Oregon Health Authority
Northwest Regional Newborn Bloodspot Screening Advisory Board

Meeting Summary — May 29, 2024

Location
Videoconference

Quorum
Board attendees constituted a quorum for the duration of the meeting.

Board Members Attending
Marilyn Hartzell, M.Ed., Board Chair, Family Representative
Pamela Domingo, Representative of Disability Rights Oregon
Andrea Keating, LDM, CPM, Representative of a statewide association of midwives
Charlene Lai, MD, Representative of Oregon Pediatric Association
Awe Lapcharoensap, MD, Representative of a birthing center or hospital
Sherly Paul, Representative of a statewide association of nurses
Elizabeth Powers, MD, FAAFP, Representative of birthing center or hospital
Kara Stirling, MD, Representative of a birthing center or hospital
Amy Yang, MD, Contracted medical consultant

Board Members Absent
Jill Levy-Fisch, Advocacy association regarding newborns with medical or rare disorders
Dawn Mautner, MD, MS, Representative of Medicaid or insurance industry

NBS Program Staff
Patrice Held, Newborn Screening Program Manager
Amber Gamel Miller, Public Health Nurse, Newborn Screening Program

Guests
None

Members of the Public
Dr. Therman Allen Merit

Jensen Strategies Facilitation Team
Erik Jensen, facilitator
Amelia Wallace, senior associate
Cicely Bergsma, project associate

ACTION ITEMS

A. The program will begin a scientific review of Krabbe Disease.
B. Draft Legislative Report to be sent to Advisory Board members for review
C. The Jensen Strategies team will send a doodle poll to Newborn Screening (NBS) Advisory Board members to schedule four meetings for the next year (July 2024 – June 2025)
D. Erik Jensen and program staff will schedule a funding subcommittee meeting before the next board meeting.
E. Update language as approved for the Disorder Review Protocol.

MEETING AGENDA ITEMS

1. Welcome

Chair Marilyn Hartzell opened the meeting welcoming all the participants and noting key agenda items including discussions of the draft Disorder Review Protocol, consideration to start scientific review of Krabbe disease, and draft Advisory Board Legislative Report.

2. Facilitator's Introduction

New Advisory Board facilitator, Erik Jensen provided an introduction of Jensen Strategies and facilitation team including senior associate, Amelia Wallace, and project associate, Cicely Bergsma.

Board Member Interviews: Erik reviewed the collective feedback he received from the Advisory Board members he interviewed. He noted all interviewed agreed that scheduling meetings out for a year would be helpful and his team would follow-up with a Doodle poll to schedule four meetings for the next year.

Board Member Appointments**:** Upcoming Board member terms ending this year and current vacancies were discussed noting: Dr. Awe Lapcharoensap has decided not to renew her membership and the program will be seeking someone to fill the position which represents a statewide association of pediatricians; Jill Levy-Fisch and Sherly Paul have agreed to renew their four-year terms; Dr. Dawn Mautner has not decided on renewing her membership (Note: subsequently, she decided not to renew her term); and the program will be seeking to fill the vacant position for a representative of an advocacy association regarding newborns with medical or rare disorders. Board members were encouraged to forward any recommendations of individuals for the vacant position to the program or Erik.

Erik also reminded Board members of the discussion protocols and noted that decisions would continue to be made using the 1-5 consensus tool as prescribed by the group's Charter.

3. Program Updates

Patrice Held, NWRNBS Program Manager, provided an update on the program's recent projects and activities.

Updated Specimen Collections Guidelines Update: Specimen collection is particularly important for premature babies in the NICU and the recommendation is for three screens. However, some babies are in the NICU for reasons unrelated to pre-maturity and hospital feedback has suggested the third screen may not always be necessary. After the program cross-referenced its protocols with the Clinical Laboratory Standards guidelines, it updated the specimen collections guidelines to require only babies less than 34 weeks gestational age or less than two thousand grams to receive the third screen.

In addition, if a baby is going to have a transfusion, the first screen must happen before the transfusion to avoid interference the testing protocol.

If a baby is transferred from a home or small facility within the first 24 hours of life, the responsibility is on the receiving entity to conduct the screening.

One question was asked about the update in the guidelines:

- Q: How are updates to the screening guidelines communicated to providers? *A: The program has records of entities that submit samples including hospitals, midwives, and clinics. They have also tried to gather emails for individuals at those locations which are used to disseminating information. It can be a challenge to keep the list updated. The program has a public health nurse who communicates monthly with all hospitals and midwives through the dissemination of quality insurance reports, newsletters, and email notifications. This information is also on the website. Program staff appreciates feedback on how the most effective communication tools and timing.*

OSPHL LIMS Project(s): The NBS program has two ongoing laboratory information management systems (LIMS) projects. The first project is an update to its case management system, Neometrics. This update is now complete. The second project aims replace the LIMS with one that can be used for all units. A bid process to select a vendor has been initiated. This is a five-year project will be a major undertaking for all units within the public health laboratory.

