Session 11 – No Time to Lose: Re-assessing Timeliness

Thursday, Oct. 30 – 10:30am-12:00pm

Moderators – Carla Cuthbert, PhD, Centers for Disease Control and Prevention and Patrice Held, PhD, Wisconsin State Laboratory of Hygiene

Timeliness of Newborn Screening – Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (DACHDNC) Guidance to Newborn Screening Systems

S. Tanksley, K. Kelm, S. Berberich, M. Baker, M. Caggana, G. Dizikes, D. Matern, W. Slimak, G. Piñeyro, C. Singh, C. Yusuf, J. Ojodu; Texas Department of State Health Services, Austin, TX, Food and Drug Administration, Silver Spring, MD, State Hygienic Laboratory, University of Iowa, Iowa City, IA, Wisconsin State Laboratory of Hygiene, University of Wisconsin-Madison, Madison, WI, New York State Department of Health, Wadsworth Center, Albany, NY, Illinois Department of Public Health, Chicago, IL, Mayo Clinic, Rochester, MN, PerkinElmer Genetics, Bridgeville, PA, Association of Public Health Laboratories, Silver Spring, MD

Abstract

Objective: To report on best practices to alleviate gaps and identify barriers to timely newborn screening (NBS) and assess whether current goals for timely sample collection, transit and testing are appropriate for the current NBS system.

Background: In order to effectively reduce mortality and morbidity, NBS must occur in a timely manner. Based on a public comment during the September 2013 meeting of the DACHDNC that raised the issue of timely NBS, the DACHDNC decided to review current policies and practices relating to timeliness of NBS in the United States. After an initial report in January 2014 based on survey data, discussions and review of pertinent literature, the DACHDNC recommended the following timeframes related to NBS:

- Initial NBS specimens should be collected at 24 to 48 hours of life.
- NBS specimens should be received at the Laboratory within 24 hours of collection.
- Newborn screen results for time-critical conditions should be available within 5 days of life.
- All NBS results should be available within 5 days of collection.

The Laboratory Standards and Procedures Subcommittee was tasked to (1) outline the NBS system, (2) investigate existing gaps and barriers in NBS systems, (3) identify best practices to achieving these goals, (4) develop a list of critical conditions that require urgent follow-up, (5) review the recommendations in light of new technologies and (6) suggest revisions, if needed.

Methodology: The Association of Public Health Laboratories (APHL) surveyed states to obtain information on performance measures related to timeliness, current NBS program practices and barriers to improvement of NBS timeliness. Information was also gathered from NBS system stakeholders throughout the United States. Stakeholder input and results from the APHL survey will be compiled into a report for the DACHDNC.

Results: The Laboratory Standards and Procedures Subcommittee will present a draft report to the DACHDNC in September 2014. The report and any revised recommendations will be provided in this presentation.

Conclusions: Timely NBS may be achieved through efforts to eliminate the gaps and delays throughout the NBS system (from the collection of quality specimens in the proper timeframe to the time the screening results are provided to the baby’s healthcare provider) and through sharing best practices.

Presenter: Susan Tanksley, PhD, Texas Department of State Health Services, Laboratory Services Section, Austin, TX, Phone: 512.776.3106, Email: susan.tanksley@dshs.state.tx.us

Summary

Objective: To report on the revised recommendations for timely newborn screening, identified gaps and barriers in the newborn screening (NBS) system, and best practices for improving timeliness.

Background: In order to effectively reduce mortality and morbidity, NBS must occur in a timely manner. Based on a public comment during the September 2013 meeting of the DACHDNC that raised the issue of timely NBS, the DACHDNC decided to review current policies and practices relating to timeliness of NBS in the United States. Awareness of timeliness issues in NBS was heightened after media reports in November 2013. In January 2014, based on survey data, discussions and review of pertinent literature, the DACHDNC recommended the following timeframes related to NBS:

• Initial NBS specimens should be collected at 24 to 48 hours of life.
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Methodology: The Association of Public Health Laboratories (APHL) surveyed states to obtain information on performance measures related to timeliness, current NBS program practices and barriers to improvement of NBS timeliness. Information was also gathered from NBS system stakeholders throughout the United States via in-person meetings and conference calls.

