



**NewSTEPS**

A Program of the Association of Public Health Laboratories™

## NEWSTEPS TIMELINESS REPORT

AUGUST 2016

A report submitted to the United States Government Accountability Office

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## Glossary

<b>ACHDNC</b>	Advisory Committee for Heritable Disorders in Newborns and Children
<b>APHL</b>	Association of Public Health Laboratories
<b>CoIIN</b>	Collaborative Improvement and Innovation Network
<b>ColoradoSPH</b>	Colorado School of Public Health
<b>DBS</b>	Dried Blood Spot(s)
<b>GAO</b>	Government Accountability Office
<b>HRSA</b>	Health Resources and Services Administration
<b>LIMS</b>	Laboratory Information Management System
<b>MOU</b>	Memorandum of Understanding
<b>NBS</b>	Newborn Screening
<b>NewSTEPS</b>	Newborn Screening Technical assistance and Evaluation Program
<b>QI</b>	Quality Indicator
<b>RUSP</b>	Recommended Uniform Screening Panel

## About NewSTEPs

### **Vision**

Dynamic NBS 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 NBS systems by providing relevant, accurate tools and resources and to facilitate collaboration between state programs and other NBS partners.

### **NewSTEPs Goals**

#### **Goal 1**

Strengthen the NBS system through enhancement of the existing network of stakeholders by creating a culture of trust, by providing opportunities for timely, interactive communications, and by offering a forum for collaboration among national, regional and state NBS programs.

#### **Goal 2**

Facilitate continuous quality improvement and data-driven outcome assessments in the NBS system by providing a standardized repository and by supporting the integration of health information technology frameworks, including HL7 messaging.

#### **Goal 3**

Create a dynamic national NBS technical assistance resource center that proactively provides training, addresses challenges, and supports program improvement through partnerships with key stakeholders throughout the NBS community.

## Background

### Newborn Screening Saves Lives Reauthorization Act (P.L. 113-240)

In 2008, congress passed the Newborn Screening Saves Lives Act (P.L. 110-204) that has resulted in significant progress in the areas of education, technology, follow-up care, laboratory quality standards, and consumer awareness to aide in the facilitation of comprehensive newborn screening (NBS) in every state. The Newborn Screening Saves Lives Reauthorization Act (P.L. 113-240), signed into law in December 2014, extends federal programs that provide assistance to states to improve their NBS programs and ensure laboratory quality and surveillance. Section 11 of this act requires that the United States Government Accountability Office (GAO) issue a report to congress on the timeliness of NBS by December 2016 and within the report include content on the analysis of the time elapsed from birth to specimen collection, specimen collection to receipt by the laboratory, specimen receipt to results reporting, reporting to follow-up testing, and follow-up testing to confirmed diagnosis. Additionally, the report is required to include a summary of guidelines and best practices available to states and healthcare providers as well as an analysis of any barriers and solutions to maintaining timeliness within the NBS system.

### NewSTEPs Data Repository

The Newborn Screening Technical assistance and Evaluation Program, or NewSTEPs, is an initiative funded by the Health Resources and Services Administration (HRSA) under Cooperative Agreement #U22MC24078 (CFDA #93.110) with the Association of Public Health Laboratories (APHL) that strives to provide relevant, accurate tools and resources to facilitate collaboration between NBS partners. NewSTEPs is a collaborative effort between APHL and the Colorado School of Public Health (ColoradoSPH) with both organizations operating in partnership to further the initiative's mission and references to NewSTEPs in this document reflect this combined work.

NewSTEPs developed a NBS data repository, the NewSTEPs Data Repository, that collects two categories of data that describe timeliness of NBS: 1) state level Quality Indicators (QI); and 2) public health surveillance case level data for disorders detected by NBS. Data collection efforts for all repository data categories have been ongoing since 2013. For security, privacy and transparency reasons, NewSTEPs required that NBS programs have a signed

Memorandum of Understanding (MOU) with APHL in order to enter QI and case data into the repository. As of June 30, 2016, 29 states have a signed MOU with APHL and NewSTEPs continues to work with the remaining NBS programs in an effort to secure each of their MOUs.

In March 2016, the GAO asked NewSTEPs to provide state-level data in the area of timeliness in NBS for the purpose of including the content in the report to congress described above.

### Quality Indicator Data

The NewSTEPs Data Repository collects annual data on eight QIs that are used to provide longitudinal comparisons within a NBS program and to aggregate data across programs. The QIs were initially developed in 2011 by state NBS program experts and underwent careful evaluation by stakeholders to ensure agreement on definitions. There was also a public comment period that allowed for the NBS community to provide comments and suggested edits. QI data can be entered into the NewSTEPs Repository either manually or by utilizing a data import template. While the data elements requested are common across all NBS programs, each program collects and defines the information differently for their own programmatic needs. Understanding these differences has led to a series of activities to improve the quality indicator definitions.

In November 2015, NewSTEPs convened a QI workgroup composed of experts and stakeholders from the NBS community, and implemented a Delphi process for the purpose of refining the conceptual definitions of the QIs and to establish a collaborative plan to collect and extract the information across states and laboratory information management system (LIMS) vendors. This process included three Delphi survey rounds and an in-person meeting held at APHL's Silver Spring, MD offices in February 2016. In April 2016, the workgroup reached consensus on QI revisions which are reflected in [Quality Indicator Source Document Version 2.0](#). These changes had not been implemented in the NewSTEPs Data Repository at the time of the GAO data request.

### Case Data

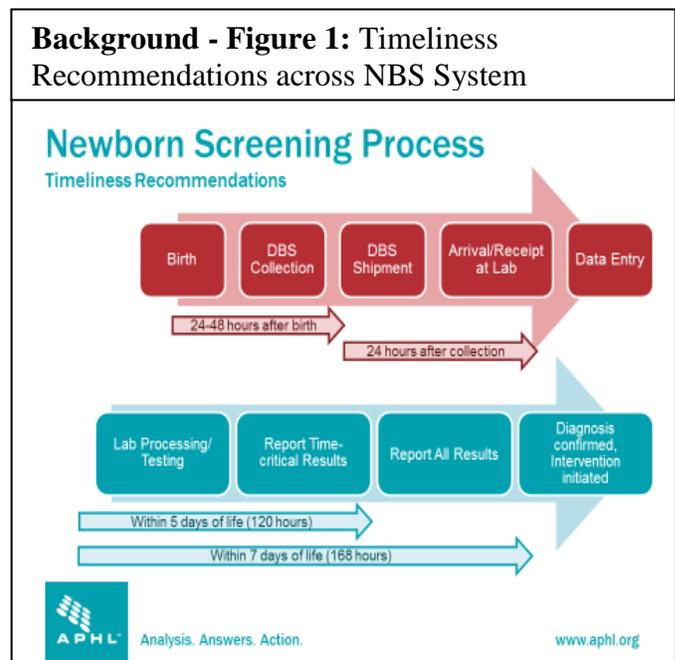
The NewSTEPs Data Repository collects basic demographic and diagnostic information on all newborns born with a disorder diagnosed through NBS in the United States. The public health surveillance case definitions were developed through a network of clinical specialists

under the direction of HRSA (2011-2013). The purpose of applying case definitions is to categorize the certainty of the diagnosis for each condition on the Recommended Uniform Screening Panel (RUSP). In addition, timeliness measures are collected on each case including hours from birth to specimen collection, days from birth to specimen receipt at the laboratory, days from birth to reporting results, days from birth to intervention, and days from birth to a confirmed diagnosis. This allows NewSTEPs and programs entering data to track continuous timeliness measures for confirmed cases throughout the NBS process by disorder, by disorder category, and by the time critical nature of treating the disorder.

### Timeliness in NBS

NBS is a time sensitive process (Background - Figure 1) in which a delay in specimen collection, transport, testing, and/or reporting of results could lead to serious consequences for a newborn that is affected by one of the disorders currently screened. In September 2013, the Secretary of Health and Human Service’s Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) made NBS timeliness a priority after a Colorado mother who lost her newborn to Medium-chain acyl-CoA dehydrogenase (MCAD) at four days after birth due to process

delays presented her case to the committee. Then, in November 2013, NBS emerged in national headlines through a series of articles addressing inefficiencies in timeliness related to the delivery of DBS samples from birthing centers to NBS programs<sup>1, 2, 3</sup>.



<sup>1</sup> Gabler E, Johnson M, Fauber J. Deadly Delays. *Milwaukee Journal Sentinel* November 16, 2013.

<sup>2</sup> Fauber, J. (2013). More than half of state labs do not process newborn samples on weekends, creating critical delays in the process. *Milwaukee Journal Sentinel*. Milwaukee, WI. , Journal Sentinel, Inc.

<sup>3</sup> Johnson, M. (2013). Testing delay puts newborn's life at risk. *Milwaukee Journal Sentinel*. Milwaukee, WI, Journal Sentinel, Inc.

ACHDNC made the following recommendations around timeliness of NBS in February 2015:

In order to reduce delays in NBS and avoid potential harm to infants:

1. Presumptive positive results for time-critical conditions should be immediately reported to the newborn's healthcare provider but no later than five days of life.
2. Presumptive positive results for time sensitive conditions should be reported to the healthcare provider as soon as possible but no later than seven days of life, and
3. All NBS results, including normal results, should be reported within seven days of life.

In order to achieve these goals:

1. Initial NBS specimens should be collected in the appropriate time frame for the baby's condition but no later than 48 hours after birth, and
2. NBS specimens should be received at the Laboratory as soon as possible; ideally within 24 hours of collection.

#### Timeliness CoIIN and the Timeliness Report of the ACHDNC Laboratory Subcommittee

To assist NBS programs toward improving timeliness, NewSTEPS facilitated a Collaborative Improvement and Innovative Network (CoIIN) for Timeliness in NBS project (this project was also funded through Cooperative Agreement #U22MC24078 between HRSA and APHL). To learn more about the NewSTEPS CoIIN project and the activities and successes of state NBS program participants, please refer to the [CoIIN Final Report \(Addendum 4\)](#).

In addition, APHL worked with the ACHDNC's Laboratory Standards and Procedures Subcommittee to develop a survey to identify the gaps and barriers to achieving the noted recommendations. See Background - Table 1 for specific examples of gaps and barriers identified from the survey and CoIIN participants.

**Background - Table 1: Needs Assessment Findings Based on the NewSTEPs CoIIN for Timeliness in NBS and on the Timeliness Report of the Laboratory Standards and Procedures Subcommittee of the ACHDNC**

CHALLENGE ( <i>Source where Identified</i> )	EXAMPLE
<b>Pre-Analytical</b>	
Lack of clear and timely feedback to birthing facilities/submitters on performance ( <i>Timeliness Report &amp; CoIIN</i> )	<ul style="list-style-type: none"> <li>• Lack of staff in the NBS laboratory to analyze performance data and to provide technical assistance</li> <li>• Lack of a system to accurately record and track timeliness of NBS</li> <li>• Reports not getting to nursing staff and/or reports being difficult to decipher</li> </ul>
Lack of nursing staff knowledge about NBS ( <i>CoIIN</i> )	<ul style="list-style-type: none"> <li>• Treat DBS cards as regular mail vs. as laboratory samples requiring immediate attention</li> <li>• Not knowing the ideal time to collect DBS specimens</li> </ul>
Midwives/Out-of- hospital birthing attendants' knowledge on NBS ( <i>CoIIN</i> )	<ul style="list-style-type: none"> <li>• Not understanding the importance of NBS</li> <li>• Not understanding why 24-48 hours is the ideal time to collect DBS specimens</li> <li>• Inability to bill for newborn screen</li> </ul>
Lack of electronic data sharing mechanisms ( <i>Timeliness Report</i> )	<ul style="list-style-type: none"> <li>• Lack of electronic receipt of laboratory orders</li> </ul>
Transporting DBS specimens sent from birthing facilities to NBS lab ( <i>Timeliness Report &amp; CoIIN</i> )	<ul style="list-style-type: none"> <li>• Sending DBS specimens in batches to the laboratory</li> <li>• Utilizing postal service; mail delays</li> <li>• Lack of a dedicated courier service</li> <li>• Costs associated with providing courier services due to a state's geographic area</li> <li>• Availability of commercial couriers in rural regions</li> <li>• Courier contracts do not include Saturday pickup and/or pickup is not enforced</li> </ul>
State regulations allow wide window for specimen collection ( <i>Timeliness Report</i> )	<ul style="list-style-type: none"> <li>• Time of specimen collection between 48-72 hours</li> </ul>
<b>Analytical</b>	
NBS program operating hours ( <i>Timeliness Report and CoIIN</i> )	<ul style="list-style-type: none"> <li>• Lack of funding to adequately operate laboratory/ follow-up outside of "regular" business hours</li> <li>• Lack of administrative support</li> </ul>
Lack of interface between NBS LIMS and State/Territory Vital/Birth Records ( <i>Timeliness Report</i> )	<ul style="list-style-type: none"> <li>• Inability to track specimens</li> <li>• Inability to read patient information on the DBS card</li> </ul>

Constraints based on the testing methodologies and systems in place ( <i>Timeliness Report and CoIIN</i> )	<ul style="list-style-type: none"> <li>• Some primary screening methods require longer periods to test than others</li> <li>• Second-tier testing to reduce false positives requires follow-up and confirmatory testing and may delay the time to obtain results.</li> <li>• Only one lab in a region can perform new tests</li> </ul>
<b>Post-Analytical</b>	
Lack of electronic data sharing mechanisms ( <i>Timeliness Report</i> )	<ul style="list-style-type: none"> <li>• Lack of electronic reporting of results with birthing facilities/submitters, healthcare providers, etc.</li> </ul>
Lack of standard reporting procedures ( <i>Timeliness Report</i> )	<ul style="list-style-type: none"> <li>• Delayed diagnosis, management, and treatment of affected babies</li> </ul>

### NewSTEPS 360

In September 2015, ColoradoSPH was awarded \$5.4 million from HRSA through Cooperative Agreement #UG8MC28554 (CFDA # 93.110) to lead activities designed to improve NBS timeliness. ColoradoSPH also works in partnership with APHL on this project, NewSTEPS 360, that builds on the NewSTEPS infrastructure to bring together national partners to achieve timely results reporting in 95% of newborns who receive DBS NBS within each participating state. Following a rigorous application process, 16 quality improvement teams representing 20 state NBS programs were chosen to participate in NewSTEPS 360. Over the course of the project, NewSTEPS 360 will provide financial and technical assistance to participating states to implement innovative processes targeted to improving NBS timeliness. Based on the gaps and barriers listed in Table 1, NBS program activities are centered on six focus areas:

- **Focus Area 1:** Developing education in the hospital, birthing facilities, and/or with midwives (out-of-hospital births) regarding timely and appropriate collection and shipment of samples.
- **Focus Area 2:** Identifying and/or strengthening courier system to deliver NBS DBS.
- **Focus Area 3:** Expanding operating hours to provide more uniform coverage for NBS throughout the week and across holidays.
- **Focus Area 4:** Evaluating the efficiency of laboratory processes and/or workflows.
- **Focus Area 5:** Communicating results with provider and clinical specialists and ensuring timely diagnostic work-up.
- **Focus Area 6:** Using Health Information Technology (HIT) to improve timeliness through electronic demographic and order submission and result reporting.

To track progress, QI data specific to measuring timeliness is collected on a monthly basis from participating states in the NewSTEPS Data Repository. Data collection began in January 2016 and will be ongoing until the project concludes in August 2018.

## Methods

### Annual Quality Indicator Data Collection and Analysis

NewSTEPS contacted 53 NBS programs (all 50 states, Washington DC, Puerto Rico and Guam) via email in April 2016 informing them of the timeliness data request from the GAO. At the time, NewSTEPS made a formal request for annual QI data for 2012-2015 with an initial deadline of May 16, 2016, which was later extended to May 26, 2016. The director and associate director of NewSTEPS made follow-up phone calls to inform NBS programs of the expedited nature of the data request and to address state specific questions.

NewSTEPS requested the following QI measures for timeliness from NBS programs:

- **QI5a.i:** Time from birth to first DBS specimen collection.
- **QI5a.v:** Time from birth to subsequent DBS specimen collection.
- **QI5b.i:** Time from first specimen collection to receipt at a state's NBS laboratory.
- **QI5b.ii:** Time from subsequent specimen collection to receipt at a state's NBS laboratory.
- **QI5c.i:** Time from specimen receipt at a state's NBS laboratory to reporting out results for time critical disorders.
- **QI5c.ii:** Time from specimen receipt at a state's NBS laboratory to reporting out results for non-time critical disorders.
- **QI5c.iii:** Time from specimen receipt at a state's NBS laboratory to reporting out normal and out-of-range results for all disorders from first specimens.
- **QI5d.i:** Time from birth to reporting out results for time critical disorders.
- **QI5d.ii:** Time from birth to reporting out results for non-time critical disorders.
- **QI5d.iii:** Time from birth to reporting out normal and out-of-range results for all disorders from first specimens.

For more detail on the definitions and data categories for each of these QIs, please refer to the Results and Discussion sections below for each QI.

## Data Collection Mechanisms

Data collection occurred using two methods, depending upon whether a state had a signed MOU with APHL. States with a signed MOU entered data directly into the NewSTEPS Data Repository. States without a signed MOU entered data into an excel spreadsheet designed by NewSTEPS. Alternative forms of data sharing were also accepted on a case-by-case basis in order to accommodate state's needs, including state-developed excel spreadsheets and text documents.

NewSTEPS 360 funded states are required to submit monthly data by the middle of the following month. Monthly QI data for NewSTEPS 360 was collected via the NewSTEPS Data Repository or an excel spreadsheet. Data for January through May 2016 are presented.

Case data are collected voluntarily only by states with a signed MOU. In February 2016, NewSTEPS sent an email notification to all states requesting that all case data for infants born in 2012-2014 and diagnosed with a time critical disorder be entered by May 16, 2016.

All data received via the NewSTEPS Data Repository and excel spreadsheets were cleaned and merged into one dataset. Any data received using custom methods were also merged if the data formatting was appropriate. Tables and plots were developed to assess trends over time.

Annual QI data was analyzed using Chi-Square tests, or Fisher's exact test to account for low cell counts, and Wilcoxon Ranked Sum tests to test associations between QI cut-offs and potential covariates, including lab weekend operating hours, courier service status, lab type (private, state, or regional lab), birth rate (calculated as the number of births per 1,000 women aged 15-44), number of annual births, and whether a state is a one or two screen state. Box plots and bar graphs were developed to assess trends over time.

All cases were stratified by designation as either time critical or non-time critical disorders<sup>4</sup>. Case data was analyzed using Wilcoxon Ranked Sum to test whether timeliness measures for confirmed cases changed from 2012 to 2015. In addition, Wilcoxon Ranked Sum

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<sup>4</sup> Please see [Addendum 3: Table of Time Critical Disorders](#) for a list of disorders categorized as time critical based on ACHDNC recommendations.

was used to test whether cases meeting pre-analytic ACHDNC recommendations led to faster results reporting, and whether meeting analytic ACHDNC recommendations led to faster intervention times. All results are blinded per the APHL MOU with the intent to protect NBS programs from the release of sensitive information. All data management and analysis was performed using SAS version 9.4

## Results & Discussion

### Annual Quality Indicator Responses

Of the 53 NBS programs contacted, 39 (73.6%) submitted annual quality indicator data. Of these, 20 (51.3%) have a signed MOU with NewSTEPS and data was entered directly into the repository. Nineteen (48.7%) NBS programs did not have a signed MOU with NewSTEPS and submitted data using the provided spread sheets or an alternative method. One of these 19 (5.3%) submitted data in a format that could not be merged or interpreted with the larger dataset and is

not included in the results. Therefore, 38 (71.7%) NBS programs are included in the analysis and reporting of the annual QI data. The rate of missing data for each QI is reported in the sections below.

NBS programs that responded to the request are: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana,

#### Understanding Boxplots

Box plots (also referred to as box and whisker plots) are utilized in this section to graphically depict the distribution of data based on five key values: minimum, first quartile, median, third quartile, and maximum. The central rectangle represents the interquartile range (IQR). The bottom line of this rectangle represents the first quartile (Q1) and indicates the value where 25% of the observations lie below. The middle line of the rectangle represents the median and indicates the value where 50% of the observations lie below. The top line of the rectangle represents the third quartile (Q3) and indicates the value where 75% of the observations lie below. Vertical lines, or whiskers, extend from the central rectangle and stop at a lower and upper horizontal line. If no outliers exist in the data, these two lines represent the minimum and maximum values of the distribution. If outliers do exist, these two lines represent the lower and upper bounds of 97.5% of the observations. Outliers, if applicable, are plotted as individual points. The space between the different sections of the box indicate the degree of dispersion (spread) and skewness in the data.

