NewSTEPs Collaborative Improvement and Innovation Network (CoIIN) for Timeliness in Newborn Screening

Final Report
October 2016

The Newborn Screening Technical assistance and Evaluation Program (NewSTEPs) is funded through Cooperative Agreement #U22MC24078 from the Health Resources and Services Administration (HRSA). The Association of Public Health Laboratories (APHL) partners with the Colorado School of Public Health (ColoradoSPH) to implement NewSTEPs by providing quality improvement initiatives, an innovative data repository and technical assistance resources for newborn screening programs.

www.newsteps.org | newsteps@aphl.org

Table of Contents

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 (CSPH). 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 Newborn Screening 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 dried blood spot testing.

NewSTEPs CoIIN for Timeliness in Newborn Screening Overview

NewSTEPs initiated the CoIIN for Timeliness in Newborn Screening (NBS) in response to the community's recognition of a need to improve the time elapsed between birth to the reporting out of newborn screening 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 newborn screening system as outlined by the recommendations from the Secretary's Advisory Committee on Heritable Diseases in Newborns and Children (ACHDNC)[1]. 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 newborn screening):

- 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 newborn screening community. Finally, states developed resources that they continue to share with one another as well as the broader newborn screening community.

[1] It should be noted these recommendations were revised a few months after the 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.[2]
- 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.[3]
- 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[4]: 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.[5]

Progress towards ACHDNC Recommendations

Specimen Collection Prior to 48 hours of life

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).

[2] 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.

[3] Colorado and Wyoming reported QI5b in the following categories 0-2 days, 3-4 days, 5-6 days, 7-14 days, and unknown.

[4] Data were reported in aggregate (time critical and non-time critical conditions). Therefore, results reflect 7 day reporting.

[5] 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 life. 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.

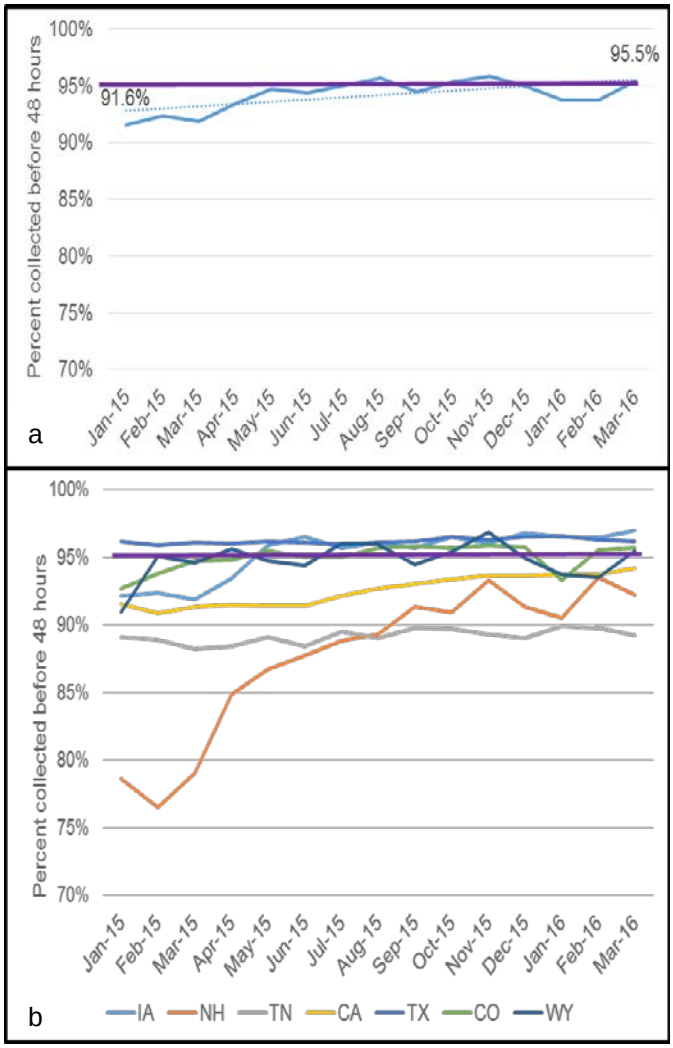


Figure 1a. Median percent from all participating states of specimens collected after 48 hours after birth

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[6]

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 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,

