



# NewSTEPS

A Program of the Association of Public Health Laboratories™

## SITE VISIT REPORT (DRAFT)

**[REDACTED] Newborn Screening Program**

**[REDACTED] Month Year**

*The work described in this report was conducted by the Newborn Screening Technical assistance and Evaluation Program (NewSTEPS) for the [REDACTED] Newborn Screening Program. The development of this report was supported by the Health Resources and Services Administration (HRSA) under Cooperative Agreement #U22MC24078 for \$950,000. This information or content and conclusions are those of the authors and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the US Government.*

## About NewSTEPS

NewSTEPS is funded through a cooperative agreement between the Association of Public Health Laboratories (APHL) and the Genetic Services Branch of the Health Resources and Services Administration (HRSA). APHL is collaborating with the Colorado School of Public Health to implement NewSTEPS.

Newborn Screening (NBS) is a state-based public health system that tests newborns for inherited disorders that may not show clinical symptoms at birth, but can cause permanent disability or death if not detected or treated within the first couple days of life. It is a complex system that involves education, laboratory analysis, follow-up, treatment, and monitoring and evaluation. Each year in the United States, 4 million newborns are screened and 12,000 newborns diagnosed with serious, but treatable conditions grow up healthy because of newborn screening. The Health and Human Services (HHS) Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) evaluates and recommends conditions to be included on the [Recommended Uniform Screening Panel \(RUSP\)](#). Each state, however, mandates the specific conditions to be screened by their own program, implements system processes including follow-up of out-of-range (screen-positive) results, and is responsible for quality improvement and assurance of the entire NBS system.

The formation of NewSTEPS has been a critical step in ensuring that states can adequately evaluate, analyze, and benchmark the performance of their laboratory tests and the quality of their NBS programs. To be effective and successful, NBS systems require partnerships that include families, health care providers, and local, regional, state, national and private organizations. The activities of NewSTEPS are designed to build partnerships with the ultimate goal of maintaining and improving quality in NBS. The purpose of NewSTEPS is to expand upon previous quality improvement efforts and to strengthen existing newborn and genetic screening programs by providing data, technical and educational resources to various NBS stakeholders. The project entails facilitating the harmonization of NBS activities through innovation and technology with the goal of being able to analyze, compare and continuously improve NBS systems.

**Vision:** Dynamic newborn screening systems have access to and utilize accurate, relevant information to achieve and maintain excellence through continuous quality improvement.

**Mission:** To achieve the highest quality for newborn screening systems by providing relevant, accurate tools and resources and to facilitate collaboration between state programs and other newborn screening partners.

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## Executive Summary

In April 2017, a team of expert reviewers comprised of public health professionals and the Association of Public Health Laboratories (APHL) Staff conducted a site visit at the [REDACTED]. This site visit assessed various components of [REDACTED]'s NBS system including the laboratory program, birth facilities, and follow-up program for quality improvement purposes.

The following report will further articulate these highlights and opportunities for improvement and will include recommendations for optimizations within the system. Some of these recommendations the program may be address internally, while others will require support from stakeholders in other areas of the public health system (external).

## SWOT ANALYSIS

In addition to the recommendations articulated in the Results section of this report, the Strengths, Weaknesses, Opportunities, and Threats (SWOT) Analysis in the tables below addresses specific programmatic areas of strength and improvement that are further described in the report.

### STATEMENT OF STRENGTHS

Programmatic Areas	Strengths
<b>Organizational Structure</b>	
<b>State Legislation and Policy</b>	
<b>Funding Models</b>	
<b>Laboratory System</b>	
<b>Emergency Preparedness</b>	
<b>Short-Term Follow Up (STFU) System</b>	
<b>Long-Term Follow Up System</b>	
<b>Birth Facilities</b>	
<b>Point of Care Testing</b>	
<b>Education</b>	
<b>Information Systems</b>	

