

Background Briefing

Newborn Screening for Critical Congenital Heart Disease

Timeline

July 2009 – AHA/AAP statement on role of pulse oximetry in detecting congenital heart defects.

January 2010 – Condition Nominated, SACHDNC (Secretary's Advisory Committee on Heritable Disorders in Newborns and Children), committee unanimously votes to nominate condition and begin external review process.

January - September 2010 – External workgroup continued assessment and gap analysis of condition and screening, reports to SACHDNC.

September 2010 – Report and SACHDNC review, Committee votes to recommend all newborns in the United States be screened for Critical Congenital Heart Disease stating:

Undetected critical congenital heart disease is an important cause of morbidity and mortality.

Newborn pulse oximetry screening has been recommended to promote early detection and intervention.

October 2010 – Formal letter from Chairman Howell and the SACHDNC sent to the Secretary of Health and Human Services recommending newborn screening for Critical Congenital Heart Disease.

January 2011 – HRSA convened a federal Implementation Workgroup to develop strategies for implementation of safe, effective, and efficient screening programs and included experts in pulse oximetry screening, general pediatrics, neonatology, pediatric cardiology, nursing, healthcare delivery, public health, advocacy, medical education, and genetics, and representatives the United States Department of Health and Human Services.

Results: There was uniform support among the workgroup for screening for CCHD, and consensus for a standard protocol for screening. A Strategies document was developed to reflect the workgroup's guidance, which has been endorsed by the CDC, NIH, HRSA, AHA, AAP, and ACC (to be published in *Pediatrics*, Fall 2011).

Conclusions: There was strong consensus among the workgroup members that there is sufficient evidence to begin pulse oximetry screening, a low-cost, non-invasive, point of care evaluation to determine oxygen saturation in the blood, in well-baby and intermediate-care nurseries.

The workgroup called for additional research to evaluate service infrastructure and delivery strategies (e.g., telemedicine) for nurseries without onsite echocardiography. Public health agencies will have an important role in quality assurance and surveillance.

April 2011 - The Department of Health and Human Services held a stakeholder call to announce the Secretary's interim statement on the SACHDNC recommendation. It was clearly stated that the Secretary recognizes the critical importance of CCHD screening, and requested further efforts be undertaken immediately to work through the issues surrounding the pulse ox technology itself, follow up diagnostics, service infrastructure, and follow up.

The Newborn Screening Saves Lives Act (of 2007) required the formation of this supplemental Interagency Coordinating Committee on Newborn and Child Screening issues. This committee includes directors of the CDC, HRSA, NIH and AHRQ – tasked with the immediate review of the CCHD recommendation and to provide a plan of action within 90 days.

July 2011 – The ICC's action plan has been delivered to the Secretary and is awaiting a response.

August 2011 – Report developed by the expert federal workgroup on Newborn Screening for CCHD is published in *Pediatrics*, and endorsed by the American Academy of Pediatrics, the American Heart Association, and the American College of Cardiology.

About Newborn Screening for Critical Congenital Heart Disease

1. **Unprecedented support.** There has been an unprecedented level of collaboration for the recommendation, which is supported by three separate federal bodies (NIH, CDC, HRSA), the American Academy of Pediatrics, the American Heart Association, the pediatric cardiology, neonatology and parent advocate communities. It underwent a rigorous and established process - that is squarely in place to provide the Secretary of Health and Human Services with a comprehensive, fully-vetted and peer-reviewed recommendation

The Obama Administration has stated, as recently as February of this year, as supporting investments in research, early diagnosis and earlier treatment options for heart disease.

2. **Low cost, easy implementation.** Because of its non-invasive nature, this simple diagnostic tool is already known as “the 5th vital sign” among the health care community. Pulse oximetry equipment is already available in every US hospital and birthing center.

