

# Performance Evaluation and Assessment Scheme

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# NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

## Purpose:

To support improvement of newborn screening (NBS) systems, and ultimately patient services, by developing a Program Evaluation and Assessment Scheme (PEAS).

## Grant activities:

1. Develop multi-disciplinary project team(s)
2. Collect and assess PEAS tools/activities currently available
3. Create a comprehensive PEAS for the NBS system
4. Develop an interactive electronic means of using PEAS
5. Plan PEAS implementation pilot testing and improvement



Previously

TQM

Total Quality Management

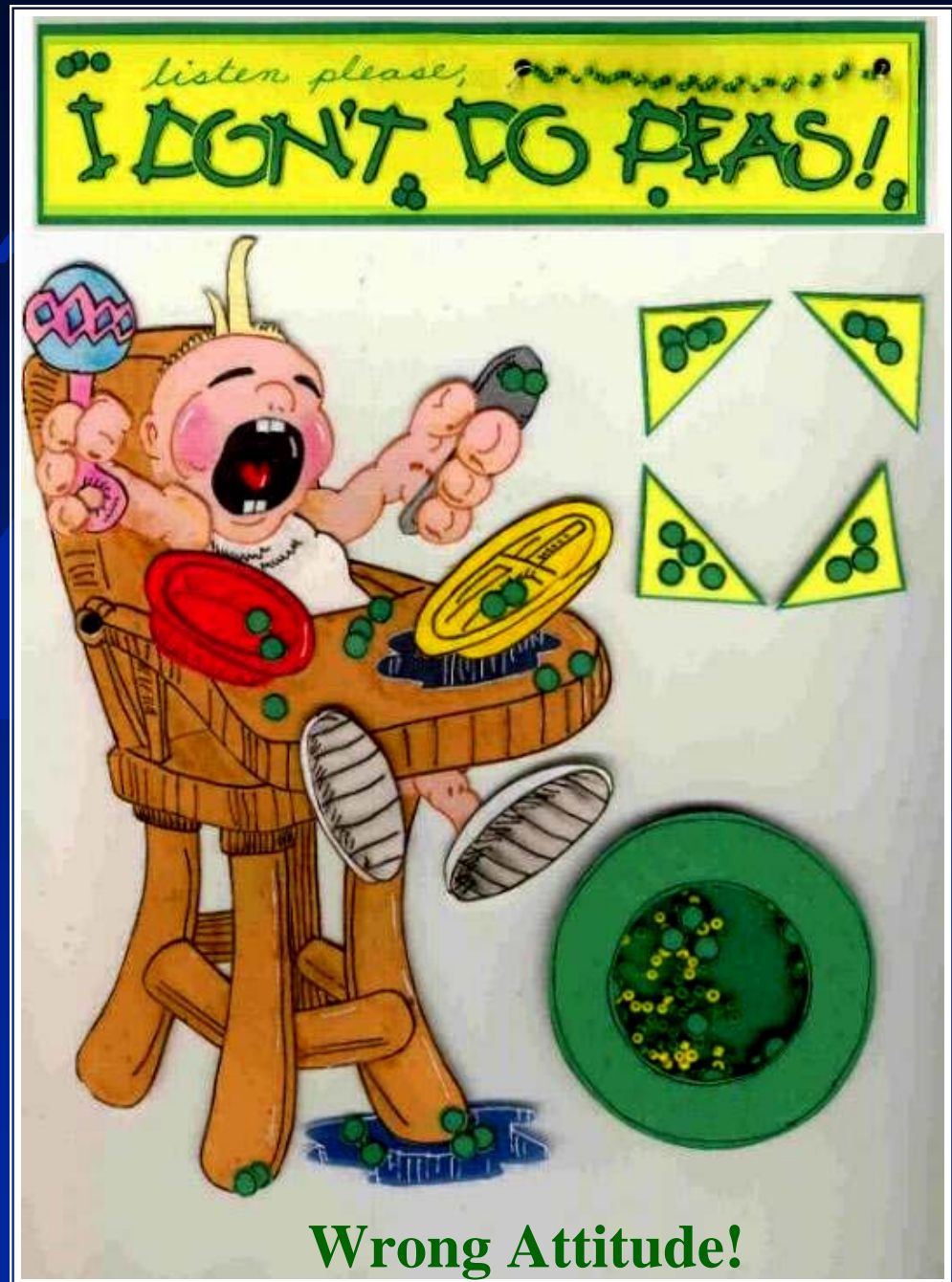
CQI

Continuous Quality Improvement

Now

PEAS

Performance Evaluation and  
Assessment Scheme



# PEAS PROJECT OVERSIGHT/ADVICE COMMITTEE

## Committee Members

William Becker

E. Stephen Edwards

Charlie Homer

Alex Kemper

Kelly R. Leight

Trish Mullaley

Patricia McLaughlin

David Ross

Nancy Wade

## Project Overall Direction (POD)

Brad Therrell

Michele Puryear

Marie Mann

Harry Hannon

Marion Schwartz

Carol Southard

Association of Public Health Laboratories

American Academy of Pediatrics

National Initiative for Children's Healthcare Quality

University of Michigan (Evaluation Specialist)

CARES Foundation, Inc. – Lay Advocate

(CAH Research, Education, and Support)

Genetic Alliance – Lay Advocate

(PKU and Allied Disorders)

Association of Women's Health, Obstetric and

Neonatal Nurses (AWHONN)

Public Health Informatics Institute

Association of Maternal and Child Health Programs

NNSGRC

HRSA

HRSA

CDC

Follow-up/Education Working Group

Laboratory Working Group



# NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

## SELF-ASSESSMENT PERFORMANCE CHECKLIST With Example References/Activities for Improvement

⚡ PRE-ANALYTICAL  
⚡ ANALYTICAL  
⚡ POST-ANALYTICAL

PERFORMANCE INDICATOR

FINDINGS

EXAMPLES/REFERENCES

Yes    In Prep    No



# FOLLOW-UP/EDUCATION WORKING GROUP

## Project Co-Manager:

Marion Schwartz

