Meeting Minutes: Advisory Committee on Heritable and Congenital Disorders (Newborn Screening Advisory Committee) Summer 2025 Meeting

August 20, 2025

Minutes prepared by: Amy Dahle
Location: Virtual (Teams)

Attendance

Present:

- Sue Berry
- Kaitlyn Campbell
- Tricia Hall
- Bob Jacobson
- Dietrich Matern
- Randal Richardson
- Katie Pfister
- Emelia Rogers
- Kali Schreiner
- Kathy Stagni
- Queenie Tan

Absent:

- Alex Boucher
- Rae Blaylark
- Christen Ebens
- Brooke Moore
- Jennifer Arveson
- Courtney Jarboe
- Teresa Rink
- Annamarie Saarinen
- Renee Temme

Decisions Made

- Designated questions on the Evidence Review Pre-Workgroup Survey can be completed by subject matter experts, and they would not be expected to know/complete other sections on the survey.

Action Items

- MDH will update documents based on today's feedback.
- Updated materials will be sent out, along with NSAC bylaws, 30 days prior to the October meeting.

Agenda

1. Welcome
2. Condition Nomination Process Map
3. Condition Nomination Form
4. Steering Committee Nomination Check List
5. Evidence Review Pre-Workgroup Survey
6. Advisor Survey
7. Next Steps

Meeting Notes

1. Welcome
    a. Roll call was taking via the chat. Carrie encouraged participants to use the chat and raise hand feature.

2. Condition Nomination Process Map (see the Condition Nomination Process Map for more details)
    a. NEW: Steering Committee Members will complete a Nomination Check List
    (Paused for questions…no questions were asked)
    b. NEW: Evidence Review Workgroup Survey (It's a RedCap form)
    c. Evidence Review meets and then reports their findings/recommendation to the advisors
    (Paused for questions… no questions were asked)
    d. NEW: A virtual meeting will be scheduled to hear the Workgroup's findings
    e. NEW: Advisor Survey will be sent out (It's a RedCap form)
    f. NEW: If denied, advisors will anonymously provide reasons to NSAC Coordinators (Likely, a RedCap form)
    (Paused for questions….no questions were asked)

3. Condition Nomination Form (see the Condition Nomination Form for more details)
    a. 3 questions regarding the **Condition**
    b. 7 questions regarding the **Screening Approach**
    c. 5 questions regarding the **Diagnosis & Follow-Up**
    d. 5 questions regarding the **Intervention/Treatment**
    e. 3 questions regarding the **Public Health Considerations/Impact of Screening**
    f. NEW: References added to bottom of the form
    g. NEW: New Steps and Internal tracker
    (Paused for questions)
        i. Q: Sue asked how MDH envisions supporting people who want to fill out the new Condition Form. In addition, what do see as being the role of MDH in assisting in that process.

ii. A: Carrie mention that not every single piece has to be completed. If the individual doesn't know the screening part of the process, we can help and assist. Such as, if information is missing form the form, we will help guide them where it can be found. Carrie acknowledged that the form is very complicated, and it could be a barrier.
iii. Q: Sue asked how to plan to "weed out" a nominator if there was no test.
iv. A: Carrie explained when we meet with the nominator that would be discussed. For example, if the nominator wanted something screened in urine, we would let them know that would be a dealbreaker (now). The meeting with the nominator would occur prior to them filling out the nomination form.
v. A: Amy mentioned that during the initial meeting with the nominator if a parent or advocacy group did not have a co-nominator, we could help make connections so they could team up with a specialist and/or laboratory specialist to assist with technical support.
vi. Q: Sue asked about MDH's capacity to take on this new process.
vii. A: Carrie said that we are hoping, in this new process, to create a realistic timeline with the nominator. The timeline will need to be flexible depending on how many conditions are already in the process. Carrie also mentioned that Steering Committee can be a hard stop in the process.

