Newborn Screening Quality Improvement: State Initiatives to Improve Newborn Screening Processes

Association of State and Territorial Health Officials
January 28, 2015
NBS Quality Improvement Speakers

- **Health Resources and Services Administration:**
  - Michael Lu, MD, MS, MPH, Associate Administrator Maternal and Child Health

- **Association of State and Territorial Health Officials:**
  - Paul Jarris, MD, MBA, Executive Director

- **Arizona Department of Health Services:**
  - Will Humble, MPH, State Health Director
  - Celia Nabor, MPA, Office of Vital Records Chief and Office of Newborn Screening Project Manager

- **Wisconsin Department of Health Services:**
  - Karen McKeown, RN, MSN, State Health Officer and Administrator of Public Health

- **Association of Public Health Labs (APHL):**
  - Yvonne Kellar-Guenther, PhD, NewSTEPs Evaluator, Colorado School of Public Health
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Associate Administrator of Maternal and Child Health Resources and Services Administration (HRSA)
Paul Jarris, MD, MBA
Executive Director
Association of State and Territorial Health Officials
Newborn Screening Quality Improvement

Paul Jarris, MD, MBA
Executive Director
Association of State and Territorial Health Officials
January 28, 2015
Newborn Screening Timeliness

  - 160,000 blood samples sent late or via inappropriate mail delivery.

Recommendations:
- Standardize the number of conditions tested
- Transparency in hospital transit times
- Labs open on weekends, three-day holidays
- Track how quickly hospitals send samples
- Samples sent quickly and by overnight delivery or courier services
Systems Thinking in NBS

Hospital of Birth → NBS Sample Transit → Public Health Lab

Family → State MCH/NBS Program → Medical Home
Components of NBS System

- Screening: Sample collection and submission, Laboratory testing
- Follow-up: Obtain test results, results to family, repeat tests if needed, ensure diagnostic testing
- Diagnosis: Subspecialist assessment, results shared with family, counseling
- Management: Treatment, long-term follow-up, specimen storage
- Evaluation: Quality assurance, outcomes evaluation, cost effectiveness
- Education across all steps
Embracing Quality Improvement

Ellen Gabler accepts the ASTHO Presidential Meritorious Award from then ASTHO President Terry Cline (OK) at the 2014 ASTHO Annual Meeting.
ASTHO Resources

- Newborn Screening: http://www.astho.org/Programs/Maternal-and-Child-Health/Newborn-Screening/


- President’s Challenge on Healthy Babies Clearinghouse of Best and Promising Practices: http://www.astho.org/healthybabies/
Will Humble, MPH

Director
Arizona Department of Health Services (ADHS)
Celia Nabor, MPA

Chief, Office of Vital Records
Project Manager, Office of Newborn Screening Transit Time Project
Arizona Department of Health Services (ADHS)
A Glance at Arizona’s Newborn Screening Transit Time & Future Initiatives

Will Humble, MPH, Director
Celia Nabor, MPA
Agenda

• Background on the AZ Transit Time Project
• Lessons Learned
• Cost
• Accomplishments
• Future Initiatives in Arizona
Quick AZ Facts

- 6th largest land/water
- 6.5 million population
- 15 Counties
- 48 birth hospitals
  - 43 send samples to lab
- 86,000 births
- One state laboratory
- 103 confirmed bloodspot cases in 2013
"Arizona has one of the worst track records in the country, with 17% of all newborn screening samples arriving at the state lab five or more days after collection in 2012."
☑ Director set as agency priority
☑ Announced a statewide goal
☑ Collaborated with Licensing Division
☑ Developed an interagency Transit Time taskforce
☑ Assigned executive sponsorship
AIM High

“Within six months (by July 1, 2014), 95% of newborn screening bloodspots (initial screens) will be received at the Arizona Public Health Laboratory within three days of collection.” Will Humble

Be SMART
2013 Baseline Transit Time Data

- 67% ≤ 3 days
- 20% 4 days
- 9% 5 days
- 4% > 5 days
Partnered with

- Arizona Perinatal Trust (APT)
- Arizona Hospital and Healthcare Association (AzHHA),
- March of Dimes (MoD)

Released baseline data to hospital

- CEOs, Director of Nursing, & Director of Laboratory
Identifying the Problem

1. Hospitals *Batched* Samples
2. Lack of *Awareness* of urgency
3. *Courier Limitations*—only ran Mon-Fri, some didn’t realize it was free
4. *Restricted Lab Operating Hours* (Mon-Fri), No holidays
5. *Lack of Knowledge* about legal requirements
6. *High Turnover*; Inconsistent/deficient training at sites
7. Hospital *QA/QI* systems were often inadequate
8. *Performance reports* were not routinely provided
Identified Potential Limitation to Meeting “THE GOAL”

