Lessons Learned From Newborn Screening for Critical Congenital Heart Defects

Matthew Oster, Emory University
Susan W. Aucott, Johns Hopkins University
Jill Glidewell, Centers for Disease Control and Prevention
Jesse Hackell, Pomona Pediatrics PC
Lazaros Kochilas, Emory University
Gerard R. Martin, Children's National Health System
Julia Phillippi, Vanderbilt University
Nelangi M. Pinto, University of Utah
Annamarie Saarinen, Newborn Foundation|Newborn Coalition
Marci Sontag, University of Colorado

Only first 10 authors above; see publication for full author list.

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Lessons Learned From Newborn Screening for Critical Congenital Heart Defects

Matthew E. Oster, MD, MPH\textsuperscript{a,b}, Susan W. Aucott, MD\textsuperscript{c}, Jill Glidewell, APRN, MSN, MPH\textsuperscript{a}, Jesse Hackell, MD\textsuperscript{d}, Lazaros Kochilas, MD, MSCR\textsuperscript{b}, Gerard R. Martin, MD\textsuperscript{e}, Julia Phillippi, PhD, CNM\textsuperscript{f}, Nelangi M. Pinto, MD\textsuperscript{g}, Annamarie Saarinen, MA\textsuperscript{h}, Marci Sontag, PhD\textsuperscript{i}, and Alex R. Kemper, MD, MPH, MS\textsuperscript{j}

\textsuperscript{a}National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, Atlanta, Georgia \textsuperscript{b}Children’s Healthcare of Atlanta, Emory University, Atlanta, Georgia \textsuperscript{c}Johns Hopkins University School of Medicine, Baltimore, Maryland \textsuperscript{d}Pomona Pediatrics PC, Pomona, New York \textsuperscript{e}Children’s National Health System, Washington, District of Columbia \textsuperscript{f}Vanderbilt University School of Nursing, Nashville, Tennessee \textsuperscript{g}Department of Pediatrics, University of Utah School of Medicine, Salt Lake City, Utah \textsuperscript{h}Newborn Foundation|Newborn Coalition, Saint Paul, MN \textsuperscript{i}Colorado School of Public Health, University of Colorado Anschutz Medical Center, Aurora, Colorado \textsuperscript{j}Duke Clinical Research Institute and Department of Pediatrics, Durham, North Carolina

Abstract

Newborn screening for critical congenital heart defects (CCHD) was added to the US Recommended Uniform Screening Panel in 2011. Within 4 years, 46 states and the District of Columbia had adopted it into their newborn screening program, leading to CCHD screening being nearly universal in the United States. This rapid adoption occurred while there were still questions about the effectiveness of the recommended screening protocol and barriers to follow-up for infants with a positive screen. In response, the Centers for Disease Control and Prevention partnered with the American Academy of Pediatrics to convene an expert panel between January and September 2015 representing a broad array of primary care, neonatology, pediatric cardiology, nursing, midwifery, public health, and advocacy communities. The panel’s goal was to review current practices in newborn screening for CCHD and to identify opportunities for improvement. In this article, we describe the experience of CCHD screening in the United States with regard to: (1) identifying the target lesions for CCHD screening; (2) optimizing the algorithm for screening; (3) determining state-level challenges to implementation and surveillance of CCHD; (4) educating all stakeholders; (5) performing screening using the proper equipment and in a cost-effective manner.
manner; and (6) implementing screening in special settings such as the NICU, out-of-hospital settings, and areas of high altitude.

In September 2011, the US Secretary of Health and Human Services added newborn screening for critical congenital heart defects (CCHD) to the Recommended Uniform Screening Panel (RUSP) upon the recommendation of the Secretary’s Advisory Committee on Heritable Disorders in Newborns. The addition of CCHD to the RUSP was the culmination of nearly a decade of research on the utility of pulse oximetry to detect CCHD, combined with the determined efforts of the congenital heart disease advocacy community and important guidance on implementation strategies stemming from a January 2011 stakeholder meeting endorsed by many professional societies (the American Academy of Pediatrics [AAP], the American Heart Association [AHA], and the American College of Cardiology [ACC]) and advocacy organizations (March of Dimes and the Newborn Foundation).

