



NewSTEPS

A Program of the Association of Public Health Laboratories™

Newborn Screening Technical assistance and Evaluation Program (NewSTEPS)

USER GUIDE

June 19, 2018

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1 Introduction

Welcome to the Newborn Screening Technical assistance and Evaluation Program (NewSTEPS) Data Repository. This user guide will help you get started with using the system.

Please note that entering the data into the NewSTEPS data repository occurs on a voluntary basis. All data elements do not have to be provided if they are not available. Please provide as much information as you can.

The high-level workflow diagram (Figure 1) shows an overview of how you can interact with the NewSTEPS Data Repository. After you have registered for an account, you should plan to:

1. Update state profile (annually or on an as-needed basis)
2. Enter cases (frequency to be determined by state; recommended that cases be entered at diagnosis and updated as changes are known)
3. Enter quality indicators (annually - by April 15)

This user guide will walk through these basic steps to get you started.

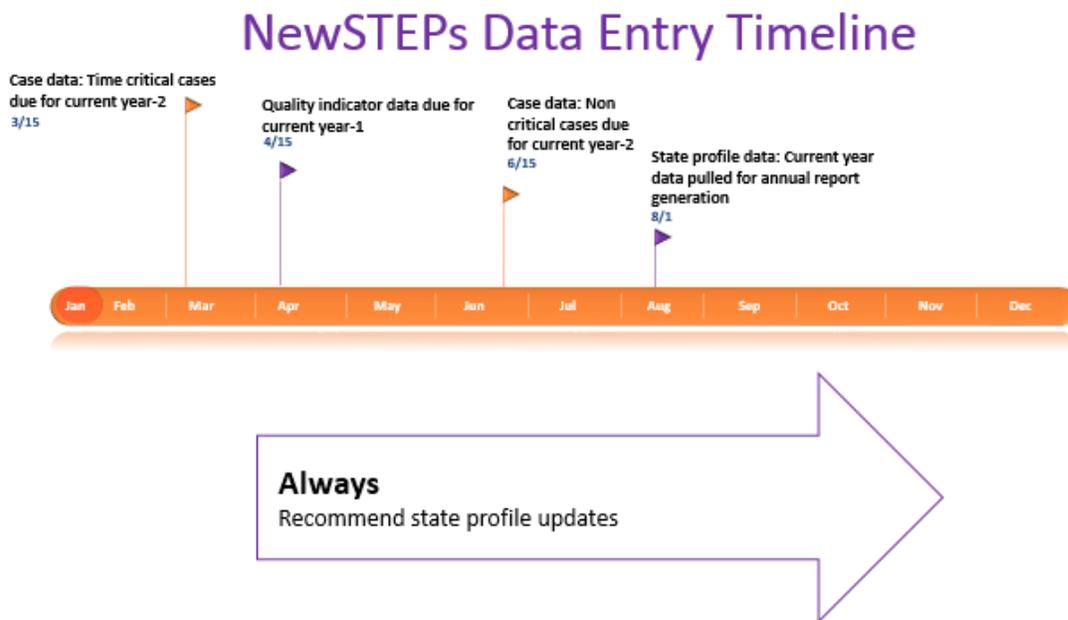


Figure 1: High Level Workflow



2 Document and application information

2.1 Legend

Within this document, we use two conventions to indicate system controls:

Italics - indicates a link

Bold - Indicates a button

2.2 Browser Compatibility

NewSTEPs makes use of new capabilities available in modern, up-to-date browsers, which also provide improved security and performance. The NewSTEPs Data Repository supports only current versions of Internet Explorer, Chrome, and Firefox.

2.3 System Messages

A red asterisk next to the data field name denotes required fields.

Warning messages are shown in red in a light red background.

Infant Demographic Information

State unique id *

State unique id must be set



If left blank

2.4 Getting Help

Although the NewSTEPs Data Repository was designed to be easily understood, we do include help and more detailed information within the system. To access this, click on the question-mark icons throughout the NewSTEPs Data Repository.

Ethnic Distribution:  

3 Registering for an Account

You must register for an account to enter information about your Newborn Screening (NBS) program into the NewSTEPs Data Repository. To register for a new account, follow the steps below:



1. On the [home page](#), locate the Login box. Click on the *Register* link in this box.

Login

Email Address

Password

Login

Forgot password? Register

Password Expired?

2. You will be taken to the Register for an Account page. Enter in the required fields.

Note that the Institution Name field will auto-populate with existing institutions when you begin typing. Take care to ensure you select a pre-populated institution, if one exists. This helps NewSTEPS to link people from the same organization.

NewSTEPS
A Program of The Association of Public Health Laboratories®

HOME STATE PROFILES NEWSTEPS DATA REPOSITORY

Register for an Account

Why Register? Register to browse state newborn screening program information.

Get Started Here (* indicates required field)

First Name *

Last Name *

Country *

Address *

City *

State/Province/Territory

Zip/Postal Code *

Phone *

ext.

Institution Name *

(Start typing name or select)

Institution Type *

Represented State(s) *

Choose Your Sign In Information

Email Address *

- Email is used as your Sign In
- Will not accept personal email addresses (gmail, hotmail, yahoo, etc.)
- Will only accept email addresses affiliated with institutions

Re-type Email Address *

Create Password *



3. Click the **Submit Registration Now** button to complete your registration.
4. When your account has been approved, you will receive an email at the email address you supplied during registration.
5. State Administrators: One person from each state will be designated as a state administrator and will have the ability to add additional users within the state program. To be designated as a state administrator, please contact Careema Yusuf (careema.yusuf@aphl.org) once you receive the approval email. Login to the NewSTEPS Data Repository using the email address and password you created during registration.
6. Other state users: Other individuals that would like to have access to enter, edit, or read data for their state should contact the state administrator. On the user registration form, you will be asked to indicate what state you represent. The state administrator is identified on the NewSTEPS State Profile page for each state. For more information on how state administrators can assign user roles, please see the [State Administrator's User Guide](#) on the Data Repository Landing page.

