NewSTEPs
A Program of the Association of Public Health Laboratories™

Short Term Follow Up Technical Assistance Webinar

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Presentations:

- State Profile Minnesota—Amy Gaviglio, MS, CGC
- HIPAA Rule Change: Possible Impact on NBS Programs—Katharine Harris, MBA
- Ethical Implications of Direct to Patient Test Reporting—Aaron Goldenberg, PhD, MPH

Moderator:

- Thalia Wood, MPH, Specialist, NewSTEPs

Thalia Wood:	Thank you, everyone. We're in record mode now. I'm also going to mute the lines, so there's no background noise. Speakers, please remember to push *7 before you speak. After you're done speaking, you can do *6 to mute yourself. At the end of the presentations, I will unmute the lines for discussion. Right now I'm going to mute the lines.
Recorded Voice:	The conference has been muted.
Thalia Wood:	Thank you again. This is Thalia Wood, so Amy, you're up first. Go ahead and unmute your line. I'll get your slides going, and I'll go ahead and advance your slides for you.
Amy Gaviglio:	Okay, thanks. Can you hear me, Thalia?
Thalia Wood:	I can, thank you.
Amy Gaviglio:	Okay, perfect. Thank you very much, I am happy to give everyone a brief overview of the newborn screening in Minnesota. Though we are the 12th largest state in the country, we do have a relatively I think average number of births. Likely this is because much of Minnesota is fairly sparsely populated, or is actually taken up by our 11,000+ lakes. If you go to the next slide.

Our program, we are housed in St. Paul, which is the capital and really where a large proportion of Minnesotans live. Nearly 60% of the population is in the Twin Cities, so Minneapolis/St. Paul metro area.

You can see here, these are some members of our newborn screening program, which is integrated to include blood spots screening, early hearing detection and intervention, as well as critical congenital heart disease. Our program is made up of five units, and you can see those. They are along with the number of FTEs within each unit.

Our Operations Unit takes care of data entry and accessioning of newborn screening specimens. They also do all of our program activities like financial oversight of the sales of the card. The laboratory, of course. There are 15 FTEs within the laboratory, and they are open six days a week. We have our short-term [bottle up 02:16] staff, and this again encompasses blood spot [inaudible 02:20]. There are nine FTEs within that unit.

Our Communication and Education Unit. There are six-and-a-half FTEs in there, and that's made up of genetic counselors, health educators, and audiologists.

Then we have a Long-Term Follow-Up Unit, which I do think is fairly unique amongst programs. This unit is actually housed in Children and Youth with Special Health Care Needs, but there are seven FTEs there. Made up of primarily public health nurses, as well as an epidemiologist. Next slide.

I mentioned our birth numbers, kind of average, or about 68,500. We saw definitely a decrease, as I think most states did, with the recession. Now we're seeing a slight increase as things are getting better. About .2% of infants in Minnesota died without, or died before screenings could be done. We see about 99.5% are screened in Minnesota.

We do have about 150 refusals each year. I just wanted to point that out. Because I have noticed that though we do get refusal paperwork, and that's how we do the count of refused screening, we do see that at least in this cohort, at least 26 of these kids actually got a screen. What happens generally is we see them refuse screening, then we get a screen later on. I find that very curious, and I'd be interested to know if anyone else ever sees that in their state. We can move on.

I think like other states, congenital hypothyroidism, cystic fibrosis and Hemoglobinopathies are our most common pick-ups in Minnesota. You can also see what we have seen by way of [SCID 04:14] so far. I think much like what others see is primarily is [DGRG or 22Q], and then idiopathic. We have had two actual SCIDs pick-ups in 2014, but both of them had positive family histories for SCID. Next slide.

As far as some other conditions that maybe weren't represented in the previous slide. [Traits 04:39], we see about 1,280 kids a year that are found with trait, and we pick up about 350 kids a year with congenital hearing loss. I want to point out as well is that we've been working really hard in our [EHDI 04:54] program to reduce lost to follow-up, which is a problem nationwide with EHDIs.

Right now, from time of birth, including that initial screening or any missing results to a diagnosis or a follow-up, we are at 6.6%. It seems high, when you compare to blood spot, but in the realm of EHDI is really quite good. We continue to work on that here in Minnesota. Next slide.

NewSTEPs has asked me to put together some exciting or new developments in the state. These are ones that were kind of positive that I could think about.

Timeliness obviously as with other states, we have been working on timeliness of specimen receipt, and we've seen some really nice improvement so far in 2014. We're seeing over 93% of our specimens coming in within two days after collection date. That's something we'll continue to work on with hospitals that seem to be struggling. That's been a nice jump we've seen from 2013 to 2014.