Screening for CCHD became the second point-of-care newborn screening test after screening for congenital hearing loss to be added to the RUSP. Unlike dried blood spot–based screening, point-of-care screening requires health care providers to administer the test, interpret the results, act on the findings, and report the outcomes of screening to the newborn screening program. Contrary to screening for congenital hearing loss, newborns with a positive screen for CCHD require immediate evaluation for potentially life-threatening conditions before hospital discharge. The advisory committee recommended that CCHD be added to newborn screening instead of simply being a component of usual clinical care; adding it to newborn screening would both help assure universal access to a test that was believed to have high potential for producing a significant health benefit and facilitate public health monitoring to enact and hopefully improve the screening protocol.

Since the addition of CCHD to the RUSP, the AAP has published a policy statement regarding the importance of screening for CCHD and the recommendations of a subsequent stakeholder meeting to provide further guidance on implementation. Adoption of CCHD newborn screening has been rapid; within 4 years of the addition of CCHD to the RUSP, nearly all newborns are being screened. Despite this apparent success, there are gaps in implementation and surveillance that may affect the quality of care received by many newborns. Such gaps include confusion regarding the definition of CCHD, lack of conformity in the algorithms being used, debate about appropriate evaluation after a positive screen, and a lack of infrastructure to conduct population-level surveillance. Therefore, the Centers for Disease Control and Prevention (CDC) partnered with the AAP to convene an expert panel between January and September of 2015 to review current practices in newborn screening for CCHD and to identify opportunities for improvement. Panel members (Supplemental Information), representing the broad array of primary care, neonatology, pediatric cardiology, nursing, midwifery, public health, and advocacy communities, met bimonthly via telephone and in-person for a 2-day meeting (May 19–20, 2015). The present special article summarizes the current state of CCHD screening in the United States and provides a roadmap for continued improvement of the process.
TARGETS OF SCREENING

Having a well-defined list of the screening targets is central to public health monitoring of the effectiveness of the screening program. Although the goal of CCHD screening is to detect potentially life-threatening lesions in infancy, the term CCHD is ambiguous. CCHD can be based on the specific defect, the type of intervention needed, or both. The term CCHD was first used in the New England Regional Infant Cardiac Program to denote cases that typically required surgery or catheter-based intervention in the first year of life. Although this definition is suitable for hospital-based programs, it is often not suitable for public health surveillance because of the time lag between screening and outcome or the availability of data regarding the outcome. In a 2009 AAP/AHA scientific statement on screening for CCHD, the investigators considered 13 specific defects, as well as a category listed as “other major heart defects.” In reviewing the evidence for screening for CCHD, the Secretary’s Advisory Committee on Heritable Disorders in Newborns considered 7 of these defects (hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus) as targets for CCHD screening. As a group, these defects represent the most common critical lesions that typically present with hypoxemia in the newborn period. However, these were not intended to be the only conditions to be targeted for screening or monitored by public health programs. Recognizing that there are other important defects that may be less common but often present with hypoxia, or more common but less likely to present with hypoxia, the CDC includes 5 additional lesions when studying CCHD screening: coarctation of the aorta, double-outlet right ventricle, Ebstein’s anomaly, interrupted aortic arch, and single ventricle. Because of the complexity and variation of CCHD, any list will be incomplete. However, the expert panel identified the core conditions listed in Table 1 for monitoring, including the 12 conditions monitored by the CDC as well as an option for other critical cyanotic lesions not otherwise specified.

CCHD screening is currently based on the detection of hypoxemia using pulse oximetry, but not all cases of hypoxemia detected indicate the presence of a CCHD. In up to 79% of “positive” screens, a newborn may have a CCHD or another potentially serious and treatable condition. These non-CCHD conditions include a noncritical congenital heart defect, sepsis, other infection, persistent pulmonary hypertension, parenchymal or anatomic pulmonary disease, transient tachypnea of the newborn, hypothermia, and hemoglobinopathies. Although not the primary targets of CCHD screening, these secondary conditions can be detrimental to the infant if not diagnosed and treated in a timely manner. This situation creates a challenge for public health agencies that monitor the outcome and assess the benefit of newborn screening. Systematically tracking these secondary conditions of screening (ie, causes of significant hypoxemia not due to CCHD) in addition to the core conditions (ie, cases of CCHD) would allow public health agencies to better determine the benefits of newborn screening by using pulse oximetry. In the future, CCHD-screening approaches with pulse oximetry might change (eg, timing, threshold for a positive screen) or pulse oximetry might be replaced by some new technology (eg, automated echocardiogram), leading to greater accuracy for the detection of CCHD but decreased detection of these secondary targets. Monitoring case detection and outcomes of newborns identified with
secondary conditions will allow a better understanding of the overall benefit of current CCHD screening practices and will allow policy makers to consider whether these secondary conditions should be promoted to a primary target of screening in the future.