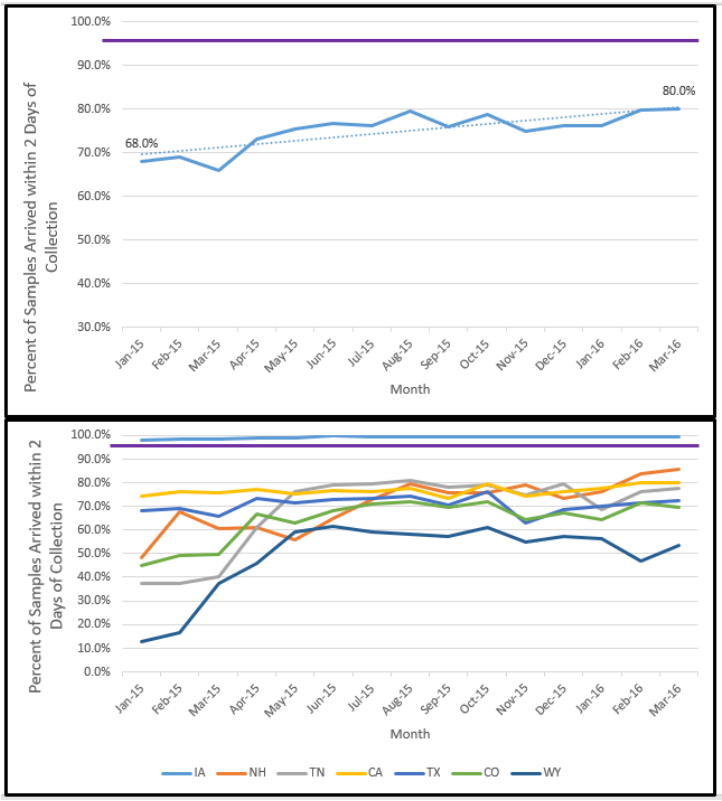


Figure 2a. Median percent from all participating states of samples received within two days of collection

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

[6] This includes specimens who were received same day, day 1 and day 2 after collection as reported by the states.

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.

Results Reported Out within 3 Days of Receipt by Laboratory

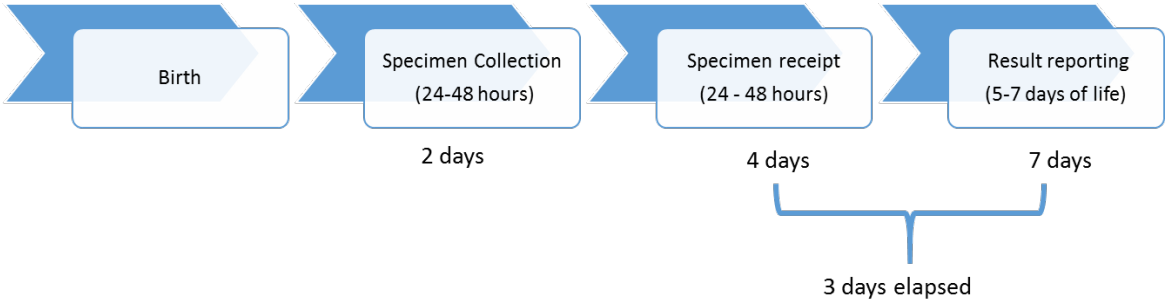


Figure 3: Schematic demonstrating timeline of newborn screening activities through the reporting of results, based on ACHDNC Recommendations.

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[7] 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).

[7] The benchmark presented in this report was used for the CoIIN participants. It may differ from the benchmark used in other NewSTEPs timeliness reports.

