

Expanding Newborn Screening Services

A TOOLKIT TO IMPROVE NEWBORN SCREENING TIMELINESS BY INCREASING LABORATORY AND COURIER OPERATIONS

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INTRODUCTION

Each year, 12,000 babies with serious, but treatable conditions grow up healthy because of newborn screening (NBS). NBS is a vital public health program that identifies newborns at risk of developing critical disorders that may not show symptoms at birth, but can cause permanent disability or death if not detected and treated in the first few days of life. It is a complex system that involves families, birthing facilities, laboratories, follow-up programs and healthcare providers. Any delay in the newborn screening process may jeopardize the health and survival of affected babies.

In November 2013, the article [Deadly Delays](#) in the *Milwaukee Journal Sentinel* found evidence of serious delays in newborn screening programs across the country due to laboratory closures on weekends and holidays, limited use of courier services to transport samples from hospitals to the NBS lab, and little to no consequences for hospitals that sent late samples.

Throughout the toolkit, there are embedded links to supplemental resources, templates, case narratives, infographics, etc. Resources accompanied with an eye infographic (👁️) indicate a link to a video or webinar.

Over the past 2-4 years, many states have implemented a number of changes in newborn screening practices in order to improve health outcomes for newborns. The most significant of these changes include solutions to address courier transit times and the expansion of NBS laboratory operating hours. In particular, allowing labs to remain open six to seven days per week, greatly increases the lab's ability to receive and process specimens on the weekends. It has been demonstrated that states who have expanded newborn screening lab hours are more likely to achieve the 95% timeliness reporting goal.¹ To support these findings, a policy statement from the Association of Public Health Laboratories (APHL) is forthcoming; please check the [NewSTEPS website](#) for more information.

The toolkit for expanding newborn screening services was developed by NewSTEPS 360, a collaboration between the Colorado School of Public Health (CoSPH) and APHL to support states to make improvements in their courier and NBS laboratory operations. It is designed to assist state NBS programs, advocates, legal, and public health professionals to shape appropriate policies and communicate the value of weekend and holiday courier and laboratory operations in order to improve timeliness in newborn screening.

The material contained in this toolkit are designed to be customized based on the needs of the individual state or newborn screening program. This is a “living” toolkit that will be modified with new information and materials. For any questions or suggestions of content to add, please contact Sarah McKasson at sarah.mckasson@ucdenver.edu.

¹ For more information, see the [2016 NewSTEPS Timeliness Report](#) submitted to the United States Government Accountability Office.

DESCRIPTION OF TOOLKIT RESOURCES

Table 1: Description and Intended Use of Toolkit Resources and Materials

Name of Resource	Description and Intended Use
Making the Case for Change: A Tip Sheet for NBS Programs (pg. 6-7)	This tip sheet is intended for NBS program staff. It is meant to help the user develop and make the case for changes and improvements to state and/or health department leadership. Includes links to state stories, ROI tool, a sample fact sheet and issue brief.
Policy Guide (pg. 8-12)	This guide is designed for advocates who may be new to state NBS policy and provides a “how to” on the options and general steps to take towards changing the laws and regulations to meet NBS timeliness goals.
Law and Regulations Decision Tree (pg. 13)	This is a decision tree to guide users to determine where in the legislative/regulatory change process they currently are and the steps that need to be taken to make changes in their program.
Cookbook (pg. 14)	A guide for NBS staff with important steps to consider when making policy changes. Veteran NBS advocates may also find it helpful.
Communication Materials (pg. 15)	Provides a list of communication tools and examples that your team may consider using during the advocacy process, including talking points, fact sheets, social media, etc. Of particular interest is the issue brief develop by the March of Dimes, providing information, data and potential policy solutions specific for expanding NBS services.
Current State of NBS Operations & Case Narratives (pg. 16)	Maps and infographics from the NewSTEPS Data Repository show the number of operating days, weekend/holiday hours and activities by state. Additionally, the weekend/holiday operation summary tables highlight state specific processes regarding weekend and holiday laboratory operations, staffing and follow-up.
Steps and Considerations for NBS Program Staff (pg. 16)	Checklist of logistical, staffing, specimen delivery, costs, and approval process considerations at the programmatic level. This list should be used by NBS program staff to make sure that all bases are covered before moving forward with implementing expanded operations with the NBS lab, follow-up and courier.
Implementation Stories (pg. 18)	Features 10 state case narratives providing a roadmap of <i>what</i> and <i>how</i> to implement expanded NBS services for laboratory operating hours and courier. Also includes the Missouri volunteer model for weekend staffing. Please use these examples and lessons learned when implementing change in your own state.

DEVELOPING A STRATEGY

Making the Case for Change: A Tip Sheet for NBS Programs



Tell a Story

Craft a compelling story to illustrate why newborn screening is a vital public health program in your state, and what challenges and barriers exist in the current system to help make the case for change. Use data to help tell the story and to support your proposed policy or initiative. Some sources of data to consider: transit times tracked by the lab, birth defects registries, Medicaid, and early intervention services. *Resources:* [NewSTEPs State Profiles](#)

Research Laws/Regs.