Because of the high prevalence of secondary conditions, it is important for the clinical team to consider all causes of oxygen desaturation when responding to a positive screen. Additional evaluation and testing of the infant should be prioritized according to the conditions most relevant for each case, and such evaluation should not be delayed while awaiting an echocardiogram. Depending on the resources of the birthing location where the newborn is tested, transfer to another center where adequate resources exist to complete the evaluation might be required. The child should not be discharged without resolving the cause of desaturation or at least before excluding potentially life-threatening conditions. If a cause other than CCHD is identified and appropriately treated with resolution of hypoxemia, an echocardiogram might not be necessary.13

SCREENING ALGORITHM

The CCHD screening algorithm endorsed by the AAP, AHA, ACC, March of Dimes, and the Newborn Foundation was based primarily on data from Sweden.2,9 This algorithm was designed for use in the newborn nursery and indicates that screening should be performed at >24 hours of age (or before discharge if discharge is at <24 hours) on the right hand (preductal) and either foot (postductal). If either reading is <90%, the result is considered a fail. If either reading is ≥95% and the difference between the 2 readings is ≤3%, the result is considered a pass. Results outside of these 2 ranges require repeat testing in 1 hour for up to 2 additional tests. A child who has not passed the screening by the third testing is considered to have failed. Most states and hospital systems adopted this protocol, and many have reported their experiences to date, including Minnesota,15,16 Washington,17 California,18 Arkansas,19 Wisconsin,20 Maryland,21 and Vermont.22 Some states, however, have chosen to adopt a different algorithm, a decision which provides an opportunity to better understand the comparative effectiveness of different approaches.23 New Jersey requires a minimum oxygen saturation of 95% in both the preductal and postductal sites with a difference of ≤3%.24 This modification would be expected to increase the sensitivity but could also decrease specificity. Tennessee attempts to decrease the time and costs needed for screening by first testing only in a foot (ie, a postductal site). If the saturation in the foot is ≥97%, the result is a pass; if the saturation is <90%, the result is a fail. If the saturation is 90% to 96%, the right hand is then tested, and the AAP protocol is followed. From a physiologic standpoint, the postductal site would be expected to have a higher saturation than the preductal site in only rare circumstances. Table 2 summarizes the AAP, New Jersey, and Tennessee algorithms.

Further modifications of the screening algorithm have been suggested for use in the NICU or for locations with higher altitude (see Special Settings section). Other protocols have been evaluated in other countries, with differences not only in saturation cutoff points but also the timing of screening.25 Performing screening before 24 hours may have the benefit of earlier detection and decreased morbidity but may negatively affect both sensitivity and specificity.5
There are many factors to consider when determining the optimal screening algorithm. The first issue is the balance of sensitivity and specificity. Screening programs typically aim for very high sensitivity, but increasing sensitivity (such as that achieved by raising the oxygen saturation level required to pass) also reduces specificity and increases the false-positive rate. This approach increases the need for follow-up testing, which potentially results in a greater burden on families and the medical system. However, further testing may detect conditions associated with hypoxemia other than CCHD. Another important issue is resource utilization and cost. Simplifying the screening in the initial step (as in Tennessee) may reduce the costs of equipment and labor and decrease the need for follow-up testing, thereby reducing the burden on the family, delays in hospital discharge, and need for transport. A final important consideration is the ease of use of the screening and testing. Nurseries in Minnesota and California found a number of procedural inconsistencies due to misinterpretation of the AAP algorithm by the screening staff. These studies highlight the need for rigorous training of the screening staff and simplification of the protocol. Other research has suggested that the use of computer-based tools or apps can help to decrease the rate of misinterpretations. Further study of screening in practice is needed to identify the optimal algorithm for particular settings.

**STATE-LEVEL IMPLEMENTATION AND PUBLIC HEALTH SURVEILLANCE**

By August 2015, screening had become nearly universal in the United States, with 46 states and the District of Columbia including CCHD as part of their newborn screening program. The AAP maintains a current list of each state’s CCHD newborn screening requirements and related laws and policies (available upon request from the AAP Division of State Government Affairs [stgov@aap.org]). Each state has their own process for expanding newborn screening, usually involving a combination of advisory committee panels and legislation.

