

US DEPARTMENT OF HEALTH AND HUMAN SERVICES

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HEALTH RESOURCES AND SERVICE ADMINISTRATION

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THE ADVISORY COMMITTEE ON HERITABLE
DISORDERS IN NEWBORNS AND CHILDREN

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MEETING

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TUESDAY,
MAY 10, 2016

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The Committee met in the Conference Room at NIH Events Management, 5635 Fishers Lane, Suite T500, Rockville, Maryland, at 10:00 a.m., Joseph A. Bocchini, Jr., Chair, presiding.

MEMBERS PRESENT:

JOSEPH A. BOCCHINI, JR., Chairperson
JEFFREY BOTKIN
COLEEN BOYLE
CARLA CUTHBERT
KELLIE B. KELM
FRED LOREY*
DIETRICH MATERN
STEPHEN McDONOUGH
KAMILA B. MISTRY
JOAN SCOTT
CATHERINE Y. SPONG
CATHERINE A. L. WICKLUND

DESIGNATED FEDERAL OFFICIAL:

DEBI SARKAR, Health Resources and Services
Administration

ORGANIZATIONAL REPRESENTATIVES PRESENT:

NATASHA F. BONHOMME, Genetic Alliance
CHRISTOPHER KUS, Association of State &
Territorial Health Officials*
CAROL GREENE, Society for Inherited Metabolic
Disorders
ADAM KANIS, Department of Defense*
EDWARD R. B. McCABE, March of Dimes*
ROBERT OSTRANDER, American Academy of Family
Physicians
SUSAN M. TANKSLEY, Association of Public Health
Laboratories*
BETH TARINI, American Academy of Pediatrics
KATE TULLIS, Family Health and Systems
Management Delaware Division of Health
CATE VOCKLEY, National Society of Genetic
Counselors
MICHAEL S. WATSON, American College of Medical
Genetics and Genomics

ALSO PRESENT:

LISA FEUTCHBAUM
ALEX R. KEMPER
K.K. LAM
TIINA URV

* via teleconference

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P-R-O-C-E-E-D-I-N-G-S

(10:00 a.m.)

CHAIR BOCCHINI: Welcome to the second day of the May meeting of the Advisory Committee on Heritable Disorders in Newborns and Children. I'm going to start by taking attendance for this session. First committee members, Don Bailey?

MEMBER BAILEY: Here.

CHAIR BOCCHINI: Jeff Botkin?

MEMBER BOTKIN: Here.

CHAIR BOCCHINI: Coleen Boyle:

MEMBER BOYLE: I'm here.

CHAIR BOCCHINI: And Catherine hasn't made it yet. Kellie Kelm?

MEMBER KELM: Here.

CHAIR BOCCHINI: Fred Lorey, on the phone.

MEMBER LOREY: I'm here.

CHAIR BOCCHINI: Dieter Matern?

MEMBER MATERN: Here.

CHAIR BOCCHINI: Steve McDonough?

MEMBER MCDONOUGH: Here.

1 CHAIR BOCCHINI: Kamila Mistry?

2 MEMBER MISTRY: Here.

3 CHAIR BOCCHINI: And then Joan Scott
4 for HRSA?

5 MEMBER SCOTT: Here.

6 CHAIR BOCCHINI: And Alexis is unable
7 to join us today. Cathy Wicklund?

8 MEMBER WICKLUND: Here.

9 CHAIR BOCCHINI: And Debi Sarkar?

10 MS. SARKAR: Here.

11 CHAIR BOCCHINI: And then for the
12 organizational representatives, Bob Ostrander?

13 MR. OSTRANDER: Present.

14 CHAIR BOCCHINI: Beth Tarini?

15 MS. TARINI: Here.

16 CHAIR BOCCHINI: Michael Watson?

17 MR. WATSON: Here.

18 CHAIR BOCCHINI: Joseph Biggio, by
19 phone? Joseph Biggio, by phone?

20 (No audible response)

21 CHAIR BOCCHINI: Kate Tullis --

22 MS. TULLIS: Here.

1 CHAIR BOCCHINI: Susan Tanksley, by
2 phone?

3 (No audible response)

4 CHAIR BOCCHINI: Chris Kus, by phone?

5 (No audible response)

6 CHAIR BOCCHINI: Adam Kanis, by phone?

7 MR. KANIS: Here.

8 CHAIR BOCCHINI: Natasha Bonhomme?

9 (No audible response)

10 CHAIR BOCCHINI: Ed McCabe, by phone?

11 MR. MCCABE: Here.

12 CHAIR BOCCHINI: Cate Walsh Vockley?

13 MS. VOCKLEY: Here.

14 CHAIR BOCCHINI: And Carol Greene?

15 (No audible response)

16 CHAIR BOCCHINI: I want to thank you
17 for joining us for this second day. We're going
18 to start today with a presentation. I think that
19 we certainly have significant concerns about
20 issues with retained blood spots. And so, Jeff
21 Botkin today is going to discuss prenatal
22 education about newborn screening and dried blood

1 spots. Jeff?

2 MEMBER BOTKIN: Thank you, Dr.
3 Bocchini. And, Alaina, thanks for setting that
4 up. This is really a nice opportunity to be able
5 to present some of the results of a study that
6 we've been conducting here over the last couple
7 of years. And it's a wonderful opportunity for
8 us to be able to let you know what we found but
9 also, hopefully, obtain some feedback from this
10 very learned and experienced group about what
11 next steps might be in this particular line of
12 work.

13 And so what I'm going to do is present
14 a little bit of background material about issues
15 that this group will be quite familiar with, show
16 you a couple of movies that we've developed on
17 these issues, and then show you some results
18 about prenatal education, about these topics and
19 the response that we've had from our study.

20 All right. So again, a bit of Coals
21 to Newcastle for this group. Education in this
22 domain has primarily been through brochures

1 provided in birthing facilities. I think it's
2 widely recognized that that's not a particularly
3 effective way to educate or inform parents about
4 these issues.

5 For the most part, these brochures are
6 not read, providers do not consistently address
7 this material. Everybody knows the perinatal
8 period is not conducive to a thoughtful
9 discussion about these issues. And frankly,
10 there's been relatively little incentive for
11 health departments to do a more energized job in
12 this domain.

13 So what the surveys have shown over
14 the years, a number of them, is that parents want
15 to know about this information prenatally.
16 Pregnant for a long period of time, they're very
17 interested in almost anything that is relevant to
18 the baby. And so this theoretically would be an
19 opportune time to address these issues rather
20 than in the perinatal period alone.

21 But we do know at this point, or at
22 least what surveys tend to show, is that prenatal

1 care providers are not really plugged into
2 newborn screening and are not addressing these
3 issues on any sort of consistent basis.

4 So the AAP, back in 2000, had their
5 statement supporting prenatal education about
6 these issues. And in addition, in 2011 ACOG also
7 had a statement that basically says obstetric
8 care providers should make resources available to
9 patients during pregnancy.

10 And they provide a couple of thoughts
11 about how that would be done. And it's a fairly
12 passive statement in terms of making materials
13 available. But it's significant. And ACOG has
14 influence, substantial influence over the
15 obstetric care community. Although this
16 statement, to our knowledge, has not had a
17 substantive impact on how obstetricians address
18 this issue or whether they do.

19 So this is a study by Terry Davis'
20 group at LSU. Dr. Bocchini was a co-author on
21 this paper. This has been an influential study.
22 It really provides an evidence base for the type

1 of information that they felt ought to be
2 provided to parents.

3 They did a series of focus groups and
4 developed seven things parents ought to be,
5 parents ought to know about newborn screening.
6 And I'm not going to go through these in detail.
7 You can see how simple they are. And I think
8 this is consistent with our experience as well.
9 People don't need a list of the 35, 34 conditions
10 on the RUSP. That's not the type of information
11 that's useful for people.

12 It's really a basic set of information
13 about how the programs work, what they can
14 expect, what's going to happen to the baby, et
15 cetera. So our educational interventions have
16 been based around this data about what parents
17 want to know.

18 Residual dried blood spots, again,
19 folks are familiar with this issue, available on
20 virtually every baby for at least a period of
21 time and potentially are highly useful for QA,
22 QI, rarely for forensic uses and biomedical uses,

1 biomedical research, of course, being the primary
2 potential use of these. That is controversial.

3 I mean, QA, QI is really the primary, most
4 frequent use. But the research applications are
5 the ones that are potentially more controversial.

6 This is from NewSTEPS. Marcy Sontag,
7 from August of this last year, giving a breakdown
8 on what current blood spot retention times are in
9 state newborn screening programs. And so you can
10 see diversity still exists with a number of
11 states keeping them for ten years and longer.

12 So the blood spots really do have
13 extraordinary potential value for biomedical
14 research. Folks have done a whole host of
15 studies, genetic epidemiology, infectious disease
16 studies, HIV and CMV being good examples,
17 particularly useful in some of the early stages
18 of the HIV/AIDS epidemic and really demonstrating
19 who was infected, how many folks, pregnant women
20 were infected. Who were those folks in terms of
21 the geographic locations, et cetera?

22 I'm going to predict that the Zika

1 epidemic, it's not an epidemic yet, but the Zika
2 development is going to demonstrate the clear
3 utility of blood spots for demonstrating when and
4 where these infections are occurring in pregnant
5 women.

6 We are currently conducting a
7 literature review. We've identified so far 1,900
8 publications in the English language that report
9 use of dried blood spots from newborn screening
10 sources. And we're going to break those down on
11 what types of research are being conducted, what
12 states are involved, et cetera.

13 So we should have our report out in
14 the next six months or so about that, which I
15 think will help support the field in terms of
16 demonstrating how useful these have been
17 traditionally.

18 So we've been conducting a project
19 over the last couple of years, a four-year
20 project, NHGRI supported. I'm the overall PI.
21 Nancy Rose is the site PI for Intermountain
22 Healthcare in Salt Lake City. Miriam Kupperman

1 was site PI for UCSF and Siobhan Dolan at Albert
2 Einstein in New York City.

3 Oh, here's the rest of the team. This
4 was just a terrific team and quite a bit of fun
5 to conduct this study over the three sites.
6 Utah, California, and New York chosen as sites,
7 in part because of the quality of these
8 collaborators but also because they approached
9 newborn screening and dried blood spot management
10 in a similar way.

11 So we didn't have to create separate
12 informational resources for the individuals, for
13 the parents in those states. Their policies over
14 the retention of blood spots and permitting
15 parents to opt out was also consistent across
16 those three states. Obviously, all of that's
17 changed now in the aftermath of the
18 Reauthorization Act. But this was true during
19 the conduct of this study.

20 So here are our specific aims.
21 Determine what pregnant woman, young mothers, and
22 their partners want to know regarding the

1 retention and use of residual blood spots.

2 Create multimedia tools to use in the
3 prenatal care environment, so provide basic
4 information about newborn screening and then
5 dried blood spots.

6 Implement those tools and determine
7 the impact of that prenatal education on
8 knowledge, attitudes, and decisions regarding
9 newborn screening services and the retention of
10 dried blood spots and then to examine the ethical
11 implications of those results.

12 So here's the results from specific
13 aim one. What do parents want to know about this
14 dried blood spot issue, and policies, and
15 practices? So we, too, identified seven things
16 that sort of, theoretically based, is a good
17 number that people can readily remember.

18 So these are the first four of those
19 seven. And again, you can see the level of
20 sophistication of these. The parents want to
21 know basically what happens and what they can
22 expect in terms of information.

1 So a couple of key things that we
2 hadn't necessarily anticipated beforehand, no
3 extra heel pricks are done to collect the blood
4 for potential uses. So this was a big deal for
5 parents. They would have been quite a bit more
6 concerned about this practice had there been an
7 extra stick for the baby.

8 Safeguards in place to protect privacy
9 and to ensure the ethical conduct of research.
10 This was a revelation to most folks in our focus
11 groups. Folks had, of course, no idea what the
12 process of research is. And as you described,
13 basically the IRB process, it's like, well,
14 that's a pretty good idea. Because the other
15 ways don't have any idea how it is that
16 investigators decide what to do with these blood
17 spots.

18 One of the things that you'll see in
19 the movie is that consistently folks came forward
20 to say yes. I mean, what would be your concerns
21 about research in this domain? Folks don't have
22 a vocabulary, they don't have a background. And

1 so cloning came forward as the single most
2 frequent concern that folks had. So as you see
3 in the movie, we try to address that quite
4 explicitly.

5 So this is the other three of our
6 seven things parents want to know. You
7 identified blood spots, and therefore you're not
8 going to get results back from the research.
9 This was also a consistent expectation of folks
10 to say, well, if you're using my baby's blood
11 spot, I would expect to get the results of that
12 research back. So you have to let folks know
13 that that's not how the system is likely to work.

14 Then the last one, parents may request
15 that their baby's blood not be used. Again, this
16 is pre-Reauthorization Act language.

17 So our interventions are theory-based.
18 I'm not going to go through these, but we tried
19 to make these interventions as rigorous as we
20 could, both in terms of the empiric data from
21 parents about what they wanted to know and how to
22 structure these interventions.

1 So I'm going to show you the two
2 movies now and hopefully get some feedback.

3 (Off the record comments)

4 (Video 1 playback started)

5 FEMALE SPEAKER: Newborn screening,
6 what parents need to know. Most babies are
7 healthy when they are born. However, some babies
8 that look healthy at birth have serious diseases.

9 These diseases can cause them to
10 become sick within days. Without treatment,
11 these diseases can cause serious health problems,
12 such as mental retardation. But when these
13 diseases are detected early through newborn
14 screening, the babies can be given a special
15 diet, medication, or other treatment before they
16 become sick.

17 Newborn screening is one of several
18 tests done on all babies right after they're
19 born. It's one of the ways your state health
20 department is working to protect your baby's
21 health. Since the program began 50 years ago,
22 newborn screening has saved countless lives.

1 FEMALE PARENT: Before our first
2 child, I had no knowledge of newborn screening.

3 MALE PARENT: Eli came back from the
4 nursery with a A while on his heel. And I kind
5 of vaguely remember a nurse saying they took some
6 blood tests which was routine.

7 FEMALE PARENT: Our pediatrician
8 called me and let me know that the test had come
9 back either inconclusive or possibly positive for
10 PKU. We repeated the blood work to confirm that
11 it was positive for PKU. If we had not had
12 newborn screening, the results could have been
13 absolutely devastating. And they would have
14 mental handicaps at this point.

15 MALE SPEAKER: I worked in the
16 storeroom at the University of Utah Hospital. We
17 basically just stocked everything for all the
18 nurses and the doctors.

19 FEMALE PARENT: We try to make their
20 life as normal as possible. We've encouraged
21 them to never allow PKU to limit their activities
22 or their abilities.

1 FEMALE SPEAKER: What health
2 conditions are screened for? Because it's so
3 important that every baby be tested, newborn
4 screening is run by state health departments.
5 Different states test for different diseases, but
6 most screen for at least 30 treatable conditions.

7 FEMALE PARENT: How will my baby be
8 tested?

9 MALE SPEAKER: Newborn screening is
10 very simple test. While the baby's in the
11 nursery, a few drops of blood are taken from the
12 heel of the baby with a simple heel prick. Those
13 blood drops are put onto a filter paper and sent
14 to a laboratory. In the laboratory, those few
15 drops of blood can be used to measure a whole
16 host of disorders.

17 FEMALE PARENT: Will I receive the
18 test results?

19 FEMALE SPEAKER: The test results come
20 back to your baby's healthcare provider in about
21 two weeks. At your baby's first visit, be sure
22 to ask the provider about the results.