## Members:

Sharon Anderson

Louis Bartoszesky

Penny Hatcher

Pam King

Marcia Lavochkin

Fred Lorey

Julie Miller

Charles Myers

Ellie Mulcahy

Sheila Neier

## Observers:

Irene Forsman

John Eichwald

## Oversight

Brad Therrell

Marie Mann

New Jersey – Follow-up Coordinator

New Jersey – Practicing Nurse

Delaware – Physician Consultant

Minnesota – Follow-up Supervisor (DBS/NHS)

Oklahoma – Follow-up Supervisor

New Hampshire – Follow-up Coordinator

California – Development/Evaluation Director

Nebraska – Program Manager

Louisiana – Program Manager

Maine – Program Manager

Washington – Follow-up Supervisor

HRSA – Newborn Hearing Screening

CDC – Newborn Hearing Screening

Texas – NNSGRC – Laboratory Operations

HRSA – Contract Officer



# SLEEP IN HEAVENLY PEAS



ASHLEY  
COOPER

FunnyGreetings.Net

# NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

## FOLLOW-UP/EDUCATION: CROSS CUTTING ISSUES

### 1. EDUCATION

Plan

### 2. DATA SYSTEMS

Data System Integrity  
Data Integration

### 3. MONITORING OF TIMELY AND UNIVERSAL SCREENING

Monitoring required screening  
Subsequent screens

### 4. PROGRAM POLICY AND FINANCING ISSUES

Administration  
Financing





# NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

## FOLLOW-UP EDUCATION: PRE-ANALYTIC

### 1. PRENATAL AND BIRTHING FACILITY EDUCATION FOR PARENTS/CONSUMERS

Prenatal educational materials

Distribution of prenatal educational material

Evaluation of impact of prenatal educational materials

### 2. PRENATAL PROFESSIONAL EDUCATION

Professional educational materials

Distribution of professional educational materials

Evaluation of impact of professional educational materials



# NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

## FOLLOW-UP/EDUCATION: POST-ANALYTICAL

### 1. OVERALL FOLLOW-UP SYSTEM EVALUATION

Evaluation plan

Minimum evaluation elements

### 2. FOLLOW-UP OF PRESUMPTIVE POSITIVE RESULTS

Written follow-up policies and procedures

Communication (of results)

Documentation (of communication)