#### Understanding Bar Graphs

Bar graphs are also used in this report to graphically depict each NBS program's performance compared to other NBS programs. Each bar graph represents one year, and each bar represents a specific NBS program across each graph. If there is a blank space for a particular year where a bar exists in another, that particular NBS program did not report any specimens for that year for the QI of interest, or did not collect any specimens within the referenced time frame.

Maine, Minnesota, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

#### Data Requested vs. Data Reported

Of the annual QI data requested, that is listed in the section above, results for QI5a.v and QI5b.ii, which measure time to collection and time to receipt at the state's NBS laboratory for subsequent specimens, are omitted from this report for the following reasons. Firstly, ACHDNC recommendations for timely NBS are focused on improving the process intervals of first specimens collected as these represent the majority of specimens tested, and the process map for first specimens are better documented and more consistent across NBS programs. State efforts have therefore been focused on improving timeliness for first specimens collected. Secondly, inconsistent definitions of "subsequent" specimens and complex processes of collecting subsequent specimens that involve a different set of stakeholders could lead to unreliable data and therefore lead to misinterpretations of the results. QI5a.v and QI5b.ii were omitted from the NewSTEPS 360 results as well for the same reasons.

Quality Indicator 5d.iii: Time from Birth to Reporting out Normal and Out-of-Range Results for all Disorders from First Specimens

**Definition:** Number of first DBS specimens with a normal or out-of-range result for any disorder reported out in the specified time intervals from birth, divided by the total number of first DBS specimens with a normal or out-of-range result for any disorder.

Total number of first DBS specimens with a normal or out-of-range result for any disorder is calculated through the summation of values entered for each time interval category:

- Less than or equal to 48 hours after birth
- Greater than 48 to 72 hours after birth
- Greater than 72 to 96 hours (4 days) after birth
- Greater than 96 hours (4 days) to 120 hours (5 days) after birth
- Greater than 120 hours (5 days) to 144 hours (6 days) after birth
- Greater than 144 (6 days) to 168 hours (7 days) after birth
- Greater than 168 hours (7 days) to 192 hours (8 days) after birth
- Greater than 192 hours (8 days) to 216 hours (9 days) after birth
- Greater than 216 hours (9 days) to 240 hours (10 days) after birth
- Greater than 240 hours (10 days) after birth
- Time elapsed unknown

**ACHDNC Goal: 95% of first specimens with a normal or out-of-range result for any disorder reported out within seven days of birth.**

**Results:** The ACHDNC recommends all NBS test results be reported out within seven days of birth. Twenty-eight NBS programs provided data for at least one year for QI5d.iii. The national median percent of first DBS specimens with normal or out-of-range results for any disorder reported out within seven days of birth increased from 45.4% in 2012 to 59% in 2015 (QI5d.iii – Figure 1).

Twenty-one states (75%) increased the number of specimens with results reported out within seven days (median increase 2.23%). In 2012, 3 of the 27 states (10.7%) reported all normal and out-of-range results for any disorder within seven days of birth for at least 95% of first specimens. Two states (7.1%) met this goal in 2013 and 2014, and five states (17.9%) in 2015 (QI5d.iii – Figure 2). A higher proportion of NBS laboratories open seven days a week achieved

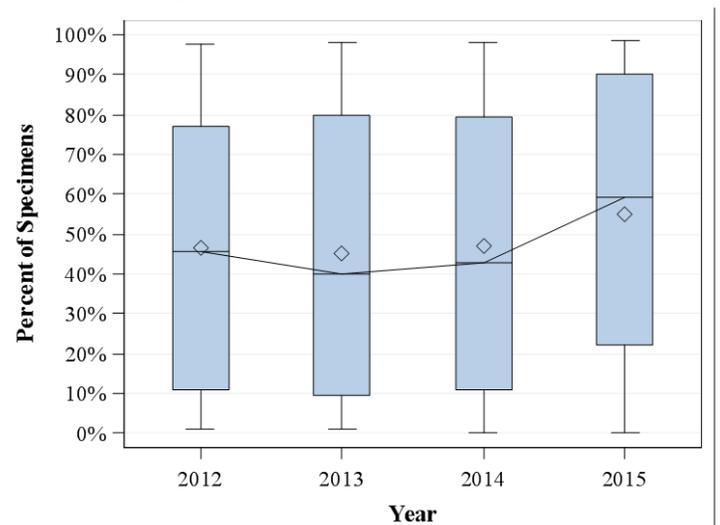
the 95% of specimen reporting goal in 2015, compared to labs who were either open six days (Monday through Saturday) or open only five days (Monday through Friday) (QI5diii – Table 1).

*Discussion:* There has been steady improvement in the percent of NBS results reported within seven days of birth. These data reflect the reporting of all results, including normal and out-of-range results, for all conditions listed on state NBS panels. In most cases, results that require action by a healthcare professional would be called out

earlier than seven days when the final results are complete. There were 21 states that demonstrated an improvement in this QI over the four year period, however it is clear that states are still working toward the goal of reporting results by seven days of life for 95% of first specimens.

This indicator is the summation of all of the components of the NBS system, and allows us to understand the impact of delays that may occur throughout the pre-analytic and analytic processes. Delays in collection, transport, and laboratory processes will result in a delay in the overall time to reporting out results. Programs that successfully report at least 95% of results within seven days likely have similarly strong outcomes in the processes impacting timeliness that precede reporting of results. This points to opportunities for improvement in states who have not yet met the goal of reporting in days. For example, states that have increased NBS laboratory

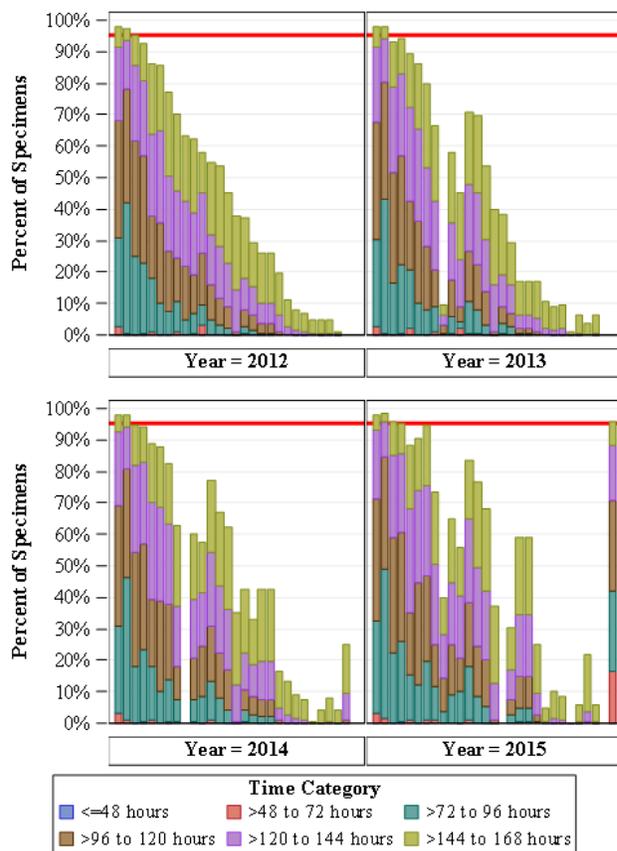
**QI5d.iii—Figure 1:** Distribution of Out-of-Range and Normal Results for All Disorders Reported Out within Seven days of Birth, by Year



Year	N	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2012	27	0.8	11.1	45.4	77.1	97.8
2013	27	1.2	9.5	40.1	79.8	98.1
2014	28	0.0	11.1	42.6	79.6	98.1
2015	27	0.0	22.0	59.0	90.2	98.5

**QI5d.iii - Figure 1:** Aggregate data over the four year period demonstrates that the median percent of first DBS specimens with normal or out-of-range results for all disorders reported out within seven days of life increased from 45.4% to 59%.

**QI5d.iii—Figure 2: Percent of Out-of-Range and Normal Results for All Disorders Reported Out within Seven days of Birth, by Year**



**QI5d.iii - Figure 2:** By 2015, five states (18.5%) had consistently reported all results for at least 95% of first DBS specimens received within seven days of birth. From 2012-2015, 13 states increased the number of specimens reported for this category by at least 2.23%.

operating hours (open additional days) are more likely to reach the 95% timeliness reporting goal. Expanding operating hours to the weekend permits laboratories to receive and process specimens on weekends, run assays, perform repeat screens to confirm out-of-range results and to call out critical results. States vary in terms of which of these activities they perform during weekend operating hours. However, each of these activities can ultimately reduce the time between specimen receipt and calling out of results. This association could only be assessed for the most recent full year of data (2015).

These data represent a snapshot of current trends in the country, and do not imply a causal relationship. Expanding laboratory operating hours is one component of continuous quality improvement that can contribute to

improvements throughout the system. While other factors did not reach statistical significance, improved outcomes in reporting are frequently paired with couriers providing seven day service and improved collection times resulting from educational activities that motivate nursing staff at birthing facilities to collect samples in a timely manner and to utilize provided courier services. Further investigation is warranted to better understand the factors that influence state NBS program data reporting.

**QI5d.iii—Table 1: Association between Lab Weekend Hours and Achieving 95% of Specimen Reporting within Seven Days of Birth for 2015**

Closed Weekends	Open Saturday	Open Saturday and Sunday	p value
0/10 (0%)	1/11 (9.1%)	4/6 (66.7%)	0.004

Limitations: Data reported for QI5d.iii may only include first specimens in some states but include first and subsequent specimens in other states. Additionally, states who perform second mandated screens have expressed concern that combining both screens may result in a longer reporting period as a result of subsequent screens sometimes undergoing different testing than first screens. As a result of the discussions that arose during the Delphi process (please see Background section above), additional indicators were developed to collect time to reporting for subsequent specimens and specimens collected from second screens. Additionally, some state LIMS have difficulties differentiating between data recorded for first specimens and data recorded for subsequent specimens, posing a challenge for personnel to stratify this data and report it separately.

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## Quality Indicator 5a.i: Time from Birth to First DBS Specimen Collection

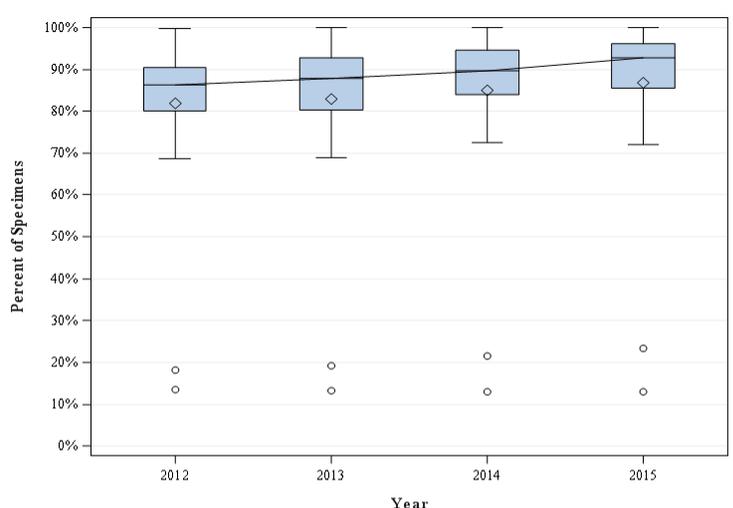
**Definition:** Number of first DBS specimens collected in the specified time intervals from birth, divided by the total number of first DBS specimens collected.

Total number of first DBS specimens collected is calculated through the summation of values entered for each time interval category:

- Less than 12 hours from birth
- 12 to 24 hours from birth
- Greater than 24 to 48 hours from birth
- Greater than 48 to 72 hours from birth
- Greater than 72 hours from birth
- Time elapsed unknown.

**ACHDNC Goal: 95 % of specimens should be collected within 48 hours of birth.**

**QI5a.i—Figure 1: Distribution of First DBS Specimens Collected within 48 hours of Birth, by Year**



Year	N Obs	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2012	33	13.5	80.1	86.3	90.4	99.8
2013	33	13.2	80.4	87.8	92.8	99.9
2014	35	13.0	84.0	89.6	94.5	100
2015	35	13.0	85.6	92.8	96.6	99.9

**QI5a.i - Figure 1:** Aggregate data over the four year period demonstrates that the national median percent of first DBS specimens collected within 48 hours of birth increased from 86.3% to 92.8%, but the interquartile range may indicate room for improvement as 25% of states reported collecting 85.6% of first specimens or less within 48 hours from birth by 2015.

**Results:** The ACHDNC recommends that first DBS specimens be collected in the appropriate timeframe for the condition, but no later than 48 hours after birth. Thirty-five (87.5%) NBS programs provided data for at least one year for QI5a.i. The national median percent of first DBS specimens collected within 48 hours of birth increased from 86.3% in 2012 to 92.8% in 2015. By 2015, the bottom quartile of NBS programs reported collecting at least 85.6% of first DBS specimens within 48 hours

of birth (QI5a.i – Figure 1).

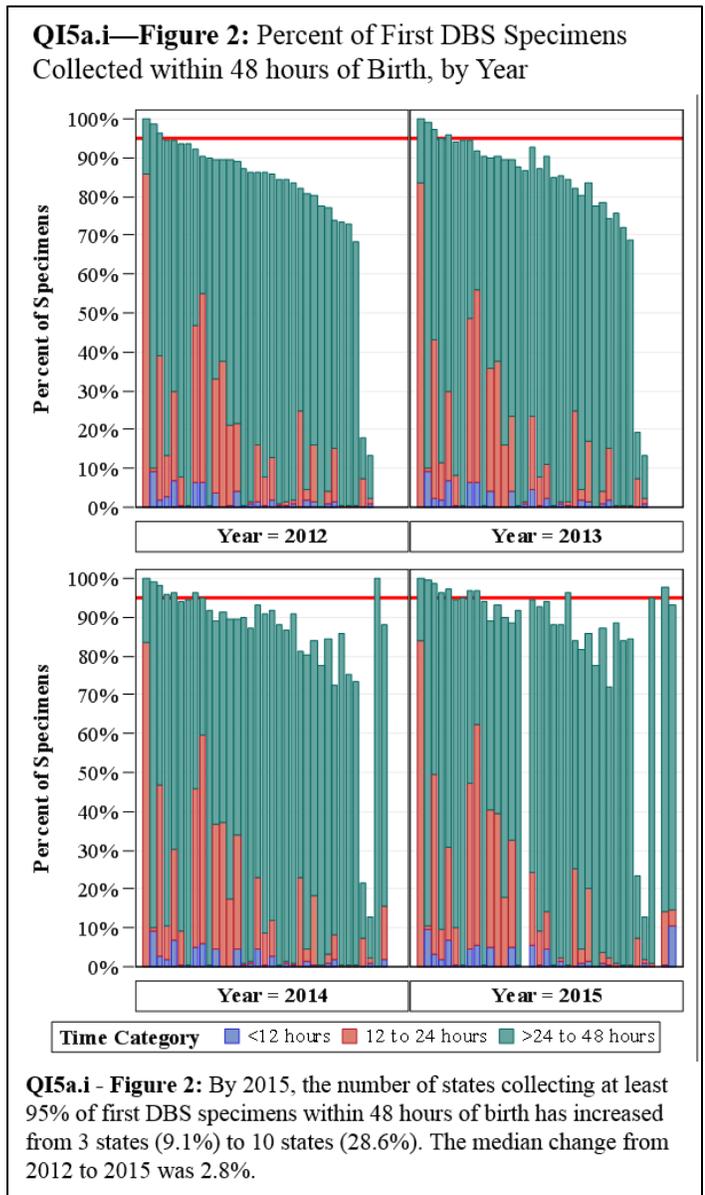
Three states (9.1%) met the goal in 2012 (collecting at least 95% of first DBS specimens within 48 hours of birth), and this increased to 10 states (28.6%) in 2015 (QI5a.i – Figure 2). Twenty-seven (71.1%) of 38 states increased the number of first DBS specimens collected within

48 hours of birth over the four year period (median increase was 2.79%). There were no associations found with lab weekend operating hours, courier service status, lab type, birth rate, annual births, or whether a state is a one or two screen state.

Discussion: Specimen collection times have gradually improved, and in 2015, 10 states achieved the goal of collecting at least 95% of first DBS specimens within the ACHDNC recommended time frame. While this is a great improvement, change is slow, highlighting the need for NBS programs to partner with birthing facilities and midwives to make improvement in this metric.

The relationship between NBS programs and birthing centers or midwives who collect DBS specimens is critical to improving the time to collection. NBS programs may indirectly affect collection times through education initiatives, including the development of videos and brochures provided to hospital staff and midwives emphasizing the importance of timely collection and shipment of DBS specimens.

Most state regulations specify DBS collection time within a particular time frame, however, some require that specimen collection occurs at least 48 hours after birth. Such laws prevent NBS programs from collecting samples during the recommended time frame. Additionally, the current recommendations may result in specimen collection prior to 24 hours



under the assumption that earlier collection is better. However, the impact of earlier collection (prior to 24 hours after birth) is not well understood.<sup>5</sup> Early collection may adversely affect both the sensitivity and the positive predictive value of test results for a particular analyte. Further analyses are being performed on this as part of the NewSTEPs 360 project.

*Limitations:* There remains variability in data collection methods across states. Some NBS programs only record the first satisfactory specimen received at the laboratory while others record the first specimen received, whether satisfactory or not. The former approach will result in longer collection times for a subset of the specimens. Additionally, infants initially screened out-of-state that receive a subsequent screen in-state are included as first specimens by some states and may falsely increase collection times for a small subset of specimens. Finally, collection times can only be recorded for specimens that are received at the NBS laboratory and cannot account for lost or destroyed specimens; however, instances of this outcome are not anticipated to differ by state.

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<sup>5</sup> Tang, H. (2015, December 10). Damaged goods?: An empirical cohort study of blood specimens collected 12 to 23 hours after birth in NBS in California. Retrieved August 02, 2016, from <http://www.nature.com/gim/journal/v18/n3/abs/gim2015154a.html>

## Quality Indicator 5b.i: Time from First Specimen Collection to Receipt at a State’s NBS Laboratory

**Definition:** Number of first DBS specimens received at state’s NBS laboratory in the specified time intervals from specimen collection, divided by the total number of first DBS specimens received at your state’s NBS laboratory.

Total number of first DBS specimens received is calculated through the summation of values entered for each time interval category:

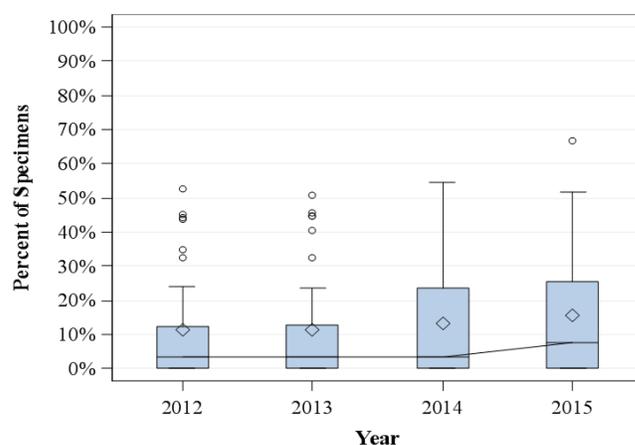
- Less than or equal to 24 hours after specimen collection
- Greater than 24 to 48 hours after specimen collection
- Greater than 48 to 72 hours after specimen collection
- Greater than 72 to 96 hours (4 days) after specimen collection
- Greater than 96 (4 days) to 120 hours (5 days) after specimen collection
- Greater than 120 (5 days) to 144 hours (6 days) after specimen collection
- Greater than 144 hours (6 days) after specimen collection
- Time elapsed unknown

**ACHDNC Goal: 95 % of specimens should be received at the state’s NBS laboratory within 24 hours of specimen collection.**

**Results:** The ACHDNC recommends that first DBS specimens should be received at the NBS laboratory as soon as possible, but ideally within 24 hours of collection. Thirty-four (87.2%) NBS programs provided data for at least one year for QI5b.i. The percent of first DBS specimens that were received at the state’s NBS laboratory within 24 hours of collection is presented in QI5b.i – Figure 1. The national median percent of first DBS specimens received at the laboratory within 24 hours of specimen collection increased from 3.4% in 2012 to 7.4% in 2015 (QI5b.i – Figure 1). Recognizing that the 24 hour benchmark is an ambitious goal, we also assessed the data using a 48 hour benchmark.

