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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.

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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]