### 3. FOLLOW-UP OF UNSATISFACTORY SPECIMENS

Timely notification

Specimen receipt monitoring

Continued



# NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

## FOLLOW-UP/EDUCATION: POST-ANALYTICAL

4. A MECHANISM FOR EVALUATING THE TIMELINESS AND EFFECTIVENESS OF DIAGNOSIS AND TREATMENT

Diagnosis

Medical intervention

5. PARENT/CONSUMER EDUCATION FOR NEWLY DIAGNOSED NEWBORNS

Education

Counseling

6. OUTCOME MEASURES FOR EVALUATING LONG-TERM FOLLOW-UP

Medical management

Long-term outcome



# LABORATORY WORKING GROUP

## Project Co-Manager:

Carol Southard

New Jersey – NBS Laboratory Director

## Members:

Lisa Bates

Florida – NBS Laboratory Director

Roger Eaton

Massachusetts – Regional NBS Laboratory Director

Cheryl Hermerath

Oregon – Regional NBS Laboratory Director

Gary Hoffman

Wisconsin – NBS Laboratory Director

Eldridge Hutcheson

Texas – Laboratory Operations Manager

Mark McCann

Minnesota – NBS Laboratory Director

John Sherwin

California – NBS Laboratory Director

## Oversight:

Brad Therrell

NNSGRC

Marie Mann

HRSA

Harry Hannon

CDC

## Ex Officio:

Dona Williams

NNSGRC – Texas NBS Laboratory QA



# NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

## LABORATORY: PRE-ANALYTICAL

At Birthing Facility

### 1. HEELSTICK BLOOD COLLECTION

- Specimen collection (heelstick procedure)
- Specimen preparation (drying)
- Specimen information review (accuracy)
- Record keeping

### 2. SPECIMEN TRANSPORT

- Transport process
- Data tracking



# NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

## LABORATORY: PRE-ANALYTICAL

### At Screening Laboratory

#### 1. EMPLOYEE TRAINING

- Employee competency
- Employee training

#### 2. EMPLOYEE SAFETY

- Laboratory safety training
- Laboratory safety manual
- Bloodborne pathogens exposure control
- Chemical hygiene plan

#### 3. SPECIMENS

- Collection card quality (during and after printing)
- Specimen verification (following transport)



# NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

## LABORATORY: PRE-ANALYTICAL

At Screening Laboratory

### 4. ACCEPTABILITY OF DRIED BLOOD SPECIMENS

Dried blood specimen acceptability review  
Submitter notification

### 5. TRANSPORT PROCESS

Specimen transport/transmittal  
Specimen check-in

### 6. SPECIMEN QUALITY (INCLUDING ACCOMPANYING INFORMATION)

Patient data/demographic information review  
Patient data/demographic test interpretation information review  
Demographic data entry  
Patient confidentiality  
Pre-analytical quality assessment



# NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

## LABORATORY: ANALYTICAL

### 1. ANALYTICAL PROCESSES

Procedure manuals

Quality assurance for the screening process

Kit validation (unmodified FDA-cleared or approved)

Method validation (unmodified FDA-cleared or approved)

Method validation (modified FDA-cleared or approved, in-house methods)

Reagent validation (purchased or in-house)

Proficiency testing

Quality control procedures

Control validation (purchased, kit or in-house)

Calibrators/standards validation (purchased, kit or in-house)

Analytical quality assessment





# NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

## LABORATORY: ANALYTICAL

### 2. LABORATORY INSTRUMENTATION

Instrument calibration and validation (function check)  
Instrument operation  
Maintenance of all laboratory instrumentation

### 3. SUPPLIES/REAGENTS

Quantity and quality of consumables (inventory)  
Supplies/reagents storage

### 4. LABORATORY ENVIRONMENTAL CONDITIONS

Laboratory environment

### 5. LABORATORY INFORMATION SYSTEM (LIS)

Laboratory computer system



# NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

## LABORATORY: POST-ANALYTICAL

### 1. SCREENING TEST RESULTS

Assay acceptability

Specimen testing and result reporting

Accuracy validation of computer data

Accuracy validation of test result reporting

Report correction(s)

### 2. ARCHIVAL RECORD KEEPING

Records management

Residual dried blood spots - storage, access and use

Continued



# NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

## LABORATORY: POST-ANALYTICAL

### 3. CLINICAL FEEDBACK

Differences between screening and clinical testing results  
Critical test results - reporting and tracking  
Diagnostic confirmation

### 4. CONTINGENCY PLANNING

Laboratory contingency plan



# NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

## Other Ongoing Activities:

- Compendium of PEAS Resources
- Review of electronic media interactive strategies – CD and Internet

