State of Maryland

Department of Health and Mental Hygiene
State Advisory Council on Hereditary and Congenital Disorders

Martin O'Malley, Governor • Joshua M. Sharfstein, MD, Secretary
Miriam G. Blitzer, PhD, Chair

December 31, 2011

The Honorable Thomas Middleton, Chair
Senate Finance Committee
Miller Senate Office Building
3 East Wing, 11 Bladen Street
Annapolis, MD 21401-1991

The Honorable Peter Hammen, Chair
House Health and Government Operations Committee
House Office Building
Room 241, 6 Bladen Street
Annapolis, MD 21401-1991

RE: HB 714/SB 786 (Ch. 552/Ch. 553) of the Acts of 2011
2011 Legislative Report on Critical Congenital Heart Disease Screening in Newborns

Dear Chair Middleton and Chair Hammen:

House Bill 714/Senate Bill 786 (2011) requires the State Advisory Council on Hereditary and Congenital Disorders to convene an expert panel to study the implementation of critical congenital heart disease screening of newborns in Maryland and submit its findings and recommendations in this one-time legislative report.

I hope this information is useful. If you have questions about this report, please contact me at 410-706-3480 or mblitzer@peds.umaryland.edu.

Sincerely,

Miriam G. Blitzer, PhD
Chair

Enclosure

cc: Senate Finance Committee Members
House Health and Government Operations Committee Members
Marie L. Grant, JD
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STATE ADVISORY COUNCIL ON HEREDITARY AND CONGENITAL DISORDERS

RECOMMENDATIONS ON IMPLEMENTATION OF SCREENING FOR CRITICAL CONGENITAL HEART DISEASE IN NEWBORNS

2011 LEGISLATIVE REPORT

Martin O'Malley Governor	Anthony G. Brown Lt. Governor	Joshua M. Sharfstein, MD Secretary, Department of Health and Mental Hygiene

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Executive Summary

Federal Recommendation

House Bill 714 (crossfile Senate Bill 786) (2011) charged the Maryland State Advisory Council on Hereditary and Congenital Disorders (Advisory Council) with convening an expert panel to study and develop recommendations on the implementation of critical congenital heart disease (CCHD) screening of newborns in Maryland. This legislation further requires that if the Secretary of Health and Human Services (HHS) issues federal recommendations on critical congenital heart disease screening of newborns, the Department of Health and Mental Hygiene is required to adopt the federal recommendations. On September 21, 2011, HHS Secretary Kathleen Sebelius recommended that CCHD be added to the Recommended Uniform Screening Panel (RUSP); the RUSP is a list of hereditary and congenital conditions that are nationally recommended for inclusion in each state's newborn screening program; Maryland's recently enacted legislation requires DHMH to adopt HHS's recommendation to add screening for CCHD to the RUSP. States typically implement the national RUSP recommendations as soon as feasible even without legislation requiring them to adopt the recommendations.

Major Findings and Recommendations of Maryland's Expert Panel

After careful consideration of the scientific literature, national activities, and Maryland hospital resources, the following are the findings and recommendations of the Advisory Council's expert panel:

- All newborn infants should receive pulse oximetry screening to detect CCHD prior to discharge from the hospital.
- When screening for CCHD in newborns, hospitals should follow the screening protocols developed by the Secretary's Advisory Committee on Hereditary and Congenital Disorders in Newborns and Children and published in the December 2011 issue of the journal *Pediatrics*. These screening protocols have been endorsed by the American Academy of Pediatrics, the American Heart Association, and the American College of Cardiology.
- Quality assurance that all infants are screened and that positive screening results are evaluated appropriately should be the responsibility of the birthing hospital. The tracking and follow-up of infants who are not screened prior to hospital discharge should also be the hospital's responsibility. The reason for this is because the entire process from screening to testing and management of any identified concerns occur completely within the hospital and must be carried out within two weeks of the infant's birth in order to prevent or reduce morbidity and mortality.
- All birthing hospitals in Maryland have the resources to perform pulse oximetry screening; however there is variability in the capacity of hospitals to do further evaluation of infants who screen positive. Hospitals without pediatric cardiology continuously available and without telemedicine capabilities would need to either establish a telemedicine infrastructure, or implement protocols that include the transport of infants who screen positive to a facility with pediatric cardiology services.

- Due to the variability in patient population, regional resources, and existing referral patterns, each birthing hospital will need to develop its own procedures for the follow-up and management of abnormal results that arise from pulse oximetry screening for CCHD in newborns.
- DHMH should collect surveillance data on infants screened in each hospital, as well as the results of screening tests, to assist with quality assurance. The collection of data that will allow for the evaluation of the effectiveness of CCHD screening in newborns is strongly recommended.
- Education should be provided to consumers, clinical staff performing the screening test, and community pediatric healthcare providers using a variety of formats.
- The Office of Healthcare Quality should require each hospital to provide a protocol for newborn pulse oximetry testing and for the tracking and follow-up of infants who were not screened prior to discharge.
- The main costs to hospitals for implementing CCHD screening in newborns are costs associated with hospital staff time to screen and track results and follow-up on missed infants, education of parents and providers, staff training, the purchase and maintenance of screening equipment (pulse oximeters and echocardiography ultrasound machines), and verification and evaluation of a positive screen. Additionally, hospitals without pediatric cardiology available seven days per week would need to invest in a telemedicine infrastructure or else transport infants with a positive screen to a facility with pediatric cardiology services. CCHD screening also has a fiscal impact on the State, primarily for DHMH to conduct data surveillance and program evaluation, and to a lesser extent for education and technical assistance relating to quality assurance.

Introduction

House Bill 714 (crossfile Senate Bill 786) (2011) charged the Maryland State Advisory Council on Hereditary and Congenital Disorders (Advisory Council) with convening an expert panel to develop recommendations on the implementation of critical congenital heart disease (CCHD) screening of newborns in Maryland. The recommendations are to be based upon findings made after: (1) reviewing medical and public health studies and literature, and (2) examining the impact of implementing mandatory CCHD screening, including an examination of costs, insurance reimbursement, necessary medical equipment and staff training, screening protocols, quality oversight, and risk of harm. The legislation further requires that if the Secretary of Health and Human Services (HHS) issues federal recommendations on CCHD screening for newborns, the Department of Health and Mental Hygiene (DHMH) shall adopt the federal screening recommendations (see Appendix A for SB 786 (CF HB 714) (2011)).

The Advisory Council convened an expert panel comprised of neonatologists, pediatricians, geneticists, pediatric cardiologists, and nurses to evaluate the use of newborn pulse oximetry screening for CCHD. On September 21, 2011 which occurred during the expert panel's study, HHS Secretary Kathleen Sebelius recommended that CCHD be added to the Recommended Uniform Screening Panel (RUSP); the RUSP is the national recommendation informing states of the hereditary and congenital conditions that should be included in each state's newborn screening program. Therefore, DHMH is required to adopt HHS's federal recommendation on CCHD in newborns. Although the federal CCHD recommendations must be followed, the Advisory Council's expert panel proceeded with its CCHD study and implementation recommendations.

The expert panel was divided into three subcommittees: Clinical/Feasibility, Education, and Quality Assurance (see Appendix B for a list of Advisory Council and expert panel subcommittee members). Each subcommittee met a minimum of three times via conference call, and corresponded between calls through e-mail. The subcommittees then developed consensus recommendations regarding their focus area, and reported to the Advisory Council. These three reports were combined to produce this Legislative Report.

Overview of Critical Congenital Heart Disease

CCHD is a group of heart-related conditions present at birth that cause three percent of all infant deaths in the first year of life. The seven defects targeted by CCHD screening are:

- Hypoplastic left heart syndrome
- Pulmonary atresia (with intact septum)
- Tetralogy of Fallot
- Total anomalous pulmonary venous return
- Transposition of the great arteries
- Tricuspid atresia
- Truncus arteriousus

While congenital heart disease affects nearly one percent of newborns, CCHD affects only one quarter of those infants. CCHD requires intervention soon after birth to prevent significant

morbidity or mortality. Some babies with CCHD can appear healthy at first and may be discharged from the hospital before their heart defect is detected. Failing to detect CCHD in early infancy may lead to cardiogenic shock or death. Later detection of CCHD in infants also increases the risk of brain damage, resulting in neurologic injury and developmental delay.

In the United States, it is estimated that approximately one to two infants per 1,000 have CCHD, and as many as one quarter of those infants may be missed by routine newborn care with proper cardiac examination.[1] This results in about 4,800 babies born with CCHD each year in the U.S., and an estimated 280 infants with undiagnosed CCHD being discharged from newborn nurseries each year.

The prevalence of congenital heart disease in Maryland was intensively studied in the Baltimore-Washington Infant Study, which took place in the 1980s. One article published from this work found that in the eight years from 1981 to 1989, there were 76 infants who died of undetected CCHD.[2] This translates to approximately nine to 10 infant deaths per year. A recent review of Maryland's HSCRC-Inpatient Discharge Dataset from 2010 (hospital discharge data) revealed that the incidence of CCHD in Maryland births is similar to that found in other studies. In 2009, the rate was two per 1,000 births, and in 2010 it was 2.3 per 1,000 births.

The diagnosis of CCHD is frequently made by prenatal ultrasound, by observation of signs in the newborn, or by clinical exam. Infants with CCHD have heart disease that causes low oxygen saturation in the blood or a difference in oxygen saturation between the upper and lower body. Because there is a gradual transition in the newborn from fetal to infant circulation, affected infants are sometimes able to compensate for their abnormal heart/blood vessel structure in the first weeks of life and appear normal. These infants are at risk for significant morbidity or mortality prior to detection and treatment since they lose their ability to compensate for structural anomalies as their circulation matures.

Approximately 60 percent of cases of CCHD in newborns can be detected using pulse oximetry screening, which is a simple, non-invasive, and painless test to determine the amount of oxygen in the blood. Pulse oximetry screening is performed by a nurse or nurse extender, and involves placing a small sensor on both the baby's hand and foot to measure oxygen saturation of blood hemoglobin. The typical screening protocol calls for a baby with an abnormal pulse oximetry reading to be examined by a physician. If no other reason for low oxygen saturation is found, an echocardiogram (an ultrasound of the heart) is done to check for CCHD. Infants diagnosed with CCHD must then be seen by cardiologists and receive special care and treatment to reduce the risk of death and rates of long-term disability.

Literature and Data Review

Major strengths of using pulse oximetry to detect CCHD are that it adds an additional safety net for detecting CCHD in newborns, it is inexpensive, non-invasive, and all Maryland birthing hospitals have and are trained in the use of pulse oximeters. However, pulse oximetry screening identifies a little over 60 percent of infants with CCHD, a rate comparable to that of physical examination alone. Using both methods combined, about 80 percent of infants with CCHD are identified. This has led to the examination of the effectiveness of implementing pulse oximetry

testing, given the questions surrounding the sensitivity (proportion of positives correctly identified) and specificity (proportion of negatives correctly identified) of this tool to detect CCHD in newborns.

Whether pulse oximetry is a reliable diagnostic tool to detect CCHD has been examined in the scientific literature since the late 1990s. Until recently, however, these have been relatively small studies with variability in the screening protocol and in how pulse oximetry was performed. Variables included which extremities were used for testing, how long after birth the test was performed, how many times testing was repeated if abnormal, and what cutoff scores were used.

In 2007, a group in the United Kingdom conducted a meta-analysis of eight studies on the use of pulse oximetry screening for CCHD in newborns.[3] There were 35,960 infants screened across all eight studies. Authors of this meta-analysis concluded that newborn pulse oximetry screening has potential as a useful tool in detecting infants with CCHD, but that given the small number of infants currently undetected, larger studies were needed to clarify the sensitivity of the test to determine if screening should be universally recommended.

A joint statement of the American Heart Association (AHA) and the American Academy of Pediatrics (AAP) was published in 2009.[4] This statement acknowledged the need for larger studies, stating that while pulse oximetry screening for the detection of CCHD in newborns appears promising, "future studies in larger populations across a broad range of newborn delivery systems are needed to determine whether this practice should become standard of care in the routine assessment of the neonate." The joint statement further indicated that pulse oximetry in hospitals with pediatric cardiology services could be done at little cost and with little risk of disruption to newborn care under most circumstances. However, the 2009 AHA/AAP statement noted concerns that the costs and the stress to families with a positive screen would be quite different in hospitals without pediatric cardiology services available. In addition, the joint statement acknowledged that pulse oximetry screening still misses some infants with CCHD, that hospitals need to assure the quality of their pulse oximetry testing, and that families need to be informed that a negative screen does not rule out CCHD.

There have now been three large studies evaluating the effectiveness of CCHD screening in newborns, all of which were conducted in Europe. All of the studies reviewed by the expert panel in the course of their evaluation are included in the Reference section of this report. However, only summary data and a more detailed review of the recent, larger studies are included within the main body of this report.

The first was a large study conducted by Granelli et al. in Sweden, and involved over 38,000 newborns.[5] This study does not comment on any diagnoses prenatally, and infants were screened on the hand and foot at a median age of 38 hours. Of the 38,429 infants in their final analysis, 87 infants (0.2 percent) had a positive screen: 18 (or 20 percent of those with a positive screen) had true CCHD; 31 (or 36 percent of those who screened positive) had another condition requiring treatment; and 38 (or 44 percent of those who screened positive) were found to be normal. Of the 38,269 infants who screened negative, 10 were ultimately found to have CCHD. One infant out of 73 who had inconclusive screens was ultimately found to have CCHD. In summary, pulse

oximetry screening identified 62 percent of the infants in this study who had CCHD, and 44 percent of those who had a positive screen did not have a condition requiring treatment. The authors noted that pulse oximetry is a tool to be used in conjunction with the physical examination, as each method of evaluation may identify infants that are missed by the other method. Each method independently identified 62 percent of the infants with CCHD. When used together, these methods identified 83 percent of the infants with CCHD.