4. Steering Committee Nomination Check List (see the Steering Committee Nomination Check List for more details)
    a. All criteria on the form must be marked yes before moving to the NSAC committee.
        i. 6 questions are asked (yes, no, unsure)
    b. If any questions are marked no or unsure, the NSAC Coordinators will contact the nominator for additional information.
    (Paused for questions….no questions were asked)

5. Evidence Review Pre-Workgroup Survey (see the Evidence Review Pre-Workgroup Survey for more details)
    a. NEW: Workgroup members will be asked to fill out a RedCap survey
    b. 6 questions regarding the Clinical Characteristic of the Condition
    c. 6 questions regarding The Screening Test: Availability and Characteristics
    d. 5 questions regarding the Screening Follow-Up & Diagnosis
    e. 7 questions regarding the Treatment & Management
    f. 2 questions in Closing
    (Paused for questions)
        i. Q: Sue commented that is going to much more work and how can we expect people to volunteer for that amount of time to complete it. that the Evidence Review Pre-Workgroup Survey seems like a lot of work.
        ii. A: Carrie agreed and explained that the survey would be in RedCap, and we could see how long it takes a person to fill it out. In addition, we will test out that the survey can be completed in sections, saved, and a user could fill out the remaining form at another time. Carrie acknowledged that other likely have the same concerns.
        iii. Q: Kaitlyn asked if the workgroup could divide and conquer certain sections based on subject matter expertise.
        iv. A: Carrie said yes, that's a great idea. We can direct subject matter experts to fill out certain sections.
        v. Q: Tricia mentioned that in the absence of the ACHDNC this is going to be a lot more labor intensive and challenging but there is no way around it.

vi. A: Carrie said that these documents are not fixed document, (that will never change). Every time we have a new condition we learn for it. If we find out that the Pre Work Group Survey does not work or not working as intended, we will adjust. In the absence of the ACHDNC, we would like to have a through and robust process.
vii. A: Amy mentioned that the survey is less daunting when it's in RedCap.
viii. A: Carrie agreed but said it will still take a lot of time for the workgroup members to complete.

g. Once all the information is gathered form the survey, the workgroup members would have their meeting to discuss the evidence.
h. A virtual NSAC Meeting will be scheduled, to have the Evidence Review Workgroup report out their findings.
i. Q: Sue asked if the Evidence Review Workgroup would be making any recommendations? She stated that at the national level, that was one of the tasks for the workgroup. They would gather the information, then a summary was presented, and a recommendation was made to the committee. "Or is it going to be left entirely to the advisors at the bigger format? For them to take the information and go from there."
j. A: Carrie mentioned that we were hoping it wouldn't be a recommendation on which way the advisors should vote, but whether or not there is enough information for the advisors to be able to make a decision on it.
k. Q: Sue said "So what I'd say is that in the other context, they did make a recommendation, and the committee didn't always agree with it. So that's slightly different and I'm OK. I just want to know what our terms of engagement are."
l. A: Carrie, yes
m. Q: Bob stated that as a workgroup member he did ask that Evidence Review Workgroup members make a recommendation up or down. If all these people are gathering the information, they should be making a recommendation. "I think that the committee's in a better position to give that recommendation and it doesn't make sense for the committee just to say we've looked at all the evidence and we think you guys can vote on it. I'd prefer that they don't take. They don't even send it to the advisory group if they don't think there should be a change.
n. A: Sue said that is what she was thinking too, so that is why she asked. "If you have gone to all this trouble and have all these expert people making thoughtful considerations of it all. To then just send it with no interpretations essential seems inappropriate to me."
o. Q: Carrie "So there, if the workgroup does not feel there is like enough information to move forward that it would stop here. And so maybe we need to add an additional piece here. To make it clear that. It's like recommended to not move forward to the advisors to vote. Is that what I'm hearing?"
p. A: Bob said that he is suggesting that the committee put forth a motion, to adopt or to decline to the advisory group. Then there is a discussion and vote. "And as Sue said, at the RSUP, they can turn down the workgroup's recommendation. But at least they have a recommendation."
q. A: Carrie: mm-Hmm
r. A: Bob "at lest you have a direction set by the people who looked at the data most intensely. That's a little different that saying, I think we have enough data to move it to the advisory group. This is saying we have enough data that we can recommend up or down with."
s. A: Sondra said "The reason we veered away from that was because, for those of you who are around, when we didn't have a formalized process, and we were reviewing multiple lysosomal storage disorders (Pompeii, MPI, XALD). We did have a work group that came together to help us review the evidence and we presented to the committee. They made a recommend to the Committee whether or not they felt we should be if they're ready or not. We did receive feedback from advisors at that time. Granted this was years ago, they felt like that decision making somewhat limiting the roles and responsibilities of the

