Every Drop Counts: Improving Sample Quality in Arizona

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NewSTEPs CQI 2021 National Meeting
May 25, Aug 24, Dec 7 • An APHL™ Event

BACKGROUND

Arizona is a 2 screen state that receives a high volume of unsatisfactory samples each day. The follow up program has had to dedicate 1 FTE to following up on these samples and the volume is not sustainable.

The aim of the project was to reduce the amount of unsatisfactory screens submitted to the Arizona State Public Health Laboratory from a statewide high of 2.6% (roughly 2080 samples requiring follow up) in 2019 to 1.5% by April 1, 2021.

METHODS

- Used Tableau reports to identify high volume submitters of unsatisfactory samples
- Created training materials and resources to provide training
- "Borrowed" pictures and inspiration from other states projects to create resource and training materials
- Key contacts identified at the practices
- Monitored progress on reducing unsat rates with targeted facilities by providing monthly data on their progress
- Make training materials available broadly to all collection sites including hospitals
- Regular check ins with practice to review progress and reinforce proper collection methods

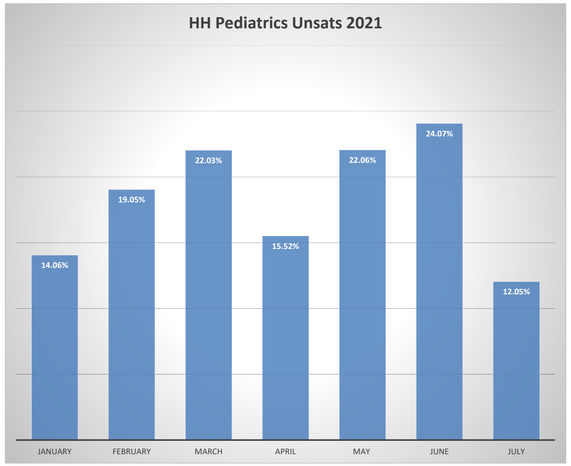
RESULTS

Initially , the Arizona team partnered with Sonora Quest Laboratories (a high volume lab with hundreds of draw stations around the state) to identify draw stations with high volume unsats to target interventions.

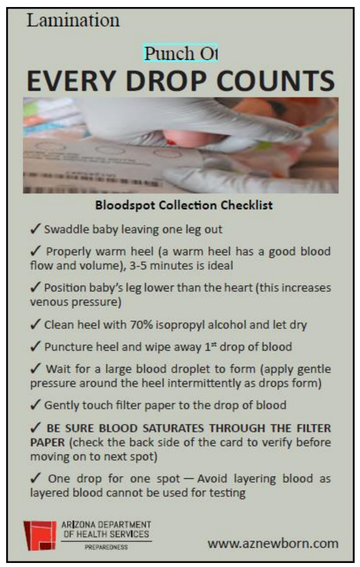
- NBS provided stamps to collect site codes to identify specific sites
- This took a long time to disseminate and track usage with limited impact

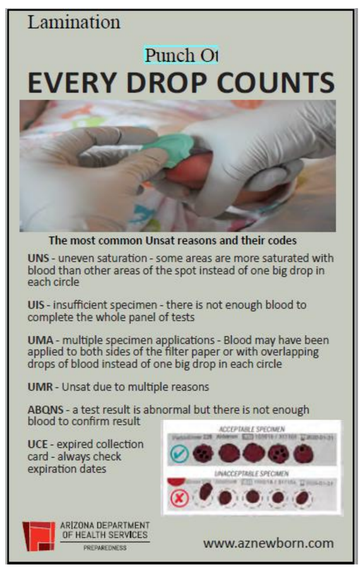
Next, the focus shifted to one specific high volume pediatric practice that was identified as the top submitter of unsatisfactory samples in the state between January 2021 to April 2021. Baseline data was reviewed, a PowerPoint training was presented to key contacts who then provided training to the MA's at all 3 practice locations in May. In June, data was reviewed again demonstrating no change. The ***Badge Buddy*** and ***Bloodspot Collection Checklist*** were then provided to reinforce best practices in July. July data was reviewed again in August and improvements could be seen. Immediate feedback to the practice to reinforce the progress was made. Data will be monitored and the next intervention, if needed, will be hands on training.

Unsat Rates Jan-July

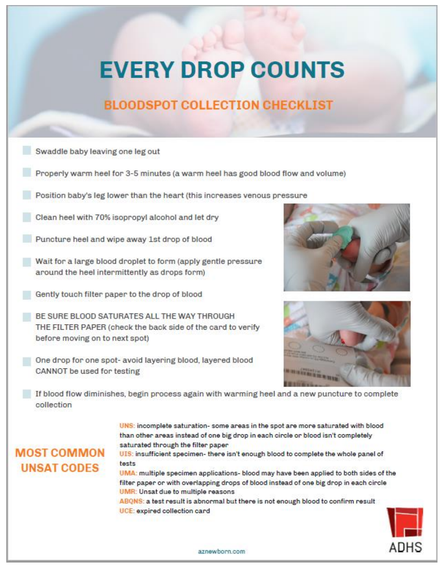


Badge Buddy





Checklist



CONCLUSIONS

- Don't be afraid to "start over"
  - Every step in the process builds on what you have learned
- Partnership development is key
- Develop training materials early in the project
  - Badge buddy has been disseminated to all Sonora Quest Phlebotomists to wear on their badge (1,000 were distributed)
  - Badge buddy is currently being disseminated to hospital post partum units and pediatrician offices
- The CQI team continues to be engaged and will revisit the targeted interventions with the Sonora Quest Draw stations
  - Revisit metrics for specific draw stations and phlebotomists
  - Providing monthly data to Sonora Quest and targeting training

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Acknowledgements / Sources

Thank you to the South Dakota and Georgia teams for their inspiration and pictures used on the Badge Buddy and Checklist!.

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Addressing the Impact of the COVID-19 Public Health Emergency on Newborn Screening: Virtually Creating the Virtual Site Visit

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BACKGROUND/INTRODUCTION

The COVID-19 public health emergency resulted in the suspension of the ongoing Newborn Screening Program (NBS) Area Service Center (ASC) mandated in-person site visits. These site visits are regularly performed by the ASCs to assess perinatal licensed health facilities' compliance with California NBS regulations and the integrity of the NBS specimen chain of custody processes. A typical site visit entails the introductions of staff, the review of process from collection to shipment, the review of Online Specimen Tracking (OST) of specimen receipt by the screening laboratory, a PowerPoint presentation specifically related to the facility's Continuous Quality Improvement (CQI) issues such as timeliness, and a walking tour of the areas involved with screening. All seven centers in California came together virtually to create a Virtual Site Visit (VSV) model by developing, testing, and validating homogenized tools for use and customization by the ASCs. Association of Public Health Laboratories (APHL) Public Health Emergency funding was used to support the VSV model development.

METHODS

A Virtual Site Visit quality improvement plan with detailed timelines was developed virtually by all ASCs with Genetic Disease Screening Program (GDSP) in January 2021 that included the creation of tools for the VSV and conducting pilots of seven VSVs (Figure 1 and Figure 2).

- A readiness survey was designed and administered to measure facilities' ability to participate in a proposed VSV.
- A tracer tool was created to measure regulatory compliance and to document the NBS specimen chain of custody with photographs (Figure 3). Key areas included: specimen collection processes including handling and shipment, documentation of specimens not collected, specimen tracking, and facility changes due to the COVID-19 pandemic.
- A library of slides were created to provide ASCs with pre-formatted templates for VSV presentation. See Figure 4 for two sample slides.
- NBS resources were packaged to be used by each ASC based on facility needs and interest.
- A pre and post VSV evaluation was designed for facility completion.
- An all-ASC final project evaluation was completed in July 2021.