Another large study was conducted in Germany by Riede, et al.[6] In this study, 63 percent of infants with CCHD were detected prenatally, and these were excluded from screening. Infants were screened between 24 and 72 hours of life and only one extremity was tested – either the left hand or a foot. Of the 41,445 infants screened, 54 (0.1 percent) were positive: 14 of these infants (or 26 percent of those who tested positive) had CCHD; 13 (or 24 percent of those who tested positive) had infections; and 27 (or 50 percent of those who tested positive) had no condition requiring treatment. There were four infants who had a negative screen that were later found to have CCHD.

The third large study was done in the United Kingdom and included 20,055 infants screened at birth.[7] Infants were still included in the study if they were suspected prenatally of having CCHD. There were 192 infants who screened positive (one percent of infants). Eighteen of these infants (nine percent of those who screened positive) had CCHD. Forty infants (21 percent of those who screened positive) had other conditions requiring treatment, and 134 infants (or 70 percent of those who screened positive), required no intervention. One of the reasons for the high number of positive screens was that the majority of infants were screened before 24 hours of life, resulting in many more infants who were still transitioning to life outside the womb. It is more common for such young infants to have mildly low oxygen saturations. Of the 4,953 infants screened at greater than 24 hours of life, there were 32 who screened positive (0.6 percent of those screened), and only one infant had CCHD (three percent of those who screened positive). There were also 11 false negative screens in this group, meaning that 11 infants (0.2 percent of those screened) passed the screening despite having CCHD. In the entire study, 63 percent of the infants who screened positive did not have a disorder requiring treatment, and 38 percent of those with CCHD were missed by pulse oximetry screening.

In summary, because each of these studies used different protocols, it is difficult to combine the results of the studies to make overall predictions regarding the potential number of infants that would be identified in a newborn screening program for CCHD. The study by Granelli et al. uses the protocol most closely aligned with that recommended by the expert panel for implementation in Maryland. Using this study's results, approximately 0.2 percent of infants would be expected to screen positive. Of these, 20 percent would have CCHD, while another 36 percent would have another diagnosis requiring treatment. Forty-four percent of babies who screen positive would not have a diagnosis requiring any intervention, and would therefore be false positives.

National Activities

In October 2010, the U.S. HHS Secretary's Advisory Committee on Hereditary Disorders in Newborns and Children (SACHDNC) recommended newborn pulse oximetry screening to

promote early detection of CCHD in newborns. Secretary Sebelius responded saying that the SACHDNC's recommendations were not ready for adoption. The Secretary instead referred the SACHDNC's recommendations to the Interagency Coordinating Committee on Screening in Newborns and Children (ICC) for additional review and input regarding implementation. Specifically, the Secretary asked the ICC to review evidence gaps and propose an implementation plan to address: identification of effective screening technologies, development of diagnostic processes and protocols, education of providers and the public, and strengthening service infrastructure needs for follow-up and surveillance. Consequently, the SACHDNC convened a CCHD workgroup consisting of representatives chosen by the SACHDNC from the AAP, the AHA, the American College of Cardiology (ACC), as well as physician and nurse providers, public health professionals, and academicians to carry out these activities.

On September 21, 2011, after reviewing the ICC Plan of Action, Secretary Sebelius decided to adopt the recommendation to add CCHD screening to the RUSP (see Appendix C). The Secretary simultaneously cited the need for the following federal actions to take place in a timely manner to facilitate state implementation of CCHD screening: (1) The National Institutes of Health should fund research activities to determine the relationship between CCHD screening and health outcomes of affected newborns; (2) The Centers for Disease Control and Prevention (CDC) should fund surveillance activities to monitor the link between CCHD and infant mortality and health outcomes; (3) Health Resources Services Administration (HRSA) should guide the development of screening standards and infrastructure for a public health approach to point of care screening for CCHD; and (4) HRSA should fund the development of CCHD education and training materials for families and public health and health care professionals. HRSA funding opportunities for demonstration projects were also recommended. The ICC Plan of Action contains a caveat that the federal agencies will carry out these activities commensurate with available resources.

The complete SACHDNC's CCHD workgroup report, which Secretary Sebelius also considered in arriving at her decision, was published in the journal *Pediatrics* in December 2011 (see Appendix D for a copy the article entitled "Strategies for Implementing Screening for Critical Congenital Heart Disease").[8] This article contains valuable guidance to states in implementing CCHD screening. The expert panel recommends that Maryland hospitals review this article in full for important guidance on CCHD protocols, including those involving screening technology, screening criteria, and diagnostic strategies. The screening protocols outlined in this article were recently endorsed by the AAP, AHA, and ACC.

Other States' CCHD Legislation and Pilot Programs

Prior to the HHS recommendation to add CCHD to the RUSP, state level support was already emerging for the use of pulse oximetry to screen for CCHD in newborns in the United States. Beyond the CCHD legislation that was recently enacted in Maryland, there are currently two other states with statutes mandating the use of pulse oximetry for CCHD screening of all newborns – Indiana and New Jersey. The two CCHD state mandates require the following:

- Indiana – Statute requires the Indiana State Department of Health to develop procedures and protocols for CCHD testing and report to the Indiana Legislative Council on the costs

of implementation and possible funding sources. Beginning on January 1, 2012, it is required that every infant receive a pulse oximetry screening at the earliest possible time.
- New Jersey – Statute requires licensed birthing facilities to perform pulse oximetry screening for every newborn after they reach 24 hours of age. This law went into effect on August 31, 2011.

CCHD Legislation has also been unsuccessfully introduced in a number of states in recent years:

2011
- Missouri – House Bill 838 would expand newborn screening requirements to include pulse oximetry before newborns can be discharged from birthing facilities.
- New York – A-7941 would require all birthing facilities to perform pulse oximetry screening on newborns a minimum of 24 hours after birth. This State's fiscal note indicates "no fiscal implications" of this legislation for the State.
- Pennsylvania – SB 1202 would require each healthcare provider that performs birthing and newborn care services to perform pulse oximetry screening on every newborn a minimum of 24 hours after birth.
- Tennessee – Senate Bill 65 and its crossfile, House Bill 373 would require the Genetic Advisory Council to develop a screening program, and require hospitals and birthing facilities to provide screening. Those born outside of hospitals must be referred to appropriate screening facilities. In addition, all screening results must be reported to the State health department.

Introduced earlier than 2011
- Mississippi - House Bill 1052 (2005) would have required physicians or other persons attending a birth to have oxygen saturation tested within 24 hours of birth, and, in the case of oxygen saturation levels below 95 percent, to administer retesting at one and two weeks following.
- Nebraska – LB 1067 (2010) would have required pulse oximetry screening to be conducted on all infants. If births were attended by a person other than a physician, the individual registering the birth would have responsibility for referring testing to be performed as prescribed by the health department.

In addition to legislative initiatives taking place in the aforementioned states, a number of states are also implementing pilot programs (http://www.cchdscreeningmap.com/, accessed October 4, 2011). Since the announcement by Secretary Sebelius in September 2011 that she had decided to adopt the SACHDNC's recommendation to add CCHD to the RUSP, some states are beginning to plan for implementation of screening without legislation.

Implications for Maryland

Maryland has approximately 74,000 births per year. It is estimated that the University of Maryland Hospital and Johns Hopkins Hospital identify about 68 percent of infants with CCHD prenatally; however, when infants born in all hospitals across the State are considered, the rate of prenatal diagnosis is likely lower since many infants identified with CCHD before birth are referred to these tertiary care hospitals for delivery. If approximately 2.3 out of 1,000 infants

born in Maryland each year have CCHD, as was found in the review of hospital discharge data previously noted, and about 60 percent of those are identified prenatally, this leaves at least 70 infants a year in Maryland not previously diagnosed. Using the combined estimates from the Granelli study cited above, 0.2 percent (148 infants) of the 74,000 live born infants in Maryland could be expected to screen positive. Of these, 20 percent, or 30 babies, can be expected to have CCHD. Another 36 percent, or 53 infants, will have another cause for low oxygen saturation that may require treatment. Forty-four percent, or 65 babies who screen positive, will not have a condition requiring intervention. Another 20 infants a year with CCHD may still leave the hospital undiagnosed. In conclusion, since it is estimated that 60 percent of infants with CCHD would be identified by clinical examination, if all Maryland hospitals implemented CCHD screening for newborns, it is estimated that 10 babies with CCHD who would have otherwise been undetected would be identified.

Comparison to Other Newborn Screening Programs

Newborns receive many types of routine care in the nursery. Checking of vital signs, blood sugar testing, and vitamin K shots are all considered routine standard of care. However, other procedures carried out in the nursery are the result of mandated newborn screening in Maryland. With one exception, these newborn screening tests consist of blood spot testing for a number of hereditary and congenital disorders. The only mandated newborn screening testing in Maryland that does not involve the laboratory analysis of dried blood spots is newborn hearing screening. However, both blood spot testing and newborn hearing screening involve in-hospital testing, and rely on later follow-up by DHMH after the baby is discharged from the hospital. Ample time is available for DHMH to conduct its follow-up activities which generally occur within the first months after discharge.

In contrast, CCHD screening is very different in that the entire process from screening to follow-up and management of any identified concerns must occur entirely at the hospital. As a result, the role of public health agencies and staff is also very different than it is for other newborn screenings. The timeline for pulse oximetry screening and follow-up does not allow a direct role for DHMH in immediate follow-up for these infants with positive screens, as their diagnostic evaluation and emergency care must be initiated prior to discharge. Additionally, there is no practical way for DHMH to follow-up in a timely manner on those infants who missed screening prior to hospital discharge, since there is only a small window of opportunity, at most two weeks, in which to identify infants with CCHD to prevent or reduce morbidity and mortality. Also, many infants with a positive pulse oximetry screen have other conditions besides CCHD that require treatment. Therefore, the expert panel recommends that pulse oximetry testing should be performed on all newborns as part of the standard of care in the routine assessment of infants, not as part of a State newborn screening program. (It is important to note that pursuant to Maryland's recently enacted statute on CCHD screening, the requirement that DHMH adopt the HHS Secretary's recommendation to add CCHD to the RUSP of the State's newborn screening program supersedes the expert panel's recommendation that CCHD screening be made a part of routine care rather than a State newborn screening program). Furthermore, because pulse oximetry testing of newborns has been promoted nationally as a newborn screening program, and since the federal recommendation is to add CCHD screening to the RUSP, it is unlikely that

professional organizations would publish policies recommending that the screening should be standard of care instead.

Implementation

Despite the State's inherent limitations with respect to its role in CCHD screening of newborns, DHMH is able to provide surveillance and program evaluation. Data regarding numbers of infants screened, positive and negative results, and the process for resolving positive screens can be collected. Birthing hospitals currently enter data on all Maryland births into the electronic database for newborn hearing screening. This database can be modified to include a module for newborn pulse oximetry screening results that will collect information on whether an infant was screened, and results of that screen. A newborn screening follow-up nurse will then be able to contact birthing hospitals regarding infants with a positive screen in order to determine what tests were required to evaluate the infant and the ultimate outcome. The screening and follow-up data will provide information that can be used to evaluate the success of the screening program.

It would be beneficial to states, healthcare facilities, and individual clinicians to have the SACHDNC and other public health experts partner with HRSA to provide guidelines regarding the role of state health departments, and to provide technical assistance with regard to follow-up of missed infants. Even absent such guidance, implementation of newborn pulse oximetry screening to detect CCHD in Maryland presents a unique opportunity to collect information on the effectiveness of this screening and costs, and to expand the body of scientific knowledge on this topic.

The initiation and maintenance of this screening program will require resources (see Costs section). HRSA recently announced a funding opportunity for demonstration projects on pulse oximetry screening for newborns. DHMH plans to partner with academic institutions to pursue this grant funding which, if received, will help to defray the burden of initial costs of CCHD screening implementation. The grant award must be used for enhancing the state screening infrastructure, including the implementation of an electronic health information exchange for reporting and collecting pertinent information from hospitals, as well as education and training of various stakeholders on testing methodology and follow-up protocols. This funding opportunity will enable HRSA to make an estimated seven grant awards of $300,000 each year for three years.

Feasibility

To determine Maryland's readiness to implement newborn screening for CCHD, a survey to assess birthing hospital readiness for pulse oximetry screening of newborns was e-mailed to all nursery nurse managers in Maryland (Appendix E). Questions addressed whether the hospital was currently performing newborn pulse oximetry screening, as well as resources currently available on-site for performing both the screening test and follow-up for infants who do not pass the screen. Currently, 11 out of 34 birthing hospitals in Maryland perform pulse oximetry screening of all newborns. All birthing hospitals have the resources to perform the actual pulse oximetry screening; however, there is great variability in the capacity of hospitals to do follow-up evaluation of infants who screen positive. The majority of hospitals have either cardiology consultation available seven days per week, or the ability to do an echocardiogram and consult

pediatric cardiology via telemedicine. An echocardiogram on a newborn requires not only knowledge and skill, but ongoing practice. Although hospitals may have a pediatrics-trained technician, without sufficient practice in doing pediatric echocardiograms, the quality of the results may be inadequate. In this case a more experienced echocardiogram technologist would need to be available, or the baby would need to be transported.

