Minutes for the Newborn Screening Technical Advisory Committee
October 28, 2024
Hybrid Meeting
ASL (or CART) and Spanish interpretation available
Washington State Public Health Laboratory
1610 NE 150 St
Shoreline, WA 98155
Virtual meeting: ZOOM Webinar

Technical Advisory Committee Members present:

In-Room Participants:

Kelly Oshiro, JD, Board Vice Chair and TAC Co-Chair
Nirupama (Nini) Shridhar, MPH, PhD, TAC Co-Chair
Eric Leung, Washington Chapter of the American Academy of Pediatrics (WCAAP)
Joon-Ho Yu, Department of Epidemiology, University of Washington Bioethics, Treuman Katz Center for Pediatric Bioethics and Palliative Care
Byron Raynz, Parent Advocate
Roberta (Bobbie) Salveson, Mary Bridge Children's Hospital Biochemical Genetics
Emily Shelkowitz, Seattle Children's Hospital Biochemical Genetics
Priyanka Raut, Yakima Valley Farmworkers Clinic
Krystal Plonski, Naturopath, Seattle Children's Hospital, and Washington Association of Naturopathic Physicians (WANP)
María Sigüenza, Commission on Hispanic Affairs
Heather Hinton, MultiCare Yakima Memorial

Online Participants:

Joan Chappel, Washington Healthcare Authority (HCA)
Peggy Harris, Parent/Child Advocate, Save Babies Through Screening Foundation
Kristine Alexander, Regence Health Plans
Lisa McGill Vargas, Sacred Heart Medical Center Neonatology Intensive Care Unit (NICU)
Taylor Kaminski, Global Perinatal Services

State Board of Health (Board) staff present:

Michelle Davis, Executive Director
Kelly Kramer, Newborn Screening Project Policy Advisor
Molly Dinardo, Policy Advisor
Melanie Hisaw, Executive Assistant
Crystal Ogle, Administrative Assistant
Michelle Larson, Communications Manager
Anna Burns, Communications Consultant

Guests and Participants:

Allegra Calder, Facilitator
John Thompson, Department of Health
Megan McCrillis, Department of Health
Tony Steyermark, Department of Health
Samantha Fuller, Department of Health
Stephen Kutz, State Board of Health Member

1. **WELCOME & INTRODUCTIONS**

   Allegra Calder, Facilitator, and Kelly Kramer, Board staff, provided introductory remarks and overviews of the language interpretation channels and Zoom meeting functions.

   Facilitator Calder then invited TAC members to introduce themselves and share something they did for the first time over the past year.

2. **TAC OVERVIEW & MEETING NORMS**

   Kelly K. provided an overview of the TAC meeting agenda.

   Facilitator Calder outlined the proposed meeting norms.

   Kelly Oshiro, Board Vice Chair and TAC Co-Chair, and Nini Shridhar, TAC Co-Chair shared details about the TAC, including potential meeting schedules, timelines, and the purpose of today's meeting.

3. **OVERVIEW OF WASHINGTON STATE AGENCY CONDITION REVIEW PROCESS AND IMPLEMANTATION CONSIDERATIONS AND TIMELINES**

   Kelly Kramer, Board staff, provided an overview of the condition review process, Washington agencies and their roles in this process, implementation considerations, and timeline for the committee (see presentation on file).

   Joan Chappel, Committee Member, from the Washington Health Care Authority (HCA) provided additional information about the contracting timeline for managed care organization (MCO) rates and the accompanying fiscal analyses the agency needs to complete. Member Chappel explained that HCA is currently working on MCO rates set to take effect in June 2025 and emphasized that increases to the newborn screening fee impact MCO rates, requiring time to implement any changes.

   Allegra Calder, Facilitator, summarized the condition review timeline and provided additional information about agency decision packages (DPs). Facilitator Calder noted that DPs often face challenges in securing the requested funding.

   Eric Leung, Committee Member, from the Washington Chapter of the American Academy of Pediatrics, shared some perspective on the timeline and suggested that the Board could benefit from aligning its condition review process with the two-year Washington State legislative and budget cycles.

   John Thompson, Department of Health (Department) staff, noted that the process for reviewing candidate conditions and convening a TAC has varied, as petitions can be submitted anytime. However, John agreed with Member Leung that having a set review schedule could be helpful.