The national median percent of DBS specimens received at the state’s NBS laboratory within 48 hours increased from 36.2% in 2012 to 53.1% in 2015 (QI5b.i – Figure 2).

**QI5b.i—Figure 1:** Distribution of First DBS Specimens Received at the NBS Laboratory within 24 hours of Collection, by Year

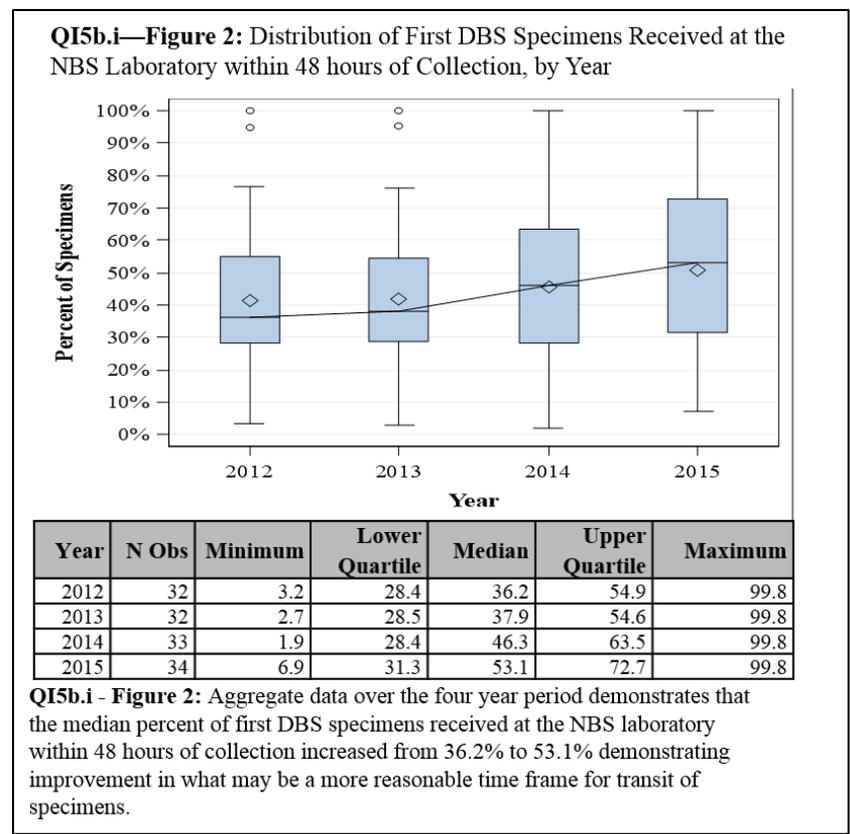


Year	N Obs	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2012	32	0.0	0.0	3.4	12.1	52.8
2013	32	0.0	0.0	3.5	12.9	50.7
2014	33	0.0	0.2	3.4	23.5	54.7
2015	34	0.0	0.2	7.4	25.6	66.6

**QI5b.i - Figure 1:** Aggregate data over the four year period demonstrates that the median percent of first DBS specimens received at the NBS laboratory within 24 hours of collection only reached 7.4% by the end of 2015 indicating that transit processes may be an area that deserves attention if states are to meet ACHDNC’s recommendations on transit times.

Two NBS laboratories consistently received at least 95% of first DBS specimens within 48 hours of collection and no (0%) NBS laboratories received at least 95% specimens within 24 hours of collection (Q15b.i – Figure 3). Twenty-six of 34 states (76.5%) increased the number of first DBS specimens received at the lab within 48 hours of collection (median increase was 3.7%) over the four year period. There were no associations found with lab weekend operating hours, courier service status, lab type, birth rate, annual births, or whether a state is a one or two screen state.

*Discussion:* Specimen receipt times have gradually improved since 2012, and the improvement is more apparent when examining the number of specimens received within 48 hours



after collection. The ACHDNC recommendation is laudable, but may be an unreasonable goal based on the small proportion of specimens that are delivered within 24 hours across all reporting NBS programs. There are several opportunities for improvement to achieve optimal times of specimen receipt by labs. The Clinical and Laboratory Standards Institute (CLSI)<sup>6</sup> has developed a guideline that

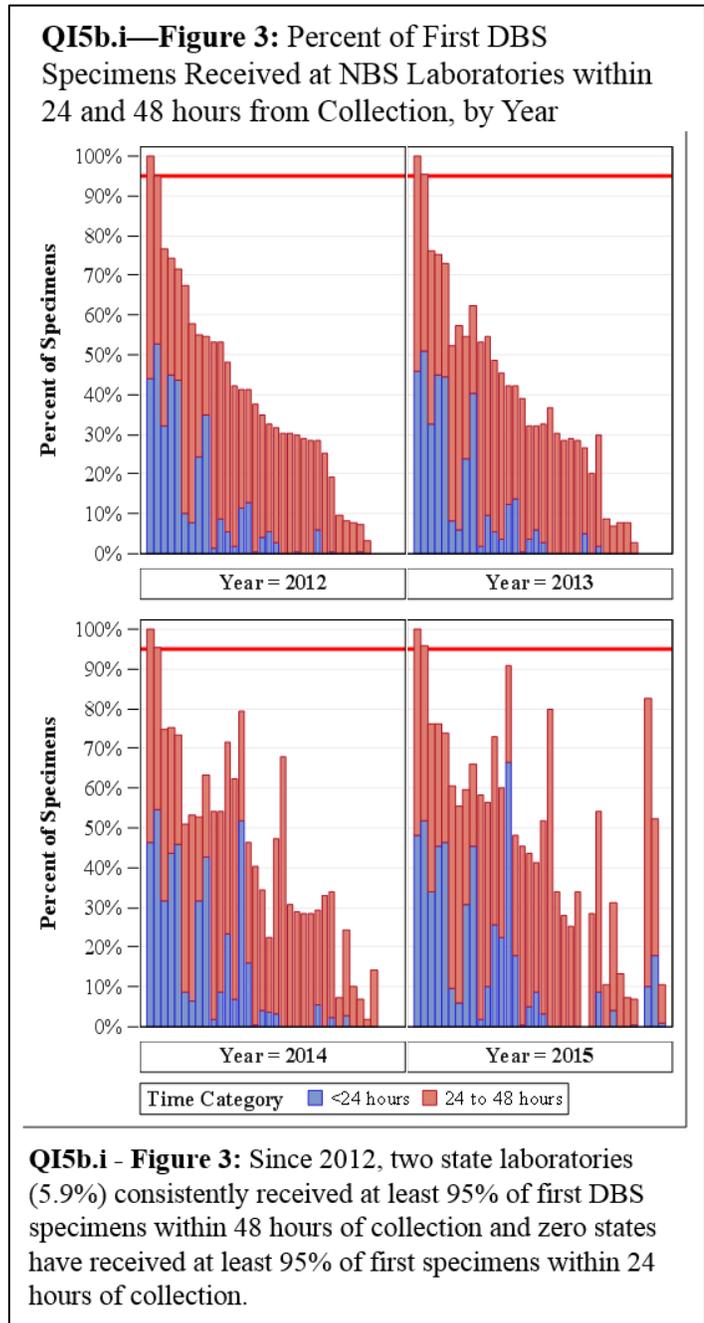
describes the correct procedures to ensure DBS specimens arrive at the NBS laboratory in a quality and timely manner. The guideline includes how long to dry the filter paper and how to package

<sup>6</sup> Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fifth Edition. CLSI document LA4-A5 (ISBN 1-56238-644-1). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007).

the filter paper for transport to the NBS laboratory. Historically, some birthing facilities have batched specimens for shipping at a later date, and in some cases confusion occurs at the birthing facility when locations for pickups are not clearly communicated.

DBS specimens are transported to the NBS laboratory in various ways that include state provided courier services, commercial courier services (e.g. UPS, FedEx) and United States Postal Service (USPS) mail. Courier services can be efficient methods of transport and may provide the fastest transit times. Some states provide courier services for all birthing facilities while others recommend that birthing facilities utilize a commercial courier, but do not actually provide the service, and some states may use a mixture of both. State provided courier services come at an increased cost to NBS programs and may not be provided equitably to smaller/rural birthing facilities or out-of-hospital births. Commercial couriers can be a cost effective and an equitable solution to transporting specimens, but may offer less flexibility and rigid schedules. For instance, after a shipment of specimens is picked up, it may be sent out-of-state to a regional distribution center prior to being shipped to the state lab, adding time to the shipment process.

Laboratory operating hours and courier service days can also affect transit time. Expanding a state courier service to pick-up and deliver specimens on Saturdays can reduce time to receipt at



the laboratory, but as shown above in the discussion for QI5d.iii, if the state lab is not open Saturdays to process shipments and to test specimens, expanding the courier service may not result in reduced transit times. It is important for NBS laboratories to develop a plan that accounts for expanded courier service days, operating hours, personnel time, and budgeting appropriately to account for the increased costs that may accompany these changes.

Limitations: Quality Indicator 5b.i is challenging to collect consistently across NBS programs due to the variability of how programs record time of specimen receipt at the laboratory. Some NBS programs record the date of specimen receipt, but not the time, resulting in a rounded calculation in units of days instead of hours. In turn, this also affects the calculation of specimen receipt to reporting of results (Quality Indicator 5c). Additionally, variation exists in how each state defines when a specimen is received at the lab, including the time a specimen is delivered by courier, a specimen is logged into the LIMS system, or testing of the specimen is initiated. In order to better understand this variation, the NewSTEPS Data Repository now collects information on how a state defines specimen receipt at the NBS lab. The field was added to the repository in June 2016, therefore it is not yet possible to stratify the results by these categories of collection.

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Quality Indicator 5c.iii: Time from Specimen Receipt at a State’s NBS Laboratory to Reporting out Normal and Out-of-Range Results for all Disorders from First Specimens

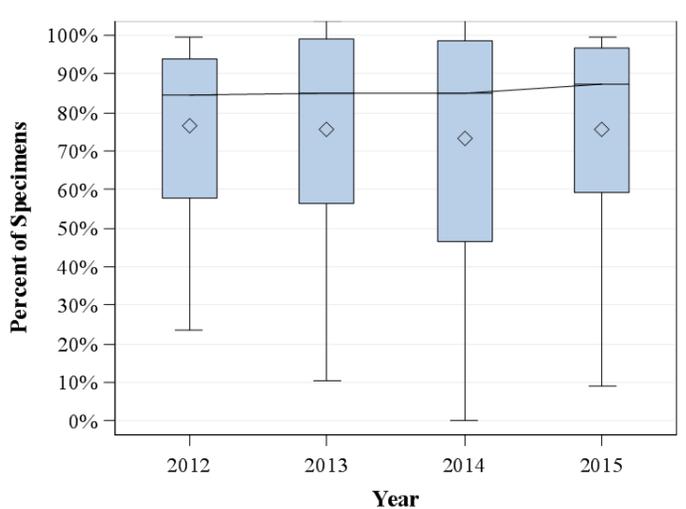
*Definition:* Number of first DBS specimens with a normal or out-of-range result for any disorder reported out in the specified time intervals from specimen receipt at your state’s NBS laboratory, divided by the total number of first DBS specimens with a normal or out-of-range result for any disorder.

Total number of first DBS specimens with a normal or out-of-range result for any disorder is calculated through the summation of values entered for each time interval category:

- Less than 12 hours after receipt
- 12 to 24 hours after receipt
- Greater than 24 to 48 hours after receipt
- Greater than 48 to 72 hours after receipt
- Greater than 72 to 96 hours (4 days) after receipt
- Greater than 96 (4 days) to 120 hours (5 days) after receipt
- Greater than 120 (5 days) to 144 hours (6 days) after receipt
- Greater than 144 hours (6 days) after receipt
- Time elapsed unknown

**ACHDNC Goal: 95% of specimens with a normal or out-of-range result for any disorder reported out within four days of receipt.**

**QI5c.iii—Figure 1:** Distribution of Out-of-Range and Normal Results for All Disorders Reported Out within Four days of Specimen Receipt, by Year



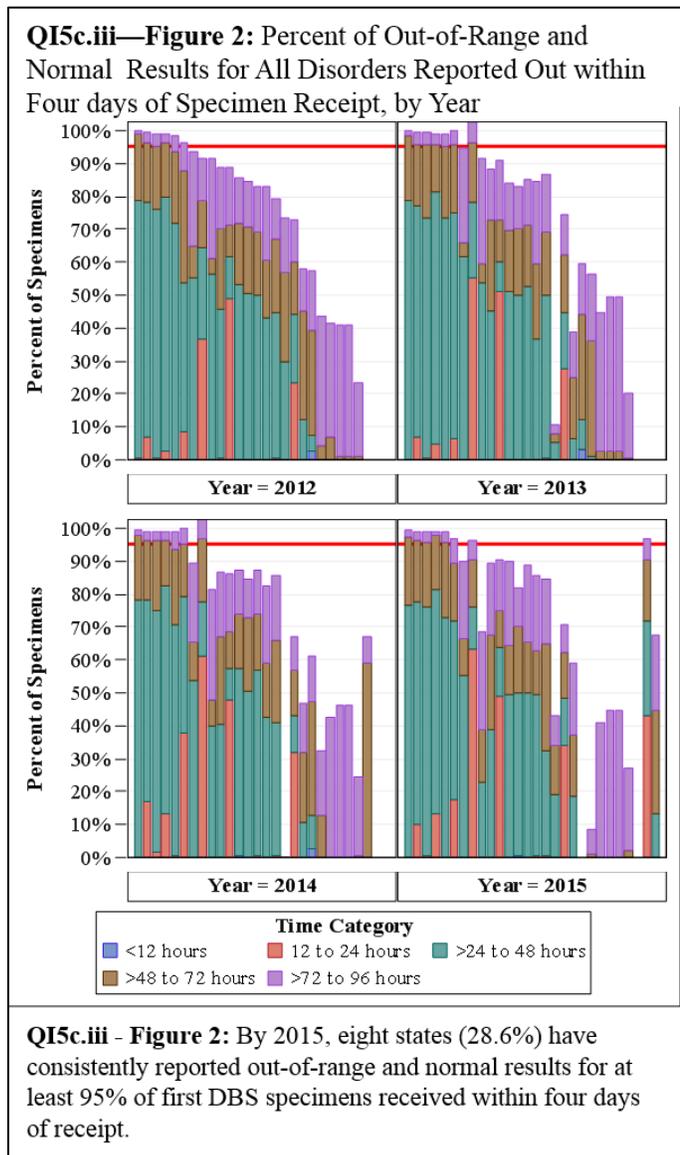
Year	N	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2012	25	23.6	57.8	84.6	93.7	99.7
2013	25	10.5	56.4	85.1	99.1	104.1
2014	26	0.0	46.7	85.0	98.8	104.9
2015	26	8.8	59.0	87.3	96.7	99.3

**QI5c.iii - Figure 1:** Aggregate data over the four year period demonstrates that the median percent of first DBS specimens with normal or out-of-range results for all disorders reported out within four days of receipt increased from 84.6% to 87.3%.

*Results:* The ACHDNC recommends all NBS tests results for any disorder be reported out within seven days of life. In accordance with the recommendations on collection (48 hours) and specimen receipt (24 hours), this equates to approximately four days after receipt. For the purposes of this report, four days will be used as the goal for this quality indicator, recognizing that this is an extrapolation from the current recommendations. Twenty-six

(66.7%) NBS programs provided data for at least one year for QI5c.iii. The national median percent of first DBS specimens with normal or out-of-range results for any disorder reported out within four days of receipt slightly increased from 84.6% in 2012 to 87.3% in 2015 (QI5c.iii – Figure 1).

In 2012, 6 of the 26 states (23.1%) reported all normal and out-of-range results for any disorder within four days of receipt for at least 95% of first specimens received, as did seven (26.9%) in 2013 and 2014, and eight (30.8%) in 2015 (QI5c.iii – Figure 2). For the year 2015, a higher proportion of NBS laboratories open Monday through Saturday achieved the 95% of specimen reporting goal (25%) than did NBS laboratories open Monday through Friday (12.5%), and a higher proportion of NBS laboratories open seven days a week achieved the 95% of specimen reporting goal than both the previous groups (66.7%) (QI5c.iii – Table 1).



**Discussion:** The strength of QI5c.iii is the ability to account for any delays that occur at the laboratory once the specimens are received. Longitudinal depictions of the data show little

**QI5c.iii—Table 1: Trend between Lab Weekend Hours and Achieving 95% of Results Reporting within Four Days of Specimen Receipt for 2015**

Closed Weekends	Open Saturday	Open Saturday and Sunday	p value
1/8 (12.5%)	3/12 (25%)	4/6 (66.7%)	0.119

change over the four year period, but sustained high median values of 84.6% to 87.3% reflect NBS programs’ priority to report test results as quickly as possible once the specimens are received at the lab and to avoid any delays that could be attributed to

laboratory processes. By 2015, the number of states reporting all results for at least 95% of specimens within four days of receipt increased to eight. Similar to the results for QI5d.iii discussed previously, laboratory weekend operating status showed an upward stepwise trend with reaching the 95% goal in 2015. This could be attributable to several levels of activities that can occur during weekend operation including receiving specimens, testing specimens, reporting results, and running repeat tests to confirm out-of-range results. States vary in terms of which of these activities they perform during weekend operating hours. Optimally, a state would be performing the full spectrum of activities from receiving specimens to reporting results, but even a minimum of receiving specimens and performing data entry of demographic information can reduce the workload for staff on Mondays so that specimens can be tested and results reported sooner. These data are just a snapshot of the current trends in the country and do not imply a causal relationship. This trend could not be assessed for all years as laboratory weekend operating status as collected in the NewSTEPS Repository is only representative of the most recent full year elapsed, in this case 2015. Further investigation is warranted into this trend.

*Limitations:* Data reported for QI5c.iii may only include first specimens in some states and include first and subsequent specimens in other states. Additionally, states who perform second mandated screens have expressed concern that combining both screens may result in a longer reporting period as subsequent screens may be tested differently than first screens. As a result of the discussions that arose during the Delphi process, additional indicators were developed to collect time to reporting for subsequent specimens and specimens collected from second screens. Data collection for these additional indicators has not yet begun. Additionally, some state LIMS have difficulties differentiating between data recorded for first specimens and data recorded for subsequent specimens, making it difficult for personnel to stratify this data and report it separately.

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Case Data: Timeliness Outcomes from Confirmed Cases entered into the NewSTEPS Repository.