Find out about the existing laws and regulations that guide newborn screening in your state. Determine whether the existing language in statute or codes/regulation give your agency/program/health official authority to implement changes without going through a formal rule-making or amendment process. This will also help you estimate a timeline for the change and who will be affected. With the approval of your agency, consult your office of government affairs or your attorney general when needed to obtain opinions.

Learn from Other States

Find out how other states have improved their newborn screening processes and addressed similar challenges and barriers. Other states' experiences provide a roadmap for change that can be very helpful for making your case. If your state would be the first to implement a certain policy or initiative, this could also be an opportunity for your state to be a leader. *Resources:* [Arizona](#), [Kentucky](#), [Missouri](#), [New Jersey](#), [Wisconsin](#), [Fact Sheet](#)

**Know the Costs
& Benefits**

Be mindful of your state's political climate and fiscal needs and be prepared to discuss the cost of implementing your proposed policy or initiative. Determine whether the proposed change would create a burden on hospitals or providers and whether this is related to a cost issue or a resource/training/staffing issue. Investigate ways to solve these issues and whether or not there are cost benefits or returns on the investments. As with many public health prevention programs, newborn screening has been shown to reduce costs long term.

Resources: [MOD Issue Brief: Newborn Screening Saves Lives](#), [ROI Tool](#)

**Partnerships
are Paramount**

Identify partners within your agency or other state entities or organizations who would support your proposed policy or initiative and work collaboratively with them to gain information and construct the case. Partners might include the state lab, NBS advisory committee, hospitals, hospital associations, maternal and child health advocates, parent and caregiver groups, and health care providers. **Also consider** nontraditional partners who you may be able to bring to the table when planning: including your office of government affairs, regulatory arms of your agency such as departments of licensure and certification, Medicaid, state committees, councils and task forces, and community partners and schools of public health as a resource.

Follow Up

Follow up with your leadership and with your partners to share progress or successes that have resulted from your program. They want to hear from you!

Policy Guide

Each state or territory by law operates its own newborn screening program. Therefore, although all states have laws that require screening, changing those laws and policies governing newborn screening programs can vary by state. This guide highlights the general steps needed to secure a policy change to address newborn screening timeliness goals.

What is newborn screening (NBS)?

Each year, 12,000 babies with serious, but treatable conditions are identified by state newborn screening programs. Newborn screening is a vital public health program that tests newborns for critical disorders that may not show clinical symptoms at birth, but can cause permanent disability or death if not detected and treated in the early days, weeks or months of life. Newborn screening is multi-step system that involves families, birthing facilities, laboratories, follow-up programs and healthcare providers where any delay in the newborn screening process may jeopardize the health and survival of affected babies.

All newborns should be screened between 24 and 48 hours after birth. For most tests a small blood sample is taken from the newborn's heel and placed on a newborn screening card. This card is then sent to the state public health laboratory for analysis. If an unusual result is detected, the baby's health provider is notified, who then works with the family to receive confirmatory testing and other necessary services.

Why is Timeliness Important?

In November 2013, the *Milwaukee Journal Sentinel* article series, [Deadly Delays](#), reported on serious delays in testing and follow-up among newborn screening programs across the country. Key factors in these delays included laboratories being closed on weekends and holidays, slow transport of samples, and insufficient tracking of hospitals that sent late samples. Since then, state and federal officials and stakeholders have been working to improve programs.

In 2015, the U.S. Department of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) recommended several [timeliness goals](#) for newborn screening and encouraged benchmark progress of achieving 95% of each goal by 2017. The overall goal is to communicate all

presumptive results for time-critical conditions within five days of the baby's life. All other conditions should be communicated no later than seven days of life. To achieve this and reduce delays initial specimens should be collected no later than 48 hours of life and should be received at the laboratory within one or two days for testing. For more information about the ACHDNC timeliness recommendations, click [here](#).

For more information about the importance of NBS timeliness, including personal stories, watch [Every Hour Counts](#), created by the Colorado and Wyoming Newborn Screening Programs (2016).

Barriers and Solutions

Newborn screening is a state-specific public health activity, and therefore hospital protocols and lab requirements vary from state to state. Newborn screening is a multi-step process that involves individual health care providers, hospital administrators, couriers to transport samples, and state health department laboratory and follow-up staff. As a result, there are multiple junctures where barriers to timely screening can occur. These include a lack of understanding and awareness of the importance of timely screening, inconsistent hospital protocols across municipalities and states, transporting samples in batches that contain multiple days of bloodspots, insufficient lab hours and workforce to process samples.