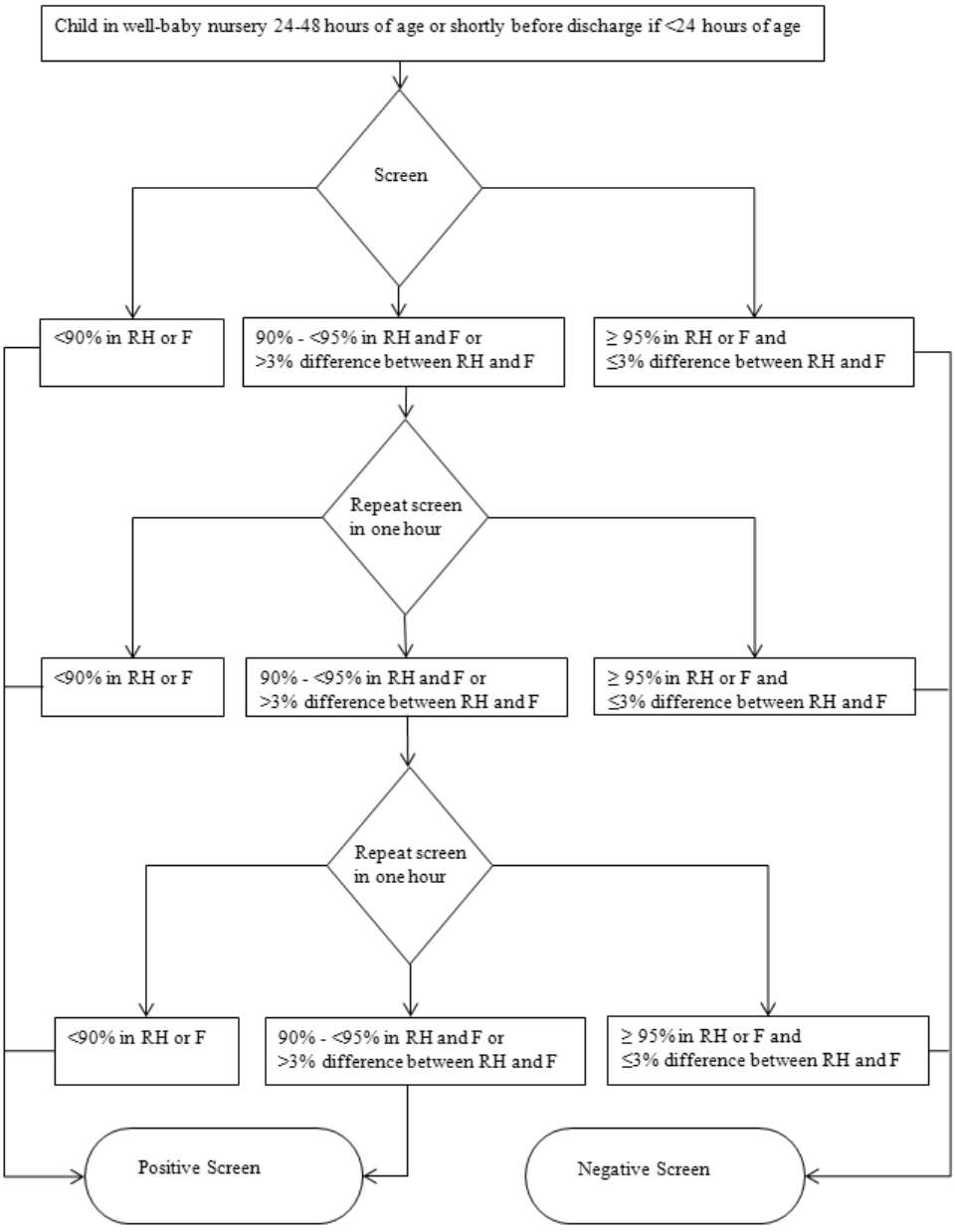
Detailed results of the nursery survey are included at the end of this report as Appendix F. Approximately 59 percent of nursery nurse managers reported that they had pediatric cardiologists available, and 50 percent had access seven days per week. Seventy-eight percent of birthing hospitals have echocardiography technicians who have pediatric training, and all but one of these hospitals has technicians available seven days per week. Sixty-nine percent of birthing hospitals have the capacity for pediatric telemedicine consultation for cardiology, making approximately two-thirds of Maryland's birthing hospitals well-equipped to follow-up on newborns with positive pulse oximetry screens. The remaining one-third of the birthing hospitals will need to create a mechanism for handling these infants.

Many infants that do not have CCHD will have a positive pulse oximetry screen. Some of these infants may have other conditions requiring treatment; some may require an echocardiogram. Most of these infants will be born at facilities with the resources for follow-up; a small percentage of infants without another cause for low oxygen may be born in facilities without access to pediatric cardiology services. DHMH is working with the Maryland Hospital Association (MHA) to determine what support is needed for those hospitals that do not currently have access to the services needed to evaluate infants who screen positive.

Clinical Considerations

The expert panel recommends following the screening procedure that was endorsed by the AAP, AHA, and ACC (see Appendix D). This recommended protocol involves screening all healthy term newborns prior to discharge but not before 24 hours of age, and performing pulse oximetry on the right hand and either foot. Recommended cut off scores are defined for passing, failing, and borderline readings that require repeat testing after an hour. Infants in the Neonatal Intensive Care Unit (NICU) routinely receive pulse oximetry monitoring, so any infant discharged from the NICU at greater than 24 hours of age would not be included in this screening protocol. It is important to note that this screening does not replace observation, careful physical examination, or the recommendation that newborns remain in the hospital for 48 hours after birth. Since pulse oximetry screening is non-invasive, the only risk of harm from this screening is the stress caused to families of infants with a positive screen.

The screening protocol recommended by the expert panel is set forth in the algorithm immediately below. For the full discussion of this screening protocol see Appendix D.



The expert panel recommends that DHMH distribute the aforementioned endorsed screening protocol to all birthing hospitals and offer educational Webinars on implementation. Primary care providers should also be educated about the initiation and implementation of this screening program, as they must help assure that all of their newborn patients are screened. In addition, primary care providers must be made aware that some types of CCHD will not be detected, so

that they do not lower their threshold for evaluating a symptomatic baby based on a negative screen.

One study done in Maryland to evaluate the feasibility of pulse oximetry screening is currently in press.[9] Study authors made their results available early to the authors of this report. In order to evaluate implementation of pulse oximetry screening for CCHD, Children's National Medical Center in Washington, DC partnered with Holy Cross Hospital, a large community hospital in Silver Spring, Maryland. During the research period of January 2009 – June 2010, 6,860 infants were enrolled and 6,745 infants (98 percent) were fully screened. The average amount of time required to conduct a screen was 3.5 minutes, although the expert panel, experienced in the initiation of blood spot screening, estimates that the time to complete the entire process of finding the infant, doing the screening, and recording results, will likely take at least five minutes per baby. Obstacles with equipment were reported with one percent of infants screened, obstacles with the infant were reported with 0.3 percent of infants screened, obstacles with the family were reported with 0.1 percent of infants screened, and obstacles with the staff were reported with 0.6 percent of infants screened. Average time to overcome these obstacles was 3.2 minutes. No additional staff was added to support screening.

Quality Assurance

Three specific concepts were considered paramount for quality assurance:

1) How can appropriate screening be assured (quality assurance of the test)?
2) How can screening of all babies be assured?
3) How can appropriate follow-up evaluation of babies with abnormal screening results be assured?

The difference between ideal versus realistic quality assurance was considered, as well as possible outcomes if pulse oximetry screening of newborns was made standard of care instead of a mandated screening program. The context of the expert panel's deliberations regarding quality assurance was that pulse oximetry is point of care testing, and further evaluation of positive test results must occur prior to discharge from the hospital. Statewide information regarding the effectiveness and efficiency of screening should be gathered, and while that data can be collected by DHMH, the analysis of that data in a clinical context may be more appropriate as a research study at an academic center.

Specifically addressing each question of the charge:

1) How can appropriate screening be assured (quality assurance of the test)?

DHMH can provide education and guidance on how to perform the screening test, but cannot assure the quality of the actual test. Nurses or nurse extenders with nursing oversight would be performing the test, and although they would require basic training with regard to the placement of the pulse oximeter and test criteria, these professionals are familiar with the basic use of this technology. Most equipment runs self-checks upon start-up, and hospitals have biomedical departments that inspect equipment at least annually. The actual reading of the pulse oximetry test and follow-up using an appropriate algorithm are matters of professional practice. Quality of the testing and the follow-up evaluation involve on-site equipment and personnel, and is the

responsibility of the local birthing hospital or other birthing center. Oversight is provided by The Joint Commission (an independent, not-for-profit organization, that accredits and certifies health care organizations and programs in the United States), and by agencies that oversee professional licensure.

2) How can screening of all babies be assured?

Hospitals are responsible for performing current newborn screening tests on all infants born in their facility, and they carry out this responsibility as part of their professional standards and licensure. DHMH cannot follow-up in a timely manner on infants who miss screening prior to hospital discharge, as this would require being notified of the birth, locating the family, and directing them to screening resources all within a few days. Instead, the expert panel recommended that the Office of Health Care Quality (OHCQ) should require all birthing hospitals to establish protocols for performing pulse oximetry screening on all newborns and for tracking and following-up on babies who were not screened prior to hospital discharge.

Although DHMH cannot assure screening of each individual baby, the expert panel recommends that DHMH track the percent of newborns screened as well as screening results for each birthing hospital. This would identify outliers and provide a basis for offering technical assistance to those hospitals missing significant numbers of infants, or reporting unusually high numbers of false positives. DHMH uses a database to track newborn hearing screening results. The addition of a module will enable this same system to store CCHD testing data. This system would allow surveillance of the CCHD screening program, as it would provide data on the number of births in each facility, the number of infants screened, and pass/failure rates. Intermittent review of data from each individual hospital will reveal outliers in terms of the number of infants screened and the number of infants with positive screens. These hospitals would be offered technical assistance from DHMH. These data can also be compared to hospital discharge data for CCHD and provide a mechanism to evaluate the effectiveness of the screening program.

3) How can appropriate follow-up evaluation of babies with abnormal screening results be assured?

The quality of the evaluation and care of babies with positive screens is once again a matter of professional standards. Physicians assessing an infant with an abnormal pulse oximetry reading will use their clinical judgment to determine next steps. The screening protocol requires that any infant that does not have an identified etiology for their abnormal screening test must have an echocardiogram. Due to the variability in regional resources and existing referral patterns, each birthing hospital will need to develop its own method for completing this evaluation. It is not possible for DHMH to monitor compliance with recommendations for follow-up evaluation of each individual infant in real time. However, birthing hospitals should be contacted after the fact to determine the evaluation conducted, and the ultimate outcome for any infant who has a positive screen.

Education

The content of the educational material for consumers and providers can be incorporated from national sources, including the CDC's Webpage on CCHD screening in newborns and the SACHDNC CCHD workgroup report published in *Pediatrics*. The CDC has already published a parent brochure on CCHD screening in newborns that hospitals and providers can use. The CCHD brochure is available online at http://www.cdc.gov/ncbddd/pediatricgenetics/pulse.html.

The recommended target audiences for educational efforts on screening for CCHD, as well as best methods for providing this information to each audience are presented here. There are three target audiences for educational outreach:

- Consumers - expectant parents, women of reproductive age, parents
- Individuals conducting CCHD screening - primarily nurses, nursing assistants, patient care technicians
- Other Healthcare Providers - hospital and community-based physicians including cardiologists, echocardiographers, OB/GYNs, pediatricians, neonatologists, general practitioners, and nurse mid-wives

The focus of the educational materials will vary among these audiences:

- Consumers - Educational materials for expectant parents should provide an overview of the background and significance of CCHD and pulse oximetry screening. Parents should be informed of how the pulse oximetry screening is performed and that this screening does not detect all forms of CCHD; it may identify other conditions associated with oxygen deprivation such as respiratory disorders or infections. These educational materials should be written at a literacy level that will be understandable to the lay consumer.
- Individuals conducting the CCHD screening - Educational materials for individuals conducting CCHD screening should provide an overview of the background and significance of CCHD and pulse oximetry screening, screening protocols, information on the management of patients who have failed screening, and recommendations for communicating with parents of infants. Providers who are responsible for conducting screening should receive training on protocols for performing pulse oximetry screening, and methods for ensuring saturations that are reported are accurate. Nurse midwives who attend home deliveries should be informed of variations in screening protocols based on these circumstances. Information on additional educational resources should be provided to those conducting screening.
- Other Healthcare Providers - Educational materials for providers who may come in contact with the CCHD screening protocols should provide an overview of the background and significance of CCHD and pulse oximetry screening, the screening protocol, and management of patients who have failed screening. In addition, providers need to be informed of recommendations for communication with parents. An important educational message for providers is that infants who pass pulse oximetry screening may still have CCHD.

The type of educational method used should be tailored to the target audience:

- Consumers should be informed about CCHD through fact sheets available at:

  - Healthcare provider offices
  - Prenatal education classes
  - Stork's Nest Programs (March of Dimes-funded programs that provide incentives to encourage pregnant women to attend prenatal classes and keep prenatal appointments)
  - Centering Pregnancy (model of care that provides prenatal care in a group setting)
  - Local health departments
  - The Newborn Screening and Children with Special Healthcare Needs pages of the DHMH Website

- Individuals conducting the CCHD screening should be informed through:
  - Distribution of the written recommended protocol, which DHMH should disseminate to all birthing hospitals prior to the initiation of screening.
  - Nursing Seminars – Hospital-based educational programs typically offered for continuing education units (CEUs) and conducted by nurses who are experts on the subject matter.
  - "Train the Trainer" - On-site sessions or Webinars conducted upon request at Maryland birthing hospitals and offered for CEUs.

- Other Healthcare Providers should be informed through:
  - Grand rounds at Maryland birthing hospitals conducted upon request, to educate healthcare providers about the CCHD screening protocol. Grand rounds are hospital-based educational programs typically offered for continuing medical education hours (CMEs) and conducted by physicians or other healthcare providers who have expertise on the subject matter.
  - Fact sheets to be distributed to all private and public healthcare agencies serving pregnant women, including local health departments.
  - A provider section with information and frequently asked question (FAQ) sheets posted on DHMH's Website for download.

