Actionable Patient Safety Solutions (APSS) #7B:

Detecting critical congenital heart disease (CCHD) in newborns

How to use this guide

This guide gives actions and resources for creating and sustaining a plan to improve your organization's detection of critical congenital heart disease (CCHD) in newborns. In it, you'll find:

Patient Safety MOVEMENT

Executive summary checklist

Congenital heart disease (CHD) is one of the most common types of birth defects. 40% of deaths from CHD are caused by critical congenital heart disease (CCHD), including ductal- dependent lesions. CCHD is life threatening, represents at least 25% of CHD and typically requires intervention in the first months or up to the first year of life. Use this checklist to help you prioritize your actions and measure your organization's progress in detecting CCHD in newborns.

STEPS to creating a universal pulse oximetry screening program

- ☐ Choose a proven an FDA-approved technology cleared for use in newborns that can accurately monitor and read through during motion and low perfusion
- ☐ Establish the screening protocol. The current AAP-recommended screening protocol (2019) includes:
  - ☐ SpO2 of less than 90% from any site, or SpO2 of less than 95% from the right hand or either foot OR if the difference between the hand and foot is >3%, REPEAT within one hour. Persisting saturations that are greater in the foot compared to the right hand require immediate evaluation by the primary care physician.
    - ☐ If the 2nd and 3rd measurements are greater than 95%, the screening is **negative**
    - ☐ If the 2nd and 3rd measurements are less than 95%, the screening is **positive**
  - ☐ **A greater-than 3% difference in SpO2 measurements between the right hand and either foot.** For these results, take 2nd and 3rd measurements as described in the items above.
  - ☐ If 2nd screen is positive, REPEAT the screening within on hour. If results are same as above, the screen is considered POSITIVE and primary care physician should be notified for further evaluation and/or testing:
  - ☐ Take a perfusion measurement if it is available on your device. Consider the following guidance to help corroborate differences in perfusion. If oximetry values do not corroborate the presence of CCHD consider the following:
    - ☐ **For a PI measurement of less than 0.7**, increase the need for assessment
    - ☐ **For a PI measurement of less than 0.4**, assess the baby immediately
- ☐ Provide regular pulse oximetry screening training for all care providers. This will help them:
  - ☐ Engage with families
  - ☐ Understand protocols for positive screenings
  - ☐ Understand the results reporting policy
- ☐ Develop a process for continuous improvement:
  - ☐ Educate and communicate with staff
  - ☐ Implement measures to improve processes to meet the universal newborn screening objective
- ☐ Use patient stories – in written and video forms – to find gaps and inspire change in your staff

What we know about failure to detect CCHD in newborns

Problems of detecting CCHD in newborns

CHD is the most common birth defect, affecting approximately 8 in 1,000 live-born infants (Reller et al., 2008; Bernier et al., 2010). Each year, nearly 40,000 infants are born with CHD in the U.S., and 1.35 million infants are born with CHD globally (Hoffman and Kaplan, 2002; Van et al., 2011).

One-quarter to one-third of these infants have CCHD, including ductal dependent lesions (Oster et al., 2013; Glidewell et al., 2015; Ailes, Gilboa, Honein, and Oster, 2015). CCHD causes (Hoffman and Kaplan, 2002):

- About 40% of the deaths from congenital anomalies
- Most of the deaths due to CHD that occur in the 1st year of life

Before newborn screening programs were introduced in the U.S. in 2012, it was estimated that between 70-100 infants died each year from late-diagnosed CCHD (Govindaswami, Jegatheesan and Song, 2012). Screenings show that the number of deaths from CCHD is closer to 120 each year (Grosse et al., 2017).

Many CCHD deaths are preventable

Antenatal ultrasound (during pregnancy) and physician examination after birth improve detection and perinatal outcomes for certain forms of CCHD (Tworetzky et al., 2001; Bonnet et al., 1999). Evidence shows that prenatal detection:

- Increased every year from 2006-2012
- Now occurs in 34% of patients (Quartermain et al., 2015)

A CCHD diagnosis before birth allows for parent counseling and coordination of delivery at an experienced cardiac center.