1 FEMALE PARENT: Will my baby need to
2 be retested?

3 FEMALE SPEAKER: Your baby might need
4 to be retested for these reasons. If there is a
5 problem with the blood sample, such as too little
6 blood was collected. If your state requires a
7 second set of tests. Your baby may need to be
8 retested if the first test shows your baby might
9 have a health problem. A second test can confirm
10 or rule out a serious disease.

11 If your baby needs additional testing,
12 a provider or the state health department will
13 contact you. They will tell you why your baby
14 needs to be retested and what to do next. It is
15 very important that you follow their
16 instructions.

17 FEMALE PARENT: Can I choose to not
18 have my baby screened?

19 FEMALE SPEAKER: Newborn screening
20 identifies babies with certain serious diseases.
21 The health benefits of early treatment for these
22 babies are so important that most states do not

1 ask parents' permission to do the testing.

2 However, most states allow parents to refuse
3 newborn screening for religious or personal
4 beliefs.

5 What parents need to know. It is
6 important to do everything possible to help
7 children lead happy, healthy lives. Newborn
8 screening is one way you can help your baby get
9 off to a healthy start.

10 Here is a summary of the key things
11 you should know about newborn screening. The
12 state requires a blood sample to be collected
13 from all newborn babies before they leave the
14 hospital. This sample is used to test for over
15 30 serious disorders.

16 Babies with these disorders may look
17 healthy at birth. If the disorders are found
18 right away, treatment can begin before a baby
19 gets sick. A nurse will take a few drops of
20 blood from your baby's heel for testing. The
21 test results will be sent to the baby's
22 healthcare provider and the hospital. Ask about

1 the results at your baby's first checkup.

2 If your baby needs to be retested, you
3 will be notified. For the health of your baby,
4 it is very important to get retested as quickly
5 as possible. Talk to your baby's healthcare
6 provider if you have questions.

7 FEMALE PARENT: As new parents, there
8 are so many things that we do for our babies that
9 help them to grow and help them to have normal
10 lives. And I think newborn screening is just one
11 of those responsibilities that we have as parents
12 to ensure that our children are healthy and can
13 have as normal a life as possible.

14 (Video 1 playback ended)

15 (Video 2 playback started)

16 FEMALE SPEAKER: After newborn
17 screening, what parents need to know about
18 leftover blood spots. Newborn screening is
19 testing a baby gets right after birth. These
20 important tests identify babies with certain
21 serious diseases so they can receive treatment
22 before they get sick.

1 Testing is done on small circles that
2 are punched out of the newborn screening card.
3 The testing usually doesn't use up all of the
4 dried blood spots on the newborn screening card.
5 Leftover blood spots are the un-punched part. In
6 this movie, you will learn about what happens to
7 this leftover blood.

8 What happens to the leftover blood
9 spots? States keep the blood spots for different
10 lengths of time. Some states keep the spots only
11 long enough to do the newborn screening tests.
12 Other states keep them for months or years. Some
13 states keep the blood spots for decades.

14 What might leftover blood spots be
15 used for? Most spots that are stored will not be
16 used after newborn screening. Some spots might
17 be used by state health departments to make sure
18 the newborn screening tests are working properly.

19 Leftover blood spots can be used to
20 check that labs get correct and consistent
21 results. This quality control is by far the most
22 common use for leftover blood spots.

1 Health departments also work to make
2 the newborn screening program better. Leftover
3 blood spots can be used to develop new tests for
4 babies. Fifty years ago, newborn screening
5 started with just one test. Today, babies are
6 tested for over 30 disorders. Many of these
7 tests were developed using leftover blood spots.

8 MALE SPEAKER: Now, these leftover
9 blood spots have proven to be remarkably valuable
10 for a variety of different types of research
11 projects. Now for example, projects have looked
12 at toxins in the environment that mothers may be
13 exposed to while they're pregnant. Those toxins
14 can pass into the baby's system and be detected
15 in these leftover blood spots.

16 Now, the second type of project would
17 be to look for infections that mothers might have
18 while they're pregnant. Again, these infections
19 may pass into the baby's system and be detected
20 in the leftover blood spots.

21 A third type of project has looked at
22 rare genetic conditions. And in these projects,

1 they may use tens of thousands or perhaps
2 hundreds of thousands of blood spots to look for
3 how common these conditions are in babies when
4 they're born.

5 For research purposes, there aren't
6 any extra heel sticks that are done for the
7 babies. They use extra blood that is just
8 leftover once the newborn screening testing is
9 finished.

10 FEMALE SPEAKER: Because newborn
11 screening is done on all babies in the United
12 States, leftover blood spots represent newborns
13 of all ethnic backgrounds, income levels, and
14 geographic areas. Leftover blood spots are an
15 important window into the health of the whole
16 population.

17 What are the safeguards for families?
18 If a baby's leftover blood spots are used in
19 research, personal information will remain
20 private. However, this means that the results of
21 any research done with the baby's leftover blood
22 spots cannot be returned to the parents.

1 Blood spots and research information
2 are stored in secure areas that only authorized
3 people can access. Insurance companies and
4 employers cannot get this information.

5 Anyone who wants to use leftover blood
6 spots for research must have permission from a
7 review committee made up of doctors, nurses,
8 scientists, and community members. The committee
9 allows spots to be used only in studies that are
10 ethical and protect babies and their families.

11 **MALE SPEAKER:** This type of research
12 has proven be remarkably safe for mothers and
13 families. Now, there have been no reports of
14 loss of privacy or confidentiality from research
15 using leftover blood spots.

16 **FEMALE SPEAKER:** Leftover blood spots
17 would never be used for things like cloning or
18 stem cell research.

19 What if a parent does not want their
20 baby's leftover blood spots used in research?
21 Parental consent may be required for the use of
22 leftover blood spots in most research. If a

1 parent does not want their baby's leftover blood
2 spots to be used in research, the baby will still
3 receive all the benefits of newborn screening.

4 Key things parents need to know about
5 the storage and use of leftover blood spots.

6 Here's a review of the key things you should know
7 about leftover blood spots.

8 Some states save leftover blood spots
9 after newborn screening is completed. Leftover
10 blood spots can be used to improve the public's
11 health in many ways. The most common use is to
12 maintain the quality of newborn screening tests.
13 No additional blood is collected. Only leftover
14 spots are used.

15 Safeguards are in place to protect the
16 privacy of babies and families and to ensure that
17 research is ethical. If used in research, the
18 baby's name or other identifiable information is
19 not attached to the leftover blood spots.

20 Because most research with leftover
21 blood spots is done anonymously, parents will
22 usually not get results back. Parental consent

1 may be required for the use of leftover blood
2 spots in most research.

3 For more information about leftover
4 blood spots, contact the newborn screening
5 program at your state's health department.

6 (Video 2 playback ended)

7 MEMBER BOTKIN: Okay. Thank you. All
8 right. So the length of these is a little long.
9 We struggled quite a bit with that. The feedback
10 we get from folks is that this is about the limit
11 of their attention span in that particular time
12 period. But we had difficulty trying to shorten
13 it.

14 The other thing I'll just highlight
15 for you that's relevant to our results is you can
16 see that there's a very positive spin on both
17 aspects of this enterprise, newborn screening,
18 certainly, but also the dried blood spots.

19 We tried to be reassuring, et cetera.
20 And I think you'll see some reassurance in our
21 data as a result. But again, we sort of
22 struggled with what the right balance should be

1 as you present the educational materials to
2 folks.

3 So here's our recruitment diagram
4 here. We approached 1,247 folks. Seventy-two
5 percent of them agreed to participate. So that's
6 a pretty good number. And folks were then
7 randomly assigned to one of three groups.

8 The control group for standard care,
9 those folks got whatever parents normally get as
10 part of their obstetric and neonatal service
11 about newborn screening and dried blood spots.

12 Yes, Joan?

13 MEMBER SCOTT: Was the demographics of
14 the individuals that you approached to look at
15 this apparent, you know, in the parental age --

16 MEMBER BOTKIN: Right.

17 MEMBER SCOTT: -- it would be?

18 MEMBER BOTKIN: Yes. I'll show you
19 that in the next slide. I'll give the whole
20 breakdown here on who agreed to participate with
21 us.

22 So folks just got whatever they

1 normally were going to get as part of their
2 obstetric and neonatal care. We had folks who
3 just looked at the newborn screening video. And
4 again, this is at about 36, 38 weeks gestation.

5 And then other folks watched both of
6 the movies. We subsequently then did follow-up,
7 post-delivery of the baby. And I'm going to give
8 you those results shortly, so about 77 percent,
9 75 percent retention rate at that stage. So
10 again, pretty good for this type of research.

11 Here's our demographics, 31 years.
12 And important point here, the gap in time between
13 our intervention and our assessment of knowledge
14 and attitudes was about seven weeks. So that's a
15 fairly substantial period of time.

16 Pretty good mix in terms of race and
17 ethnic background with 70 percent Black or
18 African American, 28 percent or so Hispanic.
19 Most of those folks chose to engage with us in
20 English. Although we had the movies in Spanish
21 and the surveys in Spanish as well for those
22 folks who wanted that, had that language choice.

1 I don't have all the income breakdown
2 here, but you can just see from these two sides
3 of the income spectrum that we had pretty good
4 representation for folks of modest incomes and
5 higher incomes and then a pretty good breakdown
6 in terms of education. We were not really
7 significantly over-represented with professional
8 or graduate degree folks. The majority of folks
9 had a college education.

10 So here's our results. Knowledge
11 about newborn screening, so standard care group,
12 69 percent correct and then increasing to 79 and
13 75 with the intervention.

14 And we'll put a highlight here in a
15 second, what I think is an important outcome of
16 the whole study which is the actual knowledge
17 increase is not all that impressive. But what
18 you'll see is a more dramatic difference in the
19 changes in attitudes about these phenomena.

20 Nevertheless, statistically
21 significant increase in knowledge seven weeks
22 afterwards. And if you break that down by

1 education, you see a very similar effect. So
2 folks who had high school or less are here in the
3 brown, some college in the light green, and then
4 professional or graduate degree. And so
5 consistent effect regardless of education level,
6 although the starting point differed with each of
7 those groups.

8 Also true for ethnicity here, showing
9 you Hispanic and non-Hispanic participants.
10 Again, parallel results regardless of ethnicity.
11 And this is knowledge about newborn screening.

12 Here's knowledge about dried blood
13 spots. And the dried blood spots, of course, we
14 only gave them information in the dried blood
15 spot plus newborn screening here.

16 And so you would expect these two to
17 be similar. And indeed they are. There's no
18 statistically significant difference between
19 these two groups but significant increase in
20 knowledge about dried blood spots for the folks
21 who saw the dried blood spot movie.

22 Similar sort of pattern here about

1 dried blood spots with respect to the education
2 level of the participants. Professional or
3 graduate folks saw a fairly significant increase,
4 so a more dramatic increase in their knowledge.
5 But each of the groups showed increase in
6 knowledge across that range, similarly with
7 ethnic background.

8 So here are some of the attitude
9 questions. From your experience and what you
10 understand about newborn screening, how
11 supportive are you of this program?

12 And what you see, of course, is that
13 all three groups are very highly supportive.
14 Folks get the whole notion of newborn screening,
15 and they're very supportive of these programs.
16 So all of these groups are 96 to 99 percent
17 either very supportive or moderately supportive.

18 You see some change here with many
19 more individuals in the very supportive category
20 who saw the newborn screening movie in
21 particular.

22 I'm satisfied with the information I

1 have received about newborn screening. And folks
2 could either completely agree with that
3 completely disagree. And here you see, again, an
4 increase in satisfaction with both of the movie
5 groups here compared to standard care baseline.

6 So the degree of increase, we think,
7 in the attitudes and support for the program
8 really was out of proportion to the actual
9 knowledge increase that folks had.

10 So I think that there may be a
11 phenomenon here where folks appreciate being told
12 about these things. It engenders a higher level
13 of trust in the program and a higher level of
14 satisfaction, even if their knowledge levels have
15 not dramatically improved.

16 Satisfied with the information they
17 have about the use of dried blood spots after
18 newborn screening. And of course, both of these
19 groups got nothing in the way of dried blood spot
20 information. So they weren't particularly
21 satisfied. And the dried blood spot movie group,
22 a pretty high level of satisfaction between

1 either completely agree or mostly agree.

2 How concerned are you that your state
3 saves leftover blood spots from babies after
4 testing is done? So again, we see a progressive
5 increase here in particular with this group being
6 not concerned at all at 43 percent or not very
7 concerned at 28 percent. But still 12 percent of
8 folks with a high level of concern.

9 So this decreased somewhat with the
10 education, but did not go away. So I think this
11 is a feature to be expected. There's a modest,
12 smaller number of folks who will remain concerned
13 about this practice, sort of regardless of our
14 educational interventions.

15 How supportive are you of using these
16 blood spots for research? Really a high degree
17 of support across the board. And again, that
18 level of support increases with more information
19 about this practice.

20 In your opinion, when would be the
21 best time to educate parents about newborn
22 screening? And you can see almost identical

1 responses across the three groups.

2 So our education didn't have any
3 impact on responses here, with the largest group
4 saying early in pregnancy, consistent, 37 percent
5 for each group saying later in pregnancy, and
6 then smaller percentages here saying after the
7 baby is born. So again, reinforcing the fact
8 that folks really want this information
9 prenataally.

10 So some obvious conclusions here. The
11 dynamics of the population screening for rare
12 disorders makes adequate education a real
13 challenge.

14 Parents want this information in the
15 prenatal period, and we think that concise, high
16 quality, multimedia tools can increase knowledge
17 and enhance support for these programs. So I
18 think that such --- so this is sort of a core
19 conclusion.

20 I think state programs can be more
21 aggressive about education without any blowback
22 or negative consequences. I think it enhances

1 the reputation and trust in these programs.

2 Now the data I'm not showing you here
3 is that we had nine parents who said that they
4 declined newborn screening in our study. All of
5 those people were in the standard care group.

6 And we got narrative answers from them
7 about why they refused newborn screening. And
8 almost everybody gave an answer that made it
9 clear they didn't understand what newborn
10 screening was, that they were confusing it with
11 prenatal screening.

12 Now we had three people in the dried
13 blood spot group and two in the standard care
14 group who said they called the state to have the
15 state not use the dried blood spots for research
16 purposes. So again, no difference in terms of
17 the dropout of either newborn screening or dried
18 blood spots through the education.

19 Now, of course, we're only engaging
20 here, and we're not engaging all tens of
21 thousands of people in these states. And so a
22 small percentage increase in refusal would be

1 significant. But we didn't detect any impact of
2 that sort.

3 So the challenge is now how do we
4 effectively incorporate multimedia tools into
5 prenatal care and how to effectively promote
6 choice about dried blood spots in the prenatal
7 environment for postnatal retention and use,
8 assuming that informed consent requirements are
9 going to remain in place for the indefinite
10 future.

11 Is it conceivable that we could foster
12 choice during the prenatal period rather than the
13 postnatal period? I think we can foster at least
14 education in that regard.

15 So our efforts now, we've got a small
16 implementation study that we're doing in Utah
17 that would like to take this work forward to try
18 to see how this can be done.

19 Our concept is that if we can decouple
20 some of this education from the responsibilities
21 of the clinicians themselves it would help.
22 Because I think we're hearing from obstetricians

1 that they just don't have time. There's just too
2 many other issues. This is not a high priority
3 for them. And having the obstetrician set aside
4 time is probably not a realistic expectation.

5 But if we can embed links to films in
6 scheduling emails or have information available
7 in the clinic where folks can go to websites and
8 tend to this information, you know, those are
9 beginning to be things that we're attempting to
10 do that may make some impact on this domain.

11 So I thank you for your attention to
12 this. And we've got, fortunately, a little bit
13 of time left. I very much welcome any questions,
14 certainly, or any comments or thoughts about this
15 effort.

