



NewSTEPS

A Partnership between The Colorado School of Public Health
and The Association of Public Health Laboratories™

NBS Timeliness: CQI Workbook

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Program Overview

NewSTEPs

NewSTEPs is a partnership between the Association of Public Health Laboratories (APHL) and the Colorado School of Public Health (CoSPH) and operates with the mission to support the highest quality for newborn screening (NBS) systems by providing relevant, accurate tools and resources to states. NewSTEPs facilitates collaboration between NBS partners for both dried blood spot (DBS) and point-of-care newborn screening. Further, NewSTEPs provides quality improvement initiatives, an innovative data repository and technical resources NBS programs.

NewSTEPs activities remain driven by active partnerships with state and territorial NBS programs, pediatric sub-specialists, and stakeholders from the Maternal and Child Health Branch (MCHB) of the Health Resources and Services Administration's (HRSA) funded programs.

Goal of NewSTEPs 360

State newborn screening (NBS) programs are encouraged to identify areas to improve timeliness in the NBS system. NewSTEPs 360 aims to support states through technical and financial means to achieve timely reporting of results in 95% of newborns that receive dried-blood spot (DBS) NBS.

ACHDNC Recommendations

In alignment with the recommendations from the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC), NewSTEPs 360 awardees must be able to demonstrate the potential to impact timeliness in at least one of the following categories:

1. Presumptive positive results for time-critical conditions should be communicated immediately to the child's healthcare provider but no later than the fifth day of life.
2. All presumptive positive results for all other conditions should be communicated to the child's healthcare provider as soon as possible but no later than seven (7) days of life.
3. All NBS results should be reported within seven (7) days of life.

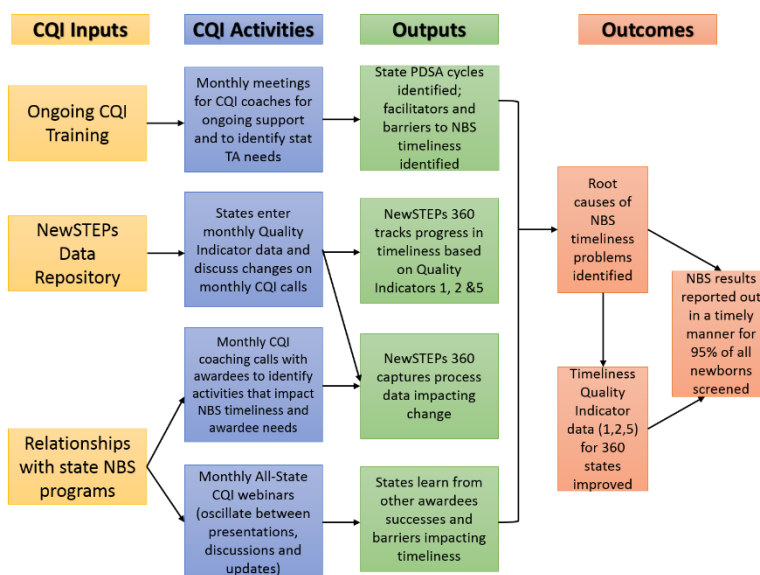
In order to achieve these goals (and reduce delays in newborn screening):

- 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.



NewSTEPs 360 Activities

NewSTEPs 360 is a program supporting innovative activities to improve the timeliness in newborn screening. The program is designed to give a 360 view of the newborn screening system allowing awardees to collaborate, participate in Continuous Quality Improvement (CQI) processes, and measure progress and the impact of their program activities. NewSTEPs 360 awardees are expected to participate in the following activities:



- **Quality Improvement Coaching** for status updates, gathering data and identifying educational and technical assistance needs. Routine coaching calls will allow awardees to discuss action steps, barriers and successes as well as provide an opportunity to connect with other states who may be able to share ideas and resources.
- **Monthly webinars and annual in-person meetings** where awardees will share successes and lessons learned, continue to CQI training, and identify educational needs.
- **Meet regularly as a team** in-person or via videoconferences and/or teleconference calls.
- **Enter into a Memorandum of Understanding (MOU)** to access and utilize the NewSTEPs Data Repository.¹
- **Provide monthly Quality Indicator (QI)** data to allow NewSTEPs 360 to track timeliness progress.
- **Provide process and outcome data** as identified.

What is a CoIIN?