The gap in patient safety

- More than 30% of CCHD deaths have been attributed to late or missed diagnosis (Chang, Gurvitz and Rodriguez, 2008)
- Each year, an estimated 2,000 infants die or are undiagnosed in the U.S. and some 300,000 infants die or are undiagnosed globally (Salvi, 2016)
- In the developing world, fewer than 50% of CHD cases are diagnosed in the 1st week of life (Hoffman, 2013). The magnitude of the problem has been extensively documented (Singh, Rasiah, and Ewer, 2014; de-Wahl Granelli et al., 2014; Ewer, 2014; Ewer, 2013; Ewer, 2013; Granelli et al., 2007).

Evidence for change in diagnosing CCHD

Evidence for pulse oximetry

Pulse oximetry measures oxygen saturation (SpO2) and pulse rate in a non-invasive way:

- In 2009, de-Wahl Granelli and colleagues published a breakthrough cohort study in which 39,821 infants were screened for CCHD by identifying abnormal SpO2 measurements from Signal Extraction Technology (SET) pulse oximetry. SET's ability to measure through motion and low-perfusion is essential for accurate CCHD screening (de-Wahl Granelli et al., 2009).

- In a separate CCHD screening study of 20,055 asymptomatic newborns, Ewer et al, confirmed the importance of utilizing SET technology that can "produce accurate saturations that are stable in active neonates and in low perfusion states, making them suitable for use in the first few hours of a newborn baby's life" (Ewer et al., 2012).
- In 2014, Zhao and colleagues reported similar positive results from a prospective study using an additional pulse oximetry measurement in more than 100,000 newborns in China (Zhao et al., 2014)

Adding pulse oximetry screening to antenatal ultrasound and physical examination may increase detection rates for CCHD to over 90%. It also helps detect non-critical CHDs and significant non-cardiac neonatal conditions, such as respiratory problems or early-onset sepsis.

However, clinicians need to know that the problem will still be missed in some infants. The *Journal of Pediatrics* published a study estimating that universal pulse oximetry screening for CCHD can miss the problem in some infants (Frank et al., 2013). CDC researchers estimated that each year in the U.S.:

- About 1,755 infants with CCHDs would be diagnosed late (on or after the 3rd day after birth)
- Of these, pulse oximetry would detect about half (875 infants) with a CCHD, but an equal number (880 infants) might still be missed

Evidence for adding perfusion measurement to screening

Most studies report that the lesions most often missed are those causing obstruction to aortic outflow (such as coarctation and interrupted arch). They may not be detected in antenatal ultrasound, physical examination, or by abnormal SpO_2 values from pulse oximetry.

However, an additional pulse oximetry measurement, perfusion measurement, may help detect CCHD with obstructions to aortic outflow. It is an assessment of strength of perfusion at the monitored site. The use of the perfusion measurement is crucial but it is equally important to understand that the pulse oximeter should be used only on the hand for accurate data. Attention to limb positioning is important in the interpretation of perfusion measurement.

In a 2007 study, Granelli and colleagues showed that adding abnormal perfusion measurement to pulse oximetry screening may increase sensitivity to identifying CCHD with an obstruction to the aortic outflow. The authors of this study also noted that adding perfusion measurement to the screening criteria may also result in an increase in false positives (Granelli et al.,, 2007).

In 2011, a federal CCHD workgroup developed a report, Strategies for Implementing Screening for Critical Congenital Heart Disease (Kemper et al., 2011). After a thorough review, the workgroup relied upon a thorough body of evidence and independent published studies to recommend:

> Screening [should] be performed with motion tolerant pulse oximeters 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 (Kemper et al., 2011).

The workgroup included members selected by the U.S. Health and Human Services Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, the American Academy of Pediatrics, the American College of Cardiology Foundation, the Newborn Foundation, the March of Dimes, and the American Heart Association.

Several domestic and international studies have shown that parents are predominantly satisfied with pulse oximetry screening:

- Parents whose babies had a false positive result were no more anxious than those with true negative tests (Ewer 2012)
- Parents generally perceived it as an important and valuable test to detect ill babies

Additionally, all staff groups (healthcare assistants, midwives, nurses, and doctors) were mostly positive about the testing procedure and perceived the test as important. In 2013, Peterson and colleagues found that screening for CCHD:

- Reduces pain and suffering of infants and families
- Reduces costs associated with severe cardiovascular and other organ or neurological compromise upon delayed admission to a cardiac unit
- Has been tied to:
  - Significantly reduced mortality
  - Fewer poor surgical outcomes
  - Lower incidence of prolonged ventilation and potential developmental issues