Figure 1

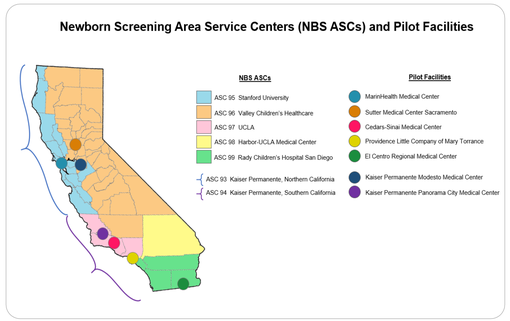


Figure 2

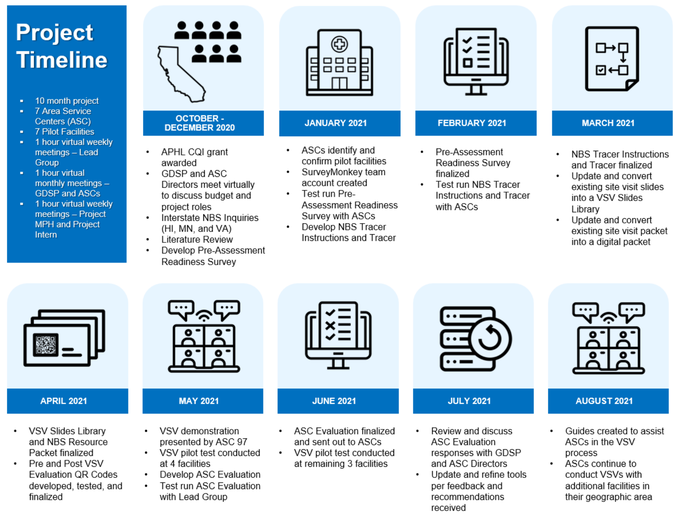


Figure 3

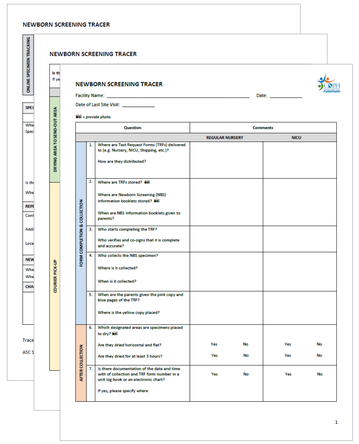
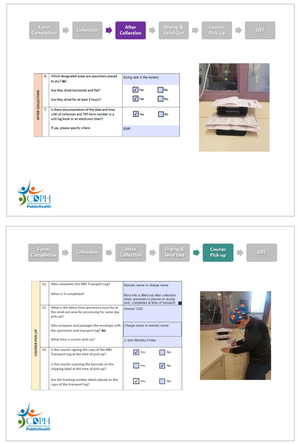
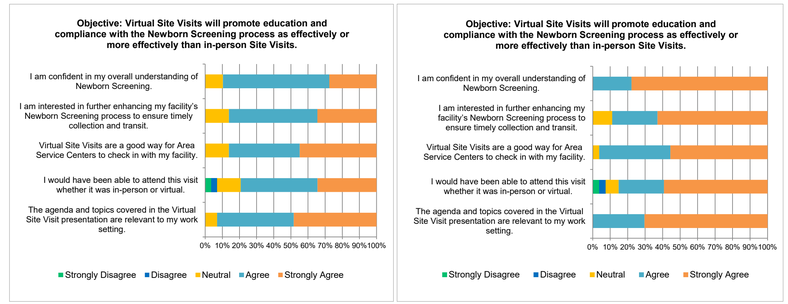


Figure 4



RESULTS



Results from the Pre-VSV Evaluation (left) and Post-VSV Evaluation (right) of all pilot facilities.

CONCLUSION

Evidence supports the use of a Virtual Site Visit model to continue to assess time critical chain of custody activities related to compliance with state screening regulations, quality monitoring, and education within a crisis situation. Despite ASC staff not being able to conduct in-person site visits due to the COVID-19 pandemic, they were able to facilitate the identification of processes that need further improvements at licensed perinatal health facilities, and provide the additional support and education in a virtual format that otherwise would not occur. Seven VSVs were conducted throughout California at private hospitals, university medical centers, community hospitals, and Kaiser Permanente. ASC staff found that the survey and evaluation tools can be accessed using any device. Video conferencing platforms such as Zoom, Microsoft Teams, and WebEx met all of the requirements necessary for meeting and engaging with the facility staff virtually. The complete set of VSV tools and guides were given to all ASCs to continue conducting additional VSVs within their geographic area (Figure 5). The utilization of a VSV allows state follow-up programs to provide real-time assessment and support that can be utilized both during and outside of a public health emergency.

Figure 5

Virtual Site Visit Tools	Virtual Site Visit Guides
1. Pre-Assessment Readiness Survey 2. Newborn Screening Tracer 3. Pre-Virtual Site Visit Evaluation 4. Virtual Site Visit Slides Library 5. Post-Virtual Site Visit Evaluation 6. Newborn Screening Resource Packet	1. Virtual Site Visit Process Guide Template 2. Virtual Site Visit Guide for Attendees 3. SurveyMonkey QR Codes and Links 4. Using Adobe Acrobat PDF 5. Downloading Pre-Assessment Readiness Survey Responses on SurveyMonkey 6. Downloading Pre/Post-Virtual Site Visit Evaluation Responses on SurveyMonkey

For More Information

Harbor-UCLA Medical Center NBS ASC • (310) 222-3751
UCLA NBS ASC • (310) 826-4458
Rady Children's Hospital San Diego NBS ASC • (858) 966-8708
Valley Children's Healthcare NBS ASC • (559) 353-6416
Stanford University NBS ASC • (650) 724-8120
Northern CA Kaiser Permanente NBS ASC • (510) 752-6192
Southern CA Kaiser Permanente NBS ASC • (844) 343-9372

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Acknowledgements / Sources

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The Mystery of Malonic Acidemia False Positives: An Investigation

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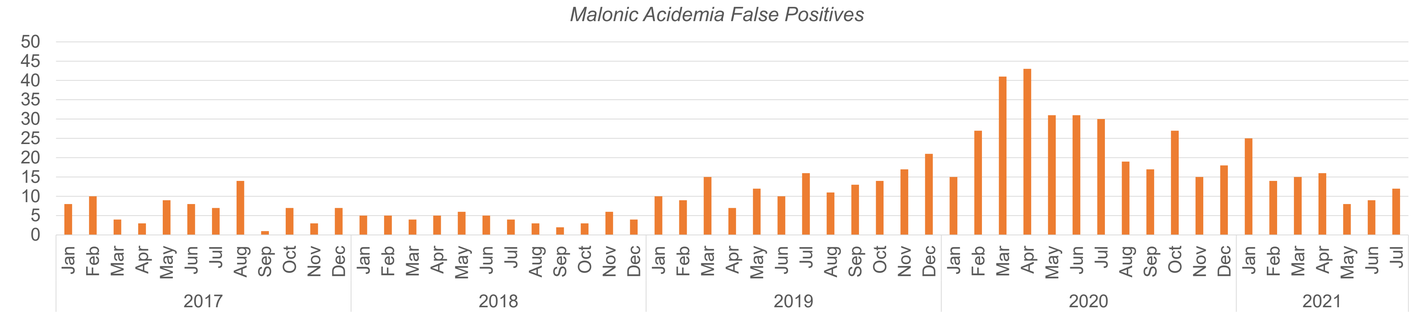
Genetic Disease Screening Program, California Department of Public Health

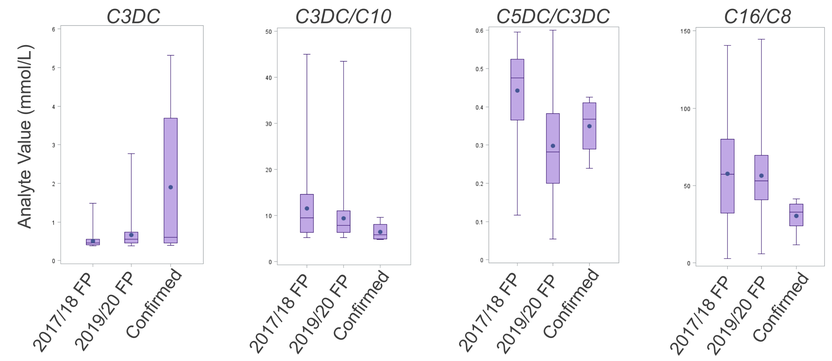
Background

Malonic acidemia (MAL) is a rare metabolic disorder that affects about 1 in 750,000 California (CA) newborns. A deficiency of malonyl-CoA decarboxylase can cause complications that are life-threatening in the neonatal period but can be managed through diet and supplementation. The CA Newborn Screening (NBS) Program observed an increase in MAL false positives (FP) in January of 2019, which remained elevated into early 2021. The increase in FPs has led to several negative consequences, including parental anxiety, concern about NBS methodologies by clinicians, and overburdening of follow-up care providers. This report describes the investigation into CA's increase in MAL FPs as well as the interventions to reduce FP rates.



Study Design

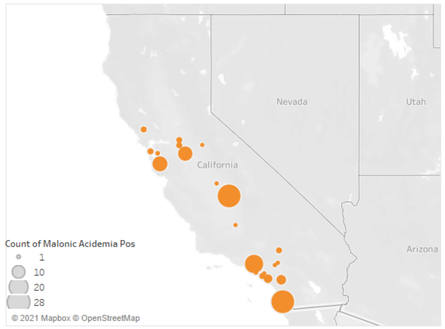
- To screen for MAL, the CA NBS Program evaluated C3DC, the ratio of C3DC to C10 (C3DC/C10), and the ratio of C5DC to C3DC (C5DC/C3DC) in dried blood spots (DBS) using PerkinElmer's NeoBase™ Non-derivatized MSMS kit.
- Procedural interventions were implemented at hospitals to increase awareness of collection workflows and at regional laboratories to retest screen positive specimens.
- We analyzed screening data for specimens accessioned from January 1, 2017 through March 31, 2021 to determine the magnitude and cause of the issue, and to formulate a new screening algorithm.
- On May 5, 2021, a new screening algorithm was implemented which uses the analytes below.



