

Advisory Committee on Heritable Disorders in Newborns and Children

Cutoffs and Risk Assessment in Newborn Screening

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Catalysts for Discussion

- **Committee Discussion**
- **NBS Advocates**
- **NBS in the News**
- **State NBS Programs expressed a need**

Issues Raised by Stakeholders

- Missed cases
- Borderline results
 - Communication from NBS program
- Lack of uniformity
 - Laboratory methods
 - Conditions screened

Challenges Identified

- **Due to different screening methods and multiple factors that impact screening results, cutoffs and screening algorithms can not be directly compared with one another**
- **No consensus on the definition of a borderline result or how to process borderline results**
- **Incomplete dataset on missed cases**

Challenges Identified

- **Lack of resources to implement QA/QC activities**
- **Access to data (and staff with expertise to analyze and interpret complex data) that can inform the evaluation of cutoff values and screening algorithms**

Addressing Challenges - Work in Progress

- **Association of Public Health Laboratories - Risk Assessment in Newborn Screening Resource Document**
 - **A resource for states on approaches that can be used to assess risk and the tools available to assist in these efforts**
 - **Near final draft, posting on website, anticipated in June, 2018**

Addressing Challenges - Work in Progress

- **CDC's Newborn Screening Quality Assurance Program – Harmonization Activities**
 - Reporting de-identified normalized cutoffs to NBS laboratories to help them compare their cutoffs to their peers
 - Development of new proficiency testing and borderline materials for states to use
- **NBS Technical Assistance Center and Data Repository**
 - Supports state program evaluations

Are There Additional Ways The Committee Can Support States?

- Provide guidance on developing a systematic approach to evaluation of cutoffs and screening algorithms
- Support efforts to improve access to data, laboratorians, epidemiologists or biostatisticians as needed, who can conduct complex analyses on the data available, at the state level
- Provide rationale for development of resources at the state level to implement needed activities

Discussion