Costs

There are numerous costs associated with implementing CCHD screening of newborns in Maryland. The main costs to hospitals are those associated with hospital staff time to screen and track results and follow-up on missed infants, education of parents and providers, staff training, the purchase and maintenance of screening equipment (pulse oximeters and echocardiography machines), and verification and evaluation of a positive screen. CCHD screening also has a fiscal impact on the State, primarily for DHMH to conduct data surveillance and program evaluation and to a lesser extent for education and technical assistance relating to quality assurance.

Screening

The cost of the actual pulse oximetry test to detect CCHD is minimal, as it involves placing a sensor on an infant and reading the pulse oximetry results. It is estimated to take approximately five minutes of nursing/nurse extender time to perform pulse oximetry screening, and it is

unlikely that hospitals will need to hire additional staff to perform the screening. Both reusable and disposable one-time use probes are available. The cost of reusable probes can be amortized to approximately $1 per use; these probes require cleaning between uses. Disposable probes cost about $12 each. The cost of probes would ultimately be an expense to the hospital because newborn service costs are bundled. Some hospitals may require new equipment to perform pulse oximetry testing on newborns, though the survey of nursery nurse managers indicated that all birthing hospitals had at least one pulse oximeter, and the majority have more than one. A pulse oximeter for newborns can be obtained for approximately $200.

There will be a cost to the hospitals to track and follow-up on infants who are not screened prior to hospital discharge. Hospitals will need to follow-up on missed babies which will require staff time. In hospitals with a discharge coordinator for the nursery, it would likely be part of that job function. Hospitals without a discharge coordinator will have to assign this function to other staff. It is important for hospitals to have their tracking and follow-up protocols in place before implementing CCHD screening. A hospital may be exposed to liability if an infant with CCHD is not screened prior to discharge and then is not identified due to lack of or inadequate follow-up.

Evaluation of Infants with Positive Screens

The evaluation of babies who screen positive will result in expenses for insurance providers, or in the case that families are uninsured, to the Maryland Medical Assistance Program (Medicaid), or to families. The following estimates are maximal in that they include infants discharged from the neonatal intensive care unit (NICU). There are approximately 6,000 infants a year in Maryland discharged from NICUs. The infants in NICUs already receive ongoing pulse oximetry monitoring, and therefore the monitoring of these infants would not result in additional costs from the State's implementation of CCHD for all infants.

The follow-up of infants who screen positive includes physical examination and possibly a chest x-ray if respiratory disease is expected, or blood tests if infection or another disease is suspected. Any infant who does not have another medical reason for their low oxygen level will require an echocardiogram. Currently there is no data available to help predict how many infants will receive chest x-rays or other tests, such as blood cultures, to evaluate their oxygen saturation. The cost estimates for this report are the costs expected if all infants screening positive who did not have another condition identified, received an echocardiogram.

The amount billed for performing and reading an echocardiogram is approximately $1,500, which is what insurance companies and uninsured families would be invoiced. Based on a review of the literature, an estimated 65 infants are expected to have false positive screens each year. Approximately 40 percent of Maryland children are enrolled in the Medical Assistance Program for children, Maryland Children's Health Program (MCHP). MCHP reimburses $600 for an echocardiogram, so the estimated cost to the State for approximately 26 false positives would be $15,600.

Hospitals without pediatric cardiology available seven days per week and without telemedicine capabilities will either need to purchase telemedicine equipment or implement protocols that

include transport of infants who screen positive to a center capable of providing a cardiology consultation. Approximately five percent of births in Maryland occur in hospitals that do not have pediatric cardiology coverage seven days per week and do not have telemedicine capabilities. Five percent of the 65 infants without CCHD would be three infants a year requiring transport. Currently, neonatal transport to a higher level of care requires use of intensive transport services at a cost of approximately $7,000 per transport, resulting in an estimated cost of $21,000 per year for these services.

DHMH Activities

Quality assurance, as described above, will be the responsibility of hospitals, as it involves equipment and professional standards, areas which are already under the oversight of other professional organizations or hospital protocols. With the addition of a CCHD module to the infant hearing database, DHMH will be able to identify hospitals with unusual rates of positive or missed screens, and to target those facilities to provide technical assistance. Surveillance and program evaluation will require data collection to determine rates of children failing screening and the ultimate outcome of those who fail. Modification to the current electronic infant hearing database will cost $20,000 for the addition of a new module for CCHD data collection, and an additional $20,000 per year for a portion of maintenance for the entire database.

The initiation of a CCHD newborn screening program at DHMH will require a half-time nurse to help create educational materials and disseminate them to target audiences. This nurse will also be involved in setting up the surveillance system used by DHMH to track screening rates and follow-up on infants with positive screens. Once the program is established, it is estimated that 30 percent of the follow-up nurse's time will be spent on surveillance and program evaluation. The ongoing surveillance will consist of monitoring the electronic database for those hospitals with unusual rates for failed or missed screens, and the provision of technical assistance to those hospitals. In order to evaluate the CCHD screening program, this nurse will collect data on the evaluation process and ultimate outcomes of those infants with positive screens. The cost of the salary and fringe benefits for the part-time nurse to carry out these activities are estimated at $45,000 for the initial year (1/2 time nurse) and $30,000 for each subsequent year (1/3 time nurse).

DHMH must direct its provider education at two different groups: (1) nurses and physicians performing the screening and immediate evaluation of babies in the nursery, and (2) primary care physicians and cardiologists who will be receiving test results and providing follow-up services to infants after a positive screen. Nurses and physicians in hospital nurseries will need to receive information about the expert panel's recommended algorithm for screening and follow-up of those with positive results.

DHMH would incur costs associated with providing educational materials. DHMH estimates that it would contract with an outside vendor to develop 100,000 CCHD screening brochures at a cost of approximately $60,000 for the first year, and 50,000 brochures at a cost of $30,000 for the second year. After all of the brochures are distributed, DHMH would post the brochure online. In addition, any additional printing of the online brochure would cost the State $.60 per brochure. Printing costs would be minimal after the first two years. DHMH intends to post

CCHD screening information on the Newborn Screening and Children with Special Health Care Needs pages of the DHMH Website.

DHMH intends to work through the Maryland Chapter of the AAP (MDAAP) to have CCHD screening information disseminated via the MDAAP's listserve without cost. CME opportunities for physicians provide an incentive for physicians to receive training. Certification of training material on the CCHD screening program for continuing CMEs are estimated to cost $500 through the MDAAP. If DHMH is awarded the HRSA implementation grant that it is currently seeking, then DHMH intends to pursue certification of training material on the CCHD screening program for CMEs through MDAAP. This would result in a one-time cost to DHMH of $500. (See page 15 of this report for more details on the HRSA grant application.)

Savings

Cost savings are expected for infants who would not have been identified without this screening program. While the current number of CCHD positive infants missed by existing screening methods is unknown, one baby presenting in significant distress and circulatory collapse not only accrues significant medical bills for their treatment, but, if disabled as a result of their distress and collapse, may also require special care and services over the lifespan, resulting in significant expenditure of resources for both their families as well as society at-large.

Outstanding Issues

There are several issues which remain unresolved. These include the development of protocols for screening infants born in birthing centers and at home, as well as procedures for the follow-up of infants who are not screened prior to hospital discharge. Possibilities include follow-up at the primary care provider's office, or through a follow-up home visit by the nurse midwife.

Conclusion

Screening for CCHD in newborns is an emerging trend that has been gaining acceptance, particularly in recent years. New Jersey and Indiana enacted legislation in 2011 that mandates Statewide CCHD screening of all newborns while other states have introduced CCHD legislation that did not pass. In addition, hospitals in a number of other states have established CCHD screening pilot programs without legislation.

Legislation enacted in Maryland during the 2011 legislative session required the State Advisory Council on Hereditary and Congenital Disorders to convene an expert panel to study and make recommendations on the implementation of CCHD screening of newborns in Maryland. After considerable review, the expert panel highly recommends that pulse oximetry testing of all newborns in Maryland should be conducted as part of routine care but not mandated as part of a State newborn screening program involving State administration and oversight. The expert panel determined that the screening would improve identification of infants with CCHD as well as assist in identifying other medical conditions involving low oxygen saturation such as respiratory disorders and infections.

The expert panel's reasoning was due to the inherent limitations in what would be possible for the State's role in such a screening program. Unlike other newborn screening programs in Maryland, the timeline for pulse oximetry screening and follow-up does not allow a direct role for DHMH or any other external State agency in immediate follow-up for infants with positive screens. There is no practical way for DHMH to follow-up in a timely manner on infants who are not screened prior to hospital discharge since there is only a narrow period of not more than two weeks in which to identify infants with CCHD to prevent and reduce morbidity and mortality.

Notwithstanding the expert panel's recommendations, during the course of their study, the HHS Secretary of Health and Human Services recommended that CCHD be added to the RUSP; the RUSP is the national recommendation informing states which hereditary and congenital disorders should be included in each state's newborn screening program. States typically implement the national screening recommendations as soon as feasible even though the screening is recommended and not required. However, in the case of CCHD screening of newborns, the CCHD screening legislation that was enacted in Maryland during the previous session requires that if the HHS Secretary issues federal recommendations on CCHD in newborns, DHMH is required to adopt the federal recommendations. Consequently, CCHD screening in newborns must be implemented as a newborn screening program in Maryland. Performing pulse oximetry screening on all newborn infants corresponds to the Maryland State Health Improvement Process (SHIP) Healthy Babies Objective 2, which is to reduce infant deaths.

Eleven out of 34 birthing hospitals in Maryland are already screening for CCHD in newborns. DHMH intends to solicit public comment in early 2012 to obtain feedback from hospitals, providers, and other interested parties as to a reasonable date to begin CCHD screening of all newborns in Maryland. DHMH intends to issue policies or promulgate regulations in 2012 to further guide implementation, including the date on which universal CCHD screening of newborns must begin in Maryland. OHCQ, the Maryland Institute for Emergency Medical Services, and the MHA have provided input during this study and have indicated their willingness to continue to work with DHMH to assist in the successful implementation of CCHD screening for all newborns in Maryland.

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Appendix A

SENATE BILL 786

J1 1lr2660
CF HB 714

By: **Senators Montgomery ~~and Forehand~~, Forehand, Astle, Garagiola, Glassman, Kelley, Kittleman, Klausmeier, Mathias, Middleton, Muse, and Pugh**
Introduced and read first time: February 4, 2011
Assigned to: Finance

Committee Report: Favorable with amendments
Senate action: Adopted
Read second time: March 25, 2011

CHAPTER _____

AN ACT concerning

Health – Newborn Screening Program – Critical Congenital Heart Disease

FOR the purpose of requiring ~~that the Department of Health and Mental Hygiene's Newborn Screening Program include screening for critical congenital heart disease~~ the Department of Health and Mental Hygiene to adopt certain federal recommendations on critical congenital heart disease screening in newborns under certain circumstances; requiring the State Advisory Council on Hereditary and Congenital Disorders to develop certain recommendations for critical congenital heart disease screening of newborns in the State; requiring the Advisory Council to convene certain experts to provide certain information; requiring the Advisory Council to examine the impact of implementing mandatory critical congenital heart disease screening; requiring the Advisory Council to review certain studies and literature; requiring the Advisory Council to submit a certain report to certain committees of the General Assembly on or before a certain date; and generally relating to the State Advisory Council on Hereditary and Congenital Disorders and newborn screening for critical congenital heart disease.

BY repealing and reenacting, with amendments,
Article – Health – General
Section 13–111
Annotated Code of Maryland
(2009 Replacement Volume and 2010 Supplement)

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.
Underlining indicates amendments to bill.
~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

Preamble

WHEREAS, Congenital heart disease is the most common birth defect and affects approximately eight out of every 1,000 infants each year; and

WHEREAS, More than 36,000 infants are born with congenital heart disease each year in the United States; and

WHEREAS, Congenital heart disease is the leading cause of death for infants born with a birth defect despite survival rates now approaching 96% for all affected children; and

WHEREAS, A major cause of infant mortality as a result of congenital heart disease is that a significant number of children affected are not detected as having heart disease in the newborn nursery; and

WHEREAS, An effective newborn screening mechanism for congenital heart disease before newborns leave the nursery can reduce infant mortality; and

WHEREAS, Pulse oximetry has been shown to be an effective screening test to detect congenital heart disease before infants leave the newborn nursery; and

WHEREAS, Children's National Medical Center has worked with Holy Cross Hospital to become leaders in the implementation of pulse oximetry screening in community nurseries; and

WHEREAS, The Secretary of Health and Human Services' Advisory Committee for Heritable Disorders in Newborns and Children recommended the addition of screening for critical cyanotic congenital heart disease to the core panel for universal screening of all newborns in the United States; now, therefore,

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

13–111.

(a) The Department shall establish a coordinated statewide system for screening all newborn infants in the State for certain hereditary and congenital disorders associated with severe problems of health or development, except when the parent or guardian of the newborn infant objects.

(b) Except as provided in § 13–112 of this subtitle, the Department's public health laboratory is the sole laboratory authorized to perform tests on specimens from

newborn infants collected to screen for hereditary and congenital disorders as determined under subsection (d)(2) of this section.

(c) The system for newborn screening shall include:

(1) Laboratory testing and the reporting of test results; ~~[~~and~~]~~

(2) Follow–up activities to facilitate the rapid identification and treatment of an affected child~~; AND~~

~~(3) SCREENING FOR CRITICAL CONGENITAL HEART DISEASE~~.