Causes of newborn death

- In the developing world, the prevalence of certain neonatal conditions varies significantly on the global map, as does the burden of hypoxemia-related conditions such as neonatal pneumonia, sepsis, necrotizing enterocolitis (NEC), and PPHN (Hoffman 2013)
- Every year, nearly 41% of all under-age-5 child deaths are among babies in their 1st 28 days of life or the neonatal period (WHO, 2012)
- Three-quarters of all newborn deaths occur in the 1st week of life
- One-third of these deaths are from infection, such as pneumonia, tetanus, and sepsis

Each of these conditions are likely to manifest with below-normal oxygen saturation. Some are preventable deaths; when diagnosed in a timely fashion, clinical staff can save a life or improve an outcome by giving a course of antibiotics and/or supplemental oxygen therapy.

Considerations when using algorithms for screening

A recent review describes CCHD screening in the U.S. and the efforts to optimize the algorithm for screening, educate all stakeholders, and perform screening using the proper equipment (Oster et al., 2016).

There are many factors to consider when you determine the optimal screening algorithm, including the balance of high altitude, timing of screening, sensitivity and specificity, resource utilization, and cost. For this reason, other screening protocols have been evaluated in the U.S. and in other countries (Ewer and Martin, 2016; Ewer, 2016).

High altitude

Infants at high altitude may have a lower oxygen saturation than those at sea level with potential implications at elevations over 6,800 feet:

- To identify the optimal algorithm in particular settings, you may need to modify the screening protocol described in this document, including the saturation cutoff points and the timing of screening
- Although usually reserved for former premature infants going to a high altitude, any infant who fails high altitude stress testing (HAST) also merits special consideration and

may require an echocardiogram to confirm normal anatomy

Timing of screening

A certain degree of controversy still remains, and debate continues regarding the most appropriate time to screen, the most effective screening pathway, what saturations are acceptable, which conditions we are trying to identify, and screening outside the well-baby nursery.

Sensitivity, specificity, and false-positive/false-negative rates

When evaluating algorithms, it is important to consider sensitivity, specificity, and false-positive and false-negative rates. In addition:

- It is vital that screening leads to timely diagnosis, such as before an infant presents with acute collapse
- The screening should be pre-and post-ductal, because analysis of raw saturation data from infants who had both limb measurements showed that some infants with CCHD would be missed by post-ductal testing alone
- False-positive rates are significantly higher with earlier testing (less than 24 hours of age). This led to recommendations that screening be performed after 24 hours of age.
- However, analysis of recent studies shows that many false-positive tests (30%–80%) indicate alternative non-cardiac conditions (such as congenital pneumonia, early-onset sepsis, or pulmonary hypertension), which may be equally as life threatening as CCHD if diagnosed late
- In published studies that adopted earlier screening (less than 24 hours), the false-positive rate was higher, but more non-cardiac disease was identified
- In some countries, mothers and infants are discharged from the hospital within 24 hours after birth, and an increasing proportion is born at home. In these circumstances, screening in-hospital at less than 24 hours is not practical.

Be this as it may:

- If SpO_2 is less than 90% in either limb, the infant needs to be assessed immediately
- If SpO_2 is between 90-94% in one or both limbs and the infant does not look completely healthy, clinical assessment is mandatory without delays for repeated measurements
- If infant is completely healthy, measurements should be repeated as described

In summary, not having a systematic approach for detecting and treating CCHD significantly affects patient safety, quality, and cost of care. Universal newborn screening with pulse oximetry technology has been shown to increase the detection of CCHD by identifying potential abnormalities that are not apparent in prenatal or postnatal examinations.

Closing the performance gap with CCHD will require hospitals, healthcare systems, and all members of the neonatal healthcare team (RNs, RTs, and MDs) to commit to action in the form of specific leadership, practice, and technology plans for all newborn infants.

Leadership plan

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce preventable events from unrecognized CCHD in newborns.

