HB 184

<TARGET><BILL>HB 184</BILL><SUBJECT>HB 184</SUBJECT><COMM>HHSS28</COMM></TARGET>

Alaska State Legislature

House of Representatives

Member:

Judiciary
Rules
Legislative Council
Military & Veterans Affairs

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House Bill 184: Newborn Screening for Heart Defects
(28-LS0506\N)
Sectional Analysis

Section 1:

(a): Requires that an infant, born in a licensed facility that provides birthing services, be screened for congenital heart defects at least 24 hours after birth and before discharge.

(b): Requires that confirmatory testing and interventions be performed on an infant whose CCHD screening is abnormal.'

(c): Requires that the licensed facility that performs the screenings annually report the results to the Department of Health and Social Services.

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Research Brief

TO: Representative Pete Higgins

FROM: Tim Spengler, Legislative Analyst

DATE: April 5, 2013

RE: Screening for Critical Congenital Heart Defects in Newborns: Provisions in Indiana and New Jersey
LRS Report 13.345

You asked for information on the mandates in Indiana and New Jersey that call for the screening of all newborns for critical congenital heart defects. Specifically, you wanted to know how many infants typically test positive in these states and, of these, how many receive false positive results. Additionally, you asked if state costs for these screening programs have risen since implementation.

Briefly, the laws in Indiana and New Jersey providing that all newborns receive a *pulse oximetry screening* to detect critical congenital heart defects (CCHD) have been in effect for less than two years and limited outcome data are available.[1] In both states, less than point one (0.1) percent of infants screened test positive. False positive rates for pulse oximetry screening are not available for Indiana and New Jersey, but a major 2012 study estimates false positive rates for this screening to be very low—between 0.05 and 0.14 percent. Program costs for these states have not risen in the short time the tests have been in effect, according to our sources. Below we summarize the screening process and discuss what data are available from Indiana and New Jersey.

Pulse oximetry newborn screening is a test that measures the level of oxygen in a baby's blood. The screening is recommended for all newborns by the American Academy of Pediatricians in order to determine the health of a baby's heart and lungs and to better identify CCHDs.[2] Frequently the test is conducted by a nurse or other professional who has been trained to administer this simple screening. The pulse oximetry screen is done by placing a probe (a small device with a red light that measures a person's oxygen level) on the baby's right hand and a foot. The screening takes only a few minutes to perform.

Infants with low oxygen levels in their blood may have critical congenital heart defects. Typically, when a baby fails the screening a doctor will perform a thorough physical examination and often have an echocardiogram performed to determine if CCHD is present.[3] Once identified, babies with a CCHD are usually seen by a cardiologist and receive specialized care and treatment including medications and/or surgery that can prevent disability and death early in life.

As we mentioned, there are limited data from Indiana and New Jersey regarding the states' screening mandates. Officials in both states stress that their programs are still very new and that they are working out bugs in their data collections systems where screening results are tabulated and analyzed.[4] Nevertheless, the number of infants who have tested positive is low in both states. In 2012, of the roughly 81,000 births in Indiana, 45 infants, or roughly 0.06 percent, failed pulse oximetry screening; and, of the approximately 73,000 tested babies in New Jersey (August 2011 through May 2012), 49, or about 0.07 percent, did not pass their screening. In other words, in these two states, fewer than one (1) of every 1,000 newborns tested showed signs of CCHD. State officials stress that these data should be viewed as preliminary.

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[1] At least four states—Connecticut, Tennessee, Virginia, and West Virginia—enacted similar legislation in 2012. Bills to require screening of newborns for CCHD are pending in several other states including Alaska (HB 184). A number of hospitals in Alaska already administer pulse oximetry newborn screenings as a matter of course.

[2] Critical congenital heart disease occurs when a baby's heart does not develop correctly. Seven different heart defects can be identified with pulse oximetry newborn screening. Heart defects require some type of treatment (often involving surgery) soon after birth; if a baby has CCHD and does not receive treatment shortly after birth, the baby has a higher chance of developing other problems, including premature death.