Results

- MAL FP rates rose from 0.01% in 2017-2018 to 0.05% in 2019-2020.
- No confirmed cases have been reported since 2018.
- The 99.9 percentile for C3DC increased from 0.43 to 0.46, and the 0.1 percentile of C5DC/C3DC decreased from 0.48 to 0.37, respectively. No changes were observed in C3DC/C10.
- FPs were primarily concentrated at 5 hospitals which collected DBS for 75% of FP but only 5% of CA's DBS.

DBS Collection Facilities with Malonic Acidemia Positives, Aug 2020 - Feb 2021



- No significant changes in workflows were identified at hospitals with large volumes of FPs.
- A laboratory investigation into the effect of sanitation wipe contamination on DBS yielded insignificant results.
- After considering 5 adjustment scenarios, we found the greatest FP reduction when adjusting cutoffs for C3DC and C5DC/C3DC in our historical algorithm and adding a new cutoff for C16/C8. In theory, the new algorithm would cause 64% of previously interpreted false positives between January 2019 and March 2021 to recalculate to negative.
- After adjusting our screening algorithm, FPs were reduced by 57%. The FP rate decreased from 0.05% in 2019-2020 to 0.03% from May 5, 2021 through July 31, 2021. No false negatives have been identified since the new algorithm was implemented.

	C3DC (>=)	C3DC/C10 (>=)	C5DC/C3DC (<=)	C16/C8 (<=)	Predicted FP Reduction, 1/2019-3/2021	Observed FP Reduction, 5/2021-7/2021
Historical cutoffs	0.38	5.2	0.6	-		
Adjustment #1	0.38	5.2	0.50	-	6%	-
Adjustment #2	0.40	5.2	0.50	-	11%	-
Adjustment #3	0.38	5.2	0.6	50.0	56%	-
Adjustment #4	0.38	5.2	0.50	50.0	60%	-
Adjustment #5	0.40	5.2	0.50	50.0	64%	57%

Conclusion

An investigation into the rise in MAL FPs indicates that contamination of DBS may be the source of the issue, though it is unclear where the contamination is originating. We implemented several workflow changes at hospitals and laboratories but adjusting our screening algorithm provided the greatest reduction in MAL FPs. Our MAL FP rate remains slightly elevated compared to rates before this issue began, and continuous monitoring will be key to determining if further intervention is warranted.

Contact

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A Collaborative Effort by Nemours Cystic Fibrosis Center and Delaware Newborn Screening Program to Improve Referrals for Newborns with Abnormal Screen Results

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INTRODUCTION

• Newborn Screening (NBS) for Cystic Fibrosis (CF) accounts for the majority of new diagnoses since mandated by all 50 states by 2010.

• CF NBS measures immunoreactive trypsinogen (IRT) as the first indicator of positive screening. When elevated, a second tier of testing is initiated. Subsequent utilization of DNA testing improves sensitivity and specificity of diagnosing CF patients (IRT/DNA).
  • Another strategy repeats IRT (IRT/IRT), but use is declining due to risk of missed diagnoses and delayed follow-up.

• The goal of CF NBS is to achieve early CF diagnosis so that comprehensive medical and psychosocial therapies can be implemented in infants prior to the onset of clinical symptoms to improve disease outcomes.
  • Thus, infants require diagnostic testing by <4 weeks of age.

• The Delaware (DE) NBS Program transitioned from IRT/IRT/DNA to IRT/DNA testing strategy in January 2018. DNA testing has always included a 39+4 CFTR mutation panel.

• This study outlines the collaborative effort by the DE NBS Program and CF Clinic at Nemours-A.I. duPont Hospital for Children to improve timeliness of referral and diagnostic testing of infants with abnormal CF NBS before and after the screening test strategy transition took place.

METHODS

- The medical records of infants with abnormal CF NBS referred by the DE NBS Program were reviewed from January 2017-December 2020.
- Charts were queried for: infant date of birth, age at referral to schedule diagnostic sweat testing (ST), family contact and age at ST completion with discussion of results. Infants referred during national COVID-19 pandemic "shutdown" between 3/13/2020-05/14/2020 were excluded.
- The DE NBS Program and CF clinic routinely communicate and collaborate to provide and review infant referrals and their testing outcomes as shown in Figure 1.
- Number of infants referred by DE NBS Program by year (testing strategy):
  - 2017: 16
  - 2018: 38
  - 2019: 57
  - 2020: 64
- A simple t-test was used to compare data obtained in 2017 (using IRT/IRT/DNA strategy) vs. 2018-2020 (following transition to IRT/DNA strategy), with $p \leq 0.05$ considered significant.

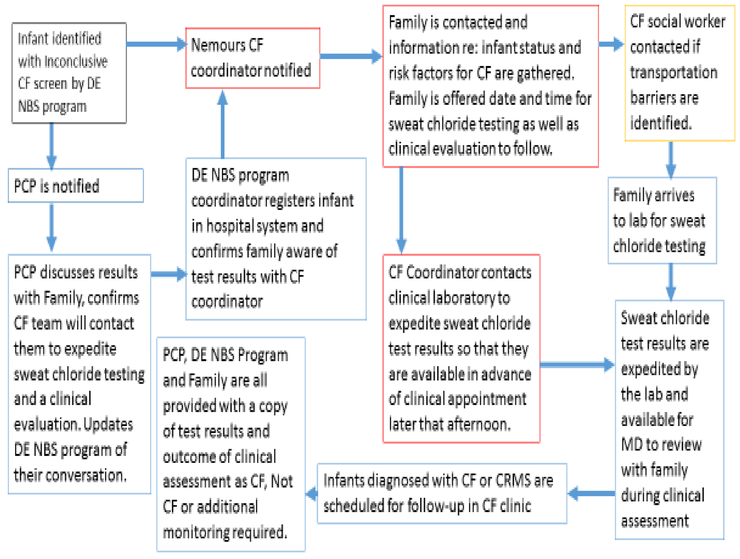

Figure 1: Collaborative Pathway arranged by Nemours- A.I duPont Hospital for Children CF Center with State of Delaware Newborn Screening Program and Local Primary Care Providers (PCP) by which families of infants with abnormal CF NBS are (1) notified of results, (2) scheduled for timely diagnostic testing and review of results and (3) arranged for appropriate follow up (if indicated).

RESULTS

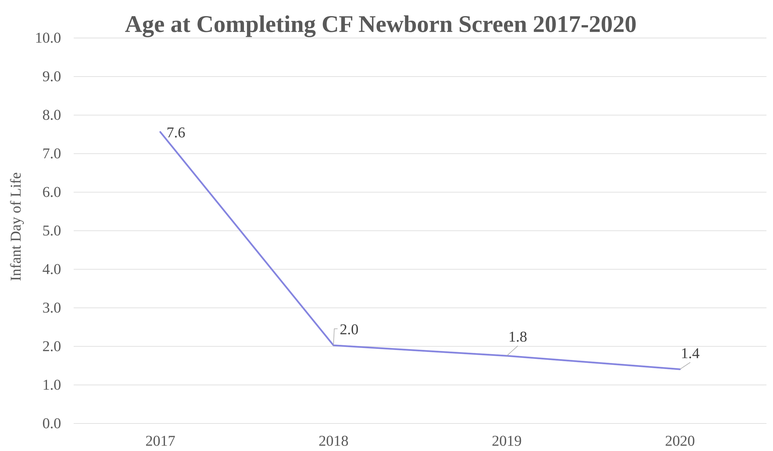

Figure 2: Average age at completion of CF NBS improved from 7.6 ± 5 days in 2017 to 2 ± 3 days in 2018, 1.8 ± 2.7 days in 2019 and 1.4 ± 1 days in 2020.

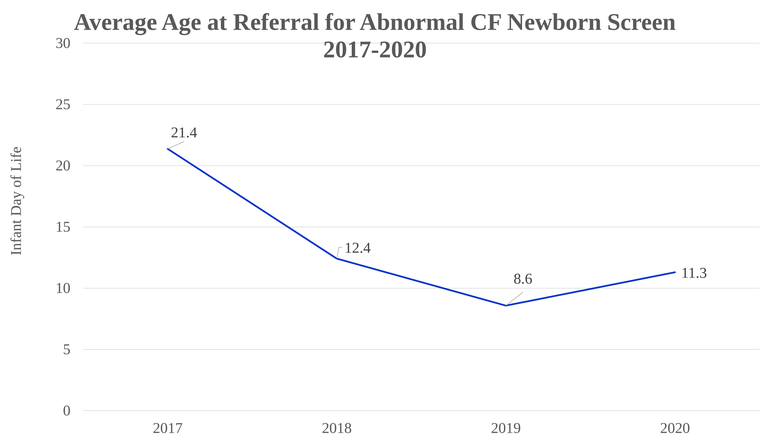

Figure 3: Average age an infant was identified with abnormal CF NBS and referred for diagnostic testing decreased from 21.4±11.3 days in 2017 to 12.4±13.8 days in 2018 ($p=0.02$) and further decreased to 8.6±3.8 days in 2019 ($p=3.3E^{-10}$). In 2020, age at referral (11.3±13.9 days, $p=0.15$) was unchanged compared with those evaluated in 2019.