4 How to Manage Your Account

If your account information should change over time, you may edit your account details to make changes.

1. Sign in to the NewSTEPS Data Repository and click the *Account* link in the top navigation bar to access your account details.
2. Make the desired account changes to your account details and click the **Save** button to complete the operation.

5 Resetting a Forgotten Password

If you should forget your password, you may reset it from within the NewSTEPS Data Repository:

1. On the home page, locate the Sign In box. Click on the *Forgot Password?* link in this box.
2. You will be asked to enter the email address associated with your account. Enter it and click **Submit**.
 - * You will receive an email with a link to change your password.
3. Once you have successfully changed your password, you may sign in to the NewSTEPS Data Repository with your new password.



6 Home Landing Page

Once you are logged in you will see the landing page, below. The landing page will contain important information that NewSTEPS wants to share with the community about the program, events, and deadlines.

Welcome to the NewSTEPS Data Repository

The repository is now ready for data entry for basic state profiles, cases and quality indicators. We anticipate updates to occur on a quarterly basis, or sooner if needed. Please continue to check this page for announcements of new features. FAQs for the NewSTEPS Data Repository can be found [linked here](#).

Case Definitions

Each state has the ability to review and enter **cases** through one designated state contact.

Quality Indicators

The 8 Quality Indicators that will be used to provide longitudinal comparisons within a program as well as comparisons to aggregate data across programs can be found [linked here: Quality Indicators](#).

Reports

State Profile derived **reports/queries** are updated on a real-time basis.

Memorandums of Understanding

State Profile data can be entered prior to the ratification of the MOU. NewSTEPS offers a **video** detailing the benefits of signing **Memorandums of Understanding (MOUs)** that are entered into between APHL and newborn screening programs. NewSTEPS has contacted state representatives to help facilitate signatures. We request that all Quality Indicator and Infant level data entry be held until the MOUs are fully ratified.

Historical Data

Currently the historical data entered into the National Newborn Screening Information System (NNSIS) prior to June 1, 2012 has not been provided to NewSTEPS by the Health Resources and Services Administration (HRSA) in a manner that will allow for longitudinal comparisons.

Questions

We welcome feedback from you as we develop the repository and related reports. For any questions or feedback please contact Careema Yusuf at Careema.Yusuf@aphl.org or at 240-485-2761

Figure 2 - NewSTEPS Data Repository landing page



7 Managing Your State’s Newborn Screening Program Information

NewSTEPs asks states to share information because the collection of data at the national level allows for quality improvement in the newborn screening system. When all states share data, each program will be able to compare outcomes and trends from their state or region to the national summary data. These data will also provide the ability to accurately calculate the birth prevalence of the rare disorders as detected by newborn screening.

7.1 How Will the Information Be Used?

NBS programs that enter data into the NewSTEPs repository will have access to their own data plus aggregate data from other participating NBS programs. Please see below for Table 1: NewSTEPs Data Repository: How will these elements be used?

Table 1: NewSTEPs Data Repository Data Elements: How will these elements be used?		
Data Element	Publically Available (website and aggregate reports)	Other State Newborn Screening Programs Only (queries and reports)
State Profile: Program Overview		
State/ Territory Name	•	
Region	•	
Website URL	•	
Racial, Ethnic and Sex Distribution	•	
Annual Births	•	
Number of Required Screens	•	
Year	•	
Responsible Laboratory	•	
Screening Card Image	•	
State Profile: Disorders		
Disorder Screened (Not Screened, Universally Screened, Likely to be Detected and Reported Due to Universal Screening of Another Disorder, Offered to Select Populations)	•	
Disorder Screened Status (Proposed/ Actual Implementation Date for Universal Screening)	•	
	•	
First Screen First Tier Method	•	



First Screen Second Method	•	
First Tier Target	•	
Second Screen First Tier Method	•	
Second Screen Second Tier Method	•	
Second Tier Target	•	
Equipment	•	
State Profiles: Policies		
Recommended Initial Screening Age	•	
Recommended Second Screening Age	•	
Second Screen Policy	•	
CLSI Guideline Adoption Status	•	
DBS Retention Time and Storage Conditions	•	
Data Retention Policy Exists?	•	
Data Storage Period for Normal and Abnormal Specimen Data	•	
Courier Service Usage Status	•	
Courier Provider	•	
Definition of Specimen Receipt at Lab	•	
Consent for Newborn Screening	•	
Consent Recording Method	•	
Opt-out Policy	•	
Opt-out Recording Method	•	
Residual Specimen Uses	•	
Specimens Consented for Research?	•	
Specimen Sharing Policies	•	
Short-Term Follow-up Definition/ Description; Unique Follow-up Methods; Follow-up Period for Inconclusive Diagnosis	•	
Long-Term Follow-up activities? Long-Term Follow-up Description	•	
Missed Diagnosis Reporting Process		•
Process for Reporting Missed Diagnosis?		•
Matching NBS Records to find Unscreened Babies?		•
Matching Data System?		•
Result Matching Method		
Unsatisfactory Specimen Testing Policy		•
Provide Emergency/ Disaster Support? Provide Emergency/ Disaster Agreement in Place? Provide Emergency/ Disaster Plan Written? Provide Emergency/ Disaster Plan Testing Frequency? Receive Emergency/ Disaster Support Policy? Receive Emergency/ Disaster Support Policy Description	•	