16 CHAIR BOCCHINI: Jeff, thank you for
17 sharing that with us. That was a -- sharing your
18 resources -- very nice presentation and good
19 information. So, let's go around the table. And
20 I think everybody raised their hand at the same
21 time. So why don't we start with Kamila, and
22 then we'll go around the table.

1 MEMBER MISTRY: I hope mine's an easy
2 question. So I was just wondering about non-
3 participants. So in your flow chart, when folks
4 didn't participate, did you look at who those
5 folks were and how that could have affected the
6 overall result?

7 MEMBER BOTKIN: We did. And actually
8 there was no statistically significant difference
9 in those who declined participation from those
10 who did participate. So we did not see any real
11 discrepancies in that regard.

12 MEMBER MISTRY: Even with regard to
13 folks that refused the newborn screening and ---
14 was that one of the characteristics you looked
15 at?

16 MEMBER BOTKIN: Oh, folks who refused
17 newborn screening, those were nine people.

18 MEMBER MISTRY: No, I mean when you
19 asked, when you asked people to participate ---

20 MEMBER BOTKIN: Right.

21 MEMBER MISTRY: -- that wasn't an
22 inclusion or exclusion criteria. So where did

1 those people --- did you look at that as a
2 characteristic of folks who participated or -- I
3 hope I'm asking this correctly --- who
4 participated or didn't participate? You know, if
5 you would look at participants versus non-
6 participants and make sure that there was no
7 differences with that, one of the characteristics
8 you looked at.

9 MEMBER BOTKIN: Was what one of the
10 characteristics?

11 MEMBER MISTRY: Whether they refused
12 newborn screening. Because the nine ended up in
13 the final. But I'm saying was that ---

14 MEMBER BOTKIN: Right.

15 MEMBER MISTRY: -- ever looked at as
16 ---

17 MEMBER BOTKIN: No. That was not. We
18 did not look at refusal for the folks who had
19 declined to participate with us. We didn't have
20 that information.

21 And all of our --- we didn't want to
22 try to draw information from the state programs

1 about peoples' decisions. So we only got their
2 self-reports. So we didn't have that information
3 on folks who didn't participate.

4 CHAIR BOCCHINI: Cathy?

5 MEMBER SPONG: Thank you for the
6 presentation. And I just have a quick question.
7 Like, if it's going to be implemented in a
8 prenatal clinic, you know, and maybe I missed
9 this, the video that talks about newborn
10 screening in general, do you think there will be
11 any confusion from a mother's part about prenatal
12 testing or screening during the pregnancy versus
13 waiting until, you know, newborn screening? I
14 just was wondering if there was ---

15 MEMBER BOTKIN: Yes.

16 MEMBER SPONG: -- any concern about
17 that. Granted, it might not make a difference.

18 MEMBER BOTKIN: Well, I think
19 particularly since our intervention was at sort
20 of 36, 38 weeks --

21 MEMBER SPONG: Yes, that one.

22 MEMBER BOTKIN: -- that folks --

1 MEMBER SPONG: I was thinking earlier.

2 MEMBER BOTKIN: Folks would minimize
3 the confusion there. But it is pretty clear that
4 when those folks, those nine people said that
5 they had refused newborn screening, that they
6 were talking about a very type of screening.

7 So I think there is risk that there
8 will be confusion. The other confusion that we
9 were most concerned about was confusing newborn
10 screening and confusing the dried blood spot
11 issue. And we didn't want folks to say well, you
12 know, my best option for -- if I'm concerned
13 about dried blood spot, my best option is to not
14 do newborn screening.

15 We didn't see that happen. But we
16 tried to give a very different look and feel to
17 the movie so that it sort of clearly separated
18 that these were different issues that they had to
19 be aware of.

20 MEMBER KELM: So thanks, that was a
21 really nice presentation and very nicely done
22 videos. I have a couple of questions. One

1 question, you sort of touched on it. But it
2 almost raised, to me, by having the two separate
3 movies, that this is something you should be
4 concerned about.

5 So I was interested in why not just
6 include, as part of that initial movie, well,
7 this is what happens to your blood spots
8 afterwards. And I recognize that they get too
9 long after a while, and so it may not be feasible
10 to do that. But it almost raises it as another
11 issue, where someone may not have thought of it
12 as an issue. That's my first question.

13 MEMBER BOTKIN: Yes. And as we're
14 going into a small implementation pilot, that's
15 exactly what we're doing. We're combining those
16 two movies in a way that makes it a more seamless
17 experience. And you can eliminate some of the
18 time just by the little bit overlap there is
19 between the content of those. So I think that
20 there's probably no good reason to have a
21 separate ---

22 MEMBER KELM: I mean, I do think it's

1 good to have separate videos in the sense if
2 someone has that question. You can just give
3 them that information. But I wonder if it
4 wouldn't also be useful to have one video that
5 kind of covers it all. So, I mean, I think it's
6 well done. And there's always more work to be
7 done. So I just wanted to raise that.

8 I was curious a little bit about the
9 idea of using blood spots for Zika. We have not
10 heard that at all. And I'm wondering if you're
11 aware of someone who is working on that.

12 You know, Zika virus itself can only
13 be detected for a very, very short period of
14 time. And if you're looking for the IgM, it
15 cross reacts with Dengue currently. So it's, in
16 an endemic area it's very difficult to use.

17 I don't know that the -- I'm
18 interested to know would you really be able to
19 and are you aware of people looking at blood
20 spots to, as you said, get the timing of
21 infection. And how would you do that?

22 MEMBER BOTKIN: Yes. So you clearly

1 know much more about it than I do. And --

2 MEMBER KELM: Oh, I was excited that
3 you knew something.

4 MEMBER BOTKIN: No, I'm not aware of
5 anybody who's doing that. But it seemed
6 conceptually feasible. But it may well not be
7 for exactly the sorts of reasons you -- I don't
8 know whether, Joe, you've heard anything about
9 Zika with blood spots or not.

10 MEMBER BOYLE: I have not.

11 MEMBER BOTKIN: Yes.

12 MEMBER CUTHBERT: Yes. So we looked
13 in ---

14 MEMBER BOTKIN: Well, you heard it
15 here first, folks.

16 MEMBER BOYLE: Yes. I was going to
17 say we looked into it a little bit. And I know
18 Carla is here as well. And I heard from a
19 laboratory perspective it's very challenging to
20 use the --- particularly the RNA. It gets very
21 sticky. Is that right?

22 MEMBER CUTHBERT: We've not been

1 approached. So the guidance that I got from my
2 director was that the infectious disease people
3 at CDC have this under control.

4 And they know that we do blood spots.
5 And if they have an interest in contacting us
6 they would. But I think that, I don't think that
7 they have approached it, they have an interest
8 yet in doing it that way. But we'll be available
9 if they --

10 MEMBER BOTKIN: Okay. Thank you for
11 clarifying my optimism that that might be an
12 issue.

13 MEMBER BAILEY: So, you know, first,
14 great videos and everything, wonderful images of
15 babies, and children, and great educational
16 principles, and adult learning, and so forth. So
17 really, kudos to you and your team.

18 I have two things. One is are these
19 available to other people, either for research
20 purposes or for clinical purposes now? Or are
21 you still keeping them and working on them? And
22 then secondly, you already asked the question I

1 was going to ask which is, okay, these are great,
2 how do we get people to actually look at them.

3 MEMBER BOTKIN: Yes.

4 MEMBER BAILEY: And to me, that's the,
5 in this day and time, 12 minutes of video is an
6 eternity. And how do we get people, first, and
7 the people who we most want to see it? That's
8 the implementation challenge, I think. And
9 obviously you're working on that.

10 MEMBER BOTKIN: Well, we're thinking
11 about it. There are just some enormous
12 challenges in that regard.

13 So these are basically finished now.
14 The dried blood spot one we did revise to be
15 consistent with the Reauthorization Act. So it
16 actually is a little bit different than what
17 families saw back in the study.

18 We are happy to make these available.
19 We haven't found the right avenue to do that.
20 They're not posted yet in a downloadable form.
21 But we're sort of discussing the best way to
22 approach this.

1 And I've even thought about the
2 possibility of creating a commercial product out
3 of these as a way to market it in a way that, I
4 don't know, might be more attractive as a
5 commercial product as opposed to just somebody
6 posting it on the Web. But we're thinking about
7 all of those possibilities.

8 MEMBER MCDONOUGH: A very impressive
9 video, it was high quality. The only suggestion
10 I have on the first video, when the results are
11 often, if they're positive, get there sooner than
12 the two weeks that's indicated in the video.

13 I think there's an opportunity for use
14 in hospital prenatal classes, doctors' waiting
15 rooms, maybe not in the doctors' clinic office,
16 but a lot of doctors or clinic waiting rooms have
17 ongoing educational stuff that just runs on a
18 continuous loop. And you can get information in
19 there where people often are waiting more than
20 six minutes to get to see their physician. And
21 so I think it could be done prenatally.

22 And I think there's going to be a good

1 market for it, particularly if the state public
2 health labs get out to the hospitals and start
3 promoting this. A lot of state public health
4 labs annually visit hospitals. And this is
5 something they could show them.

6 And then I think it should be repeated
7 in the hospital. When you're there for a day and
8 a half having a baby, a lot of moms, when I go in
9 there and bring the baby in, or talk about the
10 baby's exam, how the baby's doing, they're
11 watching a video on something, breast feeding, or
12 changing diapers, or whatever it's going to be.
13 And I think this would fit well in there.

14 So I just want to compliment you on
15 the very high quality. And I think there'll be a
16 market for it and a way to get this out. And I
17 think it's going to, it'll be really nice
18 actually if you had this, if this would have been
19 available for Congress when we went through the
20 Reauthorization Act, and they could have a chance
21 to look for that. Maybe we're not left with some
22 of these obstacles we have.

1 MEMBER BOTKIN: Good. Well, thank
2 you. And we need to try to better understand
3 exactly how those video tools, other video tools
4 are being used in both the prenatal and postnatal
5 environment.

6 I think hospitals may have a health
7 channel that may include stuff relevant to all
8 patients as opposed to this particular subclass
9 of patients. But we need to better understand
10 the landscape to see where this might fit.

11 MEMBER BOYLE: Yes. So we know the
12 privacy issues have a lot of regional variation
13 based on our experience with storage of blood
14 spots. And you have three sites. Is that
15 correct?

16 MEMBER BOTKIN: I'm sorry?

17 MEMBER BOYLE: You had three sites?

18 MEMBER BOTKIN: Yes.

19 MEMBER BOYLE: New York, California,
20 Utah.

21 MEMBER BOTKIN: San Francisco, New
22 York, Salt Lake.

1 MEMBER BOYLE: And, I guess, thinking
2 about Utah versus the other two sites, did you
3 see any variation by sites?

4 MEMBER BOTKIN: No, we didn't,
5 actually. Yes, there were no significant
6 differences by site.

7 MEMBER BOYLE: And then one other
8 question. And maybe I just didn't follow it. So
9 your seven principles, one of them was if a blood
10 spot is used in research, the baby's name is not
11 attached to the blood spot, which is not
12 necessarily true if it's used in anonymized
13 research. So I just felt like that was perhaps -
14 -- maybe I was misunderstanding that piece.

15 MEMBER BOTKIN: Well, it's obviously
16 a three level issue. You have spots that are
17 linked back to identifiers. But typically, in
18 those contexts, the investigator himself, herself
19 does not have that identifying information.

20 And that's why, in most of those
21 circumstances, of course, it's not human subjects
22 research in that particular context even though

1 somebody else might be able to track back that
2 identity.

3 I think many spots are used that are
4 completely anonymized. And so part of the
5 challenge for us was to sort of articulate that
6 type of protection in a way that we thought was
7 accurate and understandable.

8 So I think that statement's still
9 true. Although once we do our study of the 1,900
10 publications, we'll have a better idea exactly
11 what level of the identification was done. I
12 mean, I'm only aware of one study in which
13 identifiable blood spots were used. It was a CMB
14 study in Utah actually. But I don't know if
15 that's helpful.

16 CHAIR BOCCHINI: Joan?

17 MEMBER SCOTT: That was really great,
18 Jeff, and very interesting. As I recall, about
19 half of your participants had had a child before?

20 MEMBER BOTKIN: Yes.

21 MEMBER SCOTT: Did you notice any
22 difference based on whether or not they were

1 repeat parents or this was their first pregnancy?

2 MEMBER BOTKIN: Good question. I
3 don't think we looked at that. But we can easily
4 pull those data. So that actually would be
5 interesting.

6 MEMBER SCOTT: It might be also
7 interesting to ask if they have any family
8 history of issues. Because I would expect that
9 would also skew responses.

10 MEMBER BOTKIN: Yes. And it might be
11 -- well, yes. What we found in a separate study,
12 looking at parents of kids with PKU and kids with
13 leukemia, they have distinctly different
14 attitudes about dried blood spot research than
15 families in the general public. So that's a good
16 point.

17 And I don't remember whether we asked
18 whether families had a child affected with
19 something. Doesn't necessarily have to be a
20 newborn screening condition. But we would
21 anticipate that might impact attitudes.

22 MR. WATSON: So I'm curious what's

1 going on with ACOG and AWONN? Last I saw, they
2 were sort of doing education for themselves about
3 newborn screening at ACOG. Do we know where they
4 are? Because obviously getting their support for
5 getting this into offices and things would be key
6 to getting it out there.

7 MEMBER BOTKIN: I don't. We've had
8 some discussion, or Nancy Rose has had some
9 discussion with their education office. And they
10 are interested in these materials. But we
11 haven't taken any particular steps at this point.
12 I'm not sure what ACOG otherwise is doing. We
13 have a representative here, don't we?

14 CHAIR BOCCHINI: We do. Is Dr. Biggio
15 on the phone?

16 (No audible response)

17 CHAIR BOCCHINI: No, not today. But
18 we do.

19 MEMBER SPONG: I can tell you they
20 have a committee opinion out on it saying what
21 should be done.

22 MEMBER BOTKIN: Right. Yes.

1 MS. BONHOMME: Hi. This is Natasha
2 Bonhomme with Genetic Alliance. We've been
3 interested in that question as well.

4 So in June we are actually going to be
5 doing focus groups with the nurse leadership of
6 AWONN to see where those types of decisions
7 actually take place and how do you actually
8 implement change.

9 This focus group will be around
10 timeliness, but I think one of the reasons why we
11 don't know is, while we may be able to find a
12 committee opinion, we oftentimes don't actually
13 ask the nurses who are in the nurseries how does
14 change actually happen here.

15 So once we do those focus groups, and
16 that's in partnership with NewSTEPS 360, we'll be
17 happy to share kind of from the nurses
18 themselves, like, how do you actually implement
19 something in the nursery, how do you get
20 education at that level. We'd be able to share
21 that.

22 MEMBER BOTKIN: I'm sorry. You mean

1 in the obstetric service domain?

2 MS. BONHOMME: They will be nurses
3 from across, so whether they were prenatally or
4 in the nursery. So hopefully that will give us
5 at least some insight in terms of how do things
6 actually happen on the ground there.

7 MEMBER BOTKIN: Great.

8 MS. GREENE: Carol Greene, SIMD. Also
9 relevant to the issue, although it's getting a
10 little old now, we were not able to publish a
11 survey of neonatal nurses and nursery staff that
12 shows extremely poor knowledge of newborn
13 training. Maybe we'll try and resurrect that
14 paper and get it published. And so that would be
15 another avenue.

16 I would also like to thank you for the
17 beautiful video. I do wonder what might be your
18 plans before very large distribution of such a
19 very beautiful video that answers almost all of
20 the questions.