4. **INTRODUCTION TO THE RECOMMENDED UNIFOR SCREENING PANEL (RUSP)**

   Megan McCrillis, Department of Health (Department) staff, walked the TAC through the federal process for reviewing conditions for inclusion on the Recommended Uniform Screening Panel (RUSP), which was recently updated in August 2024. Megan outlined the steps involved, including condition pre-nomination and full nomination, the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) evidence-

based review process, and the final committee review, discussion and recommendation (see presentation on file).

Eric Leung, Committee Member, inquired about the pre-nomination and nomination process and whether the nominator can be a member of the public or if it needs to be a person within an ACHDNC committee workgroup who sponsors the nomination.

Megan clarified that the nomination can be submitted by a member of the public or a group of collaborators.

Member Leung asked whether the difference between the pre-nomination and nomination package is that the latter is a more detailed submission.

Megan explained that, as they understood the process, nominators were putting significant effort into submitting ACHDNC condition review packages, only to find that they did not meet basic criteria. To address this, ACHDNC created a pre-nomination form—a simple four-question form—as an initial assessment before allowing nominators to submit the complete nomination package.

Bobbie Salveson, Committee Member, expressed concerns about the RUSP, particularly the lack of parity in newborn screening conditions across states, leading to inequalities in testing and diagnosis.

Facilitator Calder asked Member Salveson to share more about the differences in screenings across states relative to the RUSP.

Member Salveson provided the example that Oregon screens for Fabry Disease and Gaucher's Disease, while Washington does not, and vice versa for Spinal Muscular Atrophy (SMA). Member Salveson noted that Oregon screens for conditions not on the RUSP, while Washington focuses on those on the RUSP. Member Salveson emphasized the lack of consistency across states in their screening practices, even for RUSP conditions.

Byron Raynz, Committee Member, inquired whether the changes in the federal committee's condition review process would affect or change the process in Washington.

Megan responded that Washington's process is not tied to the federal process or RUSP in any way, so these changes did not affect our current process. Megan added that some states follow federal processes more closely, a change that this TAC could potentially recommend to the Board.

Member Leung shared perspective on changes in newborn screening, noting that advances in screening technology and shifting population demographics have made factors that once influenced states' decisions to add conditions to their panels less relevant.

Priyanka Raut, Committee Member, echoed concerns about screening inequities across states.

María Sigüenza, Committee Member, asked if staff had identified any differences between those who submitted reviews before and after the federal process change. Member Sigüenza questioned whether the changes place more responsibility on the person submitting the request and raise equity issues or considerations that the committee should discuss.

Megan responded that adding the pre-nomination step may lower the barrier to submitting an initial request, but getting to the complete nomination package stage likely still requires a well-organized, resourced, and coordinated effort among medical partners, advocacy organizations, researchers, and more. Without this support, it would be hard for a person to complete this on their own.

Member Salveson added that many advocacy groups lead the nomination process. Member Salveson used the example of Krabbe Disease, which took over ten years of work from advocacy groups and other experts for ACHDNC to recommend the condition to the RUSP.

Krystal Plonski, Committee Member, inquired about how the Washington State newborn screening panel compares to the RUSP and whether Washington screens for non-RUSP conditions.

Kelly K. shared that Washington screens for most RUSP conditions, but three are not on Washington's panel.

Emily Shelkowitz, Committee Member, asked if staff could share more about Washington's condition nomination process and how requests are brought to the Board.

Kelly K. responded that the Board reviews conditions on a case-by-case basis, typically through petitions for rulemaking or direction from the Legislature. Kelly K. added that the TAC could consider several options for aligning with the RUSP, which staff plan to share more details about later in the meeting.

Molly Dinardo, Board staff, shared more about how condition requests have been made to the Board, most often through petitions for rulemaking, as the Board's rule establishes the conditions on the newborn screening panel. Molly briefly outlined the petition process, which the Administrative Procedures Act requires. Molly also noted petition submissions vary, ranging from detailed packages with research and data on a condition to an email or form asking the Board to consider a new condition.

Kelly Oshiro, TAC Co-Chair, thanked staff for explaining the process and noted that condition reviews directed by the Legislature are beyond the Committee's control. However, the Committee can address questions such as: If a condition is added to the RUSP, should it bypass TAC review, or would the TAC still want to review these conditions to determine their suitability for Washington? Additionally, does the TAC want to continue reviewing conditions on an ad hoc basis?