[3] An echocardiogram uses sound waves to produce images of a heart. This test allows medical experts to see how a heart is beating and pumping blood. A doctor can use the images from an echocardiogram to identify various abnormalities in the heart muscle and valves.

[4] In Indiana we corresponded with Bob Bowman, director, Newborn Screening, Indiana State Department of Health, (317) 233-1231. In New Jersey we spoke with Dr. Lorraine Garg, medical director, Newborn Screening, New Jersey Department of Health, (609) 984-0755.

No relevant data are currently available pertaining to increased state costs related to CCHD screenings; however, according to the experts we consulted, pulse oximetry screenings are not costly. Dr. Terry Anderson, a pediatric cardiologist at the Children's Hospital of Philadelphia, estimates that the cost for processing each test averages around $5 to $7. Additionally, the screening devices are relatively inexpensive and are usually supplied by the hospital or birth center. While neither of the state authorities with whom we corresponded had precise costs for setting up their respective programs, they both agreed that the biggest cost involved the establishing of a database/registry to house the information.

At present neither Indiana nor New Jersey is able to provide false positive rates for their respective screening programs; however, a meta-analysis completed in 2012 of pulse oximetry screening studies—involving nearly 230,000 births in all—identified and analyzed 12 cohort studies and one case-control study, each of which assessed the accuracy of pulse oximetry in the detection of critical congenital heart defects.[5] Among the findings from this analysis was that the overall false-positive rate for pulse oximetry screening was 0.14 percent for tests conducted within 24 hours of birth, and 0.05 percent when conducted later than 24 hours after birth. As Attachment A, we provide an abstract that summarizes this analysis taken from the National Center for Biotechnology Information (NCBI) website.[6] Dr. Shakila Thangaratinam, lead author of the study, said the following about the findings:

> The findings of this meta-analysis provide compelling evidence for introduction of pulse oximetry as a screening method in clinical practice. The sensitivity of the test is higher than present strategies based on antenatal screening and clinical examination, and the false-positive rate is very low, especially when done after 24 hours of birth.

Notwithstanding the low false positive rate, it is undeniable that families whose infants experience such false positive results will be caused unneeded stress. Additionally, the subsequent testing will add to medical costs, especially if infants must be flown to larger communities to receive specialized care and/or echocardiograms. This could certainly be the case in rural Alaska communities without access to advanced medical care. On the other hand, the detection of severe heart disease in a baby before leaving the hospital may eliminate other extreme costs, like emergency room visits and expensive surgical repair and may be an important factor in saving lives.

We hope this is helpful. If you have questions or need additional information, please let us know.

[5] A meta-analysis is a quantitative statistical analysis of several separate but similar experiments or studies in order to test the pooled data for statistical significance. The study was headed up by physicians at the Women's Health Research Unit, Centre for Primary Care and Public Health, London School of Medicine and Dentistry, Queen Mary University of London.

[6] The NCBI's mission is to develop new information technologies to aid in the understanding of fundamental molecular and genetic processes that control health and disease(*www.ncbi.nlm.nih.gov/*)

Attachment A

"Pulse Oximetry Screening for CCHD in Asymptomatic Newborn Babies: a Systematic Review and Meta-Analysis," (An Abstract) 2012, from the National Center for Biotechnology Information's website.

Lancet. 2012 Jun 30;379(9835):2459-64. doi: 10.1016/S0140-6736(12)60107-X. Epub 2012 May 2.

Pulse oximetry screening for critical congenital heart defects in asymptomatic newborn babies: a systematic review and meta-analysis.

Thangaratinam S, Brown K, Zamora J, Khan KS, Ewer AK.

Women's Health Research Unit, Centre for Primary Care and Public Health, Barts and the London School of Medicine and Dentistry, Queen Mary University of London, London, UK. s.thangaratinam@qmul.ac.uk

Abstract

BACKGROUND: Screening for critical congenital heart defects in newborn babies can aid in early recognition, with the prospect of improved outcome. We assessed the performance of pulse oximetry as a screening method for the detection of critical congenital heart defects in asymptomatic newborn babies.

