Newborn Screening Roadmap

Before getting into the mechanics of how to get a condition added to newborn screening, it's helpful to understand the general expectations for conditions that may be appropriate for newborn screening programs.

Key Criteria for Newborn Screening Programs

While every state determines what conditions to screen for, generally there should be evidence to support the following statements:

- The condition is medically serious.
- The condition has a well-defined case definition that describes the range of symptoms in newborns and children.
- The condition has well-defined treatment protocols and approved therapies available to treat babies.
- There is a valid screening test that is reasonable to implement in a newborn screening program that is sensitive enough not to miss any newborns, while having a low rate of false positives.
- The screening process is specific enough to detect newborns who have the condition and will most likely benefit from treatment.
- There is existing data to support how well the population-based screening works to find affected newborns, often referred to as "pilot studies."

Adapted from federal NBS evidence requirements.

Achieving these criteria for NBS requires the collective effort of many different **stakeholders** working together over many years.

Here are some **tips** to keep in mind at whatever stage of the process you may be at now. They may also be helpful as you progress through the steps identified in this Roadmap.

This **NBS Resource Roadmap** is designed to orient people to key topics related to newborn screening and resources to help them prepare to advocate effectively for NBS for one (or more) rare diseases in one (or more) U.S. states.

As you walk through each step in the Roadmap, you'll answer questions and will be directed to resources designed to assist you in determining next steps based on your responses.