Results: Newborn screening programs in all 50 states and one US territory responded to the survey. Information from the survey was compiled into a report “Newborn Screening Timeliness – Survey Report.” The Laboratory Standards and Procedures Subcommittee presented a draft report to the DACHDNC in September 2014 based on information gathered from the states and other work performed by the Timeliness Workgroup. In light of existing gaps and barriers in the system, the recommendations were revised with a focus on the outcomes of the baby. The revised recommendations are:

In order to achieve the best outcomes for babies:

1. Presumptive positive results for time-critical conditions should be immediately reported to the child’s healthcare provider but no later than the 5th day of life.

2. All presumptive positive results for time sensitive conditions should be reported to the healthcare provider within 7 days of life.
3. All NBS results should be reported within 7 days of life.

In order to achieve these goals (and reduce delays in newborn screening):
1. Initial NBS specimens should be collected in the appropriate time frame for the baby’s condition but no later than 48 hours after birth.
2. NBS specimens should be received at the laboratory within 24 hours of collection.

Gaps and barriers in newborn screening systems that impact the ability to meet these revised goals include:
- Lack of awareness of the urgency of NBS
- Lack of training/High turnover of staff performing NBS specimen collection
- Batching by birthing facilities
- Geographic distance from birthing facility to NBS laboratory
- Lack of availability of courier/overnight delivery services
- Inadequate operating hours of the courier
- Inadequate operating hours of the NBS program (laboratory and short-term follow-up)
- Lengthy testing algorithms to avoid high false positive rate
- Lack of ability to collect complete data
- Inefficiencies in the system. Examples include:
  - Specimens collected in the proper timeframe may not be dry or available for pick up when the courier arrives.
  - Laboratory results may be ready before demographic information is available in the laboratory information management system.

Best practices to eliminate gaps and alleviate barriers in newborn screening systems include:
- Providing educational activities to birthing facility staff, laboratory staff and parents
- Utilizing courier or overnight delivery services
- Expansion of NBS program operating hours (laboratory & short-term follow-up)
- Improving reporting and communications mechanisms such as utilizing electronic laboratory orders and electronic laboratory reporting between electronic medical records and laboratory information management systems
- Focusing on continuous quality improvement activities. Examples include:
  - Reducing batching by birthing facilities/submitters
  - Decreasing time from receipt in the laboratory to reporting
  - Improving data collection procedures and mechanisms to allow for system evaluation
  - Monitoring performance and providing feedback throughout the system
  - Considering policy, rules, or legislative changes when needed

Stakeholder input and results from the APHL survey will be compiled into a report for the DACHDNC, and revised recommendations will be voted on at the February 2015 S/DACHDNC Meeting.

**Conclusions:** The recommendations for timeliness should be viewed as GOALS for NBS systems to achieve the best outcomes for affected babies. Timely NBS may be achieved through efforts to eliminate the gaps and delays throughout the NBS system and through sharing best practices. However, all parts of the newborn screening system must buy-in to the need for timeliness and work together for
system wide improvement, and there must be funding for these improvement initiatives. Finally, it is critical that as we work to improve timeliness, we achieve a balance and not negatively impact the NBS system by introducing additional false positives or false negatives.

**On Time/Every Time: A Partnership of Safety and Reliability for Newborn Screening**
K. Tomashitis, South Carolina Department of Health and Environmental Control, Columbia SC

**Abstract**

In response to the Milwaukee Journal Sentinel series on newborn screening, a Rapid Improvement Cycle (RIC) partnership between the South Carolina Hospital Association (SCHA) and the South Carolina Department of Health and Environmental Control (DHEC) was implemented in February 2014. The following goal was set: All SC birthing hospitals will submit 100% of their newborn screening specimens within 24 hours of collection. Elements of the RIC include the following:

- Kickoff – February 10, 2014 with a press release describing the partnership
- 2 Webinars – March 5, 2014 (to introduce the partnership and provide an update on correct newborn screening procedures) and May 1, 2014 (to update hospitals on progress to date and newly implemented procedures)
- Office Hours – March 25, 2014 (opportunity for hospitals to call SCHA and DHEC)
- Monthly data reports February 2014 through February 2015
- Quarterly data reports beginning April 2015
- June 9 – End of Collaborative
- July—Event to celebrate success

At the beginning of the collaborative, 46.73% of specimens were postmarked within 24 hours of collection. After just one month, that percentage had increased to 64.78%. In addition, time to reporting of all test results to providers has improved. Other changes include:

- Phased in Saturday/holiday testing and follow-up services
- 24/7 availability for courier drop off and improved informational signage at lab for couriers
- NBS dedicated email that is monitored 6 days/week by follow-up staff
- Establishment of multidisciplinary networks in all birthing hospitals to support NBS (ie, Lab Directors, Nursery Directors, Quality/Safety Directors)
- Encouraging use of previously developed QA/Training program for all birthing hospitals

**Presenter:** Kathy Tomashitis, MNS, South Carolina Department of Health and Environmental Control, Division of Children's Health, Columbia SC, Phone: 803.898.0619, Email: tomaskkf@dhec.sc.gov

**Summary**

**Background:** The Milwaukee Journal Sentinel (MJS) series on newborn screening put a spotlight on processes that could lead to delayed identification of infants with a condition on state test panels. Initially, health department legal and management staff in SC determined that the data requested by
the MJS was not able to be released per the state law related to newborn screening. Once the series of articles was published in November 2013, newborn screening program staff notified legal and management staff of a revised data request from the MJS. This new request was determined to be releasable, and hospital level data was sent to the MJS in mid-January 2014. Some highlights of the 2013 data are listed below:

- 33.75% of specimens took 5 days or longer for receipt at the state laboratory (range: 21% to 70.59%)
- Distance from hospital to state laboratory was not the issue
  - Hospital with best % - 126 miles from laboratory
  - Hospital with worst % - 117 miles from laboratory
  - Hospital closest to lab (6 miles) - 24.41% of specimens took 5 days or longer

SC was the focus of a follow-up article in the MJS on January 28, 2014 titled “South Carolina among worst in nation on newborn tests.”

In response to the series on newborn screening, a Rapid Improvement Cycle partnership between the South Carolina Hospital Association and the Department of Health and Environmental Control was implemented in February 2014. The following goal was set: All SC birthing hospitals will submit 100% of their newborn screening specimens within 24 hours of collection. Elements of the RIC include the following:

- Kickoff – February 10, 2014 with a press release describing the partnership
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The 24 hour mailing requirement had always been a part of the newborn screening regulation, but there had been no way to monitor it using the current LIMS. A new supplemental data system was implemented to allow documentation of “postmark” data for each initial specimen. At the beginning of the collaborative, 55.68% of specimens were postmarked within 24 hours of collection. After just one month, that percentage had increased to 72.36%. In addition, time to reporting of all test results to providers has improved. The decision was made by management staff to exclude any specimens collected on Saturdays because there was no consistent mail service (USPS, commercial carriers) that would routinely pick up and deliver specimens on Sundays.

Other changes necessary to support the collaborative included:

- Phased in Saturday/holiday testing and follow-up services
- 24/7 availability for courier drop off and improved informational signage at lab for couriers
- NBS dedicated email that is monitored 6 days/week by follow-up staff
- Establishment of multidisciplinary networks in all birthing hospitals to support NBS (ie, Lab Directors, Nursery Directors, Quality/Safety Directors)
- Encouraging use of previously developed QA/Training program for all birthing hospital

To implement these changes, newborn screening staff accomplished the following major program changes within 30 days of the data release:

- Modified urgent abnormal test reporting protocol for Saturdays/holidays in coordination with appropriate specialty care providers
- Revised and distributed the Official Departmental Instructions that serve as the legal underpinning for hospital and medical provider responsibilities related to newborn screening
- Implemented the new supplemental data system for postmark documentation and report data for urgent abnormal test results

Limited laboratory and follow-up services began March 1 with no increase in staff for either program area. Full services began May 3 with some additional modifications to normal week day laboratory and follow-up services based upon recommendations from specialty care providers. Two new laboratory staff were hired in mid-May to help with the Saturday rotation. One follow-up coordinator position was approved in February, but was not filled until October. Follow-up staff are allowed to utilize the Epi on-call staff in the local health regions if there is difficulty in contacting families.

