

WASHINGTON STATE BOARD OF HEALTH PROCESS TO EVALUATE CONDITIONS FOR INCLUSION IN THE REQUIRED NEWBORN SCREENING PANEL

The Washington State Board of Health has the duty under RCW 70.83.050 to define and adopt rules for screening Washington-born infants for heritable conditions. Chapter 246-650-020 WAC lists conditions for which all newborns must be screened. Members of the public, staff at Department of Health, and/or Board members can request that the Board review a particular condition for possible inclusion in the NBS panel. In order to determine which conditions to include in the newborn screening panel, the Board convenes an advisory committee to evaluate candidate conditions using guiding principles and an established set of criteria.

The following is a description of the Qualifying Assumption, Guiding Principles, and Criteria which the Board has approved in order to evaluate conditions for possible inclusion in the newborn screening panel. The Washington State Board of Health and Department of Health apply the qualifying assumption. The Board appointed Advisory Committee applies the following three guiding principles and evaluates the five criteria in order to make recommendations to the Board on which condition(s) to include in the state's required NBS panel.

The Washington State Board of Health Newborn Screening Criteria for including conditions on the newborn screening panel is dedicated to Mr. Michael Glass. Mr. Glass was the Newborn Screening program manager for more than 30 years and instrumental in developing these criteria. Mr. Glass passed away in 2015. The Board honors Mr. Glass and the important contribution he made to this work that has helped improve the lives of many Washington families. The Board is honored to dedicate these criteria in his name.

QUALIFYING ASSUMPTION

Before an advisory committee is convened to review a candidate condition against the Board's five newborn screening requirements, a preliminary review should be done to determine whether there is sufficient scientific evidence available to apply the criteria for inclusion.

THREE GUIDING PRINCIPLES

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

- 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/condition should outweigh harm to families, children and society.

CRITERIA

- Available screening technology: Sensitive, specific and timely tests are available that can be adapted to mass screening.
- 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.
- Prevention potential and medical rationale: The newborn identification of the condition allows early diagnosis and intervention. Important considerations:
- There is sufficient time between birth and onset of irreversible harm to allow for diagnosis and intervention.
- The benefits of detecting and treating early onset forms of the condition (within one year of life) balance the impact of detecting late onset forms of the condition.
- Newborn screening is not appropriate for conditions that only present in adulthood.
- Public health rationale: Nature of the condition justifies population-based screening rather than risk-based screening or other approaches.
- Cost-benefit/Cost-effectiveness: The outcomes outweigh the costs of screening. All outcomes, both positive and negative, need to be considered in the analysis. Important considerations to be included in economic analyses include:
 - 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.
 - The impact of ambiguous results. For example the emotional and economic impact on the family and medical system.
 - Adverse effects or unintended consequences of screening.