Joon-Ho Yu, Committee Member, asked if staff could provide more information about conditions requested through legislation and whether the addition of a condition to the RUSP should initiate a review in Washington.

John Thompson, Department staff, responded that the legislative route is often unpredictable, and the conditions brought to the Board through legislative directives likely stem from confusion or misunderstanding of Washington's candidate condition review process. John hopes this TAC will help clarify the process and create a clearer path forward.

Nini Shridhar, TAC Co-Chair, addressed Member Yu's question about whether adding a condition to the RUSP should initiate a review in Washington and discussed options for the TAC to consider how RUSP conditions could be reviewed in the state.

Member Raynz shared their experience with Washington's process, noting how easy it was to navigate the condition petition process without a medical or health background. Member Raynz highlighted factors like internet access, clear web pages with contact information, and the ability to connect with staff, all of which made the process smooth.

Member Raut thanked Member Raynz for their perspective, which addressed an earlier question about the Washington petition experience. Member Raut also inquired about making petition requests accessible to the public so community members can see ongoing work related to newborn screening in Washington and collaborate on these efforts.

Member Yu asked if the ACHDNC or Health Resources Administration (HRSA) has guidance on how states should implement their RUSP recommendations. Specifically, if the federal committee provides any social, regional, or population context with their recommendations.

Megan said the RUSP is a national guideline that states can use when identifying the conditions to include on their screening panels. If a condition is on the RUSP, it means the committee recommends that states add it.

John agreed with Megan and added that the RUSP is backed by funding from HRSA and the Centers for Disease Control and Prevention (CDC) to provide technical support to newborn screening programs for implementing RUSP conditions. Shortly after something is added to the RUSP, there's a flow of federal funding to help states support that work if they want to apply for it.

Megan asked Member Yu to clarify what they meant by social, regional, or population context.

Member Yu clarified that they were referring to the social conditions and values of states. Member Yu emphasized the importance of understanding the local context of states and their programs when making federal public health and medical recommendations.

Megan responded that Member Yu's question might be addressed in a later presentation.

Member Shelkowitz asked about the two conditions directed by the Legislature and if there is a publicly available list of ACHDNC members.

Megan shared that all ACHDNC meetings and materials are available online, and a membership list is also likely available, and staff would look for it during the break.

Kelly K. responded about the two legislatively directed conditions, which were branched-chain ketoacid dehydrogenase kinase deficiency (BCKDKD) and congenital cytomegalovirus (cCMV). The TAC will review these conditions in January and February.

BREAK

5. **OVERVIEW OF STATE PROCESSES FOR CONDITION REVIEW**
After the break, John Thompson shared a handout with in-person committee members that included the list of ACHDNC committee members.
https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/achdnc-membership-roster.pdf

Kelly Kramer, Board staff, gave an overview of condition review processes in other states to compare them with the process in Washington (see presentation on file).

6. **OPTIONS TO CONSIDER FOR THE WA CONDITION REVIEW PROCESS**
Kelly K. then presented three options for adjusting Washington's current process for the TAC's consideration (see presentation on file).

Eric Leung, Committee Member, . asked Kelly K. to clarify if the TAC is considering combining RUSP alignment with a standing two-year advisory committee.

Kelly K. responded that the TAC wouldn't be considering this as an option at this point, but they could discuss it in later meetings.

Member Leung wondered if that would be repeating efforts.

Allegra Calder, Facilitator, asked the TAC members to consider Kelly K's three options and consider any questions or clarification needed since the TAC would vote on them in the afternoon.

Peggy Harris, Committee Member, wondered if any conditions are unique to or specific to babies born in Washington State.

Member Leung couldn't recall recent examples but shared historical perspectives on conditions like sickle cell anemia, which disproportionately affected Black and African American babies. Member Leung also reiterated that, in recent years, the commonality of a condition has not been a significant factor in adding it to federal or state panels.

John Thompson, Department staff, noted that it's less about the prevalence of conditions in certain states and more about the availability of medical experts

specializing in rare conditions in different regions. This can influence whether non-RUSP conditions are reviewed or added to state panels. John cited Wilson's Disease as an example in Washington.

