

# LABORATORY STANDARDS AND PROCEDURES WORKGROUP

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May 10, 2018

Co-chairs: Kellie Kelm, PhD & Susan Tanksley, PhD

# 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\*

Michele Caggana

Rosemary Hage\*

Dieter Matern

Bonnie Taffe\*

Roberto Zori

Mei Baker

Carla Cuthbert

Tricia Hall

Jelili Ojodu

Michael Watson

Stan Berberich

George Dizikes

Travis Henry

Scott Shone

Holly Winslow

- 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/algorithm, 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

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## PHSI FEEDBACK

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# 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

	<b>Activity/Milestone</b>	<b>Not started</b>	<b>Date started</b> (MM/DD/YYYY) <i>*if exact day is unknown use 1<sup>st</sup> of the month</i>	<b>Date Completed/ Implemented</b> (MM/DD/YYYY) <i>*if exact day is unknown use 1<sup>st</sup> of the month</i>
<b>Phase 1 – Authority to Screen</b>	<b>Approval/Authority to Screen</b>			
	Obtain approval from the NBS Advisory Committee (from initial presentation/meeting to final approval).			
	Obtain approval from the Board of Health/Commissioner/other leaders (from initial presentation/meeting to final approval).			
	Other approval authority activities.			
	Mandate/approval to start screening/ state approves disorder for NBS.			
	Obtain approval from the Institutional Review Board (IRB) to initiate pilot testing, if needed.			
	<b>Approval of Funding</b>			
	Develop a budget to show costs for screen, including laboratory testing, follow-up, information technology, etc.			
	Obtain approval by NBS Advisory Committee for increase in funding.			
	Obtain approval by the State Budget Authority.			
	Other funding activities.			
	Approval for fee increase.			
	Fee increase implemented.			