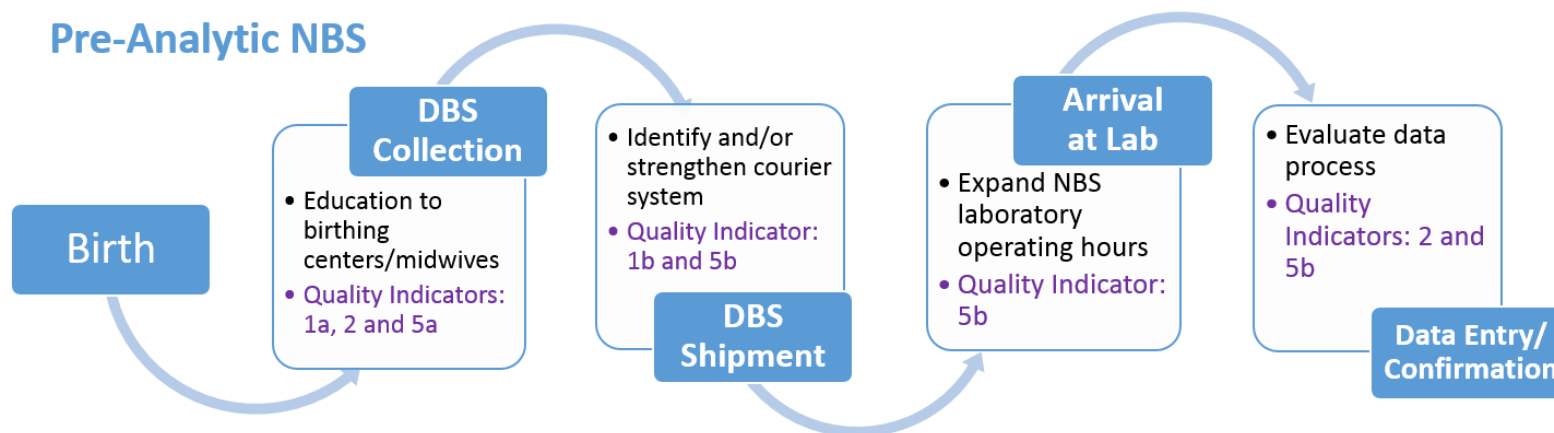
CoIIN (Collaborative Innovation and Improvement Network) is a learning collaborative approach that emphasizes the importance and necessity of sharing and learning from one another's successes and failures (within the state team as well as between state teams) to nurture improvement and change, while utilizing technology to remain connected. Key elements of a CoIIN include:

1. Reliance on distance-based technology for all team activities;
2. Expectation of rapid, on-going communication across all levels of the team; and
3. Commitment to ensuring that work processes are transparent

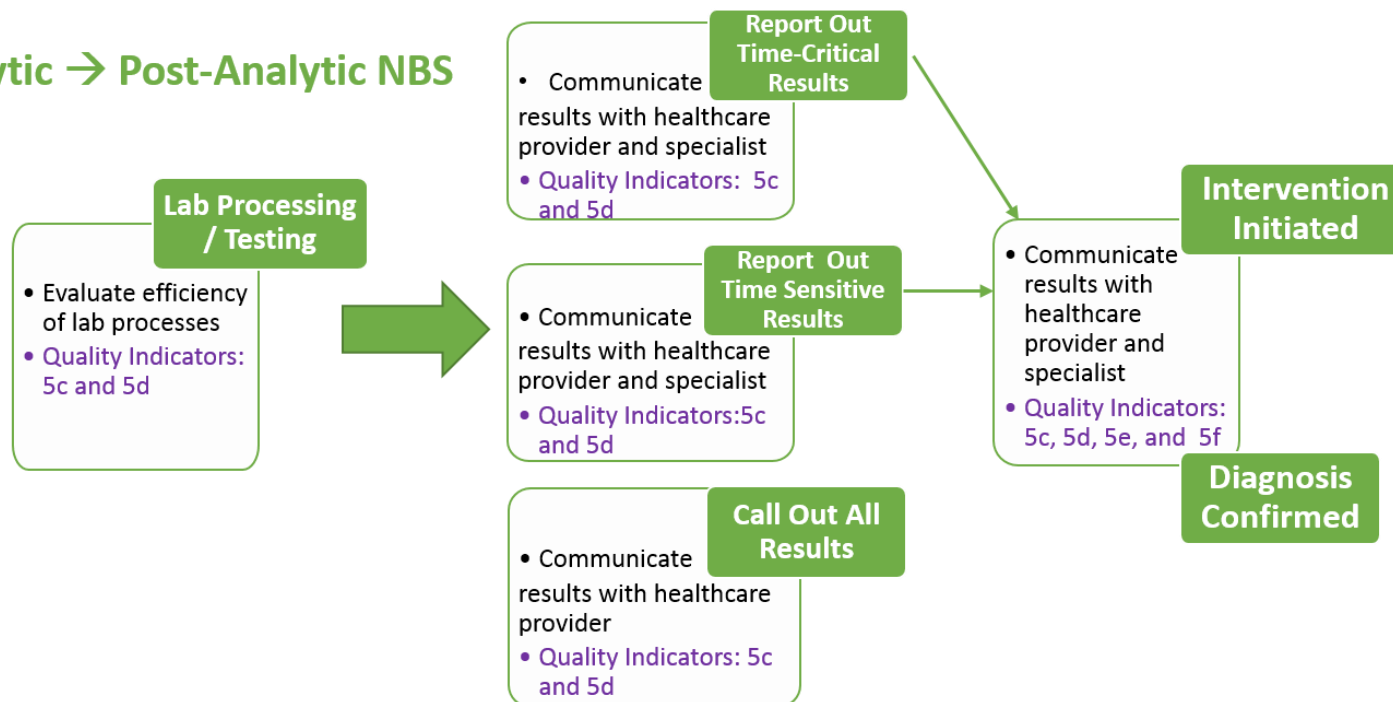
¹ For questions regarding the MOU, please contact Careema Yusuf, APHL NewSTEPs Manager, at careema.yusuf@aphl.org.

