

*Draft manuscript:*  
**“Implementing Point-of-Care  
Newborn Screening”**

**From the SACHDNC  
Follow-up & Treatment  
Sub-committee**

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# Point-of-Care Screening



## Outline:

- **Summarize manuscript**
- **Identify any remaining issues**
- **Solicit Advisory Committee's recommendations**
  - **Manuscript and next steps**

# ***What is Point-of-Care Screening?***

**POC Testing - defined as:**

**[Screening] “at or near the site of patient care.**

**The driving notion behind POC is to bring the test [and results] conveniently and immediately to the patient.**

**This increases the likelihood that the patient will receive the results” prior to discharge.**

**Analysis of DBS in a central laboratory is not point-of care screening.**

Kost, Gerald J. (2002). "Goals, guidelines and principles for point-of-care testing".  
*Principles & practice of point-of-care testing*.  
Hagerstown, MD: Lippincott Williams & Wilkins. pp. 3–12.

# Context of the Manuscript

- **Considerations precipitated by SACHDNC deliberations on other POC screening:**
  - Hearing screening - sole current model
  - CCHD and Hyperbilirubin
- **Juxtaposed public health and pediatric concerns about:**
  - **Decision-making: ACHDNC vs. other professional entities**
  - **Roles & Responsibilities & Resources:**
    - Birth hospital and provider vs. Public health
    - May vary by condition and screening paradigm

# **DRAFT: “Implementing Point-of-Care Newborn Screening”**

- Alex R. Kemper, MD, MPH, MS
- Christopher A. Kus, MD, MPH
- Robert J. Ostrander, MD
- Anne Marie Comeau, PhD
- Coleen A. Boyle, PhD (*Co-chair*)
- Denise Dougherty, PhD
- Marie Y Mann, MD, MPH
- Jeffrey R. Botkin, MD, MPH (*Co-chair*)
- Nancy S. Green, MD

***On behalf of the Follow and Treatment Sub-committee***

# Abstract

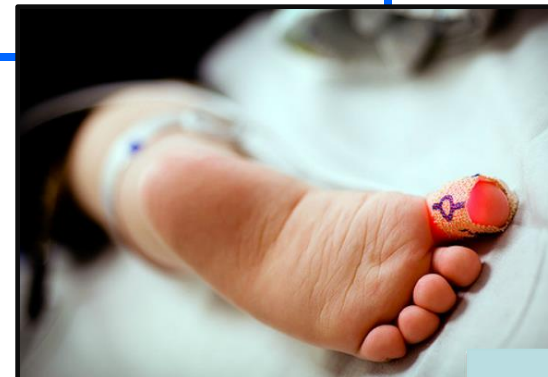
- **Framework for evaluation: whether conditions identifiable through POC screening should be added to the recommended panel**
- **Identifies key considerations for birth hospitals, public health agencies, and clinicians**

# Manuscript sections

- **Overview of Newborn Screening**
- **Defining Point-of-Care NBS**
- **Potential of Decentralized NBS**
- **Criteria for Point-of-Care NBS**
- **Roles of Public Health Agencies**
- **Implementation**
- **Concerns**

# Defines Combination of Characteristics for NBS

- **Provided under public health authority**  
*as an essential public health activity*
- **Public agencies provide direct oversight to ensure uniform quality**
- **Evidence-based recommendations**





# Criteria for Inclusion in POC NBS

## Shared imperatives of NBS,

### ***PLUS:***

- Urgent treatment is required earlier than the feasible turnaround time for a centralized laboratory;

***OR***

- When screening is based on physiologic testing requiring presence of the newborn

# Considerations for Inclusion as POC NBS

- **Major consideration: Better outcomes if performed under a public health mandate**
- **Standardized screening technology**
- **Feasibility of decentralized implementation**
- **Screening is feasible in the nursery**
- **Assure follow-up care**

# **No Single Right Way or Directive for Public Health: *Depends on the Condition, the State, Other Factors***

- **State: authorizing legislation and regulations**
- **Factors influencing degree of public health involvement:**
  - **Risk of missed affected cases**
  - **Complexity of the screening paradigm**
  - **Extent already part of standard care**
  - **Challenge of confirmatory Dx**
  - **Variability of quality of screening performance and health outcomes**

# **Issues – I**

## **Public health**

### **Roles & responsibilities of public health**

- **Assure statewide feasibility of timely, equitable screening, Dx and treatment services**
- **Assure feasibility of statewide surveillance**
- **Integrate clinical services and tracking into the existing systems for traditional NBS**
- **Assess impact of POC NBS on clinical care**
- **Informing the public**

# Issues for POC NBS – II

## Providers and Nurseries

- **Infrastructure: Dx, follow-up, education and training, tracking, reporting;**
- **Practicality of standardized screening across the variety of nursery settings;**
- **Cost of screening and implementation;**
- **Roles & responsibilities:**
  - **Providers within nurseries**
  - **primary and specialty care providers;**
- **Assessing impact on routine clinical care.**

# Issues – III

## Coordination

- **Many stakeholders:**
  - **Families, primary care and specialty healthcare providers, hospitals, public health agencies, payers;**
- **Collaboration and leadership across the participating health entities;**
- **Issues:**
  - **Coordinated follow-up**
  - **Avoid disparities in program quality**

# Implementation by Birth Hospitals

- **Obtain screening equipment**
- **Employ and train screeners**
- **Ensure nursery accommodation**
- **Provide public educational materials**
- **Continuous quality assurance**
- **Record screening results**
- **Timely reporting: families, providers, state public health agencies**
- **Coordinate timely follow-up and Dx**

# Subsequent Issues

- **Criteria used by ACHDNC differ from those used in clinical practice**
- **Interface between professional clinical standards and public health programs**
- **Assure input from professional organizations and families**
- **Data capture**
- **Gaps in funding**
- **Acceptability to parents:**
  - **Consent needed? Hearing - 7 states require (2001)**



# Summary



- **Manuscript from the F/U & Rx Sub-committee of the SACHDNC**
- **This manuscript reflects “the end of the beginning” for POC NBS**
- **Some issues may apply to childhood screening beyond newborns (future consideration)**

# ***We Seek ACHDNC Guidance***

- **Support of the manuscript by the ACHDNC**
- **Share with the Secretary:**
  - An informational document on growing opportunity for NBS
- **Submit for peer-reviewed publication:**
  - Genetics and Medicine (or public health journal)
- **Identify next steps:**
  - Focus on experience with CCHD
  - Confer with others (e.g. practice and hospital organizations, APHL)

# From the F/U & Rx Sub-committee

*Thank you for your support and input!*

