

**Oregon Health Authority
Northwest Regional Newborn Bloodspot Screening Advisory Board**

Meeting Summary

September 4, 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
Andrea Keating, LDM, CPM, Representative of a statewide association of midwives
Sherly Paul, Representative of a statewide association of nurses
Kara Stirling, MD, Representative of a birthing center or hospital
Amy Yang, MD, Contracted medical consultant
Angela Douglas, MD Representative of a statewide association of pediatricians
Elizabeth Powers, MD, FAAFP, Representative of birthing center or hospital

Board Members Absent

Charlene Lai, MD, Representative of Oregon Pediatric Association
Jill Levy-Fisch, Advocacy association regarding newborns with medical or rare disorders

NBS Program Staff

Patrice Held, Newborn Screening Program Manager
Amber Gamel Miller, Public Health Nurse, Newborn Screening Program
Kasfian Khan, OHA, Legislative and Engagement

Guests

None

Members of the Public

Cheryl Hanna, OPS
Rocky Dallum
Sarah King, OSPHL

Jensen Strategies Facilitation Team

Erik Jensen, facilitator
Emily Rehder, operations manager
Savannah Cline, project associate

ACTION ITEMS

- A. May 19, 2024, NWRNBS Advisory Board meeting summary approved with edits.
- B. Agreement to send a response letters to State Representative Owen and Dr. Thurman Merritt regarding Duchenne and CMV review requests, respectively
- C. Agreement not to reinstitute the Long-Term Funding Subcommittee and incorporate funding discussions at the full Board level

MEETING AGENDA ITEMS

1. Welcome

Chair Marilyn Hartzell opened the meeting welcoming all the participants and asked Board members and OHA staff to introduce themselves.

2. Approval of Meeting Summary

Advisory Board Facilitator, Erik Jensen, reviewed the meeting summary from the May 29, 2024, Board and asked if there were any revisions necessary. It was noted that Sheryl Paul’s affiliation was listed incorrectly and should be “Representative of a statewide association of midwives.”

Decision: The Advisory Board, by strong consensus, **approved** the May 29, 2024, meeting summary with the edit. The decision was made using the 1-5 consensus tool with members responding with 1’s and 2’s.

3. Facilitator’s Update

Advisory Board Meeting Schedule: Erik shared that the 2024-25 Board year meetings had been scheduled and reviewed the dates and key topics currently scheduled for each meeting which will all be held virtually from 9:00am to Noon:

September 4, 2024:

- Follow-up on Newborn Screening Program Site Review
- NWRNBS Advisory Board Legislative Report
- Discussion re request for Duchenne Disorder to be considered for the screening panel
- Long-term financing discussion approach

December 4, 2024:

- Krabbe Scientific Review Report (NOTE: subsequently, the schedule for this topic was changed to the March 4th meeting)

March 4, 2025:

- Krabbe Continued Review (if approved for further review)
- Long-term funding discussion [Note: later moved to the December 4th meeting.]

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May 28, 2025:

- Advisory Board Chair and Vice Chair Selection

The following questions and comments were shared about the Board's meetings and scheduled topics:

- Q: More discussion happens in person and conversations are livelier. Is it possible to schedule in-person meetings further out?
A: The member survey showed that most meeting participants prefer the online meeting format. This can be revisited for future meetings.
- Q: Regarding the potential legislation related to CMV and Duchenne disorders, are there any other bills in the 2025 session?
A: There may be something about Sickle Cell disease. The emergence of this type of legislation suggests that we need to increase and enhance our educational efforts on the Board's role, process, and criteria for adding disorders to the screening panel.

Erik shared that the 2024 NWRNBS Advisory Board Legislative Report was finalized and would be submitted to the Legislature no later than September 15th as required by the original 2019 legislation that established the Board.

He also provided an update on recruitment for the Advisory Board's vacant positions. With the addition of Dr. Angela Douglas as the new representative of a statewide association of pediatricians, there remain three open positions including two positions for advocacy association representatives and a Medicaid/insurance representative. He said OHA is actively recruiting for these positions and encouraged the current Board members to forward any potential nominees to Patrice Held, NWRNBS Program Director, or him.

Erik shared the updated Advisory Board onboarding program had been developed and the first session was held in the last week. The program included background information on the NWRNBS program, roles and responsibilities, and public meeting and records law.

Questions and comments about the onboarding program included:

- Comment: The ethics part is something I hadn't thought about. The onboarding program is very comprehensive coverage of the topics related to the Board.
- Q: Can you share the Oregon public meeting and records law so we can brush up on it?
A: The PowerPoint slides can be shared and/or current Board members are welcome to join another onboarding session. We'll put something together before the next Board meeting.

