

NewSTEPs

Newborn Screening
Technical assistance and
Evaluation Program

www.newsteps.org



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Funding Acknowledgement

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APHL is collaborating with the Colorado School of Public Health to implement NewSTEPS.



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NewSTEPs Vision

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



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What is NewSTEPs?



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NewSTEPS 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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Goals

- Goal 1 – Information gathering, building relationships
- Goal 2 – Education, Networking
- Goal 3 – Data Repository
- Goal 4 – Technical Assistance



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NewSTEPs Team



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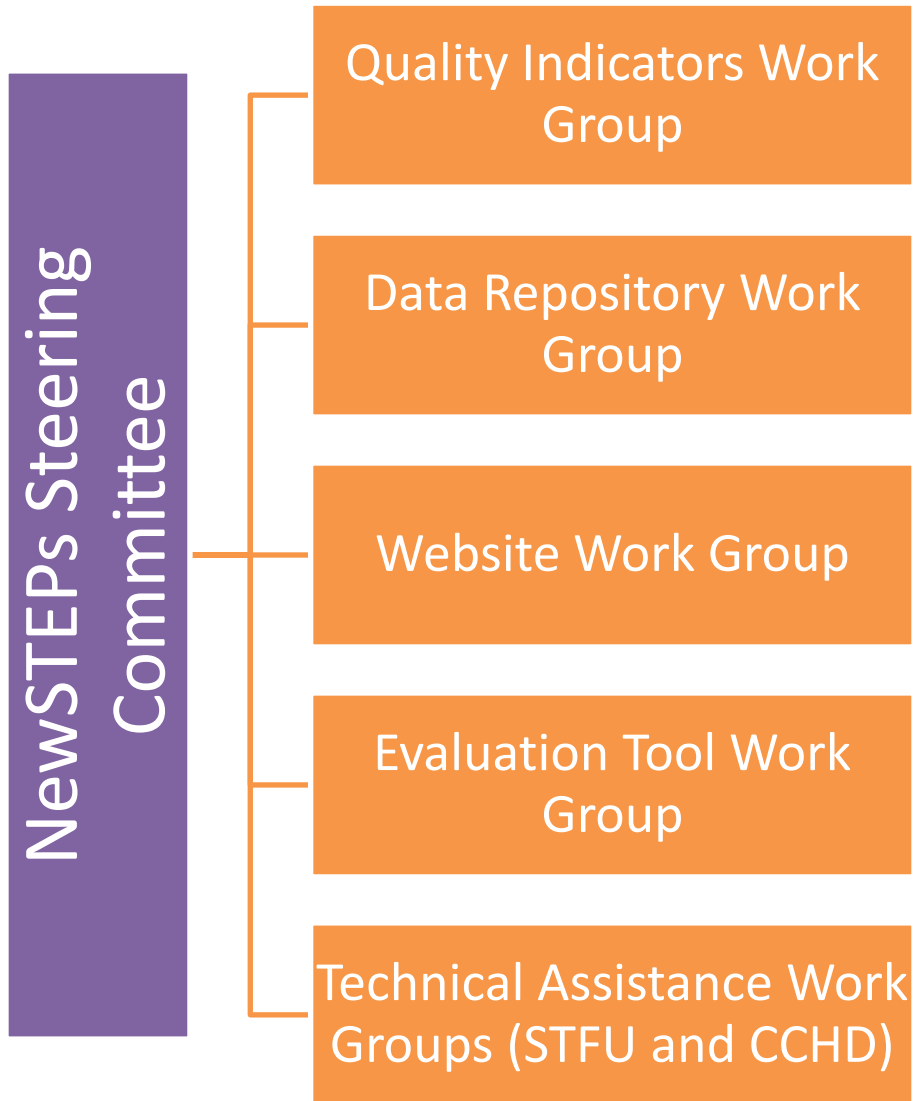
NewSTEPS Staff

- Director of NewSTEPS: **Jelili Ojodu, MPH**
- Associate Director of NewSTEPS, Colorado School of Public Health: **Marci Sontag, PhD**
- Program Evaluator, Colorado School of Public Health: **Yvonne Kellar-Guenther, PhD**
- Manager: **Sikha Singh, MHS, PMP**
- Senior Specialist: **Careema Yusuf, MPH**
- Specialist: **Thalia Wood, MPH**
- NBSGPH Liaison: **Elizabeth Jones, MPH**
- Senior Advisor: **Jane Getchell, DrPH**



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NewSTEPs Activities



Goal 1 – Information gathering, building relationships

- Identify gaps and barriers:
 - NBS education
 - PH leaders
 - NBS program personnel (new disorders, new assays, follow-up strategies.)
 - Communication
 - Data collection and reporting
- Build trust and strengthen relationships among local, state, regional, and national NBS stakeholders, private partners, and NewSTEPs.



