Newborn Screening Molecular Resources: NBS Molecular Network and CDC’s Molecular Quality Improvement Program

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9th November 2011
NBS Molecular Testing Status

39 programs offer a secondary molecular test (86% of babies born/year)
5 states offer a primary molecular test (25% of babies born/year)
Mandate from Congress: Provide Quality Assurance Materials for NBS Laboratories

NSMBB shall provide for:

- Quality assurance activities for laboratories involved in screening newborns and children for heritable disorders
- Appropriate quality control and other performance test materials to evaluate the performance of new screening tools

Newborn Screening Saves Lives Act of 2008
CDC’s Newborn Screening and Molecular Biology Branch: Team Organization

Newborn Screening and Molecular Biology Branch (NSMBB)

- Newborn Screening Quality Assurance Program
- Newborn Screening Translation Research Initiative
- Molecular Risk Assessment Laboratory
- DNA Banking (NHANES) and Genetics Laboratory
- Biochemical Mass Spectrometry Laboratory
- Molecular Quality Improvement Program
Molecular Quality Improvement Program

**Mission:**
*Work with public health laboratories to detect newborn disorders with molecular methods, and provide a public health forum to exchange molecular practices, quality improvements and educational resources to enhance laboratory performance.*

- Second tier and primary molecular methods are now being used by a number of newborn screening laboratories

- Molecular screening brings new and different technologies into the NBS laboratory creating a need for newborn screening laboratory resources
  - NBS Molecular Network and Steering Committee
NBS Molecular Network

Public health partners working synergistically to enhance newborn screening with molecular tests

Goal 1: Plan strategies to enhance communication, education and dissemination of molecular laboratory practices and resources

Goal 2: Define collaborative projects to fill gaps in molecular NBS

Goal 3: Prioritize newborn screening disorders for which a molecular test could enhance the primary test's sensitivity or specificity

Steering Committee Members:

- Mei Baker
- Mike Glass
- Stan Berberich
- Rachel Lee
- Michele Caggana
- Fred Lorey
- Kevin Cavanagh
- Mark McCann

Public health partners working synergistically to enhance newborn screening with molecular tests
Activities and Priorities for 2011

- Creation of a NBS molecular laboratory resource website
- Implementation of NBS Molecular Assessment Program (MAP)
- Quality assurance research to identify and develop molecular methods for the DBS matrix
  - Performance Evaluation of DBS DNA Extraction Methods in PCR Based Newborn Screening Assays
Activities and Priorities for 2011 cont.

- Laboratory created QC materials for CF NBS testing
- Molecular characterization of quality assurance materials (e.g. cystic fibrosis and hemoglobinopathies)
- Development of molecular test for CAH
- Education/Training: CDC and APHL sponsored Molecular Training Workshop
  - June 28th–30th in Atlanta, GA at the CDC laboratory
Molecular Quality Improvement Program
Team Members

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.