FOLLOW-UP Survey of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment

IMPLEMENTATION PROCESS

1. Describe the status of screening for [condition x] in your state. ~~The first few questions deal with the implementation process and some of the decisions your program had to make. In what capacity are you screening for Condition X? How long have you been screening?~~

   Probe 1: If you have initiated screening for [condition x], how long have you been screening?

   Probe 2: If you are in the process of adding [condition x] to your state panel, describe where you are in the process.

   Probe 3: If you are currently conducting evaluation activities or a pilot study, please describe the nature and timeline of activities. Would the screening procedure be the same if/when you add the condition as part of the state newborn screening panel? If not, what screening procedures would you use ~~for live newborn screening~~?

   Probe 4: If you have not initiated screening for [condition x], do you plan to?

   Probe 5: If you plan to implement screening for [condition x], when will you start the process for adding condition x?

~~2. *(States with mandate)* If you have not started screening, when do you plan to start?~~

~~3. (*States that are in the pilot stage*) How long do you anticipate to be in a pilot phase? Was this planned? Please explain.~~

4.2. Please tell usdescribe how you implemented/plan to implement screening for [cCondition x]X.

5.3. *(For Sstates that have started screening)* After having gone through theis implementation process, was there something you would have changed?

6.4. *(For sStates that have started screening)* Did you have any surprises with implementation? Please explain.

7.5. What has been/will be the most significant barrier challenge(s) with implementingto screening for cCondition X?

8.6. Is there something specific to your program that has/will aid facilitatein implementation of ing screening for [cCondition x]X?

METHODOLOGYLABORATORY

7. What Describe the methods you are you using to screen for [condition x] (if screening has begun) or /do you plan to use (if you are in the process of adding [condition x]) to screen for Condition X?

Why did you choose x method?

Probe 1: Discuss why you chose this method.
Probe 2: How long did it take to validate the method for [condition x] or how long do you anticipate it will take you to validate the method?
Probe 3: Do you use/plan to use a kit? In-house method? Multiplex with another assay?
Probe 4: Describe the screening algorithm for [condition x].
Probe 5: What equipment did your program already have/does have to screen for [condition x]? What did you have to purchase/anticipate needing to purchase to add [condition x]? (e.g. equipment, reagents/supplies, other disposables, ancillary equipment, etc.)

9. Please explain what new equipment you needed to/will need to procure for this method?

8. *(For states that have started screening~~If screening has begun~~)* Describe your experience with the screening test for [condition x].
~~Are you getting the outcomes you expected with this method? Please explain why or why not.~~

Probe 1: Are you getting the outcomes you expected with this method? Please explain why or why not.

Probe 2: Have you had to adjust your cutoff? If so, why? Has this changed your outcomes?

Probe 3
Do you have concerns with the method you are using/planning to use? Please elaborate.

Probe 4: Are there any issues/challenges with your method?

Probe 5: Where do you get QA/QC and PT materials? CDC? Other sources?

Probe 6: Will you continue using this method? ~~Explain~~Please elaborate.

~~DIAGNOSIS~~CONFIRMATORY TESTING AND SHORT-TERM FOLLOW-UP

9. Have you developed a follow up protocol and/or educational materials for [condition x]? If so please describe ~~it~~the steps for short-term follow and how ~~it~~ the plan was developed.

Probe 1: W~~w~~hat confirmatory testing center/lab ~~you~~ have you ~~will~~ used? What confirmatory testing procedures are done?

Probe 2: W~~w~~ill you need to engage specialty/diagnostic centers?~~-~~ If yes, what is the availability of ~~molecular~~the specialty diagnostic centers? What diagnostic testing procedures are used? ~~molecular genetic sequencing of positive screens? If yes, what is the availability of molecular diagnostic centers?~~

Probe 3: ~~a~~Are ~~the~~ clinical specialists ready for referrals and diagnosis of confirmed positive screens in newborns? Are there guidelines about how to manage these babies and children and when treatment should start?

Probe 4: Discuss the availability of the specialty centers in your state? Rest of the country? Is that adequate given the expected incidence? How about for treatment centers? Health care specialists who provide treatment?

~~a.~~

10. Are you finding any challenges with follow-up on ~~with regards to~~~~of~~ screening results for condition~~s~~ x? If so, what are they?
11. Is your program planning to identify and report carriers? If so, please elaborate on the challenges that may arise.

TIMEFRAME

12. *(For states that have started screening)* How long did it take your NBS program to initiate screening for [condition x], from the point you started to consider screening to commencing screening for all newborns in your state? (Please factor in things such as obtaining authority to screen, obtaining funding, meeting with advisory committees, setting up the screening test, updating the LIMS system, preparing follow up staff, preparing specialists in the community, etc).

~~12.~~13. In an attempt to better understand the timeframe for ~~a~~ various~~ety~~ ~~of~~ implementation activities, ~~we would like to know~~please describe how long it took/will take you to do the following ~~(answer options < 1yr., 1-2 yrs., 2-3 yrs. >3 years)~~:

a. Obtain and procure equipment for screening
b. Hire necessary laboratory and follow-up staff
c. Consult with medical staff and specialists
d. Select, develop, and validate the screening test within your laboratory
e. Add the screening test to the existing outside laboratory contract
f. Pilot test the screening process within your state, after validation has taken place
g. Implement statewide screening for all newborns, including full reporting and follow-up of abnormal screens after validation and pilot testing
h. Entire process from obtaining equipment to implementing statewide screening (assuming that some activities occurred simultaneously)

Possible timeframes:
- 12 months or less
- 13 to 24 months
- 25 to 36 months
- 37 to 48 months
- More than 48 months

13.14. What advice do you have for other state NBS programs in order to ensure smooth and timely implementation?

PERSONNEL AND FOLLOW-UP

The next few questions are more specific and deal with personnel requirements and follow-up issues.

14.15. The next few questions are more specific and deal with personnel requirements and follow-up issues. Do you have staffing concerns with screening for C[condition x] X? If so, what are they?

16. How many FTEs and what level (education/experience) are needed to add screening for condition X in your state? (*confirm #babies screened/year*)

17. do you have for screening for [cCondition x]X (technical only)?

a. Probe 1: If yes, how many FTEs are for laboratory staff, for and for what position(s)/level(s)?
b. Probe 2: how many Are the FTEs are needed for for laboratory staff, follow up staff, or both? For what position(s)/level(s)?

18. Do you anticipate needing to hire/add FTEs to screen for [condition x]?

a. Probe 1: If yes, how many FTEs for lab staff, and for what each position(s)/level(s)?
b. Probe 1: How many Are the FTEs for laboratory staff, follow up staff, or both, for which position(s)?

15.19.

16. This question pertains to follow-up. Do you have concerns with short-term and long-term follow up for [cCondition x]X? If so, please describe what are your concerns.?

COSTS

20. Has your program developed cost estimates or a budget analysis to adopt add [condition x]?

If Yes, are you able to share your ballpark estimates to add screening? *(Ask about marginal start-up costs to add condition - equipment, supplies, FTEs, confirmatory testing, overhead, other major costs).*

a. IF NO, have you had preliminary cost discussions? Are you able to elaborate?

~~17.~~21. What do you anticipate will be the greatest cost challenge as it relates to [condition x]?

22. What do you anticipate will be the greatest cost facilitator as it relates to [condition x]?

CONCLUSION

~~18.~~23. That concludes the formal part of the interview. Do you have anything else to add?

~~19.~~24. Name of respondent, title, how long in position.