Critical Congenital Heart Disease

More than 4 million newborns in the United States receive newborn screening each year to identify a variety of genetic and other congenital disorders. Newborn screening tests help prevent or limit the medical consequences associated with conditions that are generally asymptomatic and cannot be seen by looking at the infant (i.e., metabolic, endocrine, hemoglobin, infectious, and hearing issues). Determining these conditions prior to being discharged from the hospital can prevent serious problems later in life.

However, conditions associated with congenital cardiac malformations are not always evident through routine screening procedures and are often missed. The use of pulse oximetry to screen for these severe congenital abnormalities has been shown to be effective in identifying these conditions early and has the potential to save many newborns' lives.

> Approximately 280 infants are discharged from U.S. hospitals each year with unrecognized critical congenital heart disease (CCHD). Infants with CCHD require surgical intervention soon after birth to avoid premature death.

Congenital Heart Defect (CHD)

A congenital heart defect (CHD) is a structural or functional heart abnormality that is present at birth. Each year, approximately 40,000 babies in the United States are born with a CHD.[1,2,3,4] CHD conditions change the normal blood flow into the heart and out through the rest of the body, ranging in severity from asymptomatic defects to life-threatening conditions. Defects can involve the heart's interior walls, the heart valves, or the arteries and veins. Although CHD is present at birth, symptoms may not appear until childhood or even into adulthood.

CHD is the most common type of birth defect, affecting seven to nine of every 1,000 newborns, or approximately 1 percent of births. Parents who have had a child with a CHD are at an increased risk, about 2 to 3 percent, of having other affected children.[5] CHD is the leading cause of infant death due to birth defects, accounting for 28 percent of deaths in the first month of life and about 50 percent of deaths due to birth defects during the first two to 12 months.[6,7] Unfortunately, CHD is often unrecognized, and infants are discharged from the hospital with undiagnosed conditions. Recent studies estimate approximately one in 20,000 to one in 40,000 live births result in death from unrecognized CHD.[8,9,10]

Critical Congenital Heart Disease (CCHD)

Critical congenital heart disease (CCHD) is a group of heart defects that cause serious, often life-threatening symptoms and account for more deaths than any other type of congenital malformation.[11,12] Nearly 4,800 babies born each year in the United States have CCHD, and nearly 280 infants with unrecognized CCHD are discharged annually.[13] CCHDs often go undetected because some babies will appear healthy at first and are discharged from the hospital before any defect is detected. However, due to the severity of these conditions, immediate followup to determine the best method of treatment or intervention is necessary.

CCHD is associated with hypoxemia (insufficient levels of oxygen in the blood or tissues) among infants during the newborn period, and hypoxemia represents 17-31 percent of all CHDs.[14,15] The seven primary targets of CCHD screening include: hypoplastic left heart syndrome, pulmonary atresia (with intact ventricular septum), tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the

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great arteries, tricuspid atresia, and truncus arteriosus. Infants with these conditions require surgical or catheter intervention within the first few days or first year of life. Without early diagnosis or treatment, infants with CCHDs are at significant risk of morbidity or mortality due to physiological changes of the heart (e.g., closing of the ductus arteriosus).[16]

Screening for CCHD

In the United States, an estimated 4,800 babies born each year in the United States have CCHD, and nearly 280 of those infants may be missed by routine newborn cardiac screening.[17] Prenatal ultrasound has been used for many years to screen for congenital abnormalities and plays an important role in identifying CCHD. However, ultrasound quality can vary depending on the technician's training or the medical professional performing the test.[18]
In addition, access to and availability of this type of prenatal screening may be limited in rural or low socioeconomic status areas and within certain racial/ethnic groups.[19,20,21]

Pulse oximetry screening is a non-invasive method of determining whether a newborn suffers from hypoxemia, insufficient levels of oxygen, associated with CCHD conditions.

Once the baby is born, healthcare providers typically perform a physical examination within the first 24 hours of life and during additional nursery visits. Supplemental tests (e.g., electrocardiograms, echocardiograms, and chest radiographs) are performed when something abnormal is suspected.