Lisa McGill Vargas, Committee Member, explained that historically, Washington had specific epigenetic patterns where some conditions were more common. However, the influx of new residents changes the disease patterns providers see in newborns. Member McGill Vargas also inquired about the process of obtaining funding for conditions and whether any of the proposed options would increase the likelihood of securing the necessary funding for screening.

Member Leung said that adding a condition requires rulemaking. If the TAC chooses RUSP alignment, maybe the rule could require the budget to accommodate new conditions, or alternative ways to address this through legislation may exist.

John agreed with Member Leung.

Emily Shelkowitz, Committee Member, highlighted the importance of considering local populations, using Pompe Disease as an example. Member Shelkowitz shared that Pompe has pseudo-deficiencies more common in the Asian population and can affect screening. It's essential to consider what Washington screens for and the impact on infrastructure and other factors.

Byron Raynz, Committee Member, noted that Washington appears to be largely RUSP-aligned and asked whether the state has evaluated conditions not on our panel but recommended to the RUSP and whether we've agreed with the federal committee's recommendations.

Kelly K. shared that guanidinoacetate methyltransferase (GAMT) deficiency was recently recommended to the RUSP, and a TAC recommended adding it in Washington. Washington will also reconsider mucopolysaccharidosis type II (MPS II) later this year. Kelly K. noted that Krabbe Disease has not yet been requested for review in Washington.

Member Leung said it's not trivial that Washington is screening for or recommending screening of most of the RUSP conditions and wondered if it's because our criteria are similar.

Molly Dinardo, Board staff, shared that Krabbe Disease was recently recommended for the RUSP, despite lacking full consensus from committee members. Molly explained that somewhat aligning with the RUSP while maintaining Washington's process would allow a TAC to review conditions like Krabbe and assess whether they are appropriate for Washington.

Heather Hinton, Committee Member, asked when the most recent condition was added to the RUSP.

Molly responded that ACHDNC has quarterly meetings, and the committee recommended the most recent condition in the spring. Molly added that federal statute

outlines the timeline for the committee to review condition nominations and issue determinations.

Member Shelkowitz thanked John for sharing the ACHDNC membership roster with the TAC and commented on the perspectives missing from the committee. Member Shelkowitz pointed out that the committee doesn't have a board-certified biochemical geneticist or a parent or family representative.

Facilitator Calder clarified for online attendees that Member Shelkowitz referred to the handout John shared after the break. Staff will send it to all committee members and link the document in the meeting notes.

Joon-Ho Yu, Committee Member, asked the staff to clarify option three for condition review.

John clarified the differences between options two and three. John explained option three would allow a Washington TAC to review a condition already assessed by the federal government. In contrast, option two would have Washington add the condition, if recommended at the federal level, without further review. John also noted that under option three, the Board and Department staff would jointly provide a TAC with information on a condition, a process they'll see for BCKDKD and cCMV.

Molly added that if the committee wanted to recommend option three, it would be helpful for them to discuss timelines for convening a TAC to review a federally recommended condition.

Kelly Oshiro, TAC Co-Chair, asked about MPS II and Wilson's Disease and whether these conditions were on the federal panel or met the Board's current qualifying assumption.

Kelly K. and John responded that the federal committee has not considered Wilson's Disease, and MPS II is a RUSP condition. But the Board determined it needed more information before proceeding with a TAC.

Co-Chair Oshiro said Wilson's Disease is an example of a condition that doesn't seem to fit squarely into the proposed options for condition review, and requests for non-RUSP conditions will continue to add work for our teams.

Krystal Plonski, Committee Member, asked if there is a national trend of states trying to move towards more RUSP alignment or more standardization of which conditions states screen for.

Molly responded that it is a mix of the two. Molly shared that the current Secretary of Health and Human Services (who approves or denies RUSP recommendations) has stated they want states to align with the RUSP. Molly added that a handful of states have passed legislation formally tying them to the RUSP, and it seems to be a conversation other states are having.

Nini Shridhar, TAC Co-Chair, shared a distinction that they see with option three versus option two: Washington will have the opportunity to still review conditions before they are added.

Member Shelkowitz added to Member Plonski's question that there's a website called NewSTEPs (https://www.newsteps.org/) that provides a data visualization map of the conditions screened state by state (https://www.newsteps.org/data-center/state-profiles?q=view-state-profile).