21 But I'm hoping there might be room for
22 some revision of a next version. Because some of

1 the things that, some of the questions about
2 confusion where things could perhaps be more
3 clearly explained, but also the study that
4 Genetic Alliance and University of Maryland
5 published that shows what questions families
6 specifically have about newborn screening when
7 they have received a positive newborn screening,
8 or also some of those people who were just part
9 of a focus group who had not.

10 The video leaves unanswered some of
11 those key questions, like what is this positive
12 screen business, that means the lab made an
13 error. I mean, it's just a simple explanation of
14 what is a screen. And we set a bar, and we find
15 people who actually don't have the disease. And
16 that's why we need to recheck.

17 So there are some fundamental
18 questions that we've discovered people have that
19 were not addressed. And so I'm hoping there
20 might be room for another version before this
21 massive distribution.

22 NYMAC has a video. I think Genetic

1 Alliance has a video. And I hope there might be
2 an opportunity maybe with the education committee
3 to sort of pull together the best with the best
4 and make one that would then be the one to ---

5 MEMBER BOTKIN: Good. Thank you. I
6 know we're thinking about it. I know Don's group
7 is thinking about creative tools in this domain.
8 And the nice thing about sort of electronic tools
9 is you can layer them, or you can put a very
10 simple Page 1. And if folks want to collect for
11 deeper levels of information then that's
12 available.

13 So I think that's the type of resource
14 that would be ideal. Because obviously what we
15 found is trying to pack everything onto that
16 trifold brochure isn't effective.

17 MS. TARINI: AAP. Thanks, Jeff. So
18 two questions. One, and a comment to precede, to
19 Catherine's point about separating out the
20 videos, I actually think the separation provides
21 an interesting point which we had discussed in
22 the meetings at Utah about these findings.

1 In Slide 25, your knowledge base
2 between standard of care and newborn screening is
3 pretty similar. You get 42 to 46. And really,
4 the knowledge about dried blood spots increases
5 tremendously, right.

6 But the other piece that's interesting
7 to me is the support of the program. You get a
8 lot of support just by simply viewing the video.
9 So it goes back to this point -- I guess it's not
10 a question now, it's just a comment, sorry ---
11 that knowledge doesn't always translate into
12 support.

13 You know, and I'm saying we're
14 persuasive, but that one can be supportive and
15 still not answer all the knowledge questions
16 correctly. So it's important, as you've shown
17 here, to actually look at what our objectives are
18 in terms of education. So, that's all.

19 MEMBER BOTKIN: Yes. Excellent point.
20 And I think if we, I mean, we would have loved to
21 have seen a higher level of knowledge come out.
22 Because their questions were very simple, which

1 is why we had a baseline correct response rate
2 that was so high.

3 A little bit concerned that there's a
4 certain ceiling effect. If you make the
5 questions so easy then, you know, you're not
6 going to see any increase in knowledge, because
7 everybody gets them right at the beginning.

8 So, I think increased knowledge,
9 particularly over that span of time, is a
10 particular challenge. But the fact that we saw
11 substantial degrees of increased support for us
12 was heartening.

13 So I don't, I think that that's, from
14 my perspective, a good goal. Because obviously
15 we think both of these activities are worthwhile,
16 and should be supported.

17 CHAIR BOCCHINI: We'll go back to
18 Natasha, and then we have three people on the
19 phone who want to make comments or ask questions.

20 MS. BONHOMME: Natasha Bonhomme,
21 Genetic Alliance. Thank you so much for
22 presenting this, the videos, and also the data.

1 I have a couple of questions and a couple of
2 comments.

3 One question, for the group that saw
4 both videos what was, was there a time difference
5 in between the videos? Or did they see them one
6 after the other?

7 MEMBER BOTKIN: They saw them one
8 after the other.

9 MS. BONHOMME: One after the other.
10 Okay. And then, did you ask how people wanted to
11 get this information, or where they would like to
12 see these videos, as part of --

13 MEMBER BOTKIN: No. Actually we just,
14 we asked them their assessment of what they saw.
15 But we did not ask that question. That would
16 have been interesting.

17 MS. BONHOMME: Because I think that's
18 one thing that we found, is we know where we
19 think people should be seeing things. But people
20 are finding information, particularly around
21 pregnancy and early childhood, in a range of
22 different ways.

1 And so, being able to get a better
2 sense of where they would like to see it I think
3 could be interesting, and maybe some that, as
4 you're doing your implementation, you may be able
5 to dig into a little bit more of the how, the
6 process. I think that could be some good
7 information.

8 Let me see, I think I have one other.
9 Oh, and then the two comments. The one piece
10 around the confusion between prenatal screening
11 and newborn screening. I think that's something
12 that we consistently see. The clearinghouse
13 constantly gets questions around prenatal
14 screening in our contact form.

15 And we just have to reroute that. So,
16 on the one hand I think it's good that people are
17 engaged in their health. And it's great that
18 they can ask the question. And maybe it's not so
19 much trying to make such a harsh distinction, but
20 just to be able to guide people to the
21 information they need when they ask the question.

22 And then secondly, to the point about

1 having videos in hospitals. We actually have
2 the, a video we did with Children's National
3 around congenital heart disease. We work with
4 the Newborn Channel. And I think just hospitals
5 contract out with these different agencies, and
6 then just run whatever's on their platform.

7 And so, currently that video is being
8 shown in over 1,000 hospitals. So, once you guys
9 think you're maybe ready, or think that could be
10 a form of dissemination, we'd be happy to share
11 that contact with you.

12 Currently they screen that video in
13 English and Spanish three times a day. Just to
14 give a sense of what that landscape is like.

15 MEMBER BOTKIN: Yes. Excellent.
16 thank you. Quick response there. Just, I'll
17 highlight here the lack of challenge with
18 generalized ability.

19 We had our staff in the prenatal
20 clinics, working directly with the patients.
21 This was during a waiting time, so we weren't
22 impinging on the care of the patients. But it

1 wasn't the regular staff doing this.

2 And in addition, they would tell us,
3 you know, this was on an iPad. They don't have
4 iPads. And if they were to have iPads, they'd
5 have to worry about them getting stolen. And
6 then they have to worry about making sure they
7 were clean between patients. And so, you know,
8 each little thing has its own set of barriers to
9 overcome in that regard.

10 CHAIR BOCCHINI: So we have Fred on
11 the phone. Fred.

12 MEMBER LOREY: Yes. I'm fine. I was
13 just trying to let you know that Susan and Chris
14 want to speak.

15 CHAIR BOCCHINI: Okay. All right.
16 Susan, you were next on the list. Then Cate's on
17 the list too.

18 MS. TANKSLEY: Thank you. Can you
19 hear me?

20 CHAIR BOCCHINI: We can.

21 MS. TANKSLEY: Great. Just, thank you
22 for all the work that you've done in this arena.

1 You know that this is a special interest of mine.

2 I wanted to respond to, there was a
3 comment made earlier about whether the research
4 is anonymous, versus some that might be
5 identified. And that's a distinction that we
6 feel needs to be made. And so, we try to work
7 things appropriately.

8 Because specimens can be contributed
9 for research in an identified manner, if the
10 parents give specific consent for that. And so,
11 we try to take care in the messages that we put
12 out, so that parents are made aware of that, you
13 know, kind of like, they won't be used in a way
14 that can identify you unless you give specific
15 consent.

16 And so, they have been used. And one
17 good example are the studies that Dr. Park did.
18 We contributed many specimens to that where the
19 parents gave specific consent to send those to
20 her.

21 The second thing, I wanted to go back
22 to the comment that Beth made about knowing the

1 objective. Making sure you know the objective
2 of, you know, what do you want to get out of the
3 video? One of the things, you know, well, our
4 law changed multiple times.

5 And so, our first law required
6 disclosure that specimen would be, or could be
7 used for quality assurance, quality control
8 research. And then we moved into a consent
9 requirement for the parents to give consent.

10 And when it came time where we had to
11 collect consent, we wanted parents to make a
12 decision. So we wanted to inform them, so that
13 we could record whether they wanted it used or
14 not. So they necessarily didn't have to give
15 consent. They could also tell us, no, they
16 didn't want them used specifically.

17 So, there are some who you will never
18 change. And it's more important for the
19 integrity of the program, and keeping the program
20 safe, to be able to show them that their wishes
21 are also going to be taken, you know, that we
22 will take of their wishes as well. Thank you.

1 MEMBER BOTKIN: Good. Thank you. So
2 I know we're over time here. But one quick
3 comment about goals that I think I would
4 emphasize.

5 One of the goals I think we have here
6 is to help people be more informed patients.
7 Certainly what found in the focus groups is that
8 if you start the conversation by saying, you
9 know, what do you know about newborn screening?
10 What sort of questions do you have?

11 Folks don't have any questions,
12 because they don't know anything about it. But
13 you give them ten or 15 minutes' worth of
14 background, and then you can fill up the next
15 hour with questions and conversation.

16 And so, hopefully this is the sort of
17 thing that if you can trigger some knowledge,
18 then folks will approach the doctor to say, I
19 have these questions or concerns.

20 CHAIR BOCCHINI: So, Chris, we're
21 going to have you ask your question or comment.
22 And then Cate. And then we'll need to close the

1 discussion to move to the next topic.

2 MR. KUS: Okay. This is Chris. Jeff,
3 my question is, what's your thinking on education
4 relative to hearing screening and critical
5 congenital heart disease? Natasha mentioned that
6 there's a video for that. So the question is,
7 will we need three videos?

8 MEMBER BOTKIN: I don't have a good
9 answer for that. I think that that would be
10 overwhelming. But obviously those resources
11 ought to be out there and available. So how to
12 integrate all that together in an effective
13 fashion I think is a terrific question, and a big
14 challenge.

15 Because I think we didn't deal with
16 that at all. And in part because we were so
17 interested in the dried blood spot issue
18 specifically. But it's just an excellent point.

19 MS. VOCKLEY: Cate Wash Vockley, from
20 National Society of Genetic Counselors. Jeff, I
21 was just wondering, it's such a complicated
22 topic. We use these words every day. But did

1 you get any feedback from families about the
2 language used? And might that have some impact
3 on knowledge gained?

4 MEMBER BOTKIN: Language in terms of
5 --

6 MS. VOCKLEY: The complexity of the
7 words. I mean, even the word confidentiality is
8 confusing.

9 MEMBER BOTKIN: We did not get
10 anything specific. Folks clearly gave us
11 feedback about the length of the movies. For the
12 most part they were otherwise supportive. I
13 don't think we, I don't recall any specific
14 comments to say it was hard to understand.

15 MS. VOCKLEY: Okay. Okay. Thank you.

16 MEMBER BOTKIN: Okay. Thank you.

17 MEMBER MATERN: Okay. Just one quick
18 comment. Thank you again for all the work. It's
19 really good. There's probably in Texas, but also
20 in Minnesota, one or two districts where you
21 might want to try those videos out, and see what
22 their feedback is.

1 And the other is, looking at 1,900
2 publications where leftover blood spots are used
3 is impressive. If someone who doesn't know this,
4 they might think, well, that means there's a lot
5 of problems with blood spot testing, that you
6 have to have so many publications. Or this
7 should be a perfect test by now.

8 So, as you go through it, I suggest
9 you kind of divvy out what actually let to
10 improvements in newborn screening or, versus --
11 Because it seems like parents want to know that
12 it actually did something good.

13 MEMBER BOTKIN: Okay.

14 MEMBER MATERN: And it's not just
15 paper.

16 MEMBER BOTKIN: Yes. And I think
17 we're planning on looking at, was this
18 application related to newborn screening? Or was
19 it related to some other health problem. Good.
20 Thank you.

21 CHAIR BOCCHINI: Thank you very much,
22 Jeff. And thank you everybody for the comments

1 and questions. Next we're going to have reports
2 from two workgroups, before we break for lunch.

3 So, the first is the Cost Analysis
4 Workgroup Update. This will be presented by Alex
5 Kemper, who chairs our Condition Review
6 Workgroup. He is at Duke University in the
7 Department of Pediatrics, and the Clinical
8 Research Institute.

9 MR. KEMPER: Thank you. While
10 Alaina's getting things set up, Jeff, it was nice
11 to hear about you having to review 1,900 papers,
12 and not us for a change.

13 And I guess the other thing I was
14 thinking about as I was sitting back there is, I
15 wish we could have that sort of melancholy piano
16 music go as we talk about costs. But sadly, we
17 don't have that.

18 So, in the next 30 minutes or so I'd
19 like to update everyone with where we are. And
20 K.K.'s sitting in the back, and I may call her
21 up. Because there's some numbers that just came
22 in this past week, and I want to make sure that I

1 explain things correctly.

2 I can't use my little keyboard. But
3 I'll muddle along. So, this is just a listing of
4 -- Oh, good. Here comes Alaina to rescue me
5 again. But, members of our workgroup, some,
6 which are -- Oh, I have to use this? Okay. Some
7 of which are here. And I really appreciate
8 everybody's input.

9 Just to catch you up. And again, I
10 noticed ironically we have a charge on the cost
11 thing. But our charge was to consider methods to
12 assess the cost of newborn screening expansion as
13 required by the authorizing legislation.

14 And our deliverable is to report with
15 recommendations to the advisory committee about
16 how to incorporate cost assessment into the
17 decision making process. And I'd like to begin
18 again by reminding you where we've come from.

19 So, our original plan, which we are
20 sticking to, is to look at the budget impacts on
21 states. And in terms of sources of data we're
22 reaching out to states or other programs that are

1 involved in the process, as well as vendors who
2 make a lot of the newborn screening test
3 equipment.

4 We have several cost data targets that
5 we're interested in. So primarily we're
6 interested in those costs that are born by the
7 state to expand newborn screening. So, issues of
8 screening, laboratory costs, and short term
9 follow-up.

10 If you recall before, we talked about
11 doing things over a two year horizon. But to
12 look at things annualized. Look specifically at
13 the costs per infant screened, and to normalize
14 this to the cost per screening 100,000 newborns.

15 Our secondary goal is to also look at
16 treatment, and issues of long term follow-up
17 care. Certainly we appreciate that, you know,
18 again, screening is, you know, encompasses the
19 whole process. But we're obviously restricted in
20 the availability.

21 So, now I'm going to move into the
22 beginnings of where we actually are, and hope to

1 get your input. All right.

2 So, let me begin by describing the
3 theme which came up over and over again, which is
4 that the costs of the newborn screening vary
5 significantly across states. And a lot of people
6 that we spoke to were skeptical about our ability
7 to drill down on this.

8 I have kind of a funny mathematical
9 happenstance I'm going to show you in a little
10 bit that might find the face of this. But
11 appreciate the variability. We have
12 variabilities of state size, birth rates,
13 existing laboratory facilities, how newborn
14 screening costs are structured within the
15 program, issues of funding, laboratory
16 facilities, how they collaborate with others,
17 their use of contractors. And how everything
18 fits within the broader public health department.

19 The other thing is that there are all
20 sorts of very complicated cost arrangements
21 within, and for some states across states
22 regarding who does what related to newborn

1 screening.

2 There are very complicated issues
3 around how the test itself is gotten. So, if you
4 buy the equipment and the reagents, or do you
5 have some sort of leasing or rental agreement
6 with the vendor who, you know, provides
7 everything at a certain cost.

8 And there was, and I think we began to
9 hit on this at the last meeting, some reluctance
10 about sharing this, these numbers across states
11 as well. Because it's sort of a competitive
12 bidding sort of process. And so, and I can tell
13 you other stories that make it even more
14 complicated.

15 So, suffice it to say, at the last
16 meeting everyone said, oh, this was like really
17 complicated. And this is going to be a mess.
18 And I said, oh, no, it's not going to be a mess.