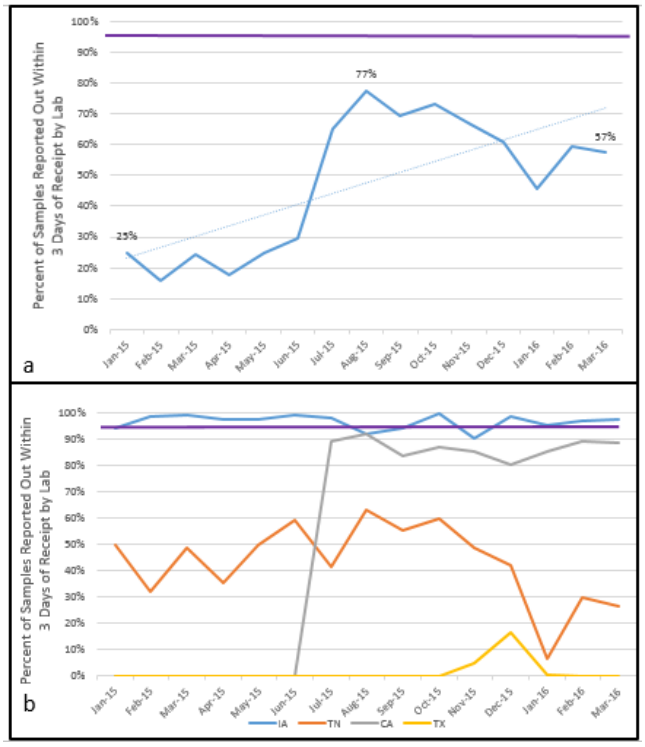


Figure 4a. Median percent of states from participating states of results reported out within 3 days of receipt by the laboratory

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 one of its regional labs. This delayed the time it took 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 because of the dependence on FDA approval for the tests which was not in the state's control. 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 which was 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 only one month with the team continuing to work on improving the 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.

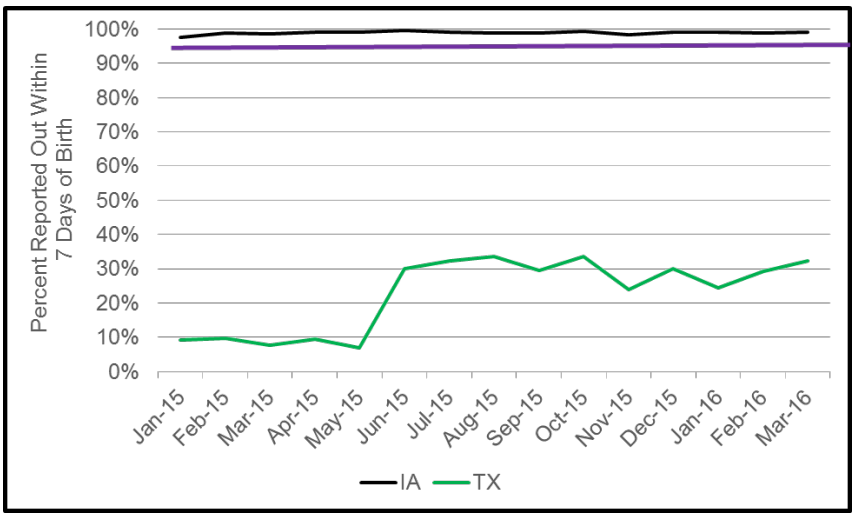


Figure 5. Percent of Specimens Reported out within 7 days of life (QI5d). Purple line indicates ACHDNC goal (95%). each state displayed independently.

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 aimed at changing their internal process flow, 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%.

Summary

All states participating in the NewSTEPs CoIIN for Timeliness in Newborn Screening were able to measure 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 newborn screening 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 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 newborn screening 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.

In the next section we show the states progress towards their individual stated goals.

State Goals

Seven states, selected via an application process, participated formally in the CoIIN for Timeliness in Newborn Screening, 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[8]. 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[9].

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 dried blood spot 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 newborn screening 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 newborn screening 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)

[8] The 2015 annual birth rates come from the state profile data in the NewSTEPs data repository. www.newsteps.org

[9] 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.

State	Goal	Status as of March 31, 2016	Progress Update
	By March 2016 ensure 100% of initial newborn screening specimens are collected prior to 48 hours. By March 2016 reduce unsatisfactory samples to <1.0% at all facilities.	Progress Made. Goal Met.	Up to 95.8% collected prior to 48 hours up from 90.9%. Unsatisfactory specimens dropped to 0.73% from 0.96% baseline statewide.
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 March 2016 increase the statewide percentage of initial NBS collected between 24-48 hours from 85.7% to 93%. By March 2016 increase the percentage of samples that arrived at the lab within 2 days of collection to 90%.	Progress Made Progress Made	Increased to 87.9% during the project. Prior to rolling out the couriers, 37.3% (median of 1st 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%.