As of April 2017, 33 newborn screening programs operate at six or seven days a week (see the NewSTEPS [map](#) for up-to-date information). States that have expanded their courier services and specimen processing schedules to include Saturdays and holidays have reduced the time between receiving samples and reporting results.

Step 1: Determine the status and needs of the newborn screening program

- Research the state's law or regulations that guide the newborn screening program's policies impacting timeliness goals such as transit time, courier services and laboratory operating hours.
- Confirm with newborn screening officials if the state is meeting the timeliness goals. View your state's timeliness quality indicators [here](#).
- Identify barriers and determine if a policy solution including funding is required to address them.

Step 2: Identify stakeholders and partners who would support a policy change

State Health Officials: Newborn screening and state health officials, including state health officers and maternal and child health directors, are critical partners in providing advocates with information and technical assistance about the newborn screening program. Key staff include lab directors and program and follow-up staff such as genetic counselors, nurses and social workers. Advocates should solicit their support, but recognize how state government employees are permitted to interact with advocates. For example, officials may be able to respond to requests for information and provide briefings to elected officials and advocates, but they are not allowed to contact legislators. It is important for advocates to involve state officials throughout the process to help develop policy that will support and/or improve the newborn screening program and allow officials to interact appropriately in the process.

Partners: Organizations that may be interested in this issue include those that represent parents and caregivers, maternal and child health advocates, healthcare providers and hospitals. Health care providers include both primary care and specialty physicians, midwives, nurses, social workers and genetic counselors.

For more information on how newborn screening programs can effectively collaborate with family advocates, watch [Working with Family Advocates in Newborn Screening](#), hosted by Baby's First Test on September 21, 2017.

Newborn screening covers a broad array of conditions and the issue is of interest to advocates from the rare disease clinical and research communities. Among interested groups are the [March of Dimes](#), [American Academy of Pediatrics \(AAP\)](#), [American Academy of Family Physicians \(AAFP\)](#), [American Congress of Obstetrics and Gynecologists \(ACOG\)](#), state hospital associations and the [Genetic Alliance](#).

State Policymakers: Successful policy making involves establishing and maintaining ongoing relationships with key elected officials including the governor and state legislators and their staff. Cultivate bi-partisan relationships with the legislative leadership and members of key committees who have jurisdiction over the newborn screening program and its budget, which is usually part of the health department. Elected officials (or their staff) who have had an experience with the issue can be a powerful ally by either sponsoring or promoting legislation. Legislatures inclined to be supportive could include one who has a personal experience with a newborn screening condition or has a professional connection (i.e. health care provider, genetics background).

Key policymakers include:

- Governor
- Lt. Governor
- State Health Officer (Secretary of Health, Health Commissioner, Director of Health)
- Senate President
- Speaker of the House/Assembly
- Minority leaders (both chambers)
- Chairs of the Health, Finance, Appropriations, Budget Committees (both chambers)

To learn how the Missouri Newborn Screening Program was able to expand laboratory and courier operations with the help from a state legislator, watch the NewSTEPS 360 webinar, [Timeliness Improvements: New Beginnings in Missouri](#) for more information.

Step 3: Determine the appropriate strategy to secure the policy change

Changes in state health policy may require several strategies with some strategies requiring more activities and resources than others. The options include: approval by an advisory committee, the health department and/or board of health; adoption of a regulation (rulemaking); passage of an appropriation bill (state budget funding); or passage of an authorization bill (legislation). Policymakers are often interested in knowing the following about a policy change:

- What is its short-or long term public health impact?
- What is the cost and cost-effectiveness of making the change?
- What has been the experience in other states that have made changes to transit times, courier services and/or laboratory operating hours?

State Health Authority: Newborn screening programs are located within the state health department, which may have the authority to change newborn screening policy through one or more of the agency's functions: the Newborn Screening Advisory Committee, the Title V (MCH) Coordinator, the State Health Commissioner, Secretary or Director of the Health, and/or the Board of Health.

Regulation (rulemaking): A regulation or rule is issued by the agency which has authority over the program and carries the force of law. Each state's administrative procedure act (or equivalent law) prescribes the guidelines for issuing regulations and allowing public comment. A regulation may be required following enactment of legislation or may be sufficient to change the policy on its own.

For more information about rulemaking, see [Know the Rules: An Overview of State Agency Rulemaking](#).

Consider the following in developing a regulatory strategy:

- Is a regulation required in order to change the policy?
- If a regulation is needed, when can it be issued and what are the steps and timeline in the process?
- Are public comments allowed, and if so, at what point in the process?

Appropriations (funding): An appropriation is a directive from the state legislature to the state treasury to obligate or spend funds for a specific purpose. A program can be funded through an appropriation without an authorization for the program. Newborn screening programs develop a budget or fiscal note for the state health department and/or other budget authority depending upon the state budgeting process.

State fiscal years vary by state, but the majority begin July 1. Exceptions are Alabama, Michigan and the District of Columbia beginning October 1, New York on June 1, and Texas on September 1. Planning for legislative budget initiatives take place months in advance.

