

Standardized Reporting of Newborn Screening Outcomes (STAR-NBS)

August 9, 2024

Background

- There is significant variation in how prospective evaluations of newborn screening tests are reported in the peer-reviewed literature
 - Creates confusion
 - Makes it difficult to synthesize data

Key Areas That Often Need Clarity

- Clinical case definition of the target of screening
- Reference standard
- How test characteristics are assessed
 - Inadequate sample
 - Loss to follow-up
 - Indeterminate diagnostic test results
 - Non-targeted conditions
 - Carrier status
 - Other phenotypes (e.g., late-onset disease)
 - Other conditions

Additional Areas That Often Need Clarity

- Whether the newborn is the unit of analysis
- Evolution of the screening algorithm
- Components of any cost analysis
- Plans for follow-up
 - After diagnosis
 - When diagnosis is unclear

STARD 2015 Guidelines for Reporting Diagnostic Accuracy Studies

Cohen JF, et al. BMJ Open 2016;6:e012799.

- 30 Items – covers most of the points needed to fully understand a study of newborn screening through diagnostic follow-up
 - Title and Abstract
 - Introduction
 - Methods
 - Study Design
 - Participants
 - Test Methods
 - Analysis
 - Results
 - Participants
 - Test Results
 - Discussion
 - Other information

Key Areas That Often Need Clarity – What is really needed as an extension

- **Clinical case definition of the target of screening**
- Reference standard
- How test characteristics are assessed
 - Inadequate sample
 - Loss to follow-up
 - Indeterminate diagnostic test results
 - **Non-targeted conditions**
 - **Carrier status**
 - **Other phenotypes (e.g., late-onset disease)**
 - **Other conditions**

Additional Areas That Often Need Clarity

- **Whether the newborn is the unit of analysis**
- **Evolution of the screening algorithm**
- **Components of any cost analysis**
- **Plans for follow-up**
 - **After diagnosis**
 - **When diagnosis is unclear**

What we have now

- Permission to develop the extension
- Some preliminary feedback
- Would like to test this with newborn screening program....

Questions