**Results:** As of June 30, 2016, 19 of 29 states (65.5%) with a signed MOU have entered public health surveillance case data for 3,358 infants with a confirmed diagnosis of a disorder initially detected

by NBS. Of these infants, 652 (19.4%) were diagnosed with a time-critical disorder<sup>7</sup> and 2,706 (80.6%) were diagnosed with a non-time critical disorder. For all infants, the median time elapsed from

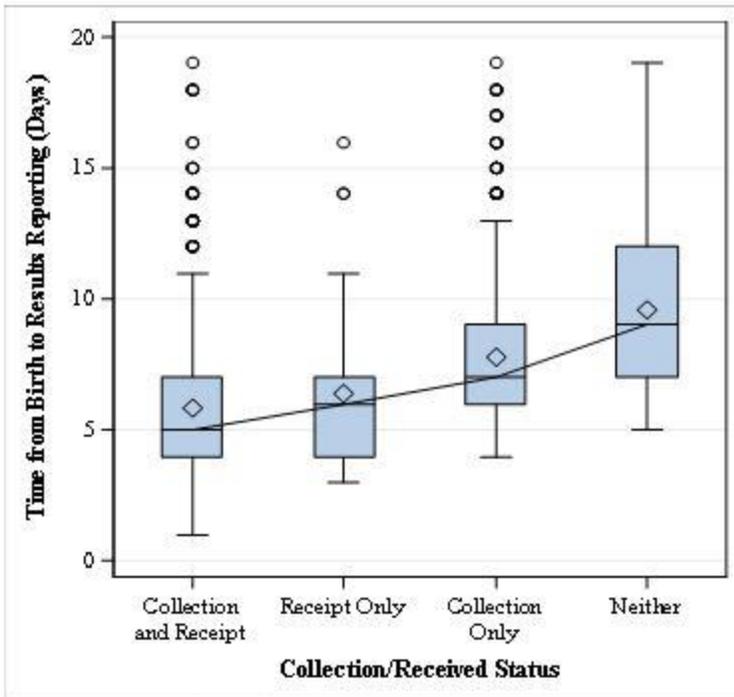
<b>Case Data - Table 1: Timeliness Metrics Improve from 2012 to 2015 in Infants Diagnosed with a Condition Identified by NBS</b>			
	<b>2012</b>	<b>2015</b>	<b>p value</b>
	n = 562	n = 785	
	<i>Median (IQR)</i>	<i>Median (IQR)</i>	
<b>Birth to Collection (Hours)</b>	35 (25 - 48)	26 (24 - 37)	<0.0001
<b>Collection to Receipt (Hours)</b>	69.6 (45.6 - 96.0)	48.0 (24.0 - 72.0)	<0.0001
<b>Time Critical Disorders</b>			
Birth to Report Out (Days)	6 (4 - 7)	6 (4 - 7)	0.229
Birth to Intervention (Days)	6 (4 - 10)	7 (4 - 11)	0.473
<b>Non-Time Critical Disorders</b>			
Birth to Report Out (Days)	7 (6 - 8)	6 (5 - 8)	0.0001
Birth to Intervention (Days)	23 (9 - 45)	19 (8 - 36)	0.005

birth to initial specimen collection significantly decreased from 35 hours to 26 hours between 2012 and 2015 ( $p < 0.0001$ ), supporting findings from the [quality indicator data](#). The median time elapsed from initial specimen collection to receipt at the laboratory significantly decreased from almost 70 hours to 48 hours ( $p < 0.0001$ ), and 25% of specimens were received within 24 hours in 2015 (Case Data – Table 1).

Each specimen was classified into one of four groups to describe the joint effects on the outcomes of reporting, evaluation, and diagnosis: 1) met recommendations for collection (within 48 hours of birth) and receipt by lab (within 24 hours of collection); 2) met recommendation for receipt by lab only; 3) met recommendation for collection only; or 4) met neither recommendation.

<sup>7</sup> Please see [Addendum 3: Table of Time Critical Disorders](#) for a list of disorders categorized as time critical based on ACHDNC recommendations.

**Case Data - Figure 1: Stepwise improvement of result reporting times based on meeting collection and/or receipt recommendations.**



Collection/Received Status	N	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	1400	1.0	4.0	5.0	7.0	19.0
2	53	3.0	4.0	6.0	7.0	16.0
3	1327	4.0	6.0	7.0	9.0	19.0
4	362	5.0	7.0	9.0	12.0	19.0

Results from specimens that were both collected within 48 hours of birth and received at the laboratory within 24 hours of collection were reported out by a median of five days of birth. Results were reported out by a median of six days of birth only if the receipt recommendation was met, and results were reported out by a median of seven days of birth if only the collection recommendation was met. Results from specimens that met neither recommendation were reported out by a median of nine days of birth (Case Data - Figure 1).

For infants diagnosed with a time critical disorder, there was no change in time elapsed from birth to reporting out results with a median of six days in both 2012 and 2015, nor

in the median time elapsed from birth to appropriate medical intervention (six days in 2012 and seven days in 2015). For infants diagnosed with a non-time critical disorder, median time elapsed from birth to reporting out results decreased from seven days in 2012 to six days in 2015 ( $p = 0.0001$ ), and the median time elapsed from birth to appropriate medical intervention decreased from nine days in 2012 to eight days in 2015 ( $p = 0.005$ ) (Case Data – Table 1).

Over the four year period, specimens collected within 48 hours of birth were received at the NBS laboratory significantly faster compared to those collected after 48 hours from birth (median of four days vs. six days from birth,  $p < 0.0001$ ), and test results were also reported out significantly faster for specimens collected within 48 hours (median of six vs. nine days from birth,  $p < 0.0001$ ). Results for specimens received at the laboratory within 24 hours of collection

were also reported out significantly faster compared to those specimens received at the laboratory after 24 hours from collection (median of five days vs. seven days after birth,  $p < 0.0001$ ).

Recognizing that the recommendation for the timeline from collection to receipt of 24 hours might be an ambitious goal, we also examined the reporting out of outcomes for specimens received within 48 hours of collection. Results were reported out significantly earlier for specimens received within 48 hours of collection compared to those received after 48 hours from collection (median of six vs. seven days comparatively).

Infants who screened positive for a time critical disorder and whose specimen results met the ACHDNC recommendations for reporting out within five days of birth received appropriate medical intervention at a younger age compared to those whose specimen results were reported out after five days of birth (Median of five days vs. eight days,  $p < 0.0001$ ). Infants who screened positive for a non-time critical disorder and whose specimen results met the ACHDNC recommendations for reporting within seven days of birth received appropriate medical intervention significantly faster compared to those whose specimen results were reported out after seven days of birth (Median of 18 days vs. 23 days,  $p < 0.0001$ ).

*Discussion:* The overarching goal of all NBS activities is to identify infants at-risk for a disorder and initiate intervention in a timely manner so adverse outcomes can be avoided. Case level data allows us to assess the timeliness of each step of the NBS process using continuous measures derived from infants with a confirmed diagnosis. The data collected thus far demonstrates a reduction in the time elapsed from birth to specimen collection and birth to specimen receipt, and a correlation between timely collection and receipt with earlier ages at clinical intervention.

Most of these infants were born prior to the issuance of the ACHDNC recommendations in 2015; however, even in the absence of the recommendations, results were released for non-time critical disorders within the recommended period of seven days in 2012, improving to six days in 2015. Time from birth to medical intervention in the non-time critical disorders has significantly improved from a median of 23 days in 2012 to 19 days in 2015. We did not observe a change in the report out or the medical intervention time for infants with a time-critical disorder, however both are close to the ACHDNC recommendation of five days.

Appropriate and timely medical intervention is a key component to saving an infant's life and/or preventing a lifetime of severe disabilities. The results show the emphasis NBS programs place on providing both timely identification of infants at-risk for conditions and notification of an appropriate healthcare professional. NBS programs that are able to achieve the goals for timely collection and timely transit are more likely to report out-of-range test results by five days of life no matter the disorder category. This is an important finding as it supports outcomes from the annual quality indicator data emphasizing that key components to successful timely NBS lie in the pre-analytic phase, specifically collection and transit.

*Limitations:* The data reported here may not represent the complete case burden for each state. NBS programs entered cases based on specific requests from the NewSTEPs program, and data collection may not yet be complete. Numerous NBS programs entered a very high proportion of their diagnosed cases (near 100%) across all of the NBS disorders, while others may have only entered cases for a specific disorder. We did not find a significant association with case level timeliness data and individual NBS programs, however it is possible that there is an underlying relationship that we did not have the statistical power to detect. States who are able to achieve timeliness goals may be more likely to enter case level data and this may bias our results in a positive direction. Some states only entered case level data for 2015 which may influence conclusions. Future analyses with larger datasets once case accrual is complete are necessary.

## Conclusion

As discussed previously, longitudinal depictions of QI5c.iii show little improvement over the four year period, but sustained high median values of 84.6% to 87.3% reflect NBS programs priority to report test results as quickly as possible once the specimens are received at the lab and avoid any delays that could be attributed to laboratory processes. In contrast, lower median values for QI5d.iii of 45.4% in 2012 to 59% in 2015 may indicate that pre-analytic processes including collection and transit of specimens should be areas of focus for improving the timely reporting of results. More specifically, low median values of specimens received at the laboratory within 48 hours of collection for QI5b.i may indicate that future activities for improving timeliness in NBS should be centered on finding novel solutions to improving specimen transit times. However, the answer to improving timeliness for struggling programs may be to investigate the possibility of

expanding operating hours to the weekend, which could result in reduced time to reporting out results by expediting both pre-analytic and analytic processes, but at higher budgetary costs. Case level data support that meeting ACHDNC pre-analytic recommendations leads to faster report out times, and meeting ACHDNC report out recommendations leads to faster intervention, therefore decreasing the potential risk of harm to newborns diagnosed with a disorder detected by NBS.

NewSTEPS plans to continue to support the improvement of timeliness in NBS through technical assistance provided by the program, the NewSTEPS 360 project, and continued data collection in the NewSTEPS Data Repository. NewSTEPS 360 is a three year cooperative agreement funded by HRSA to the ColoradoSPH in collaboration with APHL with the objective of improving the timeliness of NBS to increase the number of states that meet the ACHDNC recommendations on timeliness and the number of infants receiving timely diagnosis and treatment. NewSTEPS 360 currently supports 20 NBS programs via financial and technical assistance support and looks to add five new programs to the project by September 2016<sup>8</sup>. Beyond NewSTEPS 360, NewSTEPS will continue to provide technical assistance and education to states on best practices to improve timeliness and will begin to provide annual data reports that will include timeliness measures described in this report to aid NBS programs in identifying areas of improvement and highlight areas of success.

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<sup>8</sup> Please see [Addendum 2: NewSTEPS 360](#) for detailed information about this project.

## Addendum 1: Additional Annual Quality Indicator Results and Discussions

### Quality Indicator 5c.i: Time from Specimen Receipt at a State's NBS Laboratory to Reporting out Results for Time Critical Disorders

**Definition:** Number of DBS specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional, for time critical disorders, reported out in the specified time intervals from specimen receipt at your state's NBS laboratory, divided by the total number of DBS specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional for time critical disorders.

Total number of DBS specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional for time critical disorders is calculated through the summation of values entered for each time interval category:

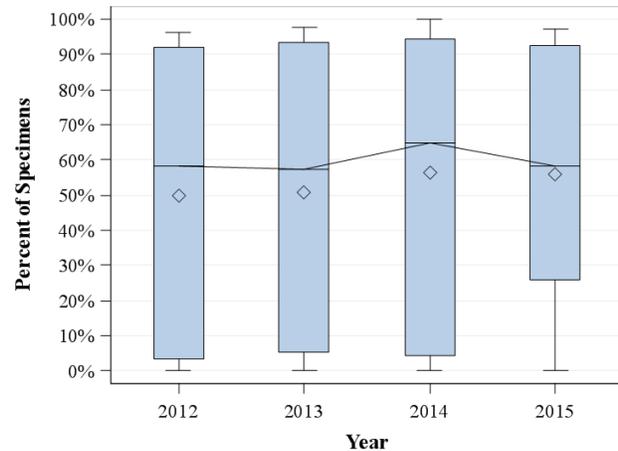
- Less than 12 hours after receipt
- 12 to 24 hours after receipt
- Greater than 24 to 48 hours after receipt
- Greater than 48 to 72 hours after receipt
- Greater than 72 to 96 hours (4 days) after receipt
- Greater than 96 (4 days) to 120 hours (5 days) after receipt
- Greater than 120 (5 days) to 144 hours (6 days) after receipt
- Greater than 144 hours (6 days) after receipt
- Time elapsed unknown

**ACHDNC Goal: 95% of specimens with out-of-range results for time critical disorders requiring clinical diagnostic workup by an appropriate medical professional reported out no later than 48 hours after receipt.**

**Results:** The ACHDNC recommends presumptive positive results for time critical conditions be communicated to the newborn's healthcare provider immediately, but no later than five days of life. In accordance with the recommendations on collection (24-48 hours) and specimen receipt (24 hours), this equates to approximately 48 hours after receipt. For the purposes of this report, 48 hours was used as the goal for this quality indicator, recognizing that this is an extrapolation from the current recommendations.

Sixteen (41%) NBS programs provided data for at least one year for QI5c.i. The percent of specimens with out-of-range results for time critical disorders reported out within 48 hours of receipt remained relatively stable over the four year period and peaked in 2014 at 65% (QI5c.i – Figure 1). There is significant variability in this indicator. Some state NBS programs are able to report out almost all time critical results within 48 hours of receipt while others are unable to

**QI5c.i—Figure 1:** Distribution of Out-of-Range Results for Time Critical Disorders Reported Out within 48 hours of Specimen Receipt, by Year.



Year	N	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2012	15	0.0	3.2	58.3	91.9	96.3
2013	15	0.0	5.2	57.1	93.5	97.6
2014	14	0.0	4.5	65.0	94.3	100.0
2015	16	0.1	25.8	58.1	92.6	97.1

**QI5c.i - Figure 1:** Aggregate data over the four year period demonstrates that the median percent of specimens with out-of-range results for time critical disorders reported out within 48 hours of specimen receipt slightly decreased from 58.3% to 58.1%, but did peak in 2014 at 65%.

report out any results. In 2015, 4 of the 16 states (25%) that submitted data reported results for time critical disorders within 48 hours of receipt for at least 92.6% of DBS specimens received and reached the goal of 95% results reported within 48 hours of receipt in at least one of the four years (QI5c.i – Figure 2). There were no associations found with lab weekend operating hours, courier service status, lab type, birth rate, annual births, or whether a state is a one or two screen state.

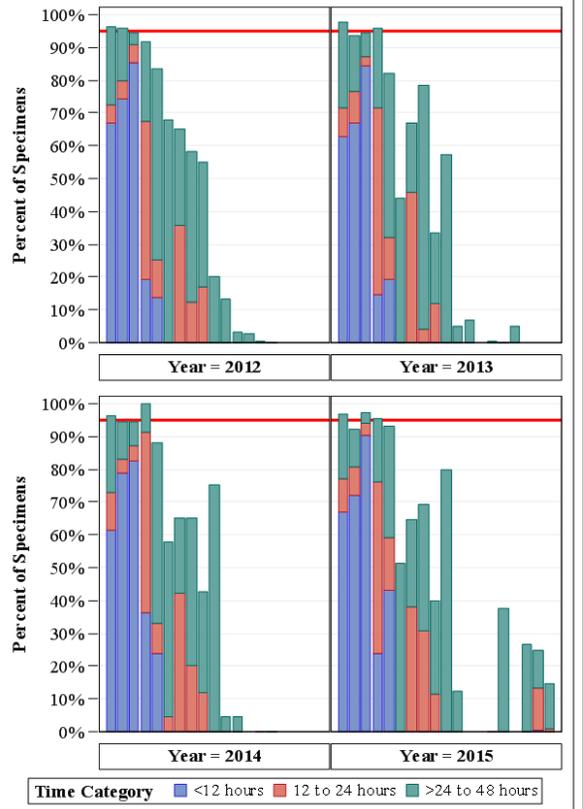
*Discussion:* While the data shows consistent high performance for a few states,

there has been little change in the percent of specimens reported out within 48 hours of DBS specimen receipt and there is wide variability between the states that submitted data. However, caution should be taken when attempting to make inferences based on this data due to the low response rate.

*Limitations:* Response rates were lower than expected for QI5c.i due to limitations of the data recorded in NBS laboratories. Many programs cannot calculate the time elapsed between specimen receipt and result reporting. As described in QI5b.i, the time a specimen was received in the lab is collected in various ways. There are similar challenges in recording the time a result was reported. In some instances, time of report out to a healthcare provider and/or hospital is captured as a note in free text form in the LIMS, and thus cannot be easily queried and extracted from the information system. In these instances, the information requires a staff member to manually sort through DBS cards to record the date.

In addition, many LIMS do not categorize test results by disorder, making it challenging to separate results into time critical and non-time critical categories. This limitation in the system makes it challenging for NBS programs to query the LIMS for time-critical disorder reporting times. Further, many LIMS only record one date corresponding to the time results were reported. The date that all results are complete and the final report is sent to providers is typically the date that is recorded. Therefore, many result reporting times that are extracted from LIMS may be later than the initial time that a critical result was reported out to a clinician.

**QI5c.i—Figure 2:** Percent of Out-of-Range Results for Time Critical Disorders Reported Out within 48 hours of Specimen Receipt, by Year



**QI5c.i - Figure 2:** Since 2012, four states have consistently reported at least 95% of specimens with out-of-range results for time critical disorders within 48 hours of receipt.

## Quality Indicator 5c.ii: Time from Specimen Receipt at a State's NBS Laboratory to Reporting out Results for non-Time Critical Disorders

**Definition:** Number of DBS specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional, for non-time critical disorders, reported out in the specified time intervals from specimen receipt at your state's NBS laboratory, divided by the total number of DBS specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional for non-time critical disorders.

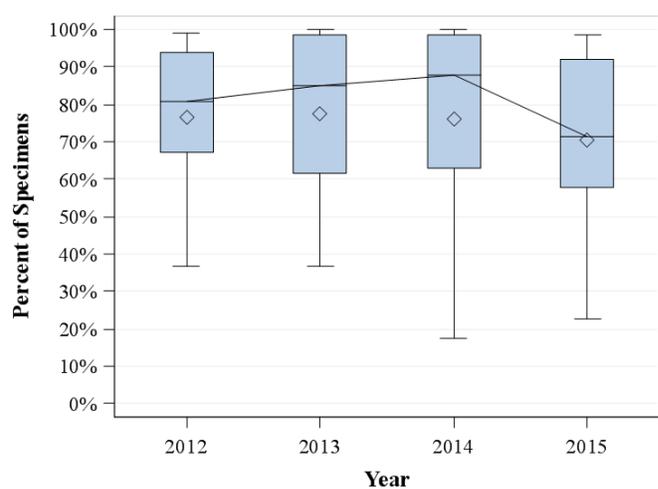
Total number of DBS specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional for non-time critical disorders, is calculated through the summation of values entered for each time interval category:

- Less than 12 hours after receipt
- 12 to 24 hours after receipt
- Greater than 24 to 48 hours after receipt
- Greater than 48 to 72 hours after receipt
- Greater than 72 to 96 hours (4 days) after receipt
- Greater than 96 (4 days) to 120 hours (5 days) after receipt
- Greater than 120 (5 days) to 144 hours (6 days) after receipt
- Greater than 144 hours (6 days) after receipt
- Time elapsed unknown

**ACHDNC Goal: 95% of specimens with out-of-range results for non-time critical disorders requiring clinical diagnostic workup by an appropriate medical professional reported out within four days of specimen receipt.**

**Results:** The ACHDNC recommends presumptive positive results for non-time critical conditions be communicated to the newborn's healthcare provider no later than seven days from birth. In accordance with the recommendations on collection (48 hours) and specimen receipt (24 hours), this equates to approximately four days after receipt. For the purposes of this report, four days was used as the goal for this quality indicator, recognizing that this is an extrapolation from the current recommendations. Fifteen (38.5%) NBS programs provided data for at least one year for QI5c.ii. The median percent of specimens with out-of-range results for non-time critical disorders reported out within four days of receipt decreased from 80.9% to 71.4% over the four year period and peaked in 2014 at 87.9% (QI5c.ii – Figure 1). Four states (26.7%) consistently reported at least 95% of specimens with out-of-range results for non-time critical disorders within

**Q15c.ii—Figure 1:** Distribution of Out-of-Range Results for non-Time Critical Disorders Reported Out within Four days of Specimen Receipt, by Year



Year	N	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2012	14	36.9	67.1	80.9	93.8	99.0
2013	14	36.6	61.7	85.0	98.7	100.0
2014	14	17.6	63.0	87.9	98.4	100.0
2015	15	22.7	58.0	71.4	92.1	98.8

**Q15c.ii - Figure 1:** Aggregate data over the four year period demonstrates that the median percent of specimens with out-of-range results for non-time critical disorders reported out within four days of receipt decreased from 80.9% to 71.4%, but did peak in 2014 at 87.9%.