- Current level of courier service wasn’t adequate
- Communication was sporadic, undependable
- Limitations on capacity, delivery timeframes, expansion potential
- Disparities for rural sites with limited pickups
- Cost to add Saturday
Conducted Hospital Survey

Determine current practice / perceptions

• How could we **Help**? On-site or webinar training?
• Could they do it on their own? Gap Analysis
  – Self-assessment tool
• Were the current resources being utilized?
• Did they have capacity to expand to Saturday?
• Were there barriers?
Synergy and Executing the Plan

Webinars
Hospital site visits
Transparency website

Who’s the audience?
What information will be highlighted?
Appeal to audience
Data integrity
Provide Positive Reinforcement

- Recognize top performers
- Feature hospitals that demonstrate improvement
- Share best practices

Make it Achievable

Took on administrative tasks from hospitals to minimize burdens
Information Portal

Transit Time Project webpage goes live
FAQ/Resources
Media
Competition Drives Improvement

Arizona Perinatal Trust levels

Peer-to-Peer Comparison

Recognized top performers on webpage
Document Observations

Level II Average Transit Time

- MARYVALE HOSPITAL
- MOUNTAIN VISTA MED CTR
- SIERRA VISTA REGIONAL MEDICAL CENTER
- BANNER BAYWOOD
- BANNER GATEWAY MED CTR
- YAVAPAI REGIONAL
- SCOTTSDALE HEALTHCARE OSBORN
- WEST VALLEY HOSPITAL
- SUMMIT HEALTH (NAVAPACHE)
- MERCY GILBERT MEDICAL CTR
- BANNER DEL E. WEBB
- BANNER IRONWOOD
- PHOENIX BAPTIST
- PARADISE VALLEY

Mean Days

http://www.azdhs.gov/lab/aznewborn, August 2014

Level II Initial screens received within 3 days

- MARYVALE HOSPITAL
- MOUNTAIN VISTA MED CTR
- SIERRA VISTA REGIONAL MEDICAL CENTER
- BANNER BAYWOOD
- BANNER GATEWAY MED CTR
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- BANNER IRONWOOD
- PHOENIX BAPTIST
- PARADISE VALLEY

% Received within 3 days

http://www.azdhs.gov/lab/aznewborn, August 2014

Health and Wellness for all Arizonans
Baby Steps Towards Success

**BANNER CASA GRANDE**

- **Mean Days**
  - Baseline: 5.00
  - January: 3.00
  - February: 3.00
  - March: 3.00
  - April: 2.00
  - May: 1.00
- **% reached within 3 steps**
  - Baseline: 10%
  - January: 50%
  - February: 60%
  - March: 70%
  - April: 80%
  - May: 90%
  - June: 100%
  - July: 100%
  - August: 100%

*Health and Wellness for all Arizonans*
Supportive Services

- Opportunity for non-traditional provider
- Transition to Local courier-EZ Messenger
- Monday-Saturday pick up and delivery
- Same day/next business day delivery
- Receiving open six days a week
Effectiveness & Projections

- Using the data to drive next steps
- Monitor information that doesn’t make sense
- Dig deeper into data that appears unusual
Ongoing Follow-up

• Providing monthly, reader friendly detailed reports
• QA initiative/bloodspot card review
• Communication about impacts to services/holidays
• Evaluate impact of holidays on data—plan for it
Partnerships at their BEST

In five months 99% of newborn screening bloodspots specimens (initial screens) collected at birth hospitals were received at the Arizona State Laboratory within three days of collection.
Lessons Learned

• Hospital features difficult to obtain
• Lab impacted by multiple daily deliveries
• Working with sites to identify a consistent pick up spot
• Acknowledge Disparities and work to eliminate
More Lessons

• Keep it exciting for hospitals – annual recognition
• Maintain as a priority internally
• Involve Business/Finance office early & often
• Know who your champions are!
Considerations

- **COST**
- Cost sharing
- Staff time
- Courier contract, including supplies
- Using locally based courier has advantages
- Look for partners invested in the same work
- Keep workgroup small
- Implement communication plan w/ approvals. Include PIO
- Schedule meetings for entire project period
- Consider changes that may impact data
Accomplishments

