the clinical coordinator in Arkansas. Barbara, are you-

Barbara: Hi! I am on.

Marci: Great! And if you wanna go ahead and share your slides.

Barbara: I have to find the button that says I can share my screen. There it is. Are they up?

Marci: They're up. They're partially up and they're not quite yet.

Barbara: Oh! They're not there. I get to figure out which button to push. Here we go, is that better?

Marci: That's perfect, yep!

Barbara: Okay. So, this is just about CF screening here at Arkansas. We have kind of a unique situation, in that our health department lab, our follow up folks in the newborn screening department at the department of children and maternal health and myself, are all within a mile and a half of each other as the crow flies. So we're not together, but we are fairly centrally located. My position is a, I'm sorry I'm not getting this to move the way I want to. My position is a contract from our University of Arkansas medical science center, pediatric specialist. I work for the genetics department that does a lot of the metabolic lab follow up. We also have endocrinology, hematology, oncology and pulmonary people for consultation. And then my services are included in that contract, so I work both for UAMS and for the Arkansas Department of Health. Makes it nice in some ways, because I'm the one that gets to grab the docs and chase them down. And I'm on campus at Arkansas Children's Hospital where our CF center is, so that is also helpful.

Arkansas is a one test state. We have our lab open 48 hours a week, which is basically six days a week. The time sensitive labs are brought on Saturday morning, and in addition to the daily lab functions. And there is follow up available through the newborn screening nurses, and we have, oh goodness I've lost count. Five or six people that cover each of the different types of disorders. We have one person that does the CF follow up specifically, and the others fill in as needed for that. So there aren't any outside specimen pick up at our health units, so we'll pick up from the hospital closest to them and give them to our lab here in Little Rock.

Some hospitals have had issues with getting down the street to the health department, getting their specimens down the street to the health department, but we're doing a lot better with that. Our initial screening yields the IRT level and we screen anything 100 and over and the top 2% for that date, or for that week's selection of tests. We have had levels as low as 53, they usually bottom out in the 60s. So anything 60s or over is tested. We've had some 800's too, go figure. And so we test all of that.

Our second tier testing is Luminex, and it's the 60 gene test. We haven't had any problems at this point with missed screenings since the national disaster, can I call it? Of the problematic test kits a few years ago. That has been something that has been

very closely followed here. And so far we haven't had any new patients show up that weren't already screened on the newborn screening.

The test set up starts on a Monday with the call from the lab results from the previous week's. They're called out on a Thursday or Friday, sometimes even on a Wednesday. Depends on the quality checks test validation and result review. It is all called out from the public health to three areas all at once. The health department follow up team, myself as a newborn screening coordinator, and the CF center folks here at Arkansas Children's Hospital.

At that point we also have an algorithm that we use to go through for sweat testing. The health department at this point, the follow up team there, just maintains records for themselves. After they acquire the name of the PCP and get the office information to me, they also fax the actually sheet and they also fax the sheet that is helpful to them to help them figure out what that test result means to them. A lot of physicians, especially in the past couple months, have been getting the copy of the initial screening in which the screen for CF is positive and they want to instantly send for the sweat test without waiting for the second screen. So it's that part of the communication process can be problematic.

If they do have a gene that shows up or more on their second tier testing, they get a report and then I also will send them a request for referral. All the CF center testing, all the CF testing, is done here at the Arkansas Children's Hospital CF center. We're the only one in the state.

And I'm gonna go back to the first slide so you can see that we do have surrounding states here. We get plenty of patients that are born in Oklahoma or Texas that are then sent here to be seen in Little Rock, because of the way our medication system is set up. Those cities that are border cities may not have birthing hospitals available, except in Oklahoma or Texas. And the babies are born there but they reside in Arkansas, and most of those families have state financed insurances that require MedicAid. That requires them to be seen in Arkansas regardless of where they live. If we don't have it covered in Arkansas then they can go to another state, but we have a good CF center here.

Memphis is the other place that's close. Otherwise, it's Dallas or St. Louis or other places in those other states. So Memphis can be a closer spot for those people there than [inaudible 00:57:25] states. I'm sorry, the Eastern part of the state.

