NEW YORK STATE | Department of Health

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JOHANNE E. MORNE, MS
Executive Deputy Commissioner

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To: Hospital Administrators, Chief Medical Officers and Health Care Providers

From: Marilyn A. Kacica, MD, MPH, Division of Family Health, New York State Department of Health

Alert to NYS Birthing Facilities Regarding Universal Newborn Screening for Critical Congenital Heart Disease

- Please distribute to all staff in Obstetrics & Gynecology, Midwives, Pediatricians, Pediatric Cardiologists, Neonatologists, Family Medicine Physicians, Nurse Practitioners, and Physician Assistants.
- Please also share with your non-hospital-based colleagues.

This notice contains updated guidance from the American Academy of Pediatrics (AAP) about birthing facility requirements to screen newborns for critical congenital heart disease (CCHD).[1] New York State Public Health Law § 2500-a(1)(g) requires all birthing facilities in New York State, and those required to register a child's birth, to use pulse oximetry screening to check for CCHD.

Congenital heart defects are the most common type of birth defects in children, occurring in almost 1% of births in the United States (8 per 1,000 live births). Congenital heart defects represent the top cause of infant mortality attributable to birth defects.[2,3] About 25% of all congenital heart defects constitute CCHD, which requires treatment within the first year of life. If unrecognized, CCHD can lead to serious complications within the first few days or weeks of life.[4] Each year approximately 500 New York State children are born with CCHD and 12% of these children die within their first year of life.

It is important that birthing facilities follow evidence-based recommendations as they administer the screening program and adhere to their protocols. Attached for your use is the new AAP algorithm for CCHD screening in newborns (**Addendum 1**). *It is expected that each birthing facility will have a written protocol in place for uniform CCHD screening and documentation*.

Pulse oximetry is an effective method of screening all newborns for CCHD and can reduce the number of infants who are undiagnosed. The sensitivity of CCHD screening is currently 50%-76%.[1] CCHD is not ruled out on the basis of a normal pulse oximetry screening alone. If CCHD is suspected and the infant has a normal pulse oximetry test, further testing should be performed.

Pulse oximetry screening can provide early detection of other serious and potentiality life-threatening conditions that are not associated with CCHD. These conditions include hemoglobinopathies, hypothermia, infection including sepsis, lung disease, noncritical congenital heart defect, and persistent pulmonary hypertension.[1] Evaluation of other non-CCHD conditions should be undertaken when appropriate.

Data collection helps in ongoing quality improvement of the screening program. Although reporting is not required, documentation and collection of the following data elements are recommended: date and time of screening; screening results (Pass/Fail); referral to medical provider after a failed screen (Yes/No); identification of an infant with CCHD by another means (prenatal ultrasound or clinical signs prior to pulse oximetry screening); diagnostic results; and, parental refusal of screening.

Infants diagnosed with congenital heart disease are to be reported within 10 days of diagnosis to the New York State Department of Health's Birth Defects Registry (BDR), pursuant to 10 NYCRR 22.3, or *alternately* Section 22.3 of Title 10 of the New York State Codes, Rules, and Regulations. Health care providers are to submit reports electronically using the BDR reporting application on the Health Commerce System (HCS). The reporting application includes fields to enter pulse oximetry results.

Resources and Additional Information

- For more information about the Birth Defects Registry see: health.ny.gov/diseases/birth_defects or contact bdr@health.ny.gov
- New York State-specific educational materials and resources for parents are available at: health.ny.gov/community/infants_children/critical_congenital_heart_disease_screening
- Information about Congenital Heart Defects from the New York State Department of Health is available here: health.ny.gov/diseases/birth_defects/chd