Receive Emergency/ Disaster Support Agreement in Place? Receive Emergency/ Disaster Support Plan Written? Receive Emergency/ Disaster Support Plan Testing Frequency? Continuity of Operations Plan (COOP) Exists? COOP Exercised?	•	
State Profile: Adding to NBS Panel		
National Recommendations Followed? National Recommendation Implementation Time Frame; Pilot Studies Required Before Implementation? Feasibility Study Done?	•	
State Profiles: Fees		
Newborn Screening Funding Sources; Fee Collection Method; Fee Holding Location; Fees; Fee Notes	•	
Fee Use Details		•
State Profiles: Program Structure		
NBS System Organizational Chart; Shared Duties; Follow-up on Unsatisfactory and Borderline Specimens; Laboratory Test Performance Evaluation; Formal Communication Structure; NBS Program Staffing Levels; Short-Term Follow-up Responsible Parties; Certification Program; Proficiency Tests; Program Information; NBS Educational Information Languages	•	
Lab and Follow-up Operating Hours and Activities; Inclement Weather Work Policy	•	
State Profiles: Contacts		
Program, Director; Program Manager; Lab; Follow-up; EHDI; CCHD; HIT	•	
State Profiles: Advisory Committee		
Existing Advisory; Advisory Committee Voluntary? Committee Structure; Charge/By-Laws; Meeting Frequency; Meeting Minutes Link	•	
State Profiles: IT Support		
Lab and Follow-up Information System	•	
Staffing Levels; IT Support Description; NBS Data Back-up Frequency; Recovery Time; Data Loss Amount From Database Failure, Data Loss Amount From Instrument Failure; IT Infrastructure Recovery Time; Disaster Recovery Hardware; IT Part of COOP? Redundant Off-site and On-Site Operations Exist?	•	
State Profiles: Health Information Technology (HIT)		
HL7 Orders Messages Accepted? Number of Birthing Centers Submitting HL7 Orders; Number of HL7 Orders Received for Specimen Testing; HL7 Result Messages	•	



<p>Sent? Number of Birthing Centers Receiving HL7 Results; Number of HL7 Specimen Results Sent; HL7 Implementation Guide Used; Terminology Standards Used; Web Portal for Sharing Data Related to the NBS Present? Web Portal for DBS Test Orders and Demographic Data Entry Present? Number of Birthing Centers Using DBS Order and Demographic Data Entry Web Portal; Number of Specimens Entered into DBS Order and Demographic Data Entry Web Portal; Web Portal for NBS Results Reporting Present? Number of Birthing Centers Using NBS Results Retrieval Portal? Submitter Performance Feedback Portal Present? Submitters Performance Feedback Portal Description; Alternative Performance Feedback Method Present? Alternative Performance Feedback Method Description;</p>		
<p>How are Hearing Results Integrated with DBS Results? How are CCHD Results Integrated with DBS Results? What is the Status of Your NBS Program Exchanging Data with the Statewide HIE? What is the Implementation status of a Statewide HIE? HIE Interfacing Funds Received? Who Can Access NBS Results Sent to/through the HIE? How are NBS Results Shared via the HIE Sent to Birthing Facilities/ Pediatric Providers? What Other Databases Interface with the HIE?</p>	<ul style="list-style-type: none"> • 	



7.2 State Profile

Your state's profile information collects program information and facts such as disorders screened, newborn screening fees, and annual births. This information is shared with the public through the NewSTEPS Data Repository, and should be updated as needed.

To enter your state profile information, click on the *State Profile* tab. There are eleven tabs within the state profile. Click on the **Edit** button on the right-hand side of the screen.

If you are certain that the information you have provided is complete for the year, please also check the **Complete** box before saving.

Program Overview

The Program Overview tab collects general demographic information about your state's program - program details; your program name; website URL; racial, number of required screens, responsible laboratory and other details. Complete all the information and click the **Save** button.

The screenshot shows the 'Program Overview' tab selected in a sidebar menu. The main form area contains the following fields:

- Annual Births for 2015:** 3590
- Name of State NBS Program:** Text input field
- Region:** Dropdown menu with '- Select -'
- Website:** Text input field
- Number of required screens:** Dropdown menu with '- Select -'
- Responsible Laboratory:** Name (text input) and Type (dropdown menu with '- Select -')
- Screening Card Image:** Document upload field with 'Browse...' button and a 'Link' text input field.
- Hearing Screening Form:** Document upload field with 'Browse...' button and a 'Link' text input field.

At the bottom of the form, there is a checkbox labeled 'Complete' with the text: 'Complete - The data for the Program Overview section have been reviewed and is complete for the current calendar year.' Below this is a 'Save' button.



Disorders

The disorders tab collects information about the disorders for which your state screens. The disorders are organized according to the Recommended Uniform Screening Panel (RUSP), as core, secondary, and other conditions.

Program Overview

Disorders

Policies

Adding to NBS Panel

Fees

Program Structure

Contacts

Advisory Committee

IT Support

HIT Elements

Core Secondary Other

Recommended Uniform Screening Panel

Core Conditions

The core conditions presented are those listed on the Secretary's Advisory Committee for Heritable Disorders in Newborn and Children Recommended Uniform Screening Panel (RUSP) and are disorders that should be included in every Newborn Screening Program. Current information for each disorder, along with the dates of implementation can be updated by individuals within each state screening program.

