



# OLR RESEARCH REPORT

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## **PULSE OXIMETRY SCREENING OF NEWBORNS**

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You asked for information on pulse oximetry screening of newborns for congenital heart disease. You are interested in basic information about the procedure; its costs, including equipment and provider time; other states' activities in requiring such screening; and any other relevant information such as research studies.

### **SUMMARY**

Pulse oximetry screening is a simple and non-invasive procedure used to measure how much oxygen is in the blood and has been found effective in screening for congenital heart disease (CHD) in newborns. It uses a light source and sensor (probe) to measure oxygen in the blood.

Last year, the Advisory Committee on Heritable Diseases in Newborns and Children, which advises the federal Health and Human Services (HHS) secretary, recommended that pulse oximetry screening for CHD be added to the uniform screenings for newborns. Citing "evidence gaps," the HHS secretary did not adopt the recommendation. But an interagency coordinating committee on newborn screening is further examining the issue and should be submitting a plan to the HHS secretary shortly.

The American Heart Association (AHA) views pulse oximetry testing of newborns as an effective and inexpensive tool to assist in diagnosing CHD.

A large scale study recently performed in the United Kingdom supports pulse oximetry screening for newborns. The United States has not had a study of comparable size to date.

Three states (New Jersey, Maryland, and Indiana) have passed legislation requiring pulse oximetry screening of all newborns. The Maryland law will not be implemented until there are federal recommendations for such screening. Other states are currently considering such legislation.

## **BACKGROUND**

The following information is from the Children's National Medical Center in Washington, D.C.

### ***What is Congenital Heart Disease?***

CHD is the most common birth defect. Infants with CHD have abnormal structure to their heart which creates abnormal blood flow patterns. Approximately eight of every 1,000 infants born in the United States each year have a form of CHD, some of which cause no or very few problems in the health and development of the child. But critical CHD can bring a significant risk of morbidity and mortality if not diagnosed soon after birth. Failing to detect critical CHD while in the newborn nursery may lead to critical events such as cardiogenic shock or death. Survivors who present late are at greater risk for neurologic injury and subsequent developmental delay.

### ***What is Pulse Oximetry and How is it Performed?***

Pulse oximetry is a simple, non-invasive and painless test that is used to measure the percentage of oxygen saturation of hemoglobin in the arterial blood and the pulse rate. It was invented in the 1970s and is widely used and accepted in clinical care.

The pulse oximetry is placed by a sticky strip (like a band-aid), with a small red light, or "probe" on the baby's foot. The probe is attached to a wire, which is attached to a special monitor that shows the pulse oximetry reading. The test takes a few minutes to perform while the baby is still, quiet, and warm. The probe does not puncture the skin and the measurement can usually be read in 30 to 60 seconds.

### ***Why is Pulse Oximetry Used to Screen for CHD?***

Pulse oximetry is used to measure how much oxygen is in the blood. It is a routinely used test that can be used to monitor a baby's oxygen level during a procedure or treatment and can also be helpful in determining if a baby's heart and lungs are healthy. Pulse oximetry can also help to identify babies with serious heart problems due to low levels of oxygen in their blood. A health care provider may ask for more testing (such as an ultrasound of the heart or an echocardiogram) when a low pulse oximetry reading is identified.

### ***Who Should be Screened and When Will the Test be Done?***

According to the Children's National Medical Center, all babies in the newborn nursery who are not already thought to have CHD should be screened. The pulse oximetry test should be performed when a baby is older than 24 hours.

### ***What is a Normal Reading?***

A pulse oximetry reading of 95 to 100 percent is normal in healthy babies. Babies with heart or lung problems may have lower readings. A low reading can be normal in newborns whose lungs and heart are adjusting after birth.

### ***Can a Baby with Serious CHD Have a Normal Pulse Oximetry Reading?***

It is possible that the test will not detect all forms of problems in the baby's heart. In such a case, the center recommends that the baby have normal visits with his or her primary care provider.

## **STRENGTHS AND WEAKNESSES OF PULSE OXIMETRY**

Dr. John Hokanson of the University of Wisconsin School of Medicine and Public Health summarizes the strengths and weaknesses of pulse oximetry screening of newborns as follows:

*Strengths* - adds one last safety net for a number of newborns; pulse oximetry devices are cheap, non-invasive, and ubiquitous in hospitals.

*Weaknesses* - will not detect all forms of congenital heart disease; false positives and negatives; and main costs are incurred by follow-up testing to the pulse oximetry screening.

## **COSTS**

Many hospitals already have pulse oximetry machines and the only additional cost is for use of the probe which is about \$1 per reusable probe, or \$7 to \$8 for a single-use probe, according to the Children's National Medical Center. New Jersey (see below) estimates a cost of \$10 per screening. A screening may be repeated if test results show the blood is lacking oxygen, and then more expensive ultrasounds or echocardiograms would be performed. Nursing time required to do pulse oximetry testing on newborns averages about three minutes per baby.