Bobbie Salveson, Committee Member, shared their perspective that RUSP alignment is influenced by who is in charge federally.

Member Leung asked if there is federal funding incentivizing states to align with the RUSP.

John confirmed that HRSA and CDC provide funding to incentivize states to align with the RUSP. John then highlighted challenges with RUSP alignment and new federal rules affecting newborn screening programs. John explained that even among RUSP-aligned states, inequities exist due to differences in how legislation ties states to the RUSP, leading to varying review and implementation requirements. John also mentioned that the FDA published a new rule in May regarding lab-developed tests, which will affect how newborn screening laboratories operate.

Member Salveson asked if the funding support from the CDC and the federal government is for the implementation of screening new conditions only or if it may also cover long-term diagnostic, follow-up, and treatment for these patients.

John said the most recent round of federal funding included long-term follow-up but less on the clinical side, such as providing therapies.

Member Raynz inquired about the current pipeline of conditions under review by the RUSP and the typical number of conditions added each year. Member Raynz also asked if the newborn screening program has any concerns with option two, specifically whether the program could be overwhelmed by new conditions on top of ad hoc condition review requests.

John acknowledged concerns about this, particularly with the new FDA rule change and its potential impact. John also noted other challenges, such as funding and the complexities of condition testing. John mentioned that laboratory space could become an issue in the future.

Member Leung commented that option number two seems to be the least expensive option because you could trust the federal committee and the RUSP to have done their homework and due diligence, and you wouldn't repeat the work.

Member Shelkowitz inquired about the RUSP criteria and asked if the TAC would review it during the meeting.

Facilitator Calder said the TAC would review the RUSP criteria after lunch and the

voting period. Facilitator Calder wondered if staff should move up the criteria overview and then vote. It sounded like committee members wanted to learn more about the RUSP criteria before voting and discussion.

Member Shelkowitz said the other piece they hope the committee will discuss is the impact of adding new conditions on providers' workloads and how this may differ from state to state based on birth rates and other factors.

Member Salveson agreed with Member Shelkowitz and said that the RUSP doesn't always consider the impact on clinicians and their perspectives. Member Salveson added that the two ACHDNC members who voted against recommending Krabbe Disease were both clinicians, which speaks loudly, and why overall RUSP alignment might not be the best idea.

Priyanka Raut, Committee Member, spoke from the perspective of living in an area where the federally qualified healthcare center is the leading facility managing primary care. Member Raut asked what perspective is given at the federal level to populations receiving care in these communities.

Facilitator Calder thanked the committee for a productive discussion and acknowledged the complexity of the topic. Facilitator Calder summarized the key points, highlighting the various perspectives and systems that must be balanced in these considerations. Facilitator Calder asked committee members to reflect further, with the TAC planning to continue the discussion after lunch.

LUNCH

7. **FEDERAL CRITERIA (RUSP) REVIEW** *(moved up in the committee agenda – from item 10 to 7)*
   Megan McCrillis, Department staff, guided TAC members through the criteria used to review conditions for the federal panel. Megan outlined the federal committee's evidence-based review questions, the decision-making matrix for assessing net benefit, and the feasibility of screening for state programs (see presentation on file).

   Bobbie Salveson, Committee Member, asked about the public health readiness piece of the review and whether it's dependent upon the number of public health surveys returned to the committee.

   Megan said they were not sure.

   Member Salveson raised a concern that if that part of the review depends on returned surveys, it could be skewed by the percentage of states that complete them, relying only on those states' responses for the readiness rating.

   Joon-Ho Yu, Committee Member, commented on the challenges of assessing the universality of newborn screening benefits using a simple yes/no binary. Member Yu raised the question: How do we understand the differential benefits for specific populations within the broader population, and how are these factors incorporated into the federal assessment?

Megan responded that the federal committee likely discusses this in their deliberations and explained that the committee's criteria differentiate between benefits for the newborn and the population.

Eric Leung, Committee Member, commented that the federal committee's approach seems like the current Washington state process.

Emily Shelkowitz, Committee Member, said it seems like a key part of the RUSP is still that treatability for the condition is limited within the first year. Member Shelkowitz asked if other states have amended this criterion in considering which conditions to add to their panels.

John Thompson, Department staff, mentioned they are unaware of state-specific nuisances when interpreting this part of the RUSP criteria.