Improvement has been steady over the course of the RIC. The most recent data indicates that 83.67% of specimens are postmarked within 24 hours of collection compared to 55.68% at baseline. Once the new follow-up coordinator is oriented, hospitals with slow progress will be targeted for onsite systems analysis. In addition, only 10.02% of specimens took 5 days or longer for receipt at the laboratory. Current data for the hospitals with the best and worst initial percentage shows the following:

- Hospital with best %—now 0% take 5 days or longer (126 miles from laboratory)
- Hospital with worst %—now 6.33% take 5 days or longer (117 miles from laboratory)
- Hospital closest to lab (6 miles)-0.78% take 5 days or longer

Future plans include continuing monthly data reports for the hospitals. The laboratory will also implement a new LIMS in the next year which should provide much more detail for hospitals to use in monitoring their processes.

**Improving a Newborn Screening Program: A Systematic Approach**

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**Abstract**

**Objectives:** (1) Identify quality indicators across the newborn screening (NBS) program, the appropriate partnerships, and responsibilities. (2) Identify high priority quality indicators where improvement can be made, and steps to attain the improvement.

**Background:** An NBS program is “successful” when all eligible infants are screened, and all affected children identified and timely treated. We recognized that all stakeholders must work together to

establish a system-wide quality assurance structure that moves NBS toward “success”. We brought together representatives from Wisconsin hospitals, the NBS laboratory, clinician-scientists, advocate organizations, and state public health to address NBS quality improvement (QI).

**Method:** A core workgroup from the Department of Health Services and the Wisconsin State Laboratory of Hygiene generated a newborn screening process map from prenatal education to long-term follow-up. The process map was presented to clinician-scientists from each NBS discipline and representatives from the Wisconsin Chapter of American Academy of Pediatrics, the Wisconsin Hospital Association, the Wisconsin Chapter of March of Dimes, and local public health departments. The group met five times over three months to discuss elements across the process map, outlining the current status of Wisconsin NBS quality, identifying and prioritizing areas for improvement.

**Results:** The group acknowledged that 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 the Newborn Screening Technical assistance and Evaluation Program (NewSTEPs), which capture all fundamental measures, and most are currently assessed. We identified the gaps, and the partnerships needed to fill the gaps in order to move toward full compliance. The group selected two areas for priority projects – (1) Reducing unsatisfactory specimen submissions, and (2) Reconciling every birth to the NBS process.

**Conclusions:** Collaboration by each discipline across the NBS process 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.

**Presenter:** Mei Baker, MD, Wisconsin State Laboratory of Hygiene, Madison, WI, Phone: 608.890.1796, Email: mei.baker@slh.wisc.edu

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**Achieving Dramatic Improvements in Sample Transit Time – The Arizona Model**

C. Nabor and S. Aponte, Arizona Department of Health Services, Phoenix, AZ

**Abstract**

A nationwide story reported by the Milwaukee Journal Sentinel identified nationwide delays in transit time for newborn screening samples from hospitals to NBS laboratories. Arizona hospitals were singled out as being among the worst in the nation. Every day of unnecessary delay has the potential to delay identification and critical treatment of affected newborns.

Arizona chose a multi-pronged approach to address this problem. First, ADHS Director Will Humble publically set an aggressive and challenging goal that, by July 1, 2014, 95% of first screen samples would be received at the state laboratory within 3 days of sample collection. Then, ADHS leadership assigned and funded a dedicated team to review data and develop strategies to reach that goal. The strategies included partnering with the state’s Hospital and Healthcare Association to leverage limited resources, hospital site visits, and a commitment to transparent regular disclosure of individual hospital performance toward the goal. Targeted outreach to lagging performers and public recognition of top performers were also helpful. Finally, supplemental funding was made available to establish a contract with an Arizona courier service for daily pickups from each hospital.
Baseline data from 2013 indicated only 67% of hospitals met the three day transit time goal. As of April (courier service began in mid-April), 89% of hospitals met the goal. We are confident that the 95% goal is within reach by July 1st.

Leadership involvement is essential to achieving an effective solution. Setting an aggressive goal and making the necessary resources available sends an unmistakable message about commitment. Our decision to work collaboratively with our partners to remove barriers, while maintaining fully transparency about project progress, led to the realization of dramatic improvements in a short period of time.