According to the National Association of State Budget Officers (NASBO), 30 states operate on an annual operating budget cycle providing appropriations for one fiscal year. Twenty states have biennial budgets providing funding for a two year fiscal cycle. For more information on your state's budget process, click [here](#).

Authorization (legislation): An authorization bill provides direction to the state health department on how to change the policy. Authorizing legislation can be considered the last option for changing the law as it requires more activities and resources, and can also put the law at risk of unwanted changes.

Consider the following in developing a legislative strategy to authorize a change in the law or to appropriate funds to support it:

- Is there support from the state health officer and the governor?
- Who should be the principal sponsors of the legislation?
- What other legislators would be willing to support the legislation?
- Do the sponsors sit on committees with jurisdiction over the program or are they in a leadership position?
- Does the issue have bipartisan support?
- Do you need separate strategies for the House and Senate?

Step 4: Develop an action plan

Successful changes in policy to improve newborn screening program timeliness goals depends on developing and implementing a comprehensive action plan. Listed below are actions that can be taken to support each strategy. Note that advisory committee and regulatory strategies do not usually require the same level of activity as legislative advocacy, but some of these actions may apply.

Agency/Board/Regulation: Activities could include public comments and meetings with state health authorities.

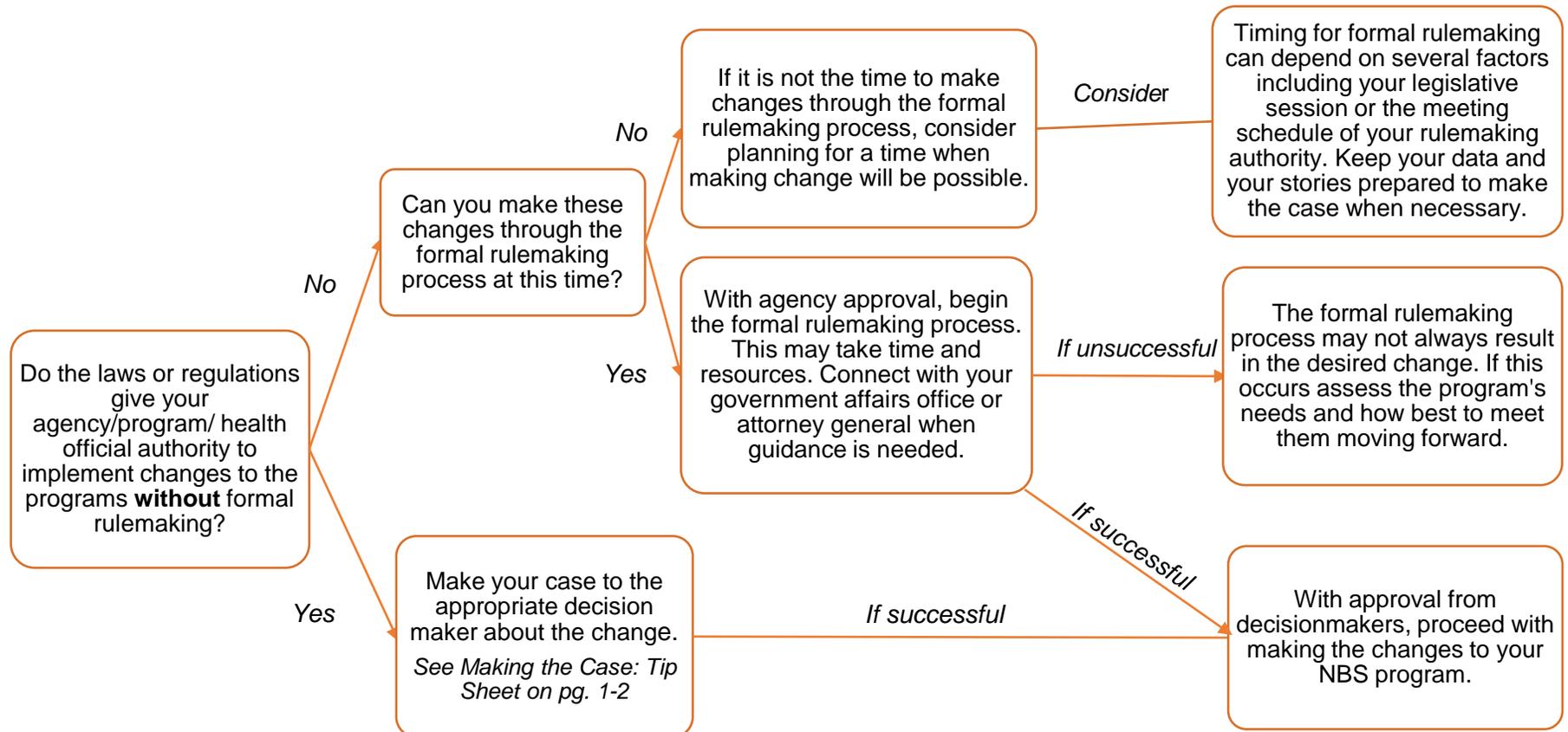
- Develop an issue brief, fact sheet and talking points
- Identify families who can share their stories
- Identify providers who can share their expertise
- Present verbal and/or written testimony to the NBS advisory committee or at regulatory hearings (include family stories and provider expertise)
- Secure support from the State Health Officer and/or Board of Health

