

Oregon Health Authority

Northwest Regional Newborn Bloodspot Screening Advisory Board

Meeting Summary

February 23, 2022

Location: Videoconference

Quorum

Board attendees constituted a quorum for part of the meeting.

Board Members Attending

Silke Akerson, CPM, LDM Representative of a statewide association of midwives
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
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

Philip Dauterman, MD, FCAP, Entity that contracts with NWRNBS for newborn bloodspot screening
Dana Hargunani, MD, MPH, Medicaid or insurance industry representative
Jill Levy-Fisch, Advocacy association regarding newborns with medical or rare disorders

Program Staff

Sheri Hearn, Oregon Health Authority, Oregon State Public Health Laboratory
Patrice Held, Oregon Health Authority, Oregon State Public Health Laboratory
Sarah Humphrey King, Oregon Health Authority, Oregon State Public Health Laboratory

Guests

Representative Susan McLain, Oregon Legislature
Carolyn Lee, Office of Representative Susan McLain, Oregon Legislature

Additional Members of Rules Advisory Committee (in addition to board members) – Attending for Agenda Item #5 only.

Dr. Laura Balestreri, Rogue Community Health Pediatrics, Physician
Dr. Kristen Ell, Pediatrician, Metropolitan Pediatrics
Ramona Greenway, Birthing Unit Nurse Manager, Sacred Heart Medical Center,
Lora Hendrickson, St. Anthony Hospital Family Clinic

Shannon Klein, Manager of the Family Birth Center, Columbia Memorial Hospital
Karen Kovak, Genetic Counselor, Oregon Health and Science University
Lauren Morris, Registered nurse, Central Oregon Pediatrics,
Laura Stone, Perinatal Clinical Practice Advisor/Interim Staff Development Specialist
Women’s Services, Asante Health System

Members of the Public

Maynard Friesz
Elsa Johnson
Andrea Keating
Anil Kumar
John Powell

Oregon Consensus Facilitation Team

Robin Harkless, facilitator
Cat McGinnis, project associate

ACTION ITEMS

- The program will find out for the board whether there is a way for individual board members to make public comments about HB 4109 to the Ways and Means Committee.
- The program will notify the board when the hearing is scheduled in Ways and Means, and will keep the board informed of the outcome of HB 4109 with an update before the next board meeting.
- The program will invite the board members to participate on the rules advisory committee related to the fee change (yet to be scheduled, summer 2022).
- The program will get information on other state’s funding models and report back to the board.
- The board should send any additional agenda items for the April meeting to Robin, Marilyn or Sarah.

MEETING AGENDA ITEMS

1. Program updates

- Sarah Humphrey King is filling in on advisory board coordination and staffing until Nicole Galloway’s position can be filled permanently.
- Several board positions are in transition and recruitment is underway:
 - Representative of Medicaid or insurance industry—Dr. Dana Hargunani, took another position with the state and has vacated this seat. Recruitment for this position is underway.
 - Representative of birthing center or hospital—A member was appointed to this position in 2019 and has not attended and no longer works for the organization she worked for when appointed. Recruitment for this position is underway.

- Representative of advocacy association regarding newborns with medical or rare disorders—This position was previously held by Anna Dennis, who vacated the seat in January 2022. Recruitment for this position is beginning.
 - Representative of a statewide association of nurses—Remains vacant
 - Representative of a statewide association of midwives—Silke Akerson will be resigning her seat and has worked with the program to ensure a smooth transition. The program will be nominating Andrea Keating to fill this position in the near future.
- Sheri Hearn shared slides providing additional program updates. Those are attached as appendix A.

2. Review of meeting summary

The November 2021 meeting summary was approved without additional edits.

3. Legislative update

- House Bill 4109 proposes changes to ORS 433.299 which originally formed the NWRNBS advisory board in 2019. The program has provided a fiscal impact statement to describe the resources needed to implement the work described in the bill. HB 4109 has been referred to the Ways and Means Committee. It is not yet scheduled for a work session. The legislative session ends March 7. The bill can be reviewed and tracked at this link: <https://olis.oregonlegislature.gov/liz/2022R1/Measures/Overview/HB4109>.
- **Action:** The program will find out for the board whether there is a way for individual board members to make public comments about HB 4109 to the Ways and Means Committee.
- **Action:** The program will notify the board when the hearing is scheduled in Ways and Means, and will keep the board informed of the outcome of HB 4109 with an update before the next board meeting.

Board comments regarding the bill:

- There is concern about moving away from requiring board members to be representatives of organizations rather than members of the general public. They might not represent the interests of the whole state, and a significant amount of knowledge might be lost from the board. Program response: The program is having difficulty finding board members that represent organizations and was looking for some flexibility, but also agrees that ideally, representatives will come through statewide organizations.
- A different board member recruitment strategy was suggested—using networks to bring people in, rather than cold calls from the program.
- A suggestion was made to the program that it would be useful to include in your impact analysis the impact of research needed for reviewing non-RUSP disorders. Program response: The program included the need for 3-4 research positions in the program’s fiscal statement on the bill.

