

“Legislative Session – SCID Implementation: Lessons Learned from North Carolina”

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Newborn Screening Program

Collaborative Partnerships

- State
 - NCSLPH
 - Children & Youth Branch, DPH, for disorder follow-up
 - UNC Division of Genetics & Metabolism, for disorder follow-up
 - Onsite testing services at birthing centers
 - Early Hearing Detection and Intervention (EHDI) Program
 - Critical Congenital Heart Disease (CCHD, testing performed in birthing hospital)
 - NC Hospital Association
 - NC NBS Advisory Committee
 - SMEs in NC
- Federal
 - CDC
 - SERC, APHL, CLSI

NBS Unit at the NCSLPH

- Conducts testing on ~120K newborns annually
 - 31 core conditions
 - 11 secondary conditions
 - Based on RUSP (31/32)
- Requirements for adding conditions to the panel
 - Easily identifiable
 - Highly sensitive testing technique
 - Minimal false-positives with no false negatives
 - Affects of the disorder are tempered by early intervention
 - Cost-effective
 - Appropriate follow-up immediately available

History of Testing at the NCSLPH

- 1966 – Phenylketonuria (PKU)
- 1979 – Primary Hypothyroidism (CH)
- 1987 – Hemoglobinopathies (Targeted)
- 1988 – Galactosemia (GAL)
- 1989 – Congenital Adrenal Hyperplasia (CAH)
- 1994 – Hemoglobinopathies (Universal)
- 1999 – Tandem Mass Spectrometry – (25 Amino Acid, Organic Acid, & Fatty acid Oxidation disorders)
- 2004 – Biotinidase Deficiency (BIO)
- 2009 – Cystic Fibrosis (CF)



SCID Implementation in NC

- **2010** – SCID added to the Recommended Uniform Screening Panel (RUSP)
- **2011** – NC Newborn Screening Advisory Committee recommends adding SCID to NC NBS panel (w/ agreement to delay until NCSLPH relocates to new laboratory)
- **2012-13** – NCSLPH relocation
- **2013** – NCSLPH Special Provision/Expansion Budget for NC General Assembly Short Session

SCID Implementation in NC

- **2014** – NCSLPH Special Provision/Expansion Budget for SFY16 Governor’s Budget:
 - A fee of twenty-four nineteen dollars (\$24.00) (~~\$19.00~~) applies to a laboratory test performed by the State Laboratory of Public Health pursuant to this section. The fee for a laboratory test is a departmental receipt of the Department and shall be used to offset the cost of the Newborn Screening Program.
 - NCSLPH White Paper prepared to financial and programmatic justification for the Special Provision
 - Not included in Governor’s Budget!

SCID Implementation in NC

- **2014-15** – Correspondence with Immune Deficiency Foundation and March of Dimes regarding lobbying efforts
- **2015** - HB698 “Baby Carlie Nugent” bill
- **2015** – Parent advocate/Medical care specialists
- **2015** – Senate Sponsor

Challenges

- Authority
 - Legislative (Fee)
 - Administrative Rule
- Advocacy
- Grant/Contract administration
- Budget

NCSLPH NBS Unit – Fiscal Landscape

- Cost to sustain the program annually:
\$8.5M
 - Direct costs for NBS tests and the follow-up program
 - Indirect costs
 - Equipment replacement
- Estimated cost to treat a missed disorder
i.e. SCID: \$2.5-5.0M
- Fees have remained unchanged since
2009 (\$19)

Implementation Solutions

- Partnerships: RTI International



- Advocacy: March of Dimes, Immune Deficiency Foundation, Duke University, UNC-CH
- Internal lobbying

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