Legislation/Appropriation: Activities could include securing legislative champions or sponsors, providing legislative language, testifying and/or providing letters of support, holding an advocacy day at the state capitol and holding other meetings with legislators, utilizing action alerts and social media messages and press activities.

- Secure legislative sponsors to champion the issue
- Develop an issue brief, fact sheet and talking points
- Identify families who can share their stories
- Identify providers who can share their expertise
- Hold an educational briefing for policymakers
- Present verbal and/or written testimony to legislative committee hearings include family stories and provider expertise
- Conduct an advocacy day at the state capitol to meet with legislators
- Implement a media strategy that includes press events, family stories, letters to the editor (targeted papers or statewide)
- Launch a grassroots campaign including legislative alerts and social media
- Use key contacts (individuals who know elected officials) to gain access to policymakers

Laws and Regulations Decision Tree

One of the keys for building the case to make changes to your NBS program is to first map out about the existing laws and regulations that guide newborn screening in your state. This decision tree is designed to help states map out next steps for making NBS policy or program change.



Cookbook Policy Guide for NBS Staff

The following provides a guide for newborn screening staff in making policy changes to the program to meet the [newborn screening timeliness goals](#).

What You'll Need: To successfully address policy changes for newborn screening programs, you should determine your state's specific needs in order to meet the timeliness goals. Some steps will include:

- Become familiar with your state's existing NBS transit times, courier service and operating hours.
- Develop contacts at other organizations who may be interested in this issue, including those who advocate for maternal and child health, parents and caregivers, health care providers and hospitals. Healthcare providers include physicians (primary care and specialists), midwives, genetic counselors, nurses, and social workers. Newborn screening covers a broad array of conditions and the issue is of interest to advocates from the rare disease and research communities.

Key Steps

1. Confirm your state's current newborn screening program's transit times, courier services and lab operating hours. See the [NewSTEPS State Profiles](#).
2. Identify the mechanism for changing this policy. In some states, it can be changed through a state advisory committee or Board of Health. In others it will require a change in regulation or through legislation. In many cases, it will require additional funding. See *ASTHO's Laws and Regulations Decision Tree on page 13 for more information*.
3. Determine whether there is currently any interest in your health department for a change in policy.
4. Determine whether there is interest in the advocacy community to take action. Other organizations may already be considering work on the issue or willing to engage. Organizations interested in NBS policy include March of Dimes (see list of contacts [here](#)), Baby's First Test of Genetic Alliance, American Academy of Pediatrics, rare disease organizations and hospital associations.
5. Determine your best arguments for promoting this policy change. State health officials and policymakers may be more interested in knowing about the short or long-term public health impact, cost and cost-effectiveness, or the experiences of other states that have already implemented the change.
6. Develop a fact sheet to explain the need for the policy change.
7. Tell an impactful story through a family experience or a narrative about a newborn screening program feature.
8. Utilize social media to help educate the public and policymakers about the program's needs.

See APHL's [Four Facts that Policy Makers Should Know about Newborn Screening](#)

Communication Materials

Issue Briefs provide information, data and potential policy solutions.

Use or modify the [Newborn Screening: Achieving Timeliness Issue Brief](#) developed by the March of Dimes to meet the needs of your state.

Fact Sheets provide basic information about how the program works and why the program needs to change. They also provide recommendations for policy solutions. See an example [Fact Sheet](#) from ASTHO.

Talking Points mirror information in the issue brief and fact sheet for use in meetings and testimony. See APHL's [Four Facts that Policy Makers Should Know about Newborn Screening](#)

Checkout this [slide deck](#) of information to share with NBS stakeholders, agency leadership and policy makers. You can modify the slide deck itself or use as an outline for talking points. Highlights the importance of NBS timeliness, state data and considerations for the implementation process to expand NBS operations and services.

Family Stories put a face to the need for the policy change. A family story about the policy you are trying to change provides perspective and gives it a personal connection for policymakers especially when policy barriers include technical language or minutiae. A

family story can help make the connection to how changing the policy will help impact them directly. Watch [Every Hour Counts](#), created by the Colorado and Wyoming Newborn Screening Programs (2016).

Newborn Screening Program Stories illustrate how the program works and impacts a family. This could feature a staff member or component of the NBS system (lab, follow up, birthing facilities, etc.), even the history of how newborn screening developed in the state. This helps put a face to a system that is complex and not easily visible to policymakers. By telling a story about the newborn screening system and its impact on newborns and families, policymakers can see how addressing barriers will improve the system for all babies born in the state.