Presenter: Celia Nabor, MPA, Arizona Department of Health Services, Office of Newborn Screening, Phoenix, AZ, Phone: 602.364.2579, Email: celia.nabor@azdhs.gov

J.D. Thompson, M. Glass, S. Shaunak, S. Weiss and L. Knowles, Washington State Department of Health, Shoreline, WA

Abstract

Background: On Nov. 16, 2013 the Milwaukee Journal Sentinel published a watchdog report entitled “Deadly Delays” that pointed out performance inconsistencies across the U.S. newborn screening landscape. Within a few days, the Seattle Times ran a spin-off article including statistics on specimen transit times for Seattle area hospitals. The following week, a similar article was run in the Spokesman Review reporting that two of the four worst performers in the state were local hospitals. This newspaper is in the home town of a state representative, who had a recent experience concerning results from his own baby’s newborn screening. This nexus of reporting and personal experience inspired him to propose legislation to improve the newborn screening law.

Objective: We will share what we learned from the watchdog report and how we took advantage of the increased awareness it created to improve public health in Washington State.

Results/Discussion: Prior to the legislative session, the state representative collaboratively informed the Department of Health that he intended to propose legislation to make changes to the newborn screening law. We recognized this as an opportunity to provide input for his efforts and to suggest revisions we had long hoped for: to require screening for all newborns (not just babies born in hospitals). The legislation proposed at the beginning of session incorporated feedback we had suggested and enjoyed broad support from hospitals, midwives and the Department of Health.

Conclusion: Conflict and controversy can create windows of opportunity. Public health programs can greatly benefit from recognizing these windows and working diligently while they are open to create lasting positive change.

Presenter: John D. Thompson, PhD, Newborn Screening, Washington State Department of Health, Shoreline, WA, Phone: 206.418.5531, Email: john.thompson@doh.wa.gov
Summary

Windows of Opportunity

Public health is a fun and challenging field influenced by scientific and technological advances, public opinion and policy makers (sometimes by people who don’t know much about public health). In the policy world, events that trigger policy change often happen unexpectedly. John Kingdon, emeritus Chair of the Political Science Department at the University of Michigan, writes about policy windows in his book Agendas, Alternatives and Public Policies: “Once [a] window opens, it does not stay open for long. An idea’s time comes, but it also passes... [And] if the window passes without action, it may not open again for a long time.” This paper tells the beginning of the story about how we took advantage of a window of opportunity in Washington State to tighten our public health security net by increasing coverage of newborn screening.

Washington State’s newborn screening law was written in 1977 and required hospitals to screen newborns by five days of age or prior to discharge, whichever came first. The midwife population in our state has always actively participated in newborn screening, but it never has been required for out-of-hospital births. We have long wanted to change the law, but were never able to gain traction. In 2008, we reported presumptive MSUD results on a baby’s first specimen collected at nine days of age. We found out that the baby was born at home and did not have a newborn screen collected until he was admitted to the hospital with severe illness. The baby died before results of the screen and other labs sent to Seattle Children’s Hospital were available. This case prompted us to consider amending the newborn screening law to require testing of all births, not just hospital births. The agency decided not to propose changes to the law; the window for policy change was not open at that point.

In 2011, a baby with cystic fibrosis (CF) was born outside a hospital. No screening was done until almost six months of age, when the baby presented with failure to thrive and had been diagnosed with CF based on clinical symptoms.

On November 16, 2013 the Milwaukee Journal Sentinel published a watchdog report entitled “Deadly Delays.” It pointed out performance inconsistencies across the U.S. newborn screening (NBS) system. We carefully read the watchdog report. The full report and some of its implications were immediately clear to us. The subject matter of timely delivery and testing of NBS specimens has been a focus in Washington State for many, many years. Washington State came out looking fairly good in the report, thanks to our long-standing efforts.

And we recognized that we could do better.

Ripples

The public health world in which we operate can be compared to a pool of water. External events, such as the Milwaukee Journal Sentinel report are like throwing a rock in the middle of the pool. It creates ripples that disturb the surface.

Within a few days of publication, the Seattle Times ran a spin-off article including statistics on specimen transit times for Seattle area hospitals (first ripple). The following week, a similar article was run in Spokane by the Spokesman Review reporting that two of the four worst performers in the state were local hospitals (second ripple). This newspaper is in the hometown of a state representative, who had a

recent experience concerning results from his own baby’s newborn screening. This nexus of reporting and personal experience inspired him to propose legislation to improve the NBS law (third ripple).

Riding the Wave
Prior to the legislative session, the state representative reached out to the Department of Health (DOH) and gave us a draft of legislation he intended to introduce making changes to the newborn screening law. His proposal would impact the way we do business so we gave him important feedback regarding the draft legislation. We thought this could be our window of opportunity: since he was already making waves by amending the law to speed up the newborn screening and reporting processes, we thought we might be able to ride in one of those waves by adding something related: language to require screening for all newborns (not just babies born in hospitals).