For each condition, select the status of screening for the condition in your state. Please also select the year and month in which population based screening began (not pilot or feasibility studies), if known.

Organic Acid Disorders

Propionic acidemia - PROP - Select subcategory -

Proposed/Actual Implementation Date for Universal Screening
Year Month

Methylmalonic acidemia (methylmalonyl-CoA mutase) - MUT - Select subcategory -

Proposed/Actual Implementation Date for Universal Screening
Year Month

Methylmalonic acidemia (cobalamin disorders) - Cbl A,B - Select subcategory -

Proposed/Actual Implementation Date for Universal Screening
Year Month



1. To complete the disorders, select the screening status of the condition in your state. Statuses are shown in the image below.

Program Overview
Disorders
Policies
Adding to NBS Panel
Fees
Program Structure
Contacts
Advisory Committee
IT Support
HIT Elements

Core Secondary Other

Recommended Uniform Screening Panel

Core Conditions

The core conditions presented are those listed on the Secretary's Advisory Committee for Heritable Disorders in Newborn and Children Recommended Uniform Screening Panel (RUSP) and are disorders that should be included in every Newborn Screening Program. Current information for each disorder, along with the dates of implementation can be updated by individuals within each state screening program.

For each condition, select the status of screening for the condition in your state. Please also select the year and month in which population based screening began (not pilot or feasibility studies), if known.

Organic Acid Disorders

Propionic acidemia - PROP

Not Screened
Universally Screened
Likely to be detected and reported due to universal screening of another disorder
Offered to select populations

Year Month

Methylmalonic acidemia (methylmalonyl-CoA mutase) - MUT

Not Screened - Select subcategory -

Proposed/Actual Implementation Date for Universal Screening
Year Month

Methylmalonic acidemia (cobalamin disorders) - Cbl A,B

Not Screened - Select subcategory -

Proposed/Actual Implementation Date for Universal Screening
Year Month

Isovaleric acidemia - IVA

Not Screened - Select subcategory -

Proposed/Actual Implementation Date for Universal Screening
Year Month

2. After you select a screening status, select a subcategory and fill additional data elements that ask about screening methodologies, equipment used and the date of implementation (month and year, or year) of the screening population-wide where known.

- Program Overview
- Disorders
- Policies
- Adding to NBS Panel
- Fees
- Program Structure
- Contacts
- Advisory Committee
- IT Support
- HIT Elements

Core
Secondary
Other

Recommended Uniform Screening Panel

Core Conditions

The core conditions presented are those listed on the Secretary's Advisory Committee for Heritable Disorders in Newborn and Children Recommended Uniform Screening Panel (RUSP) and are disorders that should be included in every Newborn Screening Program. Current information for each disorder, along with the dates of implementation can be updated by individuals within each state screening program.

For each condition, select the status of screening for the condition in your state. Please also select the year and month in which population based screening began (not pilot or feasibility studies), if known.

Organic Acid Disorders

Propionic acidemia - PROP	Universally Screened <input type="button" value="v"/>	<div style="background-color: #0070c0; color: white; padding: 2px; font-size: 0.8em;">- Select subcategory -</div> <div style="font-size: 0.7em; padding: 2px;">Required by law or rule</div> <div style="font-size: 0.7em; padding: 2px;">Not required by law or rule</div>
First Screen		
First Tier Method <input type="button" value="v"/>	First Tier Method Target <input type="button" value="v"/>	Second Tier Method <input type="button" value="v"/>
		Second Tier Method Tar <input type="button" value="v"/>
Second Screen		
First Tier Method <input type="button" value="v"/>	First Tier Method Target <input type="button" value="v"/>	Second Tier Method <input type="button" value="v"/>
		Second Tier Method Tar <input type="button" value="v"/>
Equipment	Proposed/Actual Implementation Date for Universal Screening	
Equipment <input type="button" value="v"/>	Year <input type="button" value="v"/>	Month <input type="button" value="v"/>
<hr/>		
Methylmalonic acidemia (methylmalonyl-CoA mutase) - MUT	Not Screened <input type="button" value="v"/>	<div style="background-color: #0070c0; color: white; padding: 2px; font-size: 0.8em;">- Select subcategory -</div> <div style="font-size: 0.7em; padding: 2px;">Not required by law or rule</div>
Proposed/Actual Implementation Date for Universal Screening		
	Year <input type="button" value="v"/>	Month <input type="button" value="v"/>
<hr/>		
Methylmalonic acidemia (cobalamin disorders) - Cbl A,B	Not Screened <input type="button" value="v"/>	<div style="background-color: #0070c0; color: white; padding: 2px; font-size: 0.8em;">- Select subcategory -</div> <div style="font-size: 0.7em; padding: 2px;">Not required by law or rule</div>
Proposed/Actual Implementation Date for Universal Screening		

3. When you complete the entries for core conditions, click the **Save** button, or click on the tabs to enter information for secondary and other conditions, clicking the **Save** button when completed. (Clicking **Save** will return you to the screen that will list all the selections you have made; click on any tab to return and edit it.)



Policies

The policies tab collects information about the NBS policies that your state program has. These policies include those around recommended age at initial screening and second screening; consent; follow-up services; missed cases; storage of specimens; storage of data; sharing of specimens; and other details.

