Oregon Health Authority
Northwest Regional Newborn Bloodspot Screening Advisory Board

Meeting Summary January 31, 2022

Location: Videoconference

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

Board Members Attending
Cheryl Hanna, MD, Representative of a statewide association of pediatricians
Marilyn Hartzell, M.Ed., (Chair) Person or family member of a person affected by a disorder on the Newborn Screening Panel
Wannasiri (Awe) Lapcharoensap, MD, Representative of a statewide association of pediatricians
Jill Levy-Fisch, Advocacy association regarding newborns with medical or rare disorders
Joanne Rogovoy, Advocacy association regarding newborns with medical or rare disorders
Kara Stirling, MD, Representative of a birthing center or hospital
Cate Wilcox, MPH, Honorary representative
Amy Yang, MD, Contracted medical consultant
Collette Young, PhD, Honorary representative

Board Members Absent
Silke Akerson, CPM, LDM Representative of a statewide association of midwives
Philip Dauterman, MD, FCAP, Entity that contracts with NWRNBS for newborn bloodspot screening
Dana Hargunani, MD, MPH, Medicaid or insurance industry representative

Program Staff
Cynthia Branger-Munoz, Oregon Health Authority, Government Relations
John Fontana, Oregon Health Authority, Oregon State Public Health Laboratory
Sheri Hearn, Oregon Health Authority, Oregon State Public Health Laboratory
Sarah Humphrey King, Oregon Health Authority, Oregon State Public Health Laboratory
Rachael Banks, Oregon Health Authority, Public Health Division Director

Guests
Representative Susan McLain, Oregon Legislature
Darren McCormick, Office of Representative Susan McLain, Oregon Legislature
Carolyn Lee, Office of Representative Susan McLain, Oregon Legislature

Members of the Public
Julie Schultz
Sarah Vial

Amy Davidson
Julie Hanna

Oregon Consensus Facilitation Team
Robin Harkless, facilitator
Cat McGinnis, project associate

MEETING AGENDA ITEMS

1. NWRNBS staffing update
Dr. Patrice Held took over as NWRNBS Section Manager on 2/1/22. Nicole Galloway has moved on from the program. Until the program recruits for that position, Sarah Humphrey King will have the interim role of NBS Advisory Board Coordinator.

2. Review of the Recommended Uniform Screening Panel (RUSP) approval process
In response to board questions at the last meeting, the program provided a summary of the RUSP disorder approval process. The program provided the chart on the following page as a summary of the RUSP process. The chart is the Summary of Nominated Conditions to the Recommended Uniform Screening Panel (RUSP) available publicly from the Federal Health Resources & Services Administration (HRSA) Advisory Committees on Heritable Disorders in Newborns and Children. (See next page.)

As of November 2021

Summary of Nominated Conditions to the Recommended Uniform Screening Panel (RUSP)

CONDITION	NOMINATION SUBMITTED to HRSA mm/yy	REVIEW NOMINATION N&P WG** Review mm/yy	COMMITTEE VOTE Initiate Evidence Review mm/yy	EVIDENCE REVIEW Preliminary Report and/or Presentations mm/yy	EVIDENCE REVIEW Final Report and Presentation mm/yy	COMMITTEE VOTE Recommend Adding to the RUSP mm/yy	SECRETARY APPROVAL Add to the RUSP mm/yy
Guanidinoacetate Methyltransferase Deficiency (GAMT) *3rd Nomination	6/21	7/21	Approved 08/21	11/21	-	-	-
Mucopolysaccharidosis II (MPS II)	12/20	02/21	Approved 05/21	08/21; 11/21	-	-	-
Spinal Muscular Atrophy (SMA) *2nd Nomination	2/17	04/17	Approved 05/17	08/17; 11/17	2/18	Approved 02/18	**07/18**
Guanidinoacetate Methyltransferase Deficiency (GAMT) *2nd Nomination	8/16	9/16	NOT Approved 11/16	-	-	-	-
Guanidinoacetate Methyltransferase Deficiency (GAMT) *1st Nomination	11/15	03/16	NOT Approved 05/16	-	-	-	-
Adrenoleukodystrophy (ALD) *2nd Nomination	09/13	10/13	Approved 01/14	02/15; 05/15	08/15	Approved 08/15	**02/16**
Adrenoleukodystrophy (ALD) *1st Nomination	02/12	08/12	NOT Approved 09/12	-	-	-	-
Mucopolysaccharidosis I (MPS I)	02/12	04/12	Approved 05/12	09/13; 01/14; 09/14	02/15	Approved 02/15	**02/16**
Pompe Disease *2nd Nomination	02/12	04/12	Approved 05/12	09/12; 02/13	05/13	Approved 05/13	**03/15**
22q11 Deletion Syndrome	09/11	12/11	NOT Approved 01/12	-	-	-	-
Critical Congenital Heart Disease (CCHD)	10/09	1/10	Approved 01/10	05/10	09/10	Approved 09/10	**09/11**
Hyperbilirubinemia/ Kernicterus	07/09	11/09	Approved 01/10	01/11; 05/11	01/12	NOT Approved 01/12	-

3. Roles related to legislation

- Legislators
    - Introduce legislation to propose changes to government programs.
    - Work within the legislative process for appropriations and approval for their bills.
- Newborn Screening program staff
    - Perform functions established by legislation.
    - Advise legislators regarding the impact of proposed legislation.
    - Suggest changes to bill language, if needed, to address unintended impacts to the NWRNBS program.
- NBS Advisory board
    - Accomplish the intention established by the legislation.
    - Advise legislators regarding the impact of proposed legislation.
    - Suggest changes to bill language, if needed, to address unintended impacts to the NBS Advisory Board.