NBS Process Model

Pre-Analytic NBS

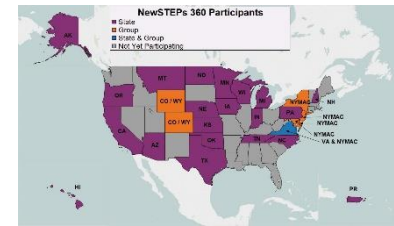


Analytic → Post-Analytic NBS





Getting to Know the 360 Teams



Team Focus Areas

Teams	Focus Area 1: Education	Focus Area 2: Courier System	Focus Area 3: Operating Hours	Focus Area 4: Lab Flow	Focus Area 5: Communication	Focus Area 6: HIT	Focus Area 7: CF
Alaska	X	X					
Arizona	X	X	X	X		X	
California	X	X					
Colorado-Wyoming	X						
Hawaii					X	X	
Indiana	X	X	X				
Iowa	X				X		
Kansas	X	X					
Michigan						X	
Minnesota						X	
Montana	X	X					
Nebraska	X				X	X	
New Hampshire	X						X
North Carolina	X	X					
North Dakota	X	X					
NYMAC ²	X				X	X	
Oklahoma	X						
Oregon	X	X		X			X
Pennsylvania	X					X	
Puerto Rico	X				X	X	
Tennessee	X						X
Texas	X				X	X	
Virginia						X	
Wisconsin					X	X	

² Delaware, Maryland, New Jersey, New York, and Virginia only.