<ul style="list-style-type: none">Program OverviewDisordersPoliciesAdding to NBS PanelFeesProgram StructureContactsAdvisory CommitteeIT SupportHIT Elements	Specimen Collection Recommended Initial Screening Age: <input type="text"/> Recommended Second Screening Age: <input type="text"/> Second Screen Policy: <input type="text"/> NICU CLSI Guideline Adoption Status: <input type="text"/> NICU CLSI Guideline Adoption Description: <input type="text"/> 3999 characters remaining. Specimen Transport, Receipt, Storage, Courier Service Usage Status: <input type="text"/>	Consent Consent For Newborn Screening: <input type="text"/> Opt Out Policy: <input type="text"/> Opt Out Recording Method: <input type="text"/> Consent Recording Method: <input type="text"/> Residual Specimen Uses: <input type="text"/> Specimens Consented for Research?: <input type="text"/> Specimen Sharing Policies: <input type="text"/> Follow-Up Short Term Follow-Up Definition: <input type="text"/>	Analysis Process for Reporting Missed Diagnoses?: <input type="text"/> Missed Diagnosis Reporting Process: <input type="text"/> 3999 characters remaining. Matching NBS Records to find Unscreened Babies: <input type="text"/> Matching Data System?: <input type="text"/> Result Matching Method: <input type="text"/> Unsatisfactory Specimen Testing Policy: <input type="text"/>
---	--	--	---

Complete all the information and click the Save button.



Adding to the NBS Panel

The adding to the NBS panel tab collects information about the policies and procedures that your state program has with regard to adding conditions to the NSB panel.

1. The General Info section collects for example, the time frame typically seen for adoption of a new condition, once a decision has been made; whether or not a pilot study and/or feasibility study is done before adoption of population wide screening; and other details. Complete all the information and click the Save button.

The screenshot shows the 'Adding to NBS Panel' form with the 'General Info' tab selected. On the left is a navigation menu with 'Adding to NBS Panel' highlighted. The main content area has three tabs: 'General Info', 'Lab', and 'POC'. The 'General Info' section contains the following fields:

- National Recommendations Followed?** with radio buttons for Yes, No, and Unknown (selected).
- National Recommendation Implementation Time Frame:** with a checkbox for 'No Formal Time Frame' and an empty text input field.
- Pilot Studies Required Before Implementation?** with radio buttons for Yes, No, and Unknown (selected).
- Feasibility Study Done?** with radio buttons for Yes, No, and Unknown (selected).

At the bottom, there is a checkbox labeled 'Complete - The data for the Adding to NBS Panel section have been reviewed and is complete for the current calendar year.' and a 'Save' button.

2. The Lab section collects information about any challenges that the laboratory may have in adding a new DBS condition to the panel. Complete all the information and click the Save button.

The screenshot shows the 'Adding to NBS Panel' form with the 'Lab' tab selected. The navigation menu on the left remains the same. The main content area has three tabs: 'General Info', 'Lab', and 'POC'. The 'Lab' section contains the following fields:

- A heading: **If your state does not perform your own testing, leave this section blank.**
- Lab Test Addition Challenges:** with a list of 13 categories, each followed by a 'Ranking' dropdown menu:
 - Gaining authority to screen:
 - Training/education:
 - Staffing (follow-up and lab):
 - Equipment/instrumentation:
 - Laboratory space:
 - Test/method availability:
 - QC materials availability:
 - Funding to implement:
 - Diagnostic testing availability:
 - Clinical subspecialty availability:
 - Treatment and follow-up costs:
 - IT and Data Systems Modification:
- Lab Test Implementation Period:** with a dropdown menu showing '- Select -'.
- Lab Test Addition Requirements:** with a dropdown menu showing 'None selected'.



- The Point Of Care (POC) section collects information about any challenges that the laboratory may have in adding a new POC condition to the panel. Complete all the information and click the Save button. If you are certain that the information you have provided is complete for the year, please also check the **Complete** box before saving.

- Program Overview
- Disorders
- Policies
- Adding to NBS Panel**
- Fees
- Program Structure
- Contacts
- Advisory Committee
- IT Support
- HIT Elements

General Info Lab **POC**

POC Test Addition Challenges: ⓘ

Gaining authority to screen: Ranking ▼

Training/education: Ranking ▼

Staffing (follow-up and lab): Ranking ▼

Equipment/instrumentation: Ranking ▼

Laboratory space: Ranking ▼

Test/method availability: Ranking ▼

QC materials availability: Ranking ▼

Funding to implement: Ranking ▼

Diagnostic testing availability: Ranking ▼

Clinical subspecialty availability: Ranking ▼

Treatment and follow-up costs: Ranking ▼

IT and Data Systems Modification: Ranking ▼

FDA approved test/method availability: Ranking ▼

POC Test Implementation Period: ⓘ

- Select - ▼

POC Test Addition Requirements: ⓘ

None selected ▼



Fees

The fees tab collects information about the state NBS fees and related information. Complete all the information and click the Save button.

- Program Overview
- Disorders
- Policies
- Adding to NBS Panel
- Fees
- Program Structure
- Contacts
- Advisory Committee
- IT Support
- HIT Elements

Funding

Newborn Screening Funding Sources: ?

None selected ▾

Fee Collection Method: ?

- Select - ▾

Fee Holding Location: ?

- Select - ▾

Fees: ?

Initial Screen Fee

\$

Repeat Screen Fee

Included in initial screen fee

\$

Second Screen Fee

\$

Fee Use Details: ?