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Information gathering

Genetics Regional Collaboratives

National Meetings

Creating a National Presence



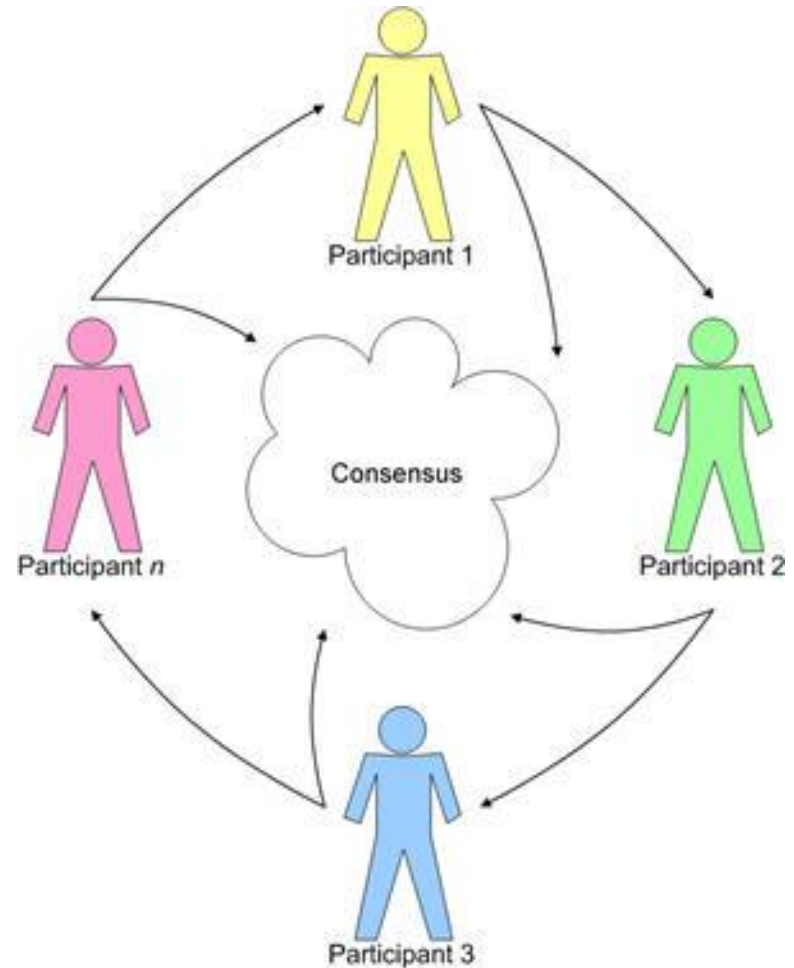
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Program Evaluation and Community Input

Sought feedback from community on

- Quality Indicators for Newborn Screening
- Case definitions
- NewSTEPs Data Use
- NBS Continuous Quality Improvement
- Identifying Components of Evaluation Tool (Delphi Survey)
- Specimen Transport
- Newborn screening awareness through Title V Director



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State Representation in NewSTEPs

State	Steering Committee	Quality Indicators Work Group	Data Repository Work Group	Website Work Group	Evaluation Tool Work Group	CCHD Work Group	Case Definitions Pilot Testing	Workshop Consultants	Repository Data Feedback/Beta Testing	QI/Case Definition Meeting 2012	Registered State Admin	STFU Work Group	QI Feedback	Title V Education Calls
Alabama							•			•	•		•	
Alaska											•		•	
Arizona		•								•	•			
Arkansas											•		•	
California										•	•			
Colorado	•			•			•			•	•	•		
Connecticut											•			
Delaware							•		•	•	•	•		
District of Columbia										•	•			
Florida	•	•								•	•		•	
Georgia										•	•		•	
Hawaii	•			•			•			•	•		•	
Idaho											•		•	
Illinois											•		•	
Indiana						•				•	•			
Iowa	•	•	•				•		•	•	•	•	•	
Kansas		•					•		•	•	•		•	•
Kentucky				•							•		•	
Louisiana							•			•	•			
Maine											•			
Maryland						•	•			•	•		•	
Massachusetts		•					•			•	•			
Michigan	•										•			
Minnesota						•		•		•	•	•	•	
Mississippi										•	•		•	
Missouri	•				•		•		•	•	•	•	•	
Montana											•		•	
Nebraska	•				•		•	•	•		•		•	
Nevada											•		•	
New Hampshire											•			
New Jersey	•					•				•	•			
New Mexico											•			
New York		•		•						•	•	•		
North Carolina	•							•			•		•	

Goal 2 – Education, Networking

- Create and support a NBS network for education and communication
 - Local
 - State
 - National
- Networks of individuals can be utilized to improve newborn screening outcomes
 - In Person and Virtual Networking
 - Sharing Successes/Challenges



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Interactive Website



HOME STATE PROFILES NEWSTEPS DATA REPOSITORY

ABOUT CONTACT

Search

NBS Laboratory, Follow-Up, and Medical Personnel ▾ Parents and Caregivers Policy Makers and Administrators

Our Vision

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

About NewSTEPS

The Newborn Screening Technical assistance and Evaluation Program (NewSTEPS) provides quality improvement initiatives for newborn screening systems, an innovative data repository, and technical and educational resources to state newborn screening programs.



STATE PROFILES

Check out map explorer for your state's data

Explore profiles



DATA REPOSITORY

Access data and more with NewSTEPS Data Repository

Visit Data Repository



TECHNICAL ASSISTANCE

Evaluation Site Visits, Model Practices, and more.

Learn more

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Short Term Follow Up

Please note that this page will be continually updated as resources are provided.

A critical component to the success of all newborn screening systems is ensuring that all infants receive appropriate testing and care. NewSTEPS is partnering with state newborn screening programs to provide a central location for Short Term Follow Up resources. If you have additional resources that you would like included, please contact Thalia.Wood@aphl.org

In the first of many upcoming activities, the NewSTEPS Short Term Follow Up workgroup is excited to announce **bi-monthly webinars** for the newborn screening community to share ideas and resources in the Short Term Follow Up arena. Announcements about each webinar will be made on the NewSTEPS listserv.

