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

Judi Tuerck & Bridget Wilcken
Co-Chairs
May 7, 2013 Atlanta, GA
Document Development Committee

- Judi Tuerck & Bridget Wilcken, Co-Chairs
- Dianne Webster, Secretary
- Irene Forsman
- Alex Kemper
- David Millington
- Jan Ostrup
- Brad Therrell
- Toni Torresani
- Jerry Vockley
NBS02-A2 (formerly I/LA27-A)
Intended Audience

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

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

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

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

- 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

- 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
ACKNOWLEDGEMENTS

- CLSI Staff (Ron Quicho & Sheryl Wildgust)
- CLSI Committee on Immunology & Ligand Assays
- Document Development Committee
- Advisors and Reviewers