Implementing Recommended Screening for Critical Congenital Heart Disease

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**KEY WORDS**
newborn screening, congenital heart defects

**ABBREVIATIONS**
AAP—American Academy of Pediatrics
ACC—American College of Cardiology
AHA—American Heart Association
CDC—Centers for Disease Control and Prevention
CHD—congenital heart disease
CCHD—critical congenital heart disease
FDA—Food and Drug Administration
HRSA—Health Resources and Services Administration
NIH—National Institutes of Health
NJDOH—New Jersey Department of Health
RUSP—recommended uniform screening panel

Drs Martin, Beekman, and Mahle served as facilitators of the February 2012 meeting, and contributed to the writing and editing of the manuscript; Dr Martin approved the final manuscript as submitted; Ms Mikula and Drs Fasules and Pearson served as break-out session facilitators at the February 2012 meeting; Ms Mikula also contributed to the writing and lead editing of the manuscript; Drs Fasules, Pearson, and Kemper contributed to the writing and editing of the manuscript; Dr Garg presented the New Jersey experience at the February 2012 meeting, and contributed to the writing and editing of the manuscript; and Dr Morrow drafted the initial manuscript and participated in the editing of the manuscript.

(Continued on last page)
In October 2010, the US Health and Human Services Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children recommended that screening for critical congenital heart disease (CCHD) using pulse oximetry be added to the recommended uniform screening panel (RUSP). After this, the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children collaborated with the American College of Cardiology (ACC), the American Academy of Pediatrics (AAP), and the American Heart Association (AHA) to convene a work group to discuss and describe strategies related to implementation. These approaches were later outlined in the article “Strategies for Implementing Screening for Critical Congenital Heart Disease,” published in *Pediatrics*,1 and have been used to facilitate the implementation of screening programs throughout the country.

In September 2011, Secretary Sebelius endorsed the addition of CCHD newborn screening to the RUSP. In addition, she supported the development of screening standards, infrastructure for point-of-service testing, educational materials by the Health Resources and Services Administration (HRSA), additional research conducted by the National Institutes of Health (NIH), and surveillance and cost-effectiveness research by the Centers for Disease Control and Prevention (CDC).2 Each state is responsible for determining best practice for CCHD screening, and state health departments have been actively engaged and typically serve as the central administrative leader for this initiative. Not uncommonly this involves educational and advisory responsibilities that differ from other newborn screening.

As states and hospitals began planning for and implementing CCHD screening, many important challenges were identified that will be addressed in detail. These challenges include the following: (1) selection of screening equipment; (2) standards for reporting of screening outcomes to stakeholders; (3) training of health care providers and educating families; (4) future research priorities; (5) payment for screening, follow-up diagnostic testing, and public health oversight; and (6) advocacy to facilitate effective and comprehensive screening. To develop strategies to address these challenges, an expert panel was convened in Washington, District of Columbia, in February 2012. In attendance were key stakeholders (see Appendix), including primary care providers, specialists (pediatric cardiologists and neonatologists), sonographers, nurses, researchers, industry representatives, parent advocates, an advocacy group (Genetic Alliance), professional organizations (AAP, ACC, AHA, American College of Medical Genetics), state public health officials, and representatives from federal agencies (CDC, HRSA, NIH, Food and Drug Administration [FDA]). This report summarizes the consensus recommendations from this meeting and provides clarification of outstanding issues not addressed in the article “Strategies for Implementing Screening for Critical Congenital Heart Disease,” published in *Pediatrics*.1

**EQUIPMENT SELECTION**

Oximeters used for screening for CCHD must be approved by the FDA for measuring arterial oxygen saturation. This approval is based on the accuracy assessed by studies performed in adults exposed to a range of oxygen concentrations. The FDA has not tested the performance of pulse oximeters in CCHD screening protocols and considers this screening only as “practice of medicine” use of the device. As such, interpretation of pulse oximetry results in newborns must take into account the clinical situation, and requires clinician judgment, interpretation, and decision-making to determine what, if any, diagnostic or therapeutic actions are appropriate. The FDA has no specific approval process for using pulse oximetry for the detection of CCHD. The expert panel developed a list of criteria for pulse oximeters to be used for CCHD screening (Table 1) to help those who are now adopting screening.