19 But in fact, it is a little bit more
20 complicated. And perhaps more complicated than I
21 had appreciated at the time. But I think, you
22 know, I think that it's important that we bring

1 up these issues. Because eventually we are going
2 to be expected to do this within the narrow
3 timeframe.

4 And what I don't want to do is be in
5 the position of just coming back with, you know,
6 presenting noise, you know. That again, we
7 really want to have something that's going to be
8 valuable to the decision making process, given
9 the concerns that we have.

10 And again, members of the condition
11 review, or the cost workgroup, as well as the
12 states that have responded to our surveys, have
13 been really helpful. So the fact that this is
14 complicated, I don't want it to be a reflection
15 on people's willingness to come through. It's
16 just difficult.

17 So, our, the aims of what we're doing
18 now are to assess the feasibility and the
19 effectiveness of the cost assessment methods. If
20 you recall before we decided to go after two
21 related conditions, MPS I and Pompe Disease.

22 Because, you know, you can either do

1 them singly, or in the case that we're going to
2 be talking about in a little bit, they can be
3 multiplexed together. And you can either do it
4 using tandem mass spec, or digital microfluidics.

5 So appreciating that digital
6 microfluidics is still undergoing, and I can't
7 comment on where it is right now. But this FDA
8 approval process. And so, for example, some
9 states can't even adopt, is my understanding, the
10 digital microfluidics until this FDA process is
11 done.

12 I'm not well versed in the nuance of
13 these FDA issues. So if anybody else has
14 something they want to add, I'd appreciate that.

15 Again, we're trying to like simplify
16 things. You know, there's a million different
17 ways of doing, you know, implementing these
18 tasks. And so we're trying to at least, you
19 know, give a range, at least not each little
20 nuance that could be done.

21 But as best as possible, as it says
22 there, we're going to gather estimates to get

1 ranges. But of course, we're going to have share
2 with you the assumptions that we make as we go
3 along. That's sort of where the train is moving.

4 So, again, as we move through this
5 pre-test process, you know, our key questions are
6 on how to gather the state cost estimates with
7 the least burden on them, and perhaps secondarily
8 us.

9 And how to standardize highly variable
10 state costs, which I'm going to show you in a
11 little bit, into a point estimate and range that
12 reflects the reality of expanding newborn
13 screening, given that, you know, I just have no
14 standard approach.

15 But there's probably variations on
16 approaches that can be used. I mentioned before
17 this issue of there is some confidential or
18 protected vendor pricing data. The estimates may
19 be uniquely specific to the particular states
20 that we gather the information from.

21 And then, one of the things that's
22 interesting is that the cost components in

1 categories may vary. So we've developed
2 questionnaires to ask for specific, you know,
3 elements.

4 And we get the numbers back in. And
5 then we had to tease out like, well, did you
6 really mean this? Or is it this and that? So,
7 it's complicated again.

8 But I hope that as we go through this
9 process at least the methods of gathering data
10 will become more standardized. And we'll be able
11 to better communicate with the programs that are
12 responding, what exactly it is that we want.

13 So, again, there are two states that
14 I'm going to be highlighting right now that have
15 provided information, Missouri and Illinois. But
16 we've reached out to the other states. And we've
17 gotten, I will say, lots of good information from
18 other states about how they do this internally
19 with different conditions.

20 So, Sylvia might want to comment on
21 Hawaii. And certainly we've had discussions with
22 John Thompson, who's also a member of the

1 condition, or the cost assessment workgroup, from
2 the great state of Washington.

3 So, these are the costs that we were
4 interested in, as originally proposed. So,
5 laboratory costs, equipment, supplies,
6 installation, space, and utility staffing, and
7 the updating of the laboratory information
8 systems, as well as staff development and
9 services, including, you know, training and
10 education, and then issues related to arranging
11 short term follow-up.

12 But, you know, not going to be
13 surprised if we have version 1.1 as we began to
14 drill things in. So, the left most column has
15 the laboratory cost categories on the right, a
16 description of these things.

17 So, for equipment we realized that
18 there is either this direct purchase, or as many
19 states do, have these, sort of the reagent rental
20 agreements.

21 Consumables, which may be subsumed
22 within the reagent rental agreement, or other

1 laboratory expenses, you know, which is sort of
2 the catch all. But could for some states include
3 the laboratory information management system.

4 There's labor. And we tried to figure
5 out exactly, you know, the category of person
6 that might need to be involved, their FTE
7 position, and salary and fringes. And I'm going
8 to show you examples of that in a little bit.

9 And then issues of confirmatory
10 testing. And then finally, overhead or indirect
11 costs. So these are kind of the big buckets.

12 Questions so far? Am I -- All right.

13 So this is an example of the kind of
14 spreadsheet that we've been using. And I'm going
15 to show you cost estimates from states that use
16 multiplex testing. And then, to try to bring it
17 down to what it might be for one of the tests on
18 there.

19 We just said, well, if they're
20 screening for four things, we'll divide by four.
21 If they're screening for six things, we'll divide
22 by six. We appreciate that that's not a very

1 realistic assumption.

2 Because there's, you know, if you were
3 going to do one thing there's like a big cost.
4 And then each thing is an additional one on.
5 But, what we haven't been able to get yet, but
6 we're working on, is from the vendors. What if
7 you had just done one thing, instead of four or
8 six things?

9 The one number that I have in there is
10 the fringe benefit from the state employees. And
11 we got this number for anybody from some like
12 Bureau of Labor statistics thing. So, but as you
13 hear in the private world, the state folk do get
14 a little bit higher fringe benefits than you
15 might used to be seeing. But they lose out more
16 on the salary side of things.

17 Any political comments can be brought
18 up after about how you feel about whether or not
19 you're getting -- It's a labor of love, I'm sure.

20 So, I just listed here, and you're
21 going to see I think in the next slide where some
22 sort of irony came into things. But we have two

1 states, State A and State B. State A has,
2 screens about 100,000 annually. And State B is
3 larger, 180,000.

4 One state uses digital microfluidics.
5 The other uses the varying, so tandem mass spec.
6 One uses multiplexes for conditions. The other
7 does six. Both use reagent rental agreements.
8 And I have the numbers up there. But in
9 addition, State B pays extra for consumables.

10 Again, we just got most of these
11 numbers last week. And we had to dig into this
12 more. But you can just, I won't read through the
13 whole things. But you can see question marks
14 where we're just trying to sort things out.

15 The FTEs are only for State A, whereas
16 costs for other employees are wrapped up into
17 other numbers provided by State B. But you can
18 see, you know, in an ideal world once you add up
19 all these things you can get the total annual
20 cost to the state.

21 And then the bottom line is, well, you know,
22 State A did four things, and State B did six

1 things. So, just to kind of get a sense, we'll
2 divide by four and six. I appreciate that that
3 doesn't, you know, doesn't entirely make sense.
4 but I just wanted to get a sense of how things
5 might play out.

6 So, this carries through before. But
7 dividing out to figure out the cost of screening
8 one infant for one condition, based on the
9 numbers we got. And so, as you can imagine, K.K.
10 and I, we were like, our like jaws to the ground
11 once we got all these numbers, and kind of
12 figured out which category they went in.

13 And, you know, did the FTE thing, and
14 added everything up, and divided things out by
15 the number babies. So it ends up being \$2.03 for
16 State A, and \$2.08 for State B.

17 So, how they ended up within five
18 cents of each other, I think is more of a, you
19 know, sort of irony in the universe. And there
20 are different things that are included for
21 different things.

22 And what I don't want people to do is

1 leave this room and say, oh, you know, for adding
2 one of these particular conditions on it's like
3 only two bucks per baby. Because there's still a
4 lot of moving parts that we need to flesh out
5 where things are.

6 So, what I would like you, or
7 hopefully what you're going to do is take a look
8 at this, and get a sense of the process that
9 we're using. Again, we got most of these
10 numbers, you know, just within a week. And we
11 need to do follow-up interviews.

12 Because it was clear that the way
13 we're describing buckets may not entirely make
14 sense to the state people. But, this is the kind
15 of picture that I hope that we end up with. And
16 I'm certain that once, you know, this is really,
17 it's like comparing an apple to a piano, is the
18 way I feel like. It's just there are different
19 things included.

20 But once we do, and we're able to more
21 specifically define the two things that we're
22 comparing, this is the kind of thing that you

1 would end up getting. So, what we need to do now
2 is finish the pre-test that we're in right now,
3 in terms of following up with the states.

4 We do need to work more with the
5 individual vendors to figure out like, well what
6 does it really mean to adopt one versus the
7 multiplex. Although, in reality, most states
8 when they go and decide to screen for one things,
9 they may go for the multiplex anyway.

10 And that would make sense at least for
11 maybe two of them. And then going beyond there,
12 if they so choose. And then we need to
13 synthesize this information, and make it more
14 digestible. And then, once we're done with this,
15 we can revise our approach to doing this, once
16 conditions come to us.

17 There are these sort of secondary
18 costs that aren't included so far, including
19 treatment to long term follow-up care. And
20 speaking for me personally, perhaps channeling
21 the rest of the workgroup, I mean, we think that
22 these are important costs for you all to

1 consider. But it's difficult to get to them.

2 So, our plan, you know, has been to
3 present the final report at the next Advisory
4 Committee meeting, how we've resolved these
5 issues. And then, of course, incorporate our
6 process into the overall nine month, you know,
7 review process that we've discussed before.

8 But, you know, I'll just leave you
9 with a bunch of sort of bigger questions. So, I
10 probably should have edited this slide a little
11 bit after Dr. Bocchini presented, you know, the
12 different kinds of pilot studies, and what things
13 ought to be gotten.

14 Or it would be nice to incorporate
15 some cost assessment into there. We need to sort
16 of figure out what the minimum cost assessment
17 estimate impact, the minimum cost estimate inputs
18 that we need to get, so that we can make
19 something meaningful, a meaningful presentation
20 at the end of this.

21 We have timing issues that I won't get
22 into. I think I've alluded to them before. One

1 of the questions that is not really ours to
2 answer, but simply to ask, to make sure that when
3 we put this together it's meaningful, which is,
4 you know, how will the cost estimates be used?

5 And how can we present this so that
6 it's helpful both for the states, when
7 something's been recommended for the, recommended
8 uniform screening panel. But also for the
9 advisory committees. They're making
10 recommendations.

11 So, I just put a bunch of questions
12 out there. And I'm going to just kind of leave
13 it there. Because I'm sure you have questions
14 for me. Thank you.

15 CHAIR BOCCHINI: Thank you, Alex.
16 That's a good progress report. Questions,
17 comments from the committee? Dieter?

18 MEMBER MATERN: Yes. Alexis, great
19 work. And I'm looking forward to the end result.
20 Could you go back to the table that --

21 MR. KEMPER: This one?

22 MEMBER MATERN: Yes. So, where do you

1 have overhead, space, that kind of stuff in
2 there? Because --

3 MR. KEMPER: Yes. So we, and this is
4 where I'm going to get K.K. to come up. Because
5 she has all the numbers, and the surveys, and
6 stuff like that. I mean, these were things that
7 we've gotten. But the issue of getting, I mean,
8 we never got to the issue of --

9 Well, there's overhead in the indirect
10 costs for once it's in there. But, did you mean
11 the cost of like, let's say they need to expand
12 their current lab?

13 MEMBER MATERN: Well, I mean, you need
14 space.

15 MR. KEMPER: Right.

16 MEMBER MATERN: And --

17 MR. KEMPER: Point K.K. out too.
18 She's going to help me.

19 MEMBER MATERN: It seems to me very,
20 the number seems to be very low to me. Because
21 for MSMS, for example, from what I understand
22 from Perk & Elmer, and what they said last year

1 in APHL/CDC meeting in Atlanta, is that the
2 reagents per enzyme will be \$1 dollar per enzyme
3 per test. So, how can you do everything when you
4 only, when it's only \$2 dollars and eight?

5 MR. KEMPER: Well, and that's two per,
6 you know, per condition. So that's where we just
7 total --

8 MEMBER MATERN: Right. But it's
9 already \$1 dollar to measure acid in one infant.
10 So then you have \$1 dollar and eight where you
11 have all the rest, the space, the electricity,
12 the equipment, the person who's doing the test,
13 the follow-up person, all should be in there. I
14 don't know how that's possible.

15 MR. KEMPER: Yes. And I, well, you
16 want to comment, K.K.?

17 MS. LAM: Yes. I mean, they are in
18 there. We'll be enter, you know, those broad
19 categories that you mentioned are in there. We
20 still have to follow-up, you know.

21 For instance, I guess it's, you know,
22 the orange spaces, all right, we're still

1 following up with the states to go back and say,
2 especially when we have them side by side like
3 this, and can see.

4 And we'll cross check and make sure
5 that all the categories are covered. So, one
6 state did list rent, space rental and utilities,
7 for instance. And that's in there on that
8 overhead indirect cost line.

9 MR. KEMPER: But I wonder too, so
10 let's say you're doing six, okay. Right. So,
11 you know, there's a lot of that extra money, you
12 know, when we divided it out, may be the
13 overhead. You know what I mean? So, we're
14 ascribing only \$1 dollar --

15 MS. LAM: Yes.

16 MR. KEMPER: -- per test for the
17 overhead. But given that you're, you know, you
18 just need the space --

19 MS. LAM: Yes.

20 MR. KEMPER: -- to do all six tests.
21 It could be really that the overhead is, you
22 know, like another \$4 dollars per infant screen.

1 And that, you know, that we should really ascribe
2 all that.

3 MS. LAM: Yes.

4 MR. KEMPER: Do you know what I mean?
5 To the one test.

6 MEMBER MATERN: Yes.

7 MR. KEMPER: Because --

8 MS. LAM: That the --

9 MR. KEMPER: There's a big cost.

10 MS. LAM: Yes.

11 MR. KEMPER: There's a big cost for
12 getting the first one. And then a marginal cost
13 for each additional one.

14 MS. LAM: Right.

15 MR. KEMPER: So they'd be like, you
16 know, a dollar an enzyme plus, you know, whatever
17 marginal thing. It's only, so we had to ascribe
18 most of the costs to the --

19 MEMBER MATERN: Yes.

20 MR. KEMPER: -- first one.

21 MEMBER MATERN: I wonder if you
22 basically tried to submit a pilot study to the

1 NIH for a grant, would you come out with \$2.08?

2 MR. KEMPER: For those people who are
3 involved in the expansion, do you have a comment?

4 MEMBER MATERN: So, when we did our --

5 MS. LAM: So, some --

6 (Simultaneous speaking)

7 MEMBER MATERN: -- study for 100,000
8 babies.

9 MR. KEMPER: Yes. But the thing is,
10 a lot of --

11 MEMBER MATERN: It was 2.4 million.

12 MR. KEMPER: -- other stuff. There's
13 a lot of other stuff that's in the NIH one too.

14 MS. LAM: Yes.

15 MR. KEMPER: It's like the follow-up,
16 and all.

17 MS. LAM: I mean, we certainly, you
18 know, the, getting the pricing. These are from
19 multiplexes, right. Because we asked about Pompe
20 and MPS I.

21 And so these are, and these particular
22 states are doing multiplexes, and in reagent

1 rental agreements. And so, we're, we'll be
2 following up with Perk & Elmer --

3 MR. KEMPER: But I --

4 MS. LAM: -- folks afterwards.

5 MR. KEMPER: I think you're right. I
6 mean, I think it's underestimating a lot --

7 MS. LAM: Yes. It's --

8 MR. KEMPER: -- of this stuff. But
9 it's only, it's, and that's why it makes me,
10 gives me a little angina. But, I mean, I can
11 only tell you what we get.