METHODS: In this systematic review, we searched Medline (1951-2011), Embase (1974-2011), Cochrane Library (2011), and Scisearch (1974-2011) for relevant citations with no language restriction. We selected studies that assessed the accuracy of pulse oximetry for the detection of critical congenital heart defects in asymptomatic newborn babies. Two reviewers selected studies that met the predefined criteria for population, tests, and outcomes. We calculated sensitivity, specificity, and corresponding 95% CIs for individual studies. A hierarchical receiver operating characteristic curve was fitted to generate summary estimates of sensitivity and specificity with a random effects model.

FINDINGS: We screened 552 studies and identified 13 eligible studies with data for 229,421 newborn babies. The overall sensitivity of pulse oximetry for detection of critical congenital heart defects was 76·5% (95% CI 67·7-83·5). The specificity was 99·9% (99·7-99·9), with a false-positive rate of 0·14% (0·06-0·33). The false-positive rate for detection of critical congenital heart defects was particularly low when newborn pulse oximetry was done after 24 h from birth than when it was done before 24 h (0·05% [0·02-0·12] vs 0·50 [0·29-0·86]; p=0·0017).

INTERPRETATION: Pulse oximetry is highly specific for detection of critical congenital heart defects with moderate sensitivity, that meets criteria for universal screening.

FUNDING: None.

Comment in

Pulse oximetry screening for critical congenital heart defects: a UK national survey. [Lancet. 2013]

Screening of newborn babies: from blood spot to bedside. [Lancet. 2012]

Newborn Metabolic Screening Program

- Home
- Services
- FAQ
- Resources
- Links
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Frequently Asked Questions (FAQ)

Please choose from one of the questions below about Newborn Metabolic Screening Program:

Why is my baby tested?

To help assure that your baby will be as healthy as possible. A simple blood test provides important information about your baby's health that you or even your doctor might not otherwise know. The Newborn Screening Program identifies the infants who may have one of the uncommon birth defects for which this program screens.

Early diagnoses and medical treatment can usually prevent complications such as mental retardation or even death from these serious conditions.

How is my baby tested?

All of the tests are performed on one tiny sample of blood obtained by pricking the new baby's heel. The blood is allowed to dry on a special absorbent paper, which is sent to the laboratory for testing.

All babies are required to be sampled prior to discharge from the hospital or birthing facility. The first specimen should be collected between 24 and 48 hours after birth; a follow-up specimen is required to be collected between 10 and 30 days of age.

Important: A sample collected before or after the recommended time period is better than no test at all. If you are not able to arrange testing or have questions, call (907) 269-4762 or 907-269-3430.

Remember: The conditions for which testing is done are treatable. The serious effects of these disorders can usually be completely prevented if treatment is started early enough.

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- Home
  - Our Programs
  - FAQ
  - Contact Us
- Adolescent Health
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  - Services
  - FAQ
  - Resources
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But we've never had any birth defects in our family. . .
Parents who have already had healthy children don't expect any problems with birth defects. They are almost **always** right. The disorders for which screening is done are not very common and chances are excellent that your child will NOT have one of these conditions. The few children who are born with these problems, however, are generally from healthy families. By testing every baby soon after birth, we can be sure that each infant who has a metabolic disorder will be identified and started on early treatment.

But my Baby seems very healthy. Are the tests still necessary?
Yes. Most infants with birth defects screened by this program show no obvious signs of disease immediately after birth. In each of these disorders there is an "invisible" problem in one of the many chemicals produced naturally in the baby's body. The Newborn Screening Program uses special laboratory tests to identify the infant who may have one of the disorders so that the baby's doctor can be alerted to the need for special care for the infant. Hopefully, this can be done before the condition has had time to cause damage.