There are opportunities to improve pulse oximetry technology used for screening for CCHD. Because neonatal oximeters are approved based on adult data, it will be helpful to provide data from CCHD screening to the FDA as additional evidence of suitability of oximeters for neonates. In particular, by tracking results of screening using a uniform protocol, differences in oximeter characteristics, including sensitivity and specificity, can be evaluated. Incorporating CCHD screening algorithms and tools to facilitate accurate interpretation of the screening results into the software for the device or as a separate device would decrease potential error in the screening process. Because many congenital defects, including those that do not produce cyanosis, result in low perfusion, improvements in detecting low perfusion by pulse oximetry might improve the sensitivity of screening.

<table>
<thead>
<tr>
<th>TABLE 1 Recommendations for Pulse Oximetry Equipment for Newborn Screening</th>
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<tr>
<td>1. Meet the International Organization for Standardization standard and be cleared by the FDA for hospital use in neonates.</td>
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<td>2. Have adequate performance under normal circumstances and tolerant of motion.</td>
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<tr>
<td>3. Use a sensor indicated for use on neonatal extremities and not require a fixation method that can affect skin integrity. Adult sensors should not be used on neonates.</td>
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<td>4. Include systems to ensure that only the proper sensors are used with the device.</td>
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REPORTING STANDARDS

Public health monitoring is critical to ensure the effectiveness of the screening activities. Reporting of results is complex because there are a number of different entities that either screen or require the screening results. These entities include the birth facilities, primary care providers, specialty care providers, and state public health programs, including the newborn screening program and birth defects registries. Each entity has different data requirements to ensure that effective screening and evaluation and validation of the screening program can be accomplished. Table 2 presents minimum data recommendations and considerations for data exchange for reporting.

TRAINING OF HEALTH CARE PROVIDERS AND EDUCATING FAMILIES

Education of health care providers and families is important to the successful implementation of CCHD screening programs. At the first stakeholder meeting, it was recommended that the benefits and limitations of CCHD screening using pulse oximetry be the primary focus of educational materials. This remains the underlying theme of educational efforts targeted to both providers and families. Additional issues that should be addressed include identification of providers responsible for teaching, recommended components and key messages of educational programs, ensuring that educational materials are culturally competent and available in languages to meet the needs of a multilingual population, provider and parent education on new technology associated with CCHD screening (ie, pulse oximetry devices, electronic health exchange systems), community education, access to and dissemination of educational materials, and creation of regional networks for educational collaborations.

Educational materials for both parents and providers should provide background and significance of CCHD screening and information on CHD and CCHD appropriate to either population according to the intended use of the materials. Parents should be provided information on limitations of pulse oximetry for detection of CCHD, what they should expect if results are positive, information on CHD resources, and signs and symptoms of CHD. In addition, materials for parents should be suitable for a diverse audience and comprehensible at an appropriate reading level as determined by the organization responsible for creating the materials. Last, materials for parents should address issues of consent where required, as well as how results will be recorded and reported.

Information for provider groups will depend on the role of the provider. In addition to providing information on background and significance of CCHD screening, educational materials should provide information on communication strategies with parents across the spectrum of care and details related to screening protocols and processes. The response to positive screens should be outlined, including the need for echocardiographic evaluation. Advice on care coordination with parents/families and supportive measures for positive screens should be provided, appropriate to the level of the provider. Providers should be given guidance on reporting and documenting results as well as quality assurance measures. The technological limitations of CCHD screening should be reviewed, as well as the use of data reported to public health. All providers should understand that a negative screen does not rule out the presence of all forms of CHD in a given patient.

To make appropriate and safe recommendations for the concerns previously described, to avoid duplication of efforts, and to provide guidance on developing and