The common challenge faced by all states is the lack of funding. Although the cost burden falls to birth centers for CCHD screening activities, state newborn screening programs are typically responsible for educating health care providers and the general public about the screening, for collecting and monitoring screening outcomes, and for quality assurance activities. Most states do not have resources for the critical data infrastructure needed to support secure data transfer between birthing facilities and newborn screening programs to monitor outcomes of CCHD screening. Instead, newborn screening programs have had to rely on volunteer reports, either made through paper-based forms or manual computer upload. The expert panel therefore focused on public health surveillance needs for effective CCHD screening.

Despite the addition of CCHD screening to the RUSP in 2011 and subsequent implementation efforts in states, appropriate data collection efforts have lagged. As a result, these data collection limitations have hampered efforts to make any sound evidence-based recommendations that would notably alter the implementation efforts to date. CCHD screening data collection at the state level requires 3 components: (1) authorization to collect the data; (2) a list of data elements to be collected on each child; and (3) a system to collect the data. As of December 2014, only 24 states were actively collecting data and 14 others
were planning to do so.\textsuperscript{27} The list of data elements being collected varies between states, ranging from individual pulse oximetry levels to simply an aggregate collection of the total numbers of cases of CCHD detected. In 2012, a minimal data set was recommended.\textsuperscript{11} Although this approach would allow for basic surveillance, an “optimal” data set would allow for more refined surveillance and, in turn, quality improvement. This tactic includes further details on screening settings and results on follow-up testing. (Table 3) The method of data collection varies as well. Some states have added fields for CCHD screening to the existing dried blood spot newborn screening card, but this method may cause delays in collecting information for screening for other conditions and requires manual entry at the health department. Other states have used electronic reporting such as through the electronic birth certificate that is completed by birthing facility staff in the first days after a birth. Further research is needed to optimize collection of data regarding infants who have undergone CCHD screening, whether by augmenting existing methods or by adopting new methods similar to those for blood lead level screening in children or immunization information systems. A national data collection system might help assess the true impact of CCHD screening on outcomes for infants with CCHD or secondary conditions.

Comprehensive and ongoing program evaluation also requires longitudinal tracking of outcomes. To align with other newborn screening conditions, patients with failed screening should ideally be followed up to determine the long-term outcomes. The authority to collect such data has been included in some legislative mandates for CCHD screening but not in others. CCHD screening also provides an opportunity for collaboration between state birth defects surveillance programs, state newborn screening programs, immunization information systems, hospitals, and the medical home. In addition to monitoring the prevalence of CCHD, state birth defects surveillance programs could incorporate data collection to evaluate false-positive and false-negative screens.\textsuperscript{28} Such efforts will also require resources, although perhaps less of an investment due to the existing infrastructure.\textsuperscript{17} Such an investment may allow for an evaluation of screening in a manner that currently remains challenging.

\textbf{EDUCATION}

Successful implementation of any public health screening program requires a multifaceted educational approach that includes providers, families, and public health officials. Providers and personnel who perform testing should be adequately trained in screening procedures, interpretation of results, and appropriate response for infants with failed screens. Various hospital training documents have been developed at both the hospital- and state-based level, and the CDC and AAP\textsuperscript{29} have developed online resources aimed at providers. Families likewise need adequate education to understand what the screen entails and what a positive result may mean for their child. Such information is available to families online.\textsuperscript{30} Although there may have been initial concern that families would have increased anxiety or refusal of CCHD screening, this scenario has not been seen in practice.\textsuperscript{31, 32} Finally, state public health agencies have had to adapt to hospital implementation of a new, bedside screening method that requires urgent follow-up before the infant leaves the hospital, which differs significantly from other newborn screening conditions. Although each state may have unique

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testing and reporting requirements, there are resources available online aimed at the public health community, including model practices and quality indicators.\textsuperscript{33}

\section*{COST AND EQUIPMENT}

CCHD screening guidelines have previously been published regarding specific types of pulse oximeters (ie, oximeters should be motion-tolerant or measure-through-motion, report functional oxygen saturation, be validated in low-perfusion conditions, be cleared by the US Food and Drug Administration for use in newborns, have an accuracy specification of 2\% root mean square).\textsuperscript{9} Ideally, providers should adhere to product labeling, patient weight considerations, and directions for use. Certain pulse oximeters have further been reviewed by the US Food and Drug Administration and cleared with specific labeling for CCHD screening.