Out of hospital births, in the realm of EHDI and soon to be in the realm of CCHD, we've been really working hard with them to increase their screening in this population. Right now they do a really great job with blood spot screening, but we were struggling with some of those point-of-care tests.

You can see that our pre-grant period that we worked with them on in 2012, less than 40% of kids who were born in the home were receiving hearing screening. Thus far in 2014, that's up to 76.2%, so we're really proud of that increase and are looking forward to working with them for CCHD as well. Next slide.

Speaking of CCHD and EHDI reporting, we recently signed a contract with OZ Systems to begin electronic reporting of both CCHD and EHDI, which will begin in July here. We're very excited about that from both perspectives. Look forward to sharing how that works with others.

For CCHD and EHDI, we've just revamped our educational materials. They look really great. Our health educator put a lot of time into it, and we'd be happy to share with anyone who is interested in seeing the look and feel of them.

In the lab realm, we recently applied for a March of Dimes Grant, with the University of Minnesota as well as the CDC to examine the feasibility of molecular second tier for CAH. We have published previously on some of our CAH metrics, both by way of false positives and false negatives.

I think many of you will agree, unless you're a two-screen state, that CAH testing could use some improvement. We'll be looking at the feasibility of adding molecular to the CAH screen in the next couple of years. We're excited to see how that works, and if we can improve screening. Next slide.

Then our final exciting and new development is we've really been focusing on prenatal education. I think unlike a lot of states, prenatal education in Minnesota is required in legislation. We are required to provide materials to prenatal care providers and make sure that they have discussion with prospective parents about newborn screenings.

We have developed some materials, and right now we're working on a survey. We will be surveying about 9,000 parents, as well as all of the prenatal care providers, or trying to all the prenatal care providers in the state. To examine the effectiveness of the prenatal education, as well as what kind of information they would like to know and how they would like to get it in that period. That's something we'll be working on for the remainder of 2014. Again, we're happy to share with anyone who may be interested.

The last slide is our contact information. I put our Program Manager, Mark McCann. Myself, as the short-term Follow-Up Supervisor, and our Lab and Comm/Ed Supervisor as well. As well as our website, if anyone wants to check out those. We did just re-do our website again, so I encourage anyone to go and see how they like it. I think that's it.

Thalia Wood: Good. Thank you very much, Amy. Just to let everybody know, we do these short state update profiles at the beginning of each of these calls. Highlighting different states so you can get a feel for what people are doing in other states.

Now we'll actually get into our topic today, which is talking about this new rule of direct patient's access to results. Kathy Harris is going to speak first. Kathy, have you got your phone unmuted?

Kathy Harris: I think so. Can you hear me?

Thalia Wood: I can, thank you. Just tell me when you want me to move your slides for you.

Kathy Harris: Okay, you can go. I'm going to give just a brief summary of the new HIPAA rule. Taken mostly directly from the federal register. This final rule amends the CLIA regulations, that upon the request of a patient, or the patient's personal representative, laboratories subject to CLIA may provide the patient, the patient's personal rep, or a person designated by the patient as applicable, with copies of completed test reports that using the laboratory's authentication process can be identified as belonging to that patient. Next slide.

Subject to conforming amendments, the final rule retains the existing provisions that require release of test reports only to authorized persons. If applicable, to the persons responsible for using the test reports and to the laboratory that initially requested the test. I don't think that's the patient per se, this is part of the old rule. Next, please.

In addition, this final rule amends the HIPAA Privacy Rule to provide individuals or their personal representatives with a right to access test reports directly from laboratories subject to HIPAA. To direct that copies of those test reports be transmitted to persons or entities designated by the individual. By removing the exceptions for CLIA-certified laboratories and CLIA-exempt laboratories from the provision that provide individuals with the right of access to their protected health information. Next slide.

These changes to the CLIA regulations and the HIPAA Privacy Rule provide individuals with a greater ability to access their health information. Empowering them to take a more active role in managing their health and health care. Next slide.

We believe these concerns ... Then they were talking about some of the comments that they got in the Federal Register. HIPAA comes back and says, or the Fed Registers. We believe these concerns, as well as the advent of certain health reform concepts. For example, personalized medicine and individual's active involvement in his or her own health care. The department's work towards the widespread adoption of EHRs, call for revisiting barriers or challenges to individuals gaining access to their health information. That's from CMS, the Centers for Medicaid and Medicare. Next slide.

The department believes that this right is crucial to provide individuals with vital information to empower them to better manage their health and take action to prevent and control disease. In addition, removing barriers in this area supports the commitments and goals regarding personalized medicine, and individual's active involvement in his or her own health care, and the widespread adoption of EHRs by 2014. Next slide.