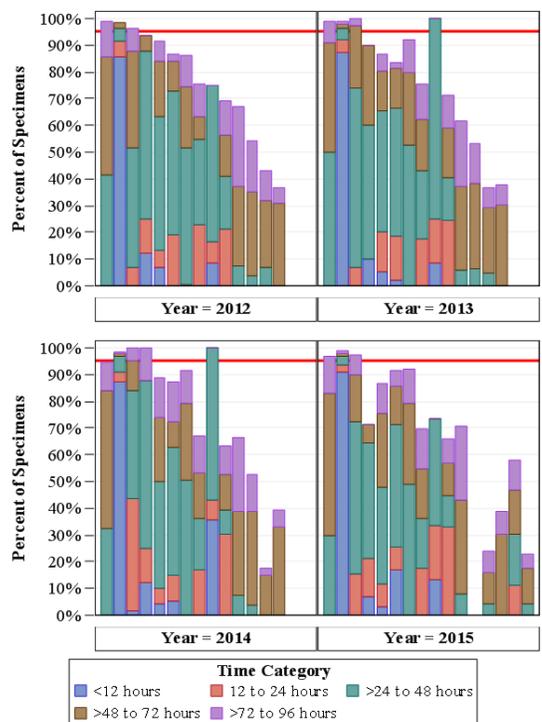
in 2015 seems to be driven by states that only provided data for that year. However, caution should be taken when attempting to make inferences based on this data due to the low response rate.

**Limitations:** Please refer to the limitations section of Q15c.i as the same limitations apply to Q15c.ii.

four days of receipt over the four year period (Q15c.ii – Figure 2). There were no associations found with lab weekend operating hours, courier service status, lab type, birth rate, annual births, or whether a state is a one or two screen state.

**Discussion:** While the data show consistent high performance from a few states, there is wide variability between states in the percent of specimens reported out within four days of receipt, and the downward trend seen

**Q15c.ii—Figure 2:** Percent of Out-of-Range Results for non-Time Critical Disorders Reported Out within Four days of Specimen Receipt, by Year



**Q15c.ii - Figure 2:** Since 2012, four states have consistently reported at least 95% of specimens with out-of-range results for non-time critical disorders within four days of receipt.

## Quality Indicator 5d.i: Time from Birth to Reporting out Results for Time Critical Disorders

**Definition:** Number of DBS specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional, for time critical disorders, reported out in the specified time intervals from birth, divided by the total number of DBS specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional for time critical disorders.

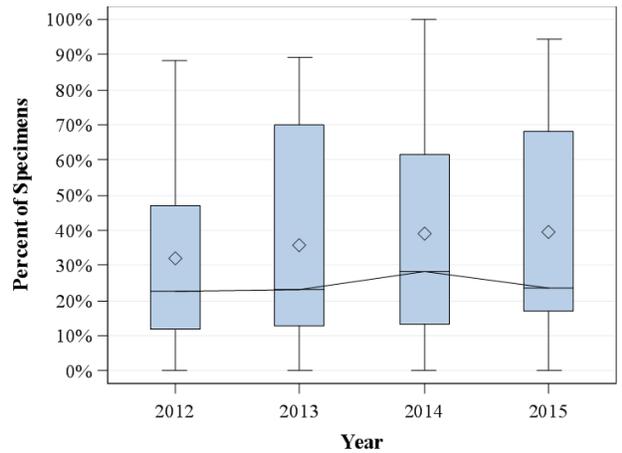
Total number of DBS specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional for time critical disorders is calculated through the summation of values entered for each time interval category:

- Less than or equal to 48 hours after birth
- Greater than 48 to 72 hours after birth
- Greater than 72 to 96 hours (4 days) after birth
- Greater than 96 hours (4 days) to 120 hours (5 days) after birth
- Greater than 120 hours (5 days) to 144 hours (6 days) after birth
- Greater than 144 (6 days) to 168 hours (7 days) after birth
- Greater than 168 hours (7 days) to 192 hours (8 days) after birth
- Greater than 192 hours (8 days) to 216 hours (9 days) after birth
- Greater than 216 hours (9 days) to 240 hours (10 days) after birth
- Greater than 240 hours (10 days) after birth
- Time elapsed unknown

**ACHDNC Goal: 95% of specimens with out-of-range results for time critical disorders requiring clinical diagnostic workup by an appropriate medical professional reported out no later than five days from birth.**

**Results:** The ACHDNC recommends presumptive positive results for time critical conditions be communicated to the newborn's healthcare provider immediately, but no later than five days of life. Sixteen (41%) NBS programs provided data for at least one year for QI5d.i. The median percent of specimens with out-of-range results for time critical disorders reported out within five days of birth showed a slight increase from 22.7% to 23.6% over the four year period and peaked in 2014 at 28.1% (QI5d.i – Figure 1). Two states reported at least 95% of specimens with out-of-range results for time critical disorders within five days of birth by 2014, but no states reached this benchmark in 2015. However, over the four year period, 12 states (75%) have increased the number of specimens with results reported out (median increase 2.64%). (QI5d.i – Figure 2). There were no associations found with lab weekend operating hours, courier service status, lab type, birth rate, annual births, or whether a state is a one or two screen state.

**QI5d.i—Figure 1:** Distribution of Out-of-Range Results for Time Critical Disorders Reported Out within Five days from Birth, by Year



Year	N	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2012	14	0.0	11.9	22.7	46.9	88.4
2013	14	0.0	12.6	22.9	70.1	89.0
2014	15	0.0	13.0	28.1	61.5	100.0
2015	16	0.0	17.0	23.6	68.0	94.2

**QI5d.i - Figure 1:** Aggregate data over the four year period demonstrates that the median percent of specimens with out-of-range results for time critical disorders reported out within five days of birth increased from 22.7% to 23.6%.

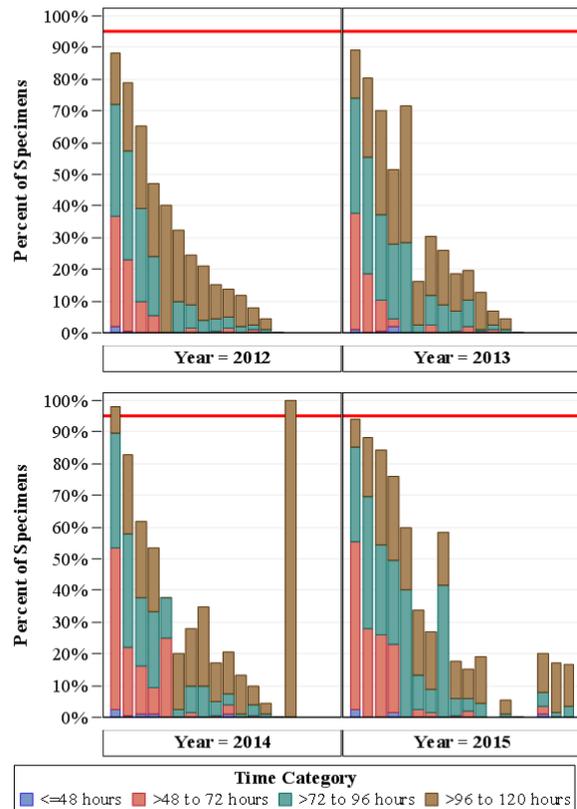
be a better reflection of actual progress towards reporting goals. Prior to the ACHDNC recommendations, there were no guidelines in place. Even in the absence of guidelines, approximately 25% of time-critical results were reported out in the recommended time period.

**Limitations:** Due to the low number of states that were able to provide data for this indicator, caution should be taken when attempting to make inferences based on these data. Please refer to the limitations section of QI5c.i as the same limitations apply to QI5d.i.

**Discussion:** This indicator is arguably

the most critical to monitor as it measures the time from birth to reporting out results for time critical disorders, which is the ultimate goal of NBS programs. While the data show that states have not historically met this recommendation, our data demonstrates it is possible to meet this goal and there has been slow, but consistent improvement over the four year period. The recommendation of five days reporting was not formally endorsed by ACHDNC until 2015, therefore data reported in 2016 and later will

**QI5d.i—Figure 2:** Percent of Out-of-Range Results for Time Critical Disorders Reported Out within Five days of Birth, by Year



**QI5d.i - Figure 2:** By 2014, two states reported at least 95% of DBS specimens with out-of-range results for time critical disorders within five days of birth, but no states reached the benchmark in 2015.

## Quality Indicator 5d.ii: Time from Birth to Reporting out Results for non-Time Critical Disorders

*Definition:* Number of DBS specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional, for non-time critical disorders, reported out in the specified time intervals from birth, divided by the total number of DBS specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional for non-time critical disorders.

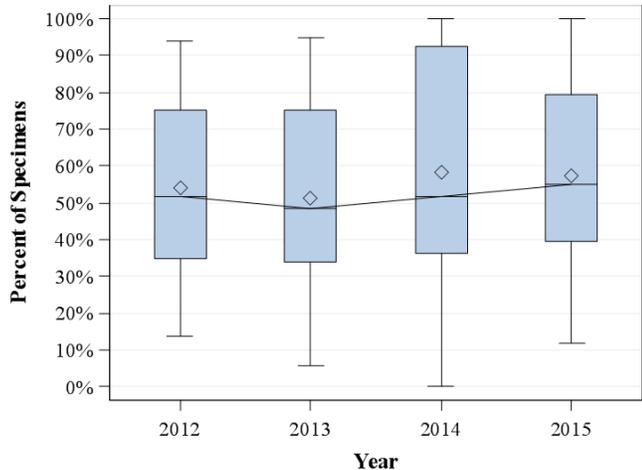
Total number of DBS specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional for non-time critical disorders is calculated through the summation of values entered for each time interval category:

- Less than or equal to 48 hours after birth
- Greater than 48 to 72 hours after birth
- Greater than 72 to 96 hours (4 days) after birth
- Greater than 96 hours (4 days) to 120 hours (5 days) after birth
- Greater than 120 hours (5 days) to 144 hours (6 days) after birth
- Greater than 144 (6 days) to 168 hours (7 days) after birth
- Greater than 168 hours (7 days) to 192 hours (8 days) after birth
- Greater than 192 hours (8 days) to 216 hours (9 days) after birth
- Greater than 216 hours (9 days) to 240 hours (10 days) after birth
- Greater than 240 hours (10 days) after birth
- Time elapsed unknown

**ACHDNC Goal: 95% of specimens with out-of-range results for non-time critical disorders requiring clinical diagnostic workup by an appropriate medical professional reported out no later than seven days from birth.**

*Results:* The ACHDNC recommends presumptive positive results for non-time critical conditions be communicated to the newborn's healthcare provider no later than seven days of life. Sixteen (41%) state NBS programs provided data for at least one year for QI5d.ii. The median percent of specimens with out-of-range results for non-time critical disorders reported out within seven days of life increased from 51.7% to 54.8% (QI5d.ii – Figure 1). Two (12.5%) states consistently reported at least 95% of specimens with out-of-range results for non-time critical disorders within seven days of birth over the four year period. Further, 10 of the 16 states (62.5%) increased the number of specimens reported within seven days of birth by a median of 0.81% of specimens (QI5d.ii – Figure 2). There were no associations found with lab weekend operating

**QI5d.ii—Figure 1:** Distribution of Out-of-Range Results for non-Time Critical Disorders Reported Out within Seven days of Birth, by Year



Year	N	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2012	14	13.8	34.7	51.7	75.0	93.8
2013	14	5.6	33.8	48.5	75.2	94.9
2014	15	0.0	36.1	51.9	92.6	100.0
2015	16	12.0	39.4	54.8	79.2	100.0

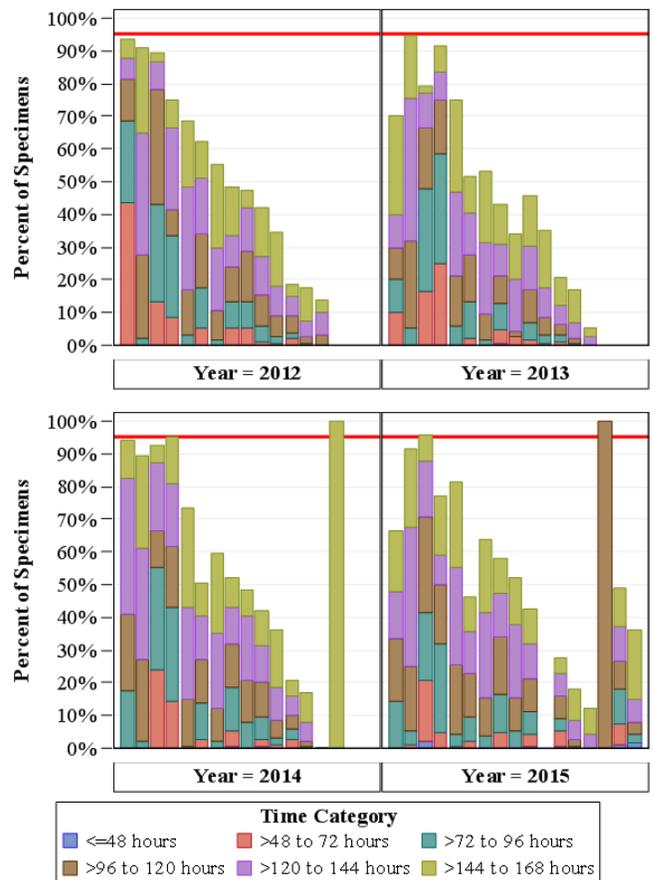
**QI5d.ii - Figure 1:** Aggregate data over the four year period demonstrates that the median percent of DBS specimens with out-of-range results for non-time critical disorders reported out within seven days of birth increased from 51.7% to 54.8%.

**Limitations:** Due to the small number of states reporting data, caution should be taken when attempting to make inferences. Please refer to the limitations section of QI5c.i as the same limitations apply to QI5d.ii.

hours, courier service status, lab type, birth rate, annual births, or whether a state is a one or two screen state.

**Discussion:** While the data shows consistent high performance from a few states, there were 10 additional states that showed improvement over the four year period.

**QI5d.ii—Figure 2:** Percent of Out-of-Range Results for non-Time Critical Disorders Reported Out within Five days of Birth, by Year



**QI5d.ii - Figure 2:** By 2015, two states (12.5%) reported at least 95% of DBS specimens with out-of-range results for non-time critical disorders within seven days of birth. From 2012 to 2015, eight states increased the number of specimens reported for this category by at least 0.81%.

## Addendum 2: NewSTEPs 360

NewSTEPs 360 is a three year cooperative agreement funded by HRSA to the ColoradoSPH in collaboration with APHL with the objective of improving the timeliness of NBS to increase the number of states that meet the ACHDNC's recommendations on timeliness and the number of infants receiving timely diagnosis and treatment.

### **NewSTEPs 360 Aims**

**AIM 1: Create and partner with a multidisciplinary collaborative network of NBS stakeholders to identify strategies to improve timeliness of the diagnosis of infants with a disorder identified by NBS.**

**AIM 2: Provide quality improvement education, educational resources, and technical assistance to stakeholders in the NBS systems to enable them to identify problems and strategize and implement solutions towards improving timeliness in NBS.**

**AIM 3: Evaluate the effectiveness of the quality improvement strategies implemented at the local, regional, and national level.**

**AIM 4: Create a model for replication and sustainability of NBS continuous quality improvement with interagency and interstate teams.**

The purpose of NewSTEPs 360 is to support teams comprised of experts from state NBS programs in order to identify and improve timeliness in NBS. While each team has identified local challenges and opportunities, NewSTEPs 360 assists programs by collecting and making accessible focused central resources in specific areas of NBS timeliness, providing programs with access to expertise outside of their individual programs. Several national organizations partner on this project to provide their expertise to programs and include the following:

- [Newborn Screening Clearinghouse \(Baby's First Test\) housed at Genetic Alliance](#)
- [National Institute for Children's Health Quality \(NICHQ\)](#)
- [Association of State and Territorial Health Officials \(ASTHO\)](#)
- [Association of Maternal Child Health Programs \(AMCHP\)](#)
- [March of Dimes \(MOD\)](#)
- [National Coordinating Center for Regional Genetics Collaboratives \(NCCRGC\) housed at the American College of Medical Genetics \(ACMG\)](#)
- [Newborn Screening Translational Research Network \(NBSTRN\) housed at ACMG](#)

Each state-based or regional quality improvement team has identified their greatest needs for improving timeliness in NBS through a guided application process that enables states to begin utilizing a Continuous Quality Improvement (CQI) approach. The needs identified within the application determined the primary focus area for their NBS quality improvement project. These focus areas are listed below.

**Focus Areas for State NBS Quality Improvement:**

**Focus Area 1** - Developing education in the hospital and birthing facilities regarding timely and appropriate collection and shipment of specimens.

**Focus Area 2** - Identifying and/or strengthening courier system to deliver NBS DBS.

**Focus Area 3** - Expanding operating hours to provide more uniform coverage for NBS throughout the week and across holidays.

**Focus Area 4** - Evaluating the efficiency of laboratory processes.

**Focus Area 5** - Communicating results with provider and clinical specialists.

**Focus Area 6** - Using Health Information Technology to improve timeliness through electronic demographic and order submission and result reporting.

**NewSTEPS 360 Participants**

The NewSTEPS 360 collaborative quality improvement network is currently composed of 16 funded programs representing twenty state-based teams of NBS stakeholders. Fourteen of the programs are individual state NBS programs and two are collaborations between multiple states. Each of these programs was selected based on a competitive application process that was announced in September of 2015. In addition to the 16 programs listed below, another application cycle was announced in June 2016 and an additional group of awardees will be funded in September of 2016 (seven new awardees expected). All of the programs will receive funding and quality improvement coaching through August 2018. Each participating NBS program is assigned a CQI coach comprised of NewSTEPS 360 staff trained by the team evaluator and experts at NICHQ. NewSTEPS 360 continues to support teams to identify process measures based on their chosen activities.

The currently funded programs are presented below with a brief overview of their timeliness activities.

- **Arizona** plans to improve the courier service for out-of-hospital births and utilize optical character recognition software to facilitate electronic demographic data entry.
- **Colorado and Wyoming** are partnering to create a video and toolkit along with a standardized curriculum for hospitals and midwives addressing timely collection and transport of NBS DBS cards.
- **California** will launch intensive education for hospitals and midwives across the state and develop infographics for high performance hospitals. They will also investigate daily courier service processes to optimize delivery of specimens to state laboratories.
- **Hawaii** will provide training to providers to utilize a web-based data system to review NBS results and will partner with four large birthing facilities to enable electronic order entry and the reporting of NBS results using HL7 messaging.
- **Iowa** is developing an educational plan to ensure hospital-based and out-of-hospital birth NBS providers understand their role in assuring timely NBS, collection and shipment of DBS cards.
- **Michigan** will utilize HL7 messaging with up to eight hospitals to develop demographic submission and results reporting to/from the state laboratory, and to verify receipt of the DBS card by the laboratory.
- **Minnesota** is partnering with hospitals to facilitate data transfer from the hospital to the laboratory by capturing demographic information from the electronic health record and transferring the data to the DBS card, and report results back to the electronic health record.
- **Montana** will improve the statewide courier service to enable hospitals and midwives to ship specimens to the public health lab from all corners of the state.