• In five months, 99% of 1st specimens collected at birth hospitals were received at the Lab within one day of collection
• Transit time webpage serves as model for statewide transparency and accountability
• Implemented six day per week pickup with 70% of samples being delivered same day.
• ADHS receiving the first ever Quality Improvement Newborn Screening Award from the March of Dimes
Spread Results

- Lab Matters article
- APHL poster and presentation
- Regional collaborative webinars
- ASTHO article
- Invited to CoIIN Training

March Of Dimes Honors Arizona With First-Ever Newborn Screening Award

Arizona Health Director Honored for Reforms to Avoid Deadly Delays

CHANDLER, ARIZONA — Thursday, September 18, 2014
New cut-offs for 14 metabolic disorders screened by mass spectrometry

• In 2014, the AZ Newborn Screening office established a novel way for calculating cut-offs

• The algorithm used to calculate the cut-offs takes into account the abnormal values from tens of thousands of babies affected with metabolic disorders around the world
• The improved cut-offs allow us to decrease the number of false positives while at the same time decreasing our risk from missing any baby with metabolic disorders

• The results were presented at the 2014 Newborn screening and Genetic Testing Symposium last October

• This novel method might create a paradigm shift on how other states calculate their cut-offs for screening of metabolic disorders
Status of Adding Disorders

• Krabbe-Arizona NBS Advisory Committee did not recommend adding to the screening panel
• CCHD & SCID-AZ Newborn Screening seeking an exemption from the rule moratorium
• Currently conducting the cost/benefit analysis for adding SCID
Continued Transparency

- **New STEPSs Quality Indicator #5 (c)Timeliness of Newborn Screening Activities**

  - Arizona NBS & SSDI will be taking a closer look at specimen receipt to reporting out of complete results
  - Preliminary goal is to develop a baseline report for the following categories by April 2015;
    
    *less that 12 hours, 12-24 hours, greater than 24-48 hours, greater than 48-72 hours, and greater than 72 hours.*
The Science of Improvement: Spread Change

“You get what you inspect, not what you expect.”

American Management Association
Thank you

www.aznewborn.com
Karen McKeown, RN, MSN
State Health Officer and Administrator
Division of Public Health
Wisconsin Department of Health Services
Newborn Screening in Wisconsin: Improving the Process

Karen McKeown
State Health Officer and Administrator,
Division of Public Health
Department of Health Services
January 28, 2015
Structure

- Newborn Screening Program (NBS) in Wisconsin
  - Department of Health Services (DHS)
  - Wisconsin State Lab of Hygiene (WSLH)

- Advisory Committee Structure
  - Specialty subcommittees
    - Endocrine, hemoglobinopathy, metabolic, molecular cystic fibrosis, immunodeficiency, hearing, education
  - Umbrella Committee
    - Chaired by Chief Medical Officer of Maternal Child Health, DHS
    - Meets twice a year
    - Reviews subcommittee reports, discusses general issues, makes operations and other recommendations
  - Secretary’s Advisory Committee
    - Meets ad hoc
    - Makes final recommendations to the Secretary regarding addition and deletion of disorders, etc.
Umbrella Committee Membership

- Chairs of subcommittees
- Department of Health Services
- Wisconsin State Lab of Hygiene
- Wisconsin Hospital Association
- Advocacy Organization (March of Dimes)
- Wisconsin Chapter American Academy of Pediatrics Representative (AAP)
- American Congress of Obstetricians and Gynecologists (ACOG)
- Ethics Representative
- Local Health Department Representative
- Registered Dietitian Representative
- Certified Genetic Counselor Representative
- Consumer/Parent Representative
- Registered Nurse Representative
- Certified Genetic Counselor Representative
Summer of 2013

Program began self-assessment using the NewSTEPs indicators

**Quality Indicator 1**: Percent of invalid dried blood spot specimens/cards due to improper collection and/or transport.

**Quality Indicator 2**: Percent of dried blood spot specimens/cards missing essential information.

**Quality Indicator 3**: Percent of eligible infants not receiving valid NBS test, reported by dried blood spot or point of care test(s).