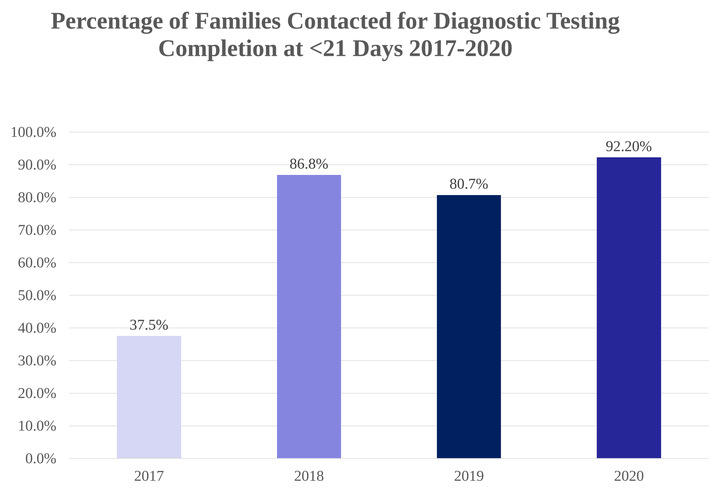

Figure 4: Percentage of caregivers contacted to schedule diagnostic testing when their infant was <21 days improved from 37.5% (n=6/16 infants) in 2017 to 86.8% (n=33/38 infants) in 2018, 80.7% (n=46/57 infants) in 2019 and 92.2% in 2020 (59/64 infants).

RESULTS

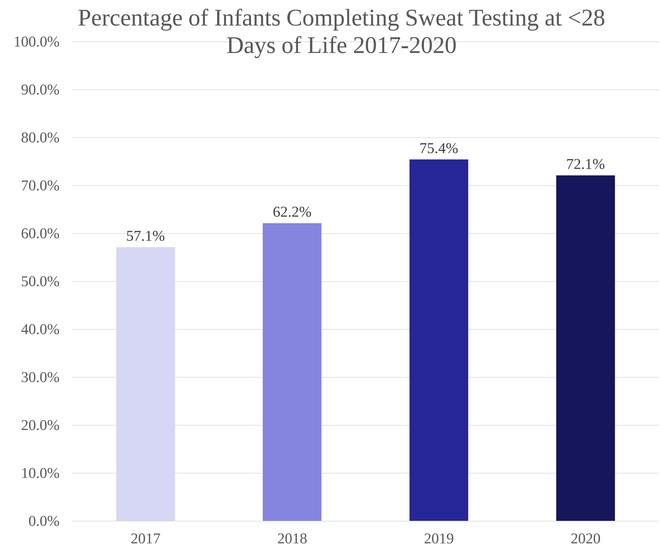

Figure 5: Percentage of Infants with Successful Sweat Chloride Testing Completion at <1 month of age improved from 57.1% (n=8/14 infants) in 2017 to 62.2% (n= 23/37 infants) in 2018, 75.4% (n=43/57 infants) in 2019 and was maintained at 72.1% (n=44/61) in 2020.

- A total of 11 infants from DE were diagnosed with CF between 2017-2020.
- Average age at CF diagnosis between 2017-2020 was 18 days.
  - 3 infants were diagnosed based on CFTR gene analysis results; all infants completed confirmatory sweat chloride testing.
  - Overall Infant age at CF diagnosis ranged from 6-43 days
    - All infants were known to the CF team while test results were pending.

CONCLUSIONS

• Transition from IRT/IRT/DNA to IRT/DNA CF NBS strategy improves timeliness of referral for diagnostic ST.

• Close collaboration between CF clinic and state NBS programs improves communication to identify infants with abnormal CF NBS and connect with families to schedule and complete diagnostic ST.

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Improving Newborn Screening Testing Turnaround Time using Lean Six Sigma

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BACKGROUND

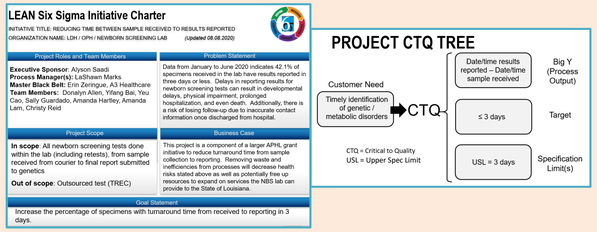
The Louisiana Newborn Screening (LA NBS) Program aims to reduce the median turnaround time (TAT) of sample collection to result reporting from six to five days by improving specimen tracking and laboratory process workflows.

METHODS

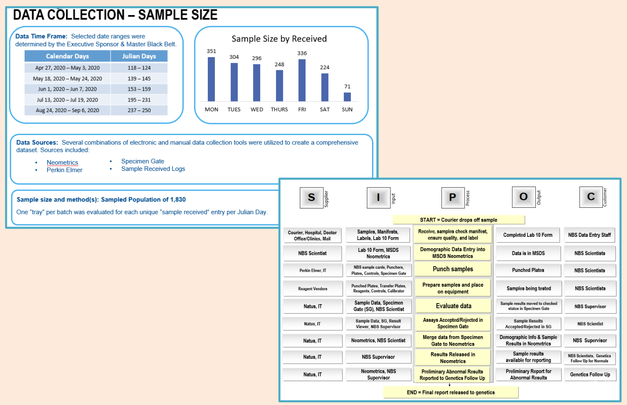
The LA NBS program employed a problem solving approach known as DMAIC (duh-may-ik) to drive a Lean Six Sigma project focused on improving laboratory process workflows by eliminating waste and process defects.

The five phases of DMAIC include:

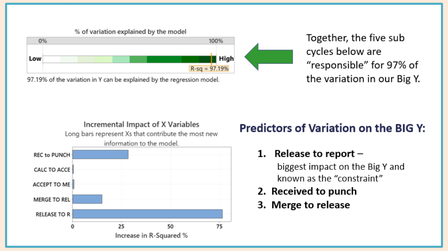
- **Define –** define the problem, improvement activity, project goals, customer requirements



- **Measure –** measure process performance, process map, capability analysis



- **Analyze -** analyze process to determine root cause of variation and defects



- **Improve -** improve process performance by addressing/eliminating root causes

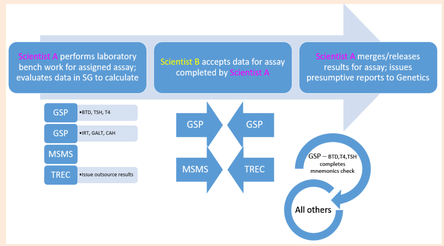
Based on the results from the Analyze phase, the NBS Lab focused improvements on the operational workflow of releasing results. The NBS Lab incorporated operational flow to "merge" by 11am and release results by 2pm daily for samples tested the previous day.

When measured, these changes improved the median turn around times as shown below:

- **from 5 to 2 days** - Sample Receipt to Results Reported
- **from 6 to 4 days** - Sample Collection to Results Reported

- **Control –** sustain improved process and future process performance, visual controls, mistake proofing

Releasing Results Process Workflow



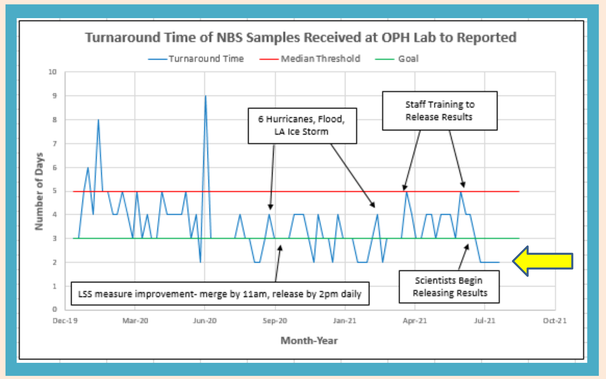
In order to sustain improvements the NBS Lab:

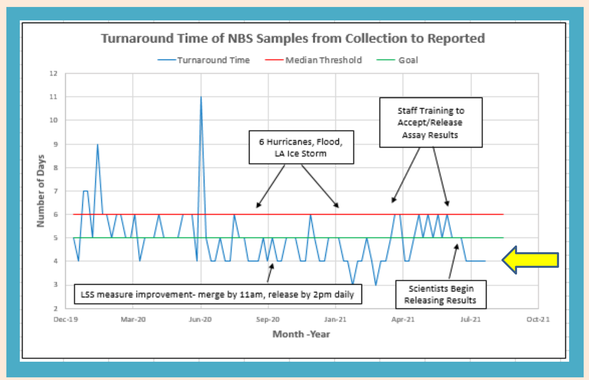
- Trained seven scientists to release results
- Monitors sample pending reports daily
- Conducts daily 11am huddle with NBS unit
- Incorporated visual control boards

RESULTS

The LA NBS Lab's process improvements resulted in a 3 day reduction in median TAT, samples received to results reported was decreased from 5 to 2 days. As of July 2021, 64.2% of samples were reported within the original goal of 3 days from receipt at the NBS Lab, an increase of 22.6% since start of the project. Furthermore, the process improvements led to a 2 day reduction in median TAT, from 6 to 4 days, for sample collection to results reported. Also, as of July 2021, 79.1% of samples have results reported within the original project goal of 5 days, which is an increase of 24.8%. It is important to note that these measurements are for the samples with *normal* results, as any sample with *abnormal* results are processed through an expedited reporting workflow for quicker notification to the Genetics Diseases Program for patient follow up.