Due to CCHD conditions' association with hypoxemia, pulse oximetry has been suggested as complementary test for newborn physical examinations.[22,23,24] Pulse oximetry is a non-invasive method to determine the percentage of hemoglobin in the blood that is saturated with oxygen. This screening method has the potential to identify hypoxemia that may not produce visible cyanosis (i.e., blue or purple skin coloration due to low oxygen), especially in black or Hispanic newborns due to the darker pigment of their skin.

Recommended Uniform Screening Panel

All 50 states, DC, Guam, Puerto Rico, and the U.S. Virgin Islands operate their own newborn screening programs. The HHS Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) endorses a recommended uniform screening panel for every newborn screening program to screen for 31 core disorders and 26 secondary disorders. Each state has their own process to assess these recommendations and apply them as applicable to their state.

On Sept. 21, 2011, HHS Secretary Kathleen Sebelius recommended that CCHD screening be added to the recommended uniform screening panel core conditions based on the advisory committee's recommendations and the document *Strategies for Implementing Screening for Critical Congenital Heart Disease*.[25] The strategies document summarizes the findings and recommendations of a workgroup—assembled by SACHDNC, the American Academy of Pediatrics (AAP), the American College of Cardiology Foundation, and the American Heart Association—to develop implementation strategies for screening and diagnostic follow up using the currently available data. AAP also endorsed the HHS recommendation for pulse oximetry screening for CCHD.[26]

Costs Associated with Pulse Oximetry Screening

Estimates for conducting pulse oximetry screening range between $5 and $10 per infant, depending on the protocol used.[27] However, there are other associated costs, including: staff time conducting pulse oximetry screening, as well as education and training; maintaining the equipment and ensuring there are ample supplies to conduct the screenings in hospitals and birthing facilities; tracking results; following up with families regarding the results; verifying positive screening results; and treatment costs.

Overcoming Barriers to Implementation

Many states are moving toward legislation requiring all of their birthing hospitals to screen for CCHD. To date, routine CCHD screening has been voluntarily initiated in many hospitals across the United States without state mandates, yet long term sustainability has not been evaluated. To assess the feasibility of and barriers to implementing universal CCHD screening, CDC partnered with the Georgia Department of Public Health in June 2012 to conduct two surveys to better understand CCHD screening practices, particularly in a state that does not currently mandate CCHD screening.[28] The barriers that were identified included the lack of a clear follow-up protocol for positive screenings, uncertainty about how often and the types of screening results to report to public health organizations, and concerns around the screening's costs. Although reports on the implementation of universal CCHD screening are limited, the CDC recommends the following to overcome any potential barriers:

1. Provide guidance to hospitals on the type and frequency of data that should be reported.
2. Develop educational materials for hospitals on CCHD's signs and symptoms and the pulse oximetry screening protocol endorsed by AAP or state-mandated protocol.
3. Develop educational materials to disseminate to parents about CCHD screening.
4. Develop working agreements with hospitals to ensure access to echocardiography and followup for all newborns with possible CCHD.

The Role of State and Territorial Health Agencies

Due to the immediate follow-up that is needed at the hospital prior to discharge for infants with positive CCHD screening results, state and territorial health agencies'(S/THAs) CCHD screening roles may be more limited than with other newborn screening programs. However, S/THAs play several important roles in CCHD screening, including:

- Informing the public about CCHD screening.
- Ensuring providers are appropriately trained and using standardized protocols.
- Surveillance activities related to CCHD screening.

S/THAs have the responsibility of informing the public about CCHD screening. This includes providing educational materials to targeted audiences to raise awareness of CCHD's significance and pulse oximetry screening. By partnering with hospitals, birthing centers, and obstetricians, S/THAs can reach expectant mothers/parents, healthcare professionals who are conducting CCHD screenings, and other healthcare providers.