advisory committee. They felt like they became a rubber stamp. So, I'm just providing that context; we got different advisors now, but that was part of our hesitation is given that historical context."

t. A: Sue "I would hate to have advisors who thought that they were only a rubber stamp. I think that all that does is promote the opportunity for a vigorous and appropriate conversation, and I think it should be really clear after the people who work to do, you're asking us to do these evidence reviews and to give our expertise and then to not come to. Any conclusion other than yeah, you can talk about it. I understand and I hear what happened historically and I differ with that that plan.
u. A: Carrie: Mm-hmm
v. A: Sue apologized as she needed to leave the meeting early.
w. A: Carrie "We will loop back with you Sue."
x. A: Randal "I'm completely fine with that. I think that sounds like a great idea."
y. A: Carrie: Okay
z. A: Tricia "I would agree with this, and I think I had the same concerns when we went met with the small group, which is I, I do think that the end result of the evidence review should be a recommendation. It doesn't have to be a motion, but it should inform a motion at the group, I think it's a lot of work to just essentially, have the committee do the same thing over again by not by having to process all of the evidence. It's kind of duplicative, if there isn't an outcome from the Evidence Review group."
aa. A: Randal "It's a great phrase. Informed motion. I like it."
bb. Carrie next informed everyone that we will make those updates and if there is a motion from the Evidence Review Workgroup to move forward with the condition versus not, then the next piece is the advisor survey.

6. Advisor Survey (see Advisory Survey for more details)
    a. 7 Questions regarding the Clinical Characteristics of the Condition
    b. 8 questions regarding The Screening Test: Availability and Characteristics
    c. 5 questions regarding Screening Follow-up & Diagnosis
    d. 5 questions regarding Treatment & Management
    e. 2 questions in Closing

    Paused for questions….no questions were asked)

7. Carrie finished reviewing the third page of the flowchart (see the Condition Nomination Process Map)
    a. NEW: Asking advisors to provide comments regarding the denied condition.
        i. It would be an anonymous, RedCap survey with very little questions (1 or 2?)
        ii. When a condition is denied, a letter goes back to the nominator. Having details on what is missing would be shared with them. We don't want someone to go through a denial and then immediately renominate if there are pieces that a missing.
    b. Q: Amy asked "Overall, for some of the advisors, are you liking the process?" Paused for a response "Cause with the feedback we have, we'll go in to talk about the next steps. But, um, this will eventually get voted on, so kind of just wanted to gauge how people are feeling. Paused for a response. "But if you need a little time to think about it, e-mail Carey and I"
    c. A: Dieter: "so I was part of the group, so I like it. But just like Trisha mentioned, I mean we did this when there wasn't an advisory committee on the federal level. We didn't except that now every condition is coming to every state. So, I think this is, a way forward. I think we will vote on it and if it goes through then we'll fuse it and then we will adjust it as necessary." Dieter mentioned that we will have to figure out as some point, a replacement of the federal group and at some level come together. Maybe this would be an opportunity for multiple evidence review groups across the country to come together.

d. A: Carrie agreed and mentioned that we are fortunate to already have a process, so we are not completely dependent up federal recommendations.

8. Next Steps
    a. We will send out a final version. This will also include new bylaws. It will be review and voted on at the October meeting.

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Prepared: 08/20/2025

Approved: 10/15/2025