Social Media is an effective way to reach policy makers, advocates and others with broad outreach and impact. Using social media is an

See APHL's [Media Toolkit](#) for tips on how to effectively communicate with policy makers and advocates via social media.

excellent way to deliver personal narratives (i.e. family and NBS program stories) to multiple parties to influence change. Online outreach can be an inexpensive and effective method for broad outreach and impact.

NBS PROGRAM CONSIDERATIONS FOR EXPANDING OPERATIONS

Current State of NBS Weekend/Holiday Operations

As of October 2017, 34 NBS programs have six or seven day laboratory operations and 18 NBS programs operated Monday-Friday only or 5 days. See the [infographics](#) on the NewSTEPS Data Repository for up-to-date information, including the specific laboratory and follow-up activities performed on weekends and holidays for each state.

For more information about expanded NBS operations by state, review the [operation summary tables](#) highlighting state specific processes regarding weekend and holiday laboratory procedures, staffing and follow-up.

Steps and Considerations for NBS Program Staff

Before your program decides to expand its services to holidays and weekends, review the list below to determine logistics, staffing, specimen delivery, costs, etc. Given the variation in NBS programmatic and state legislative processes, not all items will need to be completed by each state. Instead, this is merely “food for thought” to help your program anticipate challenges and prepare for the expansion of services and operating hours.

For more information, please refer to the Laboratory Efficiency Initiative (2012), [A Practical Guide to Assessing and Planning Implementation of Public Health Laboratory Service Changes](#).

Weekend/Holiday Program Logistics

- Work with the state Health Commissioner, follow-up staff, specialists, and the newborn screening advisory committee to determine which disorders to test and report out on weekends/holidays. Develop a protocol for your weekend/holiday notification strategy.
- Identify and procure equipment for efficient weekend/holiday screening (i.e. does your lab have appropriate back-up instrumentation in the event of failure during weekend/holiday if there is no vendor support?)
- Assess need for data entry staff on weekend/holidays.
- Assess need for contracting referral lab on weekends/holidays and which assays will be tested (i.e. all, molecular only, MS/MS, etc.). Procure any necessary contracts, including courier contract to get specimens from state NBS lab to referral lab on weekends/holidays.
- If testing is done in-house, develop an adjusted laboratory workflow to accommodate weekend/holiday screening.
- Procure vendor contracts for weekend/holiday Laboratory Information Management System (LIMS) and instrument support.
- Procure agency Information Technology (IT) support for weekends/holidays (i.e. on-call support).

- Ensure lab staff have remote access to instruments and LIMS in order to evaluate results and communicate out-of-range values to follow-up staff.
- Ensure follow-up staff have access to remote technology to receive and report out results to medical providers.

Weekend/Holiday Staffing

- Be aware of your state's union or civil service rules for changing work schedules to include weekends/holidays and determine appropriate compensation (i.e. job classification changes, overtime, on-call fee, flex or comp day, part of regular salary, etc.).
- Identify a staff "champion" to help gain buy-in from other staff for weekend/holiday operations.
- Incorporate expectations for weekend/holiday shifts for incoming staff via job descriptions, interview process, etc.
- Ensure adequate staffing, including correct expertise/management for weekend/holiday shifts and develop staffing plan (i.e. hire new part-time or full-time staff, recruit staff from other sections of the public health lab to take weekend/holiday shift, etc.).
- Develop staff scheduling system for weekend/holiday shifts (rotation, volunteer sign-up, etc.).
- Cross-train laboratory staff on different equipment/benches.
- If follow-up does not operate on weekends and/or holidays, cross-train laboratory staff on necessary follow-up protocols for calling out urgent results on weekends/holidays to specialists and/or genetic centers.

Specimen Delivery on Weekend/Holidays

- Negotiate contract with courier for specimen pickup and delivery to the laboratory on weekend/holidays. See example contract language provided in the Appendix.
- Identify other means to receive specimens on weekends/holidays, such as drop-off location at local/county health department, shared courier, etc.
- Ensure that the courier is aware of different pickup locations at the birthing facilities and/or drop-off location at the lab if different than rest of regular work week.
- Inform birthing facilities about weekend/holiday pickup and times; consider performing workflow analysis for hospitals.
- Provide education about the importance of newborn screening to the courier provider, as needed.
- Pilot test weekend/holiday courier route with large birthing facilities and then expand to additional facilities.

Approval of Funding

- Estimate the cost of expand program/delivery services on weekends/holidays (see cost estimation tool in the Appendix).
- Develop a budget or fiscal note to support the expansion of NBS program operating hours, including laboratory and follow-up staffing, laboratory testing, information technology, etc. This may be done in conjunction with adding new disorders to the panel.
- Obtain approval by NBS Advisory Committee, or other authority, for the increase in funding, as needed.
- Obtain approval by the State Budget Authority, as needed.