Definitions of Short Term Follow Up

Short Term Follow Up entails the process of ensuring that all newborns are screened, that an appropriate follow-up caregiver is informed of results, that confirmatory testing has been completed, that the newborn has received a diagnosis and, if necessary, treatment.

Resources for Follow Up Staff

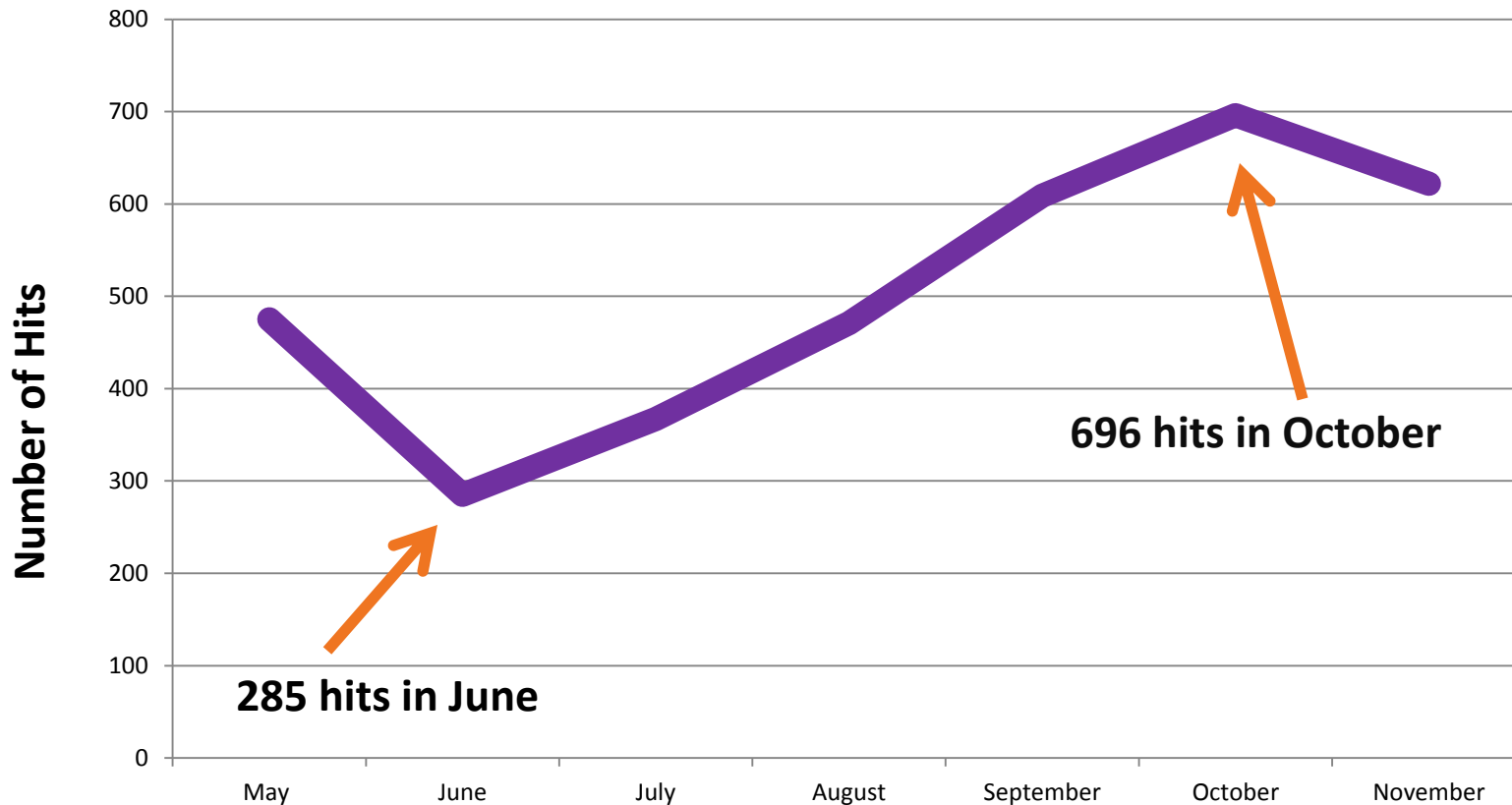
Please email Thalia.Wood@aphl.org if you have any resources pertaining to Staffing that may be shared through this website. Examples of what we would like to offer through the NewSTEPS website are as follows:



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Snapshot of Website Hits May 2013- November 2013



Month (2013)



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Educational Outreach

- **Workshops:** 2 follow-up workshops; 16 attendees
- **Dedicated Listserv:** 395 members
- **Website:** 3,609 total hits/~50% new hits last month/84 hits between December 1-3
- **Webinars:** as needed for trainings and information dissemination



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Snapshot of NewSTEPs Webinars

Fall 2013

Webinar Title	Date of Webinar	Number of Participants	Length of Webinar
Heartland MOU Webinar	8/28/13	18	~40 min
New England MOU Webinar	9/12/13	10	62 min
NYMAC MOU Webinar	9/24/13	9	38 min
Region IV MOU Webinar	9/25/13	14	~40 min
Western States MOU Webinar	9/26/13	6	45 min
SERC MOU Webinar	9/27/13	13	37 min
Mountain States MOU Webinar	10/4/13	18	47 min
Data Repository Training #1	10/9/13	9	60 min
Data Repository Training #2	10/10/13	19	53 min
Data Repository Training #3	10/11/13	27	61 min
CCHD October TA Webinar	10/11/13	51	57 min
Title V Directors Webinar	10/30/13	30	53 min
Short Term F/U Nov Webinar	11/4/13	103	90 min
CCHD November TA Webinar	11/8/13	51	70 min



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Goal 3 – Data repository

- Design, build, and validate a data repository system
 - Evaluation of newborn screening systems
 - Quality improvement and monitoring of changes in systems
 - Disorder occurrence, practices, etc.