12 MEMBER MATERN: I mean, we do this
13 testing now for one state, for three conditions.
14 And I'm sure they would like us to charge that
15 little. And I would love to give it to them for
16 that price. But we probably can't. Because we
17 already do it basically at no margin. And it's
18 more than this.

19 MR. KEMPER: Yes. I bet that's the
20 case.

21 MEMBER MATERN: But we do have very
22 nice facilities.

1 MR. KEMPER: But you need to pay for
2 the heat.

3 MS. LAM: I mean, very roughly, you
4 know, we haven't put them up here yet. Because
5 they're for, you know, technically different
6 conditions. But if you look at kind of the
7 similar set, looking at Pompe, MPS I, X-ALD, and
8 just some initial state estimates that we, that
9 aren't represented on here.

10 It seems like, you know, at rough
11 glance, that folks are coming up with between
12 about a buck 50 to, you know, eight or nine bucks
13 per, like per infant per test. So, you know, I
14 don't know what those mean, per se.

15 I kind of say, I clearly say those
16 with a grain of salt. But, you know, again, it
17 just, I think it gets back to what, how
18 meaningful are these? Or, you know, you just
19 have to keep them with a grain of salt. And keep
20 all the assumptions in there.

21 You know, we haven't gone through and
22 listed all of that. I think we'd be interested

1 in hearing how you would cost it out if you're,
2 you know, what your numbers might be from your
3 perspective, you know, and from your work. I
4 mean, not right now, if you, but --

5 MR. KEMPER: Yes. We'll have to add
6 another three hours to the meeting.

7 MS. LAM: Yes, yes, yes.

8 MEMBER MATERN: Me again.

9 MR. KEMPER: Dr. Matern.

10 MEMBER MATERN: So, you're only
11 considering the setup and running the tests. But
12 you do not consider follow-up, false/positive,
13 implications of false/positive secondary tests?

14 MR. KEMPER: Yes. I mean, I, right.
15 So there's those add on additional tests. All I
16 can, I agree. And so, these are all things that
17 we've talked about. The only -- Well, but, I
18 mean, there's a lot of work that needs to be done
19 for that.

20 Remember, this is going to be one
21 component of all the stuff that you get too. So,
22 we'll be able, you know, through like the work

1 that we do with Lisa, at least give you estimates
2 of the number of false/positives, and the rate of
3 return, and stuff like that.

4 So, I mean, I agree with you. And I
5 think that the best way to do this is to just to
6 think of it as one piece of the puzzle. But to
7 think about it in the context of all the other
8 pieces of the report. There's a matter of --
9 Oh, okay.

10 MS. TULLIS: So, have you looked at
11 any smaller states? Do you think that it will be
12 more in a smaller state? It, I'm from Delaware.
13 So, I know our numbers never look this good.

14 MR. KEMPER: I think that's probably
15 true. We're kind of restricted to the states
16 that are doing something, so we can find out from
17 them. So, unless, like --

18 MS. TULLIS: Just in general, looking
19 down at a smaller state population, smaller
20 birthrate?

21 MR. KEMPER: No, I think you're likely
22 right.

1 MS. URV: As Dieter said, you might
2 want to talk to some of the NIH contractors that
3 we have that are currently screening for Pompe,
4 MPS I, and X-ALD. They're setting up. They have
5 to detail their costs and such, for us.

6 MR. KEMPER: Oh. Is that part of the
7 --

8 MS. URV: That's part of the contract.
9 They have to --

10 MR. KEMPER: Oh, I understand.

11 MS. URV: They have to detail it. So
12 if you contact me, I can put you in contact with
13 those individuals, one of whom is sitting right
14 there. And they can probably give you a more
15 detailed outline of what we expect, and a more
16 realistic view of how much it costs.

17 MR. KEMPER: Okay. That would be
18 great.

19 MS. URV: Michelle Kujana, who's also
20 --

21 MS. SARKAR: And that was Tiina Urv
22 from NICHD. Yes. North Carolina --

1 MR. KEMPER: For the states?

2 MS. SARKAR: Right. Yes. And
3 Massachusetts.

4 MR. KEMPER: All right. I think we've
5 snowed them.

6 CHAIR BOCCHINI: Okay.

7 MR. KEMPER: Okay. With cost data.

8 MS. LAM: And it sounds like --

9 MR. KEMPER: All right. Thank you.

10 CHAIR BOCCHINI: Thank you very much.

11 MS. LAM: So that's good to know.

12 CHAIR BOCCHINI: All right. Next we
13 have a report from the Follow-up and Treatment
14 Subcommittee, Steve McDonough.

15 MEMBER MCDONOUGH: Good morning. Hi.
16 Good morning. I'm a retired pediatrician from
17 North Dakota. We had our meeting yesterday in
18 the HRSA Office Building. And maybe one of these
19 days, the Educational Committee will have the
20 opportunity to go through the screening there,
21 which is tighter than the airports.

22 So, we had a good meeting, I think.

1 We had 19 people present, and eight by phone. We
2 had a consensus on working on two priorities, our
3 clinical quality measures, and medical foods and
4 medical formulas.

5 We were fortunate that Dr. Zuckerman
6 gave a very nice presentation. He had prepared
7 slides, and previously sent out written material.
8 And he's going to be our leader in a sub-
9 workgroup of our workgroup, on clinical quality
10 measures.

11 And there will be, he and those who
12 will be working with him will be having phone
13 calls between now and the August meeting, as will
14 the medical foods subgroup.

15 These are some of the slides which I
16 took from his presentation. He has some ideas
17 about working with NewSTEPS. I won't go through
18 all of these, given our time constraints. And
19 there was representation from NewSTEPS at our
20 workgroup.

21 Also have some ideas with NBSTRN,
22 potentially working with, to promote clinical

1 quality measures, and American College of
2 Genetics. And those are there. And will be
3 shared with NBSTRN about potential collaboration,
4 and ways that we can work on to improve clinical
5 quality measures.

6 And I asked him, Dr. Zuckerman, prior
7 to the workgroup meeting a week ago, can you pick
8 three areas that you would like us to focus in
9 on, and hone on.

10 And these are case study of successful
11 use of clinical quality measures, either from
12 cystic fibrosis or sickle cell disease, or
13 possibly MCAD. You see how this would work.
14 Ways to tap in current electronic medical
15 records, and clinical quality measures.

16 A report to the full committee,
17 highlighting the background need and
18 opportunities for use of clinical quality
19 measures, and long term follow-up for newborn
20 screening. And the how to guide to developing
21 quality measures for newborn screening.

22 Now, these are some initial ideas that

1 he has. And he'll be leading the effort with
2 another member, hopefully, six, eight, ten other
3 workgroup members over the next few months. And
4 when we come back in August we'll have hopefully
5 a little bit more detailed information.

6 And that's, I really appreciate his
7 willingness to take on this responsibility. And
8 I'm very happy that the full committee has passed
9 our workgroup with medical foods.

10 We had an excellent presentation, I
11 thought, yesterday morning, which was absolutely
12 wonderful, and set the stage, I think, for -- And
13 I just want to say I'm so impressed with people
14 who want to give this one more try.

15 There are, I'm new to this workgroup.
16 There have been people working for decades to
17 help families and children who have conditions
18 that need formulas. And we're not there yet.
19 And we've not had many successes. And rather
20 than being discouraged there, we're going to try
21 it one more time.

22 I've asked, the goal for this sub-

1 workgroup over this next year, that we would
2 possibly put together a letter that would be
3 presented to this committee, to go to the
4 Secretary.

5 And then, also we're going to work on
6 a white paper that would be a source of
7 information to decision makers about how
8 important this issue is.

9 Dr. Sue Berry, from the University of
10 Minnesota, who participated by phone call, has
11 agreed to head up the medical food sub-workgroup.
12 And she has labored long and hard in this area in
13 the past, and will continue to do that.

14 And we had ten members of the sub-
15 workgroup indicate a willingness to work with Dr.
16 Berry. So I think they'll be having phone calls,
17 meetings between now and the August meeting. And
18 I'm really pleased that we have a couple of
19 important issues that we're willing to take on.

20 I would just put a personal note in
21 here. I, this is speaking for myself. I think
22 it's very important that we measure where our

1 states are at in long term follow-up and
2 treatment.

3 If you, if it can be measured, and
4 it's not being measured, I don't think people
5 think it's important. And you don't know what
6 the current mess is. And there's a big mess out
7 there with long term follow-up and treatment.
8 And you have no way of monitoring progress.

9 So, we're not working on that right
10 now. But I personally think that's very
11 important for us to do. And that's it. So,
12 thank you very much. And be happy to answer any
13 questions you have. And appreciate all the help
14 I'm getting from the workgroup members.

15 CHAIR BOCCHINI: Thank you, Steve.
16 Questions, comments? All right. We're going in
17 the right direction. Thank you very much. So,
18 before we break for lunch, I just want to do one
19 thing.

20 And that is that I think as the
21 Secretary's Advisory Committee transitioned with
22 the re-authorization to the Advisory Committee,

1 many of you were --

2 (Off microphone comment)

3 CHAIR BOCCHINI: Okay. Thanks. Many
4 of you were worried that this group of people
5 here would be permanent, because many of you have
6 served for a very long period of time, much
7 longer than the original intent of your term.

8 And so, I think that unfortunately
9 we're going to have to make some transitions now,
10 because of the fact that we now have the Advisory
11 Committee. And now we're working to try and
12 respect your time, and your contributions, as
13 well as bring on new members.

14 And as you know, two of our long term
15 members have needed to come off the committee,
16 because they have taken jobs that put them in
17 conflict with the working of the committee. And
18 that's Andrea Williams and Charlie Homer.

19 And, but certainly they have served
20 this committee quite effectively over their
21 tenure. And we want to make sure that people
22 understand that we appreciate the work that

1 they've done, and certainly the extra time that
2 they have spent on the committee.

3 So, Andrea, you're here in a different
4 role. But I wanted you to just come up and
5 receive a little certificate from HRSA, and from
6 us, to just recognize your service to us over the
7 years, to the committee and --

8 (Off microphone comment)

9 (Applause)

10 CHAIR BOCCHINI: Now, Alexis is not on
11 the phone today. But this is her last meeting.
12 And so, again, she certainly, with her background
13 in hematology oncology, has certainly contributed
14 significantly over the years to this committee.

15 And again, I want to recognize her.
16 We'll send her her certificate. But thank her
17 for all that she's done over the years for this
18 committee.

19 And lastly, this is Jeff Botkin's last
20 meeting. And Jeff and I are kind of, we came to
21 this committee together. And we've certainly
22 enjoyed working with you.

1 Your background and your contributions
2 have led to multiple contributions for this
3 committee, as evidenced by even your work that
4 you presented today, and your work on the
5 committee that developed the recommendations for
6 our pilot studies.

7 So, clearly you have had a significant
8 impact on this committee. That will continue for
9 many years, based on putting us on the right
10 track for many things. So, Jeff, if you'd come
11 up, I want to give you a similar certificate.
12 And again, thank you for all of your years of
13 work on the committee.

14 (Applause)

15 CHAIR BOCCHINI: So, with that, we
16 hope that the process by which new members become
17 available to us is working well. So, we will
18 have four replacements, we hope, for August. And
19 then, as I mentioned yesterday, we are looking
20 for additional people to replace next year's
21 transitioning members of our committee.

22 So with that, we'll break for lunch.

1 We're a little bit late. But I think we can
2 still come back. I guess we're due back at 12:45
3 p.m. So we have plenty of time. So, we'll break
4 for lunch, and see you all back here promptly at
5 12:45 p.m. Thank you.

6 (Whereupon, the above-entitled matter
7 went off the record at 11:50 a.m. and resumed at
8 12:51 p.m.)

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1 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 (12:51 p.m.)

3 CHAIR BOCCHINI: All right, let's go
4 ahead and start this session. I need another
5 roll call. So --

6 MEMBER BAILEY: Here.

7 CHAIR BOCCHINI: So first -- here?
8 Okay. Thank you, Don. Jeff Botkin?

9 MEMBER BOTKIN: Here.

10 CHAIR BOCCHINI: Coleen Boyle?

11 MEMBER BOYLE: Here.

12 CHAIR BOCCHINI: Catherine Spong?

13 MEMBER SPONG: Here.

14 CHAIR BOCCHINI: Kellie Kelm?

15 MEMBER KELM: Here.

16 CHAIR BOCCHINI: Fred Lorey by phone?
17 Dieter Matern?

18 MEMBER MATERN: Here.

19 CHAIR BOCCHINI: Steve McDonough had
20 an early flight. Kamila Mistry?

21 MEMBER MISTRY: Here.

22 CHAIR BOCCHINI: And Joan Scott?

1 MEMBER SCOTT: Here.

2 CHAIR BOCCHINI: And then Cathy

3 Wicklund?

4 MEMBER WICKLUND: Here.

5 CHAIR BOCCHINI: And Debi Sarkar?

6 MS. SARKAR: Here.

7 CHAIR BOCCHINI: And then for

8 organizational representatives, Bob Ostrander?

9 MR. OSTRANDER: Present.

10 CHAIR BOCCHINI: Beth Tarini?

11 MS. TARINI: Here.

12 CHAIR BOCCHINI: Mike Watson? Joseph

13 Biggio by phone? Kate Tullis?

14 MS. TULLIS: Here.

15 CHAIR BOCCHINI: Susan Tanksley by

16 phone?

17 MS. TANKSLEY: I'm here. Can you hear

18 me?

19 CHAIR BOCCHINI: We can hear you,

20 thank you. Chris Kus by phone?

21 MR. KUS: Here.

22 CHAIR BOCCHINI: Adam Kanis by phone.

1 MR. KANIS: Here.

2 CHAIR BOCCHINI: Natasha Bonhomme?

3 MS. BONHOMME: Here.

4 CHAIR BOCCHINI: Ed McCabe by phone?

5 Participant: He will be joining you
6 in about five minutes. This is his assistant. I
7 will be listening in for him.

8 CHAIR BOCCHINI: Thank you. Cate
9 Walsh Vockley?

10 MS. VOCKLEY: Here.

11 CHAIR BOCCHINI: And Carol Greene?

12 MS. GREENE: Here.

13 CHAIR BOCCHINI: All right, thank you.

14 So we're now going to proceed with additional
15 workgroup reports. First is the timeliness
16 workgroup update, Kellie Kelm and Cathy Wicklund.

17 MEMBER KELM: So I can start quick.
18 We didn't have a meeting yesterday, but we have
19 had I think at least one or two calls since the
20 February meeting. And so we can just update you
21 on what we've done on those last couple calls.

22 And this is just our current

1 membership trying to represent people involved in
2 all facets of newborn screening. And this is
3 just reminder of the charge from the Committee to
4 this new workgroup. Well, I guess it's been
5 almost a year.

6 So our recent calls actually focused
7 on the first charge, optimize successful
8 strategies to address newborn screening specimen
9 collection and transport and collect and
10 disseminate timeliness specific practices from
11 state newborn screening programs.

12 So first to gather success stories
13 from states and hospitals, we had presentations
14 on our phone call from Missouri and Utah on
15 improvements that they've made in timeliness in
16 newborn screening.

17 And with regards to our interest in
18 reaching out to the Joint Commission, we had a
19 brief call with Erin Dupree who is the Chief
20 Medical Officer and Vice President for Joint
21 Commission Center for Transforming Healthcare.

22 And I think I was really briefly going

1 to talk about this last point before we go into
2 depth on the presentations from Missouri and
3 Utah. So our brief discussion with Erin Dupree
4 was actually just telling her about us and what
5 we're doing, and that she was going to go back
6 and have internal discussions with some of the
7 people in her group.