**Quality Indicator 4**: Percent of loss to follow-up.

**Quality Indicator 5**: Timeliness of Newborn Screening Activities.

**Quality Indicator 6**: Percent of out of range results.

**Quality Indicator 7**: Frequency of condition detected by NBS for each disorder.

**Quality Indicator 8**: Percent of missed cases (false negatives), reported by disorder.

https://newsteps.org/quality-practice-resources/quality-indicators
Fall of 2013

- Milwaukee Journal Sentinel series brought attention to specimen transit time
- Wisconsin State Lab of Hygiene and the Wisconsin Hospital Association partnered:
  - Monthly report cards sent to hospitals
    - Specimen drawn between 24 and 48 hours
    - Key information missing from the blood card
    - Unsatisfactory specimens
    - Transit time
  - Technical assistance for hospitals
  - Additional courier options provided
  - Providers notified when sample received
  - Follow-up on > 4-day transit times
Transit Time 2013 and 2014
(time from specimen collection to receipt at WSLH)
Spring, 2014

- Broad approach to quality
- Contracted with Project manager/Lean specialist to
  - Lead an internal workgroup
  - Lead a discussion with the umbrella committee
  - Lead a Lean/Quality improvement project
Internal workgroup

- Consisted of DHS and WSLH staff
- Mapped out current processes and potential metrics
- Discussed areas for priority focus
- Defined a successful program

The NBS Program will be successful when all affected babies are identified and treated in time to prevent adverse outcomes.
NBS – System-wide Views

What do we do? How do we do it?

[Diagram showing the process and roles involved in Newborn Screening, including各个环节 such as sample collection, testing, and follow-up.]
Specimen Collection

- Healthcare Professional enters NBS card information
- Healthcare Professional performs NBS hearing test & Pulse OX and adds to specimen card
- Healthcare Professional draws blood & adds to specimen card
- Healthcare Professional adds date/time of blood draw to card
- Healthcare Professional ensures card is ready for transmission to State Lab
Spring, 2014

- **Umbrella Committee**
  - Committee charge revised to highlight critical role in quality assurance
  - All members invited to a special meeting with a focus on quality
    - Members reviewed the process maps
    - Discussed potential weak spots
    - Identified highest risk areas for priority focus
Results

*Knowledge:* The integrity of NBS depends on the entire continuum of components outlined by the process map, and can be monitored by quality indicators developed by NewSTEPs.

*Action Items:* (1) Reducing unsatisfactory specimen submissions  
(2) Reconciling every birth to the NBS process
Unsatisfactory Specimens 2013 and 2014
Fall 2014
Lean Project: Reducing unsatisfactory specimen submission

- Review of WSLH process for inspecting cards
- Identification of issues
- Prioritization of issues
  - Issue has a big impact and occurs frequently
    - Lack of a consistent site-specific process
    - Lack of instructional materials
    - Lack of training
    - No visual inspection before shipping specimens
    - Using capillary tubes
    - Blood Clotting within circles on the specimen card
- Development of solutions

By courtesy of Paula Sherman and Patrice Held
Reconciling birth to NBS process

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<th>SEX</th>
<th>Baby's Birthdate</th>
<th>Time (Military)</th>
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<th>Baby's Physician</th>
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<th>Mother's Name</th>
<th>Physician's NPI (10 digits)</th>
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<th>Baby's Race</th>
<th>Native American</th>
<th>Hispanic?</th>
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<td>wks</td>
<td>Black</td>
<td>Asian/Pacific</td>
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<td>Isle</td>
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<th>Baby in NICU?</th>
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<th>Transfusion(s)?</th>
<th>Last Txn Date:</th>
<th>Baby on TPN now?</th>
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<th>Birth Facility</th>
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<td>C.D. Bedoopp, Director</td>
<td>WSD 23113 HVO-213</td>
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<td>D. Kurthz, Med Director</td>
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<th>Right Ear</th>
<th>Pass</th>
<th>Refer</th>
<th>Left Ear</th>
<th>Pass</th>
<th>Refer</th>
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<th>Not Screened (mark reason)</th>
<th>Refused</th>
<th>Transferred</th>
<th>Deceased</th>
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<td>Echo normal</td>
<td>Confirmed heart disease</td>
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<th>Blood Not Screened (mark reason)</th>
<th>Refused</th>
<th>Transferred</th>
<th>Deceased</th>
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This box for Newborn Screening Laboratory use only

Wisconsin Department of Health Services
Conclusions

- Collaboration by each discipline across the NBS process has allowed identification of QI needs and priorities for the program.
- The shared and collaborative approach now forms a quality assurance system that allows us to identify needed improvements and relevant partnerships, and to monitor ongoing QI efforts.
- Next step: A NewSTEPs site visit?
Acknowledgements

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- Susan Uttech, MS
- Linda Hale, RN BSN EMT

Wisconsin State Laboratory of Hygiene

- Mei Baker, PhD
- Patrice Held, PhD

Umbrella Committee of the Newborn Screening Program
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Newborn Screening and Technical assistance and Evaluation Program (NewSTEPs) Evaluator
NewSTEPs

Yvonne Kellar-Guenther, PHD
NewSTEPs Evaluator

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APHL is collaborating with the Colorado School of Public Health to implement NewSTEPs.
Vision
Dynamic newborn screening systems have access to and utilize accurate, relevant information to achieve and maintain excellence through continuous quality improvement.