4. Discussion of HB 4109

The program provided a breakdown of changes proposed in HB 4109 as follows:

- Adjustments to board membership
    - No longer requires nurses, midwives, and pediatricians to represent a statewide association in order to serve on the board.
    - No longer requires the NWRNBS program manager to be a board co-chair.
    - Removes requirement for a contracted partner as a voting member.
    - Adds requirement for tribal representation.
    - Changes the member term from 4 years to 2 years.
- Adjustment to board meetings
    - Meet 4 times a year, instead of once every 6 months.
    - All meetings must be conducted according to the public meetings law.
- Adjustments to legislative reports
    - Legislative reports are due each year, instead of every even-numbered year.
    - Establishes requirements for the content of the legislative report.
- Establishes criteria for evaluating a disease
    - 10 or more states are screening for the condition.
    - A nomination for inclusion of this disease on the RUSP has been submitted to the federal Advisory Committee on Heritable Disorders in Newborns and Children.

Representative Susan McLain discussed the bill:

- Thank you to the advisory board members for their work and commitment to the board.

- New technologies warrant the change to criteria for reviewing disorders. Doing so will be helpful to families and others.
- The bill will fill gaps and strengthen the process.
- The RUSP process is very complex, time-consuming, and expensive.
- The NWRNBS board's process is watched closely by the public and people who work with children. They want to be able to comment on what should be tested for and not tested for.
- The legislative committee chair is onboard with HB 4109 and there are several supporters.
- Criteria for when to review a disorder for inclusion in the Oregon testing panel: (1) Ten states have added the disorder to their panel; and (2) The disorder was accepted in the RUSP process for the second time.

The board made the following comments about HB 4109:

- When the board was first assembled it made a determination to use addition to the RUSP as a criteria for evaluating a disorder for Oregon's panel because the RUSP process is rigorous. It addresses not only the science about the disorder, but also efficacious screening methods, implementation of treatment, and equity and access. The RUSP committee also confers with experts in the field and reviews state data and pilot processes. The NWRNBS board does not have access to that information. Oregon does not have the greatest resources for this type of pre-RUSP review and jumping ahead of the RUSP process is uncomfortable. Rep. McLain response: We included the new criteria because families were not being served. The RUSP process is a minimum and is too long.
- We can't rush good science. There are families with no voice who get a false positive and that may not be able to be resolved for years and years.
- Our organization believes that if something can be tested for, it should be tested for. New York has had huge success with Krabbe.
- Krabbe illustrates the value of the science. There was a break-through that made it possible to do a secondary test. We need to be guided by the science. We should continue to focus on the RUSP. We don't have unlimited time for review.
- Rep. McLain said that one of the proposed criteria is that the nomination had to be submitted to the RUSP a second time before Oregon would need to consider the disorder; however the bill does not include this language.
- I am concerned about the board's bandwidth under such a change, and we do not have the science.
- The policy of the March of Dimes is to not advocate for disorders that are not on the RUSP. We take advantage of national collective brain power. Just because 10 states have added the disorder doesn't mean it's the right thing to do.
- I can't support the removal of "representative of a statewide association of.." from 2(g), 2(h), and 2(i) about the nurse, midwife, and pediatrician members of the advisory board. It is important that these members be able to represent a state

association rather than just their individual perspective. For example, I am a midwife in an urban area and don't have problems mailing my NBS specimens in. If I wasn't representing a statewide organization, I might not know that there are huge mailing issues in rural areas of the state that the board and the program need to know about.

- I do not support the addition of section II. I do not support the Newborn Bloodspot Screening Advisory Board being mandated to evaluate adding new disorders before they are approved by the RUSP. I think this is unethical and would force the board to rush things in situations where there is not yet clear benefit and access to treatment.
- Regarding other changes in the bill—what is the reason for the change to 4 advisory board meetings per year? And why is the requirement being removed that particulars members—for example, midwives—be representatives of an organization?
- The latter change may introduce dysfunction in the board if members are representing their individual voice rather than their organization.
- Why is the co-chair role of a program member being removed? It seems important. Program response: to facilitate communication between the program and board.

5. Discussion related to commenting on HB 4109

The program provided the following outline of board options for commenting on the bill:

- With a quorum
    - Board members can elect to have the chair submit public comment on behalf of the board at the House Health Care Committee hearing on February 2nd.
    - The board can use this meeting time to develop public comment together.

  In addition:
    - Individual board members can submit testimony at the legislative committee meeting on February 2nd but may not represent the board.
    - You may introduce yourself as a member of the board and state that you are submitting testimony as a member of the public or as another organization, when appropriate.

- Without a quorum
    - Individual board members can submit testimony at the legislative committee meeting on February 2nd but may not represent the board.
    - You may introduce yourself as a member of the board and state that you are submitting testimony as a member of the public or as another organization, when appropriate.

- Those providing spoken testimony at the hearing need to complete the registration form at least one hour before the hearing. The registration form includes a link for

submitting written testimony—written testimony must be submitted within 24 hours of the hearing.

6. Next steps

At this point in the meeting, the meeting time was up and several participants left the meeting. There was no longer a quorum and there was a question whether decisions could be made given that there had been a quorum earlier in the meeting. While the program waited for an expert answer on this question, the board proceeded with discussing whether/how board comment on HB 4109 could be gathered and submitted to the board chair for presentation at the hearing on behalf of the board. There was a vote regarding whether to submit joint testimony. However, it was subsequently determined that the vote was not valid due to the absence of a quorum. It was also determined that there was no practical way to pull together joint testimony in time for the hearing. The program committed to sending follow-up information to the full board regarding procedures for providing comment individually if they choose to do so.

Meeting adjourned