Oregon Health Authority
Northwest Regional Newborn Bloodspot Screening Advisory Board

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Meeting Summary **November 30, 2022**

Location
Videoconference

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

Board Members Attending
Cheryl Hanna, MD, Representative of a statewide association of pediatricians
Andrea Keating, LDM, CPM, Representative of a statewide association of midwives
Jill Levy-Fisch, Advocacy association regarding newborns with medical or rare disorders
Marilyn Hartzell, M.Ed., (board 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
Elizabeth Powers, MD, FAAFP, Representative of birthing center or hospital
Joanne Rogovoy, Advocacy association regarding newborns with medical or rare disorders
Amy Yang, MD, Contracted medical consultant

Board Members Absent
Dawn Mautner, MD, MS, Representative of Medicaid or insurance industry
Kara Stirling, MD, Representative of a birthing center or hospital

Program Staff
Patrice Held
Sheri Hearn
Sarah Humphrey King
Melissa Powell

Guests
Representative Susan McLain

Members of the Public
Michael Gelb
Monaco Family
John Powell

Oregon Consensus
Robin Harkless
Manuel Padilla

Meeting Agenda Items

Program Updates - *Patrice Held, Program Manager*
Patrice provided a number of program updates along with a set of slides. Updates included:

- Practitioners Manual updated June 2022
- Added testing for Spinal Muscular Atrophy (June 2022)
- Initiate pilot project for courier services for rural hospitals (July 2022)
- Provide USPS shipping envelopes for midwives (July 2022)
- Fee for NBS Kits implemented (Aug 2022)
- Long term funding subcommittee formation (Sept 2022)
- NWRNBS Annual program meeting with OHSU Consultants (Sept 2022)
- Implementation of X-ALD (planned for January 2023)
- Changes in leadership in OSPHL
- Legislative concept updates

Updates on relevant 2023 legislative concepts *Representative McLain, guest*
Representative McLain was invited to discuss with the Advisory Board her legislative concepts that she is preparing to submit for the 2023 session. To preface this, a question was asked about the status of three nominated conditions (MPSII, GAMT deficiency, Krabbe) for the RUSP.

- MPS II was recommended in June for the RUSP and is awaiting Secretary approval. GAMT deficiency was also recommended for the RUSP and is awaiting Secretary approval. Krabbe disease is currently undergoing condition review. The secretary advisory committee for the RUSP will review the findings in February 2023 and will vote whether or not to recommend Krabbe to the RUSP. If the vote is favorable, the Secretary would need to signoff with their approval.

Representative McLain shared opening comments about the intent of the draft bill (LC 720) being discussed today. She shared that an additional companion bill related to a fee waiver for those paying out of pocket will be considered in the overall costs associated with passage of this draft bill.

The primary goals were to formalize the Board's authority and responsibility to have a clear process for adding or subtracting diseases in a responsible way, to allow parents the opportunity to weigh in and be part of that process, and to document and report to the Legislature. Her hope is that the Lab and the Board can be set up for success with the supports they need to do this important work.

Patrice Held shared slides and an outline of sections of the bill she suggested were most relevant to the Advisory Board.

Section 1 (related to Board membership and responsibilities). Patrice provided an overview using PPT slides which are available for review. Mostly, the section updates the membership and term requirements.

Section 1 Board Discussion---

- McLain **explanation**: In public settings, unless a representative specifically has a board action of the group they represent, they are only speaking for themselves, so language is included to clarify this.
- **Board comment** re: term limit. Might be easier to recruit but there is a learning curve. 2 years too short. Also limited by 1-time reappointment. Losing historical reference. Helpful to have people on board who have been part of previous discussions.
    - **Response:** Might be able to change 1- time reappointment to 2-time reappointment to take care of this while retaining intent to have the term requirements not be a barrier for individuals- wanting to keep the pool broad. Can have 1/3 of the Board up for reappointment at a given time to allow for continuity.
    - **Board member:** not changing everyone out all at once makes sense.
    - **Board member:** Echo that continuity of board is a significant issue. Creates challenges. Appreciate hearing openness to modify things.
    - **Board member:** Helpful to have slight overlap of people that are leaving and new people coming on? Mirror medical field "Sign Outs" transitions between shifts.
    - **OHA response:** Good place for that could be rules that OHA and Newborn Lab would be responsible for. Don't necessarily want to put that in statute. Lab should have the protocol. Also can be dealt within the Board Charter.
    - **Board member:** Could there be some consideration if there is someone who has been on hiatus, they could be pulled in again after a period of time?
    - **Board member:** "Reappointment is Allowed" (as more generalized language) suggested change to language.
        - **McLain Response:** We got advice not to change that from legal. Not good wording.

