

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

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0906-0014. Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N136B, Rockville, Maryland, 20857.

IMPLEMENTATION PROCESS

1. Describe the status of screening for [condition x] in your state.

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?

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. Please describe how you implemented/plan to implement screening for [condition x].
3. *(For states that have started screening)* After having gone through the implementation process, was there something you would have changed?
4. *(For states that have started screening)* Did you have any surprises with implementation? Please explain.

5. What has been/will be the most significant challenge(s) with implementing screening for [condition x]?
6. Is there something specific to your program that has/will facilitate implementation of screening for [condition x]?

LABORATORY

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

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.)

8. *(For states that have started screening)* Describe your experience with the screening test for [condition x].

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? Please elaborate.

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 the steps for short-term follow and how the plan was developed.

Probe 1: What confirmatory testing center/lab have you used? What confirmatory testing procedures are done?

Probe 2: Will you need to engage specialty/diagnostic centers? If yes, what is the availability of the specialty diagnostic centers? What diagnostic testing procedures are used?

Probe 3: Are 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?

10. Are you finding any challenges with follow-up on screening results for [condition x]? If so, what are they?

11. (If applicable to [condition x]) 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).

13. In an attempt to better understand the timeframe for various implementation activities, please describe how long it took/will take you to do the following:

- 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

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.

15. Do you have staffing concerns with screening for [condition 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 [condition x]?

Probe 1: how many FTEs are for laboratory staff, for what position(s)/level(s)?

Probe 2: how many FTEs are needed for follow up? For what position(s)/level(s)?

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

Probe 1: If yes, how many FTEs for lab staff, for each position(s)/level(s)?

Probe 1: How many FTEs for follow up, for which position(s)?

19. Do you have concerns with short-term and long-term follow up for [condition x]? If so, please describe your concerns.

COSTS

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

Probe 1: 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).

Probe 2: IF NO, have you had preliminary cost discussions? Are you able to elaborate?

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

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

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