The Road to Universal Pulse-Oximetry Screening: Are We There Yet?

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ABBREVIATION

CCHD—critical congenital heart disease

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Congenital heart disease is the most common birth defect and represents nearly 40% of all deaths caused by congenital anomalies.[1] Critical congenital heart disease (CCHD), which encompasses the more severe forms, is present in 2.5 to 3 in 1000 live births.[2] In general, prenatal ultrasound or physical examination alone can easily miss newborns with CCHD.[3,4] Failure to diagnose CCHD early in life can result in high morbidity and mortality rates, because symptoms frequently present after closing of the pulmonary ductus arteriosus, after nursery discharge. Pulse-oximetry screening is a low-cost, painless, noninvasive test that increases the ability to identify newborns with CCHD before they clinically decompensate.[5–8]

In 2009 the American Heart Association and American Academy of Pediatrics published a scientific statement regarding the role of pulse oximetry in examining newborns for CCHD.[9] Despite presenting strong support for this method, they stopped shy of recommending universal screening and called for further studies on implementation. In September 2010, the US Department of Health and Human Services (HHS) Secretary's Advisory Committee on Heritable Disorders in Newborns and Children recommended that CCHD be added to the uniform screening panel. However, the recommendation remains under consideration by Secretary of the HHS, in part because of implementation concerns.

Although no national mandates or endorsements for pulse-oximetry screening currently exist, some hospitals have chosen to develop and implement their own protocols using the best evidence available at the time. In addition, a few states have already introduced and passed legislation that promotes newborn screening for CCHD.

The report in this issue of *Pediatrics*[10] is timely and clearly outlines strategies for implementing pulse-oximetry screening, promoting standardized protocol guidelines, and identifying the infrastructure necessary for success. Written by a workgroup that was specifically convened to address concerns by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, this report has been endorsed by the American Academy of Pediatrics, the American College of Cardiology Foundation, and the American Heart Association Council for Cardiovascular Disease in the Young.

Concern has been expressed in the literature over false-positive results leading to unnecessary, costly evaluation and transfer. Rates have varied, in part, because researchers have used different definitions and screening protocols. In their report, Kemper et al[10] define specific criteria and protocols that decrease false-positive results, such as screening after 24 hours of age and, if the results are positive, having screening performed a total of 3 times before being defined as a positive screen result. In their scientific statement, the American Heart Association and American Academy of Pediatrics

described low false-positive rates that averaged 0.035% in studies in which pulse oximetry was performed after 24 hours.

Once a newborn is identified with a positive screen result, diagnostic strategies call for a comprehensive evaluation for the etiology of hypoxia. Although the screening target is identification of CCHD, the authors also recognize the importance of identifying noncardiac secondary targets such as those of pulmonary and infectious origin. If none can be found, an echocardiogram should be performed and read by a pediatric cardiologist. Delivery strategies will need to address telemedicine or transfer to another institution for those nurseries that do not have echocardiography on site. Also, although a positive screen result might require transport to a regional center that is later deemed unnecessary, it is important to realize that suspicion of CCHD based on physical examination has a much higher false-positive rate and would lead to similar management.[11]

Kemper et al[10] conclude by discussing critical gaps that must be addressed before recommending universal pulse-oximetry screening. Public health agencies will be responsible for creating the necessary infrastructure and for maintaining quality assurance and surveillance. The report defines some of the areas that need development, particularly a national technical assistance center to coordinate implementation and evaluation.

The described infrastructure required to support implementation and compliance with screening guidelines is clearly necessary. However, not all hospitals should feel the need to wait until such infrastructure has been developed. Evidence-based toolkits are already available to facilitate implementation.[12] Materials include information to educate staff, health care providers, and families about the protocol, along with training materials for those responsible for screening. Using such a toolkit will be helpful in minimizing implementation cost and effort.

Furthermore, each hospital will need to develop individualized screening strategies that fit into its own care-delivery model. For example, when implementing pulse-oximetry screening at a large community hospital, we found that assigning a single certified nursing assistant to perform pulse-oximetry and newborn metabolic screening together after 24 hours of age improved consistency and efficiency without additional staff or significant cost (E. A. B., S. C., S. Kiernan, MD, N. Nagel, MD, J. A. Booker, MD, and G. R. Martin, MD, unpublished data, 2011).

There is clear evidence supporting pulse-oximetry screening to improve identification of newborns with CCHD. Successful implementation will depend on standardized screening criteria within hospitals and the public health system's commitment to support surveillance. However, while the infrastructure is being developed, hospitals should be on the front lines trying new strategies, using the well-defined screening criteria presented by Kemper et al[10] in their report. We might still have a way to go, but we are well on our way to universal screening.

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