Oregon Health Authority
Northwest Regional Newborn Bloodspot Screening Advisory Board

Meeting Summary **May 28, 2025**

Location
Videoconference

Quorum
Board attendees constituted a quorum for the meeting.

Board Members Attending
Marilyn Hartzell, M.Ed., Board Chair, Family Representative
Angela Douglas, MD Representative of a statewide association of pediatricians
Cheryl Grabham, Representative of advocacy association regarding newborns with medical or rare disorders
Rusha Grinstead, Representative of Medicaid or insurance industry
Andrea Keating, LDM, CPM, Representative of a statewide association of midwives
Mort Murry, MD, Representative of advocacy association regarding newborns with medical or rare disorders
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

Board Members Absent
Jill Levy-Fisch, Representative of advocacy association regarding newborns with medical or rare disorders
Amy Yang, MD, Contracted medical consultant

NBS Program Staff
Patrice Held, Newborn Screening Program Manager
Amber Gamel Miller, Public Health Nurse
Kasfian Khan, Legislative and Community Engagement Coordinator
Sarah King, Client Service Coordinator
Sharon Willis, Microbiologist

Guests
Dr. Joseph Orsini, New York State Department of Health Wadsworth Center
Dr. Joanne Kurtzberg, Duke University School of Medicine

Members of the Public
Carolyn Lee, State Rep. Susan McClain's Office

Jensen Strategies Facilitation Team

Erik Jensen, Facilitator
Emily Rehder, Operations Manager

ACTION ITEMS

The Board took the following actions:

- Approved meeting summaries for the September 4, 2024, December 4, 2024, and March 4, 2015 Board meetings
- Elected Dr. Elizabeth Powers and Dr. Angela Douglas as a 2025-2027 Chair and Vice-Chair, respectively.

MEETING AGENDA ITEMS

1. Welcome / Introductions

Chair Marilyn Hartzell opened the meeting and shared Dr. Stirling and she have been reappointed for another four-year term on the Board. She reminded the Board that the vacant position previously held by Dr. Lai is still open. The Board is looking to recruit a replacement to fill the role of Representative of Oregon Pediatric Association.

Advisory Board Facilitator, Erik Jensen, facilitated formal introductions of the Board.

2. Meeting Overview & Approval of Meeting Summaries

Erik reviewed the agenda for the meeting and announced the dates for the upcoming Board meetings based on the results of the Doodle Poll that was previously sent out.

- Wednesday, September 3, 2025 9:00am – Noon
- Wednesday, December 3, 2025 1:00pm – 4:00pm
- Tuesday, March 3, 2026 9:00am – Noon
- Wednesday, May 27, 2026 1:00pm – 4:00pm

Erik reminded the Board and other attendees of the meeting Discussion / Decision Guidelines.

He called for the approval of the September 4, December 4, and March 4 Advisory Board meeting summaries and asked for a formal vote.

Decision: The summaries were approved unanimously.

3. Program Updates

Patrice Held, NWRNBS Program Manager, provided updates on the Program.

Redesign of NBS Card: Patrice shared the redesigned cards as mentioned in the December 4, 2024 meeting. The exchange process started in March and concluded in May. Nearly all of the Oregon submitters are using the new cards.

Questions and comments from the Board included:

- Q: There is concern about needing to purchase cards for families that decline. Was wondering if you had any experience with replacing the card for a customer who refuses and what that timeline looks like?
  A: The lab system has an accounting process, and it determines how many replacement cards need to be sent to the submitter. It has taken a couple of months to initiate this process, but now the program is on track to do these replacements monthly.

General Funds: NWRNBS Program was awarded general funds to cover the costs of Oregon families who pay out of pocket for screening. 239 families have been able to benefit from the subsidized cards. It was a one-time award for FY 2024-2025, but the program will extend the subsidized card offerings until December 31, 2025.