(d) In consultation with the State Advisory Council on Hereditary and Congenital Disorders, the Department shall:

(1) Establish protocols for a health care provider to obtain and deliver test specimens to the Department's public health laboratory;

(2) Determine the screening tests that the Department's public health laboratory is required to perform;

(3) Maintain a coordinated statewide system for newborn screening that carries out the purpose described in subsection (c) of this section that includes:

(i) Communicating the results of screening tests to the health care provider of the newborn infant;

(ii) Locating newborn infants with abnormal test results;

(iii) Sharing newborn screening information between hospitals, health care providers, treatment centers, and laboratory personnel; and

(iv) Delivering needed clinical, diagnostic, and treatment information to health care providers, parents, and caregivers; and

(4) Adopt regulations that set forth the standards and requirements for newborn screening for hereditary and congenital disorders that are required under this subtitle, including:

(i) Performing newborn screening tests;

(ii) Coordinating the reporting, follow–up, and treatment activities with parents, caregivers, and health care providers; and

(iii) Establishing fees for newborn screening that do not exceed an amount sufficient to cover the administrative, laboratory, and follow–up costs associated with the performance of screening tests under this subtitle.

(E) NOTWITHSTANDING ANY OTHER PROVISION OF LAW, IF THE SECRETARY OF HEALTH AND HUMAN SERVICES ISSUES FEDERAL RECOMMENDATIONS ON CRITICAL CONGENITAL HEART DISEASE SCREENING OF NEWBORNS, THE DEPARTMENT SHALL ADOPT THE FEDERAL SCREENING RECOMMENDATIONS.

SECTION 2. AND BE IT FURTHER ENACTED, That:

(a) The State Advisory Council on Hereditary and Congenital Disorders shall develop recommendations on the implementation of critical congenital heart disease screening of newborns in the State in accordance with this section.

(b) The Advisory Council shall:

(1) convene experts from the State's academic medical centers and any other hospital that the Advisory 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.

(c) On or before December 31, 2011, the Advisory Council shall submit its findings and recommendations on the implementation of critical congenital heart disease screening of newborns in a report to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2–1246 of the State Government Article.

(d) Notwithstanding any recommendation developed by the Advisory Council under this section, if the Secretary of Health and Human Services issues federal recommendations on critical congenital heart disease screening of newborns, the Department shall adopt the federal screening recommendations in accordance with § 13–111(e) of the Health – General Article as enacted by this Act.

SECTION ~~2.~~ 3. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2011.

Appendix B

Maryland Advisory Council on Hereditary and Congenital Disorders

Voting Members

Miriam Blitzer, PhD, **Chair -** Professor of Pediatrics; Obstetrics, Gynecology and Reproductive Sciences, and Biochemistry and Molecular Biology; Head, Division of Human Genetics, University of Maryland School of Medicine
Julie Hoover-Fong, MD, PhD, Vice Chair - Assistant Professor, Department of Pediatrics, McKusick-Nathans Institute of Genetic Medicine, Johns Hopkins Medical Institutions
Delegate Shirley Nathan-Pulliam, BSN, MAS - Representative, District 10
David Bromberg, MD – MedChi representative; Developmental-Behavioral Pediatrician, The Pediatric Center; faculty, University of Maryland School of Medicine
Anne Eder - Director of Program Services, March of Dimes, National Capital Area Chapter
Colleen Gioffreda - Consumer; Adoption Liaison, Little People of America, Inc.
Neil Porter, MD - Assistant Professor of Neurology, University of Maryland School of Medicine
Caryl Siems - Consumer; Board Member, Cystic Fibrosis Foundation
Anika Wilkerson - Consumer; President and Founder, The Lauren D. Beck Sickle Cell Foundation, Inc.

Ex-Officio Members

Deborah Badawi, MD - Medical Director, Office for Genetics and Children with Special Health Care Needs, DHMH
Fizza Gulamali-Majid, PhD - Division Chief, Newborn and Childhood Screening, Laboratories Administration, DHMH
Robert Myers, PhD - Director, Laboratories Administration, DHMH
S. Lee Woods, MD, PhD - Medical Director, Center for Maternal and Child Health, DHMH

Staff

Georgia Corso - Laboratories Administration, DHMH
Julie Kaplan, MD - Medical Director, Newborn Screening Follow-Up Program, DHMH; Assistant Professor of Pediatrics, Division of Genetics, University of Maryland School of Medicine
Jessica Nieto, MGC - Genetics Counselor, Newborn Screening Follow-Up Program, DHMH
Johnna Watson, RN, BSN - Nursing Consultant, Newborn Screening Follow-Up Program, DHMH
Tina Wiegand - Laboratory Manager, Newborn and Childhood Screening, Laboratories Administration, DHMH

CCHD Expert Panel
Subcommittee Lists

Clinical/Feasibility

Renee Fox, MD, Chair - Associate Professor, Division of Neonatology, Department of Pediatrics, University of Maryland School of Medicine
Carissa Baker-Smith, MD, **MS, MPH -** Assistant Professor of Pediatrics, Division of Cardiology, University of Maryland School of Medicine
Miriam Blitzer, PhD, **Chair -** Professor of Pediatrics; Obstetrics, Gynecology and Reproductive Sciences, and Biochemistry and Molecular Biology; Head, Division of Human Genetics, University of Maryland School of Medicine
Joel Brenner, MD - Associate Professor and Director, Pediatric Cardiology, Johns Hopkins Medical Institutions
Debbie Burke, RN - Nurse Manager, Chester River Hospital
Edward Lawson, MD - Josephine S. Sutland Professor of Newborn Medicine; Director, Neonatal-Perinatal Medicine, Johns Hopkins Medical Institutions
Gerard Martin, MD - Senior Vice President, The Center for Heart, Lung and Kidney Disease, Children's National Medical Center
Geoffrey Rosenthal, MD, PhD - Professor of Pediatrics; Director, Pediatric and Congenital Heart Program, University of Maryland School of Medicine
Philip Spevak, MD - Associate Professor, Pediatric Cardiology, Johns Hopkins Medical Institutions
S. Lee Woods, MD, PhD - Medical Director, Center for Maternal and Child Health, DHMH

Education

Anne Eder, Chair - Director of Program Services, March of Dimes, National Capital Area Chapter
Carrie Blout, MS, CGC - Certified Genetic Counselor, Greenberg Center for Skeletal Dysplasia
Elizabeth Bradshaw, MSN, RN, CPN - Coordinator, Congenital Heart Disease Screening Program, Children's National Medical Center
Julie Hoover-Fong, MD, PhD - Assistant Professor, Department of Pediatrics, McKusick-Nathans Institute of Genetic Medicine, Johns Hopkins Medical Institutions
Anika Wilkerson - Consumer Member, Advisory Council on Hereditary and Congenital Disorders; President and Founder, The Lauren D. Beck Sickle Cell Foundation, Inc.

Quality Assurance

Carol Greene, MD, Chair - Professor of Pediatrics and Director, Pediatric Genetics Clinic; Co-Director, Adult Genetics Clinic, University of Maryland School of Medicine
Neil Porter, MD - Assistant Professor of Neurology, University of Maryland School of Medicine
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Tanya Green, MS, CCC-A - Program Chief, Infant Hearing Program, DHMH
David Bromberg, MD – MedChi representative; Developmental-Behavioral Pediatrician, The Pediatric Center; faculty, University of Maryland School of Medicine

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Deborah Badawi, MD – Medical Director, Office for Genetics and Children with Special Health Care Needs, DHMH

Appendix C

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

September 21, 2011

R. Rodney Howell, M.D.
Committee Chairperson
Secretary's Advisory Committee on Heritable
Disorders in Newborns and Children
5600 Fishers Lane, Room 18A19
Rockville, MD 20857

Dear Dr. Howell:

As indicated in my letter to you on April 20, 2011, I determined that the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's (SACHDNC) recommendations pertaining to the addition of Critical Congenital Heart Disease (CCHD) screening to the Recommended Uniform Screening Panel (RUSP) were not yet ready for adoption. Consequently, I referred the SACHDNC's recommendations to the Interagency Coordinating Committee on Screening in Newborns and Children (ICC) for additional review and input regarding implementation. I asked the ICC to review the evidence gaps described by the SACHDNC and propose a plan of action to address: identification of effective screening technologies, development of diagnostic processes and protocols, education of providers and the public, and strengthening service infrastructure needs for follow-up and surveillance. I have received and reviewed the requested ICC Plan of Action.

As you know, congenital heart disease causes up to 3% of all infant deaths in the first year of life. Heart defects affect about 7 to 9 of every 1000 live births, one quarter of which could be detected and potentially treated by measuring blood oxygen saturation. Given this reality and the available information on the effectiveness of screening, I have decided to adopt the SACHDNC's first recommendation to add CCHD to the RUSP. In addition, I am requesting that the SACHDNC collaborate with the Health Resources and Services Administration (HRSA) to complete a thorough evaluation of the potential public health impact of universal screening for CCHD, as required by the authorizing statute, section 1111 of the Public Health Service Act (42 U.S.C. § 300b-10(b)(4)).

In arriving at my decision, I considered the recommendations from the ICC Plan of Action, the External Evidence Review, and the CCHD Workgroup Report. In addition to providing keen insight into the importance of early detection of CCHD, these reports have identified remaining evidence gaps about the public health impact of universal screening for CCHD. I have concluded that these evidence gaps should receive closer attention as implementation occurs. Specifically, it would be beneficial to states, health care facilities, and individual clinicians to have the SACHDNC and other public health experts, partner with HRSA to provide information about a number of issues, including but not limited to the following:

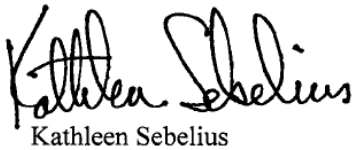
- What will be the impact on state health departments, including staffing needs, to implement this program? What are the roles of the state health departments?
- What capability is present to ensure that all babies are screened and their results are communicated to providers, including assuring that those not screened at birth receive a screen?

Regarding the four SACHDNC recommendations for action by the National Institutes of Health, Centers for Disease Control and Prevention, and HRSA to address recognized evidence gaps (Recommendations #2-#5), I have decided to adopt these recommendations. I will direct the named agencies, as well as other relevant HHS agencies, to proceed expeditiously with implementation, as described in the attachment, as feasible. I am taking this action because I believe that as we move forward, these activities will add important foundational information regarding the potential impact of implementing universal screening for CCHD, strengthen the platform on which to build the critical infrastructure for universal screening, and provide states with the data necessary to consider requiring that this condition be added to their existing newborn screening programs.

I would like to commend the SACHDNC on your success in creating and implementing an external scientific evidence review process for rare conditions that incorporates systematic evidence-based and peer-reviewed recommendations. I am encouraged by the emerging evidence base for the utility of early diagnosis and detection of CCHD via measurement of blood oxygen saturation, as well as the momentum and commitment that is evidenced at the state and federal levels to support implementation and investigation of successful screening programs. While we collectively engage in the remaining work that needs to be completed, HHS will continue to encourage states, health care facilities, and individual clinicians to provide this screening and contribute to the knowledge base in this important area.

I am committed to advancing screening for CCHD, and I appreciate the contributions of the SACHDNC in assisting HHS and states to explore ways to enhance newborn and child screening to improve the health of infants born in the United States.

Sincerely,



Kathleen Sebelius

Enclosure:
Interagency Coordinating Committee on Newborn and Child Screening (ICC): Screening for Critical Congenital Heart Disease: A Federal Agency Plan of Action - Summary of Federal Activities

Interagency Coordinating Committee on Newborn and Child Screening (ICC): Screening for Critical Congenital Heart Disease: A Federal Agency Plan of Action
SUMMARY OF FEDERAL ACTIVITIES*

Research
SACHDNC Recommendation: *NIH shall fund research activities to determine the relationships among the screening technology, diagnostic processes, care provided, and the health outcomes of affected newborns with CCHD as a result of prospective newborn screening.*

2011 - NIH will build upon the robust research portfolio of improving outcomes in children with congenital heart disease, including the National Heart, Lung, and Blood Institute's (NHLBI) Bench to Bassinet program.
2011-2015 - NIH will encourage and fund research to evaluate the impact of newborn screening on morbidity and mortality from congenital heart disease.
AHRQ's report, *Registries for Evaluating Patient Outcomes: A User's Guide, Second Edition*, (http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&mp=1&productID=531) will be reviewed by **NIH** and the **CDC** to inform the development of registries to address research questions regarding screening for CCHD.

Surveillance
SACHDNC Recommendation: *CDC shall fund surveillance activities to monitor the CCHD link to infant mortality and other health outcomes.*

2011 - CDC will evaluate the current capacity of existing population-based state surveillance and tracking to monitor the effectiveness of CCHD newborn screening programs to prevent infant mortality and morbidity.
2012 - CDC will conduct a cost-effectiveness analysis of newborn screening, in collaboration with NIH, for the early identification of children with CCHD.
2012-2015 - CDC will collaborate to leverage an electronic health record framework for congenital heart disease, including CCHD.
NIH's National Library of Medicine (NLM) will assist with the development of expanded laboratory coding terminology for blood oxygen saturation measurements and echocardiogram results integrated into electronic medical records and as part of health information exchange systems.

Screening Standards and Infrastructure
SACHDNC Recommendation: *HRSA shall guide the development of screening standards and infrastructure needed for the implementation of a public health approach to point of service screening for Critical Congenital Cyanotic Heart Disease.*

2011 - HRSA will support the development, dissemination and validation of screening protocols and newborn screening infrastructure.
2011 - HRSA will support state Title V programs in assessing, promoting and coordinating infrastructure to support a population-based approach to CCHD screening.

2012-2015 - HRSA will provide support for a demonstration program for newborn screening for CCHD.
FDA's Center for Devices and Radiological Health (CDRH) will provide guidance to industry and FDA staff on pulse oximeters.