Mission
To achieve the highest quality for newborn screening systems by providing relevant, accurate tools and resources and to facilitate collaboration between state programs and other newborn screening partners.

The Newborn Screening Technical assistance and Evaluation Program
Providing:
- quality improvement initiatives for newborn screening systems
- innovative data repository
- technical and educational resources for state newborn screening programs

www.newsteps.org   newsteps@aphl.org
State Site Review Visits

- Iterative Process
- Pre-Evaluation Forms
- Customized Evaluation Team
- Comprehensive Report Post Visit
- Recommendations
Voluntary Data Repository

NewSTEPs Data Repository

The innovative Data Repository® will serve as a central link for access to newborn screening information, data, and resources across the country.

**Purpose:** Provide tools to state newborn screening systems to adequately evaluate, analyze, and benchmark the performance of their tests and the quality of their newborn screening programs.
Components of Data Repository

- Cases
- State Profiles
- Quality Indicators

Data Repository
NewSTEPs Collaborative Improvement and Innovation Network (CoIIN) for Timeliness in Newborn Screening

• Quality Indicator 5 is on timeliness

• 7 States applied to be part and work on improving their timeliness
  – Focus is on time between birth and report out of abnormal results
  – (Quality Indicator 5 – a, b, and c)
CollIN Approach

• Root Cause Analysis
• Continuous Quality Improvement
  – Goals, SMART aims
  – Tools to track progress
• Open sharing of ideas and resources
• Address educational needs of states
• Create collaborative environment
• Teach participants how to build sustainable interagency collaborations
Issues Tackled by CoIIN

• How to work with hospitals
  – Get buy-in
  – Provide meaningful feedback

• Overcome geography issues
  – Large states
  – Private courier vs public

• Changes needed in lab to meet timeliness goals
Where are we now?

• Had 2 meetings
  – Initial phone meeting
  – 2-day face-to-face meeting

• Will meet monthly for next 14 months
Some Lessons Learned Thus Far

• Some hospitals see the blood spot cards as mail and not as specimens
• Information on NBS is not always making it down to those who are conducting the NBS
• Some labs just receive samples on Saturday, they do not run them
• We all liked to be congratulated on doing our jobs (even the couriers)
NewSTEPs Resources
Goals of NewSTEPs

1. Strengthen the newborn screening system through enhancement of the existing network of stakeholders by creating a culture of trust, by providing opportunities for timely, interactive communications, and by offering a forum for collaboration among national, regional, and state NBS programs.

2. Facilitate continuous quality improvement and data-driven outcome assessments in the NBS system by providing a standardized repository and by supporting the integration of health information technology frameworks, including HL7 messaging.

3. Create a dynamic national newborn screening technical assistance resource center that proactively provides training, addresses challenges, and supports program improvement through partnerships with key stakeholders throughout the NBS community.
Select a state or click here to view aggregate reports.
Interactive Reports and Queries

Select a state or click here to view aggregate reports.
## Screened Conditions Report

### Other Disorders

<table>
<thead>
<tr>
<th>Condition</th>
<th>Universally Required</th>
<th>Universally Offered</th>
<th>Offered Select</th>
<th>Considered</th>
<th>Req Not Implemented</th>
<th>Likely Detected</th>
<th>Pilot Tested</th>
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<tbody>
<tr>
<td>Biotinidase deficiency - BIOT</td>
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<tr>
<td>Critical congenital heart disease - CCHD</td>
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<td>Cystic fibrosis - CF</td>
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<td>Hearing loss - HEAR</td>
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<td>9</td>
<td>4</td>
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<td>Severe Combined Immunodeficiencies - SCID</td>
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<td>6</td>
<td>4</td>
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All data portrayed in this sample report are fictitious. Data do not represent actual outcomes from any newborn screening program. Any resemblance to real data from a real newborn screening program is completely coincidental.
Contact Us

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Materials from the webinar and other newborn screening resources can be found at: http://www.astho.org/Programs/Maternal-and-Child-Health/Newborn-Screening/