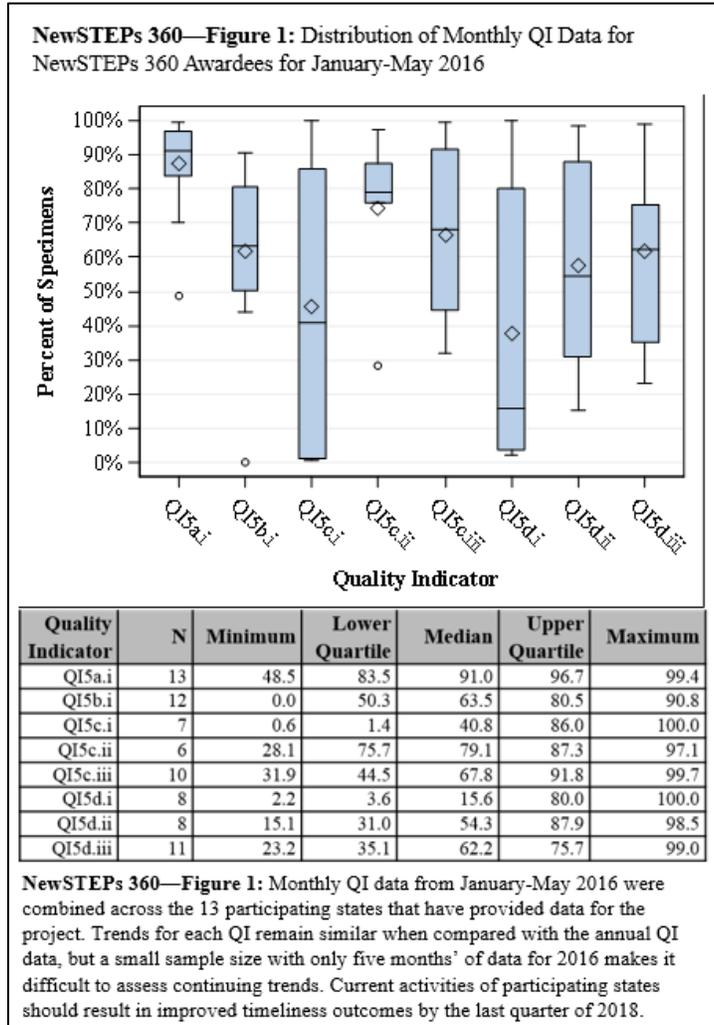
- **Nebraska** will broaden their existing health information technology efforts by including more hospitals in their initiative to receive health demographic data, and perform results reporting via HL7 messaging
- **Delaware, Maryland, New Jersey, New York, and Virginia** are partnering together to offer educational activities to health providers throughout their region to encourage the timely collection of NBS specimens and the efficient retesting of infants with abnormal screens.
- **Oklahoma** is engaging in an education effort with birthing facilities to improve the collection of specimens and the understanding of the appropriate time to collect the specimens.
- **Puerto Rico** will provide education and feedback to hospitals and birthing centers on the importance of daily transport of DBS cards to the laboratory, as well as developing an information tracking system to reduce the time to reporting of results.
- **Tennessee** is continuing to improve the communication network and courier services to shorten the time to receive DBS cards at the NBS laboratory and decrease the number of unsatisfactory specimens received.
- **Texas** will partner with birthing facilities and providers to promote demographic data entry by rural birthing centers through a web application. They will also develop training materials and videos for healthcare providers. Finally, Texas is testing a new workflow in the laboratory to reduce the time from receipt to report-out.
- **Virginia** will partner with hospitals to establish standards-based electronic order submission messaging, and in turn create tools and guidelines to facilitate the continued implementation in other hospitals and other states.
- **Wisconsin** will develop a system for the electronic submission of demographic information requested on the specimen card, and will

establish an electronic HL7 data exchange of test orders and results between hospitals and the screening laboratory.

### NewSTEPS 360 Evaluation

NewSTEPS 360 collects monthly QI data, building on the NewSTEPS Data Repository infrastructure. The sixteen funded programs have entered data through the first months of funding, and these data will be utilized as baseline data. Each of the programs is initiating change through continuous quality improvement activities designed to improve timeliness in NBS, and this will be reflected in the QI data as changes from baseline.

Baseline data for the 20 NBS programs participating in NewSTEPS 360 are presented in **NewSTEPS 360 – Figure 1**. Activities for each state are targeted to the areas identified within the root cause analysis and participating programs expect to see improvement in the QIs tied to those areas. Baseline data has been established for the 20 participating states. Quality improvement coaches are working closely with states to identify changes in QIs following implementation of new activities.



### Addendum 3: Table of Time Critical Disorders

The following table is from the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children’s (ACHDNC) recommendations on timeliness in NBS and was created based on the Society for Inherited Metabolic Disorders (SIMD) position statement and expert opinion from metabolic geneticists, hematologists, endocrinologist and pulmonologists.

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

## Addendum 4: Collaborative Improvement and Innovation Network Report



### NewSTEPS Collaborative Improvement and Innovation Network (CoIIN) For Timeliness in Newborn Screening

Final Report  
July 2016



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The Association of Public Health Laboratories (APHL) partners with the Colorado School of Public Health (ColoradoSPH) to implement the Newborn Screening Technical assistance and Evaluation Program (NewSTEPS). The development of this document was supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under Cooperative Agreement # U22MC24078 (CFDA #93.110) which provided a total of \$850,000 in the current budget period to support NewSTEPS. Its contents and conclusions are solely those of the authors and should not be construed as the official position or policy of, nor should any endorsement be inferred by HRSA, HHS or the U.S. Government.

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## Newborn Screening Technical assistance and Evaluation Program (NewSTEPs)

Newborn screening (NBS) is a comprehensive system that includes laboratory testing, diagnosis, follow-up, treatment, education, and evaluation. To be effective and successful, the NBS system requires continuous quality improvement focused on information sharing, technical assistance and standardized data. The Newborn Screening Technical assistance and Evaluation Program (NewSTEPs), which has been in existence since 2012, fulfills this need and promotes harmonization within NBS activities.

NewSTEPs is a program of the Association of Public Health Laboratories (APHL) in partnership with Colorado School of Public Health (ColoradoSPH). The activities of NewSTEPs are driven by active partnerships with state and territorial NBS programs, pediatric sub-specialists, and stakeholders from the Maternal Child Health Branch (MCHB) of the Health Resources and Services Administration's (HRSA) funded programs: Baby's First Test and the National Coordinating Center (NCC) for Genetics Regional Collaboratives (RCs). NewSTEPs proposes innovative activities to enhance the NBS system with a focus on engaging stakeholders at all levels. One such program was the initiation of a 15-month Collaborative Improvement and Innovation Network (CoIIN) for Timeliness in NBS designed to provide technical assistance to states to introduce efficiencies in and improve timeliness around obtaining, shipping, testing, and reporting out the results of newborn screen DBS testing.

### NewSTEPs CoIIN for Timeliness in NBS Overview

NewSTEPs initiated the CoIIN for Timeliness in NBS in response to the community's recognition of a need to improve the time elapsed between birth to the reporting out of NBS results with the goal of continuing to reduce mortality and morbidity. A CoIIN utilizes a learning collaborative approach that enables participants to meet regularly to share successes and challenges so that each participant can improve their own processes. The *Innovative* component of CoIINs encourages collaboration through virtual means and the integration of technology into the activities.

NewSTEPs released a competitive application throughout the NBS community in September 2014 to solicit participation in the CoIIN for Timeliness in NBS. Applicants were required to establish standing teams that included a NBS laboratory representative, a NBS follow-up representative and a hospital representative. In November 2015, NewSTEPs selected seven successful applicants to participate in the NewSTEPs CoIIN for Timeliness in NBS. States participating in the NewSTEPs CoIIN for Timeliness in NBS did not receive funding for this activity other than travel support for a kick-off meeting.

All participating state teams attended an initial face-to-face kick-off meeting in Washington DC in January 2015. The purpose of the meeting was two-fold: to build community among and between the state teams and to introduce Continuous Quality Improvement (CQI) strategies. Activities were developed to facilitate introductions among and between team members, as well as to begin the trust building process that would be necessary when sharing challenges during future, virtual monthly meetings. CQI training was provided in brief formal presentations followed by group work so that teams could apply what was being discussed. Teams identified root causes of poor timeliness, created SMART goals and objectives to guide their CoIIN efforts, developed

strategies to improve timeliness and outlined key partners, meeting times, and key duties moving forward.

Following the face-to-face meeting, the NewSTEPS CoIIN lead met at least quarterly with each state team, and all seven teams met monthly for educational purposes and to share successes and challenges. NewSTEPS arranged the educational content based on identified needs of the states by the CoIIN lead. These included: data visualization, midwives, Neonatal Intensive Care Units (NICU) screening, and military births. All monthly CoIIN meetings happened through ZOOM Video conferencing.

The overarching goal for states participating in the NewSTEPS CoIIN for Timeliness in NBS was to improve timeliness in the NBS system as outlined by the recommendations from the Secretary's Advisory Committee on Heritable Diseases in Newborns and Children (ACHDNC)<sup>9</sup>. These are:

1. Presumptive positive results for time-critical conditions should immediately be reported to the child's healthcare provider and no later than 5 days of life.
2. All presumptive positive results for time sensitive conditions should be reported to the healthcare provider as soon as possible but no later than 7 days of life.
3. All NBS results should be reported within 7 days of life (the "normal" screening results).

In order to achieve these goals (and reduce delays in NBS):

- Initial NBS specimens should be collected in the appropriate time frame for the baby's condition but no later than 48 hours after birth.
- NBS specimens should be received at the Laboratory as soon as possible; ideally within 24 hours of collection.

Progress for each of these metrics was measured by [NewSTEPS Quality Indicators](#) (QI) 5a, 5b, 5c, and 5d ([listed below](#) in quality indicators). Routine discussions with the states as well as presentations made by the states highlighted both facilitators and barriers to improved timeliness. All participating states executed CQI activities and developed partnerships within their states resulting in improvement at least one of their timeliness measures. NewSTEPS was also able to identify some facilitators of (education, courier services, and change in workflow) and some barriers (personnel shortages, rolling out a new condition) to timeliness that have been shared with the NBS community. Finally, states developed resources that they continue to share with one another as well as the broader NBS community.

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<sup>9</sup> These recommendations were revised a few months after the NewSTEPS Timeliness CoIIN began. As a result, some data was not collected in a way that could be measured against the recommendations.

## Quality Indicator (QI) 5

To monitor monthly progress, NewSTEPs provided participating states with run charts to collect data for NewSTEPs Quality Indicators 5a, 5b, 5c, and 5d. These quality indicators are listed below:

- QI 5a | Birth to specimen collection: Birth to specimen collection, data collected monthly in aggregate by state, with proportions of screens indicated in the following categories 0 to 24 hours, 24 to 48 hours, 48 to 72 hours, and greater than 72 hours.<sup>10</sup>
- QI 5b | Specimen collection to receipt by lab: Specimen collection to receipt by lab [reflected by time sample is logged in at lab], with proportions of screens indicated in the following categories same day, 1 day, 2 days, 3 days, 4 days, 5 days, 6 days, and 7 days or greater.<sup>11</sup>
- QI 5c | Specimen receipt to reporting out of complete results: Specimen receipt to reporting out complete results with proportions of screens indicated in the following categories 0-24 hours, 24-48 hours, 48-72 hours, and greater than 72 hours.
- QI 5d | Birth to reporting out complete results<sup>12</sup>: Birth to reporting out completed results with proportions of screens indicated in the following categories >48 hours, >48 hours to 72 hours, >72 hours to 96 hours, >96 hours to 120 hours, >120 hours to 144 hours, >144 hours to 168 hours, >168 hours to 192 hours, > 192 hours to 216 hours, >216 hours to 24 hours, and greater than 240 hours.

The ACHDNC did not issue recommendations regarding time of specimen receipt by laboratory to reporting out results. This data point is captured by Quality Indicator 5c. Based on ACHDNC's recommendations that all critical results are reported out by 5 days of life and that noncritical results are reported out by 7 days of life, a calculated benchmark for the report out was within 3 days of the lab receiving the specimen.<sup>13</sup>

## Progress towards ACHDNC Recommendations

### Specimen Collection No Later than 48 Hours After Birth

The median percent of specimens collected within 48 hours after birth improved for the states who participated in the NewSTEPs CoIIN (Figure 1a). The ACHDNC set a goal of 95% of all specimens be collected within 48 hours of birth (represented by the purple line).

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<sup>10</sup> Some states reported 0 to 24 hours and others reported 0 to 23 hours. It is assumed all states meant 0 to 24 hours and >24 hours to 48 hours. One state also reported greater than 48 hours as the upper category versus 48 to 72 hours and greater than 72 hours.

<sup>11</sup> Colorado and Wyoming reported QI5b in the following categories 0-2 days, 3-4 days, 5-6 days, 7-14 days, and unknown.

<sup>12</sup> Data were reported in aggregate (time critical and non-time critical conditions). Therefore, results reflect 7 day reporting.

<sup>13</sup> Three days from receipt was chosen because blood spots are collected 24-48 hours after birth, they need 3 hours to dry, and then are shipped to the lab. It was assumed that the blood spot could be received as early as 48 hours after birth and then states could run the sample and call out the results within 3 days to meet the 5 day benchmark set by ACDNCH for calling out critical results. This benchmark was used for CoIIN participants and may differ from metrics used in other NewSTEPs reports.

Five states demonstrated improvement (Figure 1b) in specimens that were collected prior to 48 hours, three of which reached the goal of 95%. Two states saw no change but one of these, Texas, had already exceeded the goal prior to the start of CoIIN and was able to maintain this high level throughout the project period (Figure 1b).

The activities in five states who saw improvement (California, Colorado, Iowa, New Hampshire, and Wyoming) that demonstrated improvements in the time to specimen collection were focused on educating hospitals and birthing facilities on the importance of collecting samples within 48 hours of birth. Products developed by each team and supporting documentation are provided in the state specific sections of this report. The activities in Texas and Tennessee were primarily focused on specimen transport which explains why they saw no improvement in specimen collection time.

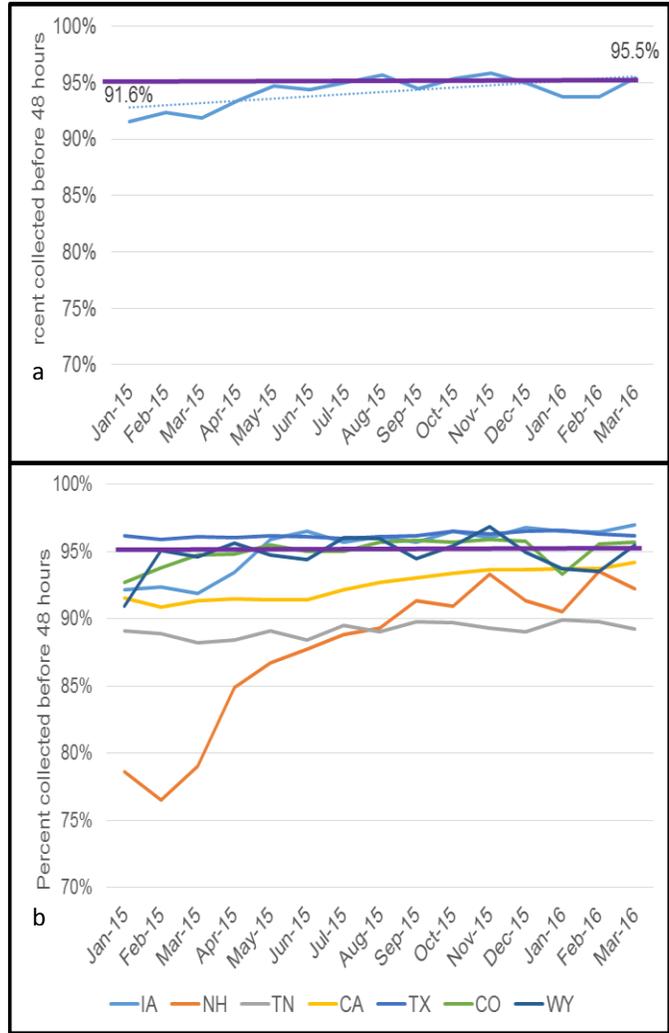


Figure 1a. Median percent from all participating states of specimens collected after 48 hours after birth

Figure 1b. Median percent of specimens collected within 48 hours after birth for all participating states by state

## Specimens Received within Two Days of Collection<sup>14</sup>

Because of the categories used to gather this data, results cannot be reported in hours. Furthermore, in two states data was reported as 0 to 2 days rather than as same day, 1 day, and 2 days; as a result, CoIIN success in this area is measured as changes in the percentage of specimens which arrived within two calendar days of collection. This differs from the ACHDNC recommendation of 24 hours which came out after the CoIIN had begun.

The median percent of specimens received at the laboratory within 2 calendar days of collection (same day, 1 day, 2 days) for the seven participating states improved from 68% to 80%, although still short of the 95% goal set by the ACHDNC (Figure 2a). All states demonstrated at least modest improvements, while four states demonstrated an increase of over 20 percentage points (Figure 2b). These dramatic changes were observed in states with new (Tennessee) or augmented courier services (Colorado, New Hampshire, and Wyoming), or an additional working day in the laboratory (Colorado and Wyoming). New Hampshire also implemented changes at the hospital level that resulted in more efficient courier pick-up of the specimens.

The only state that met the specimen delivery goal of 95% samples delivered within 2 days is Iowa, a program that is open 7 days a week, 24 hours a day with systems in place to receive samples from the 7 day/week courier (Figure 2b). Most states improved the percentage of specimens reaching the lab within 2 days (figure 2b) resulting in some lessons learned:

- Iowa learned that hospitals who were earlier on the courier route had a difficult time preparing their samples in time for the courier and were not able to achieve the 24 hour goal.
- Tennessee introduced a courier system between February and June, resulting in an increase in percentage of specimens arriving at the lab with 2 days. Progress plateaued in the months following highlighting that a courier service is not sufficient to meet the recommendation and additional quality improvement initiatives are required.
- New Hampshire discovered that couriers were not collecting samples on Saturdays, despite contractual obligations to do so, highlighting need for additional outreach to each hospital and review of the process to ensure it is being followed as intended.

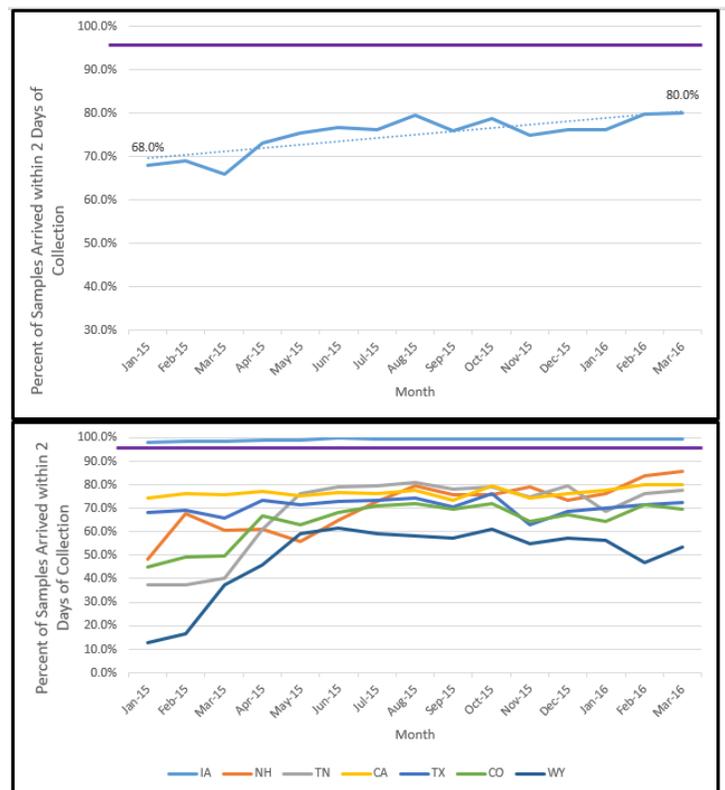


Figure 2a. Median percent from all participating states of samples received within two days of collection

Figure 2b. Median percent of samples received within two days of collection for five participating states

<sup>14</sup> This includes specimens received same day, day 1 and day 2 after collection as reported by the states.

## Results Reported Out within 3 Days of Receipt by Laboratory

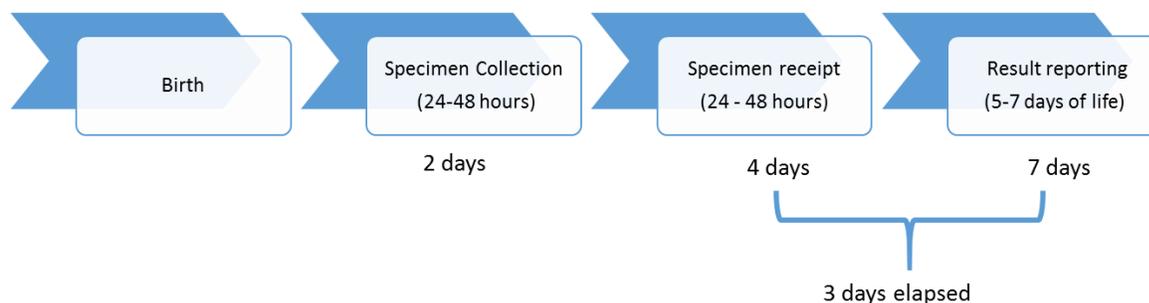


Figure 3: Schematic demonstrating timeline of NBS activities through the reporting of results, based on ACHDNC Recommendations.