Megan suggested that providing more detail on the four initial questions in the RUSP pre-nomination form may be helpful, as they haven't been discussed yet. Megan shared the four questions: 1) Is a newborn screening test available? 2) Is there agreement on the case definition of the targeted condition and diagnostic confirmation after a positive newborn screen? 3) Is there a prospective population-based newborn screening project identifying at least one infant with the condition? 4) Can identifying the targeted condition before clinical presentation allow for effective therapy and improved outcomes for screened infants?

8. **INTRODUCTION TO CRITERIA REVIEW** *(moved up in the committee agenda – from item 9 to 8)*
Kelly Kramer, Board staff, provided an overview of Washington's five newborn screening criteria (presentation on file).

Byron Raynz, Committee Member, inquired if there are any intentional differences between the Washington criteria and RUSP criteria.

John Thompson, Department staff, provided historical context on the development of Washington's newborn screening criteria and the initial RUSP, noting that the original Washington criteria were established in 2001 and 2002, before the RUSP, and updated again in 2015. John added that the original RUSP was less rigorous than Washington's criteria, but the federal group has improved its evidence review over time.

Allegra Calder, Facilitator, asked if any key distinctions between the Washington and RUSP criteria should be highlighted.

John said the fifth criterion, cost-benefit analysis, is specific to Washington and is a strength of our current process; we don't get this same level of state-specific economic analysis from the federal review.

Molly Dinardo, Board staff, noted that criterion five is a key point to consider between the three options presented to the committee before lunch. With option three, Washington would conduct its own cost-benefit analysis to determine if a federally

recommended condition is suitable for the state before proceeding. In contrast, option two would involve conducting the cost-benefit analysis only after the condition is already in the process of being added to the state panel.

Member Raynz inquired about what initiated the Board and Department to review its process and criteria.

Molly explained that this work was initiated in response to multiple newborn screening bills introduced during the last legislative session, as well as a request from the Governor's Office for the Board and Department to improve the current process and criteria to help minimize the number of newborn screening condition bills in the future. Molly also shared that there is work related to this topic at the federal level. The National Academies for Sciences Engineering and Medicine (NASEM) is conducting a national study, including a review of the RUSP review and recommendation process.

Emily Shelkowitz, Committee Member, inquired about how Washington State's newborn screening principles and criteria compare to RUSP trends. For example, the Washington criteria clearly state that universal screening is not appropriate for conditions that present in adulthood, but what about conditions that present later in childhood or adolescence?

Molly said this was a good question, and it could be explored in the TAC's discussion of possible criteria updates.

Member Shelkowitz added that another area that could be helpful to expand on in the criteria is what effective treatment means.

9. VOTING

Allegra Calder, Facilitator, provided voting instructions for committee members.

TAC Members then participated in an anonymous online vote via Microsoft Forms to select which of the three newborn screening condition review process options they would like to recommend for the Board's consideration.

10. RESULTS AND DISCUSSION

Allegra Calder, Facilitator, reviewed the TAC's voting results. Twelve TAC Members voted for option three, RUSP Meets Qualifying Assumption + Ad Hoc, while four voted for option two, RUSP Alignment + Ad Hoc.

Facilitator Calder then asked if any of the four TAC Members who voted for option two would be willing to share their perspective.

Members Sigüenza and Leung shared that they voted for option two because additional processes typically delay condition reviews and incur higher costs. They believed this option would maximize limited resources by utilizing an existing, proven federal process. Therefore, the RUSP alignment option would be the most economical and time efficient.

Peggy Harris, Committee Member commented that they had difficulty choosing between options two and three and that if they were to vote again, they would change their vote to option three; selecting option two would maybe give over too much control of our process in Washington.

Co-Chair Oshiro said they voted from the perspective of a healthcare consumer. They believed it would be better for candidate conditions to be implemented more quickly in Washington, which is why they voted for option two.

Facilitator Calder explained that, as a facilitator, their role is not to achieve consensus on a vote but to understand the reasons behind members' votes. The goal is to try to align the TAC with a majority vote, after which the Board can review the recommendations and make a final determination.