### TABLE 2 Minimum Data Recommendations and Considerations for Data Exchange for Reporting of CCHD Screening Results

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<th>Public Health Program Data</th>
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<td>1. Patient-level data: Patient identification data that allows validation that all infants had a valid screen and results Age in hours at time of screening, All oximetry saturations reported (initial screen and any subsequent screens) Final screening result Obstacles encountered during screening process (ie, obstacles with the infant/family, staff, equipment) Diagnostic results 2. Screening program data: Screening protocol being used Type of pulse oximeter used for screening</td>
<td>1. Will vary according to the legislative or executive mandate of each state. 2. Aggregate or individual data may be specified to be provided to and tracked by public health programs 3. Birthing facilities required to report to public health programs should provide data sufficient to determine whether all eligible infants were screened and, in the case of positive screens, information about the evaluation performed. 4. Ideal for positive screens: Final diagnosis should be tracked as well as interventions that follow Should include whether infants required transport for evaluation and treatment or had evaluation at the birthing facility and what treatment entailed 5. Ideal for negative screens: Subsequent identification of congenital heart defects (ie, false-negative screens) could be linked within the NBS programs. 6. Summary statistics should be provided by health departments and NBS programs to stakeholders.</td>
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NBS, newborn screening program.
disseminating educational information, the group recommended the development or identification of an “educational collaborative” including, but not limited to, states, providers, parents, national organizations, and industry (Table 3).

FUTURE RESEARCH PRIORITIES
Outcomes of Screening for CCHD
The goal of screening is to decrease morbidity and mortality from unrecognized CCHD. To verify that this goal is met, the extent to which mortality is decreased through screening, and whether serious morbidity, including end-organ damage, is prevented will need to be determined. This is difficult to assess because screening is only 1 aspect of care that affects outcome and outcomes overall have improved over time because of better care.

In evaluating outcomes, it will be important to specify the time frame of interest. The initial focus should be on outcomes in the first few weeks of life, often the most risky time period for patients with CCHD. However, newborn screening research is increasingly focused on longer-term outcomes, including neurodevelopmental outcomes, and it will be appropriate to take this approach in evaluating screening for CCHD.

Screening for CCHD should also be considered in the context of screening that already occurs, such as screening using fetal ultrasound. Routine fetal ultrasound is performed in most pregnancies in the United States and can identify several of the malformations that come under the rubric of CCHD. This leads to referral for fetal echocardiography, which may lead to the detection of up to 60% of CCHD prenatally. Postnatal screening using pulse oximetry may not be applied in cases in which there is a known prenatal diagnosis. Therefore, short- and intermediate-term outcomes should be evaluated on the basis of all forms of screening for CCHD.

Other Outcomes
Screening with pulse oximetry will identify conditions other than CCHD, including noncritical CHD and non-cardiac conditions, such as pulmonary disease, sepsis, and metabolic disease. In addition, screening may be associated with psychosocial consequences for families, particularly in the setting of false-positive screens. To obtain a complete picture of screening for CCHD, it will be essential to capture these and other secondary outcomes. In addition, nationwide screening for CCHD should increase the awareness of CHD, and it would be useful to evaluate this phenomenon.

Screening Process
The efficiency of screening for CCHD will vary across facilities and individuals. It is clear from the quality improvement literature that almost any process can be improved by studying its components. It should be possible to improve the efficiency of screening by using the natural experiments that may arise as states implement different screening processes. As experience with CCHD screening increases, it is also likely that process research questions will be identified that can be pursued using a variety of study designs.

In addition to evaluating the process of screening, it will be useful to consider evaluating potential alternatives to pulse oximetry screening, such as new technologies or other measures. Such technologies and measures could include the peripheral perfusion index, biomarkers, or advanced echocardiographic techniques to obtain data that can be collected without the need for skilled technologists and are read remotely.

Pulse Oximetry Equipment
Some pulse oximetry equipment may be better than others for screening under certain circumstances. For example, most pulse oximeters have not been validated extensively at the lower oxygen saturations associated with CCHD. One strategy for resolving this gap is through the ACC-funded Improving Pediatric and Adult Congenital Treatment registry of pediatric cardiac catheterization procedures. During such procedures, simultaneous direct measurements of oxygen saturation and pulse oximetry readings are recorded, making the registry an important source of data to evaluate pulse oximetry equipment.