Under the proposal, HIPAA covered entities that are laboratories subject to CLIA, as well as those that are exempt from CLIA, would have the same obligations as other types of covered health care providers. With respect to providing individuals or their personal representatives with access to their protected health information. Next slide.

As we discussed in the proposed rule, a laboratory that receives a request for access from an individual where the laboratory could not authenticate that the requesting individual is the subject of a test report, would be under no obligation to provide access. That's where it gets a little confusing, I think. Next slide.

I know you can all read the legislation and the comments. I did not go and read the 33 pages of comments and responses. This sort of, as I was skimming the rule change, these are some of the texts that seemed relevant to the issues with newborn screening.

The [NYMAC 14:23] Newborn Screening Follow-Up Interest Group had a meeting in Albany in May, May 16-17. The meeting included follow-up staff from Maryland, New Jersey, New York, Pennsylvania, Virginia and West Virginia. Delaware and District of Columbia reps were not able to attend. Next slide.

We had a long discussion on this, it was very interesting. A lot of people have thought about this and how to do it, how to make it work. The biggest concern expressed by each state follow-up group member is determining who has authority to get the testing results, and how to authenticate the caller. There is concern about information getting into the wrong hands.

In addition, this could mean a surge of people calling for results, whether the response of it ... You know, nobody knows, well I don't know that the labs have figured out yet, the program's figured out yet who is going to answer these questions. Is it lab staff or follow-up? Nobody has sufficient staff to handle an onslaught of calls. Next slide.

I asked for some thoughts and concerns after our meeting. I did get this back from Beth Vogel, who has been talking to our New York State Newborn Screening folks. Other questions to consider. Should newborn screening advertise that parents can get results? What will be the impact on the volume of requests? Will providers start asking their patients to get results directly from Newborn Screening?

Should Newborn Screening programs provide educational materials to go along with the report? Is there a secure electronic way to send results? You can go to the next slide, Thalia.

Do you think linked specimens (i.e., they put in the lab ID for one specimen and get all the results linked for that child), are you going to be able to do that? Will the number of NCAA requests increase? That's the sickle cell trait concerns. Can providers ask that their patients should not access a result? What do you tell the patient if their doctor does not want them to have it? Next, Thalia, please.

I really want to discuss these issues. I want to stand back and just have people talk about what they think. Thalia, if you don't mind opening all the lines, I'd really like to hear what the other states have talked about amongst themselves.

Recorded Voice: The conference has been unmuted.

Kathy Harris: Thank you. What the other states have talked about, and how they're approaching this.

Thalia Wood: If anybody would like to comment, please feel free. Then when we're done, after about another 10 minutes, we'll go into Dr. Goldenberg's presentation.

Debbie: This is Debbie [Freedenberg 17:19], and we don't have any answers. We've discussed it and we haven't come to any conclusions about any of those issues. About where the clinician's responsibility ends and where the laboratory's and where the follow-up program's responsibilities are. We continue to have these discussions and one of our discussions is what are we going to need for verification? The person requesting the information would indeed be able to get the access?

That's one issue, whether we're signing a form or something. Where somebody has to sign off an affidavit or something. We have no answers, but we're looking at all the issues.

Linda: Hi, this is Linda from Connecticut. We have a Connecticut state statute that states we are only allowed to give information to the providers. Not the parents, or the patient itself. Now with a state statute, how would that respond with the federal program too?

Kathy Harris: Yeah, I was looking at the law and did not copy that part out. The law says it trumps state regulations. The state law is no longer applicable.

Recorded Voice: [crosstalk 18:52]

Thalia Wood: Somebody has their phone on hold, it sounds like. Anybody else want to comment before we move on?

Claudia: This is Claudia Nash in Illinois and we've had this issue come up here as well, of course. Our legal staff has actually recommended that we have a release ...

Thalia Wood: Okay, it looks like I'm going to have to mute the phones again. When you need to talk, just push *7. Somebody has their phone on hold, so I'm going to mute everybody again.

Recorded Voice: The conference has been muted.

Thalia Wood: Okay ...

Claudia: Hi, this is Claudia Nash. I'll repeat that.

Thalia Wood: Thank you.

Claudia: I'm from Illinois, and our legal staff, one of our attorneys, has developed consent forms that we're using. One is for health care providers and the other's for parents or individuals that want results. Our legal staff recommended that we have the parents have the form notarized to get the results. Health care providers don't need to do that, they just need to basically sign and verify they are the provider. Then we're just sending the results.