If my baby has one of these disorders, can it be cured?
No, not really. It cannot be "cured," just as eye color and height cannot be permanently changed. The serious effects of the disorder can be lessened, however, and often completely prevented, if a special diet or other medical treatment is started early.

Will I be told the test results?
Your doctor or clinic will be informed when the tests are completed. Parents are notified only if there is a problem. You should, however, ask about the results when you take your baby to the doctor for a regular checkup. It is important to remember that these tests provide information only about some uncommon chemical disorders. An infant free of these disorders may have other medical problems for which these methods do not test. It is very important for your baby to have regular checkups and good general medical care.

If a retest is necessary, does that mean that my baby has one of these birth defects?
Not necessarily. Retesting may be required for a number of reasons. The most frequent reason is that the first sample did not contain enough blood to allow for completion of all tests. This does NOT mean there is anything wrong with your baby.

On the rare occasions when the first tests indicate a possible problem, the results are not considered final; a new blood sample is requested, and the tests are repeated. As a general rule, only when a child's test is unusual for a second time will the doctor discuss the need for further evaluation.

If you are asked to have your child retested, act quickly in order that repeat tests can be completed and final results obtained while the baby is still very young. It is very important that treatment, if needed, be started as quickly as possible.

How can I help the doctor to help my baby?
If the doctor asks you to bring in your baby for retesting, **DO IT AS SOON AS POSSIBLE!** If your child does have a disorder, prompt action is very important.

If you do not have a telephone, be sure to leave with your doctor the phone number of a friend, relative or neighbor who can contact you. Also be sure to notify your doctor immediately if you move after your baby is born. If your child should need to be retested, your doctor needs to know where to reach you. ***Remember, time is of great importance***.

For those babies not born in hospitals or maternity care facilities.
It is essential that a blood sample for screening be taken before the child is 5 days old. This can be done by a doctor or at

a Health Department clinic.

The ideal time for a sample collection is when the baby is 24-48 hours old for the 1st screen and 2-3 weeks of age for the 2nd screen. A sample collected before or after that is better than no test at all.

If my child is found to have a disorder, will my future children have it also?
It is possible in some cases that future children also may be affected. Families with affected children may obtain information about their future risks from trained professionals with the Alaska Genetic Services Program. For additional information about counseling services available in your area, call (907) 269-3430.

As a parent, you can help to assure the health of your children by your cooperation with the Newborn Screening Program.

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Answers to Frequently Asked Questions

Q: How much does the screening cost for the parents of a newborn?

The screening costs about $2.00 if a reusable probe is used. It costs about $8.00 if a disposable, single-use probe is utilized.

Q: How reliable are the screenings?

Newborn screening with pulse oximetry helps detect more than 75 percent of critical heart lesions, with a sensitivity rate of more than 99% and a false positive rate of less than .03 percent.

Q: Who manufactures the equipment for pulse oximetry testing?

To date, only Masimo corporation has been certified by the FDA as having proper testing equipment. This is because the equipment must meet a number of criteria, including that it be motion-tolerant, be able to report function oxygen saturation and have been validated in low-blood oxygen conditions.

Q: In the long run, does screening for CCHDs save money?

Yes. If an abnormal screening is detected it can lead to faster medical intervention preventing disability or death later on. The cost of screening is minimal compared to the cost of caring for a disabled child later. Not to mention the individual benefits for the child and the family.

Q: Does the Department of Health and Social Services currently have the regulatory authority to require this test?

No.

Q: Will this screening be covered by health insurers in Alaska?

Yes. See AS 21.42.345(b) and AS 21.42.351.

Q: How many other diseases are newborns screened for in Alaska?

Currently, the Department of Health and Social Services requires that 46 tests be performed on newborn infants. The vast majority of these tests are performed through the use of blood spot testing. Blood spot testing involves drawing a small amount of blood from the newborn and then sending that sample to a lab in Oregon for evaluation.

Q: How many infants will this impact?

It is estimated that 1 in 100 children will be born with a congenital heart defect. Heart disease kills more children in their first year of life than any other birth defect.