ACHDNC recommended all results to be reported out by 7 days of life, however some programs do not have systems in place to record the time a specimen is received by at the laboratory. Due to this, only four CoIIN for Timeliness in NBS states were able to provide data on the time from receipt by lab to reporting results. NewSTEPS set a benchmark of 3 days from time to receipt to reporting all results<sup>15</sup> to measure the success of CoIIN activities (Figure 3). It should be noted that this Quality Indicator was added as a result of discussion in the first CoIIN meeting.

Two states consistently reported results on more than 80% of specimens within 3 days of receipt by lab (Figure 4b) after July 2015. The other two states had significant variability (Figure 4b).

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<sup>15</sup> The benchmark presented in this report was used for the CoIIN participants. It may differ from the benchmark used in other NewSTEPS timeliness reports.

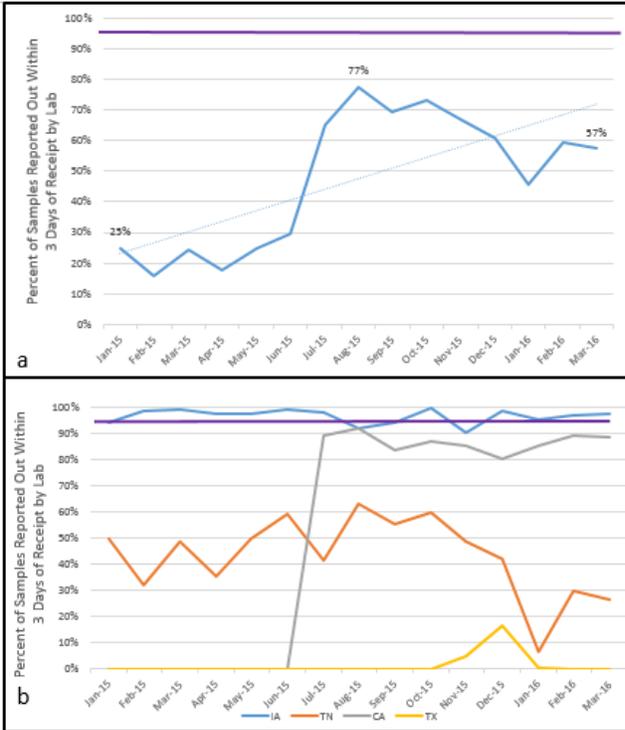


Figure 4a. Median percent of states from participating states of results reported out within 3 days of receipt by the laboratory.

Figure 4b. Percent of results reported out within 3 days of receipt by lab (QI5c), each state displayed independently.

Prior to July 2015 California had to submit specimens to the state lab for Severe Combined Immunodeficiency (SCID) testing, rather than to a regional lab. This delayed the time for results to be called out. In July, an FDA-approved SCID test was able to be used in California allowing regional labs to run all the NBS tests. This change led to none of the specimen results being called out within 3 days to 89% of the specimens in July. This activity was not a focus for quality improvement activities for California, therefore changes were not anticipated. Texas saw an increase in percent of samples reported out within 3 days of receipt by laboratory in November and December 2015 following the pilot test of a new workflow approach during the 2015 holiday season. The success of this test has led to a permanent change in the workflow approach, put into effect July 13, 2016. Tennessee experienced significant variability from month to month due to staffing and the addition of a new condition to their screening panel. The addition of SCID in January 2016 resulted in a notable shift in the time to reporting; this decrease persisted for one month with the team continuing to work on improving time to result reporting.

### Results Reported out Within 7 Days of Life

The final ACHDNC benchmark tested was the percentage of results reported out within 7 days of life (QI5d). This metric is the cumulative result of all quality improvement initiatives, representing the overarching timeliness goal: to report all results out to providers in a timely manner. Due to internal challenges with data collection and reporting, only two states--Iowa and Texas--could provide this data.

Iowa entered the CoIIN with 98% of all results being reported out within 7 days of life and through application of quality improvement techniques were able to improve to 99%. Texas implemented a focused quality improvement initiative, reaching out to hospitals with the greatest percent of delayed specimens, and expanding the reach of their courier service within the state. These combine efforts resulted in improving the percent of specimens for which results were reported within the first 7 days from 9% to 32%.

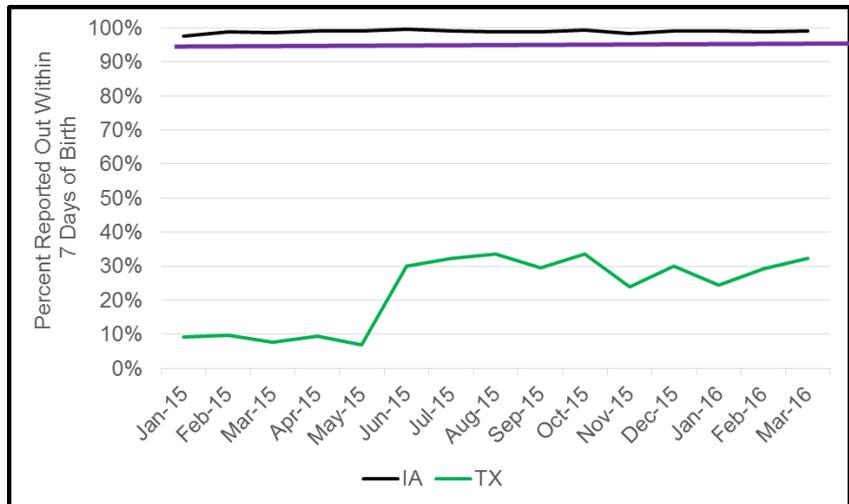


Figure 5. Percent of Specimens Reported out within 7 days of life (QI5d). Purple line indicates ACHDNC goal (95%). each state displayed independently.

### Summary

All states participating in the NewSTEPs CoIIN for Timeliness in NBS demonstrated improvements in timeliness metrics, through interactive guidance from the NewSTEPs CoIIN lead and collaborative feedback from other states. These changes were measured by the NewSTEPs Quality Indicators over the duration of the fifteen-month initiative, without specific funding targeted toward the states. Ongoing discussion with states revealed that guidance on continuous quality improvement, group education opportunities and access to a platform to share successes and challenges were key components contributing to their successes. Remarkably, states demonstrated improvements in Quality Indicators that did not represent areas of focus for their CoIIN team. This highlights the interconnectedness in the NBS system between the pre-analytic and analytic phases wherein efficiencies in one area can lead to improvements throughout the entire process.

The progress made by these seven states, in only 18 months and without dedicated funding to change timelines, demonstrates that timeliness in NBS can be improved at the state level. Most programs were not able to reach the overall benchmarks set by the ACHDNC, however, all of them identified opportunities for improvement, and in all cases, some states were able to achieve the overall goal in at least 95% of specimens, illustrating that the goals are attainable.

NewSTEPs 360, a HRSA funded initiative to support states through technical assistance and financial means to improve timeliness builds from the foundation developed during the NewSTEPs CoIIN for Timeliness in NBS. Implementing change in large, complex systems such as NBS requires a cross-discipline approach over multiple years. NewSTEPs 360 provides the structure for state NBS programs to identify solutions and collaborate with others in order to work towards improved timeliness throughout the NBS process.

## State Goals

Seven states, selected via an application process, participated formally in the CoIIN for Timeliness in NBS, with an eighth state joining during the initial training period. These states range in size with the largest state reporting 510,000 babies born in state in 2015 and the smallest reporting 8,000<sup>16</sup>. As part of the application process, states identified timeliness specific goals that would address their states root causes the team identified during the initial face-to-face meeting. The goals were revised during the first three months of the project based on discussion with the project lead and states sharing their challenges. The goals identified by each state and the progress towards meeting those are displayed in Table 1. All states demonstrated progress toward their goals, with four states successfully meeting some of their goals. Of the four, two met all of their goals. All but one state is currently engaged in the [NewSTEPS 360](#) funded initiative<sup>17</sup>.

Table 1: NewSTEPS Timeliness Goals Stratified by State

State	Goal	Status as of March 31, 2016	Progress Update
California	By March 2016 85% of initial DBS specimens will complete collection to receipt by lab within 2 calendar days (reflected by calendar day logged in at lab).	Progress Made.	Up to 79.88% from 74.3% baseline.
	95% of all initial specimens collected at 12-48 hours by March 2016.	Progress Made.	Up to 93.63% from 91.56% at baseline.
Colorado	By March 2016, reduce average transit time of all initial NBS specimens in Colorado by 1 day.	Goal Met.	Went from baseline average of 2.86 days for a result to 1.86 days.
	By March 2016, achieve 95% of initial NBS specimens received at Colorado Department of Public Health within three days of collection.	Difficult to assess based on how data is collected.	69.64% arrived at the lab within 2 days of collection. Another 26.07% arrived within 4 days of collection. (95.07% within 4 days)
	By March 2016 ensure 100% of initial NBS specimens are collected prior to 48 hours.	Progress Made.	Up to 95.8% collected prior to 48 hours up from 90.9%.
	By March 2016 reduce unsatisfactory samples to <1.0% at all facilities.	Goal Met.	Unsatisfactory specimens dropped to 0.73% from 0.96% baseline statewide.

<sup>16</sup> The 2015 annual birth rates come from the state profile data in the NewSTEPS data repository.

[www.newsteps.org](http://www.newsteps.org)

<sup>17</sup> NewSTEPS 360 is a 3 year HRSA funded project aimed at supporting states through technical and financial means so that they can achieve timely reporting of results in 95% of the newborns that receive dried-blood spot (DBS) screening. For more on NewSTEPS 360 please visit <https://www.newsteps.org/newsteps-360>.

<b>State</b>	<b>Goal</b>	<b>Status as of March 31, 2016</b>	<b>Progress Update</b>
Iowa	By March 2016 95% of NBS specimens will be received and logged in at State Health Lab by 60 hours from birth.	Goal Met.	97% of samples arrive within 1 day of collection (for last 3 months of the project). Baseline was 91.6% 97% of results are called within 3 days of receipt by lab (median since program began). Baseline was 94.2%. This has been as high as 99.3% and as low as 90%. The last 4 months of CoIIN showed steady growth and the median was 97% for those 4 months.
New Hampshire	By March 2016 increase the percentage of specimens received by lab within two days of collection to 95%.	Progress Made	Went from 48.29% at the beginning of the project being in the lab within the 2 days (same day, 1 day, and 2 day) up to 85.71%.
Tennessee	By January 2016 increase the statewide percentage of initial NBS collected between 24-48 hours from 91.8% to 93%.	Not Met	Hovered around 87.9% during the whole project
	By March 2016 increase the percentage of samples that arrived at the lab with 2 days of collection to 90%.	Progress Made	Prior to rolling out the couriers, 37.3% (median of 1 <sup>st</sup> 3 months) of TN's samples arrived at the lab within 2 days (same day, within 1 day, within 2 days). The last 4 months of the project this median percentage had risen to 76.9%.
Texas	By March 2016 95% of all first newborn screens will be received at the state lab within 72 hours of collection.	Progress Made	Went from 88% at the beginning of the project up to 91.5% at the end of the project.
Wyoming	By March 2016, reduce average transit time of all initial NBS specimens to Colorado by 1 day.	Goal Met	Decreased average transit time from 4.27 days to 2.7 days (1.5 day decrease).
	By March 2016, achieve 95% of initial NBS specimens received at Colorado Department of Public Health within three days of collection.	Progress Made	Up to 92.08% by 4 days (same reporting as CO) from 48.4% baseline.

State	Goal	Status as of March 31, 2016	Progress Update
	By March 2016 ensure 100% of initial NBS specimens are collected prior to 48 hours.	Progress Made	Up to 95.5% of samples collected within 48 hours of birth from 90.9%.
Arizona*	By March 2016 develop increase the percentage of specimens from Level 1 Hospitals that arrive in the state lab within 1 day of collection.	Goal Met	Increased the percentage of specimens from Level 1 Hospitals that arrived within the lab within 1 day from 41% to 77% during the project time. They saw a steady increase in their efforts through November.

\*Arizona was not one of the original 7 states and did not go through the application process. They joined the project after the initial face-to-face meeting where they highlighted their success in improving their NBS timeliness but their struggles maintaining that progress.

**Activities undertaken and changes to timeliness/recommendations around timeliness**

In working toward their timeliness goals, states participating in the NewSTEPs CoIIN for Timeliness in NBS engaged in four types of activities to overcome the root causes contributing to delays in newborn blood spot specimen collection, screening and reporting. These included education around timeliness, initiating or increasing courier services around the state, increasing laboratory hours for receiving and processing NBS DBS specimens, and working closely with hospitals to identify and overcome barriers. In December 2015, NewSTEPs asked participated states to share their top lessons learned, a compilation of which can be viewed in the video linked here: <https://youtu.be/ei5t-D-RkZw>

Appendix A also lists these lessons learned along with the email messages from each state stratified by process category.

**Education and Creating Reports**

Several of the states worked on educating hospital staff. For three states, they started by administering a survey. The survey identifies staff in the hospital who work on NBS and identifies the hospitals’ perceived barriers to timely NBS. California adapted Colorado and Wyoming’s survey and administered it to their hospitals in July 2015. Responses to these surveys informed education efforts made by each state. First, Colorado and Wyoming learned that the report cards the state lab sent were being reviewed but they were not being shared with the nursing or lab staff. Colorado also learned that that only 36.2% of the hospitals who completed the survey recalled receiving the Clinical Sciences and Laboratory Standards Institute’s (CLSI) NBS education video that was sent a year earlier.

These findings helped explained why the NBS programs were not seeing the desired changes in timely specimen collection and transportation. For example, Colorado determined the need for signs that could be posted in the well-baby nurseries that highlighted information regarding when specimens should be collected, instructions for completing demographic information,

recommendations for drying the blood spots, and how quickly blood spot specimens should be shipped. They then worked with a local university to create educational posters (Figures 6 and 7).

These posters have been shared with the broader NBS community via a [timeliness presentation](#) at the 2016 APHL NBS and Genetic Testing Symposium, as a report out to CoIIN states, in a presentation to the Heartland CoIIN, and on the NewSTEPS website.

Colorado also piloted a “spot checker” program to reduce the number of unsatisfactory specimens hospitals were sending. This program was successful and the number of unsatisfactory specimens in Colorado dropped to 0.73% from a 0.96% baseline statewide.

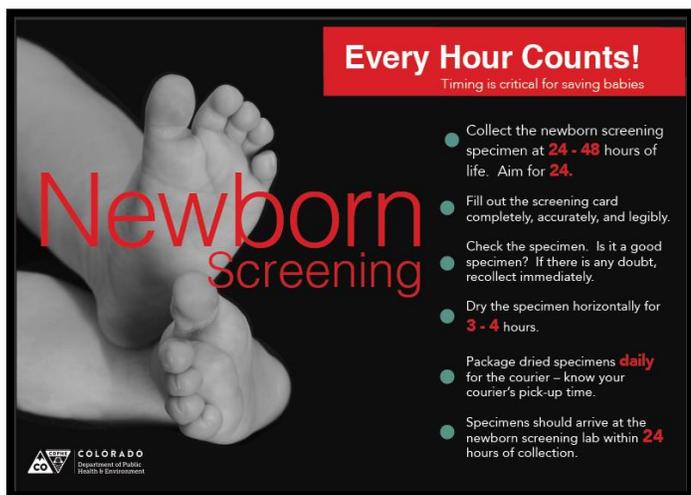


Figure 6: A poster designed to help the collectors of the bloodspots understand the importance of the information and collection for timeliness.



Figure 7: Example of an educational poster created in Colorado.

Iowa’s approach to education was through the creation of a hospital report card that was easy to read. They worked closely with a few hospitals to create and refine a reporting tool that will now goes out hospitals every month (See Figure 8).

Iowa created the first version of this report utilizing tips from the data visualization expert who presented to CoIIN states during an educational monthly call. Specifically, their use of colors and the horizontal bar chart were inspired by that presentation.

The pilot hospitals have provided additional feedback so that the results are quickly understood. As part of those talks, the Iowa team has asked the hospital staff to partner with them and determine the root causes of timeliness delays in the NBS system. The Iowa team feels these talks have been in extremely helpful in their understanding of the all the complexities within the hospital system but also highlighted what they could do at the lab to further improve timeliness.

New Hampshire was similar to Iowa in that they began issuing hospital reports to draw attention to the need for changes at the hospital level to improve timeliness. New Hampshire created reports that they shared with hospitals February 2015, May 2015, and December 2015. The reports began to get more specific with each iteration. After the May and December reports, New Hampshire saw an improvement in the time from collection of the specimen to receipt by the state lab (See Figure 9). The December report specifically named each hospital and included a graph that called attention to hospitals responsible for the lowest percentage of specimens arriving in a timely manner to the lab. The New Hampshire NBS now provides custom analysis and data sets to help any interested hospital track their timeliness progress made as they institute new changes.

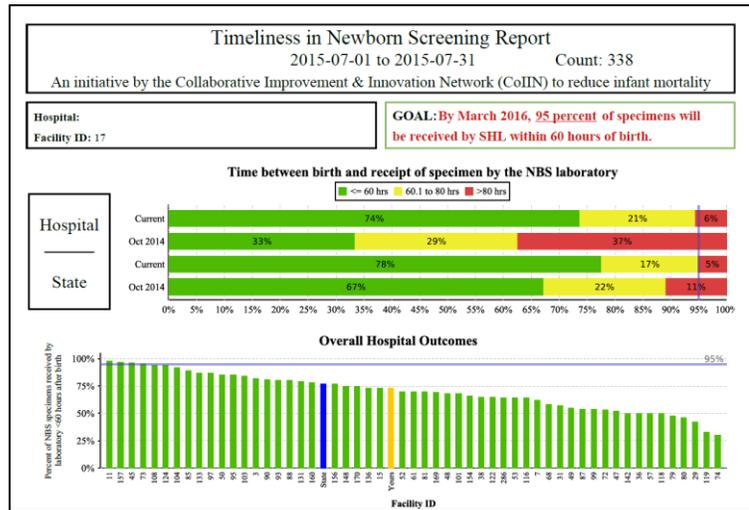
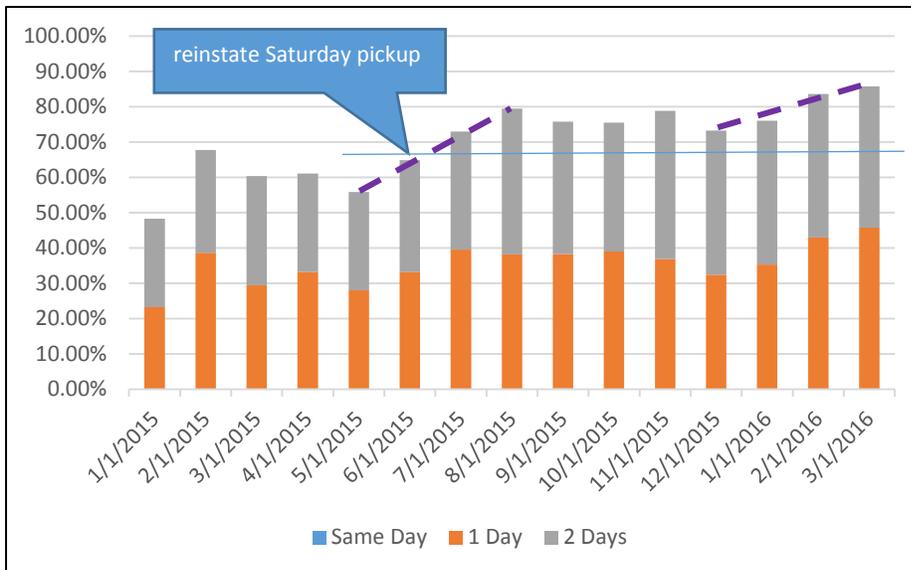


Figure 8: A sample of the reporting tool distributed to hospitals each month to show their progress or lack thereof in getting samples to the laboratory in a timely manner.



Finally, two CoIIN states have reached out to key education partners for NBS. California presented on CoIIN to the California chapter meeting of the March of Dimes and Iowa presented on the importance of timeliness in NBS at the Iowa Perinatal Meeting.

Figure 9: New Hampshire - Percent of Specimens Arriving at Lab within 2 Days of Collection. The impact of hospital education (dashed lines show increase following reports) and adhering to the courier contracts in New Hampshire

### Courier

Four states worked to either create or improve their courier system as part of the NewSTEPs CoIIN for Timeliness in NBS project. First, Tennessee rolled out statewide couriers and saw a significant improvement in their timeliness metric. Tennessee went from 37.3% of their samples arriving within 3 days of collection up to 77.6% during the rollout of their statewide courier system (See Figure 10).