They're also allowing us to send the results by email, if the individual has requested them be sent by email. Then they've also developed a third release form for allowing for email transmission of these reports. It's kind of a cumbersome process, but our follow-up staff has been handling most of these.

They're also encouraging us to put a change in our administrative rules that would allow us to charge for the results. They're proposing that we would only charge families, not providers. Just from the standpoint that the medical providers would need the results for hospital care of the patient. The parents would just need them for basically their own interest.

Thalia Wood: Great, thank you so much for that.

Claudia: Mm-hmm (affirmative).

Thalia Wood: Anyone else care to comment before we move on?

Amy Gaviglio: This is Amy from Minnesota. We met with our legal team as well, and had a similar situation that Claudia was explaining. We have a form that allows for a request of results. It requires the signature to be notarized or for the requester to submit a photocopy of their driver's license or state ID card.

This is very similar, and I don't know if other states have this. We had in place before, not limited to newborn screening results. A policy for public requests for access to Department of Health data. We're kind of using that as well, to modify it a little bit to newborn screening. It may be worth looking to see if your department has a policy on any type of public request for access to data. That's been a good model to work from.

Laura: This is Laura Taylor, in Colorado. I'm wondering does any state have any sense of how many requests have states have this policy in place long enough that they know how many requests coming in? Or are we all just flying blind?

Amy Gaviglio: This is Amy from Minnesota. I think we're primarily flying blind. I guess I would be surprised if we're going to get that many. I think where we've seen in all of our requests, and I'm sure this is true of most states, is with the sickle cell trait requests.

Laura: Thank you.

Kathy Harris: This is Kathy. The rule says the states have six months to implement this, so I think it's October 6 or 7 when this has to go in place. Obviously I would think states could go earlier if they're ready, but I'd almost be surprised.

Julie: Kathy, this is Julie, from Nebraska. You're kind of our resident expert on this, so you may know. It seems like a lot of times when there's a new regulation that comes out, there's also some guidelines oftentimes, eventually, that accompany those federal guidelines or regulations.

Are you anticipating anything to come out that would maybe clarify what they would expect as acceptable authentication, for example? Because as the CLIA sectors go out, you could have several different interpretations across the country as to what's an acceptable authentication. Are you anticipating any further guidance coming out of the feds on that?

Kathy Harris: If you're asking me, Kathy Harris, I really have no idea. I guess I would be surprised if CLIA or maybe even APHL didn't try to get a group together. At least to hash over the arguments and the concerns. Try to pull together some unified response. Otherwise, parents are going to be, depending on which state they are and where they move to, they're going to ... Every time they ask, it's going to be a new procedure. Probably would be helpful to coordinate that kind of thing.

It's a really short time frame for something this complex.

Julie: Yeah.

Michelle: This is Michelle Lloyd-Puryear

Kathy Harris: Hey, Michelle.

Michelle: Hey. Has this been presented at all in front of the advisory committee?

Kathy Harris: No. Certainly not at the meeting in May.

Michelle: Because maybe, and I think it's late, but I mean it should have already been on their agenda. Because to help address what Julie just brought up. Because you can have people from CLIA there, from CDC there. [crosstalk 24:58] there to answer some of these questions.

Thalia Wood: Those are all very good points.

Kathy Harris: Yeah, I wonder. They have us meeting in September, which would be like the day before, more or less.

Michelle: I know. I mean it's late, but it'd be important for some of these concerns ...

Kathy Harris: Yeah, that's a good idea.

Michelle: ... to be on the agenda.

Kathy Harris: At least to have ... Though there's not that many newborn screening laboratory or program people on the committee, it would be ... They can easily pull ... They've got the sub-committee that would have the expertise to really come up with a lot of the issues and solutions.

Michelle: Yes.

Thalia Wood: I think we'll go ahead and go on with Dr. Goldenberg's presentation, then we'll see if we have more discussions after that. I'm going to just change the application here real quickly. I'm going to be doing his PowerPoints a little bit different. I've got his presentation up now. Dr. Goldenberg, are you on the phone?

Aaron Goldenberg: I am, can you hear me?

Thalia Wood: I can, so you just let me know when you want me to change the slides.

Aaron Goldenberg: Awesome, thank you. I'm Aaron Goldenberg, I know many of you. For those of you who don't know me, I'm from Case Western Reserve

University. Most of my work centers around ethical and legal implications of issues in newborn screening. Perinatal ethics, more generally.

What I want to do today is to talk a little bit about some of the ethical implications of direct-to-patient delivery of test results. I think from listening to the first part of the conversation, I think there are two main issues here. Which skirt along I think the larger issue of newborn screening, which sits in this kind of quasi-space between clinical and public health. In terms of its delivery of care. In terms of its long- and short-term follow-up.