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Voluntary Data Repository



Purpose: Provide tools to state newborn screening systems to adequately evaluate, analyze, and benchmark the performance of their tests and the quality of their newborn screening programs



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Components of Data Repository



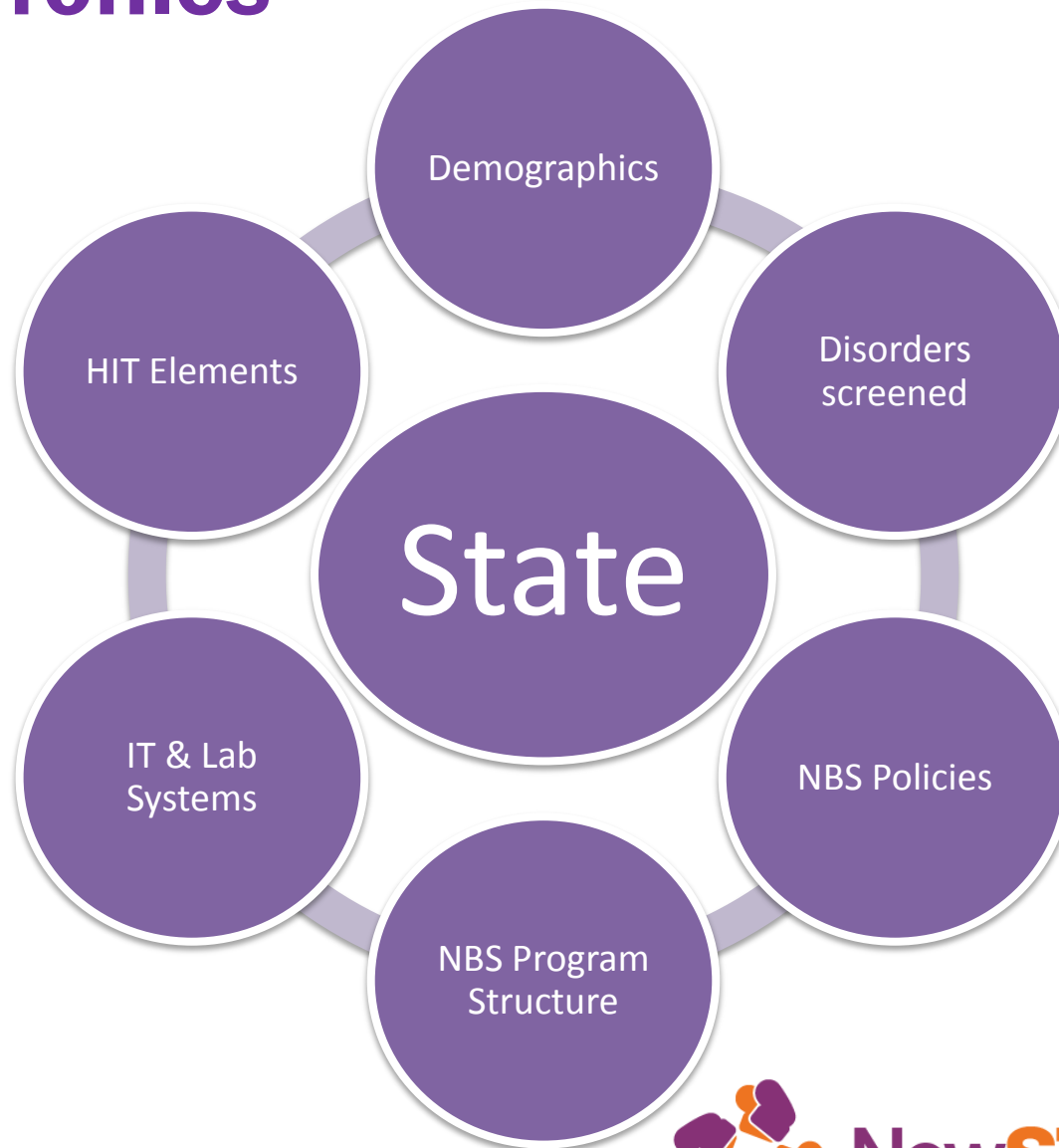
The screenshot shows the NewSTEPS website interface. At the top left is the NewSTEPS logo with the tagline "A Program of The Association of Public Health Laboratories®". To the right are navigation links for "HOME", "STATE PROFILES", and "NEWSTEPS DATA REPOSITORY". A "Sign In" button is located in the top right corner. The main content area features the text "Please select a state" above a map of the United States with state abbreviations. To the right of the map is a grid of state abbreviations: VT, RI, MD, NH, CT, DC, MA, NJ, DE. At the bottom of the page is a dark purple footer containing the copyright notice "© Copyright 2013 NewSTEPS, A Program of The Association of Public Health Laboratories®" and the email address "newsteps@aphl.org". Logos for NewSTEPS, APHL (Association of Public Health Laboratories), and the Colorado School of Public Health are also present in the footer.