State	Goal	Status as of March 31, 2016	Progress Update
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 newborn screening 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 newborn screening 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.
	By March 2016 ensure 100% of initial newborn screening 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 newborn screening blood spot 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 newborn screening and identifies the hospitals' perceived barriers to timely newborn screening. The survey used by Colorado and Wyoming is in Appendix B[10]. 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) newborn screening education video that was sent a year earlier.

These findings helped explained why the newborn screening 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 education posters. Here is a sample one of the posters created:

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

[10] The Colorado and Wyoming survey was created based on a survey Arizona used.

These posters have been shared with the broader newborn screening community via a timeliness presentation at the 2016 APHL Newborn Screening and Genetic Testing Symposium, as a report out to CoIIN states, in a presentation to the Heartland CoIIN, and on the NewSTEPs website.

Figure 7: A poster Colorado created with input from a hospital that is posted in the birthing center nurseries.

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.

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).

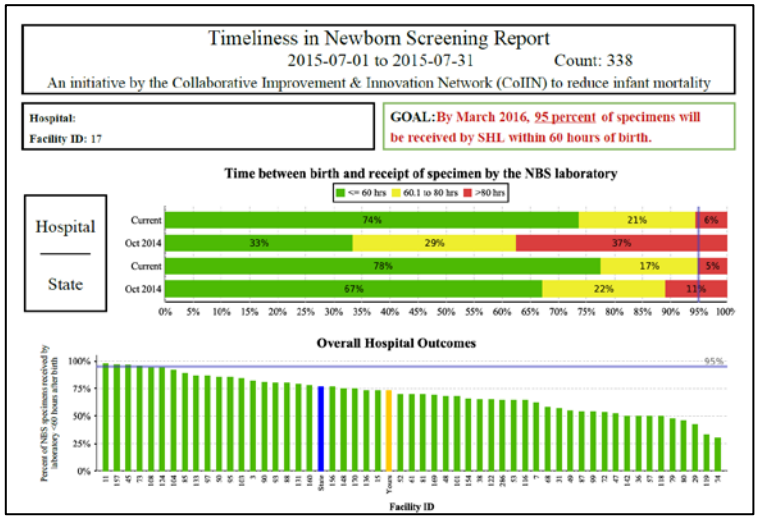


Figure 8: A sample of the reporting tool Iowa created. This report is sent out to hospitals each month to show their progress or lack thereof in getting samples to the laboratory in a timely manner.

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 newborn screening 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 newborn screening now provides custom analysis and data sets to help any interested hospital track their timeliness progress made as they institute new changes.

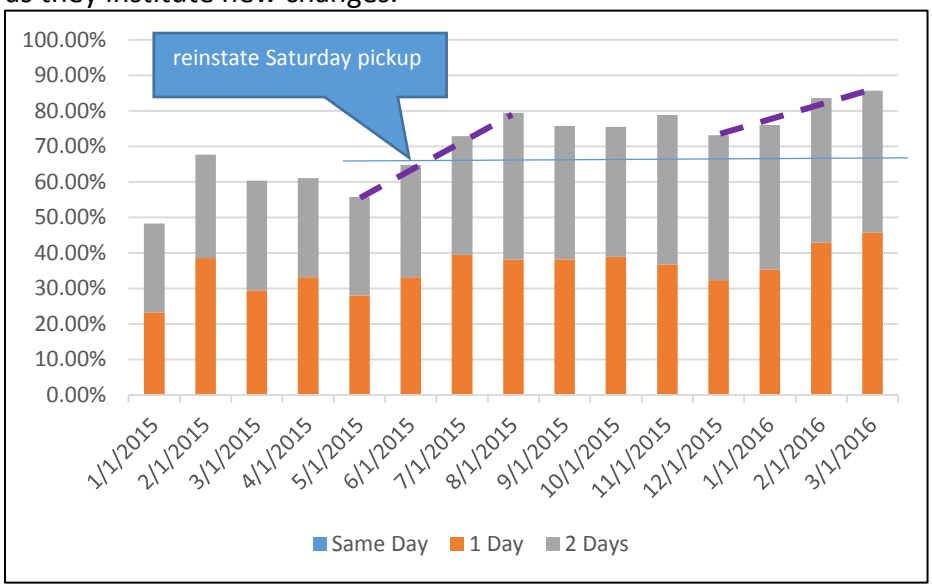


Figure 9: New Hampshire - Percent of Specimens Arriving at Lab within 2 Days of Collection. The impact of hospital education (dashed lines show increase following reports) and adhering to the courier contracts in New Hampshire

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

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).