Education and Training

SACHDNC Recommendation: *HRSA shall fund the development of, in collaboration with public health and health care professional organizations and families, appropriate education and training materials for families and public health and health care professionals relevant to the screening and treatment of CCHD.*

2011 - HRSA will expand its newborn screening educational efforts to include CCHD.
2012-2015 - HRSA will provide ongoing development of new tools and support as needed.
2012-2015 - CMS will support educational efforts through guidance issued to state Medicaid Directors for screening, follow-up and treatment that is medically necessary for children enrolled in Medicaid, as required under the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit.

** Agencies will carry out activities proposed in this plan, commensurate with available resources.*

Appendix D

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Strategies for Implementing Screening for Critical Congenital Heart Disease

Alex R. Kemper, William T. Mahle, Gerard R. Martin, W. Carl Cooley, Praveen Kumar, W. Robert Morrow, Kellie Kelm, Gail D. Pearson, Jill Glidewell, Scott D. Grosse and R. Rodney Howell

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Strategies for Implementing Screening for Critical Congenital Heart Disease

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KEY WORDS
congenital heart defects, neonatal screening, oximetry

ABBREVIATIONS
HHS—US Department of Health and Human Services
SACHDNC—Secretary's Advisory Committee on Heritable Disorders in Newborns and Children
AAP—American Academy of Pediatrics
AHA—American Heart Association
HRSA—Health Resources and Services Administration
CCHD—critical congenital heart disease
ACCF—American College of Cardiology Foundation
FDA—US Food and Drug Administration

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the National Institutes of Health, the Food and Drug Administration, or the US Department of Health and Human Services.

This report has been endorsed by the American Academy of Pediatrics, the American College of Cardiology Foundation, and the American Heart Association Council on Cardiovascular Disease in the Young.

(Continued on last page)

abstract

FREE

BACKGROUND: Although newborn screening for critical congenital heart disease (CCHD) was recommended by the US Health and Human Services Secretary's Advisory Committee on Heritable Disorders in Newborns and Children to promote early detection, it was deemed by the Secretary of the HHS as not ready for adoption pending an implementation plan from HHS agencies.

OBJECTIVE: To develop strategies for the implementation of safe, effective, and efficient screening.

METHODS: A work group was convened with members selected by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, the American Academy of Pediatrics, the American College of Cardiology Foundation, and the American Heart Association.

RESULTS: On the basis of published and unpublished data, the work group made recommendations for a standardized approach to screening and diagnostic follow-up. Key issues for future research and evaluation were identified.

CONCLUSIONS: The work-group members found sufficient evidence to begin screening for low blood oxygen saturation through the use of pulse-oximetry monitoring to detect CCHD in well-infant and intermediate care nurseries. Research is needed regarding screening in special populations (eg, at high altitude) and to evaluate service infrastructure and delivery strategies (eg, telemedicine) for nurseries without on-site echocardiography. Public health agencies will have an important role in quality assurance and surveillance. Central to the effectiveness of screening will be the development of a national technical assistance center to coordinate implementation and evaluation of newborn screening for CCHD. *Pediatrics* 2011;128:e1259–e1267

Newborn screening has led to dramatic improvements in morbidity and mortality rates for a variety of conditions.[1] Historically, newborn screening has been based on analysis of dried blood spots and has operated as a partnership between health care providers, who obtain the samples and oversee medical follow-up, and state-based public health systems, which analyze the dried blood spots, assist health care providers and families in follow-up, and monitor the effectiveness of the screening process through surveillance activities. The US Health and Human Services (HHS) Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) was authorized by the US Congress to provide guidance to the Secretary of the HHS about which conditions should be included in newborn screening and how systems should be developed to ensure appropriate screening and follow-up care.[2,3]

Before 2010, the only condition recommended for newborn screening that did not follow the dried-blood-spot paradigm was newborn hearing screening. Newborn hearing screening relies on in-hospital testing before discharge and subsequent outpatient audiology testing for those with abnormal results.[4] Unlike dried-blood-spot testing, individual hospitals and birthing centers had to invest in screening devices, maintain sufficient numbers of skilled staff to conduct the screening and interpret the results, and develop systems to track and communicate results of testing with public health departments, health care providers, and families. Because results of hearing screening originate in the hospitals and birthing centers, public health programs face significant challenges to ensuring follow-up to ensure the success of newborn hearing screening.[5,6]

In September 2010, the SACHDNC recommended that critical congenital cyanotic heart disease be added to the recommended uniform screening panel on the basis of findings from a comprehensive evidence review. The goal of this recommendation was to identify those newborns with structural heart defects usually associated with hypoxia in the newborn period that could have significant morbidity or mortality early in life with closing of the ductus arteriosus or other physiologic changes early in life. The SACHDNC considered 7 specific lesions as primary targets for screening on the basis of advice from a technical expert panel: hypoplastic left heart syndrome; pulmonary atresia; tetralogy of Fallot; total anomalous pulmonary venous return; transposition of the great arteries; tricuspid atresia; and truncus arteriosus. This subset of lesions excludes those not usually associated with hypoxia (eg, aortic valve stenosis).[7]

This recommendation built on a 2009 statement from the American Academy of Pediatrics (AAP) and the American Heart Association (AHA), which found compelling reasons for newborn screening but called for "studies in larger populations and across a broad range of newborn delivery systems" before pulse-oximetry screening should be recommended.[7] The SACHDNC was especially persuaded by a prospective screening study of nearly 40 000 newborns in Sweden[8] and a separate study of nearly 40 000 newborns in Germany.[9] Comparing the accuracy of pulse-oximetry monitoring for the 7 defects specified by the SACHDNC to that of these other studies was somewhat challenging because of differences in the lesions that were targeted for detection by the screening. For example, the study in Sweden considered all ductal-dependent lesions. The researchers' approach, for example, was to add critical aortic stenosis and coarctation of the aorta but exclude tetralogy of Fallot. With this case definition, the study from Sweden found the sensitivity of pulse-oximetry monitoring to be 62.1% and the specificity to be 99.8%; the false-positive rate was 0.17%. In contrast, the AAP/AHA statement used a broader definition, which included all lesions that would require surgery or catheter intervention in the first year of life.

The SACHDNC made the recommendation for screening with the understanding that specific activities would be undertaken, including having the Health Resources and Services Administration (HRSA) guide the development of screening standards and the infrastructure needed for implementation of a public health approach to point-of-service screening and developing education materials; having research conducted by the National Institutes of Health; and surveillance and tracking by the Centers for Disease Control and Prevention. However, the Secretary of the HHS did not endorse the recommendation from the SACHDNC to begin screening, in part because of questions about how to implement that screening. Some states (eg, Maryland, New Jersey) have legislation that promotes newborn screening for critical congenital heart disease (CCHD), which increases the urgency for a draft implementation plan.

The SACHDNC, in collaboration with the AAP, the American College of Cardiology Foundation (ACCF), and the AHA, convened a work group to outline implementation strategies for the SACHDNC, which are summarized here. It is important to recognize that many newborns with the targeted congenital heart defects do not develop clinically appreciable cyanosis until after nursery discharge, and some lesions (eg, hypoplastic left heart syndrome) may present with significant cardiovascular compromise without apparent cya-

nosis. Therefore, the work group recommended renaming the target conditions "critical congenital heart disease" (CCHD) (omitting the word "cyanotic").

METHODS

A work group was convened for a 2-day meeting in January 2011. Work-group members (see Appendix) included primary care providers; specialists, including pediatric cardiologists and neonatologists; nurses; representatives from the AAP, the ACCF, the AHA, the American College of Medical Genetics, the March of Dimes, the Association of Maternal and Child Health Programs, the Association of Public Health Laboratories, and the SACHDNC; parent screening advocates; state public health officials; and representatives from the Centers for Disease Control and Prevention, the US Food and Drug Administration (FDA), the HRSA, and the National Institutes of Health. Included were people who have implemented pulse-oximetry monitoring for CCHD in newborn nurseries in Arkansas, California, Minnesota, New York, Washington, and Washington, DC. The work group was moderated by William T. Mahle, MD, a pediatric cardiologist who led the development of the 2009 AAP/AHA statement,[7] and R. Rodney Howell, MD, chair of the SACHDNC. The work group was supported by other invited experts, including those from the Centers for Disease Control and Prevention and the FDA, and 2 who had conducted large-scale studies of screening in Europe. The work-group meeting was open to the public.

The meeting focused on recommendations for pulse-oximetry monitoring for CCHD, including recommendations for the service infrastructure needs for follow-up, and strategies for filling in important knowledge gaps. A smaller writing group prepared a summary report of the meeting, which was then iteratively revised with the work group until agreement was obtained. The report was subsequently reviewed by the AAP, the ACCF, and the AHA, each of which endorsed this report.

RESULTS

Screening Population and Targets

The work group chose to focus initially on screening in the well-infant nursery because of the risk of missed cases of CCHD among healthy-appearing newborns. The work group recognized the importance of also considering screening within NICUs. However, developing a simple algorithm for the NICU setting is challenging because of the heterogeneity of underlying conditions (eg, prematurity, meconium-aspiration syndrome, sepsis). Unlike the well-infant nursery, many infants in the NICU undergo repeated medical evaluations, are monitored by pulse oximetry, and have longer lengths of stay. However, there was concern that screening only in well-infant nurseries would miss newborns with short stays in intermediate care nurseries. The work group endorsed screening infants in intermediate care nurseries or other units in which discharge is common in the first week by using the work-group protocol for screening in the well-infant nursery. The work group chose not to focus on out-of-hospital births, which raise challenging coordination-of-care issues, which will be addressed in the future.

One of the advantages of pulse-oximetry monitoring is the ability to detect other hypoxic cardiac- or non–cardiac-associated conditions (eg, persistent pulmonary hypertension), characterized by the SACHDNC as targets secondarily detected by the screening technology ("secondary targets"). Secondary targets are common to other newborn screening tests (eg, identification of hemoglobin H disease when screening for sickle cell anemia[10]). Although the primary goal of screening on the basis of the SACHDNC recommendation is identification of the 7 specific lesions associated with CCHD, tracking rates of identification of important secondary targets could lead to modifications of the screening protocol.

Screening Technology

The work group recommended that screening be performed with motion-tolerant pulse oximeters[11] that report functional oxygen saturation, have been validated in low-perfusion conditions, have been cleared by the FDA for use in newborns, and have a 2% root-mean-square accuracy. Commercially available pulse oximeters often are labeled by manufacturers according to generation of technology (eg, "next generation"). However, generation designation is not standardized and may not be related to validity or reliability. Furthermore, no standards have been developed regarding motion tolerance. A new guidance document on the safety and effectiveness of pulse oximeters is being developed by the FDA.[12] When the guidance document is finalized, any pulse oximeter used for screening should meet FDA recommendations. Having specific FDA-cleared labeling and conformance to the relevant standard[13] will be an important strategy for ensuring that appropriate devices are used for screening.

Pulse oximeters can be used with either disposable or reusable probes. Reusable probes can reduce the cost of screening, but they must be appropriately cleaned between uses to minimize the risk of infection. Some probes have been developed to be partially reusable, which reduces the need to clean between uses and are less expensive than fully disposable

probes. Probes with close coupling to skin (ie, taped rather than clamped) provide better performance for oximetry monitoring in newborns. Pulse oximeters are validated only with the specific probes recommended by the manufacturer; therefore, to optimize valid screening, manufacturer-recommended pulse-oximeter–probe combinations should be used.

Screening Criteria

The work group recommended that screening not begin until 24 hours of life, or as late as possible if earlier discharge is planned, and be completed on the second day of life. Earlier screening can lead to false-positive results because of the transition from fetal to neonatal circulation and stabilization of systemic oxygen saturation levels, and later screening can miss an opportunity for intervention before closing of the ductus arteriosus. Screening was recommended in the right hand and 1 foot either in parallel or in direct sequence. The pulse-oximetry measure is complete once the waveform on the oximeter's plethysmograph is stable or there is another indication that the device is appropriately tracking the infant's pulse rate.

Selecting the threshold for a positive pulse-oximetry monitoring result is challenging, because it must trade-off the harm of missing CCHD against the harm of false-positive screen results. None of the studies reviewed by the SACHDNC included receiver operator characteristic curves developed from primary data, which would allow a direct evaluation of this trade-off. However, on the basis of new data from the large population-based screening activities in Sweden[8] and England,[14] the work group developed a recommendation for screening that was based on what was shown to be effective in those studies.

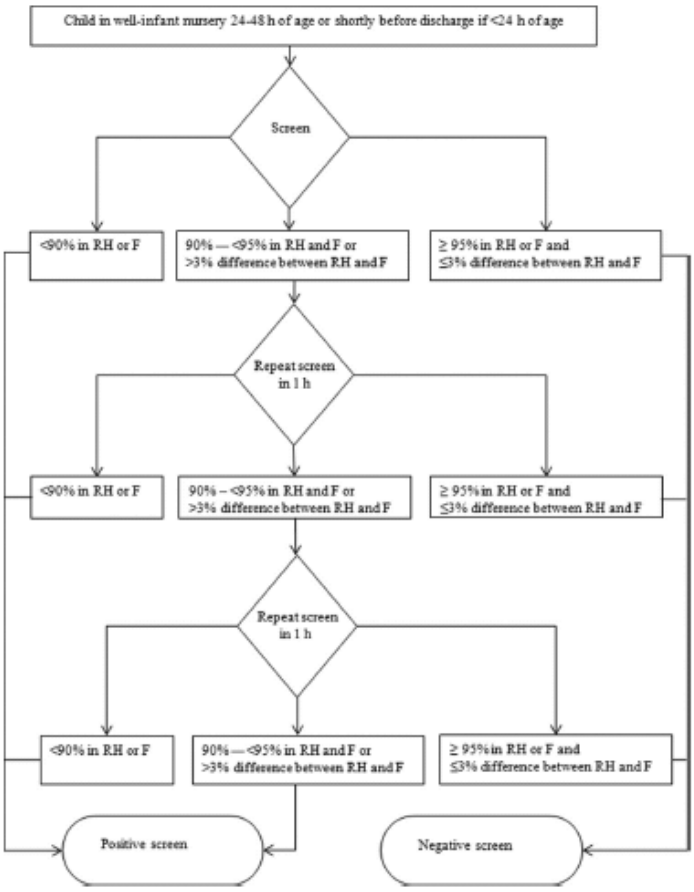

FIGURE 1
The proposed pulse-oximetry monitoring protocol based on results from the right hand (RH) and either foot (F).