Weekly Turnaround Time Beginning December 2019 to Present





CONCLUSION

By applying DMAIC, the NBS Laboratory identified a significant process constraint in sample result reporting. In order to alleviate the workflow constraint, seven NBS Scientists were trained to release results providing overlapping resources in the department, a standard operating process for releasing sample results, and consistent predictable testing turnaround times.

The Louisiana Office of Public Health NBS Lab has a median 2 day TAT for sample receipt at the lab to results reported and 4 days from newborn screening sample collection to results reported.

The DMAIC process provided our team systematic data driven tools to determine the process steps to prioritize improvements. It has introduced a "method" for the NBS program to follow for implementing and sustaining further process improvements. In addition, two team members are training for certifications to lead future Lean Six Sigma projects for the LA NBS program. Next goal is to reduce unsatisfactory newborn screening sample collections.

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Acknowledgements / Sources
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Empowering Parents to Take a More Active Role in the Newborn Screening Process Through Prenatal Education

Shelby Atkinson, MPH, Isabel Hurden, MPH, Kristen Thompson, MPH, Mary Kleyn, MSc

NewSTEPs CQI 2021 National Meeting
May 25, Aug 24, Dec 7 • An APHL™ Event

BACKGROUND

- Studies show that parents generally have limited awareness of newborn screening (NBS) and providing information to expectant parents may increase satisfaction with and support for screening.[1,2]
- In Michigan, blood spots are stored for up to 100 years after NBS is complete. Around the time of screening, families are asked to complete a consent form about whether their child's stored blood spots can be used in de-identified research.
- The goal of this project is to improve the NBS prenatal education experience in Michigan, so that parents are more active participants in the NBS process.
- Project staff will create and distribute a new educational checklist during the prenatal period through a partnership with three birthing hospitals with the goal of improving parental knowledge and participation in the NBS and BioTrust program.

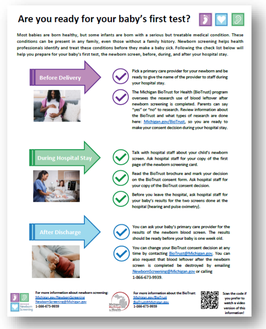
METHODS

- We will test a new educational document called the "NBS Checklist". The checklist will be provided to parents prenatally by 3 Michigan hospitals during virtual hospital tours or in educational packets at prenatal care offices. Distribution will occur between 34-38 weeks of pregnancy.
- A survey instrument will be used to establish baseline data and to evaluate the effectiveness of the proposed intervention.
- Prior to implementation of the checklist, we will survey 1,000 families who delivered at the participating hospitals. Following document distribution, we will survey an additional 1,000 families.
- To encourage survey completion, families will be offered an incentive worth $10. The incentive is a "new mother's gift bag" with first aid related items customized with the Michigan NBS logo.

RESULTS

- Since the start of funding, the following tasks have been completed:
  - Hired a student assistant dedicated to project.
  - Secured IRB approval for the survey.
  - Developed and finalized the educational document, survey, and other mailing materials.
  - Created and ordered incentives including a cooler, hand sanitizer, bandage holder, tissues, and cold pack.
  - Identified and secured a new hospital partner after staff turnover in key positions ended one of our original site's participation.
- A draft of the educational checklist and a brief survey was sent to our hospital partners, team members, and CQI coach. This feedback was used to make changes to the educational document to make it the most effective for parent communication. Of responses received, 75% thought that the document would be helpful for delivering parents.

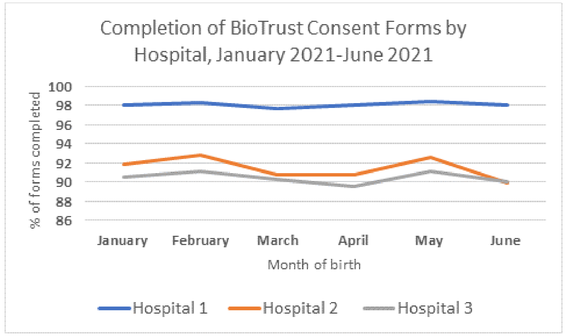
Image 1



Parent Checklist

The above image is the checklist developed by the Newborn Screening Coordinator for this project. It is designed for prenatal distribution to increase parental understanding of the importance of NBS, their role throughout the NBS process, and their choices after NBS is complete.

Figure 1



BioTrust for Health Consent Return Rates for Participating Hospitals

Completed BioTrust consent return rates are being tracked monthly throughout this grant period. These rates indicate the number of completed consent forms returned by a hospital out of all screens collected during the same time frame. Our goal is for each participating hospital to reach 98% following checklist implementation and increased parental awareness.

Results Continued

- Baseline data collection started in mid-August and is expected to last 8-10 weeks. The educational document is expected to be in the field by winter of 2021, followed by post-intervention survey collection.
- Data that will be collected and analyzed includes:
  - BioTrust consent return rates for each site
  - Percent of parents who self report completing action items related to NBS and BioTrust
  - Indicators of parental knowledge and understanding of NBS and BioTrust

CONCLUSION

- Data collection is ongoing and will extend into 2022.
- Establishing and maintaining positive relationships with hospital partners has been crucial to the planning and implementation of this project. NBS is small part of the larger hospital experience and respecting hospital staff by minimizing staff time involvement is critical to continued partner support. Hospital involvement consists of brief feedback via email, document distribution, and participation in meetings only when necessary. Each participating hospital is also receiving a free pack of NBS cards as an incentive.
- Our team faced challenges resulting from the COVID-19 pandemic
  - Key hospital staff turnover resulted in one hospital rescinding participation in the project.
  - The educational document was intended to be distributed at pre-registration tours at participating hospital. However, COVID-19 restrictions have halted in person registration tours. Hospital partners had to identify new routes of document distribution to accommodate these changes in protocol.
  - To accommodate the growing virtual environment, the MDHHS communications team is creating a YouTube video of the Checklist. Parents who prefer to watch a video will be able to scan a QR code on the document.
- Should this project indicate that the NBS Checklist increases parental awareness and involvement, the Michigan NBS team will introduce the document to all birthing hospitals and will add it to our online ordering system, so it can be ordered and distributed widely free of charge.

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Acknowledgements / Sources
[1] Ulph F, Wright S, Dharni N, et al. Provision of information about newborn screening antenatally: a sequential exploratory mixed-methods project. Health Technology Assessment 2017;21(55):1-240.
[2] Fitzgerald C, Heery E, Conneally N, et al. An evaluation of pregnant women's knowledge and attitudes about newborn bloodspot screening. Midwifery 2017;45:21-27.

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Increasing Engagement Through QA/QI

H. Winslow, T. Kaye, R. Gavin
Minnesota Department of Health, St. Paul, Minnesota

NewSTEPs CQI 2021 National Meeting
May 25, Aug 24, Dec 7 • An APHL™ Event

BACKGROUND

- The Minnesota Department of Health newborn screening program has been communicating key quality information to our screening partners (hospitals and out-of-hospital-birth providers) for over a decade.
- Blood spot, hearing, and critical congenital heart disease (CCHD) teams at MDH each sent metrics with different schedules and audiences.
- Goal: create a combined, comprehensive report to provide a complete snapshot for each screening partner.

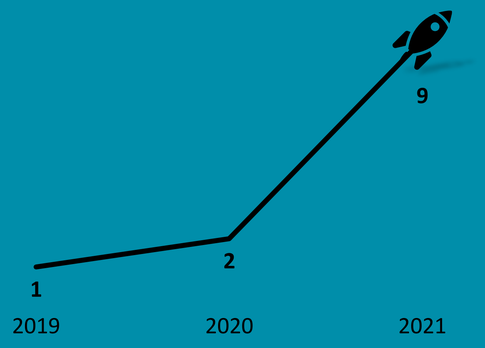
METHODS

- We surveyed partners on improvements they would like to see in our QA reports.
- We analyzed feedback, decided which suggestions could be implemented, and created a plan and timeline to test the new statistics and formats.
- We included new metrics and a new format:
  - Title page and table of contents
  - Updates pages with relevant information about NBS and QA
  - Hearing, CCHD and blood spot QA metrics
- We created consistent audience including all partners who submit a minimum number of specimens/results within the report period.