Immediate Next Steps
A number of programs are currently working to address existing research questions surrounding CCHD screening. The immediate next step is to compile a summary of the information available from existing programs and data sources, and then use this information to identify specific strategies to address the 5 research

TABLE 3 Responsibilities of Proposed Collaborative to Address Education Surrounding CHD Screening

| 1. Review and assess existing materials. |
| 2. Identify gaps in existing materials. |
| 3. Determine/identify best practices for educational materials and methods. |
| 4. Pilot and evaluate educational materials when necessary. |
| 5. Determine best practices, stakeholders, partners, and outlets for dissemination of guidelines. Strategies could include public awareness campaigns, long distance strategies (telemedicine), social media, academic education/curriculums, state public health education. |
| 6. Identify funding sources. |
priorities that follow. Funding agencies could include NIH, Patient-Centered Outcomes Research Institute, HRSA, CDC, and private foundations. Care should be exercised to avoid conflicts of interest related to industry-funded research because of issues related to propriety technology.

**PAYMENT FOR SCREENING, FOLLOW-UP DIAGNOSTIC TESTING, AND PUBLIC HEALTH OVERSIGHT**

Costs of screening include developing educational materials for screeners and families, training screeners, purchasing and maintaining calibration of pulse oximeters, purchasing sensors, paying for the time required to conduct the screening, developing and maintaining a database to support reporting to public health authorities, and conducting or arranging for follow-up evaluations in the case of failed screens. Issues of who is responsible for bearing those costs and payments by health plans or government entities need to be addressed. In addition, the costs and logistics of providing public health oversight of CCHD screening and outcomes and administrative responsibility need to be assessed.

Studies conducted in the European literature suggest that screening is cost-effective in terms of cost per case of CCHD identified, but a formal assessment of cost per life-year saved has not yet been published. In addition, the differences inherent in the US health care system mandate that similar assessments be undertaken here. A formal cost-effectiveness analysis of screening for CCHD is being prepared by CDC as part of its response to Secretary Sebelius’ letter. Such analyses compare direct medical costs with health outcomes at the level of society but do not address the issue of who bears the costs.

Additional cost and cost-effectiveness analyses should be performed after more experience has been gained by various states with screening. Such experience can be expected to decrease the time required to screen, communicate with families, and arrange for any follow-up care that is needed and result in more stable cost estimates. In addition, it would be helpful to assess the costs of screening incurred by different stakeholders, including hospitals and birth centers.

**ADVOCACY TO FACILITATE EFFECTIVE AND COMPREHENSIVE SCREENING**

Although CCHD was added to the RUSP by Secretary Sebelius in September 2011, work continues at the state level toward uniform adoption of screening for CCHD. Because adoption of the complete RUSP is not required by all states, individual state action may be required, either through legislation or executive action, to mandate or promote the adoption by health facilities and providers of screening. Working at the state level, health care provider leaders and advocates have educated state legislators and departments of health on the benefits of screening. Each state has presented different challenges; for example, determining thresholds for high-altitude screening in the mountain states. Through different models of legislation, regulation, or as a standard of care, the ad hoc coalition of physicians, nurses, parents, and other advocates has succeeded in the adoption of CCHD screening through a variety of mechanisms. Indiana was the first state to pass legislation, quickly followed by Maryland, New Jersey, New Hampshire, West Virginia, Connecticut, and California. Several states, including Alabama, Utah, Georgia, Michigan, Ohio, and Pennsylvania, have taken or are in the process of taking a regulatory route to implementation. Arkansas and North Carolina are in the process of a legislative approach to approval and work continues as a general effort in Wisconsin and Maine. There are expected to be continued efforts in the 2013 legislative session. With continued education and advocacy, some states that were initially hesitant to adopt legislation may continue to move forward.

Local support can be developed through engagement with a variety of stakeholders (ie, state AAP Chapters, the March of Dimes, the AHA, regional CHD advocates, parent advocacy groups, the Congenital Heart Public Health Consortium, local state medical societies) and by offering model legislation or regulatory language. Another important partner in the effort is the state chapter of the American Hospital Association, as many hospitals view screening as an unfunded mandate as seen in the subcommittee debate in California. Resolving concerns among advocates and articulating clearly the benefits of CCHD before attempting to secure legislative or regulatory requirements to screen is advised.

At the state level, model legislation can mandate a regulatory approach or the screening itself. Legislation can define birthing facilities, specify CCHD screening, and call on the department of health to develop regulations to implement, track, and report screening in the state. At the federal level, 6 states or groups of states (MI, New England [ME, NH, VT, RI, and CT], NJ, UT, VA, and WI) were awarded grants from HRSA to help implement and evaluate programs. Funding to better standardize reporting and tracking is still needed. Other long-term federal efforts include adding CCHD screening to the National Quality Forum—approved measures and continued engagement of regulatory agencies (ie, the Joint
Commission) in adopting CCHD screening as a standard. Eventually, CCHD screening results should be an element imbedded in each hospital’s electronic health record with a decision support tool assisting the physicians and nurses in assessing the patient and in reporting the results.