Erik gave a quick recap on the Advisory Board protocols for discussion and decision-

making.

4. Program Updates

Patrice provided updates on the NWRNBS program.

Paperless Reporting and Portal: As of July 1, screening results are no longer sent via the Postal Service. Instead, the Program is making use of the web portal to provide negative screening reports. Submitters and providers will receive and positive and inconclusive results with recommendations by fax.

- Q: Are you able to see how often people are using the portal? And how many providers are using this system?
A: There is no way to monitor how frequently any one user accesses the system.. However, user haven't accessed the portal within 60 days it will lock them out.
- Q: I have concerns about lab staff logging in and getting the results. This appears to create extra work for staff. Likewise, it is not feasible for individual clinicians to log in every time, either.
A: I'm not sure how it works in everyone's system. The NBS program would be happy to discuss workflow and address any issues a hospital/clinic/provider might have in accessing the portal.

Redesign of the NBS Card: The card has been updated to delineate place of birth, NBS specimen submitter, and follow-up care provider. Race and ethnicity have been removed. Designation of sex has been amended with three options – male, female, and indeterminate. Inclusive language was added for parent and/or guardian. There is also a field for “blood not collected” with choices for reasons including: transfer, deceased, or refusal. Family may sign the back of the card to indicate their refusal of the screening test.

A communications campaign regarding the card redesign is being launched with a series for four notifications for providers and submitters that include information about the changes, image of the card, how to exchange unused “old” cards, and education on how to complete the card. If you want to be added to the submitter list, the Program is open to who needs to be on the list.

Questions and/or comments about the redesigned NBS card included:

- Q: Do you charge for the card even if the blood isn't collected?
A: For purchased cards, we replace the card for free in the event of a refusal.
- Q: Is there another procedure to report refusal?
A: The cost of the card is minimal at \$0.33. Very few people fill out the current refusal documentation. By placing the refusal on the card, we can more accurately count refusals and also perform follow-up and education.
- Q: For babies that are transferred out, does accepting facility fill out the card?
A: The first screening isn't collected before 24 hours, so the birthing hospital fills it out.

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New LIMS Project: The Oregon State Public Health Laboratory (OSPHL) has initiated a five-year project to select a new Laboratory Information Management System (LIMS). Selection of a vendor and a contract is anticipated by November.

2024 Legislative Session Follow-up: In the Spring 2024 legislative session \$250,000 was allocated to cover out-of-pocket screening costs for families who cannot afford it. So far 56 requests have been processed.

Krabbe Follow-up: In July, the U.S. HHS Director approved the Krabbe condition be added to the RUSP panel be added to the RUSP. The results of the Krabbe scientific review are scheduled to be discussed at the December NWRNBS Advisory Board meeting. [NOTE: After the meeting, it was learned the results would not be ready until the Board's March meeting.]

HRSA Propel Grant: The grant allowed for \$345,000 annually for five years to enhance, improve, and expand the Program supporting implementation of new conditions added to RUSP. To date, the program has used these funds for MPSII screening – in year one securing another mass spectrometer. The Program is considering whether to change the use of the funds for Krabbe. Krabbe costs will include \$100,000 annually, not including staffing, and will be multiplexed with other biochemical tests, bringing the overall costs lower than MPSII. The Board will be asked to deliberate on this question from a lab cost perspective.

Questions and Comments regarding the potential reallocation of the HRSA Propel grant included:

- Q: Shouldn't the grant be used for MPSII and GAMT? It makes sense to apply the grant to those that cost the most.
A: We would need to do a fee increase to maintain screening for MPSII, after the grant ended. Fee increases take years, and it may not be available when the grant ends.
- Comment: Let's not start a precedent on budgeting decisions being made by the Board - put the money where it is needed.
- Comment: Spend money to prioritize helping the most amount of people-
- Q: Long term funding conversation should start as soon as possible regarding recommended conditions. Finance is a consideration. Know that when a child is affected- how soon can we get them tested and identified- this is a huge burden. We need to find robust mechanisms on how to sustainably fund the Program because we don't want to go backwards. Let's start the conversation and be proactive.
Q: We want children to get early diagnosis- money can be a barrier to healthcare. We need to do the work that needs to be done. Funding shouldn't be what is stopping us. Government spends money on ridiculous things.

5. Site Review Report

Patrice provided an update of the Newborn Screening Program (NWRNBS) Site

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Review Report which was sent to the Advisory Board in advance of the meeting. She highlighted some of the key findings and recommendations relevant to the Advisory Board's work.

