SOUTH DAKOTA DEPARTMENT OF HEALTH

DIVISION OF FAMILY & COMMUNITY HEALTH

Office of Lifespan Health

South Dakota Newborn Screening Advisory Committee

Meeting Minutes

November 5th, 2025, 9:30 – 11:30 am

Virtual Meeting

Present:

SD Department of Health: Sadie Hedges, Beth Dokken, Dr. Denise Hanisch (voting), Amy Wu, Katelyn Strasser, Kristy Jackson

SD Medicaid: Dr. Clarissa Barnes (voting)

SD Vital Records: Shawna Flax

University of Iowa: Ken Coursey, Zac Leeker, Emily Phillips, Sierra Daniels

University of South Dakota: Dr. Messersmith (voting)

Avera: Alyssa Christensen (voting)

Sanford: Dr. Davis-Keppen (voting)

Parent Project Muscular Dystrophy: Katherine Anderson

Parent: Shelbi Conover

State of Minnesota: Trenna Lapacinski-Ludens, Sondra Rosendahl, Carrie Wolf

Absent: Dr. Isum Ward, Dr. Rachel Li, Dr. Carly Johnson, Shelby Jepperson

Sadie Hedges started the recording.

Beth Dokken started the meeting with introductions and an overview of the division.

Beth introduced voting members, confirmed quorum was present.

Introductions of rest of committee.

The advisory committee is seeking new members from these groups : Monument, IHS, Midwife.

Agenda:

Beth Dokken explained South Dakota's nomination process.

Beth gave an update on the Advisory Committee on Heritable Disorders and its status and timing of Duchenne Muscular Dystrophy (DMD) review for the RUSP. Beth explained that due to the development needed to determine diagnostic testing and follow up processes, it would be a timeframe of 1-2 years before we would add to the legislative rules, assuming the advisory committee opted to move the nomination forward.

Beth turned the meeting over to DMD nominator Katherine Anderson, the Community Research Manager from Parent Project DMD.

Highlights of Katherine's presentation:

Expected 1:5,000 boys anticipated to have DMD

Damage begins in utero, but symptoms not noticed until age 2.5 on average, but typically not diagnosed until ages 4-6. Early Intervention Symposium focused on corticosteroids.

Overview of how various states handle NBS related to DMD

Overview of how states determine the cut-off differently. New York Pilot Post-Hoc Analysis.

Katherine shared resources to support clinicians and families: ACT Sheet, free genetic testing through PPMD, Baby Duchenne

Next on the agenda: Minnesota Department of Health.

Carrie Wolf shared their experience of screening for DMD in Minnesota. DMD nominated in 2021. Started screening in February of 2025.

Trenna Lapacinski-Ludens shared information about Minnesota's laboratory process, which uses a GSP CK kit from Revvity. Borderline results are sent for repeat screen. Card comes in, if 1 punch is elevated, they take 2 more punches and run them the same day; it's not a new card – just same collection to confirm they are seeing a borderline. This is all done before they report it out to follow-up to manage follow up numbers. Overview of NICU process.

Sondra Rosendahl, supervisor of follow up. Sondra explained their follow up process for DMD. They initially recommended a repeat bloodspot screen at 2 weeks of age. Now they request a total CK at 2 weeks of age. They do the notification, and follow up the screen with a

Fact Sheet about DMD for the family, and a list of neuromuscular specialists if they need to bring baby in. If CK is elevated, they recommend follow up within 1 week. Referrals are sent through Natus that gives them access to the screening report and a note. Diagnostic form completion is requested, the specialists fill it out and they get it back, showing CK levels, diagnostic details, molecular results, as well as initial intervention and treatment plans.

Sondra explained their outcomes–Feb thru Aug–first 6 months of screening.

Carrie shared insights from their experience related to cost considerations, the need for additional follow-up staff related to borderline, adding the test to the LIMS, molecular testing–if all went to molecular testing, this could be done in-house or contracted out.

Sondra–no DMD cases have been found at this time. They would have expected to have 3 males by this time using the prevalence of 1:5000. They have had difficulty getting repeat screens for rural or out-of-state babies, if border states are not testing for DMD, the family would have had to travel to Minnesota, so they do a total CK in lieu of repeat. Offering a total CK vs drive-time for a repeat screen. Minnesota is not removing the recommendation for a repeat screen. Also, some providers ordering clinical labs are misinterpreting CK-MB results, leading to confusion with families. Moving to the CK allows the program to give better guidance.

Questions:

Dr. Davis-Keppen: How did you choose your cut-off? Carrie Wolf explained Minnesota's process.

Dr. Hanisch: is this a higher amount of follow-up? Is it possible to just screen at 2-weeks? Minnesota explained the items on their panel, and suggested that states that are 2-screen states might be able to not report the result until 2nd screen is in.

Dr. Barnes: What was the thought process behind lumping the birth trauma cases in? Sondra: coordinating all babies to be screened at 2-weeks of age would be a nightmare vs getting the screen done at the typical time at the birth hospital. When we do the notification, we very much try to emphasize that it may normalize due to birth injury. Dr. Davis-Keppen explained that diagnosis in the first month makes a difference in newborn screening, there are a lot of infants who don't get the care they need, which is why we do the hearing screen because you don't know if you'll see them again. To do it as part of routine care would be fine for those who get routine care.

