Factors to Consider: Laboratory Procedures and Related Costs

Adding a new condition to a state's Newborn Screening (NBS) panel involves technical, financial, and policy considerations. Developing awareness of these factors helps inform proposals that address practical considerations and expenses associated with transitioning a new screening test from an idea to reality.

State's Process for Testing Bloodspots

There are broadly three ways states test bloodspots collected from newborns born in their states.

- Thirty-four states have their own **state public health laboratory** that processes NBS tests. These labs are funded by the state and other revenue sources, including processing fees charged to insurers and/or individuals. Learn more about individual states' fees for NBS.
    - These states have the most autonomy for determining which conditions to test for.
    - As you become acquainted with state lab staff, consider requesting a tour of the laboratory facilities. This will help you gain a better understanding of the resources required for NBS tests and other responsibilities lab staff must fulfill.
- Twelve states **outsource processing to another state's laboratory**. These states generally pay a fee for each test performed by the other state's lab.
    - The decision to add a new condition must factor in whether the state lab that processes their NBS bloodspot tests has the capabilities to screen for that condition, and at what additional cost.
- Four states and the District of Columbia (D.C.) **outsource processing to Revvity**, a third-party commercial laboratory, under a contract for these services.
    - The decision to add a new condition must factor in whether Revvity has the capability to process that test, and at what additional cost.

State's Process for Bloodspot Testing Follow-Up

For each bloodspot test conducted, results must be recorded and reported back to the baby's healthcare provider, generally within 5-7 days. In some states, babies automatically receive a second blood screen test 7-14 days after the initial test.

- If the test is in range, normal, or low risk, no additional tests are needed and the baby's healthcare provider likely will not contact the family.
- If the test is inconclusive or positive (out-of-range, abnormal, or high risk)
    - A representative from the state's designated newborn screening lab's **follow-up team** contacts the baby's healthcare provider.
    - The lab representative shares the results and guides them on next steps, which may include further testing, other conclusive diagnostic tests, and connection with a specialist.

- The baby's doctor informs parents of the results and guides them on next steps for intervention and care.

Scientific Rationale and Capability

Public health staff are likely to focus on the available evidence to assess the reliability of the screening test, called an **assay**. This evidence is typically collected through the conduct of one or more pilot studies. Learn more about NBS pilot studies.

Next, they need to determine if the test has been approved by the U.S. Food and Drug Administration, which can facilitate the lab's adoption of the test. If not, the lab may need to develop its own test, called a **Laboratory Developed Test (LDT)** , which requires an additional investment of resources, time, and expertise.

For states that process samples in their own laboratories, the lab also has to consider:

- **Capacity and Staffing:** Does the lab have enough skilled personnel to perform the new test and manage the increased workload? Adding a new test involves staff who are knowledgeable and experienced with data analysis, quality control, and reporting results.

- **Equipment:** Can the assay be performed using existing equipment without compromising the speed or accuracy of other screenings? Some assays can be multiplexed, meaning they screen for several conditions at once, which can increase efficiency and conserve resources. However, if new equipment or laboratory space is required to expand testing to include a new assay or a higher total volume of assays, this may require additional infrastructure approvals and funding, which is likely to add more time and complexity to implementation. Running additional tests may also require increased supplies of specimen kits, reagents, and other consumables, which may not be reflected in the operating budget.

  A recent example of how these costs can delay implementation is seen in Texas. When the state expanded NBS to include newly added lysosomal storage disorders, the state's laboratory did not have adequate physical space for the machinery or staff needed to conduct these additional assays. The state had to fund, build, and equip an addition to the state lab before implementing the new assays.

- **Data Management:** Public health laboratories utilize a Laboratory Information Management System (LIMS) to track samples, capture data on the results of each sample, and record information regarding follow-up with healthcare professionals and families. The LIMS must be capable of integrating data related to testing for and results of processing for a new condition. Some states may require specific approvals and an adequate budget to update the LIMS This, too, may factor into the process of implementing a new test.

Public Policy and the Role of Advocacy

Finding workable solutions to laboratory-related constraints may involve tapping into political will; this is where advocates play a vital role. State employees will understand what is required to implement a new test in the NBS panel. However, state employees are generally only able to provide technical assistance and may be prohibited from actively supporting or opposing any policy change being considered. Advocates are wise to build relationships with state laboratory staff and NBS program leaders as they build their case for legislative support for adding a new condition to a state's NBS program. This will help advocates identify feasible solutions to overcome concerns or objections that may arise along the way.