Team Activity

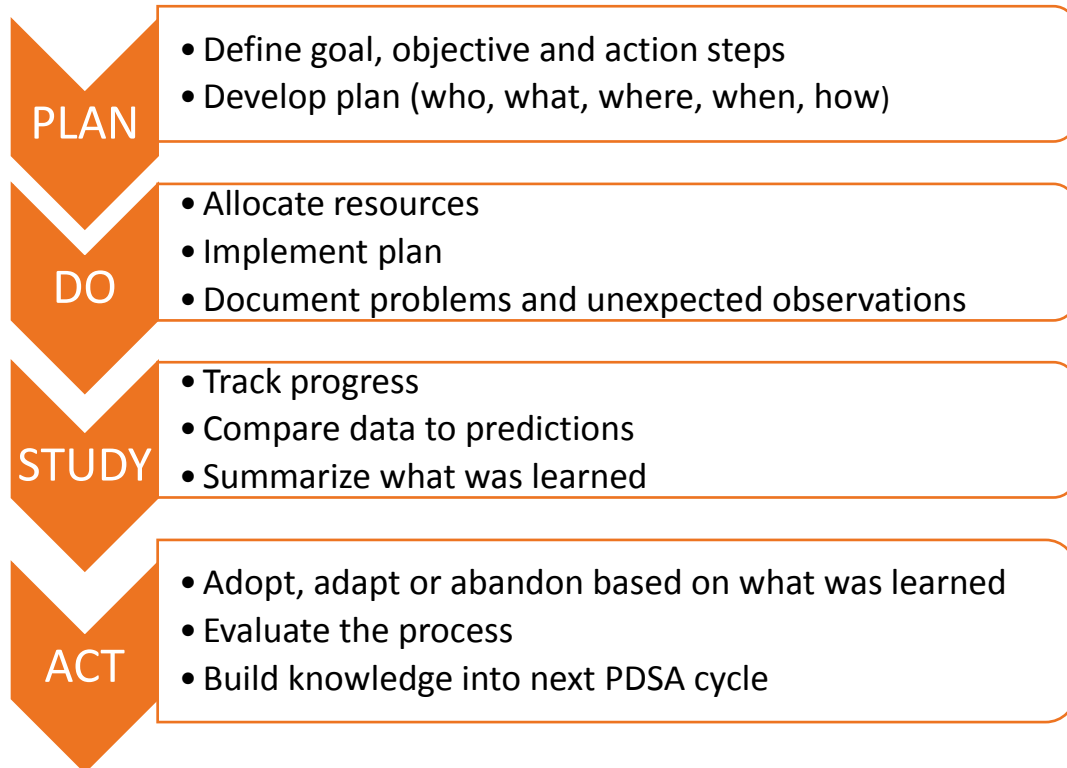
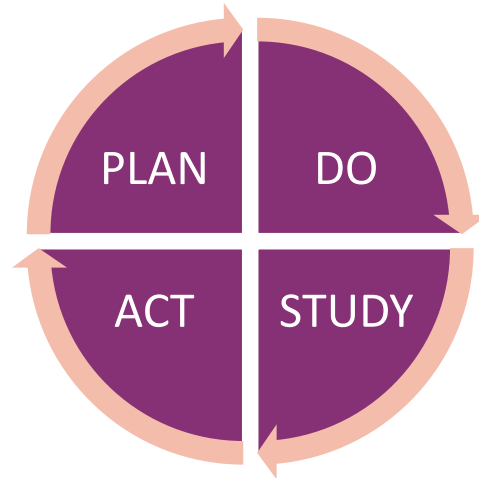
1. Introduce yourself to your group, mentioning your agency as well as the role that you will play in NewSTEPS 360. Complete the table below.

Name	Unique to Person	Potential Overlap for Team

2. What is something that your team has in common?
3. What is a team name that captures the unique aspect of your team?
4. What are the root causes your team will be addressing?
 - a.
 - b.
 - c.

Quality Improvement Approach

PDSA Cycle



Goals, Objectives & Actions



Goals

- Broad statements describing a future condition or achievement without being specific
- Usually long-term and represent global visions
- Focus on outcomes or results and are qualitative in nature in a specific priority area

Objectives

- Support the goals with a specific statement of a desired short term condition or achievement that includes a measurable end result to be accomplished by specific teams or individuals within time limits
- Define strategies or implementation steps to attain the identified goals
- Unlike goals, objectives are specific, measurable and have a defined completion date
- Answer the question: "What do we have to do to get there?"

Actions

- Individual responsibilities that are assigned to each organization or person that is participating in the process
- Have specific timelines and help the group to achieve the outcomes
- Convey activity with with an action verb that ends in -ing



Top 11 Lessons Learned from CoIIN

In January 2015 NewSTEPS initiated eight states into the first Newborn Screening Timeliness CoIIN (Collaboration Innovation and Improvement Network). While these states are wrapping up their 15 month effort, NewSTEPS asked these Timeliness CoIIN participants to share their top lesson learned.³

11. Keep at it

- Be patient and diligent. Never give up.

10. Have a strategy

- Would say I learned that having a strategy is very helpful.
- “There is always a way to do it better...find it.” *Thomas A Edison*. Speaks to the CoIIN concepts and fits so well.
- There are many right ways to approach timeliness; spend your time on the SMART ones that work within your paradigm.

9. Focus on high volume providers first

- If we focus on the high volumes providers first, our outcome data will change.

8. 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.

7. Do not overlook maintenance

- Keep climbing—when you think you're at the top, you're not.

6. Talking to and learning from other states is so important

- Collaboration with other states has generated both ideas and practical solutions.

5. Find out what is happening in each place

- Don't assume you know what happens in other departments and investigate the current processes. I was shocked to find out our newborn screens were sitting in the lab all day and were not prepared for the courier who arrives at 5pm. This was due to an age-old process when all newborn screens were drawn at 9 am (victim of "that's the way we've always done it" syndrome. Our individual hospital team really looked at each units' processes to streamline newborn screening as much as we could. Even on my own unit, we had no idea what time the courier came or that it should affect our processes.