To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions:

- Implement a plan that includes fundamentals of change outlined in the National Quality Forum safe practices, including awareness, accountability, and action
- Hospital governance and senior administrative and medical and nursing leadership should commit to becoming aware of this major performance gap in their own healthcare system
- Hospital governance, senior administrative leadership, and clinical/safety leadership should close their own performance gap by implementing a comprehensive approach to addressing the performance gap across all providers and systems
- Commit to a goal date to implement the plan you create
- Allocate a budget for the plan to be evaluated by governance boards and senior administrative leaders
- Clinical/safety leadership should endorse the plan and drive implementation across all providers and systems
- Address the performance gap with measurable quality indicators
- Conduct data collection and analysis to help implement and assess outcomes
- Use patient stories – in written and video formats – to identify gaps and inspire change in your staff:
    - The story of Cora McCormick is an example of a newborn who died because of unrecognized CCHD. That can be viewed freely here: **https://youtu.be/VXK02w6aR14**

Action Plan

This plan focuses on actions providers and hospitals can take to improve CCHD results:

- Evaluate guidelines and reviews
- Choose a screening strategy that models the recommendations below and in well-designed, large published studies
- Set concrete milestones in a timeline to implement these practices
- Select technology proven to be effective for newborn screening, including SET pulse oximetry screening strategies
- Determine the screening protocol:
  - Screen newborns more than 24 hours after delivery or before discharge
  - Get pulse oximetry measurements from preductal (right hand) and postductal (either foot) sites. The following results should be considered positive and require further testing:
    - **SpO2 of less than 90% from any site, or SpO2 of less than 95% from the right hand or either foot.** For these results, take 2nd and 3rd measurements, and:
      - If the 2nd and 3rd measurements are greater than 95%, the screening is **negative**
      - If the 2nd and 3rd measurements are less than 95%, the screening is **positive**
    - **A greater-than 3% difference in SpO2 measurements between the right hand and either foot.** For these results, take 2nd and 3rd measurements as described in the bullets above.
  - If available, ake a perfusion measurement measurement:
    - **For a perfusion measurement of less than 0.7**, increase the need for assessment
    - **For a PI measurement of less than 0.4**, assess the baby immediately
- Implement interdisciplinary strategies and educational activities for all members of the neonatal healthcare team, including:
  - Proper screening methods
  - Strategies for family education and engagement
  - Follow-up investigation protocols for positive screens
  - Public health results reporting policy
- Implement optimization and workflow guidelines to ensure staff is adequately screening, such as:
  - As a quality indicator, each week randomly assess the number of babies that should have been screened but were not
  - Communicate with staff and, based on results, implement measures to improve processes in order to meet the goal of screening all newborns
  - Use clinical decision support tools and software whenever available to avoid misinterpretation of screening results or faulty data entry
- Report screening results per state and federal requirements

Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: **https://patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/**

Select technologies that have been shown to improve neonatal oxygen targeting include:

System or Practice	Available technology
Pulse oximetry technologies that are effective in helping clinicians screen for CCHD	
Devices that reduce operator-induced variability and improve efficiency by: • Automating the screening steps • Selecting measurements • Applying those measurements to the screening criteria chosen by the hospital • Categorizing the test as a positive or negative screen	
• Public health reporting systems for newborn screening	

*Company has signed some form of the Open Data Pledge. Find more information on the Patient Safety Movement Foundation website: **https://patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/**

Measuring outcomes

Topic:

Critical Congenital Heart Defects (CCHD) is the number of patients identified with CCHD through technology-enabled pulse oximetry newborn screening. The rate is the reflection of the number of patients diagnosed with CCHD over the total number of infants screened.

Outcome measure formula:

Numerator:
Number of newborns identified with CCHD

Denominator:
Number of patients screened

- This measure is usually displayed as a percentage: Numerator/Denominator *100

Metric recommendations:

Indirect impact:
All newborns that received technology-enabled newborn screening of CCHD via pulse oximetry

Direct impact:
Number of asymptomatic infants identified with CCHD through pulse oximetry and received successful clinical intervention

Lives spared harm:
Number of asymptomatic infants identified with CCHD through pulse oximetry or echocardiogram and received successful clinical intervention

Lives saved:
Lives saved = Lives spared harm x 0.825

Data collection for direct impact:

- Both the numerator and denominator data could be collected from the medical record

Conflicts of interest disclosure

The Patient Safety Movement Foundation partners with as many stakeholders as possible to focus on how to address patient safety challenges. The recommendations in the APSS are developed by workgroups that may include patient safety experts, healthcare technology professionals, hospital leaders, patient advocates, and medical technology industry volunteers. Some of the APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

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