RESULTS

Feedback **increased dramatically** such as **updating** contact info or metrics, **asking questions** about screening practices, and **giving input** on the QA reports.

We saw **4x more engagement from partners** in process improvement initiatives.



Screening partners have been **inspired** to begin **process improvement initiatives** including **transit** time improvements, **equipment** upgrades, and **reporting** timeliness projects.

Take a picture to see example reports for hospital and out-of-hospital providers

SCAN ME

The first combined newborn screening QA reports were distributed in March of 2021. Feedback from all recipients has been overwhelmingly positive:

"Thanks for sending this report. You are correct, it was worth the wait! I love the simplified design and addition of all 3 tests! "

"Thank you so much for sharing this! I think it is a great tool and I appreciate you including OOH providers in the work you are doing!"

PAIN POINTS

- Workflow of querying, analyzing and aggregating data, creating reports for each screening partner, and combining them with the extra documents proved challenging.
- Warranted close collaboration with many staff for both content creation and review throughout a multi-week process.

CONTINUED IMPROVEMENTS

- Another survey to solicit feedback of the new report format and additional improvements requested.
- Additional data visualizations to replace tables.
- Tableau dashboards with QA metrics for on-demand QA monitoring.

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MDH QA team: B. Bloom, H. Brand, K. Bye, J. Cavazos, K. Coverstone, A. Dahle, J. Laine, S. Rosendahl, J. Simonetti

Positive Impacts of Updated Quality Assurance Activities and Training on Critical Congenital Heart Disease (CCHD) Newborn Screening Outcomes in Minnesota

Jenna Laine, EdD; Regina Marino, MPH
Minnesota Department of Health, St. Paul, Minnesota

Background

The Minnesota Department of Health Newborn Screening program identified providers who performed Critical Congenital Heart Disease (CCHD) newborn screening who were were having consistent issues with quality CCHD newborn screening results. To overcome these quality concerns, the Minnesota Newborn Screening program developed updated quality assurance processes.

Updated Process

Follow-Up Case Communication

Each CCHD newborn screening provider, including hospital and out-of-hospital providers, receive a follow-up case communication report via secure email every six weeks (Fig. 1). This follow-up report includes all records with outstanding or missing CCHD newborn screenings and those that did not follow the Minnesota CCHD protocol from that provider.

CCHD Screening Education

Education was provided regarding quality related issues such as completing additional unnecessary screening, not doing another screening when required per the protocol, or not documenting the results correctly.

Due to COVID-19, hospital and out-of-hospital birth providers received education as needed via virtual training sessions. Some sessions were one on one with nurse managers or nurse educators, and midwives, others were offered to small groups of screeners. Training and protocol guides were consistently sent and reviewed with CCHD screeners when a quality issue was identified.

Biannual Quality Assurance Report

In the Spring of 2021, the Minnesota Newborn Screening program began providing all hospital and out-of-hospital CCHD newborn screeners (who met our birth rate criteria) an overall quality assurance report for the first and second half of 2020. This included completed, missing or outstanding CCHD screens, and Minnesota CCHD protocol adherence information. These reports are sent every six months for the previous six-month period. The reports include a glossary of terms and provide results from the previous six-month period as well as comparison data to other comparable CCHD screeners in Minnesota (Fig. 2).

Hello,

The Newborn Screening program continues to work diligently to provide appropriate follow-up to the families of Minnesota. Please see below for missing or outstanding CCHD results and quality improvement opportunities for July 2021:

Well Baby CCHD Missing:

Patient's Medical No.	Patient First Name	Patient Last Name	Patient Date of Birth

Well Baby CCHD Quality Review:

Patient's Medical No.	Patient First Name	Patient Last Name	Patient Date of Birth	Quality Review
				The following patient has an additional passing screening result after an initial passing screening result, can you please let us know why additional testing was completed?

NICU CCHD Missing:

Patient's Medical No.	Patient First Name	Patient Last Name	Patient Date of Birth

NICU CCHD Quality Review:

Patient's Medical No.	Patient First Name	Patient Last Name	Patient Date of Birth	Quality Review
				This patient had a Rescreen Required suggested result, but a passing result was entered. Can you let us know if additional testing was completed?
				This patient had a suggested result of Rescreen Required, but no additional testing. Can you let us know if additional testing was completed?

Please enter any missing or outstanding results directly into MNScreen, or email with questions. We appreciate your additional time and work to ensure proper follow-up.

Fig. 1. Follow-up Case Communication Email Example. Every six weeks, follow-up case communication report is emailed to each hospital CCHD newborn screening provider in Minnesota. The report prompts for additional information for all outstanding or missing CCHD newborn screenings (including those that did not follow the Minnesota CCHD protocol) from that screening provider. A similar report is sent to out-of-hospital birth providers, with language and protocols consistent with out-of-hospital birth practices.

Newborn Screening: CCHD/Pulse Oximetry
Hospital Quality Assurance Report

July 1, 2020 – December 31, 2020

95.5% of babies were **screened**

0.0% of babies **failed screening**

Summary Data

	Your hospital	All Minnesota birth hospitals
Total eligible births[1]	1697	30015
Total infants with a complete screen[2]	1620	29547
Total parental refusals[3]	0	21
Total infants with missing CCHD screen[4]	77	468

Final CCHD Screen Results

	Your hospital			All Minnesota birth hospitals
	Count	Percent	Previous	Percent
Pass	1619	99.9%	100.0%	99.7%
Fail	0	0.0%	0.0%	0.1%
Rescreen required	1	0.1%	0.0%	0.2%
Physician override[5]	45	N/A	113	305

1. Eligible births do not include infants who died, infants whose parents refused hearing screening, or infants with a physician override result
2. Infants that had both hand and foot pulse oximetry results, with both hand and foot pulse oximetry screening performed at 24 hours of age or older
3. The infant's parents declined CCHD screening and MDH has received appropriate documentation reporting the refusal
4. Missing screens include those where no CCHD screening results were reported to MDH
5. Patients who do not receive a pulse oximetry screen due to congenital heart disease or other condition being detected by a physician prior to screening either prenatally or clinically after birth (e.g. a prenatal ultrasound, an echocardiogram)

July 1, 2020 – December 31, 2020

Number of CCHD Screens Performed

	Your hospital			All Minnesota birth hospitals
	Count	Percent	Previous	Percent
One	1598	98.6%	99.4%	98.1%
Two	21	1.3%	0.6%	1.6%
Three	1	0.1%	0.0%	0.3%

Screening Protocol QA

	Your hospital			All Minnesota birth hospitals
	Count	Percent	Previous	Percent
CCHD protocol followed correctly	1669	99.1%	99.5%	98.9%
No repeat screen performed[6]	1	0.1%	0.1%	0.2%
Extra second screen[7]	14	0.8%	0.4%	0.8%
Extra third screen[8]	0	0.0%	0.0%	0.0%
Extra second and third screens[9]	0	0.0%	0.0%	0.1%
Missing either hand or foot[10]	0	0.0%	0.0%	0.0%

6. CCHD suggested screening result indicated "Rescreen Required," but no repeat screen was performed
7. Infant's first screen result was "Pass" or "Fail," yet a second screen was still performed
8. Infant's second screen result was "Pass" or "Fail," yet a third screen was still performed
9. Infant's first screen result was "Pass" or "Fail," yet a second and third screen were still performed
10. Only the hand or foot results is reported, instead of both the hand and foot. In Minnesota, a completed CCHD screen require pulse oximetry results from both the hand and foot.

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Rev: 02/2021

Fig. 2. Biannual Quality Assurance Report Example. Twice a year, the Minnesota Newborn Screening program provides all CCHD newborn screening providers with a summary quality assurance report for the previous six-month period. The report includes data specific to that provider and provides comparative data from all Minnesota providers. A similar report is sent to out-of-hospital birth providers, with language and protocols consistent with out-of-hospital birth practices.

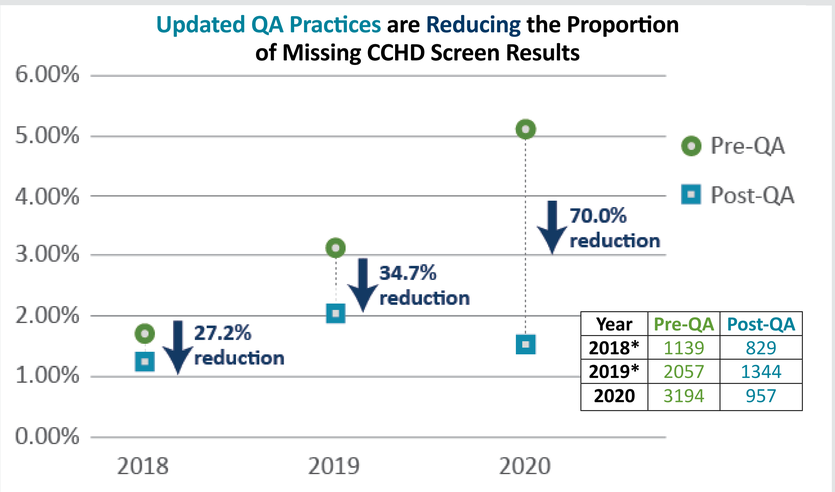
We'd like to acknowledge Jessica Cavazos for her assistance with poster design.