³ The tips, written in bold, are summary statement provided by NewSTEPS, whereas the bullets under each tip, contain the original wording submitted by CoIIN participants.



4. 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! I knew newborn screening was important, but I didn't know about the time-critical tests we perform and how a matter of minutes and hours can impact a family's life forever. Hearing real stories made an impact on me and my team members at our facility. Once that became a part of our education curriculum about newborn screens, change started happening.

3. Remember to include all the newborn screening partners within the state that impact timeliness.

- We need a multi-faceted approach to reaching our goals (i.e. hospital, lab education, carrier service, program rules).
- Champions are important—it takes a team and champions from each unit in the hospital. We created a team made up of members who had an impact on newborn screening (i.e. mother-baby, NICU, lab, Iowa Newborn Screening Follow-up Program, and our pediatric clinic). The members of this unit learned the "why" and championed change in their respective units, which greatly improved our timeliness as a facility.
- Partnership with the state designated couriers has been essential for improving timeliness.
- Everyone needs to give a little and share what they are doing to conceptualize change.
- Get the right partners—engage hospital risk managers or quality improvement managers.
- Teamwork with the individual hospitals being members of the team. Make sure you are clear about goals and whys.

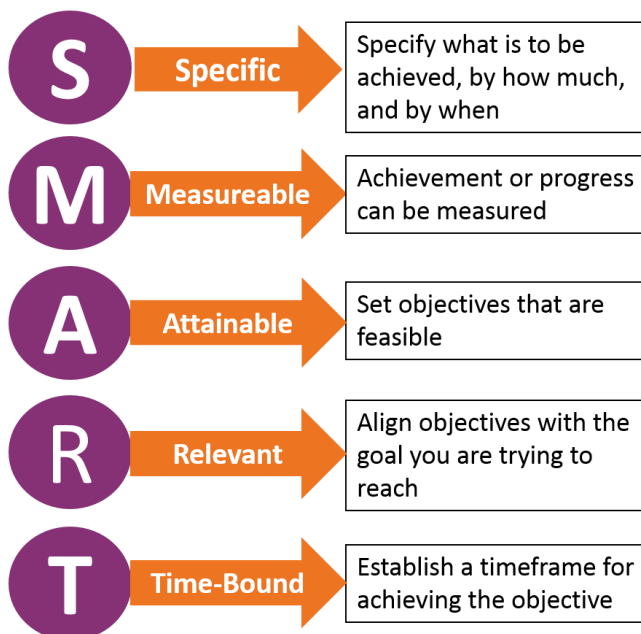
2. Education and feedback to the partners is KEY

- Education is the KEY component in all areas and the most challenging in terms of negotiating that time and engaging the stakeholders.
- Be ready for the change once others get the message—once providers are made aware of the reasons for timeliness initiatives, they will run with it. Be prepared for an increase in data and technical assistance requests.
- We've gone “Back to the Basics” for hospital education and value to importance of “Boots on the Ground.”
- Feed back to hospitals on their performance in meeting the goals.
- Even with infrastructure in place (courier; 365 days/year operation; two-shift lab), if hospitals/providers aren't aware of the resources available or how to access these, it can hinder timely submission of specimens.

1. Working with Yvonne Kellar-Guenther, PhD, Associate Director of NewSTEPS 360

- Also, there is no way to forget to do what Yvonne ask you to do. She is relentless. 😊

SMART Goals & Objectives



Specific	<ul style="list-style-type: none"> •What do I want to accomplish? •Why do I want to accomplish this? •What are the requirements? Constraints?
Measureable	<ul style="list-style-type: none"> •How will I measure my progress? •How will I know when the objective is accomplished?
Attainable	<ul style="list-style-type: none"> •Can the objective be accomplished? •Are the steps logical to accomplish this objective?
Relevant	<ul style="list-style-type: none"> •Is the objective in line with the overall goal? •Is the objective worthwhile? •Is this the right time?
Time-Bound	<ul style="list-style-type: none"> •How long will it take to accomplish this goal? •When is the completion of this objective due? •Do other objective rely on the completion of this objective?



Focus Area Breakout Session—SMART Application

The goal of this session is to review objectives that states are working towards and for the whole group to create a SMART objective. First, work with your team thinking through your overall goals and objectives. Then choose one objective and write it on the flip chart. The group will select one objective to make it SMART and complete the table below.