The screening protocol is listed in Fig 1. A screen result would be considered positive if (1) any oxygen saturation measure is <90%, (2) oxygen saturation is <95% in both extremities on 3 measures, each separated by 1 hour, or (3) there is a >3% absolute difference in oxygen saturation between the right hand and foot on 3 measures, each separated by 1 hour. Any screening that is ≥95% in either extremity with ≤3% absolute difference in oxygen saturation between the upper and lower extremity would be considered a "pass" result, and screening would end.

Anecdotal reports have suggested that false-positive results are decreased if the infant is alert, possibly by reducing the likelihood of low oxygen saturations caused by hypoventilation in deep sleep. In addition, timing pulse-oximetry monitoring around the time of the newborn hearing screening improves efficiency, assuming that the hearing screening is conducted after 24 hours or immediately before dis-

charge. The particular screening strategy should reflect the conditions within each particular nursery and the needs of infants, families, and the health care providers.

The work group noted that performing a typical physical examination alone for CCHD led to almost 10 times more false-positive results compared with using similar screening protocols in Sweden and the United Kingdom.[5,14] Repeated pulse-oximetry testing after an initial positive screen result if oxygen saturation is <95% in both extremities or there is a >3% absolute difference in oxygen saturation between the right hand and foot, as illustrated in the protocol, lowers the likelihood of a false-positive result compared with a single measurement. However, there is no need to repeat pulse-oximetry testing if the oxygen saturation is <90% in any screen.

The work group emphasized the importance of not having pulse-oximetry monitoring replace a complete history and physical examination, which can sometimes detect CCHD before the development of hypoxia. Pulse-oximetry monitoring, therefore, should be used to complement the physical examination. Although agreement was reached on the screening protocol, the work group was concerned that this screening protocol might lead to high rates of false-positive results in high-elevation communities, such as those in Denver, Colorado.[15–17] The criteria for a positive screen result may need to be modified for these areas. Regardless of the specific screening thresholds, comprehensive training will be central to implementing safe and effective screening.

Diagnostic Strategies

Any newborn with a positive screen result first requires a comprehensive evaluation for causes of hypoxemia. In the absence of other findings to explain hypoxemia, CCHD needs to be excluded on the basis of a diagnostic echocardiogram (which would involve an echocardiogram within the hospital or birthing center or transport to another institution) or through the use of telemedicine for remote evaluation. The work group also emphasized the need for high-quality echocardiograms with interpretation by a pediatric cardiologist because of the challenge of diagnosis in some cases (eg, total anomalous pulmonary venous return). The work group recommended against replacing a diagnostic echocardiogram with other evaluations (eg, chest radiograph, electrocardiogram, hyperoxia test), which can be inaccurate for diagnosing CCHD. The work group endorsed consulting a pediatric cardiologist, when feasible, before obtaining the echocardiogram.

Because of the importance of quickly establishing the diagnosis of CCHD, the work group recommended that hospitals and birthing centers establish a protocol to ensure timely evaluation, including echocardiograms and any necessary subsequent follow-up, before instituting a CCHD screening program. Future work will be needed to ensure the quality of in-center and telemedicine approaches to echocardiography. The work group also recognized the importance of training an adequate number of pediatric cardiologists to ensure that diagnostic services are available on-site, with short-distance transport, or through telemedicine. Similarly, pediatric cardiac surgery centers will have to be prepared to accept newborns with CCHD identified by pulse oximetry.

Connection to the Medical Home

The results of newborn CCHD screening should be communicated to newborns' primary care providers. During the first outpatient visit, primary care providers should ensure that all newborns were appropriately screened and received any necessary follow-up. The work group recognized the importance of developing health information exchange systems to allow primary care providers, in addition to cardiology subspecialists, to easily track this information. To facilitate this tracking, standards for electronic reporting of pulse-oximetry measurements will need to be developed. Standards for electronic reporting would also help facilitate the development of quality measures.

Primary care providers will also need to develop strategies for screening those newborns who missed screening. As with other newborn screening tests, primary care providers play a central role in ensuring long-term follow-up for those infants diagnosed with CCHD through newborn screening and coordinating their care with a pediatric cardiologist.[2]

Public Health, Quality Assurance, and Surveillance

Follow-up for a positive screen result should be managed by the hospital or birth center before discharge; therefore, the role of public health agencies in CCHD screening is different from that in the case of newborn dried-blood-spot screening or newborn hearing screening. However, public health agencies can play a central role in quality assurance and surveillance. There are several challenges to public health agencies' involvement with CCHD screening, including the inability to collect real-time screening data through health information exchange systems, absence of the direct presence of public health personnel in hospitals and birthing centers, and the financial and staffing pressures within public health departments.

State-level Title V Maternal and Child Health programs and birth-defect sur-

veillance and prevention programs should play a role in surveillance and evaluation of CCHD screening. These programs already conduct public education and outreach; train providers; and support genetic services, newborn screening programs, and services for children with special health care needs. Although state birth-defect programs could assist with CCHD surveillance, there are differences across states in resources for such activities and the approaches to case ascertainment. As of February 2011, there were 40 birth-defect surveillance programs in the United States and 6 more in development. With adequate resources, some of these programs could potentially collect and track data on populations screened or not screened or those with false-negative screening results. Data could also be collected on whether a diagnosed CCHD was detected through prenatal ultrasound or newborn pulse-oximetry monitoring. Collecting data to understand the factors associated with false-positive pulse-oximetry monitoring results could also help refine the recommended screening activities. Although there is currently no capacity in birth-defect programs to undertake real-time follow-up of CCHD-positive screen results, including short-term follow-up, the infrastructure is in place in many states for birth-defect surveillance programs to play a critical role in conducting long-term surveillance and evaluation.

Health Care Costs

The main costs of a screening program for CCHD are related to staff time for screening, tracking results, and communicating with parents, the purchase and maintenance of screening equipment, consumables associated with screening (eg, probes, adhesive wraps, cleaning supplies), the costs associated with verifying a positive screen result, and the costs associated with treatment. The cost of conducting pulse-oximetry examination and follow-up is quite low in absolute terms; published estimates are $5 or less per infant[7,8] up to $10 per infant, depending on the protocol.[14] Although screening can sometimes be completed in <1 minute, other studies have estimated that the process takes 5 minutes of staff time, including communication with parents.[14] The cost estimate compares quite favorably with cost estimates for newborn hearing screening ($30 or more per infant with an average reimbursement by private health plans in 2004 of $84 if billed separately[17]). Moreover, the cost of pulse oximetry is significantly offset by avoided costs of care. The authors of the report from Sweden calculated that the savings in health care costs from the prevention of 1 case of complications of circulatory collapse resulting from an undiagnosed CCHD may exceed the cost of screening 2000 newborns.[8]

Another potentially important cost is related to delayed discharge because of the need to repeat screening or obtain diagnostic evaluation, which leads to extra hospital days that may not be reimbursed by insurance carriers. Echocardiography is typically reimbursed well. However, the cost of transport can be high and receive variable insurance reimbursement. Although telemedicine for remote echocardiography could be important for hospitals and birthing centers without ready access, it is unclear who would pay to develop and maintain the infrastructure.

At present, there is no clear way to bill for pulse-oximetry monitoring, because the currently available *Current Procedural Terminology* (CPT) codes for pulse oximetry are only appropriate when accompanied by a diagnostic code for a pulmonary disease associated with hypoxia.[19] The AAP, AHA, and ACCF should work with the American Medical Association, which develops CPT codes, to develop the appropriate CPT codes for pulse-oximetry monitoring and with public and private payers to ensure appropriate reimbursement. However, newborn hospital-based screening services such as hearing screening are commonly not reimbursed separately if conducted by regular hospital nursery staff, even with appropriate CPT codes available. Because the cost of conducting pulse-oximetry monitoring is quite low, the cost to hospitals and birthing centers should not be a major barrier. In Switzerland, for example, most birthing centers have adopted pulse-oximetry monitoring, and an estimated 85% of infants are screened despite no mandate for either screening or insurance reimbursement for screening.[20]

The work group recognized the concerns about limited health care resources and emphasized the need to weigh the costs of pulse oximetry against the potential benefits of early diagnosis of CCHD, including the costs saved by decreasing the morbidity associated with later diagnosis. Cost data should be compared with the screening-outcomes data, such as those collected by public health agencies, to inform policymakers and to develop new interventions to improve the efficiency of screening.

Health Care Provider and Family Education

Both health care providers and families must understand the rationale for and limitations of pulse-oximetry monitoring to detect CCHD, including the important understanding that a negative screening result does not exclude the possibility of CCHD or other congenital heart disease. Similarly, educa-

tion is needed to minimize the harm that may be generated by false-positive screen results. Implementation of other newborn screening tests has been improved through the development of simple clinical decision-support tools for health care providers that explain the screening and what should be done in the event of a positive result (eg, the HRSA-funded ACTion sheets and simple fact sheets for families).[21] Similar materials need to be developed for pulse-oximetry monitoring and should be available in print and through electronic media in English, Spanish, and other local languages. Implementation toolkits used to help hospitals and birthing centers assess their degree of readiness for screening, to develop algorithms for screening, and to evaluate their ongoing activities are also important.

Coordination of Implementation Activities

The work group endorsed the development of a national clearinghouse and technical assistance center similar to the National Resource Center for Newborn Hearing Screening (www.infanthearing.org), the National Newborn Screening and Genetics Resource Center (http://genes-r-us.uthscsa.edu), and the Emergency Medical Services for Children National Resource Center (www.childrensnational.org/EMSC). These sites provide examples of ways to coordinate service delivery between health care providers and state public health agencies. Replicating this approach through partnership with state Title V Maternal and Child Health programs would allow implementation that takes into account specific local factors such as the availability of diagnostic services.

DISCUSSION

A significant body of evidence suggests that early detection of CCHD through pulse-oximetry monitoring is an effective strategy for reducing morbidity and mortality rates in young children. The work group identified strategies for hospitals and birthing centers to implement pulse-oximetry monitoring for CCHD and included the following specific recommendations.

- Screening should be conducted by using motion-tolerant pulse oximeters that report functional oxygen saturation and have been cleared by the FDA for use in newborns.
- Screening should be based on the recommended screening algorithm and be performed by qualified personnel (eg, nurses, allied health technicians) who have been educated in the use of the algorithm and trained in pulse-oximetry monitoring of newborns.
- The algorithm cutoffs may need to be adjusted in high-altitude nurseries.
- Any abnormal pattern of low blood oxygen saturation requires a complete clinical evaluation by a licensed, independent practitioner. In the absence of other findings to explain hypoxemia, CCHD needs to be excluded on the basis of a comprehensive echocardiogram interpreted by a pediatric cardiologist before discharge from the hospital. If an echocardiogram cannot be performed in the hospital or birthing center and diagnosis by telemedicine is not possible, strong consideration should be made for transfer to another medical center for diagnosis. Before implementing screening, protocols for arranging diagnostic follow-up should be established.
- Hospitals and birthing centers should establish partnerships with local and state public health agencies to develop strategies for quality assurance and monitor the impact of screening.
- Primary care providers should ensure that newborns in their practice were appropriately screened and should work to facilitate long-term follow-up for those diagnosed with CCHD.
- Standards should be developed for electronic reporting of pulse-oximetry monitoring and diagnostic outcomes.

CONCLUSIONS

The work group recognized the challenges of implementing a new screening program. To ensure that screening is implemented in a safe and effective manner, the work group strongly endorsed the development and funding of a national technical assistance center to disseminate best practices; to partner with public health agencies to monitor the impact of screening; to evaluate and make recommendations regarding workforce and related infrastructure needs; and to coordinate research to help answer the important unanswered questions regarding screening thresholds and optimal strategies for diagnosis and follow-up. The Secretary of the HHS has directed an interagency work group to develop a plan to address these critical gaps before recommending that CCHD be a part of the recommended uniform screening panel.