S/THAs should also ensure that the providers who are responsible for conducting the pulse oximetry screening are appropriately trained to conduct the screenings. To facilitate standardized implementation for their state or territory, S/THAs, working with state and national experts, can develop

and promote screening and short-term diagnostic follow-up protocols for all birthing hospitals. In addition, S/THAs can develop long-term follow-up protocols to ensure affected families have access to the appropriate care and, if necessary, help coordinate health services. This will help provide some level of quality assurance in the state/territory.

S/THAs also have an important role in the surveillance activities related to CCHD screening. Using the information that is collected through CCHD screening, S/THAs can track the number of infants who are screened, identify the rates of positive or negative screenings, and determine the number of infants who missed screenings. This surveillance helps states/territories target facilities that are reporting high rates of missed CCHD screenings and provide technical assistance through education and training. Such data collection activities will facilitate evaluating the screening's effectiveness in the short and long term. S/THAs should also coordinate efforts with their state's Title V Maternal and Child Health programs and state-based birth defects surveillance programs. Although these programs' resources and surveillance approaches vary, they have infrastructure in place and may be able to assist with collecting CCHD screening-related data.

State Strategies for Implementing CCHD Screening

New Jersey
In August 2011, New Jersey became the first state to implement legislatively mandated newborn pulse oximetry screening. The unfunded legislation (P.L. 2011, Chapter 74, Assembly No. 3744) was signed on June 2, 2011 and went into effect on Aug. 31, 2011.

Steps Taken
- The New Jersey Department of Health (NJDOH) convened the New Jersey Critical Congenital Heart Disease Screening Working Group. The group's initial focus was on developing a recommended standard protocol for birthing facilities to follow when conducting the pulse oximetry screening.
- NJDOH disseminated the protocol to each of the facilities, and education and training began through webinars, frequent communication with hospitals, and regional conferences for nurses. NJDOH also developed parent education materials and created an informational web page. In addition, NJDOH made plans to develop best practice guidelines, provide physician education, and create web-based education programs.
- NJDOH instituted a two-pronged surveillance plan to track screening consisting of: (1) aggregate screening data that the hospitals reported to NJDOH on a quarterly basis, and (2) individual level data on all failed screens reported to the New Jersey Birth Defects Registry.

Results
- Data published in the *Morbidity and Mortality Weekly Report* in 2011 from 11 surveyed hospitals revealed that incorporating mandated screening into the routine clinical nursing care posed a minimal burden. Submitting aggregate data reports was reported as a moderate burden.[29]
- In the first nine months of screening, approximately 99 percent of the 73,320 eligible infants were reported to have been screened.
- In that same time period, three infants with previously unsuspected CCHD and another 17 infants with other diagnoses or non-CCHD echocardiogram findings were detected as a result of the mandated screening.[30]

Lessons Learned

- Initial challenges to implementing the screening legislation included setting up the infrastructure within a short timeframe and limited staffing and financial resources because the mandate was unfunded.
- Using the flexibility of the existing infrastructure and the hospitals' and NJDOH personnel's collaborative efforts, high rates of screening were obtained following implementation of mandated statewide CCHD screening.
- Considering several key indicators was important to evaluate how many CCHD cases screening detected that would not have been identified through routine clinical care. These included documenting prenatal diagnosis of CCHD, whether there were symptoms at the time of the screen that would have otherwise warranted a pulse oximetry measurement, or whether a cardiac consult or echocardiogram was indicated.
- Quality assurance activities should be performed on a regular basis at hospitals to ensure that infants are not missed and that the disposition on each infant is aligned with their screening results.
- Future activities involve integrating CCHD screening results into a NJDOH electronic birth reporting system that is currently under development.

Indiana

Every baby born in Indiana is now required to receive CCHD screening as part of the state-mandated newborn screening panel. The Indiana General Assembly amended the state's newborn screening law (IC 16-41-17) in June 2011 to include pulse oximetry screening for CCHD beginning Jan. 1, 2012. The Indiana State Department of Health (ISDH) adopted the SACHDNC-approved pulse oximetry screening protocol.