Objective:

S	Specific	<ul style="list-style-type: none">• Who is going to do what (i.e. hospital, NBS lab, follow-up)?• To whom (i.e. newborn, specimen, clinician)?	
M	Measureable	<ul style="list-style-type: none">• How much change will I see (i.e. percentage change, number of people, hours change)?• How many people/hospitals/providers will you work with?• How much time/money?• Where will the data come from?	
A	Achievable	<ul style="list-style-type: none">• Can you do this in the time you have?• What resources do you have to start?• What resources do you need? How will you get them?	
R	Relevant	<ul style="list-style-type: none">• How does this move you closer to your overall goal?	
T	Time-Bound	<ul style="list-style-type: none">• When will you start? When will you end?• Does something need to happen before you can start?• Do I need to finish this objective before I can start something else?	



Organizational Culture

Discuss the following questions with your Professional Group (lab, follow-up, HIT, hospital, etc.) and find commonalities that can help the group understand the culture of your group.

1. What motivates you to come to work every day?

2. What does your organization value?

3. What does your boss or administration look for to determine that you have done a good job?

4. Why is the work you do important?
 - a. Where does newborn screening fit in to that?

 - b. Where does timeliness of newborn screening fit into that?
 - i. Time from birth to collection
 - ii. Collection to receipt by lab
 - iii. Receipt by lab to report out



Measuring Changes & Improvement

Types of Measures

Outcome Measures <i>Measures the impact or change; used to measure program effectiveness</i>	Process Measures <i>Measures how the system works and whether or not the system is performing as planned</i>	Balanced Measures <i>Measures unintended change in consequences; tracks changes that were unexpected</i>
Examples	Examples	Examples
<ul style="list-style-type: none"> 90% of labor and delivery nurses in Indiana’s Children Hospital will report that doing NBS between 12 and 24 hours of birth is important or very important by the end of the program. 98% of DBS samples will be received by the laboratory within 24 hours of collection due to HL7 messaging. 	<ul style="list-style-type: none"> Identifying the barriers to educating parents by conducting focus groups. These will be used to modify parent education protocols. Number of lab reports released to providers within 48 hours. Percent of medical centers with follow-up protocols (pre and post). Percent of laboratories receiving and testing samples 6 days per week. Percent of hospitals sending and receiving orders with HL7 messaging. 	<ul style="list-style-type: none"> Significant increase in false positives or false negatives. Significant increase in additional samples or out-of-range results. Change when hospital staff educate parents at night prior to newborn screen (moved from 9am to midnight).

Questions to Help Determine what Data to Collect

- What information is important to collect?
- Why is it important?
- Who will collect the data?
- How will you analyze the data?
- Where and when will data be collected?
- What is the numerator and denominator?

Attributes of a Quality Measure

1. Importance—relevance to stakeholders, effect on health burdens, applicability, potential for improvement
2. Scientific Soundness—reliable, valid, strength of evidence, comprehensive
3. Feasibility—detailed specifications for numerator and denominator, data availability



Quality Indicators

Each participating NBS program will submit quality indicator (QI) data to measure change and impact on NBS timelessness over time. The following QIs will be collected the 15th each month in the NewSTEPS Data Repository. ⁴

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

- a) Total number of dried blood spot specimens on which laboratories cannot report a complete newborn screening panel due to collection errors, divided by the number of dried blood spot specimens received at your state's newborn screening laboratory, multiplied by 100. This should include first and subsequent specimens.
- b) Total number of dried blood spot specimens on which laboratories cannot report a complete newborn screening panel due to transport errors, divided by the number of dried blood spot specimens received at your state's newborn screening laboratory, multiplied by 100. This should include first and subsequent specimens.

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

- Total number of dried blood spot specimens submitted with at least one missing state-defined essential data field upon receipt at the lab, divided by the number of dried blood spot specimens received at your state's newborn screening laboratory, multiplied by 100. This should include first and subsequent specimens.

Quality Indicator 5: Timeliness of NBS Activities.

- a) Time from birth to specimen collection:
 - i. Number of first dried blood spot specimens collected in the specified time intervals from birth, divided by the total number of first dried blood spot specimens collected.
- b) Birth to specimen collection/first point-of-care testing.
 - i. Number of first dried blood spot specimens received at your state's newborn screening laboratory in the specified time intervals from specimen collection, divided by the total number of first dried blood spot specimens received.
- c) Time from specimen receipt at your state's newborn screening laboratory to reporting out specimen results.
 - i. For time-critical disorders: Number of dried blood spot specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional, for time-critical disorders, reported out in the specified time intervals from specimen receipt at your state's newborn screening laboratory divided by the total number of dried blood spot specimens with out-of-range results for time-critical disorders.
 - ii. For non-time critical disorders: Number of dried blood spot specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional, for non-time critical disorders, reported out in the specified time intervals from specimen

⁴ For more information about Quality Indicators, please visit: <https://www.newsteps.org/quality-indicators-qi>.



receipt at your state's newborn screening laboratory, divided by the total number of dried blood spot specimens with out-of-range results for non-time critical disorders.