The legislation proposed at the beginning of session incorporated the feedback we had suggested. We were thrilled that the bill enjoyed broad support from hospitals, midwives and the Department of Health. It passed in March 2014 and changed the newborn screening law in five ways. The first four points were his original proposal and he added the fifth based on our suggestion. The amended law:

- requires newborn screening specimens collected before 48 hours of age
- requires delivery of specimens within 72 hours of collection
- requires reporting by the primary care provider to DOH of when parents were notified of abnormal results (only for babies needing diagnostic testing)
- requires DOH to post an annual summary of compliance on its website
- requires newborn screening for all births (not just hospital births)

Policy changes often have unintended consequences. Changing the law to require newborn screening for all births was like throwing another rock into the newborn screening pool. This one had a different set of ripples.

Historically, midwives in Washington did not have to pay for newborn screening, although there was an agreement with the state Health Care Authority to reimburse midwives for their patients covered by Medicaid insurance. After the bill passed, we communicated with the midwives that we would begin charging them for the screening. This announcement caused a flurry of discussion among the midwives and two main midwifery groups in Washington approached us to explain why billing midwives for newborn screening would have a negative impact on their practices. We met with representatives of the midwifery community and tried to understand the challenges they face. Based on their feedback, we delayed implementing billing for out-of-hospital births and a midwives newborn screening taskforce was created. This group is working to address and help mitigate the issues, and billing will commence in January 2015 for out-of-hospital births.

The requirement for us to monitor and report the transit time of specimens necessitated changing the way we receive specimens in the public health laboratory. We needed to work with Neometrics (Natus), our computer system vendor, to add the new data field to the mailer reports. Another ripple was redesigning the collection card to be able to capture the data needed for the required reporting. We also made changes to the card layout to facilitate new billing processes. Sub-ripples are the educational materials we developed to send with the new cards to submitters to help them understand how to properly fill out the card. We are now required to track how well primary care providers are communicating with parents when babies need diagnostic testing. The updated law also requires that we publish an annual report of compliance on our website.
Summary
With the number of out-of-hospital births steadily increasing over the past several years and the lower coverage rate of those births (~93 percent compliance), it was only a matter of time before something bad would happen for a baby who missed being screened. By recognizing the window of opportunity, we made a carefully-timed request to change the newborn screening law. The implications of the updated law have been much bigger than we expected and we are very pleased to have patched a hole in our public health safety net through these efforts.

Conflict and controversy can create windows of opportunity. Public health programs can greatly benefit from recognizing these windows and working diligently while they are open to create lasting positive change.

Leveraging the Attention – How Texas Took Advantage of Heightened National Awareness to Expedite Ongoing Specimen Transit Quality Improvement Efforts
B. Reilly, C. Bresette, S. Arreola, C. Chapa, S. Arshadmansab, C. Fitzhugh, A. Schlabach, R. Lee, and S. Tanksley. Texas Department of State Health Services, Austin, TX

Abstract

Objective: To evaluate the effectiveness of the Texas Newborn Screening (NBS) Program's historical, ongoing, and recently enhanced efforts to minimize the time from NBS specimen collection to receipt in the state laboratory.

Background: Over the last decade, the Texas Newborn Screening Program has launched various initiatives in a continuing effort to improve multiple pre-analytical specimen quality measures including specimen transit time. Beginning in late 2013, multiple media outlets reported on nationwide delays in delivery of NBS specimens to state laboratories. Despite ongoing efforts to reduce this issue, Texas was noted as having one of the highest rates of 1stscreen specimens received at the laboratory greater than 4 days after collection. The Texas NBS Program recognized the negative attention on this issue as an opportunity to enhance provider awareness and expedite efforts to improve specimen quality statewide.

Methodology: Effectiveness of historical, existing, and new quality improvement initiatives was evaluated. Aggregate facility specimen transit time data was analyzed in comparison with timelines of implementation of improvements and new initiatives. Individual facility specimen transit time data was compared before and after various interventions. A survey of submitting facilities was conducted to identify barriers and issues.