APPENDIX: WORK-GROUP MEMBERS

The following is a list of work-group members and the agencies or organizations they represented at the meeting (being listed as a work-group member does not imply that the members or the organization that they represent endorse all aspects of this report): Mona Barmash (Congenital Heart Information Network, Margate City, NJ), Robert H. Beekman, MD (Cincinnati Children's Hospital Medical Center,

Cincinnati, Ohio) (AAP), Elizabeth Bradshaw, MSN, RN, CPN (Children's National Medical Center, Washington, DC), Carl Cooley, MD (Center for Medical Home Improvement, Concord, NH), Sheri Crow, MD (Mayo Clinic, Rochester, MN), Stephen Downs, MD, MS (Indiana University-Purdue University, Indianapolis, IN), Charlotte Druschel, MD, MPH (New York State Department of Health, Troy, NY), Marcia Feldkamp, PhD, PA (University of Utah, Salt Lake City, UT), Sharon Fleischfresser, MD, MPH (Wisconsin Department of Health, Madison, WI), Alan Fleischman, MD (March of Dimes Foundation, White Plains, NY) (HHS SACHDNC), Tim Geleske, MD (North Arlington Pediatrics, Arlington Heights, IL) (AAP and HHS SACHDNC), Balaji Govindaswami, MBBS, MPH (Santa Clara Valley Health and Hospital System, San Jose, CA), Kimberly Hoffman, NP (Alfred I. duPont Hospital for Children, Wilmington, DE), R. Rodney Howell, MD (SACHDNC, Washington, DC) (HHS SACHDNC), Kellie Kelm, PhD (FDA, Silver Spring, MD), Alex Kemper, MD, MPH, MS (Duke University, Durham, NC), Vi Kennedy, RN, MBA (Bless Her Heart, Colleyville, TX), Thomas S. Klitzner, MD, PhD (Mattel Children's Hospital, Los Angeles, CA) (AAP), Lazaros Kochillas, MD (University of Minnesota, Minneapolis, MN), Robert Koppel, MD (Cohen Children's Medical Center, New Hyde Park, NY), Praveen Kumar, MD (Northwestern Memorial Hospital, Chicago, IL) (AAP), Michele A. Lloyd-Puryear, MD, PhD (HRSA, Rockville, MD) (HHS SACHDNC), William T. Mahle, MD (Emory University School of Medicine, Atlanta, GA) (AAP and AHA), Marie Y. Mann, MD, MPH (HRSA, Rockville, MD), Gerard R. Martin, MD (Children's National Medical Center, Washington, DC) (ACCF), G. Paul Matherne, MD, MBA (University of Virginia, Charlottesville, VA) (AHA), W. Robert Morrow, MD (University of Arkansas for Medical Sciences School of Medicine, Little Rock, AR) (AAP), Jelili Ojodu, MPH (Association of Public Health Laboratories, Silver Spring, MD), Richard Olney, MD (Centers for Disease Control and Prevention, Atlanta, GA), Matthew V. Park, MD (NorthWest Children's Heart Care/Pediatrix Medical Group, Tacoma, WA), Gail D. Pearson, MD, ScD (National Heart, Lung, and Blood Institute, Bethesda, MD), Geoffrey Rosenthal, MD, PhD (University of Maryland School of Medicine, Baltimore, MD), Annamarie Saarinen, MA (Newborn Coalition, 1in100, Shoreview, MN), Phyllis Sloyer, PhD (Florida Department of Health, Tallahassee, FL) (Association of Maternal and Child Health Programs), Barry Thompson, MD, MS (American College of Medical Genetics, Bethesda, MD), Tracy Trotter, MD (San Ramon Valley Primary Care Medical Group, San Ramon, CA) (HHS SACHDNC), Lisa Vasquez, MPA (HRSA, Rockville, MD), William Walsh, MD (Vanderbilt University, Nashville, TN), Diane Zook, BS (Mary Bridge Children's Hospital, Tacoma, WA), and Alan E. Zuckerman, MD (National Library of Medicine, National Institutes of Health, Bethesda, MD). The liaisons to the work group were Anne de-Wahl Granelli, PhD (Queen Silva Children's Hospital, Gothenburg, Sweden), and Andrew Ewer, MD (University of Birmingham, Birmingham, England).

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Strategies for Implementing Screening for Critical Congenital Heart Disease

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Appendix E

Pulse oximetry in the newborn nursery:

1. About how many babies does your hospital deliver per year? _____
2. Does your hospital currently perform pulse oximetry to check the oxygen saturation in all newborns before discharge home? ___ Yes ___ No
3. Does your hospital have pulse oximeters available in the newborn nursery?
   ___ Yes, only 1 ____Yes, more than 1 ___ No
4. Do you have staff available in the newborn nursery 7 days a week (24 hours per day) who are trained to measure pulse oxygen saturation on nursery patients? ___ Yes ___ No

Hospital cardiac care capacity for newborns:

1. What do you do if a newborn is suspected of having congenital heart disease?
   _____
   _____
   _____
   _____
2. Does your hospital employ pediatric cardiologists who are available to the hospital 7 days a week?
   ___ Yes ___ No
3. Are pediatric cardiologists available to come to your hospital for consultation?
   ___ Yes ___ No

   If so, are they available 7 days a week? ___ Yes ___ No
4. Do you currently have the capacity to perform echocardiograms on neonates at your hospital?
   ___ Yes ___ No

If so, are the sonographers pediatric trained? ___Yes ___ No

If so, is this service available 7 days a week? ___ Yes ___ No

5. Do you currently have the capacity to perform echocardiograms on adults in your hospital? ___ Yes ___ No

   If so, is this service available 7 days a week? ___ Yes ___ No

Telemedicine capacity:

1. Does your hospital have an existing relationship for remote conferencing for cardiac consultation by telephone? ___ Yes ___ No

   If yes, for adult patients? ___ Yes ___ No

   For pediatric (including newborn) patients with a pediatric cardiologist? ___ Yes ___ No

2. Do you have the ability to store echocardiographic images and upload these to another site for remote diagnosis? ___ Yes ___ No

3. Do you have the ability to perform echocardiograms with concurrent real-time monitoring by pediatric cardiologists? ___ Yes ___ No

Appendix F

Region/Hospital	Annual Deliveries	Currently Screening	Pulse OX Equipment Available	Pulse Ox Staff	Employ Pediatric Cardiologist	Pediatric Cardiologist Available	Pediatric Cardiologist Available 7 days/week
Baltimore Metro							
Anne Arundel Medical Center	**5,200**		**X**			**X**	**X**
Baltimore Washington Medical Center	**800**		**X**	**X**		**X**	
Bayview Medical Center	**1,600**		**X**	**X**		**X**	**X**
Carroll Hospital Center	**1,200**		**X**	**X**			
Franklin Square Hospital Center	**2,640**	**X**	**X**			**X**	**X**
Greater Baltimore Medical Center	**4,450**		**X**	**X**		**X**	**X**
Harbor Hospital	**1,500**	**X**	**X**			**X**	**X**
Howard County General Hospital	**3,100**		**X**	**X**		**X**	**X**
Johns Hopkins Hospital	**1,500**		**X**	**X**	**X**	**X**	**X**
Laurel Regional Hospital	**900**		**X**	**X**			
Maryland General Hospital	**900**		**X**	**X**			
Mercy Medical Center	**2,900**		**X**	**X**		**X**	**X**
St. Joseph Medical Center	**2,200**	**X**	**X**	**X**			
Saint Agnes Hospital	**1,800**	**X**	**X**	**X**		**X**	**X**
Sinai Hospital	**2,200**	**X**	**X**	**X**	**X**	**X**	**X**
University of Maryland Medical Center	**1,450**		**X**	**X**	**X**	**X**	**X**
Upper Chesapeake Medical Center	**1,250**		**X**	**X**			
Total	**35,590**	**5**	**17**	**14**	**3**	**12**	**11**
Percent	**NA**	**29.4%**	**100.0%**	**82.4%**	**17.6%**	**70.6%**	**64.7%**
Eastern Shore							
Chester River Health System	**250**		**X**	**X**			
Memorial Hospital at Easton	**1,000**		**X**			**X**	**X**
Peninsula Regional Medical Center	**2,000**		**X**	**X**		**X**	
Union Hospital	**700**		**X**	**X**			
Total	**3,950**	**0**	**4**	**3**	**0**	**2**	**1**
Percent	**NA**	**0.0%**	**100.0%**	**75.0%**	**0.0%**	**50.0%**	**25.0%**

Appendix F

Region/Hospital	Annual Deliveries	Currently Screening	Pulse OX Equipment Available	Pulse Ox Staff	Employ Pediatric Cardiologist	Pediatric Cardiologist Available	Pediatric Cardiologist Available 7 days/week
National Capital							
Holy Cross Hospital	**8,500**	**X**	**X**	**X**		**X**	**X**
Montgomery General Hospital	**750**		**X**	**X**		**X**	**X**
Shady Grove Adventist Hospital	**5,000**	**X**	**X**	**X**	**X**	**X**	**X**
Southern Maryland Hospital	**1,900**	**X**	**X**	**X**		**X**	
Washington Adventist Hospital	**1,800**	**X**	**X**	**X**	**X**	**X**	**X**
Total	**16,150**	**4**	**5**	**5**	**2**	**5**	**4**
Percent	**NA**	**80.0%**	**100.0%**	**100.0%**	**40.0%**	**100.0%**	**80.0%**
Southern Maryland							
Calvert Memorial Hospital	**870**		**X**				
Civista Medical Center	**800**		**X**	**X**			
St. Mary's Hospital	**1,100**	**X**	**X**	**X**			
Total	**2,770**	**1**	**3**	**2**	**0**	**0**	**0**
Percent	**NA**	**25.0%**	**75.0%**	**50.0%**	**0.0%**	**0.0%**	**0.0%**
Western Maryland							
Frederick Memorial Hospital	**2,450**		**X**			**X**	**X**
Garrett County Memorial Hospital	**275**	**X**	**X**	**X**			
Meritus Medical Center	**1,950**		**X**	**X**			
Western Maryland Regional Medical Center	**1,100**		**X**	**X**			
Total	**5,775**	**1**	**4**	**3**	**0**	**1**	**1**
Percent	**NA**	**25.0%**	**100.0%**	**75.0%**	**0.0%**	**25.0%**	**25.0%**

*Baltimore Metro includes Anne Arundel, Baltimore, Carroll, Harford, and Howard Counties, and Baltimore City. Eastern Shore includes Caroline, Cecil, Dorchester, Kent, Queen Anne's, Somerset, Talbot, Wicomico, and Worcester Counties. National Capital includes Montgomery and Prince George's Counties. Southern Maryland includes Calvert, Charles, and St. Mary's Counties. Western Maryland includes Allegany, Frederick, Garrett, and Washington Counties.

Appendix F

	Adult Echo	Adult Echo Available 7 days/week	Neonate Echo	Neonate Echo Available 7 days/week	Echo Staff Pediatrics Trained	Adult Telemedicine	Pediatric Telemedicine	Remote Echo	Real Time Echo
Baltimore Metro									
Anne Arundel Medical Center	X	X	X	X	X	X	X	X	X
Baltimore Washington Medical Center	X	X				X	X		
Bayview Medical Center	X	X	X	X	X	X	X	X	X
Carroll Hospital Center	X	X	X	X	X			X	
Franklin Square Hospital Center	X	X	X	X	X	X	X	X	
Greater Baltimore Medical Center	X	X	X	X	X	X	X	X	X
Harbor Hospital	X	X	X	X	X				
Howard County General Hospital	X	X	X	X	X	X	X	X	X
Johns Hopkins Hospital	X	X	X	X	X		X	X	X
Laurel Regional Hospital	X								
Maryland General Hospital	X	X	X	X	X		X		
Mercy Medical Center	X	X	X	X	X	X	X	X	
St. Joseph Medical Center			X		X	X	X	X	
Saint Agnes Hospital	X	X	X	X		X			
Sinai Hospital	X	X	X	X	X				
University of Maryland Medical Center	X	X	X	X	X			X	X
Upper Chesapeake Medical Center	X	X	X	X			X	X	
Total	**16**	**15**	**15**	**14**	**13**	**9**	**11**	**11**	**6**
Percent	**94.1%**	**88.2%**	**88.2%**	**82.4%**	**76.5%**	**52.9%**	**64.7%**	**64.7%**	**35.3%**
Eastern Shore									
Chester River Health System	X	X	X		X	X	X	X	
Memorial Hospital at Easton	X	X	X	X	X	X	X	X	
Peninsula Regional Medical Center	X	X	X	X	X		X	X	X
Union Hospital	X	X	X	X	X			X	
Total	**4**	**4**	**4**	**3**	**4**	**2**	**3**	**4**	**1**
Percent	**100.0%**	**100.0%**	**100.0%**	**75.0%**	**100.0%**	**50.0%**	**75.0%**	**100.0%**	**25.0%**

Appendix F

	Adult Echo	Adult Echo Available 7 days/week	Neonate Echo	Neonate Echo Available 7 days/week	Echo Staff Pediatrics Trained	Adult Telemedicine	Pediatric Telemedicine	Remote Echo	Real Time Echo
National Capital									
Holy Cross Hospital	X	X	X	X	X	X	X	X	X
Montgomery General Hospital	X		X	X	X				
Shady Grove Adventist Hospital	X	X	X	X	X	X	X	X	X
Southern Maryland Hospital	X	X	X	X	X		X	X	X
Washington Adventist Hospital	X	X	X		X				X
Total	**5**	**4**	**5**	**4**	**5**	**2**	**3**	**4**	**4**
Percent	**100.0%**	**80.0%**	**100.0%**	**80.0%**	**100.0%**	**40.0%**	**60.0%**	**80.0%**	**80.0%**
Southern Maryland									
Calvert Memorial Hospital									
Civista Medical Center	X		X	X	X		X	X	X
St. Mary's Hospital	X	X	X	X		X	X	X	
Total	**2**	**1**	**2**	**2**	**1**	**1**	**2**	**2**	**1**
Percent	**66.7%**	**33.3%**	**66.7%**	**66.7%**	**33.3%**	**25.0%**	**66.7%**	**66.7%**	**33.3%**
Western Maryland									
Frederick Memorial Hospital	X	X	X	X	X	X	X	X	X
Garrett County Memorial Hospital	X							X	
Meritus Medical Center	X	X	X	X	X	X	X	X	X
Western Maryland Regional Medical Center	X	X	X	X	X		X		X
Total	**4**	**3**	**3**	**3**	**3**	**2**	**3**	**3**	**3**
Percent	**100.0%**	**75.0%**	**75.0%**	**75.0%**	**75.0%**	**50.0%**	**75.0%**	**75.0%**	**75.0%**

*Baltimore Metro includes Anne Arundel, Baltimore, Carroll, Harford, and Howard Counties, and Baltimore City. Eastern Shore includes Caroline, Cecil, Dorchester, Kent, Queen Anne's, Somerset, Talbot, Wicomico, and Worcester Counties. National Capital includes Montgomery and Prince George's Counties. Southern Maryland includes Calvert, Charles, and St. Mary's Counties. Western Maryland includes Allegany, Frederick, Garrett, and Washington Counties.