One Year Experience for the Newborn Screening Molecular Assessment Program (MAP)

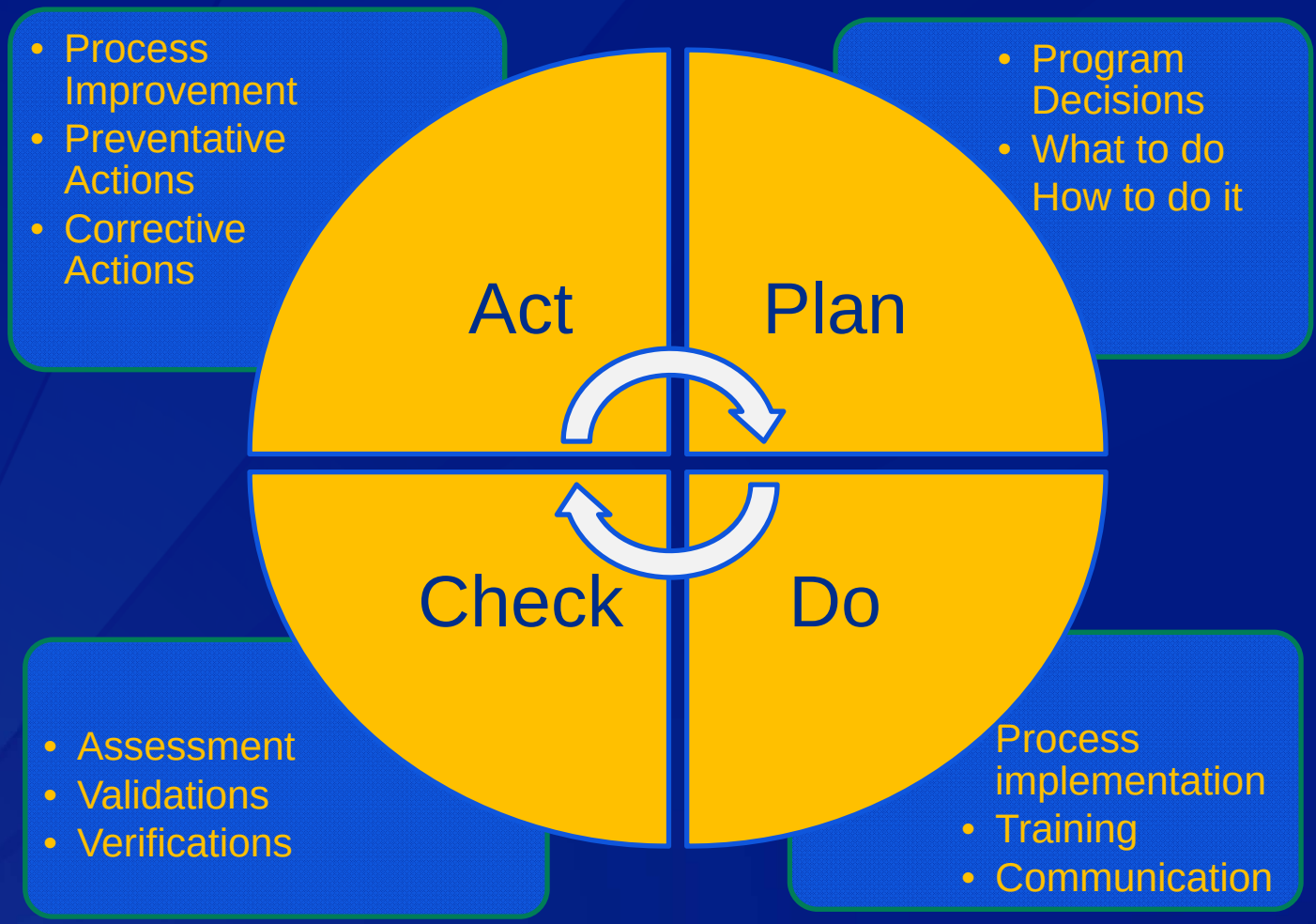
Christopher N. Greene, Ph.D.