State Profiles | Case Definitions | Quality Indicators



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State Profiles



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Components of the state profile

- State Demographics
 - Number of births, by Race, Ethnicity, Sex
 - Number of birthing centers
 - Number of babies screened
 - Number of DBS specimens received
- Disorders Screened
 - Year disorder was added
 - DBS collection card image
 - Testing methodology – 1st, 2nd screen
 - Testing equipment
 - Target(s) screened
 - Where is testing performed?
- NBS Fees:
 - How is screening paid for?/Fees for screens/How are fees are collected/What the fees pay for
- IT & Lab Systems
 - Applications in use in the lab? Follow-up?
 - COOP plans
- HIT Elements
 - Data integration and exchange policies and procedures
- NBS Program Structure
 - Organizational chart (PDF)
 - Hours of operation: lab, follow-up/Weekend hours?
 - NBS program information brochures (PDF)
 - Contact information: lab, follow-up, CCHD, EHDI, HIT
 - NBS Advisory Committee: Make up/ Charge/ by-laws
- NBS Policies on:
 - Recommended age at initial/second screening
 - Consent
 - Follow-up services
 - Missed cases
 - Birth Matching
 - Storage of specimens/Storage of data
 - Sharing of specimens
 - Plans during emergencies
 - Adding new disorders to a state panel



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Quality Indicators

- QI 1. Percent of invalid dried blood spot specimens due to improper collection and/or transport
- QI 2. Percent of dried blood spot specimens missing essential information
- QI 3. Percent of eligible infants not receiving valid newborn screening test, stratified by dried blood spot or point of care test(s).
- QI 4. Percent of loss to follow-up
- QI 5. Time elapsed from birth to screening, follow-up testing, confirmed diagnosis
- QI 6. Percent of out of range results
- QI 7. Frequency of condition detected by newborn screening for each disorder
- QI 8. Percent of missed cases (false negatives), stratified by disorder



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QI 5. Time elapsed from birth to screening, follow-up testing, confirmed diagnosis

- a. Birth to specimen collection/initial point of care testing
- b. Specimen collection to receipt by lab
- c. Specimen receipt to reporting out results [reported by analyte]
- d. Release of out-of-range results to notification of medical provider [reported by analyte/point of care test(s)]
- e. Release of out-of-range results to intervention by appropriate medical professional [reported by analyte/point of care test(s)]
- f. Birth to follow-up testing [reported by analyte/point of care test(s)]
- g. Birth to confirmation of diagnosis [reported by analyte//point of care test(s)]
- h. Birth to ruling out diagnosis [reported by analyte/point of care test(s)]



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Sample Report Graphic

II. Time from Birth to Specimen Collection

This quality indicator can be used to identify delays in time from birth to specimen collection. Used in combination with the different time components of the newborn screening system, shortening these time frames can improve the time to identification of babies at risk for newborn screened disorders.

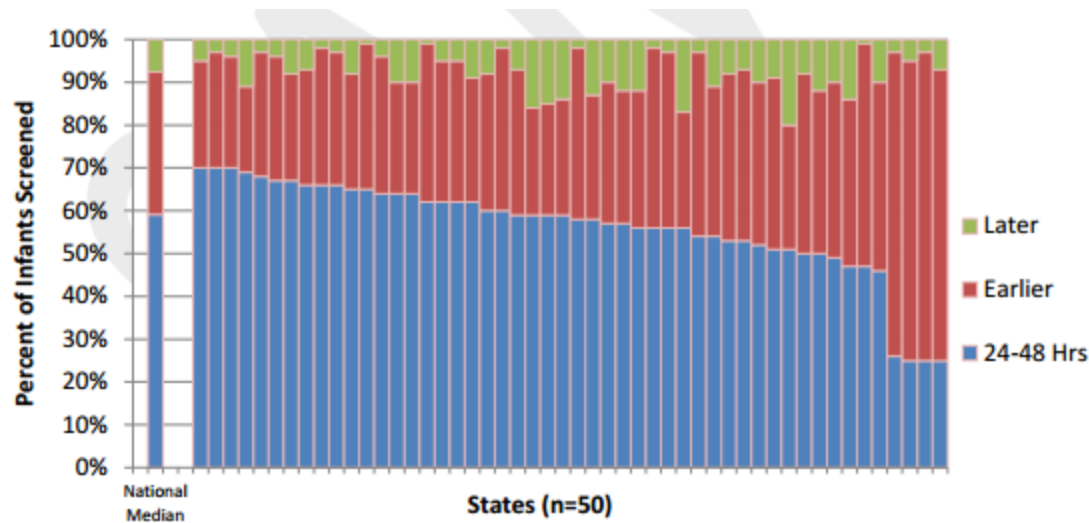


Figure 5: Percent of infants receiving screening in specified time intervals (earlier than 24 hours, 24-48 hours, and more than 48 hours) after birth for the 2012 calendar year. Each bar represents one state.

*states will not be identified except in their own confidential report

All data portrayed in this sample report are fictitious data. Data do not represent actual outcomes from any newborn screening program. Any resemblance to real data from a real newborn screening program is completely coincidental.



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Quality Indicators

Newborn Screening Quality Indicators have undergone careful evaluation by stakeholders to assure agreement on definitions and will be used to provide longitudinal comparisons within a program as well as comparisons to aggregate data across programs.

More introductory information here.

Statement and promotional information that QI data is being collected now; QI data will be coming soon.