4. Proposed NWRNBS fee increase program update

Sheri Hearn shared slides discussing the program's proposed fee increase. They are attached as appendix B. The program shared the following information:

- Historically newborn screening is fee based. The current fee is \$80 for a 2-screen kit; the proposed fee increase (per current draft) is \$175 per 2-screen kit.
- The number and complexity of the disorders being screened for by newborn screening programs continues to increase. Historically, newborn screening programs screened for disorders that were well defined. Today, new disorders are being screened that are more complex and involve advanced testing methods, including genetic sequencing. Recent advances in genetic based testing are pushing laboratories to add new and more complex disorders at a much faster rate than ever before. Recently, the NWRNBS program added four lysosomal storage disorders (LSDs) to the screening panel that have more complex reporting and follow-up requirements.
- The program aims to increase data analytics, which will increase equity by allowing the program to verify with vital records that every baby with a birth certificate is screened.
- The total cost for the NBS program ranged from \$7.58 M in 2012 to \$8.1 M in 2020 and now is estimated to approximately cost \$7.1 M per year. The program is running at a \$4 M budget deficit. To mitigate this, the program has been increasing efficiencies, has several staff on job rotations with other programs, and has reduced data entry staff.
- The program has requested fee increases in the recent past that were not approved at the level requested.
- No additional costs were projected for adding SMA screening because general funds have been received to support this effort.
- The program is currently in conversations with the Health Systems Division to support their plan to provide a separate reimbursement code for newborn screening kits for community birth providers.
- NWRNBS is intending to obtain feedback about this proposed fee increase from the Oregon Hospital Association and the Oregon Midwifery Council. They are going to increase outreach to self-pay parents to understand barriers to using fee waivers.
- By the end of the summer, the program will hold a rules advisory committee to address the proposed fee change.
- **Action:** The program will invite the board members to participate on the rules advisory committee related to the fee change. (Yet to be scheduled.).

Sheri initiated some questions for the board's consideration, including any clarification about why the increase and why now and which communities the program should be engaging with over the spring before the proposed rule changes. Further, they asked board members to consider assisting them in making connections with their respective communities and networks for outreach. Board discussion of the proposed fee increase:

- The program needs to work proactively with insurance and Medicaid reimbursements to align the amount and timing for these fee increases, to avoid delays in appropriate reimbursements.
- This is a phenomenal increase and could negatively impact family participation in screening.
- Statistics from the Center for Health Services Planned Place of Birth were shared: 0.7 percent of hospital births involve self-payment for delivery, which may include newborn bloodspot screening costs, compared to 31.2 percent self-pay for out of hospital births.
- Why does the general fund not support the program? Costs will increase over the years and it is not sustainable to raise fees every couple of years. Need a long term solution.
 - Need to ask the legislature for stable program support.
 - Need to involve parent advocacy groups in that ask and for this fee increase.
 - Parents of children with Cystic Fibrosis would support this advocacy effort.
- This funding question needs to be viewed through an equity lens. The program needs to hear from groups that serve BIPOC people. Family Forward was mentioned as one such organization to reach out to.
- As a public health measure, there should be no fee for screening.
- How have other states avoided fee increases? Is there another model?
- **Action:** The program will get information on other state's models and report back to the board.

Summary of Rep. McLain comments on the proposed fee increase:

Fee-based models are common in other public sector budgeting too, such as Education. My office wants to be supportive of this board and program, and find help for those families who are not insured. We can offer assistance with researching different funding models to support your next, long term strategic conversation.

5. Rules advisory committee

The program summarized the following proposed rule changes:

- Starting June 1, 2022:
 - Clarify several condition names
 - Edit test method for lysosomal storage disorders
 - Add testing for Spinal Muscular Atrophy (SMA) by polymerase chain reaction(PCR)
- On or before January 1, 2023, add testing for X-linked Adrenoleukodystrophy (X-ALD) by tandem mass spectrometry.
- Updates to the practitioner's manual version are referenced.
- The practitioner's manual is referenced in the rule and is therefore a part of the rule. Within the manual, the following key changes are included:
 - Sections added describing the advisory board and six conditions (SMA, X-ALD, Fabry, Pompe, MPS-I, Gaucher)

- Changes to incidence of some conditions
- Edits to condition descriptions based on contracted medical consultant input
- Various changes for clarity and accuracy
- Other changes would be noted upon review of the text

The program invited feedback from the rules advisory committee regarding the proposed rule changes and the statement of need and fiscal impact. Members of the committee made the following comments:

- On page 14 “Identification of other medical conditions”—This change does not provide for fully-informed consent for disclosure of other conditions found during screening. It is ethically thorny because there may not be effective prognoses or treatments. What other conditions? These need to be spelled out. (Another board member seconded.)
- Can mothers opt out of the SMA carrier screen? Program response: it’s a panel of tests, can’t opt out of individual tests.
- Page 34 in the manual discusses fee waivers. Needs to appear earlier in the document.
- Regarding statement of need and fiscal impact—it needs to discuss the impact on families who pay out-of-pocket, as a racial equity consideration. If this is not added to this fiscal impact statement, it needs to be tagged for a future fiscal.
- Program needs to clarify in the fiscal statement that, though there is no fee change being proposed in this rule change, there are rule changes that contribute to a proposed fee increase. Need to make this more transparent.
- Comment by member of the public: Found out about being a carrier of X-ALD through a family member’s newborn screening in another state. Family testing was covered. The board is encouraged to look at other state’s models, including Illinois. The family would not have learned about carrier status without the screening. It would be valuable for other families.

There will be a public comment period on the rule at the end of April 2022.

6. Looking ahead

The board will meet in late April /early May 2022 to tentatively discuss:

- HB 4109 impacts (if the bill passes)
- 2022 legislative report draft
- Potential introduction of new board members
- Discussion of time line for discussing other funding models that the program identifies
- RAC for proposed rule change regarding fee increase

Action: Board can send any additional agenda items for the April meeting to Robin, Marilyn or Sarah.

Adjourned

Appendix A: NWRNBS Program Updates

Newborn Bloodspot Screening

Program Updates for Advisory Board
February 23, 2022



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Project Implementation: Spinal Muscular Atrophy (SMA)

Timelines provided are subject to change.

Laboratory Test Implementation

- Staff resources have been assigned for overseeing the test implementation.
- Methodology has been selected.
- Method evaluation will begin soon ~ Estimated completion May 2022.
- Updated contracts - In process ~ Estimated completion May 2022.

NBS Result Follow-up Implementation

- Hire additional staff person – In process.
- Establish contract with a medical consultant ~ In process.
- Develop NBS Follow-up algorithms and education materials – In process.

Rulemaking

- NBS Rules are being updated to include SMA - implementation date is June 1, 2022

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Project Implementation – X-linked Adrenoleukodystrophy (X-ALD)

Timelines provided are subject to change.

Laboratory Test Implementation

- Staff resources have been assigned for overseeing the test implementation.
- New equipment and reagents have been received.
- Method evaluation will start soon ~ Fall 2022.

NBS Result Follow-up Implementation

- Develop NBS Follow-up algorithms and education materials ~ Fall 2022.

Rulemaking

- NBS Rules are being updated to include SMA and X-ALD.
- Implementation on or before January 1, 2023.

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Other projects

Cystic Fibrosis Genetic Analysis

- Current method is being discontinued by Genmark.
- We are planning to transition to ViennaLabs.
- Implementation deadline is Summer 2022.

Expand NBS Follow-up and Courier Services

- Received funds from the Oregon Health Authority.
- Planning to increase notification and outreach for sickle cell trait.
- Working to expand courier services and expedited shipping.

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Thank You

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Appendix B: Proposed NWRNBS fee increase

Oregon Newborn Bloodspot Screening

Outreach Regarding Fee Increase



February 23, 2022



Prepared by: John Fontana, Sheri Hearn, Nicole Galloway, Andy Barrett, and Sarah H. King

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Newborn Bloodspot Screening (NBS) is:

- A coordinated system that tests infants for genetic and inherited disorders that result in death or severe impairment if untreated.
- A statutorily mandated, population-wide, fee for service public program that **improves the quality of life** of impacted Oregon infants and their families.
- Administered by the Northwest Regional Newborn Bloodspot Screening Program at the OSPHL.
- A regional program
 - Including New Mexico, Tribal Nations, Guam, and others.
- 2 screens for 42 disorders.
 - Including PKU, Sickle Cell Disease, Severe Combined Immunodeficiency, Cystic Fibrosis, Congenital Hypothyroidism, and many others.

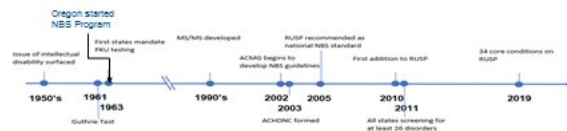


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NBS follows a national standard of care.

- Newborn Bloodspot Screening started in 1963 with 3 tests: PKU, MSUD, and Galactosemia.
- Federal recommendations were established in 2005.
- Current HHS Recommended Uniform Screening Panel includes 36 core* and 26 secondary disorders.
- US States and Territories and Tribal Nations administer NBS for their citizens.