Authority for Expanded Newborn Screening (NBS) Program Operating Hours

- Obtain approval from the NBS Advisory Committee, as needed.
- Obtain approval from the Board of Health, Health Commissioner, Title V Coordinator, etc., as needed.
- Obtain regulatory rule changes to increase NBS fee, if necessary.
- Obtain mandate/approval to start screening on weekends/holidays, if necessary.

Costs to Consider for Expanded NBS Operations

- Compensation for NBS laboratory staff to cover weekend and/or holidays (overtime pay, flex days, other).
- Compensation for NBS follow-up staff to cover weekend and/or holidays (on-call, flex days, other).
- Vendor support for weekends/holidays.
- Agency IT support for weekend/holidays.
- Courier or other specimen delivery service for weekend/holidays.
- Additional assays and other lab materials.

Implementation Stories

To learn more about states' implementation process for expanded laboratory hours and courier services, see the [case narratives](#) from 10 NBS programs detailing their experiences, challenges and lessons learned when expanding to weekend and holiday operations.

Checkout Missouri's [volunteer staffing model](#) for converting to a six day laboratory work week which was presented at the 2017 APHL Newborn Screening and Genetic Testing Symposium.

APPENDIX

Tips on Writing a Policy Statement

A policy statement describes an organization's stance on a particular topic and contributes to the policy base of the organization. Policy statements serve to clarify the intent, position and justification to stakeholders and the general public.

A good policy statement should:

- Contain a clear statement of position, preferably in the first paragraph
- Include background and rationale for the position
- Include any relevant information and cite/include links for other documents
- Avoid any contradictory statements within the policy statement or with other organizational policy statements

For more information about policy statements and policy language, including examples, please refer to APHL's [Residual Dried Blood Spot Specimens Educational Toolkit](#) (2004).

Courier Contracts: Considerations & Examples

To help hold your courier service accountable it is important to build in a formal monitoring process as part of the courier contract and include specific language on pick-up and delivery times and necessary recourse for any contract violations. For example, Colorado issues a performance improvement plan and lays out specific expectations and tangible deliverables. The bidding process should also state specific requirements, such as the delivery cutoff times by day.

It is important that NBS program staff are involved in the contract writing process to ensure that delivery needs are adequately specified. See [Michigan's Notice of Contract with STAT Courier](#) which can be used as an example to help your program create a comprehensive courier contract that will meet your state's needs.

Cost Estimation Resources

The Cost Analysis Workgroup (CAWG) of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) created a [cost estimation tool](#)² for new disorders. Although the purpose of this tool is to inform newborn screening programs about adopting a new condition, there is relevant information that programs might find useful when assessing costs for expanding laboratory and courier operations.

Please refer to the full CAWG cost assessment methods report, *Developing Methods to Assess Costs of Expanding Newborn Screening: Final Report to the Advisory Committee on Heritable Disorders in Newborns and Children*³. Of particular interest for expanding laboratory and courier services, please see the table of major NBS public health lab cost categories (pg. 12), summary

² The cost estimation tool, with a sample pretest for MPS I, is on the first tab of the excel spreadsheet. The other tabs include what other information to gather (e.g. number of births, salaries for labor position, state size).

³ As of November 2017, a link for this report has not been provided. Please continue to check the ACHDNC website to see the full report.

of general steps used by states to estimate costs (pg. 14) and the summary of general steps for cost assessment across participating states (pg. 17).

Below is a list other cost analysis tools and resources that your program might find helpful to assess costs for expanding newborn screening services:

- [WHO-CHOICE: Cost effectiveness and strategic planning](#)
- [Programme costs in the economic evaluation of health interventions](#)
- [Newborn Screening Programs: An Overview of Costs and Financing](#)
- [Budget Impact Analysis: Principles of Good Practice: Report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force](#)

Other Helpful Advocacy Resources

- [Public Health Laboratory Awareness Toolkit](#)
- [UNICEF's Advocacy Toolkit](#) (particularly chapter 3)
- [Know the Rules: An Overview of State Agency Rulemaking](#)
- [Informational NBS Webinar on Notice of Proposed Rule Marking: The Common Rule](#)
- [March of Dimes: Health Literacy, Advocacy and Quality Improvement](#)