Sections 2 and 3 related to formalizing Board role and responsibility to create and document protocol process for review; adds opportunity for families to engage in that process.

Section 2 Board Discussion

- McLain **explanation:** Important to note we worked hard on this language between my office and OHA Lab to make sure we are honoring the federal process, scoping its strengths and weaknesses, and acknowledging how different words create flexibility and nimbleness for emerging needs. I am committed to the language that exists here. Legal also advised and committed to language. If changes are needed, share your goal/intent and I will try and work on that.
- **Board member:** Understanding federal process is important and science driven, recognizing there is lag time between recommendation and implementation.
- **Board member**: The Board has developed and used a protocol for adding and removing conditions, so "pilot" is not accurate unless you are suggesting we will have an entirely new protocol? Note that lab resources to do tests have been considered within that review. This language implies that every condition recommended to be added WILL be added. But that's not necessarily true. Examples were given. So, stepping in the right direction but we already have a protocol in place that works well. Maybe it works less well for removing conditions. Agree with trying to make the process speedier.
    - **McLain Response:** "Encourages" is a word we added intentionally to give opportunity to have a local process and not just depend on the national process. Acknowledged and clarified that the intent behind pilot is to direct the group to implement and evaluate the protocol, with some of the proposed specific changes described in the legislative bill, and report to the Legislature for accountability.
- **Board member:** First Bullet point in section 2—we've already been doing that so what is the added value of that bullet?
    - **Response:** The committee will now take fresh eyes to the criteria that was established, with the changes described in the bill that include allowing for review of a disorder even if it is not on the RUSP. The bullet point allows for this. Once you have a protocol, you also review them. The protocol will not be set by the Legislature, rather the advisory committee will do this.
        - **Board member:** Should we use the term "ongoing evaluations"?
        - McLain **Response:** We will look at this and have it reviewed by legal.
        - **Board:** Overall liked that bullet point.

- **Board member:** Understand that bullet point 1 is putting the "How" in the board's hands. Glad to see that it restricts the number of diseases to 3. Noted the "encourages" language suggests there is a goal but there is also discretion. No recommended changes.
- **OHA Program staff comment:** Criteria for process was established by the board and not put into rule. Would create a delay otherwise. Takes 18 months to have administrative rules developed, reviewed and approved. Happy to make a rule but worried about a delay.
    - **Response:** We were looking for a way to do this other than put it in statute. Can do it differently. This is not part of the bill.
    - **OHA Program staff comment:** Language in 2.1 - can change it to accomplish the same goal in a shorter timeline.
    - **Response:** Send me language and I will take a look at it.

Section 3 Board Discussion

- **Board member:** This section will probably happen anyway so is it redundant? MPS2 already approved. Other 2 already in process or will be in process.
    - McLain **Response:** Don't think anything is redundant until it actually happens. Spent a lot of time talking about this. This may be your easiest year. Also looking at budget review and keeping fee-based service with budget that is sufficient for work you are being asked to do. This first report will have value to understand functionality of the protocol and process.
- **Board member:** Is it realistic to have these 3 completed within the timeline?
    - **OHA Program Manager response:** Having a preliminary report by 2024 is a reasonable goal. Already in process with 2 of the diseases.
- **Board member:** Understanding gap deficiency is that there is not a kit. Have to bring someone into the lab. Where is the money that will allow us to screen if we don't have finances to hire lab techs? Krabbe disease has not been recommended by the federal advisory committee yet. So this seems to conflict with what is said in Section 2.
    - McLain **Response:** It is not that clear, and we are trying to be nimble and thorough and recognize the federal process and its importance. As far as funding, talking about this as well. It is a parallel budget process. Want a process we can be proud of.
    - **Board member:** So we are assuming the federal process will approve Krabbe so anticipating that with Section 2 and 3?
    - McLain **Response:** yes
- **Board member:** Are there other conditions we have to give equal consideration to?
    - **OHA Program manager response:** I believe only Krabbe is being considered. Don't know yet what is next on the docket of the Fed

advisory committee. Will look into that. We made the limiting factor 3 at a time based on the advisory committee's advice. We can only ask for funds to cover activities that are reflected in this bill. Will need someone to do condition reviews. To implement screening for the disease, not putting that into the bill so not asking for funding. That is a separate process. Would be part of the next budget process.
        - **McLain**: Budget process allows the agency to put in policy option packages ("POPS"). Can ask for money in the middle of the biennium. You have my commitment to help you through the budget process to make sure you have the resources to do work you are being asked to do.
    - **Board member:** Will there be any guidelines or requirements of which diseases will be chosen if we have a 3-month backlog?
        - **McLain response:** if there is a backup then there is an opportunity. The limit of 3 allows you to have a queue and space to figure it out.