The impact of a statewide courier dramatically improved the time it took from specimen collection to arrival in the lab (Figure 11).

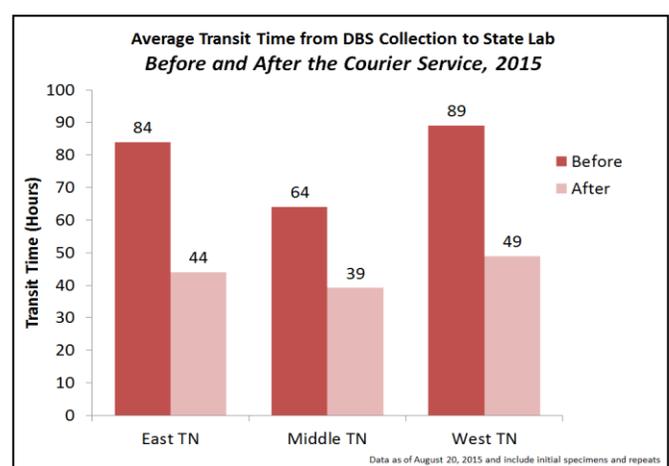
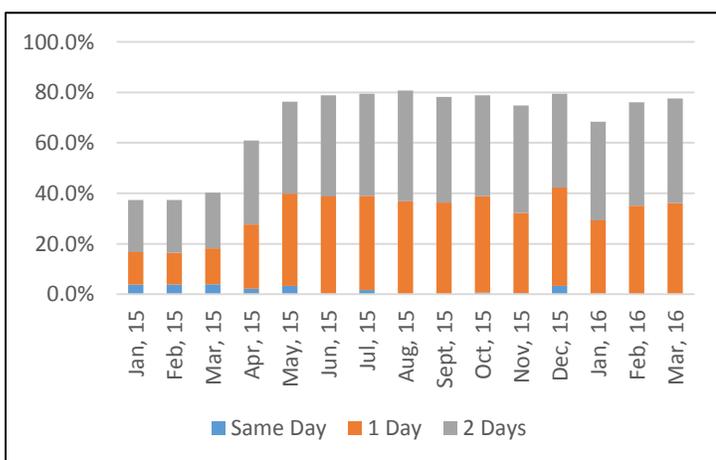


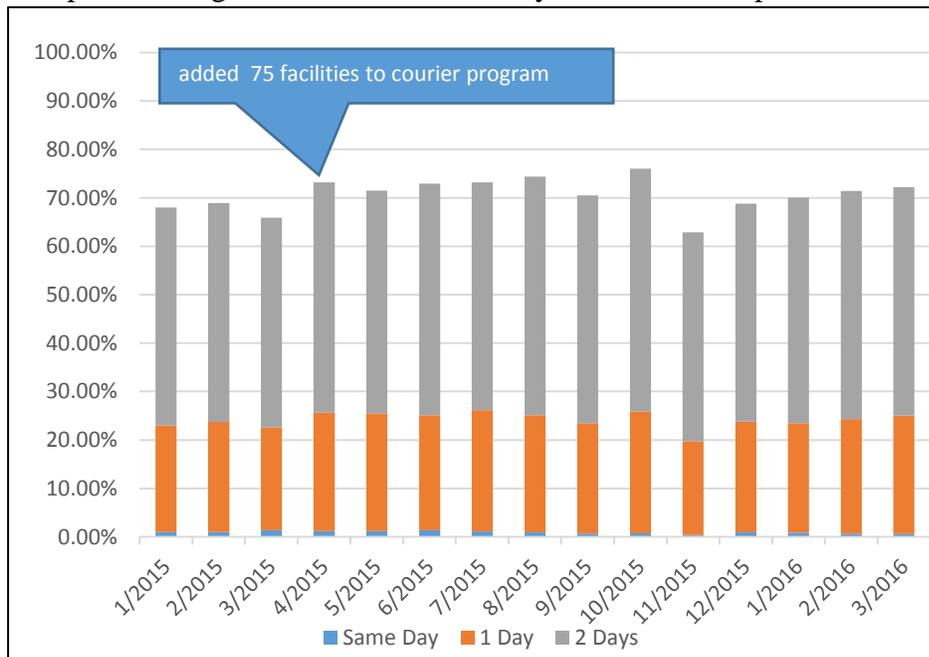
Figure 10: Tennessee - Percent of Specimens Arriving at Lab within 2 Days of Collection.

Figure 11: The change in average transit time for NBS dried blood following the introduction of a courier service.

While adding a courier yields a dramatic improvement in their timeliness, couriers are not enough to ensure that all specimens arrive at the lab in a timely manner. The two other states—that addressed courier usage within their CoIIN activities (New Hampshire and Texas) identified solutions to improve existing courier systems.

New Hampshire realized early during the CoIIN project that while their contract with the courier included Saturday delivery, this option was not being used. First, hospitals were canceling this delivery because they felt the cost was high and the number of specimens were low. In response to this, the New Hampshire program educated hospitals that the state department, not the hospitals, were paying for the courier. Saturday courier pickup was reinstated statewide in July 2015. As a result, the percentage of specimens arriving within two calendar days went from 64.8% in June to 72.9% in July and continued to stay above 73% for the rest of CoIIN. They also met with the couriers to review the contract and emphasize the importance of picking up specimens on Saturdays. Over the 15 months, New Hampshire went from 48.3% of their samples arriving within 2 days of collection to 85.7% (See Figure 9).

The Texas team examined their courier program as part of the NewSTEPs CoIIN for Timeliness in NBS. Texas is able to provide the courier for hospitals, however due to the geographic size, they are currently unable to provide couriers for all the hospitals. In April 2015, Texas reassessed their courier budget and were able to add 75 more facilities to their courier program. As illustrated in Figure 12 below, this addition to the courier service helped Texas move from 68% of their samples arriving at the lab within two days of collection up to 72.2%.



Texas is now focusing on getting a larger percentage of samples to their lab within 24 hours. They have learned that this goal requires specific adjustments to the hospital workflows but they are working with the hospitals to see what can be accomplished in terms of meeting their new goal.

Figure 12: Texas - Percent of Specimens Arriving at Lab within 2 Days of Collection. The impact of increasing courier services in Texas.

### Changing Lab Operating Hours and Workflow

Three CoIIN sites changed their operating hours during the course of the project. Both Tennessee and Colorado began receiving samples on Saturdays during the project but the Colorado laboratory also began processing samples on Saturdays in March 2015. This change in the Colorado laboratory hours prompted Colorado and Wyoming<sup>18</sup> to add a weekend day to their courier service

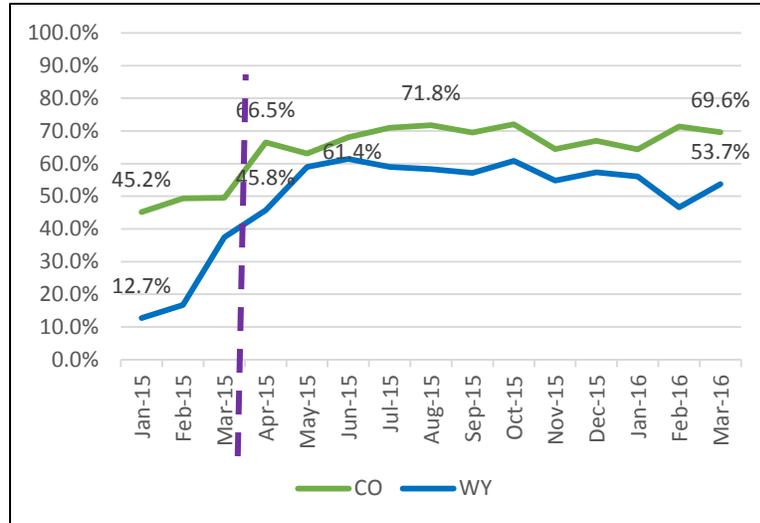


Figure 13: Colorado and Wyoming - Percent of Specimens Arriving at Lab within 2 Days of Collection. The impact of increasing laboratory hours.

to match their new laboratory hours. These modifications increased the percentage of specimens that arrived within two days of collection for both Colorado and Wyoming (See Figure 13). These changes should also decrease the time between receipt to report-out but Colorado and Wyoming were unable to report those numbers as part of the NewSTEPs CoIIN for Timeliness in NBS project.

Colorado and Wyoming, like Tennessee, saw a plateau in these timeliness measures after these two changes indicating the need for the state to identify the new root cause of samples not

arriving within two days of collection.

As part of the CoIIN, Texas conducted a PDSA (Plan-Do-Study-Act) cycle in November and December where they changed the hours the lab staff worked so that the lab staff arrived right around the time the courier began delivering specimens rather than earlier in the day. This shift increased the percentage of specimens that were reported out with 72 hours of receipt (See Figure 14.) Texas chose to test the PDSA cycle in November and December because those two months tend to have bigger challengers with timeliness due to the number of holidays. November is especially difficult for most labs because there are two holidays – Veteran’s Day and Thanksgiving. As can be seen in Table 2, Texas was the only CoIIN state reporting this quality indicator data that saw an increase in the percentage of specimens with all results reported out within 72 hours.

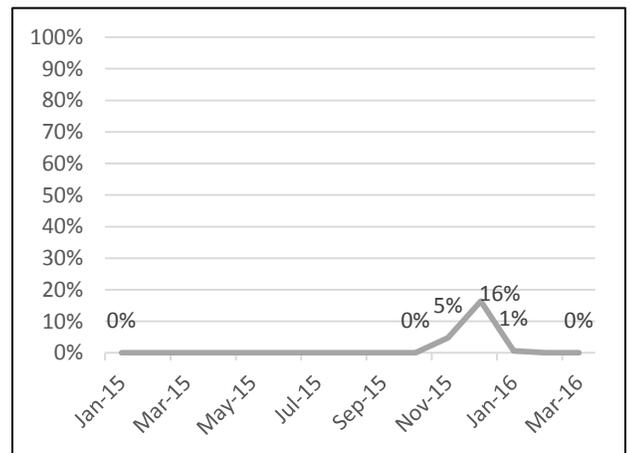


Figure 14: Texas – Percentage of Specimens with All Results Reported Out within 72 hours of Receipt by Laboratory – The impact of changing laboratory workflow in Texas during November and December 2015.

<sup>18</sup> Colorado analyzes the blood spot specimens for Wyoming.

Table 2: Change in percentage of Specimens with All Results Reported Out Within 72 hours of Receipt by Laboratory.

Month	California	Iowa	Tennessee	Texas
October	86.8%	99.3%	59.5%	0.0%
November	85.1%	90.1%	48.5%	4.8%
December	80.0%	98.2%	41.9%	16.4%
January	85.1%	95.2%	6.5%	0.7%

### Other Solutions Implemented with Hospitals

Finally, a few of the CoIIN states tested some specific strategies with hospitals to overcome barriers to timeliness within the hospitals. One hospital in Texas began piloting a program on May 1, 2015 where they requested the labor and delivery floor to use a mobile cart to collect the newborn screens in an effort to monitor the collection times. It is difficult to measure the impact of this change because Texas reported aggregate data and they have a lot of birthing hospitals. New Hampshire, however, was able to track the impact of their change because they have fewer hospitals.

In February of 2015, New Hampshire worked to decrease the proportion of specimens arriving late to the lab from one hospital; the mean proportion changed from 31.8% to 3.7% (See Figure 15).

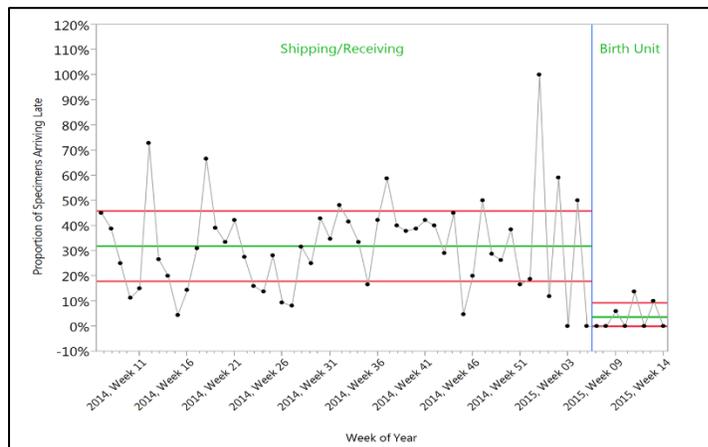


Figure 15: The impact of adding a pick up time and changing the pickup location for one hospital in New Hampshire.

15). This change was accomplished by New Hampshire and the hospital restoring the afternoon pick-up in addition to the morning pick up and changing the pickup location to the mother-baby unit where the blood spots were being collected, reducing the possibility of samples not reaching the shipping dock prior to courier pickup. During the CoIIN, Colorado designed and began testing a chain of custody

form that tracked the specimen delivery process (See Figure 16). This tool allows the NBS program to specifically identify where the delays in transportation exist (drying, packing, transport) as well as accurately captures when the specimen(s) arrive at the state laboratory. The group pilot tested this form with four hospitals from October 2014 until December 2014. As of April 2016, all Colorado birth hospitals are utilizing the chain of custody form. Colorado reported that both the hospitals and the courier appreciate having this form.

Figure 16: Chain of accountability form used by Colorado.

## Other changes

Finally, California spent effort during CoIIN to get their regulations changed. California's legislation stated that birth attendants or physicians,

*“Shall have a blood specimen collected from the newborn between the second and sixth days of age.”*

The new legislation reads,

*“This specimen collection shall occur after 12 hours but no later than 96 hours of age prior to discharge or transfer of the newborn . . .”*

That legislation was changed in May 2016<sup>19</sup> and was open for public comment until July 6, 2016. The California team is hoping to get the upper limit reduced to 72 hours from the 96 hours during the public comment period.

## Next Steps

### NewSTEPS 360

In September 2015, the Colorado School of Public Health (ColoradoSPH) in collaboration with the Association of Public Health Laboratories (APHL) was awarded \$5.4 million through a three-year cooperative agreement with the Genetic Services Branch of the U.S. Health and Human Services Health Resources and Services Administration (HRSA) to build on the success of CoIIN and work with at least 20 states utilizing a CoIIN approach to help them improve their timeliness. This project is called NewSTEPS 360. These 20 states were selected through an application process. As part of this application process states were asked to indicate up to three focus areas they wished to focus their efforts on. The focus areas were:

**Focus Area 1:** Developing education in the hospital, birthing facilities, and/or with midwives (out of hospital births) regarding timely and appropriate collection and shipment of sample.

**Focus Area 2:** Identifying and/or strengthening courier system to deliver NBS DBS.

**Focus Area 3:** Expanding operating hours to provide more uniform coverage for NBS throughout the week and across holidays.

**Focus Area 4:** Evaluating the efficiency of laboratory processes and/or workflows.

**Focus Area 5:** Communicating results with provider and clinical specialists and ensuring timely diagnostic work-up. *(Please note this cannot be the only focus area chosen)*

**Focus Area 6:** Using Health Information Technology to improve timeliness through electronic demographic and order submission and result reporting.

These focus areas were created based on lessons learned from the NewSTEPS CoIIN for Timeliness in NBS as well as the Timeliness Report of the ACHDNC Laboratory Subcommittee.

As of July 2015, 19 states and Puerto Rico are participating in the NewSTEPS 360 CoIIN and currently an application is out for a second round of funding. The NewSTEPS 360 states are similar to the CoIIN for Timeliness in NBS in that they have had a face-to-face kick-off meeting, have

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<sup>19</sup> The legislation proposed can be found at the following website.

<http://www.cdph.ca.gov/services/DPOPP/regs/Documents/DPH-09-010ENBSRegText.pdf>

monthly calls for education and sharing of successes and failures, and receive continuous quality improvement education. NewSTEPS 360, however, is a stronger model than the original CoIIN in that states are assigned a CQI coach who meets with them monthly to provide direct technical assistance as well as to systematically capture data of the state's activities so that NewSTEPS can more accurately track the barriers and facilitators of NBS timeliness. NewSTEPS 360 is also longer, 3 years, enabling states to meet face-to-face on an annual basis which assists with the sharing of ideas as well as builds trust to enable the states to openly share frustrations and challenges.

NewSTEPS 360 also has more rigorous data requirements. As with CoIIN, states must provide monthly Quality Indicator data to track progress but NewSTEPS 360 requires monthly data on [Quality Indicators 1, 2, and 5](#). For states with an MOU, this data is submitted through the NewSTEPS Data Repository. These Quality Indicators are found below:

**Quality Indicator 1:** Percent of invalid DBS specimens/cards due to improper collection and/or transport

- a. Percent of invalid DBS specimens/cards due to improper collection and
- b. Percent of invalid DBS specimens/cards due to improper transport

**Quality Indicator 2:** Percent of DBS specimens/cards missing essential information

**Quality Indicator 5:** The Timing of NBS Activities through categorization of the number of samples/screens collected within specific time intervals for each of the following milestones:

- a. Birth to specimen collection/initial point of care testing
- b. Specimen collection to receipt by lab
- c. Specimen receipt to reporting out of complete results
- d. Birth to reporting out complete results
- e. Release of out-of-range results to intervention by appropriate medical professional [reported by disorder/point of care test(s)]

In addition to these data, states are being asked to provide common measures around education and HIT because every state in NewSTEPS 360 is focusing on at least one of these two focus areas. The common measures also allow NewSTEPS 360 to more directly view the impact of the state's efforts. These common measures are being finalized with the help of the NewSTEPS 360 awardees.

### Heartland CoIIN

In addition to NewSTEPS 360, one of the CoIIN states, Iowa, is leading a CoIIN for Timeliness in NBS effort within their regional collaborative. In May 2016 the National Coordinating Center (NCC) Heartland Regional Collaborative hosted four states who were interested in improving timeliness in their state for a one-and-a-half-day face-to-face meeting. As with the NewSTEPS CoIIN, states were asked to bring a laboratory representative, follow-up representative, and hospital representative. These states were then trained on Continuous Quality Improvement. During their activities, a representative from the Iowa team sat with each state and shared their experience and provided guidance. During day two, the Iowa team led the goal setting discussions as well as a conversation about next steps. The states have decided to follow the CoIIN model and

have monthly calls, with the Iowa team taking the lead. NewSTEPS will provide technical assistance to Iowa as they lead this effort.

### **Conclusion**

Overall, the NewSTEPS CoIIN for Timeliness in NBS was successful in helping all the states improve their NBS timeliness. All states saw improvement in the Quality Indicators they were tracking. Perhaps more importantly, these states have actively shared their lessons learned and any tools they created with other states strengthening the NBS system's ability to tackle the timeliness issue. Finally, while the NewSTEPS CoIIN for Timeliness in NBS has ended, the impact of this project has not. Six of the original seven CoIIN states are continuing their work in NewSTEPS 360. Another 18 states have also begun continuous quality improvement work to improve their timeliness following the CoIIN model.

## CoIIN Appendix A – Lessons Learned

### Timeliness Top 10 Suggestions from CoIIN Participants

**Number 1. Education and feedback to the partners is KEY.** Once providers are made aware of the reasons for timeliness initiatives, they will run with it! Be prepared for an increase in data requests and TA.

**Number 2. Remember to include all the NBS partners within the state that impact timeliness.** It takes a team and champions from each unit in the hospital including risk managers and quality improvement managers and don't forget couriers.

**Number 3. Help others understand the impact of timely NBS on the families!** Don't assume everyone knows why timeliness is important. - Start with a why!

**Number 4. Find out what is happening in each place.** Don't assume you know what happens in other departments, investigate the current processes.

**Number 5. Talking to and learning from other states is so important!**

**Number 6. Don't forget maintenance. Maintaining timeliness is just as hard as getting it to happen.**

**Number 7. Keep in mind this is for the babies.** Some needed changes won't affect the outcome data, but they are the right thing to do for the newborn.

**Number 8. Focus on high volume providers first. They can make a big impact on your outcome quickly.**

**Number 9. Have a strategy.** There are many right ways to approach timeliness; spend your time on the SMART ones that work within your paradigm

**Number 10. Keep at it.** Be patient and diligent. Never give up.