Paperless Reporting: The program has started an initiative to move toward paperless reporting to give providers access their newborn screening reports through a web portal. Providers will be asked to use this online system starting on July 1, 2024. However, the program will continue to fax reports that have positive or inconclusive results.

NBS Screening Card Redesign**:** The program is working on a redesign of the Newborn Screening Card for greater delineation of the place of birth, submitter of the NBS specimen, and follow-up primary care provider. Race and ethnicity have been removed because they are not always accurate. A field is being added to indicate if blood is not collected and the reason. The new card will be implemented in January 2025.

2024 Legislative Outcomes: State Representative Susan McClain was instrumental in this year's Legislative Session in getting a $250,000 allocation to help cover the costs of Oregon families who pay out of pocket for screening.

APHL NBS Site Visit– Draft Report: The Newborn Screening Assistance and Evaluation Program (NewSTEPs), in partnership with the Association of Public Health Laboratories' (APHL), conducted a comprehensive on-site review of the Oregon newborn screening (NBS) program. A draft report has been provided to the program with the following highlights related to the work of the Advisory Board:

- Program strengths cited include: strong leadership that is open to change and promotes improvements; co-location of the laboratory and follow-up program support communication between them; the Advisory Board's high level of engagement, value of their role, and particularly around the review of new disorders; the Oregon Health Authority's (OHA) priority of addressing equity in the organization and program.
- Program challenges include: need for improved Advisory Board onboarding; the two-screen process can result in collection or contamination issues; funding is not sufficient to cover additions to the NBS panel; opportunities for families' reimbursement for NBS costs are rarely used; and although the program can roll over funding across bienniums, there is a potential liability of losing funds to other OHA needs.
- Recommendations include: statute and rules amendments; enhanced transparency of the condition review process; improved education and training for onboarding Advisory Board members; consideration of a bioethicist on the Advisory Board; exploring participation in other jurisdictions' boards/committees; review the utility of the two-screen process; review why approximately one percent of the babies are not screened and what education and outreach might be effective to reducing that number; explore pursing equity-based funding; consider invoicing for screening services; ensuring six months notification of fee increases to providers; and instituting legal safeguards against using NBS funds for non-NBS programs.

Questions from the Advisory Board included:

- Q: Right now if screen isn't collected by a community birth provider for a family they are not incurring a cost associated with using a screen. With the new redesign it looks like there is a potential the provider will be pre-producing the card for that baby regardless of whether they administered the metabolic screen to that baby. Will there be a plan in place to reduce the cost

associated with screens that were not utilized? *A: We will be asking that community birth provider to utilize the card by filling out the patient information but given the situation where they are not collecting the screen, the program will be devising a mechanism for that birth provider to be reimbursed or send additional cards to them.*

- Q: In looking at the NWRBS website, in the section "for parents" it has fee waiver or opt out but when you click on it, it doesn't show the fee waiver, only a religious exemption form. On the collection kit page, it has a community birth provider subsidized kit order. It might be worth in the parent/guardian section noting the NBS kit should not be a cost to them and to check with their birthing providers. *A: Ideally, we don't want parents ordering cards or filling out the waiver. We want that ownership to be on the birth provider. The parent section will be updated.*

4. Criteria and Process For Condition Review

Disorder Review Protocol**:** Erik reviewed an updated draft of the Disorder Review Protocol that was discussed at the January meeting and was revised during the interim based on input from the Advisory Board. The most recent update included draft language related to public input during the disorder review process. A discussion related to the draft presented included:

- Related to the 1-5 consensus decision making tool discussion focused on bringing clarity regarding how it works and the advantages of using it.
- Regarding "Step 3: Public Input on Disorder Review," some members suggested that this step doesn't have to happen exclusively in one Advisory Board meeting separate from the other steps may be included in one meeting. It was clarified through the discussion, that the Advisory Board would have the discretion to conduct one or more of the steps within one meeting and the language should allow that discretion. New language was offered to reflect that intent which stated, "Time will be dedicated during an Advisory Board meeting for public input on the disorder." No objections were made to this revised language.

Decision: The Advisory Board, by strong consensus, **adopted** the May 27, 2024, draft of the Disorder Review Protocol, with the language change noted above. The decision was reached using the 1-5 consensus tool whereby each member shares their level of support (1 - enthusiastically agrees with the proposal/recommendation, 2 - agrees with the proposal/recommendation, 3 - on the fence, has questions, or is neutral but can live with the proposal, 4 - has serious questions or concerns but is not willing to block the proposal, 5 - objects and will block the proposal). All members responded with "1."

Krabbe Disease and Duchenne Muscular Dystrophy: Patrice reviewed the national process for adding conditions to the Recommended Uniform Screening Panel (RUSP). This process involves a review of each condition by the US Health and Human Services (HHS) Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) who will make recommendation on whether the

condition should be added to the RUSP. If it is recommended for addition, it is forwarded to the HHS Secretary for approval.