Update State QIs

State *

Year *

Year for which you are entering QI information

Denominator Data - Information about denominator data

Q11 - Percent of invalid dried blood spot specimens/cards due to improper collection and/or transport

Q12 - Percent of invalid dried blood spot specimens/cards missing essential information

Q13 - Percent of eligible infants not receiving valid newborn screening test, reported by dried blood spot or point of care test(s)

Q14 - Percent of loss to follow-up

Q15 - Time elapsed from

Q16 - Percent of out-of-range results, any referral to evaluation, reported by analyte/point of care test

Q17 - Frequency of condition detected by newborn screening for each disorder

Q18 - Percent of missed cases (false negatives), reported by disorder



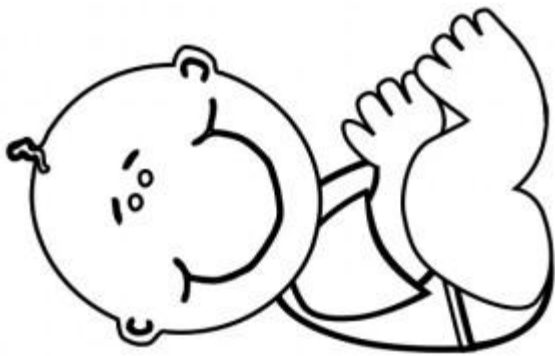
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Baby Level or Case Data

Disorder specific newborn screening data

- Basic demographics
- Timing of diagnosis, specimen transport, follow-up
- Diagnostic factors on key follow-up elements



Case Definition Worksheets

- 29 case dried blood spot NBS conditions
- Available to NBS program for data collection



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[← Back To List](#)

Case Definition

Very long-chain acyl-CoA dehydrogenase deficiency - VLCAD

Baby Demographic Information

State unique id *

ABDC123

Date of birth is used to calculate time elapsed between birth, specimen collection(s), and diagnosis. It is not stored in the system. Year of birth is stored, to calculate Quality Indicators.

Date of birth *

09/02/2013

Birth year *

2013

Gestational age in weeks

Birth weight in grams

3140

Biological Sex

Male

Screening Information

Was prenatal testing done that indicated that this infant was at risk for this disorder?

 Yes No Unknown

Which newborn screen result indicated this infant was at risk for the disorder

- Select -

Was this individual diagnosed later in life (not identified by newborn screening)?

 Yes No Unknown

The dates below are not stored in the system. Enter dates to allow the system to calculate time elapsed. Only time elapsed is stored in the system.

Initial Specimen Collection Information

Date of specimen collection

09/03/2013

Time elapsed since birth

1 days

Date of receipt by lab



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Diagnostic Workup

Were plasma acylcarnitines tested? Yes No Unknown

Was C14:1 level:

- Elevated (on more than one sample)
- Normal
- Unknown

Was C14:2 level:

- Elevated
- Normal
- Unknown

Was C14 level:

- Elevated
- Normal
- Unknown

Was enzyme analysis for VLCAD enzyme activity completed? Yes No Unknown

Was enzyme activity:

- Consistent with disease
- Normal activity (not consistent with disease)
- Unknown

Was functional analysis of fatty acid oxidation in cultured fibroblasts performed? Yes No

Unknown

Was mutation analysis done? Yes No Unknown

What genes were included in the mutation analysis?

ACADVL Gene

Check the types of variants found on:

Allele 1:

- Variant known to be disease causing
- Variant of unknown significance
- Wild Type (Normal)
- Unknown

Allele 2:

- Variant known to be disease causing
- Variant of unknown significance
- Wild Type (Normal)
- Unknown

Other Gene



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Data confidentiality

- No baby level identifiers are saved within the NewSTEPS data repository
- Date of birth and other service dates are entered on the screen, date differences calculated, and dates are erased, never saved



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User Roles delineated within the NewSTEPS Data Repository

Cumulative Permissions: Each role has the rights of the preceding role

PUBLIC WEB BROWSER
See state profiles, see public info

REGISTERED USER
See de-identified aggregate (QI) data
Access basic reports

STATE PROFILE DATA MANAGER
Enter, edit, read state-level profile + QI data,
limited by state

STATE BABY-LEVEL DATA MANAGER
Enter, edit, read state-level baby-level data,
limited by state

STATE ADMIN
View and edit rights to state data and provision state-level users

NEWSTEPS ADMIN
View and edit rights to all user, profile, and de-identified baby-level data in the system

SYSTEM ADMIN
Add and edit system content

SUPER ADMIN
Access to entire system and database

NewSTEPS IRB and OHRP

- Colorado Multiple Institutional Review Board has reviewed the project and determined it is **Non-Human Subject Research** (August, 2013, available on <https://www.newsteps.org>)
- Office of Human Research Protection (OHRP) has reviewed this project and deemed it **Non-Human Subject Research** (September 2013)
- Colorado IRB chair has written letter explaining the decision and the process that NewSTEPS has undergone (available on <https://www.newsteps.org>)



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Memorandum of Understanding

- Between NewSTEPs/APHL and each state
- Includes:
 - Data ownership
 - Data sharing
 - Data reporting
 - Security language
 - IRB and OHRP language (attachments to include letters and applications)



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Data Transfer from Other Information Management Systems

- Currently: manual data collection
- Future: developing an electronic methods for data transfer
 - Having state NBS LIMS send data to NewSTEPS
 - Using volunteer state NBS programs to help facilitate this
- Application Programming Interface (API)
 - Reduces the burden for multiple data entry points