## STATEMENT OF CHALLENGES: WEAKNESSES AND THREATS

Programmatic Areas	Challenges
<b>Organizational Structure</b>	
<b>State Legislation and Policy</b>	
<b>Ethics</b>	
<b>Funding Models</b>	
<b>Laboratory System</b>	
<b>Emergency Preparedness</b>	
<b>Short-Term Follow Up (STFU) System</b>	
<b>Long-Term Follow Up System</b>	
<b>Birth Facilities</b>	
<b>Point of Care Testing</b>	
<b>Education</b>	
<b>Information Systems</b>	

## STATEMENT OF OPPORTUNITIES/RECOMMENDATIONS

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Programmatic Areas	Opportunities
Organizational Structure	
State Legislation and Policy	
Ethics	
Funding Models	
Laboratory System	
Emergency Preparedness	
Short-Term Follow Up (STFU) System	
Long-Term Follow Up System	
Birth Facilities	
Point of Care Testing	
Education	
Information Systems	

## Introduction

In accordance with the NewSTEPs vision, a team of expert reviewers comprised of public health professionals and Association of Public Health Laboratories (APHL) staff (Appendix A) conducted a site visit to the [REDACTED] Newborn Screening (NBS) Program on [REDACTED].

The site visit team reviewed all aspects of the NBS system, including the collection of dried blood spots, laboratory analysis, education, treatment, and follow-up. Review criteria considered during the assessment included, but were not limited to, the following areas:

- Organizational Structure
- State Legislation and Policy
- Ethics
- Funding Models
- Laboratory System
- Emergency Preparedness
- Short Term Follow-Up System
- Birth Facilities
- Point-of-Care Testing
- Education
- Long Term Follow-Up System
- Information Systems

This report captures information on the [REDACTED] NBS Program/System, including the following:

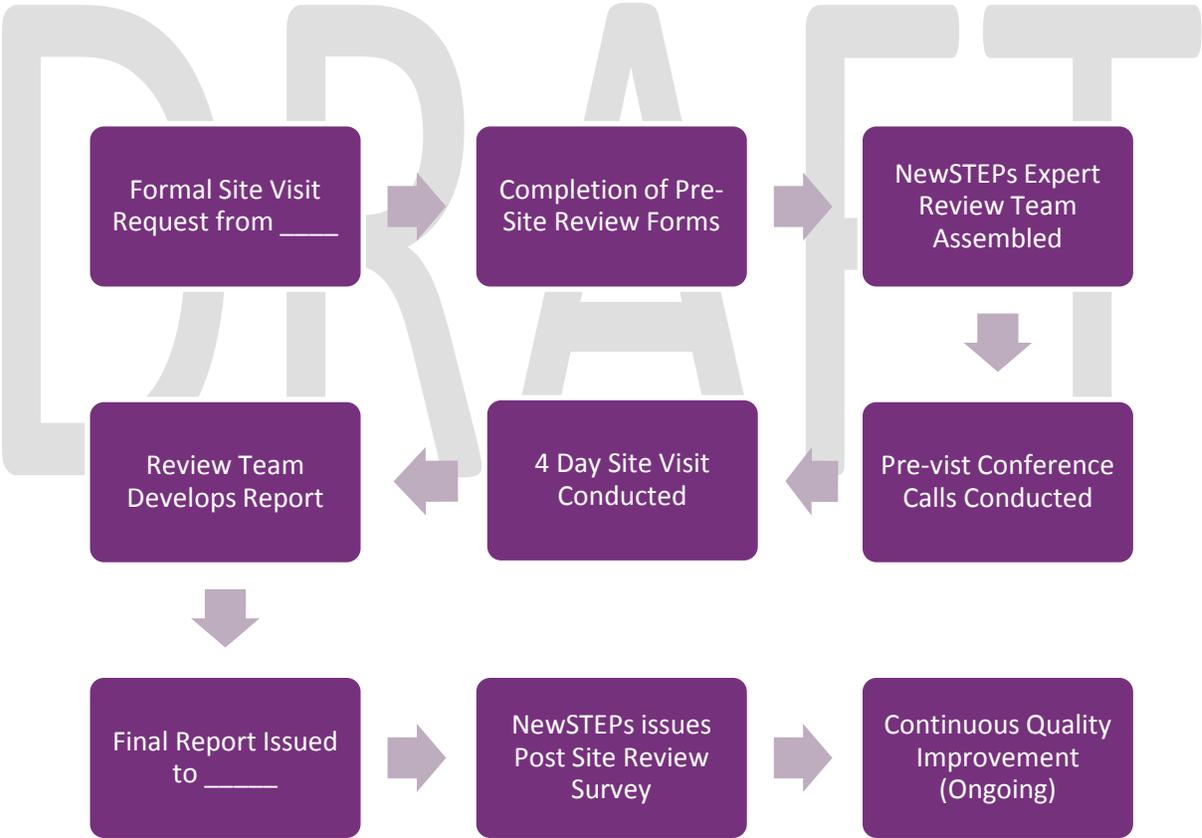
- General perceptions of the NBS Program.
- An assessment of the functions of each component of the screening program: pre-analytical, analytical, and post-analytical.
- A statement of recommendations for the [REDACTED] NBS Program.

