



Difficult Choices, Rewarding Outcomes: Delaware Newborn Screening Program

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Delaware's Newborn Screening Program prior to 2018

- Began in 1962 screening for one condition
- Mandated in 1999 and codified into legislation in 2015
- It expanded to screen for over 40 conditions
- Delaware is a two screen state
- Was part of the Office of Maternal Child Health within the Division of Public Health in the Department of Health and Social Services
- All testing from 1999 to 2017 occurred in Delaware Public Health Laboratory in Smyrna, De and included about 8 lab personal and 3 data entry people
- Follow-up program was based out of Dover, Delaware and had a staff of 5 when fully staffed
- State contracted with medical consultants to direct follow-up

Newborn Screening in Delaware at a Glance

- In 2015 Delaware received 11,731 initial samples. The state also received 11,021 follow-up specimens.
- Repeat specimens were tested for any abnormality on initial screen in addition to testing for galactosemia, congenital hypothyroidism and congenital adrenal hypoplasia.
- In addition approximately 30 individuals were monitored for PKU and in 2015 these individuals had 252 analyses performed
- Program is entirely fee-based
- Delaware's fee in 2016 was \$135/baby
 - Fee is listed as cost per baby (not per screen)
 - Fees paid by birthing hospitals or midwives and collected by the state
 - Not screening for X-ALD, MPS I or Pompe's in 2016

A Request for Proposals in 2017

- Fees had been increasing over the last decade
 - 1999 - \$41/baby screening for 4 disorders
 - 2013 - \$120/baby screening for 40+ disorders
 - 2016 - \$135/baby
- Cost difficult to qualify as it includes more than just a lab charge
- That state initially proposed a fee increase to \$185/baby starting in July 2016 but this was deferred
 - The state reduced cost by deferring needed capital expense increases such as an MSMS purchase and also froze positions
- RFP was published on 2/21/2017 and proposals due 4/20/2017 and decision by 5/7/2017

The RFP process

- Contract would be for 3 years with two optional extensions for one year each extension
- 3 options for scope of services when submitting an application for the contract
 - Solely as a laboratory provider
 - Solely as a follow-up program
 - Joint application for both the follow-up and laboratory programs
- 3 proposals were received 1 representing each category

The RFP process continued

- State reviewed all applications and used published weighted criteria to rank submissions:
- Qualifications of the Vendor – 20 points
 - History of CLIA inspections, copy of quality management plan, demonstration of capacity to handle Delaware’s newborn screening samples, past experience in successfully operating quality programs
- Methodology proposed – 30 points
 - Proposed services meets or exceeds what is currently offered, proposed services fit Delaware needs, adequacy of workplan and timeline, ability to process State of Delaware work independently of work from other states and providers
- Responses to scope of services – 25 points
- Evaluation of the detailed costs - 25 points

Awarding of RFP

- RFP awarded to Nemours/Al duPont Hospital for Children in 5/2017
 - Nemours has been committed to the health of Delaware's children for more than 80 years. In 2016, Nemours provided direct healthcare to 85,668 children who were Delaware residents. Through Nemours Health and Prevention Services, which includes partnerships with schools and early childcare centers statewide, Nemours reaches nearly every single Delaware child during their lifetime.
- Laboratory services subcontracted to PerkinElmer Genetics by Nemours
 - At the time PerkinElmer Genetics was performing testing for Pennsylvania, Nebraska, Mississippi, District of Columbia and some Louisiana hospitals as well as international clients ~ 1,000,000 newborns/year in 2016
- Negotiations continued and contract signed in 12/2017
- Go-live date was 1/1/2019

Details

- For less than the state's prior bare-bone budget and for more than a 35% savings of the state's proposed increased budget this public-private partnership is offering:
 - Expanded molecular confirmation of more than 12 disorders
 - Laboratory testing 6 days per week and 24 hours/day
 - Physician coverage 7 days per week and 24 hours/day
 - Transition to birthing hospitals shipping specimens to the lab
 - Fully staffed follow-up program
 - Electronic access to testing results
 - Urgent follow-up visits at the state's only free-standing children's hospital

Current state of the Program

- Program is based out of Nemours/Al duPont Hospital for Children which is the state's only free-standing children's hospital
- 2 follow-up staff – program manager, program coordinator
- Group of physicians who take call for program 24 hours/day 7 days/week
- Laboratory services through PerkinElmer Genetics in Pittsburgh, Pennsylvania
- Dried blood cards sent to PerkinElmer Genetics via UPS

Current state of the Program (continued)

- Specimens processed 6 days/week 24 hours/day
- Abnormal results called from the lab to follow-up team who then makes follow-up decisions and communicates recommendations to providers and specialists (if needed)
- Follow-up team provides short-term follow-up on all babies born in the state
- Does not include hearing screens or CCHD testing
- Billing of birthing hospitals is performed by the state

Results from our first year

- Cost savings: ~\$780,000 savings in 2018 from the state's proposed budget increases with more services now provided
- Continued timely reporting of results
 - Average time from sample collection to receipt at PerkinElmer Genetics to be 2.17 days and average time from receipt to final result of 1.3 days
 - Reduced average time from collection to receipt working with birth hospitals
 - Barrier: convincing hospitals of the importance of Saturday shipments
- Ability to adopt new testing without needing capital investments in laboratory equipment

Results from our first year

- Reduction in false positive screens
 - January 2017: ~ 83 overall abnormal results
 - January 2018: 45 overall abnormal results (22 collected after 24 hours of age)
 - January 2017: 68 abnormal mass spectroscopy results with 7 being referred to specialists for further evaluation and all deemed a false positive result
 - January 2018: 14 abnormal mass spectroscopy results of which 0 required a referral to a specialist for care.
 - 2017: 58 referrals to metabolic center for presumptive positive results with 6 confirmed cases
 - 2018: 7 referrals to metabolic center for presumptive positive results with 4 confirmed cases
- Partnerships with specialists within the hospital to ensure a high-quality newborn screening program
 - Worked to develop reliable methods for notification of abnormal results to specialists
 - Funded research project from the Cystic Fibrosis Foundation to improve this collaboration with the CF team

Opportunities identified from 2018

- Lack of lead time for education of birthing hospitals and primary care doctors of upcoming changes to the state's newborn screening program
- Partnering with birthing hospitals to develop reliable methods for shipment of specimens to the lab – change from a passive to an active process presented many challenges
- Educating birthing hospitals of the benefits of Saturday shipments to increase time from collection to receipt and overall available timeliness of results
- Teaming with providers and primary care doctors on the need to retrieve normal results from the Web-based results portal
- General barriers regarding speed of changes in the public-private partnerships