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

Wrong Attitude!
<table>
<thead>
<tr>
<th>Committee Members</th>
<th>Association of Public Health Laboratories</th>
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<tbody>
<tr>
<td>William Becker</td>
<td>American Academy of Pediatrics</td>
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<td>E. Stephen Edwards</td>
<td>National Initiative for Children’s Healthcare Quality</td>
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<td>Charlie Homer</td>
<td>University of Michigan (Evaluation Specialist)</td>
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<td>Alex Kemper</td>
<td>CARES Foundation, Inc. – Lay Advocate</td>
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<td>Kelly R. Leight</td>
<td>(CAH Research, Education, and Support)</td>
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<td>Trish Mullaley</td>
<td>Genetic Alliance – Lay Advocate</td>
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<td>(PKU and Allied Disorders)</td>
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<td>Patricia McLaughlin</td>
<td>Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN)</td>
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<td>David Ross</td>
<td>Public Health Informatics Institute</td>
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<td>Nancy Wade</td>
<td>Association of Maternal and Child Health Programs</td>
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<th>Project Overall Direction (POD)</th>
<th>NNSGRC</th>
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<tr>
<td>Brad Therrell</td>
<td>HRSA</td>
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<td>Michele Puryear</td>
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<td>Marie Mann</td>
<td>CDC</td>
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<td>Harry Hannon</td>
<td>Follow-up/Education Working Group</td>
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<td>Marion Schwartz</td>
<td>Laboratory Working Group</td>
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<td>Carol Southard</td>
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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

New Jersey – Follow-up Coordinator

Members:
Sharon Anderson New Jersey – Practicing Nurse
Louis Bartoshesky Delaware – Physician Consultant
Penny Hatcher Minnesota – Follow-up Supervisor (DBS/NHS)
Pam King Oklahoma – Follow-up Supervisor
Marcia Lavochkin New Hampshire – Follow-up Coordinator
Fred Lorey California – Development/Evaluation Director
Julie Miller Nebraska – Program Manager
Charles Myers Louisiana – Program Manager
Ellie Mulcahy Maine – Program Manager
Sheila Neier Washington – Follow-up Supervisor

Observers:
Irene Forsman HRSA – Newborn Hearing Screening
John Eichwald CDC – Newborn Hearing Screening

Oversight
Brad Therrell Texas – NNSGRC – Laboratory Operations
Marie Mann HRSA – Contract Officer
SLEEP IN HEAVENLY PEAS
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 TIMLINESS 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)

Continued
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 confidentially
   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

Continued
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
Other Ongoing Activities:

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