Use	Used?	% Used
Lab tests (To include salaries of laboratory personnel, supplies, instruments and equipment maintenance):	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown	<input type="text"/> %
Follow-up services (salaries and educational materials):	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown	<input type="text"/> %
Long term follow-up support (to include physician consultants, Geneticists, Genetic counselors, etc):	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown	<input type="text"/> %
Critical Congenital Heart Disease (CCHD) services:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown	<input type="text"/> %
Early Hearing Detection and Intervention (EHDI) services:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown	<input type="text"/> %



Program Structure

The program structure tab collects information about the state NBS program structure. This includes laboratory operating hours; follow-up operating hours; organizational chart; staffing levels (%FTE); and related information. You can also upload and relevant documents. Complete all the information and click the Save button.

- Program Overview
- Disorders
- Policies
- Adding to NBS Panel
- Fees
- Program Structure**
- Contacts
- Advisory Committee
- IT Support
- HIT Elements

NBS system organizational chart: ⓘ

Document

Link

Shared Duties: ⓘ

Follow-Up on Unsatisfactory Specimens: ⓘ

Responsible Party

Description

3999 characters remaining.

Follow-Up on Borderline Results: ⓘ

Responsible Party

NBS Program Staffing Level: ⓘ

Laboratory Scientists
 FTE

STFU Personnel
 FTE

Clerical Support Personnel
 FTE

EHDI Personnel
 FTE

CCHD Personnel
 FTE

STFU Responsible Parties: ⓘ

Certification Program: ⓘ

Proficiency Tests: ⓘ

Program Information: ⓘ



Contacts

The contacts tab collects contact information for the following: the overall NBS program, the Director and/ or Program Manager, the NBS state laboratory, the NBS follow-up program, the Early Hearing Detection and Intervention (EHDI) program, Critical Congenital Heart Disease (CCHD) program, and the Health Information Technology (HIT) person(s) in your state. Complete all the information and click the Save button.

- Program Overview
- Disorders
- Policies
- Adding to NBS Panel
- Fees
- Program Structure
- Contacts**
- Advisory Committee
- IT Support
- HIT Elements

Program Director Program Manager Lab Follow-Up EHDI CCHD HIT

Overall NBS Program: [?]

Main Contact:	Alternate Contact:
First Name	First Name
<input type="text"/>	<input type="text"/>
Last Name	Last Name
<input type="text"/>	<input type="text"/>
Title	Title
<input type="text"/>	<input type="text"/>
Credentials	Credentials
<input type="text"/>	<input type="text"/>
Email	Email
<input type="text"/>	<input type="text"/>



Advisory Committee

The advisory committee tab collects information on the details of the NBS advisory committee for your state NBS program. This includes, if applicable, the make-up of the advisory committee; how often the committee meets; and other details. You can also upload and relevant documents. Complete all the information and click the Save button.

- Program Overview
- Disorders
- Policies
- Adding to NBS Panel
- Fees
- Program Structure
- Contacts
- Advisory Committee**
- IT Support
- HIT Elements

Existing Advisory Committee?: [?]

Yes
 No
 Unknown

Advisory Committee Voluntary?: [?]

Yes
 No
 Unknown

Committee Structure: [?]

Description

3999 characters remaining.

Document

Link

Charge/Bylaws: [?]

Document

Link

Meeting Frequency: [?]

- Select -

Meeting Minutes Link: [?]



IT Support

The Information Technology (IT) Support tab collects information on the types of information systems your state NBS program uses. This includes the type of information system in the laboratory; the type of information system in the follow-up program; information on Continuity of Operation Plans (COOP); and other details. Complete all the information and click the Save button.

<ul style="list-style-type: none">Program OverviewDisordersPoliciesAdding to NBS PanelFeesProgram StructureContactsAdvisory CommitteeIT SupportHIT Elements	Lab Information System: ⓘ <input type="text" value="- Select -"/>	NBS Data Backup Frequency?: ⓘ <input type="text" value="- Select -"/>	IT Part of COOP? ⓘ <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown
	Follow-up Information System: ⓘ <input type="text" value="- Select -"/>	Data Loss Amount from Database Failure: ⓘ <input type="checkbox"/> Unknown <input type="text"/>	Redundant Off-site Operations Exists? ⓘ <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown
	Staffing Levels: ⓘ	Data Loss Amount from Instrument Failure: ⓘ <input type="checkbox"/> Unknown <input type="text"/>	Redundant On-site Operations Exists? ⓘ <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown
	LIMS Management <input type="text"/> FTE	IT Infrastructure Recovery Time: ⓘ <input type="checkbox"/> Unknown <input type="text"/>	
	Desktop Support <input type="text"/> FTE	Disaster Recovery Hardware: ⓘ <input type="text" value="None selected"/>	
	Network Support <input type="text"/> FTE		
	HL7 Messaging/Terminology Support <input type="text"/> FTE		
	Follow-Up Support <input type="text"/> FTE		
	IT Support Description: ⓘ <input type="text"/>		
	3999 characters remaining.		



HIT Elements

The Health Information Technology (HIT) elements tab collects information on the HIT processes and systems (if applicable) your state NBS program is implementing. This includes details on the type of messaging used (e.g., HL7 messaging); any coding used within the information systems (e.g., LOINC, SNOMED, etc.); information on data integration efforts with other NBS systems; and other details. Complete all the information and click the Save button.