From an ethics point of view, this is one of the most interesting places. It's also one of the most difficult places to be. Right? We think about ethical issues within clinical medicine very different than we think about ethical issues in public health.

We talked in the first part of the call about requests for information. Requests for access to results. Which is a much more public health framework in terms of looking at the kinds of implications of parents having access to this information.

We also, I think, need to be thinking about this along the lines of clinical access. Just like we're talking, at least in the ethics community, about for example patient access to all sorts of other results. Whether those are cancer screening markers. Whether those are cholesterol results. Whether those are ... What are the ethical underpinnings of CLIA's ... Issues within CLIA, but generally in terms of access to test results.

I hope that in the next few minutes I can talk a little bit about some of the ethical and kind of social implications of this movement. Then we can maybe get into some discussion to follow up on the discussion that we just had. If you go to the next slide.

I have some very fancy animation for you all. I'm not great at PowerPoint, so I tried to do my best. Generally in ethics, especially when it comes to things like patient information, we think about autonomy. The ability for a patient to control or a family to control their own information, or their own health care as it relates to the day-to-day decisions they may make related to their health care.

We usually try to balance that with this idea of non-maleficence. Non-maleficence, we're doing no harm. We want to do no harm. Much of the rhetoric, much of the conversations in the ethics community about direct-to-consumer or direct-to-patient access of test results, have to do with this dynamic.

How do you balance the importance of families or individuals having access to their own test results, or the test results of their children, as it relates to ... What Kathy talked about, patient empowerment. Family empowerment. Being able to have information in their hands. While also needing to think about the potential harms of having that information without appropriate education, appropriate communication, appropriate short-term follow-up and long-term follow-up.

I think for the most part from my perspective, when it comes to the ethical issues here, that's where you really sit. Is this trying to figure out a way to think about both patient control, patient access, and patient rights. Really think about patient rights to their own information. With the potential harms that could come from a patient knowing something either too early. Or knowing something with mis-information. We'll talk a little about what some of that might look like.

We also, if we think about the four main principles of bioethics, although these are not the only ones. These are the ones that we generally think of. If you hit the next slide, or the next animation.

You can see, ooh very nice. If you think of beneficence of doing benefit to a patient, you can imagine it being on both sides of this scale, right? You can imagine having access to your own child's information, or your own information, could be seen as a benefit. It could be seen as something that's going to ...

"Well if I have this information early, I can start doing my own research. I could start thinking about my own course of action, or our family's choices. It might benefit us to better educate ourselves about a particular disorder, or about a particular analyte," whatever it may be, in order to facilitate care. If you hit the next slide.

You could also think of it this way. Which is that really from a state's perspective, there may be a lack of benefits. If you're giving information to people without the proper education or proper information. States are

going to have to confront this. Well, we need to be able to give this information to patients, or give it to parents, but we're worried that it's going to actually do the opposite of benefiting them. That's clearly something that I'm sure ... That came up in your conversations, but that will come up.

Justice as well ... if you hit the next one ... could also be seen in both lights. Justice in the sense that we all should have equal access. Or not equal, but equitable access to our own information. Be able to across-the-board, given that newborn screening's a universal program, open to everyone. The information should be open to everyone as well.

Finding dynamic systems either through the internet, or through phone systems, by which giving people access in a way that doesn't inhibit them. They don't need seven forms of ID in order to get the information.

Hospitals, for example, are struggling with this right now in terms to access to things like cholesterol tests. What do you need to verify that you have a portal? Cleveland Clinic has a portal, for example, that has a couple different forms of verification. To make sure that patients are patients when they're logging on to get their test results.

If you hit it one more time. I also think again, we could think of it this way. Where we start thinking about maybe inequitable access. Where you have people who either have better access to the information because they have better computer technology access.

Or, even I think more important is access to health care facilities or other types of health care information where you might see some people who get these results as direct to access are much more likely to be able to act upon those in an appropriate way. Versus others who may not. People who haven't had ... who have lowers level of health education. Or don't have access to quality care.

I think again, all of these things match up against this larger issue. Which is why there's been this movement, which is rights of patients to have information. The rights of patients to have access to their information. Balancing in some ways, and we'll talk about this word balance in a second. Balancing the idea of autonomy, of giving patients control. Versus all these other concerns that you all may have as state representatives. Keep going to the next slide.

Clearly these are some of the things that I'm sure you all have already thought about. I'm going to go through them fast so we can try to get to conversations. There's clearly the problem of misinterpretation of data. I know CLIA has thought about some of these issues, and I know hospitals have thought about some of these issues.