Results

By providing follow-up case communciation every six weeks, there has been a reduction in the number of missing CCHD screening results reported (Fig. 3).

For the year 2020, we saw a 70% reduction in missing CCHD screening results (Fig. 3).

In 2020, follow-up case communication reports for all babies born in 2018 or 2019 who were missing their CCHD screening were sent to the appropriate birth facilities. It was assumed that the screen was performed at the appropriate time, but the results were not completely reported to the Minnesota Newborn Screening program. After receiving additional information for each case, missing CCHD screenings were reduced by 27.2% and 34.7% respectively (Fig. 3).



Year	Pre-QA	Post-QA
2018*	1139	829
2019*	2057	1344
2020	3194	957

Fig. 3. Updated Quality Assurance Practices are Reducing Missing CCHD Screen Results. Through case follow-up communication every six weeks, there was a 70.0% reduction in the number of missing CCHD screen results in Minnesota for infants born in 2020. Retroactive case follow-up for infants with missing CCHD screen results (born in 2018 and 2019), reduced the number of missing CCHD screen results by 27.2% and 34.7% percent respectively.

* 2018 and 2019 pre-QA data represent "missing, "incomplete," and "outstanding" CCHD screen results at the end of the year, which generally includes on-going follow-up. Our updated case follow-up communication was performed retroactively for 2018 and 2019 cases. The pre-QA data for 2020, represents the total number of cases that were initially "missing," "incomplete," or "outstanding," during the newborn screening reporting time frame. The synchronous usage of case follow-up communications and education during this time reduced the number of incomplete case results significantly. However, the initial pre-QA report case count was higher in 2020, we believe that this is an artifact of "real time" follow-up, and some of these cases would have eventually resolved through previous follow-up methods and be more in line with end-of-year incomplete case numbers.

Next Steps

- Continue building relationships with CCHD screening providers through communicating and explaining Minnesota CCHD screening protocols
- Continue education and training opportunities in flexible format
- Continue to send case follow-up communications every six weeks and biannual quality assurance reports
- Additional analysis needed to understand the long-term impacts of quality assurance efforts
- Additional analysis needed to determine trends in protocol adherence for each CCHD screening facility
- Additional record management software updates needed to enhance reporting and monitoring capabilities
- Engage other CCHD screening colleagues about other quality assurance efforts

Remote Access to Electronic Health Records of Minnesota Health Systems for Chart Abstraction: A Minnesota Newborn Screening Follow-up Project

Jenna Laine, EdD; Jennifer Hauser, MPH, RN, PHN
Minnesota Department of Health, St. Paul, Minnesota

Background

The Minnesota Newborn Screening program found that through traditional follow-up methods, newborn screening results for Critical Congenital Heart Disease (CCHD), hearing, and blood spot conditions and related information were not being received timely and occasionally were incomplete. To counteract this problem, we wanted to find a back-up option to get the information needed from newborn screening hospital providers. In early 2020, the Minnesota Newborn Screening program requested remote access to the Electronic Health Records (EHRs) of several Minnesota health systems. The goals of this project were to:

- Improve the efficiency and quality of the newborn screening short-term and long-term follow-up practices
- Increase access to missing or outstanding information
- Expand access and quality of long-term follow-up information, allowing for sustainable longitudinal data collection and surveillance
- Minimize the public health NBS long term follow-up data collection burden on external NBS system stakeholders

Project Roadmap

Research:

- Discussed experiences and best practices with sections at Minnesota Department of Health (MDH) with sections who currently utilize remote access to external electronic health records.
- Met with MDH's legal unit to confirm how HIPAA interacts with Minnesota newborn screening statutes and allows for the ability of EHR access for follow-up purposes
- Determined which health systems would be high-priority assets based:
  - Number of births at their facilities
  - Concerning number of missing or outstanding results
  - Additional quality concerns

Planning:

- Created introductory communications package including explanation for and intended use of remote access request to EHRs and explanation of HIPAA interactions
- Created communications tracking spreadsheet
  - Identify health system key contacts
  - Document and problem solve remote access challenges
  - Track remote access onboarding progress

Process:

- Met with health system representatives to address EHR access permissions and concerns
- Tracked agreements and forms specific to each hospital system and for each Newborn Screening (NBS) employee with access to each health system
- Once access was obtained, arranged health system specific EHR training if available or reviewed training materials
- Tested level of access NBS staff had to various health system EHRs; were we able to obtain the information we needed with the access provided?
- Created an internal Standard Operating Procedure (SOP) regarding acceptable documentation in newborn screening LIMs/record documentation systems

Challenges	Solutions
Inability to get information needed ▪ Some systems did not document information needed by Newborn Screening program ▪ Access varied across health systems (e.g. full patient look-up access vs. record request process) Quality concerns related to missing, outstanding, or incomplete newborn screening results	▪ Multiple Plan-Do-Study-Act cycles ▪ Test access to follow-up information and where to find information in the records
Health systems hesitant to allow remote access to external entity	▪ Show willingness to meet with health system to explain goals and answer questions ▪ Prepare talking points for short- and long-term follow-up

Challenges	Solutions
Delays throughout entire remote access request process	▪ Continued partnership between short and long-term newborn screening follow-up ▪ Continued partnership with internal/external stakeholders to understand best practices ▪ Focusing on positive aspects of project
Technical issues with initial remote access set-up and occasional technical challenges during utilization	▪ Designate a single point person from NBS for coordination of access with various health systems ▪ Work with 1-2 main contacts at each health system to coordinate access issues ▪ Small NBS work group formed to test each health system's EHR system, develop updated guidance and troubleshooting procedures.

Outcomes

- Requested access to 12 health systems (at time of abstract submission):
  - Granted and received remote access to 6 health systems
  - Access in progress for 7 health systems
  - 2 health systems declined for now (EHR system does not allow for reduced access to EHR for external users and unable to grant full access to external users)
- Of the 6 health systems we have remote access to, this includes 43 of the 82 birth facilities in Minnesota

Conclusions

- Remote EHR access is a supplement to current follow-up practices. It doesn't take the place of current follow-up methods (receiving follow-up results and information directly from newborn screen provider)
- Having remote EHR access does not improve the quality of the newborn screening result, there is still human error in screening and documentation, including not following protocol
- Continued quality monitoring and increased education regarding newborn screening practices is needed for all health systems regardless of remote EHR access

Next Steps

- Increase number of remote access requests to additional facilities, including border states and smaller health facilities performing newborn screening
- Request remote access for newborn screening employees coming back to role after COVID-19 reassignment
- Perform time studies to measure efficiencies of remote access to EHR

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- We'd like to acknowledge Jessica Cavazos for her assistance with poster design

Using an Evidence-Based Collaborative Approach to Champion Quality Improvement in Newborn Screening

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Kayana Walters, MPH, MT(AMT)

NewSTEPs
A Program of The Association of Public Health Laboratories®

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BACKGROUND

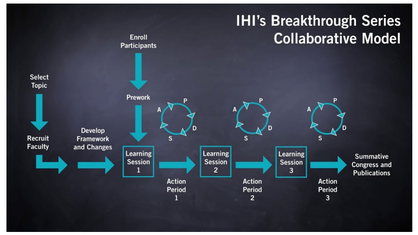
There can be many barriers to beginning a quality improvement initiative. Examples of barriers include a lack of resources (including funding, staffing, equipment, etc.), support, and access to subject matter expertise. These barriers often discourage staff and teams from initiating improvement activities resulting in band-aid solutions instead of a systems approach to addressing process issues and challenges.

The Institute for Healthcare Improvement's (IHI) Breakthrough Series (BTS) is an evidence-based collaborative model that reduces the initial barriers to starting an improvement initiative by providing a structured approach to learning and applying quality improvement methods in a team-based environment. The Association of Public Health Laboratories (APHL) Quality Improvement (QI) Projects Collaborative is modeled after the IHI BTS and has used this framework across three cohorts since its inception in 2019.

Although still in its infancy, applying the BTS framework to the QI Projects collaborative has resulted in early success and measurable improvements among participating newborn screening (NBS) programs. Improvements to metrics include timeliness, turnaround time, percent satisfactory specimens, and overall improvement in tracking the prevalence and reporting of NBS conditions. Additionally, the structure provided by the IHI BTS framework has resulted in increased collaboration, knowledge sharing, and improved understanding and application of improvement tools such as the Plan Do Study Act (PDSA) cycle and run chart.