Results: Implementation of a pilot courier service in 2010 and subsequent expansion and enhancements were identified to be highly effective in reducing delayed delivery of 1st screen specimens. Various outreach activities have also led to significant improvements. In 2009, 32.6% of 1stscreen specimens (~11000 / month) were delivered at greater than 4 days. By April of 2014, this quantity had been reduced to 3.7% (~1100 / month).

Conclusions: The geographical size and large number of NBS submitters presents unique challenges to the Texas NBS Program. However, targeted education, outreach activities, and courier system implementation have significantly improved specimen transit times. Heightened discussion and national media attention on transit times has provided a boost to the Texas NBS Program’s efforts to raise public
health stakeholder awareness of the importance of multiple quality measures in the collection and submission of NBS specimens.

**Presenter:** Brendan Reilly, BS, Texas Department of State Health Services, Austin, TX, Phone: 512.776.2477, Email: brendan.reilly@dshs.state.tx.us

**Summary**

**Objective:** To evaluate the effectiveness of the Texas Department of State Health Services (DSHS) Laboratory’s historical, ongoing, and recently enhanced efforts to assist healthcare providers in minimizing the time from collection of the newborn screening specimens to receipt in the state laboratory.

**Background:** Over the last decade, the Texas Newborn Screening Program has launched various initiatives in a continuing effort to assist submitting facilities in improving pre-analytical specimen quality measures. Improvement efforts have primarily focused on reducing unsatisfactory specimens, maximizing the number of specimens collected in the proper timeframe, and minimizing the time from specimen collection to receipt in the laboratory. The Texas Newborn Screening Performance Measures Project, initiated in 2007, identified four key pre-analytical quality goals for the Texas Newborn Screening Program:

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<thead>
<tr>
<th>Pre-analytical Measure</th>
<th>Goal</th>
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<tr>
<td>Specimen Quality</td>
<td>100% Satisfactory Specimens</td>
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<tr>
<td>Timing on Initial NBS Specimen Collection</td>
<td>100% Collected between 24 and 48 hours</td>
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<tr>
<td>Specimen Transit Time</td>
<td>100% Received within 72 hours from collection</td>
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<tr>
<td>Key Demographic Information</td>
<td>100% Submission of all key demographic information</td>
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Beginning in late 2013, multiple media outlets spearheaded by a series of investigative articles from the Milwaukee Journal Sentinel reported on nationwide delays in delivery of newborn screening specimens to state health laboratories. Despite ongoing efforts to reduce this issue, Texas was noted as having one of the highest rates of first screen specimens received at the laboratory greater than four days after collection. The Texas Newborn Screening Program recognized the negative attention on this issue as an opportunity to enhance provider awareness and expedite existing and new efforts in improving specimen quality statewide.

**Methodology:** In 2010, the Texas Laboratory Services Section implemented a pilot courier service for Medicaid providers. This service provides direct overnight or same day delivery of specimens to the Texas Laboratory. However, funding levels for the program required limitations on scope. The service, as originally implemented, covered delivery of approximately 67% of newborn screening specimens and did not include weekends or major holidays. Despite these limitations, initial implementation of the laboratory courier improved the average monthly percent of first screen specimens delivered to the laboratory within three days of collection from approximately 46% to approximately 70%. In 2013, a
Lean Six Sigma Project was implemented to study the structure of the courier and identify means to improve the program efficiency.

In November 2013, the Texas Laboratory implemented a workgroup to reassess specimen transit times, develop a strategy for improvement, and implement quality improvement initiatives.

**Issue Re-assessment Information Gathering**

Of the 392,358 first screen specimens received in 2013 from approximately 400 hospitals, birthing centers, and midwives, 70% were received within three days of collection. The 25 facilities with the highest volume of delayed specimens accounted for 37% of the issue.

The Transit Time Workgroup consulted a variety of newborn screening stakeholders including over 100 healthcare providers. These providers included:

- 25 Sites with most specimens delayed
- >50 smaller facilities with high percentage of delayed specimens
- Best performing sites

A survey was also conducted to identify provider issues with meeting transit time goals. The most commonly noted barriers to timely delivery indicated included:

- Cost and availability of courier
- Routing of specimens through a centralized facility
- Internal hospital workflow and communication issues

**System Improvement and Outreach**

Based on system analysis and submitter feedback, the Texas Newborn Screening Program initiated a series of outreach activities and system improvements. These activities included:

- A series of email list notifications
- Reorganization of courier services
- Development of a model provider specimen collection and shipment workflow
- Monthly outreach and follow-up to 10 submitters with most delays
- Expansion of courier services to include Sundays and many national holidays
- Publishing of a monthly “Spotlight” recognizing providers with excellent adherence to pre-analytical quality assurance measures
- Initiation of a pilot supplemental courier for facilities submitting only newborn screening specimens

**Results:** Improvements and new outreach activities greatly reduced the average number of first screens received greater than three days after collection.