# Methods

The team of experts facilitated a comprehensive and customized site visit to review the INSP using a flexible checklist with a focus on assessing systematic components. The pre-site visit tool and site visit manual (Appendices B and C) were developed by the NewSTEPS Evaluation Work Group with approval from the NewSTEPS Steering Committee (Appendix D).

The review team was comprised of experts in pediatric clinical care, newborn screening (NBS) laboratory, follow-up, and information systems. Guided program reviews occur on a scheduled basis following the procedure outlined in Figure 1.

**Figure 1: Site Visit Process**



**Table 1: Pre-Review Tool Summary**

LABORATORY FEEDBACK ON PRE-REVIEW TOOL	
PROMPT	RESPONSE
Significant challenges within NBS program	•
Significant accomplishments in the past two to three years	•
Site visit needs	•
FOLLOW-UP FEEDBACK ON PRE-REVIEW TOOL	
PROMPT	RESPONSE
Significant challenges within NBS program	•
Significant accomplishments in the past two to three years	•
Site visit needs	•

Following examination of the pre-site review form, the challenges identified and questions raised were addressed during the site visit. The five day site visit followed the schedule outlined in **Table 2** below.

**Table 2: State Site Review Visit Schedule**

<b>Monday,</b>	
<b>Tuesday,</b>	
<b>Wednesday,</b>	
<b>Thursday,</b>	
<b>Friday,</b>	

Following the four-day site review visit, NewSTEPS staff synthesized the notes provided by the reviewers to develop this report. It is their intention that this report will be utilized to facilitate quality improvements. Additionally, the program can utilize the Site Review Manual (see Appendix H) in the future to self- assess as needed.