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Health Information Technology Activities



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Goal 4 – Technical Assistance

- Build on existing technical assistance and training opportunities for both individuals and programs providing NBS services.
 - Pre-analytic
 - Analytic
 - Post-analytic
 - Short term follow-up
 - Point of Care
- Voluntary Newborn Screen Quality Certificate Program
- Site Visits



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Technical Assistance

- CCHD Technical Resources
 - Workgroup, webinar series, website pages
- Short-Term Follow-up Technical Resources
 - Workgroup, webinar series, website pages
- HIT survey, listserv, workgroup



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NBS Laboratory, Follow-Up, and Medical Personnel ▾ Parents and Caregivers Policy Makers and Administrators

Critical Congenital Heart Disease

Critical Congenital Heart Disease (CCHD) Newborn Screening was added to the Recommended Uniform Screening Panel[®] in September of 2011. CCHD is the second point of care newborn screen to be added to the RUSP, joining early hearing loss. As newborn screening programs work towards implementation of screening for CCHD using pulse oximetry, many new tools and resources have been developed. NewSTEPS is partnering with state newborn screening programs and federal agencies interested in CCHD to provide a central location for CCHD resources. If you have additional resources that you would like included, please contact [NewSTEPS](#).

Critical Congenital Heart Disease (CCHD) Technical Assistance (TA) Webinar

NewSTEPS and partners will be convening an in-person CCHD Meeting on February 27-28, 2014 in Silver Spring, MD. For additional details please visit the Event Site for this meeting, [linked here](#).

NewSTEPS hosts monthly CCHD TA webinars to address the needs of stakeholders in the

Educational Resources

Newborn screening for CCHD touches many aspects of the community. NewSTEPS has compiled educational resources from the community that can be used to support screening efforts in other states and regions. These can be found [linked here](#).

News and Events

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CCHD In Person Meeting

- February 27-28, 2014 in Silver Spring, MD
- **Purpose:** to convene representatives from all fifty NBS programs and pertinent stakeholders and partners to facilitate the implementation of CCHD NBS throughout the US.



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Site Visits

Pre-Evaluation Tool

Site Visit

Comprehensive report

Recommendations



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Summary- NewSTEPS

- NewSTEPS is partnering with newborn screening programs to:
 - Provide technical assistance and resources
 - Collate and summarize data in aggregate form
 - Develop opportunities for quality improvement, locally, regionally, and nationally