Emily Shelkowitz, Committee Member, commented on the international landscape of newborn screening and that it seems divergent from the U.S.'s processes and trajectory. The committee hadn't discussed this, but Member Shelkowitz wanted to share it to raise awareness. Member Shelkowitz added that well-resourced European countries are screening for fewer conditions, not because they don't have the infrastructure but because they have different interpretations of treatment availability and medical rationale.

Member Raynz said that, as a parent who had a child go through this process, they would have voted for option two, but having been a part of the process in Washington changed their perspective.

Member Leung said they still think Washington should consider a standing advisory committee in addition to RUSP alignment. They said if the TAC looks at the other four states that staff used for comparison to the process in Washington – California, Pennsylvania, Iowa, and Minnesota – three out of these four states are RUSP aligned and have a standing committee. They commented that a standing committee also allows Washington to review conditions at set intervals, which may be more efficient than convening ad hoc committees.

John agreed with Member Shelkowitz, noting that while several European countries can screen for more conditions, their government structures limit the scope of condition reviews. John also invited Tony Steyermark to weigh in on the condition review options.

Tony Steyermark, Deputy Director of the Washington State Newborn Screening Program, reflected on the TAC's morning discussion and shared their perspective on condition reviews. Tony explained that these reviews help Washington assess whether they have the resources to add new candidate conditions to the screening panel. If the program lacks the necessary resources, Tony emphasized that the reviews could help identify strategies for developing the infrastructure needed to improve the system and incorporate these conditions.

Co-Chair Shridhar shared their perspective that Washington has a robust process predating the RUSP and expressed concern that RUSP alignment could overwhelm the newborn screening program.

Member McGill Vargas expressed a desire for Washington to align with the RUSP and for the state to identify every newborn who could benefit from treatment. However, they voted for option three due to concerns about overburdening both the screening system and the systems responsible for counseling, intervention, and care. If Washington were equipped to implement RUSP conditions easily, they would have voted for option two.

Member Shelkowitz said that as a clinician who delivers the screening results to families and their newborns, they are concerned about some of the recent RUSP recommendations, such as Krabbe Disease. They emphasized that Krabbe is not a highly treatable condition and there are serious equity considerations around treatment.

Members Raut and Hinton shared that they voted for option three because they recognize that not all communities in Washington have access to the resources and specialized treatments needed for some rare diseases. They believe that the most equitable approach is to review each condition and determine its suitability for different communities.

Bobbie Salveson, Committee Member, inquired if the Legislature could overturn a TAC or Board decision on a candidate condition review.

John responded that the Legislature could technically overturn a TAC or Board decision through legislation.

Eric Leung, Committee Member, asked Co-Chair Oshiro how much the Board considers the RUSP when reviewing condition requests and whether making it a criterion for the qualifying assumption would save the Board time.

Kelly Oshiro, TAC Co-Chair, said it would save some time.

John estimated that the qualifying assumption work would not require four months of full-time effort but could total about four months of work. John added that the Board or the Department handles the qualifying assumption research. John mentioned that under option three, a formal nomination would no longer be required to be submitted to the Board; the condition would automatically become a candidate, speeding up the process.

Molly asked the TAC what timeline they would recommend for reviewing RUSP conditions if the Board agreed with the majority recommendation of option three.

Member Leung commented that based on the table staff presented earlier in the meeting comparing processes in other states, it seems they use either a two-year review or implementation timeframe or a twelve-month review. Member Leung noted that twelve months feels too quick and wouldn't be enough time.

Priyanka Raut, Committee Member agreed with Member Leung and noted that the biennial legislative period should be considered when timing reviews.

Facilitator Calder asked staff if a two-year timeline was a reasonable recommendation.

John said that if the TAC recommends that the Board adopt a biennial calendar for RUSP condition reviews, then in January of next year, staff will know what to expect and can plan accordingly.

Facilitator Calder asked any TAC Members if based on the discussion, they'd change their vote. One TAC member said they could be amenable to it, while two other members said they'd like to keep their vote but would be interested in hearing the Board's deliberations.

John commented that a goal of the TAC meeting is to discuss the Board's process and build understanding. John stated it's okay if TAC members vote differently, as consensus is not required. John also mentioned that the committee's discussions and votes will be presented to the Board at the November meeting, and they will make the final decisions.

Board staff asked Facilitator Calder if there should be another TAC vote regarding the timeline. After a brief discussion with the committee, it was determined that another form should be created to vote on a recommended timeline.