One, which I know you all struggle with generally, is this idea of confusion over a screen versus a diagnostic test. We're getting results of a test. What does that mean when I get those results in my in box? Or when I get those results over the phone? Do I understand that this is a screen, and that there's a need for follow-up diagnostic tests if something screens positive, right? Those kinds of concerns.

Clearly confusion about potential differences in age of onset or phenotypic variability of some of the conditions. Especially some of the conditions that may be being added by states currently. Pompe being one example. Could cause a lot of angst within parental and family units who don't maybe have the appropriate time. Because they're getting the information over the internet without the appropriate follow-up.

Clearly analytes that may be associated with multiple conditions. If they're getting analyte information or they're getting certain types of test information, screen information. They go to the internet. It's every doctor, every health care worker, every public health official's worst nightmare. To send information then know that they're going to go on WebMD and look something up. There's clearly some ethical implications of this misinterpretation of data.

Clearly stress or anxiety is one of those, another issue that comes up. I also think there's a potential impact on a relationship with health care providers. Potentially metabolic clinics or other genetic clinics and State Health Departments. In some ways, it's a double-edged sword.

On one hand, places that don't release medical information. Hospitals that have not made that jump yet. There are patients that have said, "Well, I don't trust my hospital anymore. Everyone else seems to be able to get access to their results, but I can't."

On the other hand, there's the potential where someone may say, "Well I don't need my doctor. I don't need to call them again. I don't need to do that follow-up. I have the information here. I'll just look it up and figure

out what I need to do." Not that they would take it less seriously, but may not think about follow-up in the same way from the parental standpoint. Next slide.

From programmatic issues. I do think there's this kind of balancing of familial rights for information, versus an appropriate interpretation and communication of that information. That's clearly going to be something that's going to ... This is, I think, Michelle's point of talking to the advisory committee. Maybe thinking about some other conversations across states to kind of think about this issue. How do you make this balance?

I also think state variability is going to be a big issue here. Which is if, for some reason, someone wanted to ... I'm not saying you would be doing this. If you were providing particular analyte levels as results, and so on. The cut-off levels were different between states. How would you address the fact that a parent might see one number in one state that would have a potentially different interpretation in another state.

Thinking about, again, the ethical implications for you all in terms of follow-up. But also for parents in terms of understandability of the information, is going to be an important one. Next slide.

We talked about this a little bit, but other considerations for follow-up. Clearly the ability to communicate or educate is going to be an issue. Just giving results. This is also ... Again, I hope this is helpful, but think generally about some of these issues.

This is an issue that hospitals are dealing with right now. Which is what do you provide on a patient portal in addition to a cholesterol figure? Do you provide follow-up information? Do you only release that information after they've talked to the doctor? Do you do it before? Every hospital is kind of handling it differently.

I actually think this may be an opportunity for states to come together to do, like we were talking about, some guidelines or recommendations so that every state isn't doing it totally differently. Because right now, in Cleveland alone, we have three main hospitals. All three are handling this giving of results completely differently.

At one hospital, you have to see a doctor before they'll actually release it to you. At another hospital, you can get it weeks before your

appointment. Another hospital, the results are released, I think, the night before. It's interesting to think about what the implications of how you educate and communicate these results will be. Clearly, as we talked about, implications for self-interpretation of results and those implications on what you all do, in terms of follow-up. Next slide.

Other general considerations or questions that I think are important for us to address. One has to do with the type of information. This is not specific about newborn screening, but generally. The AMA and another set of groups who have been dealing with patient direct access to results has tried to make a distinction between routine tests versus life-altering tests.

I think in some ways that's a qualitative divider that may not be the same for every family. Most of the laws or most of the policies that have been governing the release of information, haven't thought I think as thoughtfully or as thoroughly about this issue. About this idea of routine tests versus life-altering tests.

They also think about the severity of the condition, or the treatability of the condition when giving particular types of test results. Clearly something that will be important for us is whether or not we're talking about the patient itself or the child. In this case, the newborn.

Time frame clearly, as you all brought up before I started talking. Thinking about how you can get information quickly to parents if they request it.

Then what are the follow-up conditions under which you can give information but in cases where there may be positives. To be able to follow-up appropriately. Or if someone has something that generally wouldn't need follow-up but wants follow-up. How do you deal with the deluge of calls that we were just talking about?

I want to end by talking about two important distinction questions that I think in thinking about guidelines are going to be important. You can hit the next slide.