<table>
<thead>
<tr>
<th></th>
<th>2013 Monthly Average</th>
<th>August 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total specimens received &gt; 3 days</td>
<td>9796</td>
<td>2910</td>
</tr>
<tr>
<td>% of specimens received ≤ 3 days</td>
<td>69.6</td>
<td>91.7</td>
</tr>
</tbody>
</table>

The 25 targeted sites also demonstrated significant improvement.

<table>
<thead>
<tr>
<th>2013 Monthly Average Target Sites</th>
<th>August 2014 Target Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total specimens received &gt; 3 days</td>
<td>3351</td>
</tr>
<tr>
<td>% of specimens received ≤ 3 days</td>
<td>53.7</td>
</tr>
</tbody>
</table>

Monthly outreach and consultation of the ten facilities with the most delayed specimens in a given month had a significant impact on specimen transit times.

<table>
<thead>
<tr>
<th>% Received ≤ 3 Days Month Before Contact</th>
<th>% Received ≤ 3 Days Month After Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>67.80</td>
<td>77.80</td>
</tr>
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</table>

Conclusions: The geographical size and large number of submitting facilities (approximately 2,200) presents unique challenges to the Texas Newborn Screening Program. However, targeted education, quality improvement outreach activities, and courier system implementation and enhancements have significantly improved specimen transit times. Heightened discussion and national media attention on newborn screening transit time issues has provided a great boost to the Texas NBS Program’s efforts to raise submitting facility and public health stakeholder awareness of the importance of multiple quality measures in the collection and timely submission of newborn screening specimens.

Although these advancements are encouraging, the Texas Newborn Screening Program is assessing new measures and additional quality improvement initiatives to further improve the timeliness of newborn screening. Revised goals include maximizing the quantity of specimens received at the laboratory within

Improving Quality Indicators Associated with Specimen Collection and Transport
D. McCourt, I. Margolin and S. Shone, New Jersey Department of Health, Ewing, NJ

Abstract

Background: The timely collection and transportation of newborn screening (NBS) specimens is essential for ensuring the earliest possible detection of critical disorders. A NBS Laboratory’s internal quality is of little importance if a specimen is not collected and transferred to the laboratory in an expeditious manner. The New Jersey NBS Laboratory has been actively monitoring quality indicators (QIs) associated with the pre-analytic steps of the newborn screening process for several years, and recent events have focused national attention improving these steps.

Baseline Data: In 2011, the NJ NBS Laboratory piloted QIs, which were ultimately adopted by the Newborn Screening Technical assistance and Evaluation Program (NewSTEPs). Two QIs revealed areas for improvement: time from birth to specimen collection and time from specimen collection to receipt in the laboratory. Although state regulations require specimens be collected between 24 and 48 hours after birth only 91.8% of initial specimens fell in this category. Further, NJ expects initial specimens to arrive within 3 days of collection; however, only 85% of specimens arrived at the NJ NBS Laboratory within that window.

Quality Improvement: To improve the pre-analytic steps, the NJ NBS Program engaged with specimen submitters, including provision of guidelines for collection of specimens, reinforcement of regulatory requirements, discouragement of batching specimens for shipment, education of overnight courier shipping software, and transparent discussions of best practices. Those submitters who failed to remain compliant with regulatory requirements were referred to the Department of Health’s licensing division for further review.

Results: As a result of these quality improvement initiatives, the percent of initial specimens collected 24 to 48 hours after birth during the first quarter of 2014 increased to almost 95% with a median age of the newborn at time of specimen collection of 36 hours. Moreover, as of April 2014, over 91% of initial specimens arrived in the NJ NBS Laboratory within 3 days of collection.

Conclusion: Building on the success of these quality improvement initiatives, the NJ NBS Laboratory is engaging additional members of the NBS system to address remaining gaps and minimize barriers to improvement in other areas.

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