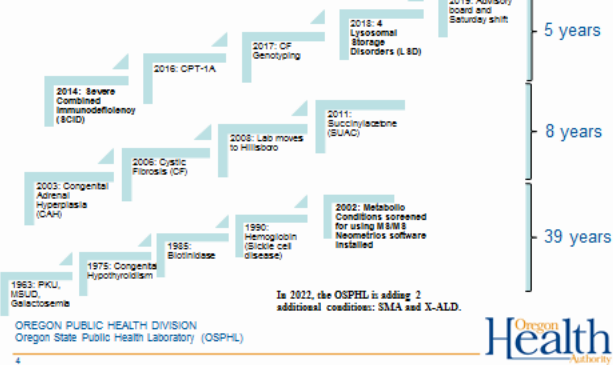
* Hearing screening and critical congenital heart disease are not performed by Public Health Laboratories.

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The rate of progress is increasing rapidly.

History of test additions at the OSPHL



NBS helps improve infant health outcomes



NBS is a Public Health Achievement

- More than 1 in 500 babies have abnormal results reported.
- Over 100 Oregon babies a year are referred to medical services to prevent life-altering complications.
- Early detection and treatment can prevent need for expensive, life-long care.

NBS is Equity Focused

- Population-wide mandatory screening promotes equitable health outcomes.
- Screens for Sickle Cell Anemia and other disorders that impact minority communities.
- Provides additional testing, when practical, to help preserve maternal-child bond.

NBS is Modernizing to Increase Equity

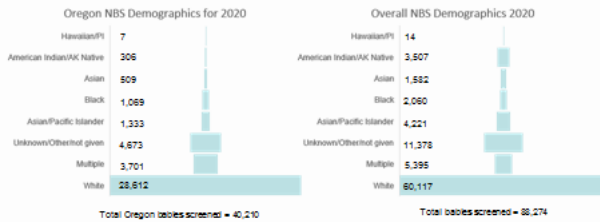
- Enhance NBS Follow-up services for carriers with health impacts (sickle cell trait).
- Upgrade the NBS lab information system.
- Improve courier services.
- Broaden education and translation services.

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Demographics served by NBS

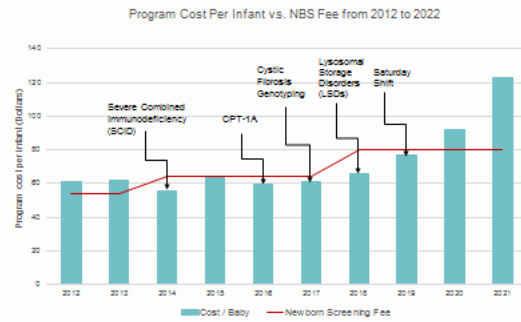
- Mandated for all births in Oregon.
- Oregon has >40,000 births per year.
- In 2020, 74 Oregon babies were diagnosed with a disorder by the newborn bloodspot screening system.
- 8,857 (22%) of babies screened were identified as Hispanic.



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Cost of NBS Program vs. test fees



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A fee increase is needed to ensure timely, quality, equitable services to promote the health of Oregon infants

- Current biennial shortfall is projected at \$4 Million.
- A fee increase from \$80 to \$175 would provide resources needed to ensure program sustainability and to advance improvement initiatives.
- For the United States, fees for Newborn Screening programs range from \$75 to \$220.*

NBS Improvement Initiatives:

- Expand courier and follow up services.
- Add additional disorders:
 - SMA and X-ALD
- Develop electronic reporting to comply with the 21st Century CURES Act.
 - And to meet REAL-D requirements.
- Appropriately screen for complex disorders (Gene Sequencing).
- Improved Continuity of Operations Plan.

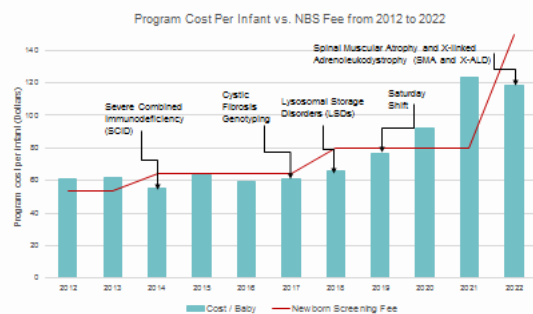


* Programs with grant funding and consistent alternative sources of funding are excluded.

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Projected budget deficit and fee increase



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How are NBS fees paid? By whom?

- NBS collection kits are purchased by medical practitioners as single, double or triple kits.
- Single kits = \$59.00
- Double / Triple kits = \$80.00
- Practitioners are reimbursed by insurance plans.
 - Global package payment for inpatient birthing services.
 - Community birth providers are reimbursed for a supply bundle.
- 50% of Oregon births are covered by OHP.



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Additional Considerations

- Do you have any questions about why this fee change is important for the NBS Program?
- What else do we need to consider before moving forward?
- Are there community groups or organizations from which we should obtain feedback?

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