Questions and comments from the Board included:

- Q: Is the fee attached to the card?
  A: Yes, $175
- Q: Does the provider/practice carry the burden of the cost?
  A: Yes, initially. The provider purchases the card from the NBS program and then the providers bill the clients insurance, once the specimen has been collected.
- Q: Is there a way to determine if the cost was prohibiting/hindering people from declining?
  A: Don't really know exactly why families decline, but we never want cost to be a barrier. With the change in the card format, we can now start collecting data real time on refusals. We are hoping to understand what barriers families cite, that prevent them from having their baby screened. This may lead to enhanced education/outreach efforts.,
- Comment: Clarify whoever is purchasing the cards. At the hospital level, all the costs for the birth of the baby get bundled into one price. When the cost of screening went up, there wasn't a way to increase the reimbursement. There also wasn't a way to separate the screening from the overall costs.
- Comment: When they joined the Board in 2022, they did a small-scale survey of community providers to understand the impact of the fee increase. 92.6% had said that the screening fee increased affected their practice. 53% respondents in that poll said they had at least one family decline screening due to the cost. Cost does affect whether families decide to do the screening.

Validation of NeoLSD: The Program has begun validation of NeoLSD assay for Infantile Krabbe disease. Evaluation of incubation times (18 hours and 40 hours and plans to go live for Fall of 2025.

Validation of GAMT deficiency:
The Program will begin validation of GAMT deficiency, which is planned to go live December 2025.

Implementation of new instrumentation: To keep up to date with the latest technology:

Two GSP instruments used for CF, CH, CAH screening were upgraded, a new SeqStudio instrument for CF molecular testing was purchased, and the laboratory added a Sebia instrument for hemoglobinopathy screening, which replaces the HPLC method.

Algorithm Updates: The lab began using a new algorithm for congenital hypothyroidism with TSH as the sole analyte as discussed in December 4, 2024 meeting. The laboratory made updates to cutoff for succinylacetone to screen for tyrosinemia type I and changed the biotinidase procedure to reduce false positives.

New video: NBS program created a four-minute video to inform families about the value of screening, which featured an Oregon family, whose daughter who was identified with MCAD deficiency through the screening. The video was played for the Board.

Questions and comments from the Board included:

- Comment: In the context of the previous conversation on General Funds grants and their experience, a board member questioned whether the ideal screening timeline presented in the movie was true. As a rural physician, we don't get results that quickly. Their experience is that their results are not available in real time. The video doesn't portray this reality.
- Comment: A send out laboratory test may take a couple of weeks for results to be available. Newborn screening is a send out laboratory test. I worry about the questions people in their county will ask, regarding why they don't have the results and if this is legislatively mandated, why am I being charged for it.
  Response: OHA is able to track the time from birth of the baby to report of results; 95% of samples are reported within 7 days of life. However there is additional time needed to upload result reports into patient's chart and communication of the result to parents, possibly extending up to 14 days after birth.
- Comment: They typically see results in the 5–7-day window with electronic reporting, that I found this really useful. The screening lab also sends the nurse manager turnaround times for any results.
- Comment: Rural Oregon has barriers such as having to travel farther, and they don't pick up on certain days. If minutes count, why are they not getting the urgency.
  Response: It is recommended to get the monthly QA report. OHA also offers a courier. The program will look into the details of this specific situation and see if changes can be made to decrease turn-around times.
- Comment: We have met with Jackie Omstead and walked through the process to get things sent out on time. There are barriers for rural areas that need to be addressed but with electronic reporting results, they might be able to get results sooner.

NBS x WGS: Patrice discussed the option to join the Newborn Screening by Whole Genome Sequencing (NBSxWGS) Collaboratory Initiative. The research opportunity if administered by the NIH and the purpose is to assess the feasibility of a collaborative, multi-state model for newborn screening (NBS) using whole genome sequencing as a first-tier assay for analysis of a select group of genetic conditions that are actional in the

first year of life. For more information go to the link: https://commonfund.nih.gov/venture/nbsxwgs/funding-opportunities/OTA-25-004

Legislation Session 2025: Patrice reviewed and updated items from the 2025 Legislative Session: HB 2741 passed and it allows for families to decline screening for any reason and states that CCO must cover the costs of the screening; states that all information and documents related to screening and the subsequent care of a newborn are confidential and not subject to disclosure; specifies that OHA will implement and educational program to include information on the medical conditions and the importance of screening; specifies that OHA will conduct a follow-up program to improve the long term care of individuals with medical conditions, subject to available resources; and gives updates to language and definitions.