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Newborn Screening

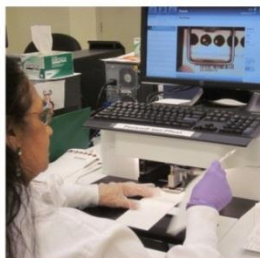
50 Years of Saving Babies' Lives



Contact Us

<https://www.newsteps.org>

newsteps@aphl.org

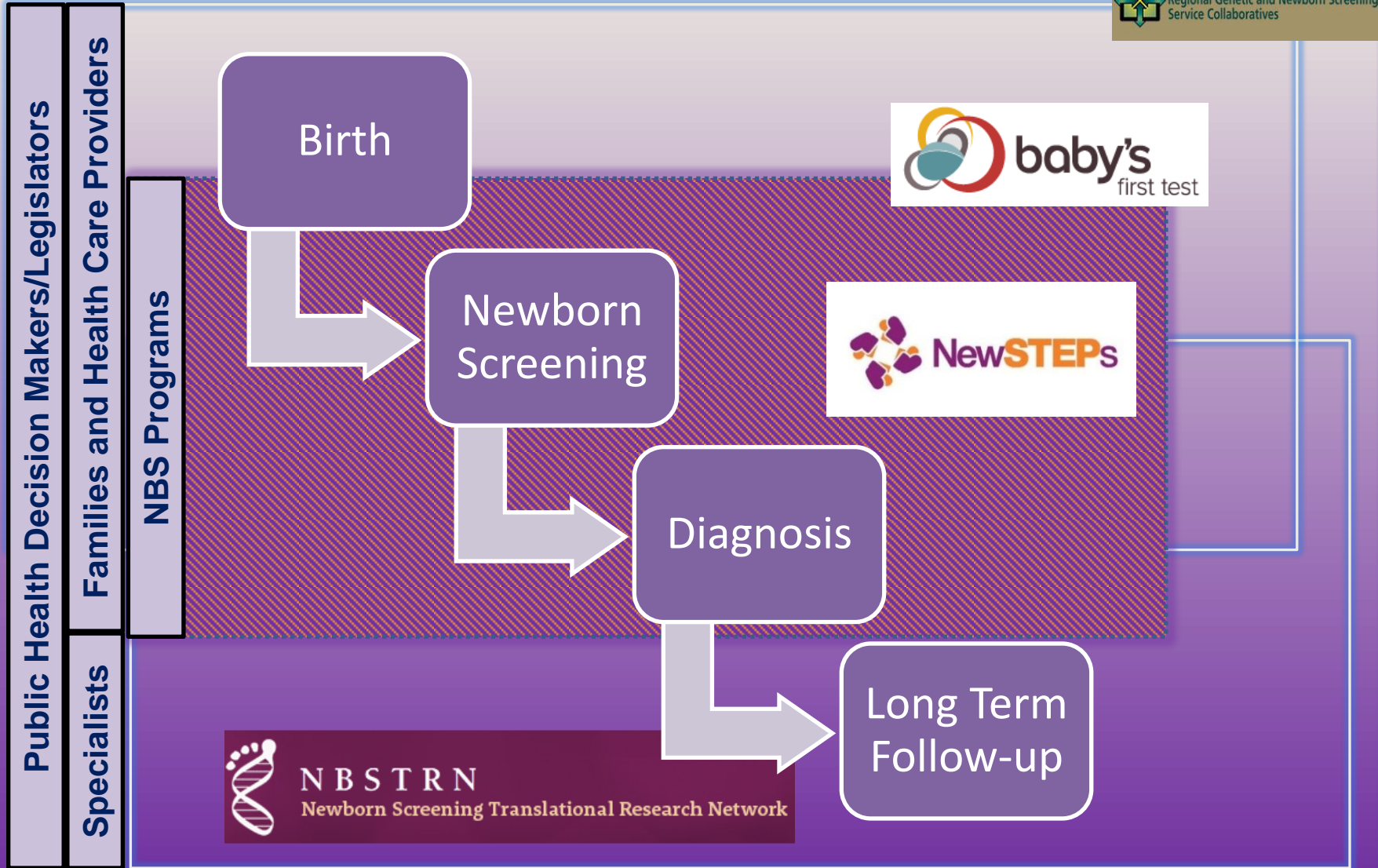


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Partners in Newborn Screening

 National Coordinating Center for the Regional Genetic and Newborn Screening Service Collaboratives



Public Health Decision Makers/Legislators

Families and Health Care Providers

Specialists

NBS Programs

Birth

Newborn Screening

Diagnosis

Long Term Follow-up



Research and Development in Newborn Screening

Case Data Entry

Date of Birth, Date of Screening, Date of Diagnosis

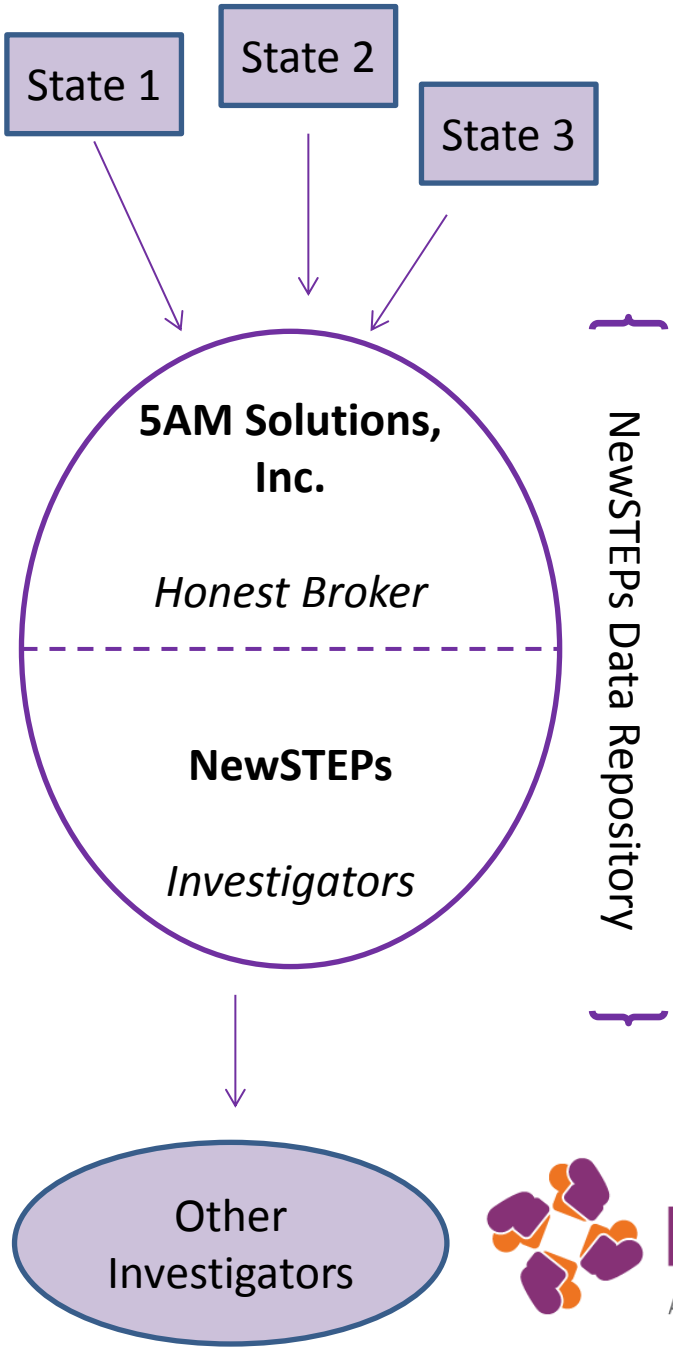
*DATES NOT SAVED
ENTERED FOR CALCULATIONS
and then erased*

De-Identified Data Transfer

Calculated Age of Screening, Age of Diagnosis, Diagnostic Information

Information Sharing

Aggregate Reports, Regional Snapshots, Reviewed by Steering Committee



Summary of Facts

- Data Sharing within the NewSTEPs Repository will be governed by MOUs with each State.
- 5AM Solutions, Inc. will serve as an honest broker of the data, with no ability to share or identify data.
- 5AM Solutions, Inc. will calculate date differences providing epidemiologic information to NewSTEPs staff, per signed Coded Information Agreements .
- All data shared with investigators will be approved by Steering Committee and held to the Rule of 5.
- No information identifying newborns will ever be shared.



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