The New Jersey Experience

On June 2, 2011, Governor Christie of New Jersey signed legislation mandating newborn pulse oximetry screening. The law went into effect 90 days later on August 31, 2011, making New Jersey the first state in the nation to implement mandatory screening for CCHD. As such, critical review of the New Jersey experience can provide important lessons for other states implementing or planning to implement statewide CCHD screening. The New Jersey Department of Health (NJDOH) led the implementation efforts and established the New Jersey Critical Congenital Heart Disease Screening Working Group, which includes neonatologists, cardiologists, nurses, nurse midwives, pediatricians, parents, NJDOH staff from the New Jersey Birth Defects Registry, the newborn screening program, and newborn hearing screening program, as well as representatives from the NJDOH Division of Health Facilities Evaluation and Licensing, the AAP New Jersey Chapter, Maternal and Child Health Consortia, and the New Jersey Hospital Association. The NJDOH, with input from members of the CCHD Screening Working Group, developed a recommended screening protocol, trained hospital providers, and instituted a 2-pronged approach to data collection. Challenges to implementation identified in the New Jersey experience were the short implementation period, the unfunded mandate, and barriers associated with initiation of a new surveillance system.

CONCLUSIONS

CCHD newborn screening presents new challenges and opportunities to health care providers, families, hospitals, and state and federal health agencies. Addressing the challenges and acknowledging the opportunities for further work provides an opportunity to strengthen screening and newborn care networks in ways that should benefit children born with CCHD.

APPENDIX

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):

- Swapna Abhyankar, MD; National Institutes of Health, National Library of Medicine
- Mona Barmash; Congenital Heart Information Network
- Amy Basken; Adult Congenital Heart Association
- Robert Beekman, MD, FACC; American Academy of Pediatrics, Section on Cardiology and Cardiac Surgery; Cincinnati Children’s Hospital Medical Center
- Ulf Borg; Covidien
- Elizabeth Bradshaw Mikula, MSN, RN, CPN; Children’s National Medical Center
- Waldemar (Wally) Carlo, MD; American Academy of Pediatrics, Section on Perinatal Pediatrics
- Lynn Colegrove; American Academy of Pediatrics
- Sarah Copeland, MD; Health Resources and Services Administration
- Sheri Crow, MD, MS; Mayo Clinic
- Susan Cummins, MD, MPH, FAAP; FDA/Health and Human Services, Center for Devices & Radiological Health
- Olivia Easley, MD; Bless Her Heart
- James Fasules, MD; American College of Cardiology
- Lori Garg, MD, MPH; New Jersey Department of Health
- Rebecca Goodwin, JD; National Institutes of Health, National Library of Medicine, Lister Hill National Center for Biomedical Communications
- Balaji Govindaswami, MBBS; Santa Clara Valley Medical Center, Division of Neonatology
- Anne de-Wahl Granelli, PhD; The Queen Silvia Children’s Hospital and Gothenburg University, Sweden
- Scott Grosse, PhD; Centers for Disease Control and Prevention
- John S. Hokanson, MD; Wisconsin Department of Health and Human Services/Critical Congenital Heart Disease Ad Hoc Task Force
- Patrick Johnson; American Academy of Pediatrics
- Kellie Kelm, PhD; Food and Drug Administration
- Lazaros Kochilas, MD; University of Minnesota
- Praveen Kumar, MD; American Academy of Pediatrics; Northwestern University Feinberg School of Medicine
- John Laschinger, MD; Food and Drug Administration
- Jody Lemacks; Mended Little Hearts
- Keila Lopez, MD, MPH; Texas Children’s Hospital Baylor College of Medicine, Congenital Heart Public Health Consortium
- Jeannette Lowe; March of Dimes, National Office of Government Affairs
- William Mahle, MD, FACC, American Heart Association
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The federal and state authors are not involved in the advocacy activities discussed herein.

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