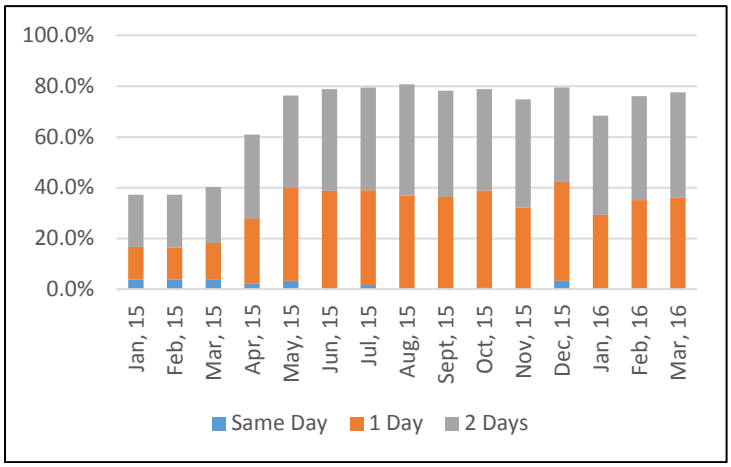


Figure 10: Tennessee - Percent of Specimens Arriving at Lab within 2 Days of Collection.

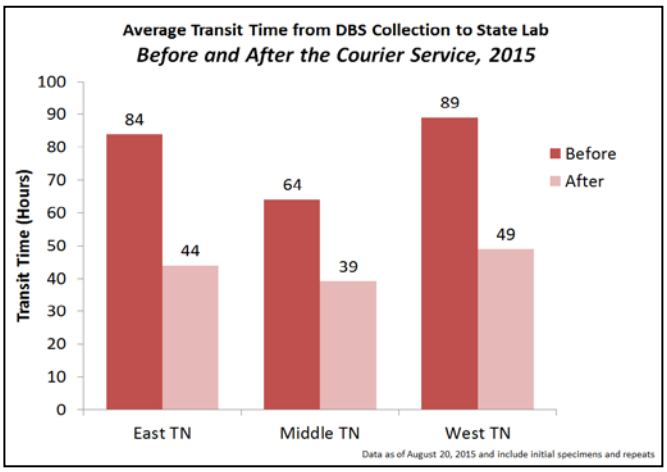


Figure 11: The change in average transit time for NBS dried blood following the introduction of a courier service. This graph was created by the Tennessee CoIIN team.

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 funding distribution limitations, 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%.

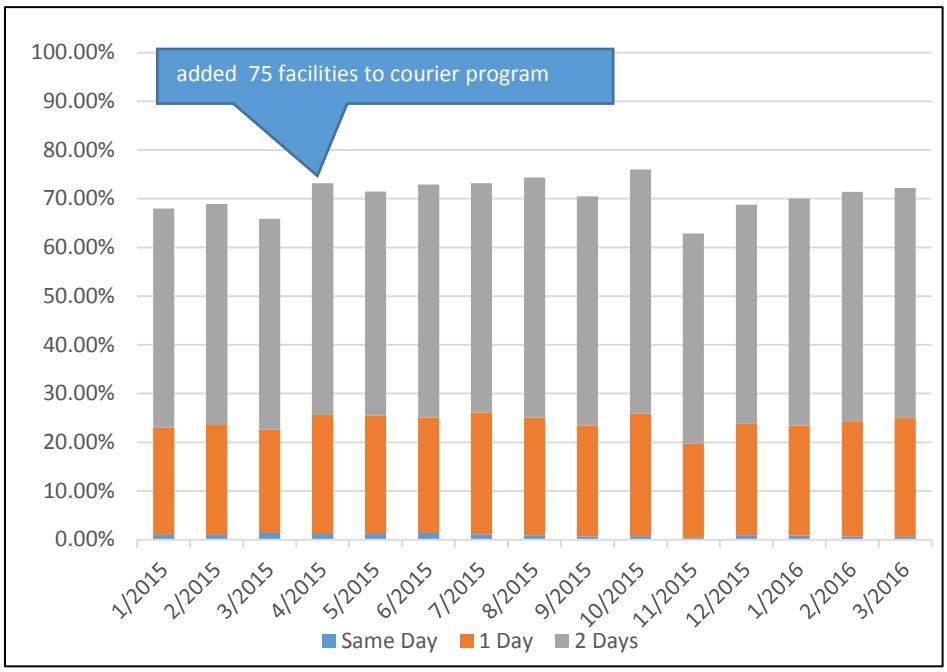


Figure 12: Texas - Percent of Specimens Arriving at Lab within 2 Days of Collection. The impact of increasing courier services in Texas.

