

February 8, 2013 – Responses to Inquiry

The State of Alaska, Division of Public Health, Section of Women's, Children's, and Family Health (WCFH) has assembled a steering committee of healthcare providers in Alaska related to the implementation of pulse oximetry screening of newborns for critical congenital heart defects in Alaska. We are creating a toolkit for birthing centers which will include a State of Alaska position statement on pulse oximetry screening in newborns, resources for health care providers and birthing centers on this practice, the American Academy of Pediatrics/American Heart Association recommendations, and a procedural flowchart for pulse oximetry screening. This steering committee will provide feedback and recommendations on this toolkit and help WCFH promote this practice throughout the state. Many of the larger birthing hospitals in the state have already implemented this testing such as: Samuel Simmonds, Kakanak, Fairbanks Memorial, Bassett Army Hospital, Mat-su Regional, Alaska Regional, Alaska Native Medical Center, Providence Alaska Medical Center, and Mt. Edgecombe Hospital.

1. Is the list of tests from the third party website (Baby's First Test) accurate?

The list on the Baby's First Test website is accurate. The list on our public website notes the categories of conditions we screen for, along with some of the most common disorders. Both sets of information are accurate. For health care providers in Alaska, The State of Alaska and Oregon Public Health Lab created the "Alaska Practitioner's Manual" which lists all of disorders tested on the newborn screening blood spot. The link can be found here:

<http://dhss.alaska.gov/dph/wcfh/Pages/metabolic/resources/manual.aspx>.

2. Why are the following disorders not tested for? (Using the American College of Medical Genetics code)

The State of Alaska has a contract with the State of Oregon Public Health Laboratory (OPHL) to run our blood spot tests. The number and type of tests we screen for are guided by the states that are served by OPHL. OPHL bases their screening on the national recommendations of the federal Secretary's Advisory Committee on Heritable Disorders in Newborns and Children and has generally been one of the first labs in the country to implement new screening recommendations as they are published. There are some tests that are on the list that are not able to be detected during the newborn period and so are not currently on the panel. The physician consultants and lab director participate on national committees that advise the Secretary's Advisory Committee.

- SCID (Severe Combined Immunodeficiencies) – OPHL will be adding this disorder to the newborn screening panel in 2013. They are finalizing plans to ramp up to screen for this as a large scale process. Once OPHL is able to screen for this disorder (as it requires a different method of testing), it will be included in the Alaska panel as well.

- M/SCHAD (Medium/Short-chain L-3-hydroxyacyl-CoA dehydrogenase deficiency) – Not screened for by OPHL or in most other states as it is unlikely to be detected on the newborn screen. It is also considered a secondary condition and not part of the core newborn metabolic conditions.
- MCAT (Medium-chain ketoacyl-CoA thiolase deficiency) – Not screened for by OPHL or in most other states as it is unlikely to be detected on the newborn screen. It is also considered a secondary condition and not part of the core conditions.
- DE RAD (2,4 Dienoyl-CoA reductase deficiency) -- Not screened for by OPHL or in most other states as it is unlikely to be detected on the newborn screen. It is also considered a secondary condition and not part of the core conditions.
- BIOPT (BS) (Biopterin defect in cofactor biosynthesis) -- Not screened for by OPHL as this is done as a follow-up if there is a positive screen. This is also called reflex testing which would be done through diagnostic testing at a different laboratory.
- BIOPT (REG) (Biopterin defect in cofactor regeneration) -- Not screened for by OPHL as this is done as a follow-up if there is a positive screen. This is also called reflex testing which would be done through diagnostic testing at a different laboratory.
- TYR III (Tyrosinemia, type III) -- Not screened for by OPHL as it is extremely rare.
- GALE (Galactosepimerase deficiency) -- Not screened for by OPHL as this is reflex testing which would be done through diagnostic testing at a different laboratory.
- GALK (Galactokinase deficiency) -- Not screened for by OPHL as this is reflex testing which would be done through diagnostic testing at a different laboratory.

3. Do you have the statutory or regulatory authority to require these tests?

The Division of Public Health does not have statutory or regulatory authority to require these tests. Our interpretation has been that the current regulations only cover the blood spot test. Please see the link below for the statutes (AS.18.15.200 and AS.18.15.210) related to newborn bloodspot screening:

<http://www.legis.state.ak.us/basis/statutes.asp?title=18#18.15.200>.

4. Do you have the statutory or regulatory authority to require pulse oximetry (PO) testing for CCHDs? From my reading of the statutes and regulations, it is unclear.

The Division of Public Health does not have the statutory or regulatory authority to require pulse oximetry testing for CCHD. At this time, our approach has been to engage the birthing hospitals and birthing centers in adopting this screening as a best practice and this approach has been widely accepted.

5. Can Medicaid cover the cost of the whole screening program, or just part?

Currently, Medicaid does pay for the cost of the newborn screening blood spot test for newborns eligible for coverage. We also confirmed with State of Alaska Medicaid program that pulse oximetry screening is covered. They reimburse for the CPT code 94760 at \$4.08.

6. Do most major health insurance plans cover the cost of newborn screening?

We suspect that most private health insurance plans cover the newborn screening blood spot test. The State of Alaska distributes and pre-charges the blood spot kits to birthing centers in the state. The birthing facilities in turn bill the patient for this screening as a part of their hospital or birthing center stay. The charge covers the required two blood spot screens.

As a part of our contractual relationship with OPHL, OPHL provides metabolic genetic medical consultation to health care providers in Alaska regarding children with abnormal newborn screening results who need further testing or follow-up. In addition, the metabolic geneticist comes to Alaska four times per year with a specialty Registered Dietician to conduct state-sponsored clinics specially designed for individuals diagnosed with metabolic disorders. These patients are followed through adulthood.

7. Is there a way for low-income families, or families with no insurance, to receive newborn screening for low or no cost?

For low-income families on Medicaid, this cost would be covered. For those families who are self pay or underinsured, most birthing centers work with the family on their health care costs associated with a delivery, postpartum and newborn care.

8. If PO testing is required, do you have an idea of how much this would cost the family?

The hospitals and birthing centers will be charging the family for this testing. The State of Alaska does not set facility fees thus this is not information that we capture.

9. If PO testing is required, do you know how much would it cost the average hospital or birthing facility to set up the instrumentation to screen for CCHDs?

The average cost for the instrumentation is around \$200. This will vary depending on the type of instrument the birthing centers choose to purchase. The cost will also vary

depending on the size of the facility and the number of births they have annually. There would also be some costs related to training hospital personnel. Some instruments contain training videos but it takes an average of two hours per nurse for training. There are also costs related to consultation and referrals, data entry, quality assurance activities, and working with the State of Alaska on developing a system to report abnormal results.