Some critics of mandatory pulse oximetry screening raise the issue of the added cost of echocardiography in false-positive cases.

## **FEDERAL RECOMMENDATIONS**

Requiring pulse oximetry screening for newborns has been a state level issue for several years with proposals to have it included with other mandatory screenings for newborns. In October 2010, the Department HHS Advisory Committee on Heritable Diseases in Newborns and Children made a recommendation to add CHD to the uniform screening panel. It stated that "although there are recognizable evidence gaps, there are compelling reasons for recommending newborns for CHD."

HHS Secretary Kathleen Sebelius had 180 days to either adopt or reject this recommendation. In April 2011, she responded in a letter to the Advisory Committee's chairperson acknowledging the "recognizable evidence gaps" and stated:

"After consultation with HHS agency leadership, I have determined that the Advisory Committee's recommendations are not ready for adoption. However, because this is such an important issue, I am referring these recommendations to the newly established Interagency Coordinating Committee on Newborn and Child Screening (ICC) for additional review and input regarding implementation."

(The secretary's complete correspondence can be read at: <http://www.hrsa.gov/heritabledisorderscommittee/correspondence/CCCHDsecResponse042011.pdf>)

The ICC includes the National Institutes of Health, Centers for Disease Control and Prevention, Health Resources and Services Administration, Agency for Healthcare research and Quality, and the Food and Drug Administration. The ICC is examining the evidence gaps as described by the Advisory Committee and will propose a plan of action to address the identification of effective screening technologies, development of diagnostic processes and protocols, education of providers and the public, and strengthening infrastructure needs for follow-up and surveillance.

## **AHA POLICY POSITION**

The AHA issued a policy position statement on pulse oximetry screening of newborns in November 2010. It states:

The AHA continues to advocate for effective, comprehensive screening for critical (requiring surgical or catheter intervention in the first year of life) congenital heart disease in newborns. Pulse oximetry testing before discharge may be one important strategy for such screening as it can be an effective, noninvasive, inexpensive tool to assist in diagnosing critical congenital heart disease. While the risk for use of this screening is minimal, and the benefits are still being fully elucidated, the AHA reaffirms its current recommendation supporting consideration of pulse oximetry as a screening methodology (Class IIA-Level of Evidence C)<sup>1</sup> based on consensus science versus extensive randomized controlled trials.

## **RECENT UNITED KINGDOM STUDY**

In one of the largest studies of its kind, United Kingdom researchers have demonstrated that pulse oximetry testing of newborns improves the detection of critical congenital heart disease, identifying defects that go undetected with antenatal ultrasound. The study, published in *Lancet* this month, involved the pulse oximetry screening, between February 2008 and January 2009, of 20,055 apparently healthy newborns from six maternity units across the United Kingdom. Of the total number of babies, 53 had major congenital heart disease (24 critical), a prevalence of 2.6 per 1000 live births. Pulse oximetry detected 75% of the critical cases and 49% of all major congenital heart defects.

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<sup>1</sup> This indicates that the benefit exceeds the risk, and it is reasonable to perform the procedure. The recommendation is in favor of the treatment or procedure being useful/effective. The evidence is based on consensus/opinion of experts, case studies, or standard of care.

Lead author of the study Dr. Andrew Ewer stated that “pulse oximetry is a better more sensitive test than antenatal ultrasound and physical exam, although we are not suggesting we should replace those, but rather include pulse-ox as an additional screening tool, which would allow us to identify the majority of babies with critical congenital heart disease.”

For a link to the study go to:  
[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(11\)60753-8/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60753-8/fulltext)

## **ACTIVITY IN OTHER STATES**

New Jersey was the first state to require that every newborn be tested for congenital heart disease using pulse oximetry screening. Maryland was actually the first state to pass such legislation but has not yet implemented it as it awaits federal recommendations. Indiana recently passed a screening requirement as part of a budget bill. Other states currently considering legislation include New York, Pennsylvania, and Tennessee. Minnesota is operating a pulse oximetry screening pilot program at five hospitals in the state.

### ***New Jersey***

New Jersey passed legislation earlier this year requiring each birthing facility licensed by its Department of Health and Senior Services to perform a pulse oximetry screening for CHDs on every newborn in the state that is at least 24 hours old (P.L. 2011, Chapter 74, Assembly No. 3744). A “birthing facility” means a licensed inpatient or ambulatory health care facility that provides birthing and newborn care services. (The act takes effect August 31, 2011.)