8 And Kathy and I actually need to
9 circle back to her and see if there is any
10 interest or anything they can help us with. So
11 that call was more of a, I guess, get to know you
12 kind of call.

13 So if we hear anything more on that
14 point, we'll get there. But I'm not so sure she
15 was too knowledgeable about timeliness in newborn
16 screening when we had the discussion.

17 MEMBER WICKLUND: But she had some
18 very specific ideas about individuals within the
19 organization that she wanted to reach out to and
20 have further discussion with to see if there was
21 a way some of our messages could be delivered
22 through some of the channels that they already

1 have existing. So I just sent an email yesterday
2 to try to follow up to see if she had a chance to
3 have any of those conversations. So we'll see.

4 MEMBER KELM: All right. So are you
5 doing Utah?

6 MEMBER WICKLUND: Yes, I'm doing Utah.
7 So first I want to say just forgive me. This is
8 not my presentation, and Andy needs to forgive me
9 about presenting some data from Utah.

10 We thought you guys might be
11 interested in kind of hearing what just high
12 level overview of what we got back from some of
13 the states we talked to. So I think it's pretty
14 exciting actually.

15 I think that, you know, the
16 timeliness, the work that the pre-timeliness 1.0
17 version and all of the reports has really had an
18 effect with a lot of the grant funding that has
19 come out, addressing timeliness issues, and then
20 the states have really had great success stories.

21 So I think what we're trying to do is
22 highlight some of those successes and also think

1 about, though, how to further disseminate that to
2 other states, and that's what we're trying to
3 think about now.

4 But just in general, this is just a
5 brief overview of what Andy presented from the
6 Utah experience. So if anybody is part of the
7 Utah state screening program and wants to add
8 anything in or I'm misrepresenting something,
9 please feel free to do so.

10 So basically they looked at it, the
11 four different processes in the actual newborn
12 screening process. And what they were doing is
13 trying to look at turn around time in each one of
14 those categories, whether sample collection and
15 logistics, receiving, testing, reporting, follow
16 up, and coordination.

17 So that's how they broke it down and
18 then started tackling each one of those different
19 processes. So one of the biggest things was the
20 transport time.

21 So what they did was actually made or
22 developed a partnership with FedEx that actually

1 provided courier service for hospitals with a
2 greater than three day turnaround time.

3 And that obviously did have a cost.
4 That cost about \$19,000. So we also talked a lot
5 on our phone calls about the cost involved in
6 implementing some of these things, and then where
7 did that money come from.

8 So some of it was absorbed. Some I
9 think got additional funding. I can't quite
10 remember, but that was obviously a question a lot
11 of states had was how did you pay for this.

12 MEMBER KELM: So Utah, I believe
13 that's considered a no cost added. They moved
14 money from other sources, and I think Missouri
15 actually got money from their legislature,
16 governor in order to actually be able to cover
17 some additional activities.

18 MEMBER WICKLUND: Yes, Joan?

19 MEMBER SCOTT: Is this an annual cost?

20 MEMBER WICKLUND: I believe it was.
21 Isn't it? I think it's an annual cost because it
22 wasn't just to get the partnership developed. I

1 think it's the cost of having a FedEx courier.

2 But again, I could be misspoken. Again, we're

3 trying to present somebody else's data.

4 But I think that that was a huge
5 impact, being able to have this. And they really
6 were able to reduce the transit turnaround time
7 that they were able to see.

8 So, and they also found that this
9 transport time, there was also about the status
10 of the hospital I believe played a role in the
11 turnaround time as well, like, the corporate
12 status which was kind of an interesting finding.

13 So again, some of this just being
14 shared between states, I think other states
15 helped them to tackle their own issues that are
16 similar.

17 The other thing with underperforming
18 hospitals, they use carrot and sticks. The
19 carrot, as we heard over and over again, was
20 going out and establishing personal
21 relationships.

22 I would say that was definitely

1 something we heard from most of the states we've
2 heard from so far is going out, establishing
3 those personal relationships, focus on the role
4 in transparency, get feedback, do site visits,
5 training, you know, process consulting with the
6 underperforming hospitals.

7 And then in Utah, the stick was they
8 made a rule change that basically mandated sample
9 collection between 24 and 48 hours of life. So
10 they actually did the combination of making a
11 rule change plus going out and establishing the
12 personal relationships.

13 And then what you can see here is that
14 they did better from 2013 to 2015 which is in the
15 dark, the black, that they were able to reduce
16 the transit time, you know, over these past few
17 years. So, successful.

18 And the other was just the operations
19 and opening up seven days rather than a more
20 limited time period. And everybody dealt with
21 this a little bit differently.

22 There was concern about their long

1 time employees being unhappy maybe with having to
2 work on weekends. So people approached it in
3 different ways. I think one site maybe did more
4 like it was mandatory everybody had to do weekend
5 hours, and then the other state actually left it
6 open for volunteers. And people actually stepped
7 forward to be able to do it because it maybe
8 worked out better for their schedule.

9 So they opened up additional days
10 which helped with, you know, specimen, result
11 reporting, on call follow up. And so that helped
12 as well.

13 And then they also had a faster turn
14 around time through the seven day operation. So
15 you can see that for all the different
16 conditions, it shows that they had a better turn
17 around time when they were open more often than
18 less.

19 And then the third bottleneck was, I
20 think, also just some of the resources they used.
21 Actually temp workers for some of the more
22 mundane or less specialized work that need to be

1 done. So they had temp workers for data entry on
2 high-demand days only.

3 They also substituted manual data
4 entry with expanded scanning. So there were a
5 lot of things they also did to just try to, like,
6 reallocate what was happening to different ways
7 of doing it that helped the efficiency of the
8 personnel that they had.

9 MEMBER KELM: So Patrick Hawkins spoke
10 from Missouri about what they've been doing. And
11 this was when they broke down all of their sort
12 of steps in newborn screening. These are the
13 main issues that they found in terms of impacting
14 turn around times.

15 So no weekend or holiday courier
16 pickup, the impact of the state labs when they
17 were open including holidays and some other
18 things in terms of funding and traceability, et
19 cetera.

20 So they said they did a number of
21 things at first, which was a no cost which was,
22 for example, and it was interesting, they said

1 they found some of these things and they were
2 simple fixes that were, you know, pretty amazing.

3 But working with hospitals that were
4 not on the state courier system to just
5 self-transport their samples to the nearest
6 county health department where they could hook up
7 with, for example, the available courier service.

8 And so, and actually, it looks like
9 the public health lab actually helped, like,
10 each, you know, some of those groups to
11 specifically identify where they could do that.

12 Worked one on one with hospitals that
13 had issues, and then they talked a lot about
14 customized timeliness reports in some
15 institutions, and then doing a lot of education,
16 using phone conversations, they were doing a top
17 ten reminders.

18 There was educational material going
19 out with cards from the lab and things like that.
20 So improvements that required funding with
21 changes in the, actually adding holiday courier
22 pickup and then other things.

1 So testing on the weekends, and adding
2 more courier sites to some of the places that
3 probably didn't have it. And you can see that
4 they sort of broke it out per year for that.

5 So for Saturday and the holidays, this
6 is, as she said, this is where they saw 100
7 percent voluntary staffing process in that they
8 had, you can sort of read some of these details
9 about where they actually did hire an FCE
10 specifically for the expanded days.

11 And then they also were hiring new
12 employees that specifically were agreeing to
13 working, for example, a Tuesday through Saturday,
14 and then maybe down the line they can move to
15 Monday, Friday. And then obviously, you know,
16 that would be better for them. But as they were
17 newer, they would do Tuesday through Saturday.

18 And then they actually had four other
19 adjunct employees that actually worked that
20 actually worked in other parts of the public
21 health lab, not in newborn screening, but they
22 were pulling them in, and it was completely

1 voluntary for them to come in and work other
2 Saturdays and holidays.

3 And they said that they were basically
4 putting up the schedule ahead of time and asking
5 for volunteers and that so far they had really
6 not had any issues with people stepping up and
7 volunteering to work some of those extra days.

8 And then this is the data that
9 Missouri gave us showing the improvement in
10 sample transit time improvements. You can see,
11 you know, things getting to them between zero and
12 three days after collection, went from 61 percent
13 all the way up to 87 percent with some of the
14 most recent changes.

15 And you can see they have broken out
16 in the bottom where some of the changes that they
17 have made, for example, holiday courier pick up,
18 Sunday courier pick up, and then the extra
19 Saturday holiday testing. So this is actually
20 data combined for all those changes that they
21 have made.

22 And they talked a little bit about the

1 portal that they have added to help sites be able
2 to obviously get the information faster than for
3 example relying on mail to send things. And
4 we've heard that from another programs that are
5 interested in portals, you know, to get
6 information to their providers.

7 And I'm not going to read this, but
8 obviously they saw many benefits for moving to a
9 portal type of communication process. So that's
10 it for the update from our group for the last
11 couple of months. So any questions, comments?

12 CHAIR BOCCHINI: No questions. Thank
13 you very much. This is, it's great that the
14 states are sharing this with the group and seeing
15 the progress that's being made. So thank you.

16 MEMBER KELM: Thank you.

17 CHAIR BOCCHINI: Next, we have the
18 report from the Education and Training Workgroup.
19 So Cathy is going to stay up there.

20 MEMBER WICKLUND: All right, it's me
21 again, not Don. I'm not there. All right, you
22 guys. So Beth and I are going to give you an

1 update on the education and training workgroup.

2 Actually, we forgot to change the title, sorry.

3 So we were able to meet yesterday. We
4 cut our meeting a little bit short just because
5 we had to get out of the room. But we did, I
6 think manage to make a little bit some progress.

7 Basically, we always start out with
8 relevant updates from our Members because so many
9 of our Members represent different organizations
10 in which are doing a lot of educational
11 activities.

12 And I think always our challenge in
13 education that we are not redoing or reinventing
14 the wheel, and are cognizant of what everybody
15 else is doing. So we did that, we reviewed our
16 Subcommittee projects. We'll talk more about
17 that. We had an update on the nomination
18 education project and we also discussed
19 additional education needs and project ideas.

20 So first of all, Natasha gave us an
21 update on the nomination education project. So
22 basically remember, this was to provide

1 educational guidance to groups who might be
2 interested in preparing a nomination package.

3 And Natasha's working with the,
4 collaborating with Alex and his team. And I
5 believe they're almost done and most likely
6 actually would be completed by August, I think,
7 not December. But where's Natasha. Right?
8 August, I think is where we were thinking. Maybe
9 you might be able to present.

10 (Off microphone comments)

11 MEMBER WICKLUND: Look at by August.
12 Okay, yes. So we'll look forward to that. And
13 then our role is going to be able to give Natasha
14 and the rest of the team some feedback from the
15 education and training workgroup.

16 The two projects, we'll talk about
17 them individually. The first one was to create a
18 tool that provides primary care providers with
19 guidance on how to communicate positive newborn
20 screening results. So it's really more about the
21 communication process itself and not necessarily
22 the medical information around a positive screen.

1 As you guys know, ACMG has the act
2 sheets, and so the idea was that we could add
3 supplementary material, either linked to the act
4 sheets or other, not just the act sheets but
5 other venues. So it actually is talking about
6 the communication process itself and would be
7 more general, and could be applied to any screen
8 positive.

9 So we wanted to make sure that we
10 weren't again, re-inventing the wheel. So I know
11 that Carol who's not here, oh there you are, had
12 mentioned a couple times and Natasha as well
13 about the work they did together that resulted in
14 this article on focus groups that they did with
15 families and asking them how they wanted to be
16 told, what they wish they would have been told.

17 So Natasha has a one page kind of
18 bulleted tips on communicating newborn screen
19 results which actually lives on early -- no, yes.
20 Baby's first test, thank you. Baby's first test
21 at the time.

22 And we really want to try to do is

1 think about how can we actually either look at
2 the content we have right now, potentially do we
3 need to update it, change it in any way, shape or
4 form. And we also, we didn't have time to do
5 this, but we just kind of wanted to circulate
6 these questions in the group to be able to think
7 about what information do we want on these
8 sheets.

9 But then the next thing is to really
10 talk about dissemination and thinking about
11 different organizations that we can perhaps
12 partner with and get them to actually link to
13 this and get more, you know, play from other
14 individuals because, you know, we're not sure
15 right now how many people are using them. Would
16 you say that's a fair statement, Natasha? Yes.

17 So we're thinking about different
18 organizations that we can partner with that would
19 hopefully link to this and provide more
20 information for the PCP's. So that's where we're
21 at right now.

22 So yes, next steps will be to look at

1 the actual content of the information and then
2 also start working with other organizations to
3 see how they could partner with us. All right.

4 MS. TARINI: The next project was the
5 Educational Outreach Project which is a broader
6 project that seeks to map basically educational
7 resources that are out there for newborn
8 screening and then disseminate them to target
9 audiences, have them embed them within their
10 resources, the outcome being linkages achieved as
11 a metric of dissemination or I would say, like, a
12 middle ground metric.

13 So the strategy being that mapping
14 will allow us to identify gaps in available
15 educational resources. And so what the format is
16 is that we would start with a very defined goal
17 of audiences that we're wishing to assist and
18 create, in locations that we would be looking for
19 these pieces of information, basically trusted
20 organizations.

21 So in other words, you wouldn't start
22 just Googling newborn screening, prenatal. You

1 would compile a list of trusted sources and then
2 from there, you would move forward and say okay,
3 on these trusted sources for this audience, I'll
4 give you an example. I took it off of the slide.

5 But I'll give you an example. So for
6 parents in the prenatal period on the following
7 sources, locations who created these resources?
8 What is the mode? Are they video, are they
9 interactive, are they print and what are the
10 goals of the material?

11 And then basically what you get is
12 sort of a descriptive web of what's available.
13 And what it allows you to do is describe the
14 landscape and see the gaps and then also start to
15 see where the gaps exist.

16 You can start to help, you can create
17 new content if you want. But I think the first
18 piece is to help people extend into others and
19 fill in those gaps.

20 For instance, if March of Dimes had
21 something very useful that the AAP could use,
22 I'll take my own organization, then the AAP could

1 link to that. And if they had a gap in that
2 area, then the AAP could link to the March of
3 Dimes.

4 So the next steps are identifying the
5 target audiences that we would like to evaluate
6 and the goals of that type of education. Like,
7 for instance, do we want people to be better
8 prepared, to be better prepared about newborn
9 screening, dried blood spots would be one
10 example.

11 Do we want parents to be better
12 prepared about the newborn screening process
13 prenatally, do we want parents to be better
14 prepared about positive screening results. All
15 of these are possible audience/goals.

16 And so the next step is that we as a
17 Committee will start to brainstorm the audience,
18 the goals of education. And then the process of
19 searching and mapping will happen alongside work
20 that the clearinghouse is doing in building their
21 resource repository, the goal of which is to
22 collate multiple educational resources. So we'll

1 leverage the existing work being done by the
2 clearinghouse. Any questions?

3 CHAIR BOCCHINI: Okay, thank you very
4 much, both of you. And now Kelly comes back up.
5 Laboratory procedures and standards workgroup
6 update.

7 MEMBER KELM: Perfect, thank you. I
8 hope Susan's on the phone, so she can pipe in
9 too. So we had a meeting yesterday afternoon, a
10 somewhat shortened lab standards and procedures
11 workgroup.

12 And actually, it was really exciting
13 to have some of our new projects that we're
14 working on. So this is the current roster, and
15 we had a fairly good number. I actually need to
16 edit it. I realized that some people have
17 probably retired and probably need to be edited.
18 But anyway, we had a great number of people that
19 were present as well as on the phone joining us.

20 And this is just our updated workgroup
21 charge that was only somewhat clarified a little
22 bit during our February meeting. And so we wound

1 up having presentations on both projects that the
2 committee had chosen for us at the February
3 meeting.