# Site Visit Results

## Organizational Structure

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*Recommendation:*

## State Legislation and Policy

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*Recommendation:*

## Ethics

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*Recommendation:*

## Funding Models

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*Recommendation:*

## Laboratory System

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*Recommendation:*

## Emergency Preparedness

---

*Recommendation:*

## Short-Term Follow-Up System

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***Recommendation:***

## Long-Term Follow-Up System

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***Recommendation:***

## Birth Facilities

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***Recommendation:***

## Point-of-Care Screening

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***Recommendation:***

## Education

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***Recommendation:***

## Information Systems

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***Recommendation:***

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## List of Acronyms

APHL	Association of Public Health Laboratories
CAP	College of American Pathologists
CCC	Clinical Care Coordination
CCHD	Critical Congenital Heart Disease
CDC	Centers for Disease Control and Prevention
CF	Cystic Fibrosis
CLIA	Clinical Laboratory Improvement Amendments
CLSI	Clinical and Laboratory Standards Institute
CQI	Continuous Quality Improvement
HRSA	Health Resources and Services Administration
EHDI	Early Hearing Detection and Intervention
LBW	Low Birth Weight
LIMS	Laboratory Information Management System
LTFU	Long Term Follow-Up
MOU	Memorandum of Understanding
MS/MS	Tandem Mass Spectrometry
NBS	Newborn Screening
NewSTEPS	Newborn Screening Technical assistance and Evaluation Program
NICU	Neonatal Intensive Care Unit
NNSGRC	National Newborn Screening and Global Resource Center
PEAS	Performance Evaluation Assessment Scheme
POC	Point of Care
QA	Quality Assurance
QC	Quality Control
QI	Quality Indicators
RUSP	Recommended Uniform Screening Panel
SCID	Severe Combined Immunodeficiency
SOPs	Standard Operating Procedures
SWOT	Strengths, Weaknesses, Opportunities and Threats analysis

## List of Appendices

Appendix A: Site Review Team Members

Appendix B:  Newborn Screening Program Profile (2016)

Appendix C:  NBS Program Organizational Charts

Appendix D: NewSTEPs Evaluation Work Group Members and Steering Committee

Appendix E: Possible Considerations for Follow-Up in Continuity of Operations Plan (COOP)

Appendix F: Advisory Committee on Heritable Conditions in Newborns and Children's (ACHDNC)

List of Time Critical Disorders

Appendix G: Sample Medical Director Job Description

Appendix H: Full NewSTEPs Site Review Manual

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**Appendix A:  
Site Review Team Members**

**Jelili Ojodu, MPH:** Mr. Ojodu is the Director for the Newborn Screening and Genetics Program at the Association of Public Health Laboratories (APHL). He is also the Project Director for the Newborn Screening Technical assistance and Evaluation Program (NewSTEPS). Mr. Ojodu is responsible for providing guidance and direction for the Newborn Screening and Genetics in Public Health Program. Prior to joining APHL, he spent four years at Georgetown University Medical Center on a National Institutes of Health initiative to reduce infant mortality in the District of Columbia as a research associate. He received his Master's in Public Health from The George Washington University and a Bachelor of Science degree in Biological Sciences from the University of Maryland, College Park.

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**Ruthanne Sheller, MPH:** Ms. Ruthanne Sheller is a Specialist for the Newborn Screening Technical assistance and Evaluation Program (NewSTEPS) at the Association of Public Health Laboratories (APHL). Ruthanne serves as a Severe Combined Immunodeficiency (SCID) liaison, working directly with newborn screening (NBS) programs on issues related to SCID programmatic activities. Under cooperative Agreement (UG5MC27837) with the Health Resources and Services Administration (HRSA), she manages all sub-awards and develops relationships between state public health NBS programs, follow-up staff, patient advocacy groups, and clinical networks. Additionally, she coordinates educational and training activities for stakeholders. She received her Master's in Public Health and Bachelor of Science degree in Community Health from the University of Maryland, College Park. Prior to her current position, she worked as a Senior Research Assistant, supporting early detection and intervention research at Kennedy Krieger Institute.

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**Appendix B:**

**Newborn Screening Program Profile (2016)**

Below is a glimpse of state profile information that was entered into the NewSTEPS Data Repository for [redacted] in 2016. Please visit the NewSTEPS website ([data.newsteps.org](http://data.newsteps.org)) to view additional state profile information for [redacted] as well as other newborn screening programs across. Information can also be viewed in the interactive data infographics (<https://www.newsteps.org/data-infographics>).