<ul style="list-style-type: none">Program OverviewDisordersPoliciesAdding to NBS PanelFeesProgram StructureContactsAdvisory CommitteeIT SupportHIT Elements	HL7 Order Messages Accepted? ⓘ <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown	NBS Data Sharing Portal Exists? ⓘ <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown	Databases Integrated with NBS Systems: ⓘ None selected ▾
	HL7 Interfacing Birthing Center Count: ⓘ <input type="text"/>	DBS Data Entry Portal Exists? ⓘ <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown	Hearing Result Integration Method: ⓘ - Select - ▾
	Electronically Ordered Sample Count: ⓘ <input type="text"/>	Count of Birthing Centers Using Entry Portal: ⓘ <input type="text"/>	CCHD Result Integration Method: ⓘ - Select - ▾
	HL7 Result Messages Sent? ⓘ <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown	Count of Samples Entered Using Entry Portal: ⓘ <input type="text"/>	HIE Implementation Status: ⓘ - Select - ▾
	HL7 Result Message Recipient Count: ⓘ <input type="text"/>	NBS Result Retrieval Portal Exists? ⓘ <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown	HIE Data Exchange Status: ⓘ - Select - ▾
	Electronically Reported Sample Count: ⓘ <input type="text"/>	Count of Birthing Centers Using Retrieval Portal: ⓘ <input type="text"/>	HIE Interfacing Funds Received? ⓘ <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown
	Implementation Guide and HL7 Version: ⓘ <input type="text"/>	NBS Activities Feedback Portal? ⓘ <input type="text"/>	NBS Result Accessor: ⓘ - Select - ▾
			NBS Result Sending Method: ⓘ - Select - ▾



7.3 Cases identified by newborn screening

The conditions detected by newborn screening are rare, therefore it is only with the combined births across the U.S. that we will be able to identify trends in the true birth prevalence of disorders, and also understand trends over time. Consistent data collected across all programs in the country will provide valuable data for state public health departments, Title V reporting requirements, reports to legislators, and clinical care providers caring for children with these rare disorders.

** Please note that your state must have a signed Memorandum of Understanding (MOU) with NewSTEPS/APHL before case information can be entered. For more information about the MOU process, please contact NewSTEPS at newsteps@aphl.org.*

1. To enter a case, click on the *Cases* tab, then click on the **Add New Case** button.
2. First, select the condition, either by typing it in the text field on the left side, or selecting it on the right side (where conditions are organized by category). Click the **Next** button.

[← Back To List](#) **Case Definition**

State *
- Select -

Disorder
Start typing a condition name

OR

Select a condition

Fatty Acid Disorders
- Select -

Organic Acid Disorders
- Select -

Amino Acid Disorders
- Select -

Other Disorders
- Select -

Endocrine Disorders
- Select -

Lysosomal Storage Disorders
- Select -

Hemoglobin Disorders
- Select -

OR
[Import Case Demographic and Screening information from csv file](#)

3. After a condition is selected, the form for entering case details will load. The system will require you to input a state unique identifier and the infant's date of birth. Note that the NewSTEPS Data Repository does ask for date of birth and dates and times of service, which are collected only in the browser for the purpose of calculating differences in dates and times (i.e., days elapsed between birth and screening) - other than birth year, NO date or time is stored in the NewSTEPS Data Repository.



Enter as much information as you can with infant detailed information, screening details, and collection information.

Some conditions include diagnostic workup data, including enzymatic test details and molecular genetic testing results. As a public health surveillance program, it is critically important for NewSTEPS to have accurate definitions of each disorder.

NewSTEPS has partnered with HRSA to provide case definitions for use in public health newborn screening. A tool kit that includes the case definition worksheets, a sample letter to a medical provider, etc. are provided for your use on the NewSTEPS website and are [linked here](#) and should be completed in collaboration with the clinical care providers. For those conditions with an attached Diagnostic Workup within the repository, you can find a PDF version of the [worksheets](#) on the NewSTEPS website. You can print out and fill out the worksheet by completing demographic information and any data available from within the newborn screening program. These worksheets are intended to be tools to help in the collection of the data elements within the case definitions. The case definitions are not intended to change the diagnosis from the clinicians, but to allow categorization of the certainty of the public health surveillance reported case. Please use the provided worksheets to collect the appropriate information. When possible, please collect the laboratory results for your internal records. These will never be shared beyond your program, but will help to support the case definition.

Many positive newborn screening results take significant time for resolution. We ask that the case definitions be closed after a year from the child's birth and all relevant data be entered by this point.

Diagnostic Workup

Enzymatic

Final Diagnosis as determined by metabolic geneticist or clinician performing the follow-up

- Select -

Were urine organic acids tested?

Yes No Unknown

Were plasma acylcarnitines tested?

Yes No Unknown

Was C₃ level:

Elevated
 Normal
 Unknown

Was C₅-OH level:

Elevated
 Normal
 Unknown

Were infant chemistries (biotinidase) studies completed?

Yes No Unknown

Was enzyme analysis for holocarboxylase synthetase deficiency enzyme activity completed?

Yes No Unknown

Complete - The case data entry is complete. All available data related to this diagnosis (obtained through one year of age) has been entered.

Molecular Genetics

Was mutation analysis done?

Yes No Unknown

What genes were included in the mutation analysis?

HLCS 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

Save | Cancel



4. After all information has been entered, click the **Save** button. If you are certain that the information you have provided is complete for the year, please also check the **Complete** box before saving.



5. The new case will then be visible in the table of cases on the *Cases* tab.
6. To edit an existing case, click on the edit icon from the cases table, as shown below.

1-3 of 3 Results

20 Per Page

Add New Case

Back 1 Next

State Unique ID	Birth year	Condition	Last Updated	Action
trg-10312-1-q104	2012	S,S disease (Sickle cell anemia) - Hb SS	09/16/2013	 
trg-8446-1-q81	2012	Cystic fibrosis - CF	09/16/2013	 
trg-9873-1-q76	2012	3-Methylcrotonyl-CoA carboxylase deficiency - 3-MCC	09/16/2013	 

view *edit*



7.4 Quality Indicators

The [eight Quality indicators \(QI\)](#) 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. QIs are calculated using information from state profiles, cases, and QI-specific information.