Estimated costs for pulse oximetry are based both on equipment use and time required. Cost estimates range from $\sim$5 to $14 per infant screened,\textsuperscript{15, 34–36} with an estimated cost of $40–385 per life-year potentially gained through screening. This estimate does not include potential life-years gained through diagnosis of secondary conditions; the estimated cost per life-year gained may be lower if these cases were included. Time and motion studies have revealed that point-of-care screening incurs $\sim$3.5 to 9 minutes per infant.\textsuperscript{24} Opportunities to reduce costs include lowering the costs of labor by minimizing the time to perform screening as it becomes part of standard routine care and automation of data collection becomes more widespread, and lowering costs of resources by using reusable pulse oximetry sensors instead of disposable, single-use sensors.\textsuperscript{34, 37} More comprehensive cost-effectiveness analyses will become feasible as more detailed data collection is implemented at the state level, including analyses of costs or savings of CCHD screening and subsequent treatment.

\section*{SPECIAL SETTINGS}

\subsection*{NICU}

Initial guidelines for screening newborns for CCHD focused only on those in the newborn nursery.\textsuperscript{9} Given that premature infants typically have lower saturations than term infants, screening in the NICU can lead to a higher false-positive rate than in the newborn nursery.\textsuperscript{38} This concern for higher false-positive rates and the lack of clear guidelines for screening in the ICU or intermediate care nurseries have led to wide variation in practice. Many units perform CCHD screening according to the standard AAP protocol, whereas others have modified the protocol based on timing or use of supplemental oxygen. Some have chosen not to perform standardized screening at all, operating under the assumption that monitoring the infant in the ICU nursery for a standard period of time is sufficient. Regardless of the practice, all children without a previous postnatal echocardiogram should be screened for CCHD, and the goals behind CCHD screening should be followed (namely, to detect CCHD in children before they become symptomatic from the disease). Given that supplemental oxygen can make interpretation of CCHD screening difficult, it is reasonable to wait until a child is weaned from oxygen before screening or to obtain an echocardiogram in the child that is unable to be weaned before discharge.
Out-of-Hospital Settings

The recommendation that all newborns receive CCHD screening regardless of birth location produces some challenges for children born in out-of-hospital settings. Although standard guidelines recommend screening at >24 hours of age, many infants born at home or at a birth center are no longer under the care of a health provider at that time. Screening at <24 hours of age can be performed but at the expense of potential negative effects on the sensitivity and false-positive rate. Infants with a failed screen or equivocal findings need continued assessment and monitoring. Infants with failed screens may benefit from oxygen and transfer to higher level facilities because low oxygen saturation can indicate an underlying problem, whether of cardiac or noncardiac origin. All birthing centers and providers of home births should be encouraged to have a clear CCHD screening protocol, such as that developed in the Netherlands. Feasibility for CCHD screening of US home births has been documented on a voluntary basis. An outpatient pediatric office is not the ideal location for screening or evaluation, but screening is acceptable if the facility has proper equipment and trained staff.

High Altitude

Due to alterations in oxygen-hemoglobin dissociation with changes in the partial pressure of oxygen, infants at higher altitude typically have a lower oxygen saturation according to pulse oximetry than those at sea level. This difference has important implications for CCHD screening, particularly at elevations >6800 feet. Some Colorado hospitals have made adaptations to their screening protocol due to an unacceptable frequency of false-positive findings in newborns at high altitude. These modifications include repeating pulse oximetry testing every 4 hours while awaiting the echocardiogram results, placing the newborn in an oxygen hood to replicate sea level atmospheric oxygen tension, and delaying the screening to 30 hours to allow more time for transition. Further investigation of these approaches and others are needed to evaluate their efficacy.