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.

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[11] also began processing samples on Saturdays in March 2015. This change in the Colorado laboratory hours prompted Colorado to add a weekend day to their courier service to match their new laboratory hours. Also, around the same time Wyoming added a Sunday pick-up at two top volume hospitals. 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.

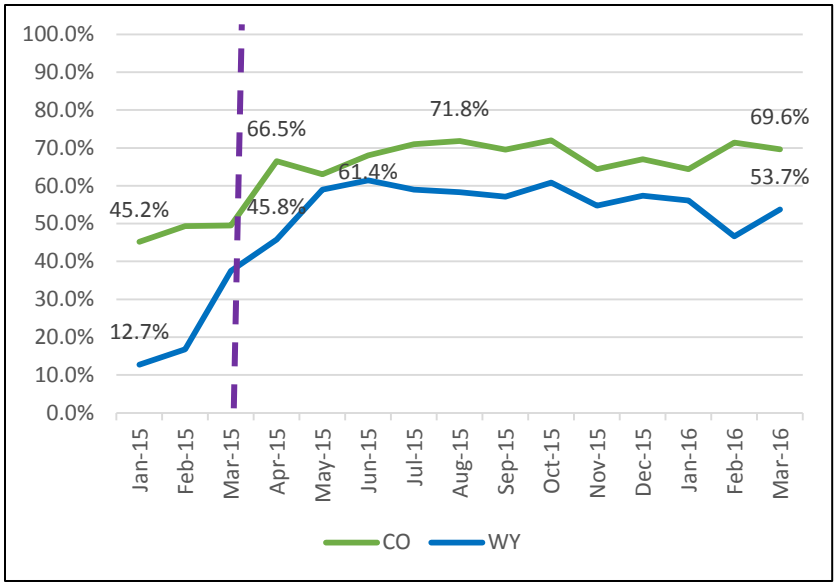


Figure 13: Colorado and Wyoming - Percent of Specimens Arriving at Lab within 2 Days of Collection. The impact of increasing laboratory hours.

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 they tested a compressed workflow and elimination of wait times between separate processes within that workflow. These changes in workflow 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

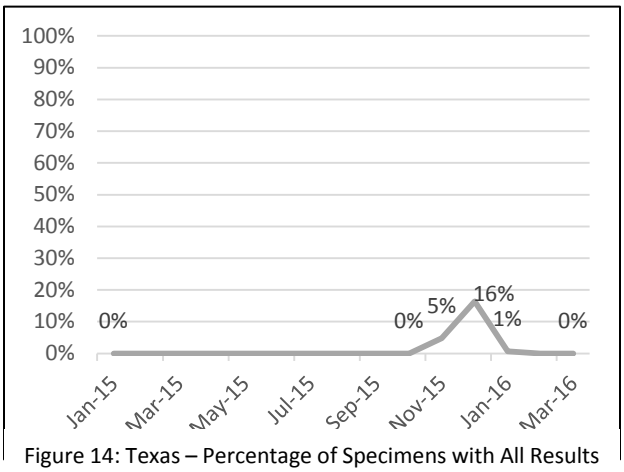


Figure 14: Texas – Percentage of Specimens with All Results Reported Out within 72 hours of Receipt by Laboratory – The impact of changing laboratory workflow in Texas during November and December 2015.

[11] Colorado analyzes the blood spot specimens for Wyoming.

indicator data that saw an increase in the percentage of specimens with all results reported out within 72 hours.

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). 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.

