Agenda

1. Welcome and roll call (5 min)
2. Introduce New Members to the Lab Workgroup (10 min)
3. NBS Risk Assessment and Cutoffs (45 min)
   - Follow up on Committee’s Discussion/Charge
   - APHL Guidance Document
4. Public Health System Impact Survey (45 min)
5. Wrap-up, next steps and adjourn (10 min)
Workgroup Roster

Liz Amos*  Mei Baker  Stan Berberich
Michele Caggana  Carla Cuthbert  George Dizikes
Rosemary Hage*  Tricia Hall  Travis Henry
Dieter Matern  Jelili Ojodu  Scott Shone
Bonnie Taffe*  Michael Watson  Holly Winslow
Roberto Zori

• Chair:  Kellie Kelm
• Co-chair:  Susan Tanksley
• HRSA staff:  Ann Ferrero, Andrea Matthews, Morgan Moore
Risk Assessment/Cutoffs

- The workgroup’s recommendations to the committee on policies that states should consider regarding risk assessment/cutoffs:

- States should have written processes in place:
  1. for the validation of the test systems to determine if a newborn is normal/in-range/low risk vs. abnormal/out-of-range/high risk
  2. for revisiting cutoffs/algorithms, including how often they reassess
  3. for reviewing missed cases

- States should disclose the targets for their newborn screening program

- Encourage participation in normalization and downstream QA/QI efforts
Next Steps

• Workgroup will discuss APHL Risk Assessment Guidance Document when it is finalized in June
  • Will circle back to committee if the workgroup has any recommendations with regards to the document
LABORATORY STANDARDS AND PROCEDURES WORKGROUP

PHSI FEEDBACK

May 10, 2018

Co-chairs: Kellie Kelm, PhD & Susan Tanksley, PhD
Public Health System Impact Survey

• Survey should capture the impact of securing funding and authorization to screen for a new condition
  • How long does the process take?
  • How difficult is it to secure funding/authorization?
• Factors/activities should be analyte/condition/method agnostic (e.g. instead of “onsite genotyping as part of a second tier test”, state “second tier test available onsite, if needed”)
• Remove question 10
• Utilize questions and possibly look at information gathered from the NewSTEPS readiness tool
### NewSTEPs Readiness tool

<table>
<thead>
<tr>
<th>Activity/Milestone</th>
<th>Not started</th>
<th>Date started (MM/DD/YYYY)</th>
<th>Date Completed/Implemented (MM/DD/YYYY)</th>
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<tbody>
<tr>
<td>Approval/Authority to Screen</td>
<td>Obtain approval from the NBS Advisory Committee (from initial presentation/meeting to final approval).</td>
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<td>Obtain approval from the Board of Health/Commissioner/other leaders (from initial presentation/meeting to final approval).</td>
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<td>Other approval authority activities.</td>
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<td>Mandate/approval to start screening/state approves disorder for NBS.</td>
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<td>Obtain approval from the Institutional Review Board (IRB) to initiate pilot testing, if needed.</td>
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<tr>
<td><strong>Phase 1 – Authority to Screen</strong></td>
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<td>Approval of Funding</td>
<td>Develop a budget to show costs for screen, including laboratory testing, follow-up, Information technology, etc.</td>
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<td>Obtain approval by NBS Advisory Committee for increase in funding.</td>
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<td>Obtain approval by the State Budget Authority.</td>
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<td>Other funding activities.</td>
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<td>Approval for fee increase.</td>
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<td></td>
<td>Fee Increase Implemented.</td>
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