CONCLUSIONS

Screening for CCHD by using pulse oximetry is an important public health program with the goal of improving the lives of children by detecting the presence of CCHD before the onset of symptoms; an added benefit is identification of children with hypoxemia due to secondary conditions. Many important lessons have been learned from the implementation of this program at the national level, lessons which may guide future similar screening efforts for other diseases. However, many questions remain for CCHD screening, and these cannot be answered without appropriate data from public health agencies. As data collection efforts improve, CCHD screening may ultimately be improved via optimizing the algorithm used for screening, ensuring the quality of screening, and modifying the screening protocol for special settings.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.
Acknowledgments

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ABBREVIATIONS

AAP American Academy of Pediatrics
ACC American College of Cardiology
AHA American Heart Association
CCHD critical congenital heart defects
CDC Centers for Disease Control and Prevention
RUSP Recommended Uniform Screening Panel

References

10. Mahle WT, Martin GR, Beekman RH III, Morrow WR, Section on Cardiology and Cardiac Surgery Executive Committee. Endorsement of Health and Human Services recommendation for


<table>
<thead>
<tr>
<th>TABLE 1</th>
</tr>
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<tbody>
<tr>
<td>Conditions Detected Via Screening for CCHD With the Use of Pulse Oximetry</td>
</tr>
<tr>
<td><strong>Core conditions (CCHD)</strong></td>
</tr>
<tr>
<td>Coarctation of the aorta</td>
</tr>
<tr>
<td>Double-outlet right ventricle</td>
</tr>
<tr>
<td>Ebstein’s anomaly</td>
</tr>
<tr>
<td>Hypoplastic left heart syndrome</td>
</tr>
<tr>
<td>Interrupted aortic arch</td>
</tr>
<tr>
<td>Pulmonary atresia</td>
</tr>
<tr>
<td>Single ventricle (not otherwise specified)</td>
</tr>
<tr>
<td>Tetralogy of Fallot</td>
</tr>
<tr>
<td>Total anomalous pulmonary venous return</td>
</tr>
<tr>
<td>D-transposition of the great arteries</td>
</tr>
<tr>
<td>Tricuspid atresia</td>
</tr>
<tr>
<td>Truncus arteriosus</td>
</tr>
<tr>
<td>Other critical cyanotic lesions not otherwise specified</td>
</tr>
<tr>
<td><strong>Secondary conditions (non-CCHD)</strong></td>
</tr>
<tr>
<td>Hemoglobinopathy</td>
</tr>
<tr>
<td>Hypothermia</td>
</tr>
<tr>
<td>Infection, including sepsis</td>
</tr>
<tr>
<td>Lung disease (congenital or acquired)</td>
</tr>
<tr>
<td>Noncritical congenital heart defect</td>
</tr>
<tr>
<td>Persistent pulmonary hypertension</td>
</tr>
<tr>
<td>Other hypoxemic condition not otherwise specified</td>
</tr>
</tbody>
</table>
# TABLE 2

Common Algorithms for Newborn Screening for CCHD With the Use of Pulse Oximetry in the United States

<table>
<thead>
<tr>
<th>Algorithm Source</th>
<th>Cutoff for Passing With First Measurement</th>
<th>Retest Criteria for Subsequent Measurements</th>
<th>Fail Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAP</td>
<td>$O_2$ sat ≥95% (in either RH or F) AND $</td>
<td>hand-foot</td>
<td>$ $O_2$ sat ≥3%</td>
</tr>
<tr>
<td>New Jersey</td>
<td>$O_2$ sat ≥95% (in both RH and F) AND $</td>
<td>hand-foot</td>
<td>$ $O_2$ sat ≥3%</td>
</tr>
<tr>
<td>Tennessee</td>
<td>$O_2$ sat ≥97% (F)</td>
<td>$O_2$ sat &lt;95% (in both RH and F) OR $</td>
<td>hand-foot</td>
</tr>
</tbody>
</table>

F, either foot; $O_2$, oxygen; RH, right hand; sat, saturation.
### TABLE 3

Optimal Data Set for Surveillance of Screening for CCHD

<table>
<thead>
<tr>
<th>Minimal core data set</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (hours) at screen</td>
</tr>
<tr>
<td>Pulse oximetry saturation levels for each screen (preductal and postductal)</td>
</tr>
<tr>
<td>Screening outcome (pass/fail)</td>
</tr>
<tr>
<td>Type of CCHD detected, if any</td>
</tr>
<tr>
<td>Demographic characteristics as defined by newborn screening program</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting (newborn nursery, NICU, home, other)</td>
</tr>
<tr>
<td>Type of non-CCHD condition detected, if any</td>
</tr>
<tr>
<td>Results of echocardiogram, if performed</td>
</tr>
<tr>
<td>Prenatal diagnosis status</td>
</tr>
<tr>
<td>Long-term outcomes</td>
</tr>
</tbody>
</table>