- iii. Normal and out-of-range results for all disorders from first dried blood spot specimens: Number of first dried blood spot specimens with a normal or out-of-range result for any disorder reported out in the specified time intervals from specimen receipt at your state's newborn screening laboratory, divided by the total number of first dried blood spot specimens with a normal or out-of-range result for any disorder.
- d) Time from birth to reporting out specimen results
- i. For time-critical disorders: Number of dried blood spot specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional, for time-critical disorders, reported out in the specified time intervals from birth divided by the total number of dried blood spot specimens with out-of-range results for time-critical disorders.
 - ii. For non-time critical disorders: Number of dried blood spot specimens with out-of-range results requiring clinical diagnostic workup by an appropriate medical professional, for non-time critical disorders, reported out in the specified time intervals from birth, divided by the total number of dried blood spot specimens with out-of-range results for non-time critical disorders.
 - iii. Normal and out-of-range results for all disorders from first dried blood spot specimens: Number of first dried blood spot specimens with a normal or out-of-range result for any disorder reported out in the specified time intervals birth, divided by the total number of first dried blood spot specimens with a normal or out-of-range result for any disorder.



Shared Process Measures

Participating NBS programs are asked to submit shared process measures that aim to track progress at the intermediate steps for education and HIT quality improvement initiatives. The collection of these data is not required, but strongly encouraged as they measure progress at the hospital level which may determine impact of activities before seeing changes in the quality indicator data. These data will be collected in a separate excel workbook that will be disseminated after this meeting.

Education Numerators	HIT Numerators
Quality Indicator 1: <ul style="list-style-type: none"> • Number of birthing hospitals that submitted $\leq 1\%$ of DBS specimens that were unacceptable due to improper collection • Number of birthing hospitals that submitted $\leq 1\%$ of DBS specimens that were unacceptable due to improper transport 	Engaged and Expressed Interest Champion Identified Hospital & IT Leadership Approves
Quality Indicator 2: <ul style="list-style-type: none"> • Number of birthing hospitals that submitted $\leq 1\%$ of DBS specimens that were missing at least one missing state-defined essential data field 	Identified & Agreed upon Data Elements Transport Mechanism/System Chosen
Quality Indicator 5: <ul style="list-style-type: none"> • Number of birthing hospitals that collected at least 95% of first DBS specimens within 48 hours from birth. • Number of birthing hospitals that you received at least 95% of first DBS specimens within 48 hours after specimen collection. • Number of birthing hospitals where at least 95% of first DBS specimens with normal and out-of-range results for all disorders reported out within 7 days from birth. 	Order System Developed Order System Tested Order System in Production Result System Developed Result System Tested Result System in Production
Denominators Number of hospitals proposed Number of birthing hospitals in state	



Measurement Planning Form

While Quality Indicator data are helpful, they may not be enough to track the impact of your activities on your goals nor can they provide insight into why changes are taking place or provide insight into unseen barriers. As a result, NEWSTEPS 360 awardees should consider gathering other to assess how well your project is going and if changes need to be made.

Measurement Planning Form—Example ⁵	
Measure	Percentage of children whose confirmatory testing results were communicated to their families by 4 months of age.
Type	<input type="checkbox"/> Outcome <input checked="" type="checkbox"/> Process <input type="checkbox"/> Balanced
Rational (Why is this measure important?)	In children with sickle cell disease (SCD), illness and death can be reduced through prompt communication with families. This measure would highlight gaps where providers or health systems are falling short and encourage early and consistent treatment for all young children with SCD.
Operational definition	Numerator: Number of children with results of confirmatory testing communicated by less than or equal to 120 days of age. Denominator: Number of SCD cases reported in state’s NBS program records within measurement year.
Target population	Newborn
Exclusions	Children who died within 120 days of birth excluded from the denominator
Source of data	Medical records and state NBS records
Data collection & sampling method	Access evidence of results communicated (letter, telephone call, email, face-to-face discussion) with a child’s parents (mother, father, primary care giver) from January 1 of measurement year to April 1 of the following measurement year.
Who will collect this information?	Follow-up staff from state NBS program
How will this data be analyzed and reported?	Rate or proportion; run chart of the monthly rate, annotated to indicate our test cycles and system changes
Useful stratifiers	Geographic location, patient characteristics, point-in-time
Baseline data	29% on April 2015
1 st re-measurement date	April 2016
Target/goal	95% by April 2018