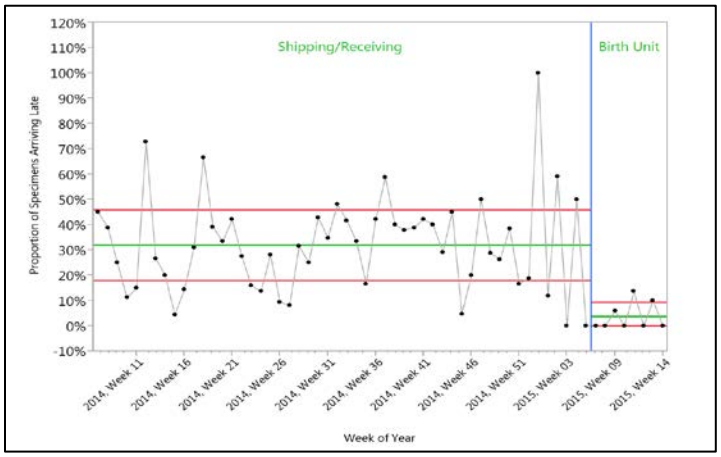
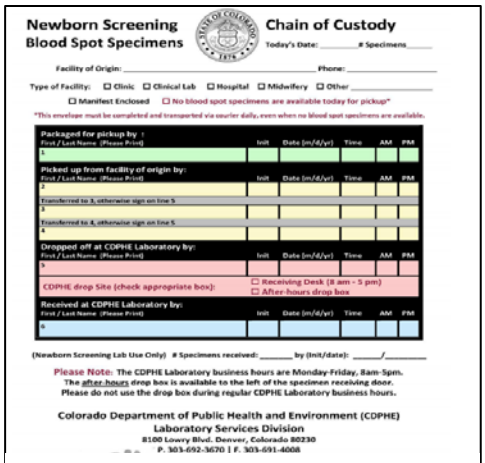


Figure 15: The impact of adding a pick up time and changing the pickup location for one hospital in New Hampshire. This graph was created by David LaFlamme.

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 newborn screening 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


Newborn Screening Blood Spot Specimens

Chain of Custody

Today's Date: _____ # Specimens_____

Facility of Origin: _____ Phone: _____

Type of Facility: ☐ Clinic ☐ Clinical Lab ☐ Hospital ☐ Midwifery ☐ Other _____

☐ Manifest Enclosed ☐ No blood spot specimens are available today for pickup*

*This envelope must be completed and transported via courier daily, even when no blood spot specimens are available.

Packaged for pickup by : First / Last Name (Please Print)	Init	Date (m/d/yr)	Time	AM	PM
1.					
Picked up from facility of origin by: First / Last Name (Please Print)	Init	Date (m/d/yr)	Time	AM	PM
2.					
Transferred to 3, otherwise sign on line 5					
3.					
Transferred to 4, otherwise sign on line 5					
4.					
Dropped off at CDPHE Laboratory by: First / Last Name (Please Print)	Init	Date (m/d/yr)	Time	AM	PM
5.					
CDPHE drop Site (check appropriate box):	☐ Receiving Desk (8 am - 5 pm) ☐ After-hours drop box				
Received at CDPHE Laboratory by: First / Last Name (Please Print)	Init	Date (m/d/yr)	Time	AM	PM
6.					

(Newborn Screening Lab Use Only) # Specimens received: _____ by (Init/date): _____/_____

Please Note: The CDPHE Laboratory business hours are Monday-Friday, 8am-5pm. The after-hours drop box is available to the left of the specimen receiving door. Please do not use the drop box during regular CDPHE Laboratory business hours.

Colorado Department of Public Health and Environment (CDPHE)
Laboratory Services Division
8100 Lowry Blvd. Denver, Colorado 80230
P. 303-692-3670 | F. 303-691-4008

Figure 16: Chain of accountability form used by Colorado.

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.

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[12] 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 newborn screening dried blood spots.
Focus Area 3: Expanding operating hours to provide more uniform coverage for newborn screening 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.

[12] The legislation proposed can be found at the following website.
http://www.cdph.ca.gov/services/DPOPP/regs/Documents/DPH-09-010ENBSRegText.pdf

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 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 newborn screening 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 dried blood spot specimens/cards due to improper collection and/or transport
a) Percent of invalid dried blood spot specimens/cards due to improper collection and
b) Percent of invalid dried blood spot specimens/cards due to improper transport

Quality Indicator 2: Percent of dried blood spot 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 newborn screening 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 newborn screening 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.

Appendix A – Lessons Learned from CoIIN

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 newborn screening 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 newborn screening 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.