

NBS02-A2 (formerly I/LA27-A) *Newborn Screening Follow-up; Approved Guideline* - *Second Edition*



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May 2006

NBS02-A

Newborn Screening Follow-up; Approved Guideline

This guideline describes the basic principles, scope, and range
of follow-up activities within the newborn screening system.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

Intended Audience



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Global document applies to those involved in any aspect of NBS follow-up:

- NBS follow-up personnel
- NBSS administrators
- Maternity and newborn health care providers
- Medical home providers
- Confirmatory services/sub-specialty providers
- Parents

Newborn Screening System



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- Screening
- **Follow-up** (short-term follow-up)
- Diagnosis
- Treatment/Management
- **Evaluation** (included in long-term follow-up)
- Education

Goal of FU Guidelines



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To enhance the quality of follow-up services for newborns screened in public health or other newborn screening programs.

Bloodspot Screening

Point of Care Screening

Hearing Loss

Congenital Heart Defects



The *2nd* edition aimed to:

- Obtain more global input
- Harmonize with other CLSI/NBS guidelines
- Update or reaffirm FU activities within NBS systems
- Further define long term follow-up roles and responsibilities
- Emphasize the importance of condition (case) definitions to short and long term follow-up



Obtaining Global Input

- Increased non US committee and advisory members
- Use of CLSI Internal Organization for Globalization
- Decreased use of US statistics when possible

Harmonize with CLSI/NBS guidelines



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In-range is now **Screen Negative**
Out-of-range is now **Screen Positive**

Update or Reaffirm FU Activities



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Reaffirmed Principles of STFU

- Is an integral part of the NBS system
- Should be centralized if possible
- Activities should be uniform across conditions, jurisdictions
- Activities should be prioritized and accomplished quickly
- Should be active for screen positive, invalid specimen/result cases
- All cases should be resolved within a given time frame

STFU activities need evaluation

Long Term Follow-up Roles and Responsibilities



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Update LTFU

- Long term FU: the primary responsibility of the subspecialty care providers, governmental agencies, universities, rather than NBSP
- NBSP should be in a supportive role to LTFU efforts
- LTFU data are integral to evaluation of the NBS battery of tests (vital to know if we are providing a benefit)

Condition Definitions



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- Standard case definition of the condition is important for consistent newborn screening data reporting, surveillance, and outcomes analysis
- There has been an extensive effort to develop consensus worldwide (Europe, Australia, New Zealand and the US)

Incidental Changes



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- Minor changes and additions of definitions
- Reorganization of the Table of Contents
- Education section relates primarily to the needs of practitioners and parents for “just in time” information
- Additional references



Future (what we forgot?)

- **Compare STFU protocols for efficacy**
- **Evaluate the new STFU models in CCHD screening**
- **Continue working with NBSS to refine condition definitions or define for new conditions**

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- Document Development Committee
- Advisors and Reviewers