Program Strengths: Leadership is engaged and open to change for improvements; Laboratory and dried blood spot follow-up staff are co-located; strong sense of camaraderie among staff; contracts with medical consultants at OHSU who care for babies with positive screen results and very engaged and supportive of the Program; Advisory Board members are very engaged and value their roles; and OHA has made equity a priority to address.

Program Weaknesses: Need more effective training and onboarding for Advisory Board members; the two-screen process can be cumbersome; current funding will not support future additions to the panel; and the mechanism for families to get reimbursements are rarely used.

State Legislative & Policy Recommendations: urgent priority – amendments to the statute and rules; medium priority – enhance transparency of the disorder review process; improve education, training, and onboarding of Advisory Board members; consider inclusion of bioethicist on the Board; assess the utility of a two-screen program; investigate why 1% of babies are not screened and consider enhanced education.

Funding Model Recommendations: urgent priority – identify ways to increase program revenue; medium priority – explore equity-based funding; consider invoicing for screening services rather than pre-pay model; communicate with birth providers at least six months in advance of fee increases.

Birth Facility Recommendations: medium priority. Consider educational resources to help midwives and families understand that DNA is not kept, about Program data retention policies, and parental access to specimens. Offer state-funded courier system for birthing centers and providers without them.

Long Term Follow-up Recommendations: lower priority – Consider defining the Program scope and mission; reach out to other states for advice and mentorship on long-term follow-up programs.

Questions and comments regarding the Newborn Screening Program Site Review Report:

- Comment: Really great quality work- see things we have discussed- happy to see it.
- Comment: I liked the bioethicist recommendation.
- Comment: Amazed by how expensive things are and I didn't know there was long term care- the funding will have to come from somewhere.

6. Request for Addition of Duchenne Condition

Erik shared that Oregon State Representative Mark Owens had sent a letter to the Advisory Board, via Patrice, on behalf of one of his constituents asking the Board to review Duchenne disorder for inclusion on the screening panel. It was noted that the Board's disorder review protocol requires the disorder to be reviewed by the ACHDNC and be formally added to the RUSP to be considered for the NWRNBS panel. Duchenne has not been approved for addition to the RUSP at this time. A draft response letter was provided to the Board for consideration to share the disorder review protocol requirements and that Duchenne has not met the criteria yet as well as invite an opportunity to discuss the issue if desired.

- Comment: This prompts question about CMV. I'm uneasy about this approach. It's hard to keep up with disorders and the floodgates that could open if any condition proposed was reviewed. This is an unacceptable risk. We're seeing new conditions every year- and if a condition is added by legislation, that will be a difficult situation.
- Comment: We could put in language to the letter inviting him to attend a meeting to understand the challenges and limitations of the Program. Maybe they could go back come up with General Fund monies. We are siloed- they don't understand our process.
- Comment: This will continue to happen. The goal is to add as many conditions as possible. We should invite them to join to see we are following the rules and for the Legislature to understand there are time and money limitations.

The Board members agreed to send response letters, signed by Chair Marilyn Hartzell, to State Rep. Owens and Dr. Merritt (who had a similar request related to CMV at the previous Board meeting) advising them of the Board's disorder review protocols and inviting them to meet with Patrice to gain a better understanding of the Program's limitations and challenges.

7. Long-term Finance Subcommittee

Erik facilitated a discussion about a continued consideration of long-term Program funding. Two years ago, the Board had engaged a subcommittee on long-term funding, but discussions had not been completed on the topic. The Board was asked what forum they would prefer for this ongoing discussion – a reconstituted subcommittee or as a full Board?

- Comment: Perhaps we could invite someone who can help navigate this discussion if they have been successful somewhere else.
- Comment: The previous subcommittee felt lost not sure how much

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leverage/power it had making recommendations. They were not able to make decisions. They felt rudderless with no engine.

- Comment: In practice the subcommittee didn't lead to what was covered in the Board meeting. Full Board meetings have been more productive in terms of achieving funding ideas. I would vote is to have funding discussions with the full Board.
- Comment: It would be helpful for someone help educate what options are available to us. I'm not sure where the current money came from and more understanding of the funding since we are not experts in this area.
- Comment: Having someone speak to the funding and how to talk to the Legislature about getting more funding. Grants are short term and not sustainable. How do we tap into the General Funds monies? That is where we need to go.

The Board agreed the subcommittee is not the best venue to vet options due to limited member time and the work required outside of the Board meetings. It was agreed the best forum will be at the full Board meetings with information to have a constructive and productive discussion.

8. Public Comment

No comments were presented.

9. Wrap-up

Chair Hartzell thanked everyone for their work and noted the Rules Committee would follow.