METHODS

The Institute for Healthcare Improvement's (IHI) Breakthrough Series (BTS) model uses a collaborative approach to teaching and spreading systems changes and improvements (Figure 1). The BTS model typically spans a year. It includes three day-long learning sessions (national meetings) where attendees gain the quality improvement knowledge needed to successfully implement an improvement project.



The learning sessions are followed by action periods where teams return to their organizations/agencies to apply the skills and tools learned in their workplace.

Action periods also include regular reporting and conference calls with BTS faculty, which provides teams with subject matter expertise, technical assistance and ensures the project remains on track.

Figure 1: The IHI BTS Model

Similar to the IHI BTS model, the APHL Quality Improvement (QI) Projects Collaborative consists of three day-long national meetings focused on advancing the knowledge and application of quality improvement in NBS, monthly reporting and project status updates, access to QI subject matter expertise, and tailored QI coaching and project management support. Figure 2 summarizes the activities and resources offered via the QI Projects Collaborative.

Activity		Purpose
Monthly Reporting	Required	Teams document project updates in the form of run charts and small tests of change (PDSAs - Plan Do Study Act).
Monthly QI Coaching Calls	Required	During calls, coaches provide feedback, technical assistance, and guidance to teams.
Annual Reporting	Required	Opportunity for teams to reflect on project successes and growth over the last year.
Bi-monthly QI Webinars	Required	Webinars focus on teaching the practical application of QI tools to further support project teams and provides an opportunity to showcase the work of participating programs.
CQI National Meeting	Required	Three day-long national meetings provide attendees the opportunity to further develop applicable skills to advance the work of their QI projects.
Bi-monthly Discussion Group	Optional	Closed forum that provides teams the opportunity to share project successes and collaborate on ways to address project challenges.

Figure 2: Summary of QI Projects Activities and Resources

RESULTS

Among the nineteen newborn screening programs participating in the QI Projects Collaborative measurable improvements have been observed in the areas of teamness/collaboration, QI knowledge/confidence and in the Newborn Screening Technical assistance and Evaluation Program (NewSTEPs) quality indicator 5d.iii (time elapsed from birth to reporting all results).

Teamness/Collaboration

Teamness and collaboration are important components of the QI Projects Collaborative. Shared learning and a team-based approach to quality improvement helps to ensure the success of teams over the course of their improvement projects.

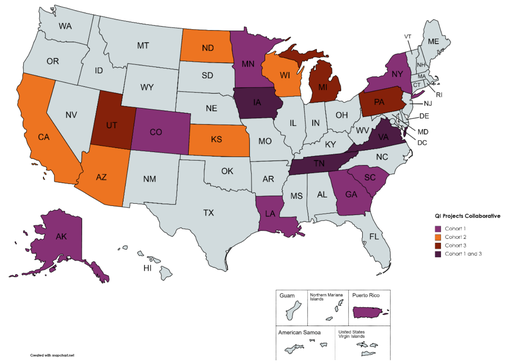


Figure 3: Map of all participating programs in the QI Projects Collaborative

Collaboration is encouraged through bi-monthly discussion groups, national meetings and bi-monthly webinars. During these events, states have the opportunity to connect with other newborn screening programs, share their work and lessons learned, and brainstorm solutions to shared challenges.

As a result of these activities, there is an increase in and more frequent collaboration among the nineteen newborn screening programs (Figure 3) participating in the QI Projects collaborative.

Teamwork is another important component of the QI Projects Collaborative and is regularly promoted by staff and QI coaches. To assess teamwork among project teams the QI Projects incorporates and adapts the Assessment for Collaborative Environments (ACE-15) into the annual report. The ACE-15 is a validated tool that assesses a team's level of "teamness" or interprofessional teamwork.

Overall, project teams continue to report high levels of "teamness" in 2020 and 2021 as illustrated in Figure 4 and Figure 5.

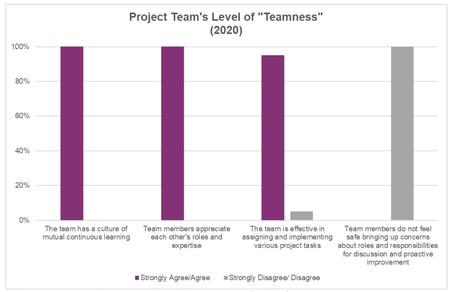


Figure 4: Median reported teamness (2020)

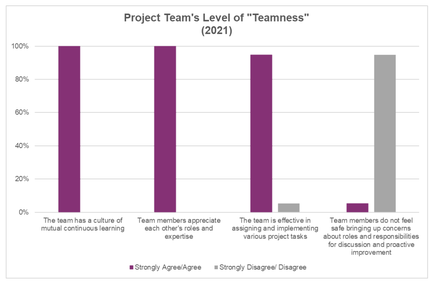


Figure 5: Median reported teamness (2021)

QI Knowledge and Confidence

An over-arching goal of the QI Projects Collaborative is to strengthen knowledge and the application of continuous quality improvement in newborn screening.

To assess the success of the QI Projects in achieving this goal, the QI Projects annual report requests program's to self-report their confidence and skill with various QI tools as "Not Confident at all", "Somewhat Confident", "Fairly Confident", or "Completely Confident". As illustrated in Figure 6 and Figure 7, from 2020 to 2021 there is an increase in participating program's reporting being fairly confident or completely confident with various QI tools including action plans, Plan-Do-Study-Act (PDSA) cycles and run charts.

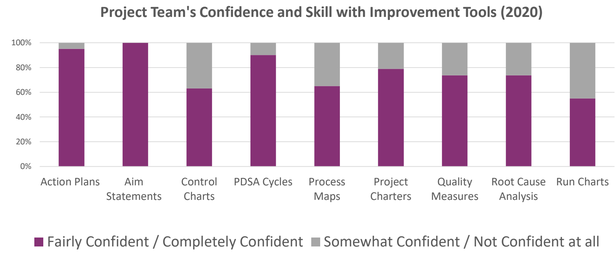


Figure 6: Median reported confidence and skill with QI tools (2020)

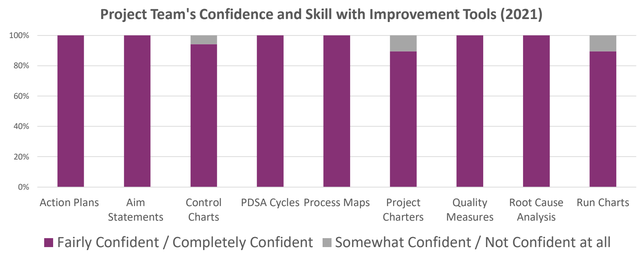


Figure 7: Median reported confidence and skill with QI tools (2021)

NewSTEPs QI5d.iii: Time Elapsed from Birth to Reporting all Results

As a requirement of the QI Projects Collaborative all participating state newborn screening programs are required to submit quality indicator data annually to the NewSTEPs data repository. It is encouraged that data is submitted for all quality indicators however due to the unique challenges states have with extracting and reporting data this is not always possible.

At the start of their improvement projects, programs also define process and outcome measures. Many of these project-level metrics have the potential to influence larger system-level measures. One such measure is quality indicator measure QI5d.iii, the time elapsed from birth to reporting all results. There are currently thirteen programs participating in the QI Projects Collaborative consistently reporting data for QI5d.iii (Figure 8). Since the start of the QI Projects in 2019, these thirteen programs continue to report a significant increase in the percent of all newborn screening results reported in 7 days or less, the recommended number of days set forth by national guidelines.

Median Percent of Specimens for which "Birth to Results Reporting" was 7 Days or Less	
Year (N)	**Percent of all specimens reported in ≤ 7 days**
2018 (13)	76.86%
2019 (13)	89.98%
2020 (13)	92.55%

Figure 8: Median Percent of Specimens for which Time Elapsed from "Birth to Results Reporting" Was 7 Days or Less for 13 states participating in the CQI collaborative cohort

CONCLUSION

The QI Projects Collaborative began in late 2019. Therefore, more time is needed to truly understand the long-term benefits and impact of the collaborative on NBS systems. However, initial success can be observed in the increased collaboration across NBS programs, increased team work within NBS programs, and team's improved skill and confidence applying continuous quality improvement tools. And as illustrated in figure 8, these successes have the potential to improve larger newborn screening system measures.

Limitations of this intervention include team's self-reporting QI skills, confidence and teamness. To address this limitation, over the next year the collaborative will aim to bolster the quantitative data collected with qualitative data. This includes capturing stories of teamness, collaboration and improved knowledge among participating programs in addition to data collected from the QI Projects annual report.

Additionally, over the next year more resources will be dedicated to understanding how quality indicator data can provide further insights to the impact of the QI Projects Collaborative on newborn screening systems and potential areas for improvement.

Lastly, as we continue to model the QI Projects Collaborative after the IHI BTS we hope to further inform how this structured evidence-based collaborative model can be used to advance current and future quality improvement activities aimed to improve newborn screening systems.

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