Table 3: [redacted] State Profile Information (2016)

<b>Annual Births (2015)</b>	
<b>Number of Birthing Hospitals in [redacted]</b>	
<b>Number of Conditions Screened</b>	
<b>Number of Blood Spot Screens</b>	
<b>Time of Collection</b>	
<b>Dried Blood Spot Retention Time</b>	
<b>Dried Blood Spot Storage Conditions</b>	
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**Appendix C:  NBS Program Organizational Charts**

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## Appendix D: NewSTEPs Evaluation Work Group Members and Steering Committee

### NewSTEPs Evaluation Work Group Members

Harry Hannon, Patrick Hopkins, Julie Luedtke, Susan Tanksley, Judi Tuerck

NewSTEPs Steering Committee Members	
Name	Organization
Willie Andrews	Virginia
<b>Mei Baker (Chair)</b>	<b>Wisconsin</b>
Carla Cuthbert	Centers for Disease Control and Prevention
Christine Dorley	Tennessee
Roger Eaton	Massachusetts
Sari Edelman	NewSTEPs, Association of Public Health Laboratories (APHL)
Erin Darby	NewSTEPs, APHL
Lisa Feuchtbaum	California
Kathryn Hassell	University of Colorado
Kshea Hale	NewSTEPs, APHL
Yvonne Kellar-Guenther	NewSTEPs, Colorado School of Public Health (CSPH)
Sarah McKasson	NewSTEPs, CSPH
Joshua Miller	NewSTEPs, CSPH
Jelili Ojodu	NewSTEPs, APHL
Brendan Reilly	Texas
Catharine Riley	Health Resources & Services Administration (HRSA)
Sharmini Rogers	Missouri
Ruthanne Sheller	NewSTEPs, APHL
Debi Sarkar	HRSA
Sikha Singh	NewSTEPs, APHL
Marci Sontag	CSPH
Susan Tanksley	Texas
Beth Vogel	New York
Andrea Williams	HRSA
Careema Yusuf	NewSTEPs, APHL
Guisou Zarbalian	NewSTEPs, APHL

## Appendix E: Considerations for Follow-Up in Continuity of Operations Plan (COOP)

- Store paper copies and electronic copies (on flash drives) of all of letters, fax cover sheets, brochures, consultant lists, provider contacts, staff contact on flash drives.
- Store information in two fire protected and disaster protect heavy duty boxes at two separate locations off site.

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## Appendix F: Advisory Committee on Heritable Conditions in Newborns and Children’s (ACHDNC) List of Time Critical Disorders

Organic Acid Conditions	Fatty Acid Oxidation Disorders
Propionic acidemia (PROP)	Medium chain acyl-CoA-dehydrogenase deficiency (MCAD)
Methylmalonic acidemia (methylmalonyl-CoA mutase) (MUT)	Very Long chain acyl-CoA dehydrogenase deficiency (VLCAD)
Isovaleric acidemia (IVA)	Long chain L-3-hydroxyacyl-CoA dehydrogenase deficiency (LCHAD)
3-Hydroxy-3-methylglutaric aciduria (HMG)	Trifunctional protein deficiency (TFP)
Holocarboxylase synthase deficiency (MCD)	
$\beta$ -Ketothiolase deficiency (BKT)	
Glutaric Aciduria, Type 1 (GA1)	
Amino Acid Disorders	Other
Argininosuccinic aciduria (ASA)	Classic galactosemia (GALT)
Citrullinemia type 1 (CIT)	Congenital adrenal hyperplasia (CAH)
Maple syrup urine disease (MSUD)	

## Appendix G: Sample Medical Director Job Description

Under the direction of the Manager, Newborn Screening Unit, serves as the physician consultant. Primary consultation is provided to the Newborn Screening Program (NBS) and Genetic Services, with responsibilities to include: policy development; protocol development; educational material development; provider education; training; provider/stakeholder complaint resolution; quality assurance (QA) and monitoring, as well as clinical direction to nurse and public health staff in NBS. Additionally, as needed, provides consultation to multiple programs within the Newborn Screening Unit, Newborn Hearing Screening. Represents DSHS in genetics-related activities and serves as a resource in matters pertaining to genetic conditions and genetic services. Serves as a consultant for the Birth Defects Registry. Serves on multiple internal and external committees, providing expertise in metabolic and inheritable diseases, and genetics. Liaison to the Laboratory for newborn screening services relating to metabolic and heritable disorders.

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**Appendix H: Full NewSTEPS Site Review Manual**