⁵ Quality Measurement, Evaluation, Testing, Review, and Implementation Consortium (Q-METRIC). Basic measure information: timeliness of confirmatory testing for sickle cell disease. Ann Arbor (MI): Quality Measurement, Evaluation, Testing, Review, and Implementation Consortium (Q-METRIC); 2013 Oct 30. 40 p. [16 references]



Now complete this table for the afternoon report-out for your topic group's standardized measure.

Measurement Planning Form	
Measure	
Type	<input type="checkbox"/> Outcome <input type="checkbox"/> Process <input type="checkbox"/> Balanced
Rational <i>(Why is this measure important?)</i>	
Operational definition	Numerator: Denominator:
Target population	
Exclusions	
Source of data	
Data collection & sampling method	
Who will collect this information?	
How will this data be analyzed and reported?	
Useful stratifiers	
Baseline data	
1 st re-measurement date	
Target/goal	

To develop a solid measure, consider the following questions:

- How will we know we are making a difference?
- What can we track over time to demonstrate progress and that we are “moving the needle”
- Can progress toward achieving the outcome measure be measured in a reasonable and feasible way?



State Team Breakout Session—PDSA Cycle

Goals & Objectives

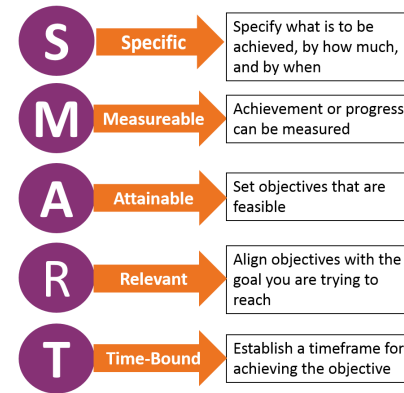
First, work with your team thinking through your overall goal and objectives; use the following questions as a discussion guide. After, revise your objectives so that they are SMART.

1. Based on what you just discovered during the organizational culture activity, complete the table below for your state team. Consider this information as you revise your overall goal and SMART objectives.

Name	What are you rewarded for?	Role on Team?



6. Now, develop/revise your SMART goal and objectives in the space provided below.



Check List

- Did you include a deadline or time frame
- Can you realistically achieve what you are proposing given time and resources needed?
- Can you measure it? How will you know when you have gotten “there”?
- Avoid being vague. Are your statements specific, clear and to the point?



7. Finally, write your revised SMART goal and objectives in the space below.

GOAL:

Objective 1:

Objective 2:

Objective 3:



Action Plan

In your state teams, compose an action plan for at least one objective.

Goal:					
Objective:					
Action Steps	Start Date	End Date	Lead Person or Organization	Measure (i.e. how will you know the change happened?)	Resources Needed / Potential Partners

Criteria for good action step—*are these steps.....*

- **Complete?** Do the steps represent changes to be sought in all relevant parts of the NBS process?
- **Clear?** Is it apparent who will do what by when?
- **Current?** Do the action steps reflect the current work? Do they anticipate newly emerging opportunities and barriers?



Goal:

Objective:

<i>Action Steps</i>	<i>Start Date</i>	<i>End Date</i>	<i>Lead Person or Organization</i>	<i>Measure (How will you know the change happened?)</i>	<i>Resources Needed / Potential Partners</i>



Now that you have developed an action plan as part of your PDSA cycle, identify the potential barriers to this work and how might they be overcome in the table below.

Potential Barrier	Solution to Barrier



Tips for Building Collaboration

1. Trust is key—relies on everyone’s understanding of the different agency’s organizational culture
 - Trust in skill
 - Know what skills you have (and what skills you don’t have)
 - Do what you say when you say it
 - Do an action step that shows your skills
 - Trust in intent
 - Know why you are part of the group
 - Use partner language (we, our, us)
 - Emphasize shared goals (save the babies!)
2. Think of your group as a blended family
 - Understand the other’s organizational culture
3. Celebrate successes
 - Remember to celebrate small steps—don’t wait for the big steps because it could take a long time
4. Measures share stake in both the process and the outcome