Kristy Jackson: If DMD is not on national RUSP, did you run into issues with commercial insurance, or do they go off of state's panel? Minnesota: We did not have a fee increase for

DMD, but varying coverage on what is covered. Insurance might be different based on follow-up that is needed. Dr. Davis-Keppen–we are able to make sure genetic is covered at no cost under Medicaid.

Shelbi: comment to Dr. Barnes and false CK levels–to families. Son's experience with CK level.

Beth opened the floor for discussion from the committee.

Dr. Davis-Keppen reminded that it was brought up for the RUSP. There is treatment now that can alter the history. About 30% of them qualify for a certain therapy. There is also gene therapy, which is not a cure. The diagnostic odyssey of families. Knowing what to do is so beneficial.

Katherine Anderson–DMD was 2 weeks from a vote when ACHDNC was dissolved. Public Comment at Federal Register is now closed. But there is not a recommendation on the timeline of the addition to the RUSP.

Dr. Messersmith asked if DOH could handle this with current capacity or if we'd need an additional FTE on follow-up. The Iowa team responded with their thoughts on follow-up staff.

Ken Coursey provided insight into lab's perspective. No staffing needed extra on lab side. State is moving to a 7-spot card so no concerns with having enough quantity of blood, and the estimated numbers they'd expect to find. Our LIMS is built by our own team so should be less of a barrier for them to build it such as it would be with a commercial provider. Follow up protocol would be done within 1 year after the approval to do so.

Dr. Davis-Keppen asked if any of the other Quad-States were considering DMD at this time. They were not.

Beth asked: what is the cost of the panel and what would it be if it increased? Ken explained how the cost would grow per screen.

Beth asked: what about coverage of the treatments. Dr. Barnes responded and Katherine Anderson explained new therapies.

Dr. Barnes: if we did this tomorrow, what would our cut-off be? Ken explained how this would work and that there is variability between labs and equipment. They cannot answer that question until they can generate their own data.

Shelbi Conover: went to doctor in Iowa City. Gave so much material in-person; it was a Duchenne clinic and connected them with Team Joseph to help with travel, PPMD, etc. So many resources provided, availability of 1:1 meetings with their genetic counselors.

Dr. Messersmith: reflecting on newborn hearing screening and the ability to provide the resources to the medical providers. Do we have a champion in South Dakota who can do this? What does the execution of this look like in South Dakota? Do we not have the capacity to provide resources to anyone in the state who has this outcome? Dr. Davis-Keppen: we do have a muscular dystrophy clinic; apologized about Shelbi's experience of learning of this later in the day. The ability to support families is much more available than it used to be.

Dr. Hanisch: commented on Minnesota's practice of giving a list to the right people when they need to be.

Beth moved on to questions/comments from voting members:

Dr. Barnes: what is the lag time to referrals to the clinic? Dr. Davis-Keppen: we work them in and see them within 2 weeks.

Beth opened up the floor to the voting members to make a motion.

Beth suggested three motions:

- Recommend not to add to panel
- Recommend that we DO add to panel
- Recommend that we aren't ready yet to make this decision and would like a later vote.

Beth opened the floor to a motion:

Dr. Davis-Keppen made a motion to add. Dr. Barnes clarified the operationalization of this and gave a 2nd to the motion.

Beth confirmed still a quorum.

Dr. Hanisch: yes

Dr. Barnes: yes

Dr. Davis-Keppen: yes

Dr. Messersmith: yes

Alyssa Christensen: yes

Dr. Ward, Dr. Li and Dr. Johnson are absent. This motion does carry forward.

Next steps:

Beth will take this forward to Secretary Magstadt, whose decision will be communicated to the advisory members via email.

At the conclusion of the DMD discussion, the advisory committee received general program updates:

Sadie shared about the advisory charter.

Sierra Daniels shared information about the update to the bloodspot card for 7-spots, which is an initiative to improve our timeliness data.

Shawna – Vital Records – shared an update on their go-live for birth certificate process. Scheduled to go-live in July. Going forward they will handle all legacy data and ensure no disruptions with the newborn screening program's birth-matching process.

Kristy – NBS system updates:

- Working with vendor to update NBS IT system; still in contracting phase. First priority will be to handle hearing screening & will be asking for input
- Data sharing agreement in place with USD-EHDI, allows for sharing of data with Hands & Voices. We will build out a module for them to do their work connecting families statewide.
- Also working on data sharing conversations with Birth-3, to help make sure babies are getting connected to intervention.
- Loaned out OAE screener to USD Center for Disabilities; they will be teaching graduate students how to do hearing screens as part of their speech/autism clinics
- DETOR – turned this over to Sierra Daniels, who is a member of the DETOR build team. DETOR allows for the sharing of electronic test orders and results in Epic. Sierra explained that they ask for 1 clinical person to be involved so we can make sure it's beneficial. Timewise, a non-electronic manual entry takes 3 minutes. When we do it electronically this takes 30 seconds.
- CMV speaker from Avera and possibly Sanford at upcoming meeting.

Beth concluded the meeting by thanking members for their support and announcing that after 5 years of leading the committee, she will be passing the baton. She plans to stay engaged as the connector between newborn screening and the legislative process, but that Sadie Hedges will chair the committee going forward.