HB 3192 was reviewed by House Committee on Behavioral Health and Health Care and was referred to Ways and Means. No new updates.

Federal Funding:
On March 24, 2025, HHS terminated roughly $117 million in COVID-era grants and funding for OHA programs. The terminated funds addressed infectious disease outbreaks, provided access to immunizations, fortified emergency preparedness for future public health threats, provided mental health and substance abuse services, and modernized critical public health infrastructure.

On May 16, 2025, a federal district court judge issued a preliminary injunction in a lawsuit brought by 23 states, including Oregon, against the U.S. Department of Health and Human Services over the termination of public health and behavioral health grants, without cause or authority. This ruling ensures federal funding can continue flowing while litigation proceeds.

OHA formed the Federal Response Planning Team (FRPY) which meets weekly and includes an executive level representative from each division.

OSPHL experienced impacts because the funding is used to cover our contracted courier service, portions of our LIMS upgrade, building maintenance, and other infrastructure needs. At OSPHL, they created a Lab Resiliency Workgroup that meets weekly to determine how federal changes affect our operations.

Advisory Committee on Heritable Disorders in Newborns and Children: was eliminated by Health and Human Services. For the last 15 years, the central role was to make recommendations about which conditions to include on a universal screening panel for newborns. In the absence of this committee, each state will need to determine how to evaluate conditions, for potential inclusion to their panel. If Board members have thoughts about the impacts on the Board's work and how they might be mitigated, they are asked to share their comments with Patrice. The Board will pick up the discussion at the next meeting on September 3, 2025.

4. Krabbe Screening Implementation

Dr. Joseph Orsini from the New York State Department of Health Wadsworth Center and Dr. Joanne Kurtzberg from Duke University School of Medicine presented to the Board about their experience screening for Krabbe disease and treating newborns for this condition.

Dr. Orsini went over the screening algorithm and suggested guidelines for screening. Suggestions including having a plan in place for infantile Krabbe disease cases to initiate treatment quickly. To date, only one of the possible late onset Krabbe disease newborns has developed symptoms – psychosine was 6.7 nM. The Krabbe Newborn Screening Council* has monthly calls and can review and make recommendations on cases. Each program should determine their "target" for screening (infantile only or infantile and later onset Krabbe disease). Second-tier psychosine is necessary and programs may consider sub-contracting this testing. If there is a decision to screen for only infantile Krabbe disease, then the false- positive rate approaches zero, but likely will miss late-infantile cases.

The Krabbe Council meets once a month and Board members can contact Dr. Joe Orsini or Dr. Kurtzberg if they would like to participate

Dr. Joanne Kurtzberg presented a clinical overview of Infantile Krabbe Disease providing an overview of the disease, its clinical manifestations, diagnostic history, current treatment options, history of adding it to the RUSP, transplantation of umbilical-cord blood, outcomes, preparedness for states, and follow-up guidelines for abnormal Krabbe disease newborn screening results.

Questions and comments from the Board included:

- Q: Is there a study on the equity of having access to transplants? Any demographics on anyone who declined?

  A: To the best extent as possible treatment and access is equitable in pediatric care. There are almost 200 pediatric transplant centers across the US so babies get equal access. In the transplant world especially in pediatrics, it is as equal as can be, most of the babies transplanted have been non-Caucasian.
- Comment: The head of the transplant center wasn't certain about their capabilities of transplanting timeframe.

5. Selection of 2025-27 Chair & Vice-Chair

Erik Jensen facilitated a vote for the 2025-27 Chair and Vice-Chair.