One, which is what are the limits of autonomy? We generally think about the idea of patient-direct access as a way to optimize or maximize patient autonomy. That doesn't mean that we should always be thinking of autonomy as a be-all, end-all of ethics. In either medicine or public

health. That there may be kinds of information, and newborn screening may be one of those, where we think about the idea that this isn't the best place to be doing patient access.

Clearly if there are legislation that's requiring direct access, that's a legal question that needs to be thought of. I just want to think from an ethics standpoint. This is always one of the questions that circulates around my brain when thinking about this. If you go to the next question.

For us, I also think there's this question about public health exemptions. We think about for example public health exemptions that we see in HIPAA. Public health exemptions that we see in other forms of information. Again, I'm not suggesting that oh, we should just have an exemption for this.

I think from an ethics standpoint, from a more of a theoretical standpoint, it's important to think about how is this different than just a regular test result? How is request for information different when it comes from a public health source? Especially one that does kind of sit in-between this clinical medicine and public health worlds.

I think when thinking about, I don't know, how to develop guidelines. Or suggestions on how to provide this information to parents. One thing to think of is what does it mean to provide this information as a public health agency? Not as a clinician. To go to the last slide.

I also want to say one thing, which is that one of the things that has always irked me about principles of bioethics and those four principles I used here today is this idea that we always have to be in balance. We always have to balance one or the other. If you hit the next slide, a very sophisticated PowerPoint.

I actually think this is not about balancing. I really don't. I think this is about maximization of patient rights. Maximization of appropriate education.

I think thinking through as a group, as people who do follow-up, in terms of how do you comply with these regulations in a way that both maximizes patient access. Also appropriate follow-up when needed, will be the true test of what happens next. What happens for parents who are thinking about accessing these test results?

I also think that there is this issue which I'd be interested in hearing more clarity from all of you. Which is is this really about access to the tests as early as humanly possible? I'm going to come home from the hospital, and I'm going to call the next day to get the test results. As I would with a cholesterol test, or some other kind of biomarker.

Or is this about parents being able to have access? More in the sense of in some ways, a freedom of information. These are my data, or these are my children's data, and I want to be able to have it. Whatever the results may be.

Is it about actionability, or is it about information? I think that that's something that can be talked about. I'll end there. I hope this was helpful. This is something that I've been thinking about. I'll be curious to see what else you guys are thinking about along these lines. Thank you.

Thalia Wood: Thank you very much, Dr. Goldenberg, I'm going to go ahead and change the screen back to the discussion. Please, unmute your lines by pushing *7. Make any comments on either this presentation, or let's continue this discussion.

Just push *7 to unmute your lines.

Julie: This is Julie again, and thank you very much for the presentations today. They've been very, very good. Would really love to hear what states are experiencing, if they're already getting an increase in the requests. Beyond what we've already been getting, to comply with the NCAA rules, or recommendations.

Because I wonder. I mean yes, we do need to be prepared for whatever it will be. If it's an onslaught, we need to be prepared for that. If it's a trickle, maybe we can all relax a little bit. Just make sure that our procedures are in place.

I don't know that we can know what to expect, but I would love to hear if people are ... What kind of numbers they're facing for these direct patient requests.

Thalia Wood: Thanks, Julie, that's a good question. I'm actually going to put up a survey slide on the screen now. If people want to go ahead and answer this, we can get a feel for those of you who are listening. Has your program been

asked for screening results? If you want to push the yes or no button, we can get a feel for people what they're doing out there.

Kathy Harris: I think generally yes, but they've always been referred to the physician because they couldn't give it out.

Thalia Wood: Oh, okay. Anybody else? Are you getting lots of requests for results?

Kathy Harris: This is Kathy Harris. While you're looking at that report, Thalia. I like the distinction Aaron was making between routine results and something that is out of the routine. I think about, you know I get my annual or whatever lab work done. I look at them, and I compare them to last year. It's kind of interesting, though I also have a background that possibly gives me a little more background.

That said, you get a newborn screening and we all ... Most of them are going to be normal, but there are going to be one in every 300 that's going to ... Or more than that. One in 300 is going to be a diagnosis, so we've got several times that that are going to have a positive screen. Without a lot ... I think the prenatal, the prebirth education that's going to be required to make any sense to these parents is going to be huge.

Thalia Wood: Yeah, that's true. I went ahead and stopped the survey. It looks like a lot of people had voted. Is anybody surprised by this?

Amy Gaviglio: This is Amy, from Minnesota. I'm wondering ... I haven't looked too much into the rule, or read much of it like Kathy. Does it say what the turnaround time has to be on a request? Because my thought has always been that you don't need ... If you haven't finished your process of calling the results out? That you don't necessarily need to give it to them before you've done what you need to do on your end to insure the right people are in the loop. Is that not a [crosstalk 46:46].