Section 4 and 5 Board Review and Discussion - Covers costs of families paying out of pocket; limits to up to 3 disorders for review within a year.

- **McLain general comment:** This is where we could revise to suggest a 1/3, 1/3, 1/3 appointment staggering/sequencing and put in the OHA realm to manage this. Current language may be getting us there already. Will give legislative counsel the suggestions made already from Board members.
- **Board member comment:** reads like all "new" board members will be appointed, clarified this is not the intent.
    - **Mclain Response:** We will make sure that the wording provides the flexibility you need. We could take out the word "new".
- **Board member comment:** The staggering of board members language could be improved upon.

Section 8 Board Discussion

- **Board member question:** What does it mean to declare an emergency upon passage of the bill?
    - **Response:** An emergency clause allows us to be nimble and current with what's going on at the federal level in terms of funding.

<u>Summary of Next Steps/Timeline</u>

Representative McLain shared her next steps and the short term opportunity remaining for the Advisory Board to input on the legislative concept:

- Deadline of Dec 21st to 'drop' the bill, but needs signatures before hand. So - **December 12** deadline to submit any additional comments on this concept. Not much room to make changes at this point.
    - **<u>Action</u>**: Board members have until noon on Friday December 12 to share any further suggestions with Rep McLain on the concept, and should direct those through Patrice Held.

Representative McLain expressed her desire to be responsive to and work in partnership with the Advisory Board and asked whether the concept she is developing helps to meet their interests and if she is being responsive to them. The Board members offered comments that expressed a nod to her collaborative approach and they thanked her for being responsive and showing up in genuine partner engagement.

The Board discussed with each other their reflections and dialogued about the desire to have diverse representation and the value of having statewide organization connections to some of the individual roles (e.g. Midwives) to help reflect the perspective of the whole constituency. One member expressed a concern about introducing 'fringe' ideas without the added accountability of associations. It was confirmed that many of the represented slots would require the member to be licensed or otherwise accredited. There was an expressed need to center equity in the review of the disorder protocol in a way that is trackable and concrete.

Public Comment

The following comments were shared by members of the public:

- Important to have RUSP alignment legislation with evidence presented and reviewed. These diseases are very rare. May not find a case in any given year. Price quotes from screening labs seem high and there should be a cost vetting of state labs.
- My son was not screened for Krabbe because Oregon doesn't screen for it, and earlier this year he died. State lab has known about Krabbe since 2012. My son was born in 2016. There is another boy who was screened and treated and they are thriving. We need to begin screening for this now. My child could have been saved. There is another child who died this year from this disease, because they were not screened at birth. How many more of these stories will we need to bring you before a change is made?
- Oregon is using an FDA approved kit that tests for Krabbe but is not reporting out the data. Costs for adding Krabbe would be very low. We can screen for it perfectly now because we have a 2nd tier test. Cost is $100 dollars per child and false positive rate is near 0.
- Is G6PD deficiency being considered?
    - **Board Response:** This disorder has not been reviewed by this Advisory Board nor at the federal level, and Oregon does not screen for it at this time. One piece of the bill allows members of the public to bring up conditions for consideration so there will be future opportunity to do so for consideration on the Oregon panel; there is also a channel for recommending on to RUSP (links to this information and process were provided in the chat).

Long Term Funding Subcommittee Updates - *Members*

Marilyn Hartzell and Andrea Keating provided a quick update:

- The subcommittee, at its last meeting on 9/21 covered: Review of public health funding models and other states' newborn screening funding models; discussed next steps and actions for continuing the information gathering. Andrea was tasked to do some outreach on how screening fees impact midwifery practice and patients. She is working through the association to distribute a survey and is working on getting it out more broadly. Andrea will put data into a presentation to raise awareness. (Andrea noted: If the draft legislative bill discussed today can cover the cost of out of pocket expenses, this may inform next steps of long-term funding committee.)

Spring 2023 Screening Panel Disorder Review - *Patrice Held*

- Process and Timeline: Slide was shared with detailed info. Should we push the reviews off or keep on schedule? Does it match well with the Bill?
    - Board member response: we should wait until things are recommended to be added by RUSP and then we should act quickly to respond. (General agreement by Board on this approach.)
    - How does review and reporting requirements align with the 18 month timeframe suggested in the bill?
        - Patrice: This could be challenging. We are hesitant to take on too much right now. We should pause doing a condition review for Krabbe for now and check in on this in February when more is known about the results of the RUSP review on this disorder. (Board members generally agreed with this approach.)

Wrap Up/ Next Steps

The next meeting will be held in the February Spring 2023, and will cover:

1. Reorient to current disorder review protocol
2. Prep for disorder reviews
3. Check in on RUSP recommendations of Krabbe
4. Check in on sub-committee work