WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Panel PROCESS & CRITERIA

PROCESS TO EVALUATE CONDITIONS FOR INCLUSION IN THE REQUIRED NEWBORN SCREENING PANEL

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The Washington State Board of Health (Board) has the duty under RCW 70.83.050 to define and adopt rules for screening Washington-born infants for heritable conditions using a dried-blood spot specimen. Chapter 246-650-020 WAC lists conditions for which all newborns must be screened. Members of the public, staff at the Department of Health (Department), and/or Board Members can request that the Board review a particular condition for possible inclusion in the newborn screening (NBS) panel.

To determine which conditions to include in the NBS panel, the Board convenes a newborn screening technical advisory committee (TAC) to evaluate candidate conditions using guiding principles and an established set of criteria.

This document describes the Qualifying Assumption, Guiding Principles, and Criteria the Board has approved to evaluate conditions for possible inclusion in the newborn screening panel. The Board and Department apply the qualifying assumption. The Board-appointed Newborn Screening TAC applies the following three guiding principles and evaluates the criteria to make recommendations to the Board on which conditions to include in the state's required NBS panel.

QUALIFYING ASSUMPTION

Before the Board convenes a TAC to review a candidate condition against the newborn screening criteria, staff should complete a preliminary review to determine whether sufficient scientific evidence is available to apply the criteria for inclusion. This is called the qualifying assumption.

If the candidate condition is on the Health Resources and Services Administration (HRSA) Recommended Uniform Screening Panel (RUSP), the Board and Department may consider the qualifying assumption met and convene a TAC.

A note on the RUSP: The RUSP is a list of conditions that the Secretary of the Department of Health and Human Services (HHS) recommends states screen for as part of their newborn screening programs. Once the HHS Secretary recommends a new condition, the Board and Department may review it for possible inclusion in the Washington NBS panel within two years of the recommendation.

Conditions pending RUSP Review or Previously Denied for the RUSP: RCW 34.05.330 of the Administrative Procedures Act (APA) allows any person to petition a state agency to adopt, repeal, or amend any rule within its authority. Agencies must respond to the petitioner within 60 days. If the agency accepts the petition, it must initiate rulemaking. An agency can deny the request for rulemaking, and in doing so, it must explain its reasons and, if appropriate, describe alternative steps it is prepared to take.

If the Board receives a request to review a condition for possible inclusion on the panel—including a petition for rulemaking under RCW 34.05.330—and the condition is currently under review for the RUSP, the Board will wait until the committee completes its review and the HHS Secretary makes a final decision before convening a TAC.

For petitions involving conditions that have already been reviewed and denied inclusion on the RUSP, the Board will instruct staff to work with the petitioner to determine if concerns raised during the federal review have been addressed before recommending that the Board convene a TAC to review the condition.

THREE GUIDING PRINCIPLES

Three guiding principles govern all aspects of the evaluation of a candidate condition for possible inclusion in the NBS panel.

- A decision to add a screening test should be driven by evidence. For example, test reliability and available treatment have been scientifically evaluated, and those treatments can improve health outcomes for affected children.
- All children who screen positive should have reasonable access to diagnostic and treatment services.
- Benefits of screening for the disease or condition should outweigh harm to families, children, and society.

CRITERIA

1. **Available Screening Technology:** Sensitive, specific, and timely tests are available that can be adapted to mass screening.
    - The sensitivity of the screening test is estimated to be ≥95%.
    - The specificity of the screening test is considered acceptable based on the estimated number of false positive results and their potential impact on the families, healthcare system, and newborn screening program.
    - A timely test is one that enables intervention before irreversible harm develops, within the current standard timeframes for specimen collection, receipt, testing, and reporting.
    - There is adequate peer reviewed evidence to evaluate this criterion.

2. **Diagnostic Testing and Treatment Available:** Accurate diagnostic tests, medical expertise, and effective treatment are available for evaluation and care of all infants identified with the condition.
    - A diagnostic test accurately identifies who needs treatment and is readily available to all newborns screened.
    - The available treatment is effective in reducing morbidity or mortality and outweighs any risks or harms of the treatment.
    - The medical expertise needed to diagnose and care for those with a positive newborn screen is reasonably available to all newborns screened.
    - The appropriate consultants and treatment centers have been identified and have capacity for the expected increase in diagnostic testing and/or referrals.
3. **Prevention Potential and Medical Rationale:** The newborn identification of the condition allows early diagnosis and intervention.
    - There is sufficient time between birth and onset of irreversible harm to allow for diagnosis and intervention.
    - The condition must have an onset form that occurs in infancy (within the first year of life); newborn screening is not appropriate for conditions that only present after the first year of life.
    - The benefits of detecting and treating infantile-onset forms of the condition (within one year of life) balance the impact of detecting later onset forms of the condition.
    - There is adequate evidence of acceptable quality to evaluate this criterion.
4. **Public Health Rationale:** Nature of the condition justifies population-based screening rather than risk-based screening or other approaches.
    - All available risk-based screening tools for the condition have been considered and are found to be inferior to universal newborn screening.
    - There is adequate evidence of acceptable quality to evaluate this criterion.

5. **Cost-benefit/Cost-effectiveness:** The outcomes outweigh the costs of screening. All outcomes, both positive and negative, need to be considered in the analysis.
    - The economic analysis considers:
        - The prevalence of the condition among newborns.
        - The positive and negative predictive values of the screening and diagnostic tests.
        - Variability of clinical presentation by those who have the condition.
        - Dollar values for costs and benefits of screening vs. no screening.
    - The impact of ambiguous results, adverse effects, or unintended consequences of screening, such as psycho-social or economic impacts on the family and medical system, must also be considered.
    - The results of the economic analysis shows that the outcomes, financial or otherwise, outweigh the costs of screening.
    - There is adequate evidence of acceptable quality to evaluate this criterion.
6. **Public Health Infrastructure Readiness:** The Newborn Screening Program's capacity to implement screening within a reasonable timeframe has been considered.
    - The systems and staffing necessary to perform the test and report screening results have been identified.
    - Resources needed to implement short/long term follow up protocols by the newborn screening program have been identified.
    - Accessibility to treatment for anyone diagnosed with the condition is considered acceptable based on the frequency of treatment needed.