The cost is equivalent to that of a diaper change and is equivalent or less than that of other currently recommended screening tests. Comparatively, the cost of newborn hearing screening is \$30 or more per infant. Pulse oximetry is routinely used in nearly every hospital in the U.S. already, requires little training, and is scalable, even in outlying areas without existing pediatric cardiology on site.

Moreover, the cost of pulse oximetry is significantly offset by avoided costs of care. The recent report on screening from Sweden calculated that the savings in healthcare costs from the prevention of one case of complications of circulatory collapse resulting from an undiagnosed CCHD may exceed the cost of screening two thousand newborns.

3. Early diagnosis. Each year, thousands of babies are going home from the hospital – seemingly healthy. We know that the costs (human and financial) of delayed diagnosis are extreme – with infants presenting in the emergency room in shock or in heart failure – often resulting in neurological impairment, developmental delays, feeding issues, organ failure, highly invasive procedures and potentially death. Early detection and early treatment of heart defects led to exponentially improved outcomes. Recent study data has shown a 10-fold increase in the number of babies that can be detected before discharge with the support of pulse oximetry screening in the newborn nursery.

Additionally, early diagnosis also supports CHD research and development of new innovations in heart repair that are less invasive and improve outcomes. Long-term costs are even more greatly reduced by mitigating against multiple surgeries, neurological and developmental delays associated with late diagnosis. And this screening saves lives – with treatments that have advanced to the level of being truly curative.

4. Public Health need. Early detection of heart disease in our youngest citizens is a vital public health issue – and has been one of the greatest unaddressed health concerns facing newborn and babies. The sheer volume of children impacted alone has long warranted a review of screening measures that can prevent morbidity and mortality.

As the most prevalent birth defect, claiming the highest number of infant lives, early detection of CCHD must be considered a vital public health need. The U.S. population of CHD survivors is increasing by 5 percent each year. With early detection, patients can benefit from improved care coordination, fewer surgical interventions, reduced morbidity and mortality.

Without this important tool for early detection, minority, rural and underserved populations in particular will continue to suffer disparities in access, quality care and outcomes.

More about the SACHDNC:

<http://www.hrsa.gov/heritabledisorderscommittee/>

More about Workgroup on Screening for CCHD:

<http://altarum.cvent.com/events/ccchd-meeting/custom-22-f8929dc795694e7aa6c588c263e31554.aspx>

Facts about Congenital Heart Disease

- Congenital Heart Defects are the #1 birth defect. Source: March of Dimes
- Congenital Heart Defects are the #1 cause of birth defect related deaths. Source: March of Dimes
- About 1 out of every 100 babies are born each year with some type of Congenital Heart Defect. (approx. 40,000/year) Source: CHF
- Nearly twice as many children die from Congenital Heart Defects in the United States each year as from all forms of childhood cancers combined.
- This year approximately 4,000 babies will not live to see their first birthday because of Congenital Heart Defects. Source: Children's Heart Foundation
- The occurrence rate for CHD is ten times that of the next nearest identified disease routinely screened for. Fewer than half of CHD cases are diagnosed prenatally – and the number dips to 25% or lower in rural and underserved areas.
- The cost for inpatient surgery to repair Congenital Heart Defects exceeds \$2.2 billion a year. Source: Children's Heart Foundation
- All of the critical defects above can be effectively detected through newborn screening for CCHD using pulse oximetry.
- Fewer than 50 percent of babies will be diagnosed during gestation, even fewer in rural and underserved communities. Sometimes the diagnosis is not made until days, weeks, months, or even years after. With few signs or symptoms, babies are routinely discharged from the hospital undiagnosed - with catastrophic consequences.
- It is a proven fact that the earlier CHD is detected and treated, it is more likely the affected child will survive and have less long term health complications. Source: March of Dimes

State by State Landscape

As of July 2011, two states have passed legislation to begin routine newborn screening for critical congenital heart defects. Six additional states have introduced legislation or and another half dozen have bills pending. A growing number of states have hospitals or health systems that are already implementing pulse oximetry evaluation in the newborn nursery as a standard of care.

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