REFERENCES

1. Ackerman, A., Kappagoda, M., & Williamson, K. A. (2015). Know the rules: an overview of state agency rulemaking. ChangeLab Solutions.
2. Adam, T., Aikins, M., & Evans, D. (2007). CostIt Software © (Costing Interventions Templates) Version 4.5. User Guide. World Health Organization-Choosing Interventions that are Cost Effective project (WHO-CHOICE). Retrieved October 10, 2017 from: <http://www.who.int/choice/toolkit/cost-it/en/>
3. Association of Public Health Laboratories (APHL; 2004). Residual dried blood spot specimens educational toolkit. Retrieved October 10, 2017 from https://www.aphl.org/aboutAPHL/publications/Documents/NBS_RDBS_Toolkit_62014.pdf
4. Association of Public Health Laboratories (APHL); Colorado School of Public Health. Newborn Screening Technical assistance and Evaluation Program (NewSTEPS). Retrieved October 10, 2017 from <https://www.newsteps.org>
5. Association of Public Health Laboratories (APHL). Newborn Screening: Four Facts Policymakers Need to Know. Retrieved October 31, 2017 from: https://www.aphl.org/AboutAPHL/publications/Documents/NBS_2012Dec20_Newborn-Screening-Four-Facts-Policymakers-Need-to-Know.pdf
6. Association of Public Health Laboratories (APHL). Public health laboratory awareness toolkit. Retrieved October 10, 2017 from https://www.aphl.org/professional_development/Pages/Public-Health-Laboratory-Awareness-Toolkit.aspx .
7. Association of Public Health Laboratories (APHL); Centers for Disease Control and Prevention. A practical guide to assessing and planning implementation of public health laboratory service changes. Silver Spring, MD; APHL; 2012. Available at <http://www.aphl.org/lei>
8. Association of Public Health Laboratories (APHL). The newborn screening story: how one simple test changed lives, science and health in America. Silver Spring, MD; 2013. Available at: https://www.aphl.org/aboutAPHL/publications/Documents/NBS_2013May_The-Newborn-Screening-Story_How-One-Simple-Test-Changed-Lives-Science-and-Health-in-America.pdf
9. Health Resources and Services Administration. (2015). Timeliness of Newborn Screening: Recommendations from the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children. Retrieved October 10, 2017 from: https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/nbs_timeliness_goals.html
10. Carroll, A.E., & Downs, S.M. (2006). Comprehensive cost-utility analysis of newborn screening strategies. *Pediatrics*, 117(5), S287-S295.
11. Eiken, D., Bock, K., & Hopkins P. (2017, September). Missouri's Volunteer Model for Successfully Converting to a 6-Day Workweek for the NBS Laboratory. Poster session at the Newborn Screening and Genetic Testing Symposium, New Orleans, LA.
12. Ensign, K. What's Your ROI? A Web-based Tool to Estimate Economic Returns on Investments for Public Health Agency Projects. Association of State and Territorial Health Officials. Retrieved October 13, 2017 from <http://www.astho.org/Programs/Evaluation>
13. Gabler, E. (2013). Deadly delays. *Milwaukee Journal Sentinel*, 16

14. Johns, B., Baltussen, R., & Hutubessy, R. (2003). Programme costs in the economic evaluation of health interventions. *Cost Effectiveness and Resource Allocation*, 1:1.
15. Kemper, A., & Lam, K. (2017). Developing methods to assess costs of expanding newborn screening. Final report to the Advisory Committee on Heritable Disorders in Newborns and Children. Cost Analysis Workgroup; Evidence Review Workgroup.
16. Morgan, R., Pakkala, L., O'Brien, P., Ortiz, I., Jenkins, R., & et al. (2010). Advocacy toolkit: a guide to influencing decisions that improve children's lives (First edition ed.). New York: United Nations Children's Fund (UNICEF).
17. Newborn Screening Technical assistance and Evaluation Program (NewSTEPS). (2016). NewSTEPS Collaborative Improvement and Innovation Network (CoIIN) for Timeliness in Newborn Screening: Final Report. Available at: <https://www.newsteps.org/sites/default/files/CoIIN%20Final%20Report%2010-31-16.pdf>
18. Newborn Screening Technical assistance and Evaluation Program (NewSTEPS). (2016). NewSTEPS Timeliness Report. Final report to the US Government Accountability Office (GAO). Available at: https://www.newsteps.org/sites/default/files/NewSTEPS%20Timeliness%20Report%20to%20GAO_%20Corrected_9-7-16.pdf
19. Sullivan, S.D., Mauskopf, J.A., Augustovski, F., Caro, J.J., Lee, K.M. Minchin, M., Orlewska, E., Penna, P. Barrios, J.R. & Shau, W. (2014). ISPOR TASK FORCE REPORT Budget Impact Analysis—Principles of Good Practice: Report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. *Value in Health*, 17(1), 5-14. <http://doi.org/10.1016/j.jval.2013.08.2291>.
20. Wyoming Department of Health, Women and Infant Health Program & Colorado Department of Public Health and Environment, Newborn Screening Program (2016). Every Hour Counts: Timely collection and transport of newborn screening specimens. [Video/DVD] Denver, Colorado: West Edge Collective.
21. United States Government Accountability Office (GAO). (2016). Newborn screening timeliness: most states had not met screening goals, but some are developing strategies to address barriers. Report to Congressional Committees No. GAO-17-196.