Newborn Screening and Molecular Biology Branch

National Center for Environmental Health

Centers for Disease Control and Prevention, Atlanta, GA

Quality Improvement Cycle



NBS Molecular Assessment Program (MAP)

- **Evaluation of molecular newborn screening programs**
  - **Invited site visit of molecular biologists from:**
    - **CDC's Newborn Screening and Molecular Biology Branch**
    - **State Public Health Newborn Screening Programs**
    - **Representatives from Association of Public Health Laboratories**
- **Support for newborn screening laboratories**
  - **Non-regulatory review of molecular testing activities**
  - **Guidance for expansion of NBS molecular testing**
  - **Provided at no cost to participating programs**

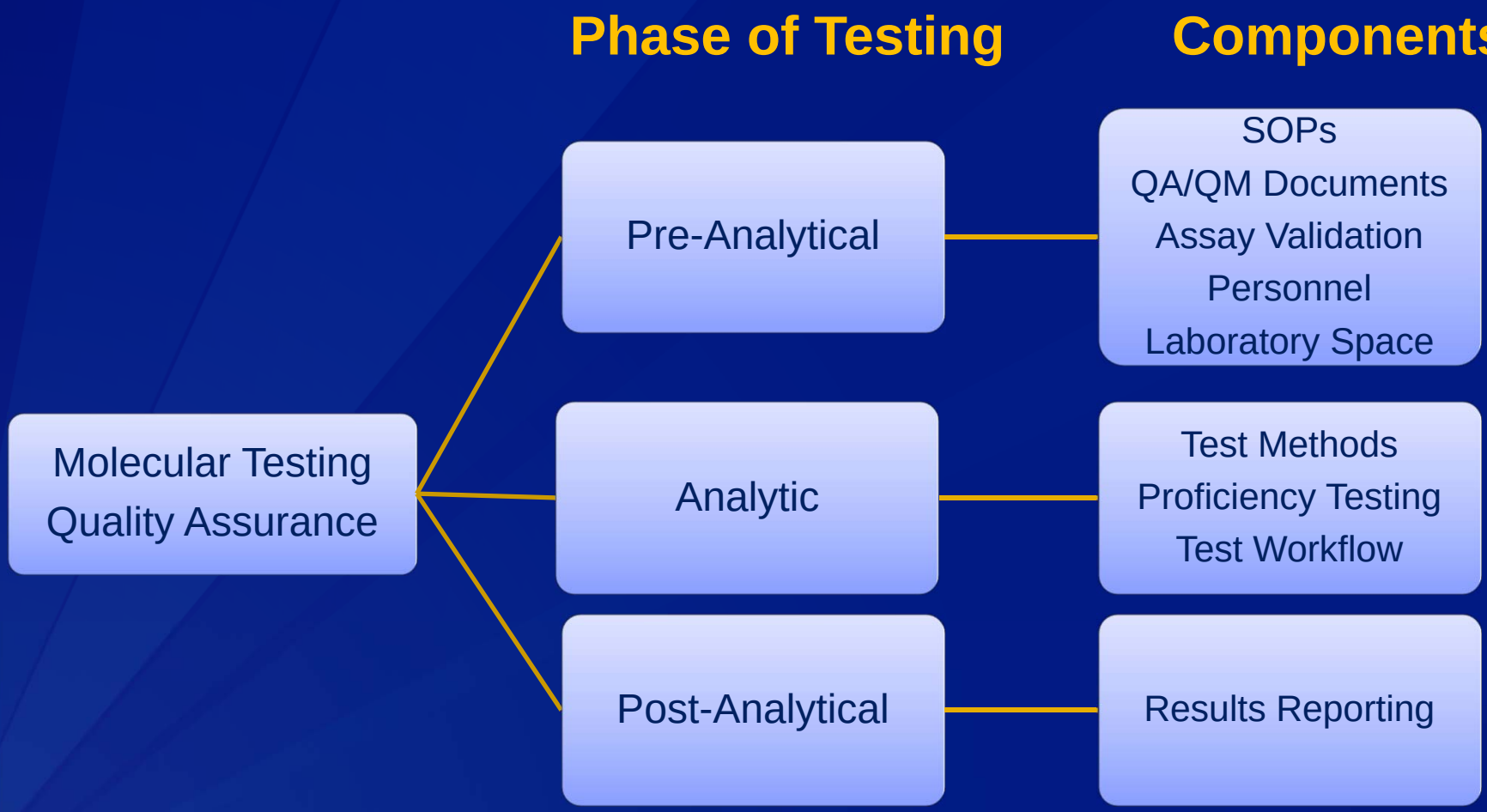
Why MAP was Developed

- Gaps in current regulatory guidelines
  - No CLIA genetic testing specialty
  - Complexity with molecular testing especially using dried blood spots does not fit standard framework
  - "Regulatory rigidity" may constrain new technologies
- Molecular tests have different quality management requirements
  - Molecular is still relatively new for many programs
  - Hiring of new staff is limited