The legislation makes a number of findings and declarations including:

1. current methods for detecting CHDs generally include prenatal ultrasound screening and repeated clinical examinations;
2. while prenatal ultrasound screenings can detect some major CHDs, these screenings, alone, identify less than half of all CHD cases;
3. critical CHD cases are often missed during routine clinical exams performed prior to a newborn’s discharge from a birthing facility;

4. pulse oximetry is a non-invasive test that estimates that percentage of hemoglobin in blood that is saturated with oxygen;
5. when performed on a newborn a minimum of 24 hours after birth, pulse oximetry screening is often more effective at detecting critical, life-threatening CHDs which otherwise go undetected by current screening methods;
6. newborns with abnormal pulse oximetry results require immediate confirmatory testing and intervention; and
7. Many newborn lives could potentially be saved by earlier detection and treatment of CHDs if birthing facilities were required to perform this simple, non-invasive newborn screening in conjunction with current CHD screening methods.

### ***Maryland***

Maryland's legislation (Chapter 553, HB 714), passed in May 2011, requires the state Department of Health and Mental Hygiene to adopt the federal screening recommendations if the HHS secretary issues recommendations on critical heart disease screening of newborns. The legislation also directs the State Advisory Council on Hereditary and Congenital Disorders to develop recommendations on implementing critical CHD screening of newborns. The advisory council must:

1. convene experts from the State's academic medical centers and any other hospital that the council considers appropriate, as well as other state organizations and professional groups, to provide information for the development of recommendations for critical congenital heart disease screening of newborns in the state;
2. examine the impact of implementing mandatory critical congenital heart disease screening, including an examination of costs, insurance reimbursement, necessary medical equipment and staff training, screening protocols and quality oversight, and risk of harm; and
3. review medical and public health studies and literature across a broad range of newborn delivery systems with respect to critical congenital heart disease screening of newborns.

The advisory council must report its findings and recommendations on the implementation of critical CHD screening of newborns, by December 31, 2011, to specified legislative committees.

Notwithstanding any recommendation the council develops, the state Health and Mental Hygiene Department must adopt the federal screening recommendations if issued by HHS.

(The fiscal note for this legislation is attached.)

### ***Indiana***

Proposed legislation in Indiana would require pulse oximetry screening of newborns for low oxygen levels beginning January 1, 2012. It requires the Indiana State Department of Health (ISDH) to (1) develop procedures and protocols for the testing and (2) report to the Indiana legislative council, by October 31, 2011, certain information on the screening (SB 0552). The bill was referred to the Public Health committee where it died. (A fiscal note prepared on the bill by the Indiana General Assembly's Office of Fiscal and Management Analysis is attached.)

Another bill, the 2011 budget bill (HB 1001), passed with did not language on pulse oximetry screening of newborns. Beginning January 1, 2012, every infant must be given a pulse oximetry screening examination at the earliest feasible time for detection of low oxygen levels. An infant is exempt from the screening if a parent objects in writing for reasons of religious beliefs only (Indiana Code, §§ 16-41-17-2).

### ***New York***

Assembly Bill 7941 of the 2011 New York Legislature requires the commissioner of the state health department to establish a newborn screening program using pulse oximetry screening to detect CHDs. The bill specifies that it is the duty of the administrative officer or other designated person at each licensed facility caring for newborns to perform such screening a minimum of 24 hours after the birth of every newborn in its care.

Facilities subject to this requirement must report to the department (1) the results of each screening and (2) other information or data that the department requires.

The bill was referred to the Assembly's health committee on May 25, 2011. No further action on the bill has been taken to date.

### ***Pennsylvania***

Legislation was introduced in the Pennsylvania General Assembly on July 25, 2011. The bill would amend the state's Newborn Child Testing Act by adding a requirement that each health care provider that provides birthing and newborn care services perform a pulse oximetry screening a minimum of 24 hours after the birth of every newborn in its care (SB 1202). No further action has been taken to date.

### ***Tennessee***

Proposed Tennessee legislation requires the state's genetic advisory committee to develop a program to screen newborns for critical CHD using pulse oximetry. It requires (1) hospitals and other birthing facilities to provide the screening prior to discharge, (2) attending health care professionals to refer newborns born in settings other than a hospital or other birthing facility to the state health department or an appropriate screening provider approved by the department, and (3) all screening providers to report their results to the department. The health department must refer newborns who do not pass the screening to appropriate providers for follow-up (SB 65, HB 373).

The bill has passed the Senate and awaits House action.

(A copy of the fiscal note is attached.)

### ***Minnesota***

In Minnesota, a working group of pediatric cardiologists, neonatologists, state officials, and administrators devised a plan to implement newborn screenings for critical CHDs. As a result of their efforts, beginning in the summer of 2010 five Minnesota hospitals are participating in a newborn pulse oximetry screening pilot program. The Minnesota Department of Health supports this project and plans to expand it to other Minnesota hospitals, eventually creating a statewide program. For more information see:  
[http://www.uofmchildrenshospital.org/fv/groups/internet/documents/web\\_content/s\\_027896.pdf](http://www.uofmchildrenshospital.org/fv/groups/internet/documents/web_content/s_027896.pdf)

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