In February 2024, the ACHDNC recommended Krabbe Disease be added to the RUSP and it is currently waiting for approval by the HHS Secretary. Historically, the HHS Secretary has always approved conditions to be added to the RUSP based on the ACHDNC's recommendation.

In May 2024, the ACHDNC did a first review the Duchenne Muscular Dystrophy and sent it back for more information before considering it further. Based on this initial review, it is not recommended that the NWRNBS Advisory Board take it under consideration at this time.

The Advisory Board discussed the possibility of moving forward with a scientific review of Krabbe Disease now given the likelihood the HHS Secretary will approve the addition to the RUSP based on the ACHDNC recommendation. Advisory Board discussion points and questions included:

- Ensuring that funding is available for the addition of Krabbe Disease, as well as recently approved conditions, to the panel.
- There is an advantage to moving forward now with the scientific review, Step 2 of the Disorder Review Protocol, so when the condition is formally approved for the RUSP, Steps 3 and 4 can commence without delay.
- Q: If the HHS Secretary declines to approve Krabbe Disease and the program moves forward with the scientific review, can the Advisory Board decide independently to move it forward for Oregon's screening panel? *A: According to the current Board review policy, that would not be possible because addition to the RUSP is a prerequisite.*

Decision: The Advisory Board, by strong consensus, **approved** moving forward with a scientific review of Krabbe Disease. The decision was reached using the 1-5 consensus tool. Members supported the decision with 1's and 2's.

Advisory Board members were asked to email Erik or Patrice with suggestions of advocacy organizations or other interested parties who should be included in the Krabbe Disease discussion assuming the process moves forward after the scientific review.

5. Legislative Report Update

Erik provided a brief update on the drafting of the Board's Legislative Report noting that a draft was not ready for this meeting. The Advisory Board should expect a copy of the draft for review in mid-June.

6. Long-term Subcommittee Update

Erik reviewed the background of the Long-term Subcommittee that has not met since 2022. The original purpose of the Subcommittee was to look at what funding model might work for the NWRNBS program. At this time, the intent is to reconvene the Subcommittee sometime before the next Advisory Board meeting. In

anticipation of reconvening the group, members were asked to share what issues they would like the Subcommittee to look into and/or come back to the Board with recommendations. The following suggestions were offered:

- How the fee for service model can be worked with so that small businesses and hospitals aren't really impacted by the increasing costs of the screening tests. Wants to look at alternative funding strategies.
- Look at legislation toward how the reimbursement system works to help the payers before the costs go up.

Board members who volunteered to serve on the subcommittee included: Andrea, Pamela and Marilyn.

7. Public Comment

Dr. Thurman Merritt –pediatrician, and Professor Emeritus at UC Davis, and Clinical Professor of Pediatrics at the College of Osteopathic Medicine in Lebanon, Oregon. Dr. Merritt shared that about one in every 200 newborns is born with congenital cytomegalovirus and while most of these babies appear clinically normal about 25% have problems including hearing loss, vestibular, and balance disorders. Several states conduct uniform screening for cytomegalovirus. In Oregon newborn hearing screens are restricted to hospitals with greater than 200 births per year which excludes about 15% of babies born in hospitals in Oregon and about 6% of babies born out of hospitals. The College of Osteopathic Medicine believes the NWRNBS Advisory Board should consider the feasibility and cost implications of screening infants for cytomegalovirus. Working with our legislators the College plans to propose a legislative bill to request consideration of uniform testing of infants or selective testing of infants who do not pass the newborn hearing screen.

8. Open Board Discussion

Erik facilitated an open Board discussion asking the members if they had any questions for Patrice. The following questions and responses were shared:

- Q: How expecting parents learn about this screening test? *A: The program's pre-natal education about this test is minimal. Informational brochures are offered to birth providers that they can share with the parents. The program is creating a newborn screening "101" for home visitors and their partnering with the MCH program to provide education around newborn screening. The program is also looking for community partnerships to help get information to families.*
- Q: Regarding the recommendations from the onsite review report, which of those stood out and will be moving forward on? The recommendation about not using funds outside of the program stands out. *A: That is a recommendation the program will be working towards.*
- Q: What should we be sharing about the onboarding process and what new members can expect? *A: Will be sending information to new Board members but hopes to work toward more dialogue with new members*.

- Q: It would be good to have more public facing information about the newborn screening. Maybe use YouTube, Facebook, etc.
- Q: Regarding Dr. Merit's comments, he asked about whether uniform or targeted testing is best. It is apparent this legislation may be coming forward and is there an opportunity to reach out to him since legislation can have a significant impact? *A: The targeted screening can be more beneficial.*
- Q: Regarding CMV, what treatments would be available if a newborn has CMV. *A: There is an oral medication that can be given that can delay the progression of hearing loss. While they still lose their hearing, the ability to for having hearing early in life can help with their communication in the future.*

9. Adjournment

The meeting was adjourned by Chair Hartzell.