Basis for Evaluations

- **Assessment criteria modeled from multiple sources:**
  - **NNSGRC Performance Evaluation Assessment Scheme (PEAS)**
  - **CLIA regulations**
  - **Molecular Pathology Checklist (CAP)**
  - **Standards and Guidelines for Clinical Genetics Laboratories (ACMG)**
  - **Clinical Laboratory Standards of Practice (NYSDOH)**
  - **Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions (MMWR)**

Assessment Components



Overview of MAP Site Visits

- **Pre-visit**
  - Review of written SOP and quality assurance manuals
- **Visit Day 1**
  - Overview of program and molecular activities
  - Assessment of molecular workspace and workflow
  - Review of quality assurance, validation documents and molecular reporting
- **Visit Day 2**
  - Exit discussion with program members
- **Post-visit**
  - Written report for program's use

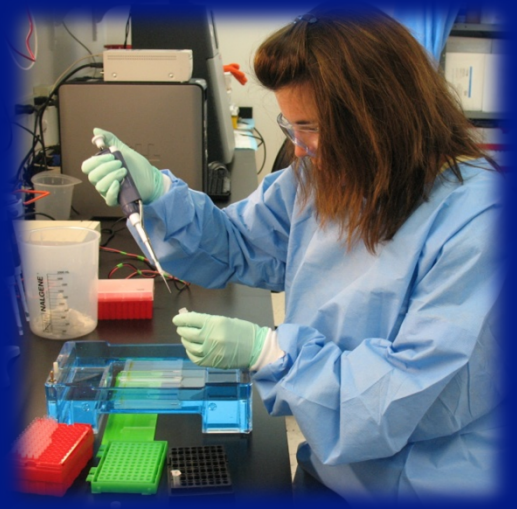
MAP Activity

- **2011 Pilot Site Visits**
  - Wisconsin
  - New York State
  - Washington State
- **Program Site Visits**
  - Michigan - 2012
  - Texas - 2012
  - Florida - 2013
  - Minnesota - 2013
  - Virginia - June 2013
- **Program Partners**
  - APHL
  - Wisconsin
  - New York State
  - Washington State
  - Michigan
  - Texas

Cited Reasons for Site Visits

- Overall evaluation of molecular activities
- Suggestions for improving workflow efficiency
- Optimizing the utilization of existing workspace(s)
- Planning for implementing new assays
- Preparation for inspections

Benefit for NBS Programs



- Approaches to incorporate molecular into screening programs
  - Application needs
  - Available resources
- MAP teams offer a range of molecular NBS expertise
  - Provide alternate strategies for molecular screening
  - Best-practices and ideas for what has worked for other programs

Results from Visits

- Harmonization of SOPs
- Definition of molecular QA processes
- Modification to workflow
- Opportunities for program collaborations

Future Directions of MAP

- **Component of NSMBB's continual quality improvement mandate**
- **Resources for NBS molecular testing community**
  - Molecular screening best practices
  - Examples and templates for APHL molecular screening website
- **Feedback to CDC**
  - QC materials for molecular testing
  - Training needs for APHL-sponsored molecular workshops

For More Information on MAP

For questions about MAP:

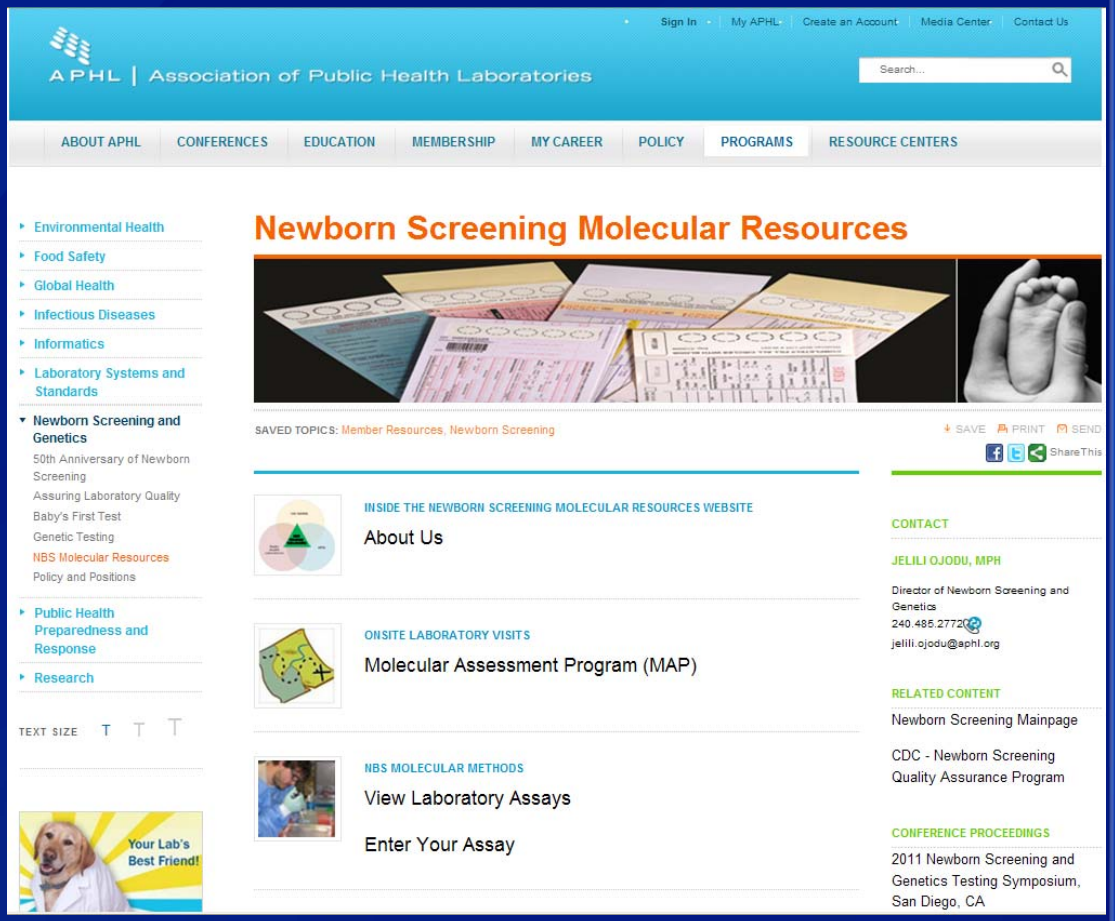
Christopher Greene

cgreene@cdc.gov

For access to the NBS Molecular Resources Website:

Elizabeth Jones

elizabeth.jones@aphl.org



http://www.aphl.org/aphlprograms/newborn-screening-and-genetics/molecular/pages/default.aspx

Benefits of MAP from the States Perspective

- "A constructive review of our newborn screening molecular program was invaluable… The objective was simply to help us validate what we were doing well and share the wide ranging experience of the team members to suggest ways we might improve" - Mike Glass, WA

- "Came away from the interaction with the assurance that we were doing certain things well as well as a list of items to improve on" - Kelly TenEyck, MI

- "Provided recommendations on the appropriate amount of QC required and advice to overcoming the barriers to acquiring rare QC materials" - Rachel Lee, Tx

Acknowledgements

State Partners

Mei Baker (WI)
Tim Davis (WA)
Rachel Lee (TX)
Heather Wood (MI)
Carlos Saavedra-Matiz (NY)
Colleen Stevens (NY)

APHL

Ruhiyyih Degeberg
Elizabeth Jones
Jelili Ojodu

CDC's NSMBB

Christopher Greene
Suzanne Cordovado
Stanimila Nikolova
Carla Cuthbert

Contact Information

MQIP	Suzanne Cordovado	scordovado@cdc.gov
MAP	Christopher Greene	cgreene@cdc.gov
APHL	Elizabeth Jones	elizabeth.jones@aphl.org

For more information please contact Centers for Disease Control and Prevention
1600 Clifton Road NE, Atlanta, GA 30333
Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: www.cdc.gov