** Please note that your state must have a signed Memorandum of Understanding (MOU) with NewSTEPS/APHL before QI information can be entered. For more information about the MOU process, please contact NewSTEPS at newsteps@aphl.org*

To enter QIs, click on the *Quality Indicators* tab. This will display a list of all quality indicators. Select the year for which you're entering quality information, then select *Demographics* to enter state demographic data.

YEAR *

SECTION *

Additional Screening Data - Additional state-level data that provides peripheral annual screening information

Quality Indicator 1 - Percent of dried blood spot specimens that were unacceptable due to improper collection and/or transport

Quality Indicator 2 - Percent of dried blood spot specimens with at least one missing state-defined essential data field upon receipt at the lab

Quality Indicator 3 - Percent of eligible newborns not receiving a newborn screen, reported by dried blood spot or point-of-care screen(s)

Quality Indicator 4 - Percent of infants that have no recorded final resolution (confirmed diagnosis or diagnosis ruled out by an appropriate medical professional) with the newborn screening program

Quality Indicator 5 - Timeliness of newborn screening activities

Quality Indicator 6 - Percent of infants with an out-of-range newborn screen result requiring clinical diagnostic workup by an appropriate medical professional, reported by disorder category

Quality Indicator 7 - Percent of disorders detected by newborn screening with a confirmed diagnosis by an appropriate medical professional

Quality Indicator 8 - Percent of missed cases, reported by disorder

Demographics - State Demographic Data

View QI Summary - A Summary of all QI data for the year and state selected with regional and national data for comparison.

Year to Year Comparison - A Summary of all QI data for the state selected compared by year.

Import Quality Indicator Data from a File.

Select a completed Annual Births csv file:

Select the Year and then click on Demographics.

Additional Screening Data

- Quality Indicator 1
- Quality Indicator 2
- Quality Indicator 3
- Quality Indicator 4
- Quality Indicator 5
- Quality Indicator 6
- Quality Indicator 7
- Quality Indicator 8
- Demographics

State Demographic Data Save | Cancel

Demographic information entered below provides details on the racial, ethnic, and gender distributions for your state.

DEMOGRAPHICS OFFICIAL?

Yes
 No

RACIAL DISTRIBUTION

White %

Black or African American %

American Indian or Alaska Native %

Asian %

Native Hawaiian or other Pacific Islander %

Not Reported %

Unknown %

ETHNIC DISTRIBUTION

Hispanic, Latino/a, or Spanish origin %

Not of Hispanic, Latino/a, or Spanish origin %

Not Reported %

Unknown %

SEX DISTRIBUTION

Female %

Male %

Unspecified %

Next, select Additional Screening Data and enter or confirm the information. Remember to click the Save button before moving on the next tab.

Additional Screening Data

- Quality Indicator 1
- Quality Indicator 2
- Quality Indicator 3
- Quality Indicator 4
- Quality Indicator 5
- Quality Indicator 6
- Quality Indicator 7
- Quality Indicator 8
- Demographics

Additional Screening Data Save | Cancel

The information entered below provides additional screening data including the number of birthing hospitals in your state, number of infants transferred to hospitals out of state and screening performed by another NBS program, number of infants who came in from other states for screening and cared for by specialists in your state, etc

BIRTH STATISTICS

How many infants screened were born in your state?

How many birthing centers are in your state?

DRIED BLOOD SPOT SCREENING STATISTICS

How many infants born in your state received DBS NBS at an out of state NBS program?

How many infants born out of state received DBS NBS through your NBS program?

EARLY HEARING DETECTION AND INTERVENTION SCREENING STATISTICS

How many infants born in your state received EHDI screening at an out of state NBS program?

How many infants born out of state received EHDI screening through your NBS program?

CRITICAL CONGENITAL HEART DISEASE SCREENING STATISTICS

How many infants born in your state received CCHD screening at an out of state NBS program?

How many infants born out of state received CCHD screening through your NBS program?

Save | Cancel

True Case Counts by Disorder

Count	Disorder
<	>
+	-



Then, select each QI and enter or confirm the information for each. For each, click the **Save** button before moving onto the next.

Please note that for each QI, enter the "Number of" the system will calculate the "Percent". Additionally, QIs 5e, 5f, 7 and 8 will be pre-calculated based on the case data entered in the "Cases" tab.



7.5 Next Steps

The NewSTEPS Data Repository will continue to be updated with new features. We anticipate that these updates will occur on a quarterly basis, with more frequent updates as needed.

7.6 Further Assistance

Contact information for Assistance: If you have any questions or feedback on the NewSTEPS Data Repository, please contact Careema Yusuf at 240-485-2761 or at careema.yusuf@aphl.org or Sari Edelman at 240-485-3839 or at sari.edelman@aphl.org.



Revision History

Changes to this document are reflected in this Revision History table.

Date	Version	Description	Revised by
09/30/2013	Version 1.0	Initial draft	Leslie Power
03/04/2014	Version 1.1	Revised draft	Careema Yusuf
05/07/14	Version 2.0	Updated to reflect new tabs	Careema Yusuf
8/09/2016	Version 3	Updated to reflect new tabs and revised QIs	Sari Edelman
6/19/2018	Version 4	Updated to reflect new order of tabs	Sari Edelman