Steps Taken

- ISDH announced the addition of CCHD screening to the newborn screening panel through an email blast in June 2011 and the Indiana Perinatal Network's CCHD-related messaging.
- Birthing facility surveys were administered in July 2011 to obtain a statewide picture of hospitals' ability to implement CCHD screening and where infants who did not pass the screening would receive care.
- A second email blast was sent to medical professionals and each facility's newborn screening coordinator in October 2011 to update them on the finalized protocol and provide more CCHD-related information, including a link to the professionals' portal on the ISDH newborn screening program website.
- A second survey was administered to OB/labor and delivery/nursery managers to capture any final questions or concerns that needed to be addressed prior to Jan. 1, 2012, when implementation of pulse oximetry screening was required.
- The ISDH newborn screening program followed up individually with any site that did not complete the survey. Birthing facilities were also required to submit the contact information of the person(s) who would be completing CCHD monthly summary reports. The new law requires facilities to submit reports that include detailed information on infants who do not pass the CCHD screening and those who did not receive a valid CCHD screen.
- Indiana's Newborn Screening Program budget allowed for the funding of CCHD screening implementation.

Results

- The initial survey results indicated that of the 49 facilities surveyed, 83.7 percent stated that their facility did not currently perform routine pulse oximetry screening on newborns. Additionally, 83.7 percent stated that their facility had the ability to perform the screening. Furthermore, 71 percent of facilities reported that they already had staff that were trained to perform the screening. Nearly 60 percent of facilities indicated that follow-up care would be performed and interpreted at their site and would not require a transfer to another facility.
- Birthing facilities use the Indiana Newborn Screening Tracking and Education Program's (INSTEP) web-based application to submit newborn screening monthly reports for bloodspot sample data as well as CCHD screening data.
- INSTEP partners with the Indiana Birth Defects and Problems Registry to obtain follow-up information about infants who do not pass their CCHD screening. The registry collects birth defects data for all children born in Indiana from birth through age 3. This data is used to ensure that infants receive timely and appropriate followup, evaluate health-related outcomes for children diagnosed with CCHD, and help evaluate the current standards of care for CCHD statewide.

