Oregon Health Authority
Northwest Regional Newborn Bloodspot Screening Advisory Board

DRAFT Meeting Summary June 29, 2020

Location: Videoconference

Attendees
Board attendees constituted a quorum.

Board Members
Silke Akerson, CPM, LDM Representative of a statewide association of midwives
Chris Biggs, MS, NWRNBS Program Manager (co-chair)
Philip Dauterman, MD, FCAP, Entity that contracts with NWRNBS for newborn bloodspot screening
Anna Dennis, MS, CGC, Advocacy association regarding newborns with medical or rare disorders
Cheryl Hanna, MD, Representative of a statewide association of pediatricians
Marilyn Hartzell, M.Ed., 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
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

Absent
Jill Levy-Fisch, representative of an advocacy association regarding newborns with medical or rare disorders
Dana Hargunani, MD, MPH, Medicaid or insurance industry

Members of the public
Sarah Viall
John Powell

Staff
Chris Biggs, MS
Nicole Galloway, PhD
John Fontana, PhD, HCLD (ABB)

Oregon Consensus Facilitation Team
Robin Harkless, Facilitator
Cat McGinnis, Note-taker

ACTION ITEMS
- NWRNBS program will draft a definition of second-tier testing for the legislative report.

- Silke Akerson will draft language for the legislative report about the impact of increases to the cost of specimen kits.
- Chris Biggs and Silke will pull together information about what income groups are experiencing burdens from the cost of kits and will bring the information to a future meeting.
- Chris Biggs and the program will look at the fiscal analysis for the fee increase and determine generally how costs divide between testing and follow-up for new testing, and general program cost increases and will share with the board at a future meeting.
- Amy Yang will draft language for the legislative report urging the legislature to put an emphasis on funding newborn bloodspot screening.
- The program will prepare information about courier services or expedited shipping for specimens for the next meeting. The board will send suggestions to Robin Harkless if they have any thoughts about what information they'd like on the topic. The program will gather and present data about delivery times based on distance from the I-5 corridor.
- For a future meeting the program will prepare information about how education is working for providers regarding unsatisfactory specimens.

1. NWRNBS program updates

Contractor recommendations. The program contracted with a consultant to get recommendations on how to improve interoperability. The consultant recommended increasing capacity and expertise and using the Rhapsody Integration Engine .

Timeliness. With the lab's new Saturday hours, timeliness of turnaround has improved and is now at 95% of the federal standard.

Program partner. The Idaho program, for which Oregon does testing, is leaving the regional program as of January 2021.

Fee package for addition of X-ALD and SMA. The fee increase package for the 2020 legislative session will not be going forward due to the fiscal impact of the COVID-19pandemic. A fee increase is essential for adding SMA and X-ALD testing. So, adding the tests to the panel will be delayed until a future legislative session.

Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC)—At the last meeting it was reported that ACHDNC was being disbanded. It has since been reconstituted and is moving forward.

2. Notes from last meeting

Notes from the February 2020 meeting were adopted without changes.

3. Legislative report

The board has previously provided edits to the draft legislative report. There were no additional board edits at this time and the draft was approved to move forward. Note that some edits arose during later discussion in the meeting.

4. Survey of states regarding SMA and X-ALD testing

In response to information requests from the board at the last meeting, the program shared the results of a survey of other states regarding testing for spinal muscular atrophy (SMA) and X-linked adrenoleukodystrophy (X-ALD). Twenty-three states have implemented or are in the process of implementing SMA. Twelve of those responded, of which nine have fully implemented testing. All

respondents have consent opt-out. Half of the respondents do only first-tier screening for SMA. Four states send specimens out for SMN2 copy number at a referral lab and two perform SMN2 copy number in-house. No state is identifying SMA carriers. Out of 15 states identified as having implemented screening for X-ALD, five responded. No program is screening only males for X-ALD and none set cut-offs based on gender. All use tandem mass spectrometry as the screening method. All are performing some kind of second-tier testing for X-ALD. Four of the five use an additional screening with mass spectrometry and one sends out to a reference lab for sequencing. All states indicated that after screening, providers are responsible for any additional or confirmatory testing. See appendix A for survey information.

5. Carrier testing with SMA and second-tier testing with X-ALD
The board agreed that it will not recommend SMA carrier testing or X-ALD second-tier testing at this time.

> Discussion—What is the overall number of cases identified by second-tier X-ALD testing in states that do it? Very low false positives—less than 0.01 percent in one state. A definition of second-tier testing will be added to the legislative report. NWRNBS program will draft the language.

6. Remaining concern about adding X-ALD to screening panel
One board member is still very concerned about the impact on the cost of the specimen kit if X-ALD is added to the screening panel. She is also concerned that the range of manifestations of the condition and the treatability are so wide that the benefits vs. harm are gray. People who are wary of newborn screening worry about whether conditions are treatable and clear cut. The board member felt that something about costs of the test kit should be added to the legislative report because people who do home births or use midwives don't have insurance coverage for the kit and either the family or the midwife has to buy the kit. Silke Akerson will draft language about kit cost for the report.

> Discussion: How much of the cost increase for adding tests is related to testing and follow-up, and how much is due to general program costs going up? Program response: It can be hard to tease out those costs. Chris Biggs will revisit the fiscal analysis for the fee increase and determine generally how costs divide up and will share with the board at a future meeting. This could be in the list of topics for strategic planning. One board member raised an equity concern for parents who have to pay out of pocket for test kits and suggested the board should advocate for equity on this issue. Silke Akerson and Chris Biggs will work to identify data about what income groups are experiencing burdens from the cost of kits and will bring the information to a future meeting.

7. Disorder removal protocol
The board reviewed a draft protocol and criteria for removing disorders from the bloodspot screening panel (appendix B). The protocol and criteria were drafted by the program with input from the board. The board discussed the draft and clarified that not all criteria would have to be met in order for a disorder to be removed from the panel. Instead, the board would consider all criteria, have a holistic discussion, and seek consensus about a disorder based on the analysis. The board made no changes to the draft protocol and criteria and did a consensus check on adopting them.

Consensus check on adopting protocol and criteria for removing disorders from the screening panel: (1=full agreement, 5=no agreement, would block action)

Silke Akerson—1
Dr. Philip Dauterman—2
Anna Dennis—1
Cheryl Hanna—1
Marilyn Hartzell—2
Wannasiri (Awe) Lapcharoensap—1
Joanne Rogovoy—2
Kara Stirling—1
Amy Yang—2

The protocol and criteria were adopted with strong consensus.

8. Public comment period
There were no written or spoken comments.

9. Charter revisions
The board reviewed minor revisions to the board charter, which added more detail to the roles of the board chair and vice chair. See appendix C for the revised charter. Discussion clarified that any communications between the chair and vice-chair to discuss board business must occur as a public meeting. The board unanimously approved the charter revisions with a yes/no response.

10. Next steps
Amy Yang will draft language for the legislative report urging the legislature to put an emphasis on funding newborn bloodspot screening. Discussions for the next meeting will include the program's research about courier service or expedited shipping for specimens. The board will send suggestions to Robin Harkless if they have any thoughts about what information they'd like about courier service and shipping. One member suggested information about delivery times per county. The program will get data based on distance from the I-5 corridor. Another potential item for the next meeting is how education is working for providers regarding unsatisfactory specimens.

Adjourned