The nominees for Chair were Dr. Elizabeth Powers and Dr. Mort Murry. The nominees for Vice-Chair were Andrea Keating and Dr. Angela Douglas.

Decision: Dr. Elizabeth Powers was voted as Chair and Dr. Angela Douglas was voted

as Vice-Chair with the Board voting as follows:

For Chair:

Dr. Powers (6): Douglas, Grabham, Grinstead, Hartzell, Paul, Stirling,
Dr. Murry (2): Keating, Powers

For Vice-Chair:

Dr. Angela Douglas (6): Douglas, Grabham, Grinstead, Hartzell, Paul, Powers
Andrea Keating (2): Keating, Stirling

6. Discussion: Krabbe Review Debrief

Erik facilitated a debrief discussion on the Krabbe review process and decision that occurred on March 4, 2025. He noted some of the challenges that were faced in the meeting were time constraints for the Board discussion and non-Board members writing in the chat. Jensen Strategies is working on a solution to the chat issue so it won't happen again.

Questions and comments from the Board included:

- Comment: As a physician I found the meeting surprisingly difficult with the ongoing discussion of the family members during the decision process. Felt like there was a lot of anger and frustration directed at the Board. Families were able to share, but the ongoing chat made me uncomfortable.
- Q: Would separating the voting from the public comment be helpful?
  A: Discuss and then vote electronically later, hearing what others vote might help you vote as well.
- Comment: The public comment was very emotional, but a helpful component to my thinking. It felt it was very confrontational. I was also unclear on what I was voting on. Wasn't sure if it was just adding the test to the screening panel or if I were voting to figure out the testing parameters as well.
- Comment: Oregon Legislature does allow public comment and then voting in a separate meeting. I appreciated hearing how everyone else voted. Giving the public participants a feedback loop in the quickest way possible is recommended.
- Comment: Having the time to be able to explain why you were voting the way you were would be helpful.
- Comment: I didn't feel attacked by the public comments. I felt that it gave humanity to the process. When we make our decision, we go off what facts were given to us. Did I feel rushed, maybe, but it worked.
- Comment: I would appreciate taking the time to think about the experience of the families that we are hearing and having the time to follow up to request more information during the deliberation period if needed.
- Comment: Found the public comment to be impactful but worried there wasn't good communication with the families and representatives about what the Board was able to do within the parameters of our vote on the issue. There seemed to be a lot of energy put into gathering information to demonstrate to the Board that we should set a different cutoff to include the later onset disease. Perhaps that is something that could have been made clearer by having conversations or sharing the materials before the meeting.

- Comment: Some of the materials submitted as written public comment were not brought up during the meeting. We need to make sure there is a way to address all of the sentiments presented to ensure all viewpoints are presented to the Board.

  Patrice added that the Secretary's Advisory Board evaluated all forms of Krabbe Disease, but only the early infantile form was added to the RUSP. It was going to be challenging to communicate this nuance to impacted families and the general public. Each state should choose whether to include only Early Infantile Krabbe Disease or all forms of Krabbe disease. Oregon voted to only add Early Infantile Krabbe disease, which is in accordance with the current protocol to align with the RUSP.

- Comment: Felt like I learned a lot in the meeting, more complex view with the families, heightened emotion, informative and nuanced.
- Comment: Public testimony was a good thing; I really liked seeing the humanity. Put the information into context so I knew what I was voting for.
- Comment: Really appreciate for the video option for people to participate.

7. Discussion: Implications of ACHDNC Dissolution

Discussion was removed from the agenda due to the lack of time but if any of the Board members have thoughts about the impacts on the Board's work and how it they should be addressed, they are asked to share their thoughts with Patrice for discussion at the next meeting.

8. Public Comment

No comments were presented.

9. Wrap-up

Marilyn Hartzell commented on how much she values the function of the Board. Appreciated the opportunity the serve as the Chair of the Board. The meeting was adjourned.