4 So this is our first project that we
5 were charged with was exploring the roll of next
6 generation sequencing in newborn screening, and
7 the second project was looking at the sort of how
8 is timeliness doing, what is the implications for
9 earlier specimen collection, and what could be
10 some unforeseen consequences in cost of
11 timeliness.

12 So we had four presentations. We
13 still wound up getting all of them in. We had a
14 fifth one that unfortunately didn't make it. But
15 we had two about sort of next gen sequencing in
16 newborn screening.

17 And that was first we had a
18 presentation from Michelle on the APHL molecular
19 subcommittee. And then May talked a bit about
20 what her lab is doing with next gen sequencing in
21 her state program.

22 And then in terms of timeliness, Lisa

1 talked about some data that came out of
2 California on how what impacts early specimen
3 collection has on the results from the program.

4 And then Marcie had some similar data on
5 unintended consequences on cost of timeliness.

6 And so I'll briefly discuss these
7 four. So we got an overview of the APHL
8 molecular subcommittee from Michelle and the
9 history sort of went through what, you know,
10 started back in 2009 and how it's grown since
11 then and number of the programs that they
12 currently offer right now that include the
13 molecular quality improvement program, the NBS
14 molecular workshops which is an intensive,
15 one-week training that they have had for a number
16 of years.

17 It's been very successful in very
18 hands-on training into a number of molecular
19 techniques that state public health labs will
20 use. A molecular assessment program. And so
21 this is actually visiting labs and doing
22 voluntary assessments of their molecular program.

1 And a newborn screening molecular
2 resources website that they have, that they host.
3 And then a program which is the paradigm for NBS
4 molecular pilots which is a number of states that
5 are, I guess, almost your centers for excellence
6 for molecular assays in newborn screening that
7 also works with CDC and they inform each other
8 and as well as working, I believe, with HRSA.

9 And the one thing that was mentioned
10 was that they are planning for a next gen
11 sequencing meeting for the newborn screening
12 community that is a project between this APHL
13 molecular subcommittee and the CDC that they're
14 hoping to have in the first quarter of 2017. So
15 watch out for that.

16 And so May, this was a presentation,
17 she provided to us that she did, also recently
18 given elsewhere, talking about what Wisconsin's
19 doing with next gen sequencing. And so I've
20 grabbed just a couple of her slides and hopefully
21 I can convey most of what she was discussing.

22 So, and she talked a little bit about,

1 I think, you know, where they're focusing right
2 now is on CF. And so obviously we have a little
3 bit of nice history here with when we started
4 with IRT and then adding DNA, expanding the
5 panel, et cetera.

6 And so what she's talking about is
7 actually bringing in information from CFTR2 which
8 is a database that I believe, Gary Cuning and
9 others at Hopkins have been accruing on other
10 variants outside of ACMG-23 sort of with the
11 clinical validity piece as well as in vitro and
12 all the other data, for example, to have
13 confidence in new CF causing variants.

14 And so the interesting thing is
15 they're actually up to 242. If you look all the
16 way over in the right hand column down over CF
17 causing. So, you know, I believe May has
18 actually expanded her panel. So she's actually
19 looking at 242 variants and even beyond.

20 She is still also trying to accrue as
21 part of her pilot information on some other
22 variants and getting some sweat test data on

1 others where we sort of, they're considered
2 having varying clinical consequence or right now
3 where they're trying to get information.

4 So this is the aims of her perspective
5 study that I believe is still ongoing until I
6 believe fall. You know, I think she mentioned it
7 was this fall where they are modifying the
8 established lumina method to expand the CFTR
9 panel up to 252 CF causing mutations and trying
10 to demonstrate that the IRT NGS CF screen
11 protocol can reduce false positive results in
12 their real world newborn screening environment.
13 So that was an update from May on their use of
14 next gen sequencing.

15 And so now if we turn to the other
16 piece which is the timeliness piece, we had known
17 that California had been gathering their
18 information, a lot of their sample collection was
19 done earlier than 24 hours.

20 And they were putting together that
21 data and luckily in the intervening few months,
22 the last few months they published it. And so we

1 had presentation from them on the data that they
2 have analyzed.

3 So they actually looked at their
4 California population level data to actually look
5 at whether or not early specimens that are
6 collected from 12 to 23 hours are also
7 satisfactory when you look at screening.

8 And they looked at specifically false
9 negative and false positive rates for four
10 disease categories, and you can see them listed
11 here. And so they compared the early collection
12 group to what they considered the standard
13 collection group which is the 24 to 48 hours.

14 And so I actually have the citation
15 down on the bottom, so if you want to look up the
16 paper you can do that yourself. At this time,
17 the data they had showed no significant
18 difference in terms of the false negative rate
19 between the two different collection timing
20 groups.

21 And in terms of false positive rate,
22 they saw a difference, they saw a higher false

1 positive rate for CH and IRT, but a lower false
2 positive rate for MSMS metabolic disorders and
3 CAH.

4 And we had Marcie Sontag talked about
5 some data that she's been working on, similarly
6 looking at how screenings impacted as we improve
7 timeliness and may even see this earlier sample
8 collection.

9 And so she's been working with a group
10 including New York and Minnesota, Wisconsin and
11 Iowa to get data and see what implications of
12 earlier collection has on screening.

13 So these are some of the concerns in
14 terms of moving collection to earlier. You
15 obviously have less time to consult with parents.
16 You know, you have concern about the NICU and
17 very low birth weight babies.

18 You know, the question is analytically
19 does this mean that we have more out of range
20 results because maybe we have to worry about that
21 in these earlier specimens and the analyte is
22 higher or lower at that point versus 24 to 48

1 hours. And then of course, you know, will that
2 impact false negatives and false positives.

3 So she actually had a lot of data from
4 each, you know, from each state. And
5 unfortunately I don't have the time to present it
6 all. So I picked one page as a snapshot to show
7 you. And so as you said, she reported percent of
8 positives by age and town of collection, looked
9 at borderline cases separately and removed the
10 very low birth weight babies.

11 So here's data we got, she got from
12 Minnesota looking at IRT. And you can see that
13 they really separated out age at time of
14 collection, and they looked at 2014 and 2015.

15 And I think the take-home message, at
16 least for this snapshot, was for example the PPV
17 is better when it's 24 hours and beyond. But I
18 think that at this time, the amount of data,
19 especially there just isn't a lot of numbers down
20 before 24 hours yet. So I think the goal is get
21 more data and do some more work in this space.

22 So that is the update on their work

1 there. So those are, that's sort of a snapshot
2 of the four presentations that we got yesterday
3 that we wanted to share.

4 CHAIR BOCCHINI: Thank you.
5 Questions. Dieter and then Colleen.

6 MEMBER MATERN: Yes, as I mentioned
7 yesterday at the meeting, Dr. Rinaldo is sitting
8 right now with colleagues from California, New
9 York, Georgia, Norway, and Iceland, in a room.
10 And he doesn't let anyone out for at least 12
11 hours a day for a whole week to discuss data,
12 covariates for all of the newborn screening
13 conditions which include birth weight,
14 gestational age and age at collection.

15 So the next steps are happening right
16 now. And I really encourage at least the
17 subcommittee to invite someone from the group to
18 give an update at the next meeting.

19 MEMBER KELM: Good idea.

20 MEMBER BOYLE: So I know that there
21 was a study was supported by the committee that
22 took many years that Stuart Shapira and Harry

1 Hannon had worked on which looked at some of the
2 conditions that the California group looked at in
3 terms of early versus late collections.

4 MEMBER KELM: I believe that was
5 actually, that was looking at first -- one single
6 screen versus two screen states.

7 MEMBER BOYLE: You're right, you're
8 right. Two screens, right. Yes, yes, yes.

9 MEMBER KELM: And I think the problem
10 was that there wasn't really a clear conclusion
11 there about whether single screeners or two
12 screens is actually more effective.

13 MEMBER BOYLE: Yes, it was different
14 for different conditions. So I was just
15 wondering, so thank you for reminding me about
16 that. But I was wondering with the California,
17 are there any takeaways from the results in terms
18 of one having high, the other having low false
19 positives?

20 MEMBER KELM: Well, and I actually
21 believe that, if I recall, that the conclusion
22 was that the differences that they saw weren't

1 large and they weren't as concerned clinically.
2 And I don't think Lisa's here today. Oh, she is
3 there. She's right in front. Do you want to --
4 you can even sit at my seat.

5 MS. WISHBAUM: Lisa Wishbaum from
6 California. Yes, I would agree. We felt that
7 the conclusions really weren't, there weren't big
8 differences between the 12 to 23 which is what we
9 called the earlier collection group and the
10 standard collection, 24 to 48.

11 There were, because we had such large
12 numbers there were some statistically significant
13 findings, but the differences were in fact small
14 differences in the false positive, in the screen
15 -- I'm sorry, the screen positive rates.

16 As far as the screen negatives which
17 are basically the missed cases, we didn't see any
18 differences in any of the disease categories that
19 we looked at.

20 With the screen positives, as was just
21 presented, there were higher rates of false
22 positives for congenital hypothyroidism and for

1 CF, but after the IRT test. And we really felt,
2 well with the CF, those cases don't even get
3 called out to the families at that point.

4 So there's really no impact, negative
5 impact on families because those cases just go on
6 for DNA panel testing and then sequencing. So
7 only after all that do we actually make a call
8 out to the family and the primary care provider.

9 So we just felt comfortable clinically
10 that that's not a big issue. And for the
11 congenital hypothyroidism, the follow up does not
12 entail the family going to a specialty follow-up
13 clinic, like going to a metabolic clinic.

14 And it's the primary care provider is
15 just asked to redraw the blood and they do the
16 serum TSH and t4. So we felt like clinically, if
17 you had to kind of pick the, you know, out of all
18 those diseases, which is the most significant
19 group that you would be concerned about having
20 high false positive rates, we felt, given that it
21 was CH and CF, we just felt that that wasn't a
22 big impact.

1 If it were MSMS disorders, that would
2 be quite a different story. So that was our
3 conclusion. But the paper has been published in
4 Genetics and Medicine. And everyone's welcome to
5 read it. And if you have questions, you can send
6 us emails.

7 CHAIR BOCCHINI: Thank you. Other
8 questions? Beth?

9 MS. TARINI: Beth Tarini, AAP. As a
10 researcher, I always hesitate to rely on
11 anecdotal data. And with all due respect to the
12 assessment, I agree an MCAD positive is different
13 from a congenital hypothyroid. But as someone
14 who's child actually had a false positive for
15 congenital hypothyroidism ironically, I can tell
16 you that, and then had to go through three
17 subsequent draws because the thyroid didn't come
18 down as quickly as it could have, it does cause,
19 I mean I didn't have a nervous breakdown, but it
20 does cause a bit of angst.

21 So because the thyroid doesn't also
22 normalize right away, and it was always trailing

1 by a point. And we could say it's a point, but
2 the doctors always made me redraw it.

3 So my child had three draws. Luckily,
4 he didn't have to have venous. He only had to
5 have foot. But we had three draws at each point.
6 So it does, you have to bring them back, it does
7 create these other issues.

8 CHAIR BOCCHINI: Other questions,
9 comments? Carol.

10 MS. GREENE: So maybe here just a plug
11 for the two screen system because I think we all
12 know, as Maryland does it, I think we all know
13 the pros and cons of DNA, positive IRT DNA.

14 You have some advantages, you can find
15 cases early, but we may, at some point, need more
16 blood. There are some things that are better on
17 the second screen, and the Maryland system is if
18 the first, if the IRT -- they have nearly as many
19 second screens as first screens, and if you have
20 a high IRT on a first screen and you don't get a
21 second screen, they go looking for the baby.

22 But the protocol is If IRT is high on

1 screen when the baby is a day old, if it's 250,
2 300 it gets called out. If it's above the
3 cut-off but it's not a hugely high number, nobody
4 knows about it until the second screen comes in
5 because it's not an emergency.

6 And only if the second screen confirms
7 the high IRT is it called out as a positive.
8 It's a two screen system, it works beautifully
9 for CF.

10 CHAIR BOCCHINI: Deter.

11 MEMBER MATERN: Before we change the
12 screening orders to a second routine screen
13 across the country and significantly increase the
14 healthcare cost, do this.

15 I would still suggest that we first
16 look at the data, looking at covariates and how
17 that can help.

18 CHAIR BOCCHINI: Thank you, Kellie.
19 Well, that concludes the agenda for our meeting.
20 I just want to now ask if there's any suggestions
21 of additional topics to be covered at our next
22 meeting.

1 I think just going forward, we already
2 are planning for a presentation from the insight
3 grantees which are funded by the NIH, and Don
4 Bailey's going to moderate that session, and the
5 presentations.

6 And that is certainly going to help us
7 kind of get into the potential disruptive changes
8 that might occur with the whole genome sequencing
9 and what impact it might have on newborn
10 screening.

11 So it will continue to kind of evolve
12 some of the discussions that we have. We're
13 going to continue long-term follow up discussion.
14 We plan to hear from states and that have
15 implemented testing for various LSDs and see
16 where they are and what kind of issues that they
17 have had with the data that they've collected.

18 And then look for long term follow up
19 issues related to hearing screening and critical
20 congenital heart disease. So we already have
21 some good topics already set.

22 We're also going to have updates from

1 new steps on timeliness activities. And then
2 Beth Tarini is going to discuss her Robert Wood
3 Johnson funded project findings. So I think we
4 have got a number of things lined up already to
5 make August another very productive meeting.

6 Are there other topics or things that
7 came out of today's or yesterday's session that
8 come to mind to add as potential topics for
9 discussion? Natasha?

10 MS. BONHOMME: Natasha Bonhomme,
11 Genetic Alliance. I don't know necessarily how
12 this would fit in, but I think one thing that did
13 come up yesterday was around policies and policy
14 around newborn screening.

15 And there have been a number of
16 different, how should I say, pushes, whether
17 that's from a legislative standpoint, on Capitol
18 Hill with some new bills that could potentially
19 affect newborn screening, also at the state
20 level, but also, just advocacy, in general.

21 And I think that's something that
22 affects the work that we do, but we don't often

1 talk about it within this committee. And so that
2 may be something that if not for August, but
3 something to think about down the line.

4 You know, just the way that efforts
5 are being pushed, it's just evolving, as
6 everything does. You know, if you actually go on
7 to change.org, there are a couple of petitions on
8 there related to newborn screening conditions and
9 just different things that I think could be at
10 least of interest for this Committee to think
11 about or to know what's going on in newborn
12 screening outside of some of the standard topics
13 that we typically touch on.

14 CHAIR BOCCHINI: Great, thank you. And
15 then, of course, we're going to add Dieter's
16 suggestion for looking at the data that's
17 becoming available on covariance that might
18 influence accuracy for newborn screening, initial
19 screens.

20 Any other items? If not, I want to
21 thank you all for your participation and
22 involvement in making this committee's work so

1 successful.

2 I want to thank HRSA for organizing
3 the meeting and Debbie Sarkar for her work in
4 developing the program here. And I also want to
5 thank Elena Harris who has done yeoman's work
6 trying to make sure that everything worked well
7 yesterday and today, electronically and
8 otherwise. So thank you much.

9 So with that, we'll conclude today's
10 meeting and look forward to seeing you all in
11 August. Thank you.

12 (Whereupon, the above-entitled matter
13 went off the record at 1:36 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: The Advisory Committee on Heritable
Disorders in Newborns and Children

Before: HHS Health Resources & Service Administration

Date: 05-10-16

Place: Rockville, Maryland

was duly recorded and accurately transcribed under
my direction; further, that said transcript is a
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Court Reporter

NEAL R. GROSS

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