Second Vote on Timeframe for Review of RUSP Conditions
TAC members then participated in an anonymous online vote via Microsoft Forms to provide recommendations on: 1) whether the Board should establish a timeline for reviewing recently added RUSP conditions, and 2) the length of the timeline.

Facilitator Calder reviewed the TAC's voting results. All TAC Members voted that the Board should establish a timeline for reviewing recently added RUSP conditions. Fourteen respondents voted for a two-year review process, starting from the date of the HHS Secretary's recommendation, and one respondent voted for an eighteen-month timeline.

11. WA FIVE CRITERIA REVIEW AND DISCUSSION

Allegra Calder, Facilitator, briefly previewed the next discussion for the TAC's consideration. Facilitator Calder summarized some of the comments that TAC members had already made about the criteria, including whether the Board should consider conditions identified outside of the newborn period. Facilitator Calder said a larger discussion on this topic would need to be continued at another time. Facilitator Calder then asked the TAC to consider whether other criteria aspects could be defined better or identify if anything was missing from the requirements.

12. DISCUSSION AND NEXT STEPS

Allegra Calder, Facilitator, outlined the next steps for the TAC, including the November Board Meeting, and that staff would send a survey to identify the next TAC meeting date. Facilitator Calder then offered an opportunity for TAC members to share closing thoughts on the criteria.

Emily Shelkowitz, Committee Member, said they would be interested in better defining available and effective treatment.

Bobbie Salveson, Committee Member, agreed with Member Shelkowitz and added that obtaining coverage or payment for treatments can be challenging for patients. Member Salveson wondered how this factor influences whether a treatment is truly accessible.

Priyanka Raut, Committee Member, added that access and outreach are additional components of the testing and available treatment criteria.

Kelly Oshiro, TAC Co-Chair shared the desire to incorporate equity more into the criteria.

Byron Raynz, Committee Member, added that false positive rates are also a concern, and that this should be highlighted in the criteria.

Member Shelkowitz reflected on how to define the treatability of a condition, noting that none of these conditions are curable. Member Shelkowitz questioned how to determine when a condition has been sufficiently modified to achieve a desirable outcome for the child rather than simply adding more medical complexity and treating one diagnosis for another.

Joon-Ho Yu, Committee Member, wondered if it could be helpful to categorize the treatment criteria based on different types of treatment.

Member Raut noted that the current criteria don't reflect the availability of community resources and the importance of community outreach and support.

Eric Leung, Committee Member, asked if the state has obligations to maintain a database or track patients long-term.

John Thompson, Department staff, responded that building out the long-term follow-up program is one of Tony Steyermark's responsibilities as Deputy Director. John shared that limited efforts are in place to provide metabolic treatment products to patients needing them. Additionally, they are partnering with the Center for Public Health Innovation on a grant to explore long-term follow-up from a health information technology perspective. This involves pulling data from electronic medical records to track which patients are being seen. John noted that they are still in the early stages of this work.

Member Raut said that technology systems and technology integration are issues and concerns for the facilities in their community in Yakima.

John added that in addition to the false positive rates Member Raynz mentioned, their program is also concerned about false negatives. John could see the benefit of tightening the language around the sensitivity and specificity of tests.

Lisa McGill Vargas, Committee Member, commented that evaluating every disease or

condition using the same criteria can be challenging. Member McGill Vargas noted that, depending on the condition, the number of false positives may not impact their work as much as expected, while other conditions may cause a lot of stress and uncertainty for parents. Not all conditions require or have the same threshold for sensitivity and specificity.

Kelly Kramer, Board staff, shared the next steps for the criteria discussion and noted that the TAC would also review BCKDKD at the next meeting.

ADJOURNMENT

Kelly Oshiro and Nini Shridhar, TAC Co-Chairs, adjourned the meeting at 2:30 p.m.

WASHINGTON STATE BOARD OF HEALTH

_____
Kelly Oshiro, TAC Co-Chair and Nini Shridhar, TAC Co-Chair

To request this document in an alternate format or a different language, please contact the Washington State Board of Health at 360-236-4110 or by email at wsboh@sboh.wa.gov
TTY users can dial 711.

PO Box 47990 • Olympia, Washington • 98504-7990
360-236-4110 • wsboh@sboh.wa.gov • sboh.wa.gov