Kathy Harris: It's 30 days, Amy. You would hope ...

Amy Gaviglio: [crosstalk 46:49].

Kathy Harris: ... and pray that parents sometime within that will be going to their physician's office.

Amy Gaviglio: Okay. For most of these, they'll be negative. It shouldn't be a new information to them if it's positive.

Kathy Harris: Right. But with 30 days, if it's screen positive, all the programs ... and people, please chime in ... all the programs are going to get that to their primary doc. If they know it's a specialist, if it's radically positive. These parents should not have to wait 30 days, ever, for the results from the physician.

Amy Gaviglio: No, I would agree with that. I was just confirming, because I think that should help alleviate some fears about giving a positive result without having any contextual background.

Thalia Wood: Okay, anybody else want to make a comment, or talk about what's been going on in your state?

Laura: This is Laura. Can you hear me?

Thalia Wood: You bet.

Laura: I'd be interested to see this graph, if you said other than NCAA requests.

Thalia Wood: Oh.

Laura: Because that may be skewing it up for yes.

Thalia Wood: That's true.

Kathy Harris: Where's the graph, Thalia? I didn't get it.

Thalia Wood: It should be on your screen. Are you looking at your screen?

Kathy Harris: Yeah. I just have the survey.

Thalia Wood: Oh yeah, that's what you were talking about. The fact that ...

Kathy Harris: I didn't get to see the results, just the question.

Thalia Wood: Okay, well the results should be up on your screen right now. It was 77% saying yes, that they had been asked by parents for screening results.

Kathy Harris: Okay, thank you.

Thalia Wood: Sure.

Female: For those of you who can't see the results, you have to answer the question first, then you'll see them.

Thalia Wood: Oh, thank you for that. That's good to know.

Kathy Harris: That's tricky. Yeah, thank you. Now I'm caught.

Thalia Wood: For those of you who are getting requests, I have another question. I just made these up myself, because I didn't have a chance to check with our short-term follow-up work group today. What method of verification will you use, or do you use, before providing results?

This is something that was discussed on another call recently. I just wondered if you have any way of checking verification of the parents before you provide them with results.

If you want to answer this question. I'll go ahead ... I just realized as I was on the other graph that it does show the results as you're responding.

Kathy, does this provide any interesting information, considering what you talked about at [9MAT 50:00]?

Kathy Harris: I like the fact that it's split, because I think that was a lot of where ... This was kind of new. We were talking in May. The rule had just come out a month earlier. People were starting their conversations within their programs. These were some of, yeah, some of the thoughts given.

Thalia Wood: Okay, anybody else care to comment? I think this has been a very interesting and timely topic. I appreciate the suggestion about having somebody work on this for a consensus among all the states. I think that that's something that probably will be looked at.

If there are no further comments. Anybody else have any final things to say before we close up today? On this month's call?

Connie: This is [Connie 51:19] in Iowa. Has there been any conversation or request as states that already have consent forms? Could they put them onto the [MRC 51:29] at [APHL 51:30], so that we could all share them?

Thalia Wood: That's a great idea. That's something we could probably put under your state profiles on the new [inaudible 51:48] website. Yes, if you have

consent forms that you don't mind sharing, you can send them to me and I'll make sure that they get on the website.

Kathy Harris: There may be some ... Many states may already have NCAA forms that they're using, even.

Thalia Wood: Yeah, that's very true. For those of you who said other means of verification, would anybody like to chime in before we're done here today about what your other means is?

Use *7 if you can chime in and tell us what your other means of verification is.

Okay, well maybe people don't want to share. That's okay. If there's no more comments ... One person did say we haven't decided yet on the verification. In the chat, I thought I'd read that to you.

Again I'd like to thank you, for the good discussion today. Thank you very much, Kathy and Aaron, for your presentations. Amy for your state profile.

We are doing these webinars every other month, so the next one will be done in September. I would like to encourage you all who are able to to sign up to come to the APL's Newborn Screening and Genetic Testing Symposium in October in Anaheim. We will be having a short-term follow-up round table. We were supposed to be getting the short-term follow-up session. We definitely want to reach out to those of you in that community and make sure that we're meeting your needs.

Again, I'll be sending out a short survey following this call, because again we like to continue to meet your needs. On what topics you think are relevant. Anybody else have anything else to say before we wrap up?

Kathy Harris: Thanks, Thalia.

Thalia Wood: All right, well thank you so much everybody for attending. I appreciate everybody on the call. Thanks again.