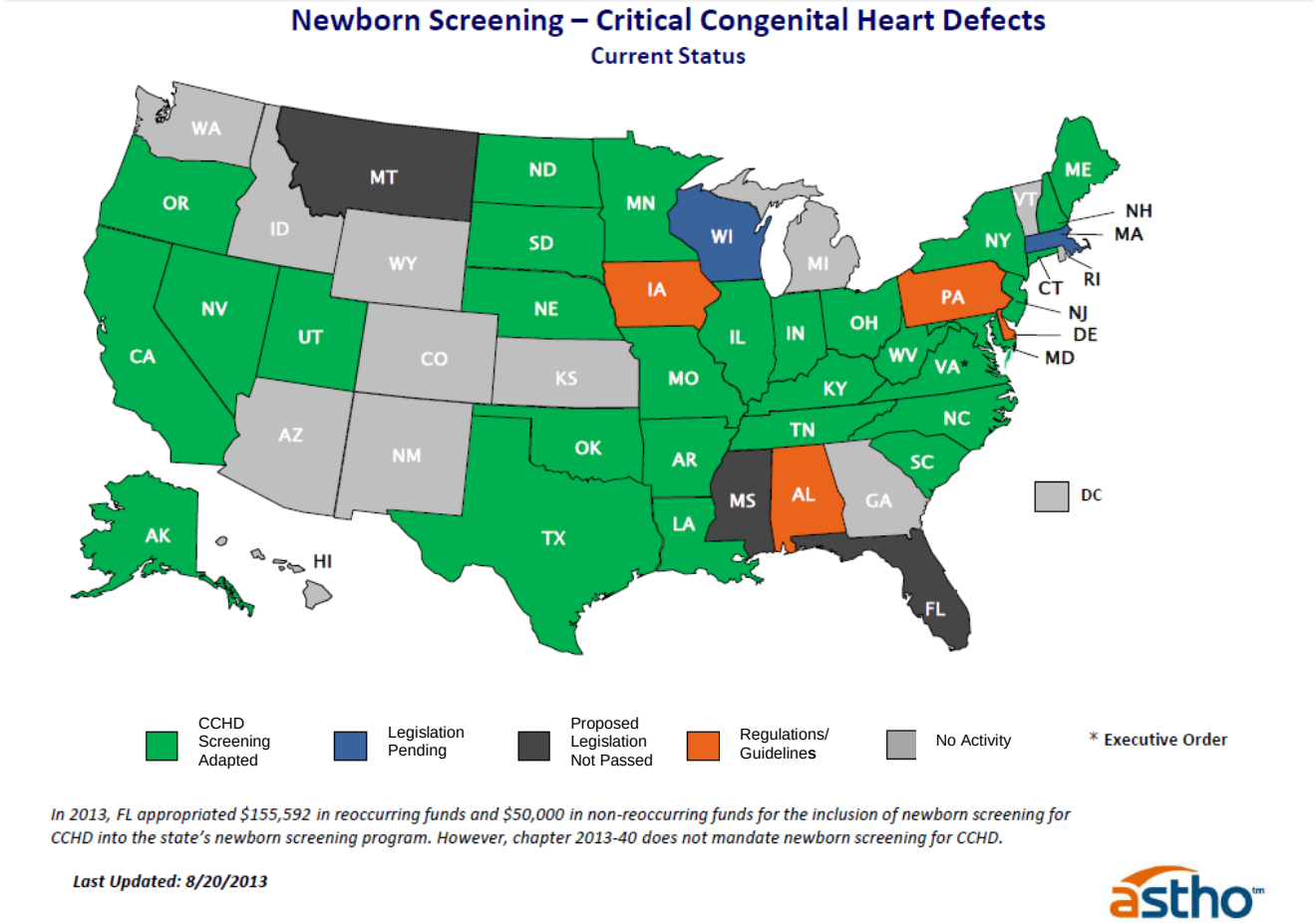
Current Status

- Beginning June 1, 2013, Indiana began collecting CCHD screening results on the bloodspot card. The state is currently evaluating follow up protocols for CCHD data obtained via the bloodspot card.
- Indiana continues to evaluate the best available methods for collecting CCHD screening data for all children, including demographic and CCHD screening results and training staff on appropriate CCHD screening protocol.

CCHD Legislation Tracking Tools

- ASTHO State Legislative Tracking: http://www.astho.org/State-Legislative-Tracking/
- ASTHO CCHD Legislative Tracking Map: http://www.astho.org/Public-Policy/State-Health-Policy/Newborn-Screening-Heart-Defects-Map/ *(link to an updated version of the map shown below)*
- Newborn Coalition CCHD Screening Map: http://cchdscreeningmap.org/

Critical Congenital Heart Disease



In 2013, FL appropriated $155,592 in reoccurring funds and $50,000 in non-reoccurring funds for the inclusion of newborn screening for CCHD into the state's newborn screening program. However, chapter 2013-40 does not mandate newborn screening for CCHD.

Last Updated: 8/20/2013

29 States That Have Passed CCHD Legislation *(current as of 8/20/13)*

State	Bill no.	State	Bill no.
Alaska	SB 87	New Jersey	AB 3744
Arkansas	HB 1468	New York	SB 270/AB 2316
California	AB 1731	North Carolina	SB 98
Connecticut	SB 56	North Dakota	SB 2172
Illinois	HB 2661	Ohio	SB 4
Indiana	HB 1001	Oklahoma	HB 1347 (download link)
Kentucky	SB 125 (download link)	Oregon	SB 172
Louisiana	HB 322	South Carolina	SB 341
Maine	HB 460	South Dakota	SB 168
Maryland	SB 786	Tennessee	SB 65
Minnesota	HB 483/SB 473	Texas	HB 740
Missouri	HB 274/SB 230	Utah	HB 276
Nebraska	LB 225	Virginia	Executive Order
Nevada	SB 92	West Virginia	HB 4327
New Hampshire	SB 348		

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