References

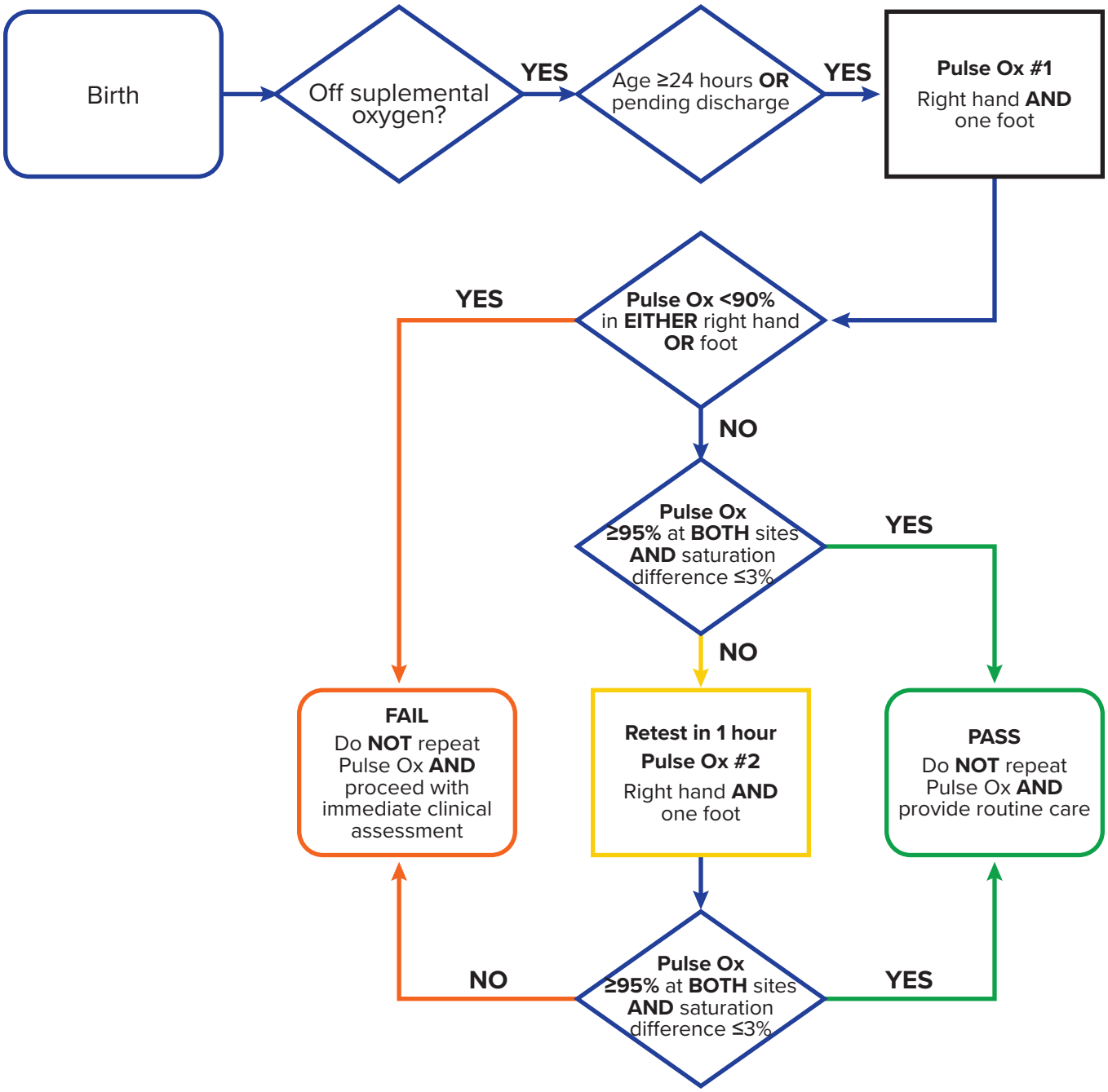
1. Oster ME, Pinto NM, Pramanik AK, et al. Newborn Screening for Critical Congenital Heart Disease: A New Algorithm and Other Updated Recommendations: Clinical Report. *Pediatrics*. 2025;155(1):e2024069667. doi:10.1542/peds.2024-069667.
2. Reller MD, Strickland MJ, Riehle-Colarusso T, Mahle WT, Correa A. Prevalence of congenital heart defects in metropolitan Atlanta, 1998-2005. *J Pediatr*. 2008 Dec;153(6):807-13. doi: 10.1016/j.jpeds.2008.05.059. Epub 2008 Jul 26. PMID: 18657826; PMCID: PMC2613036.
3. CDC. Data and Statistics. Congenital Heart Defects (CHDs). Published May 15, 2024. cdc.gov/heart-defects/data.
4. Mahle WT, Newburger JW, Matherne GP, et al. Role of pulse oximetry in examining newborns for congenital heart disease: a scientific statement from the American Heart Association and American Academy of Pediatrics. *Circulation*. 2009;120(5):447-458. doi:10.1161/CIRCULATIONAHA.109.192576.

Addendum 1

Protocol for Critical Congenital Heart Disease Screening

Recommendations from the New York State Department of Health

From: *Newborn Screening for Critical Congenital Heart Disease: A New Algorithm and Other Updated Recommendations: Clinical Report published by the AAP*



Reference: Oster ME, Pinto NM, Pramanik AK, et al. Newborn Screening for Critical Congenital Heart Disease: A New Algorithm and Other Updated Recommendations: Clinical Report. *Pediatrics*. 2025;155(1):e2024069667. doi:10.1542/peds.2024-069667.