

## INITIAL Survey of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment

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The purpose of this survey is to inform the Secretary of Health and Human Services Discretionary Advisory Committee about states' ability to add new conditions using information gathered from most of the states in the U.S.

**You have received this survey on behalf of your state.** If you are not the correct person to complete and return this form, please ensure that the correct person obtains it. We expect that whoever leads the effort to respond to this survey will need to consult with others within your state, including laboratory and follow-up staff, medical professionals and specialists, prior to completing the survey. As such, we are estimating that it will take each state an average of 10-person hours to complete this form.

1. A. Does your state NBS screening panel currently include condition x NBS?
  - Yes (*end survey*)
  - No
  
- 1B. Are you currently involved with any pilot evaluation activities, i.e., research or pre-live reporting results?
  - Yes: Please describe.
  - No
  
2. Within the last three years, has your state included...*Please check all that apply.*
  - Condition x as part of the routine NBS panel (*end survey*)
  - Condition x as any type of pilot evaluation (*end survey*)
  - None of the above (*go to question 3*)
  
3. Has there been a state-level decision to start screening for condition x as part of NBS?
  - Yes (*end survey*)
  - No
  
4. Which of the following provides NBS laboratory services for your state's NBS program? *Please check all that apply.*
  - Your own state's public health or NBS laboratory
  - A contracted regional NBS laboratory or other not-for profit laboratory
  - A contracted commercial laboratory
  - Other – please specify:
  - None of the above
  
5. Please categorize the **funding** challenges related to NBS program activities for condition x in your state.  
Major Challenge = NBS program needs 3 or more years to resolve.  
Minor Challenge = NBS program needs 1-3 years to resolve.

Not a Challenge = NBS program needs less than 1 year to resolve.

Activity	Major Challenge	Minor Challenge	Not a Challenge	Comments
Providing the screening test				
Short-term follow-up of abnormal screening tests, including tracking and follow-up testing				
Support to specialists for condition x				
Support to treatment for condition x				
Long-term follow-up for those with late-onset disease or who are carriers				
Increasing your NBS fee				

5a. Please describe any additional challenges.

6a. **Other than funding**, certain factors related to condition x might make screening easier or more challenging in your state. Please let us know the degree to which these factors impede or facilitate your ability to screen for condition x in your state. In order to respond to these questions, assume that condition x has been authorized for addition to your state’s panel and that funds for both laboratory testing and follow-up are made available. If needed, please speak with your NBS laboratory to help assist with the answers.

*If funding was made available*, based on your state’s current NBS infrastructure, to what extent do the factors below impede or facilitate the adoption of screening for condition x in your state?

Factor	Do not have and cannot get within 1 year	Do not have but could get within 1 year	No Impact	Have but needs improvement	Have and no improvement needed	Comments
Laboratory equipment needed to screen specimens for condition x using flow injection MS/MS*						
Laboratory equipment needed to screen specimens for condition x using digital fluorometry*						
Laboratory technical expertise to screen for condition x *						
Number of technical staff within your laboratory to screen for condition x *						
Availability of the screening test in your contracted laboratory~						
Onsite genotyping as part of a second-tier test						
LIMS capacity and instrumentation interface						
Sufficient number of NBS staff to notify and track NBS results						
Access to appropriate diagnostic services after a positive screen (e.g., diagnostic testing, clinical evaluations)						

Availability of specialists						
Availability of treatment for those diagnosed through NBS						

\* Please respond to these factors if you selected "Your own state's public health or NBS laboratory" at question 4.

~ Please respond to this factor if you selected "A contracted regional NBS laboratory or other not-for profit laboratory" or "A contracted commercial laboratory" at question 4.

6b. **Other than funding**, certain factors related to condition x might make screening easier or more challenging in your state. Please let us know the degree to which these factors impede or facilitate your ability to screen for condition x in your state. In order to respond to these questions, assume that condition x has been authorized for addition to your state's panel and that funds for both laboratory testing and follow-up are made available. Please refer to the webinar recording that provides background on condition x. If needed, please consult with laboratory and follow-up staff, medical professionals and specialists, prior to completing the survey.

*If funding was made available*, to what extent do the factors below impede or facilitate the adoption of screening for condition x in your state?

Factor	Will hinder implementation	May hinder implementation	No Impact	May aid in implementation	Will aid in implementation	Comments
Predicted run time to screen for condition x as it relates to other workload						
Other ongoing NBS program activities (e.g., addition of other conditions, other quality improvements)						
Extent to which screening protocol for condition x has been demonstrated in other NBS programs						
Cost per specimen to conduct screening (personnel, equipment, reagents)						
Cost of treatment for newborns diagnosed with NBS						
Expected clinical outcomes of newborns identified by screening						
Expected cost-benefit of screening in your state						
Advocacy for screening for this condition						
Other non-NBS public health priorities within your state						

6b1. Please describe any additional factors.

6c. What is the most significant barrier to NBS for condition x in your state?

6d. What would most facilitate screening for NBS condition x in your state?

7. How long would it take to achieve the following assuming that condition x was added to your state NBS panel and funds were allocated today, with your current NBS program and laboratory infrastructure? If needed, please consult with laboratory and follow-up staff, medical professionals and specialists, prior to completing the survey.

Activity	One year or less	1-2 years	2-3 years	> 3 years	Comment
Obtain and procure equipment for screening					
Hire necessary laboratory and follow-up staff					
Consult with medical staff and specialists					
Select, develop, and validate the screening test within your laboratory					
Add the screening test to the existing outside laboratory contract~					
Pilot test the screening process within your state, after validation has taken place					
Implement statewide screening for all newborns, including full reporting and follow-up of abnormal screens after validation and pilot testing					
Entire process from obtaining equipment to implementing statewide screening (assuming that some activities may occur simultaneously)					

*~Please respond to this activity if you selected "A contracted regional NBS laboratory or other not-for profit laboratory" or "A contracted commercial laboratory" at question 4.*

8. Please share any additional information regarding implementation of NBS for condition x.

9. Please provide information about the respondent:

- Name:
- Phone number:
- Email address:
- Job title:

10. How long have you had this position?

- < 1 year
- 1-3 years
- 4-6 years
- 7-9
- More than 10 years

11. Who did you consult with to answer these questions? *Please check all that apply.*

- State NBS laboratory experts
- Other NBS program staff
- State NBS advisory board
- State Title V Director
- Condition x Specialists
- Primary care providers
- Advocates within your state for condition x screening
- Others- please specify: \_\_\_\_\_
- None of the above

Thank you for completing the survey!