So on our, the newborn screening clinic here at Arkansas Children's Hospital starts the sweat testing process. Once I find a family that needs testing and I know their physician has contacted them and broken the news to them, I can call that family. Our pulmonary lab that does the testing has specific dates and times set aside just specifically for the newborn screening patients. I can do two a day here. They come in, they go to the pulmonary lab, they have their testing done, and then we discuss the results with them that afternoon or morning that same day. Then they can go home either with their mind eased, most of our children that come in with two

mutations automatically get an appointment set up with them in the CF clinic. Those aren't as frequent, but that's what we do. Most children that come in that have an inadequate or quantity not sufficient test will have a second sweat test done within the next week. And then if there's a positive sweat test at that point in time, they'll be referred to the CF clinic and speak to somebody that day. Often times if we know they're gonna have that because they have two non identical mutations, or they have an inconclusive test with two genes, they get added to the CF clinic as CRMS. Cystic Fibrosis Related Medical Syndrome.

I then relay all that information, send copies back to the health department follow up person, Ruby and she keeps all that information in our [inaudible 00:59:44] patient care system. And any other testing that needs to be done by the CF center gets taken care of. Again, I walk over there, I can talk to the physicians that are here or in clinic that cover the CF clinic the same day, and we can get a plan set up for the family for when they can come in and see the CF center. Their CF coordinator is a respiratory therapist and Lauren will come to them in clinic after I'm finished speaking with them the day of the test results. And get them started in the process, explain about isolation. The little things that families wanna know about before they get the full understanding of what's going on for their families.

I think I had pitfalls and successes here. Yep! To me the successes are, our notification is simultaneous. All the different areas get the information through an encrypted email all at once. But the sweat testing can happen easily because we have the reserved appointment times available. And that the treatment algorithm has really made it easy to know what's next. I can even get started on any blood work that needs to be done prior to their CF center appointment, both for the child or for the parents for that matter. So we can figure that part out. I do keep an Excel spreadsheet with all those types of results that is collected and sent to the CF coordinator for her to enter in her CF center database. And then Ruby at the health department takes care of entering all that into NewSTEPS.

Sometimes the appointment time it can be less than optimal to the pulmonary specialist for some of our infants. Because we do have five day a week availability and twice a day availability and we have lots of working families in Arkansas, or poor families in Arkansas, the timing is often related to who can get that family here on what day. The first two weeks afterwards is definitely the time period that we aim for. We have some people that, we had a resident who decided to go on vacation when his child's testing should have been done. So there are things like that, that you always have to deal with as far as families go. And that's what I have this morning.

Marci: Great, Barbara! Thank you so much. It's so interesting to hear how there's so many similarities across all of our programs, and yet there are important and unique differences, or unique approaches that really I think help each program to address their own needs.

So I promised we would have time for questions at the end. I know there is another call that I think many people would like to be on for the new [inaudible 01:03:09]

funding opportunity. So I will stay on this call for the next few minutes if you have specific questions, but even if the presenters need to get off I will relay those questions to you later and we can send the questions out to the appropriate questioner.

So, if there are questions?

So, the first question is from Kim Hart from Colorado and I hope Darren is still on, although he might not be. Do you apply the ultra high [inaudible 01:03:39] to the previous sick NICU infants.

Darren: I'm still here and at this time we apply it to all children. We're working on a NICU protocol to improve testing across all conditions. But as far as I know, it's applied to every child. Is Stacy still on the call? Is that her understanding, too?

Marci: Stacy had to get off.

Darren: Okay.

Marci: I guess to see some patients at clinic. I think people are logging on too just to call Emma.

Darren: Yeah, I think I'm gonna join that call too.

Marci: Okay.

Darren: Thanks so much.

Marci: Thanks so much, Darren.

Darren: Bye.

Marci: Okay, so since there is another call that is going on, I actually am going to cut questions off. If you have any questions, please forward them to myself or to Louise and we can put those questions out to the speakers, themselves. And so I'd like to end with really thanking the speakers for three very interesting presentations from three different states who have very strong programs and interesting approaches to their Cystic Fibrosis newborn screening. So thank you all, and I hope to talk to you all soon. Bu bye.