PULSE OXIMETRY SCREENING FOR CRITICAL CONGENITAL HEART DISEASE (CCHD) TOOLKIT

Minnesota Department of Health
Newborn Screening Program
2026

DEPARTMENT OF HEALTH
NEWBORN SCREENING

DEPARTMENT OF HEALTH

Minnesota Newborn Screening Program
601 Robert St. N., St. Paul, MN 55155
Phone 651-201-3548 • Fax 651-215-6285

Pulse Oximetry Screening for Critical Congenital Heart Disease (CCHD) Toolkit

REV DATE: 01/2026

Disclaimer: The information included in this document is for informational and educational purposes only. The contents of this toolkit should not be used in place of medical judgement.

For more information, contact:

The Newborn Screening Program

Public Health Laboratory Division

Minnesota Department of Health

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Saint Paul, MN 55155

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CRITICAL CONGENITAL HEART DEFECTS DEFINED

Primary Targets: Most Likely to be Detected by Pulse Oximetry Screening

Hypoplastic Left Heart Syndrome

The left side of the heart did not develop properly (either too small or absent). Because of this, the oxygen-rich blood cannot be pumped to the body in a normal way.

Pulmonary Atresia

The pulmonary valve that lets blood out of the heart to the rest of the body did not form correctly. This prevents the blood from going to the lungs to be oxygenated.

Tetralogy of Fallot

Consists of four defects: a hole between the lower chambers (ventricles) of the heart, a narrowing of the pulmonary valve and main pulmonary artery, the aortic valve is enlarged and seems to open from both ventricles instead of just the left ventricle, and the muscle surrounding the right ventricle becomes overly thickened. These defects cause the body to receive reduced oxygen levels.

Total Anomalous Pulmonary Venous Return

A defect in the veins leading from the lungs to the heart. As a result, oxygen-rich blood enters the right side of the heart instead of the left. This causes oxygen-rich blood to mix with oxygen-poor blood. This mixing results in the baby getting less oxygen to the body than is needed.

Transposition of the Great Arteries

The pulmonary artery and aorta are reversed. This causes oxygen-poor blood to be pumped directly back to the body while oxygen-rich blood from the lungs is pumped back into the lungs.

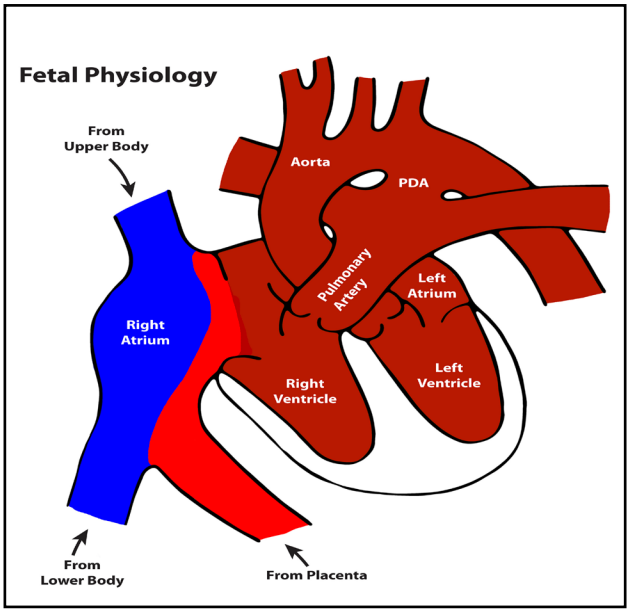
Tricuspid Atresia

The tricuspid valve did not form correctly. Because of this, the oxygen-rich blood cannot be pumped to the body in a normal way.

Truncus Arteriosus

Results in one large artery instead of two separate ones to carry blood to the lungs and the body. This causes oxygen-rich blood that should go to the lungs and oxygen-rich blood that should go to the body to be mixed together.

Normal heart connections BEFORE birth



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CRITICAL CONGENITAL HEART DEFECTS DEFINED
Continued

Secondary Targets: Potentially Detected by Pulse Oximetry Screening

Double Outlet Right Ventricle (DORV)

The aorta arises from the right ventricle instead of the left ventricle. This means that both the pulmonary artery and the aorta come from the same ventricle. This causes the aorta to deliver oxygen-poor blood to the rest of the body instead of oxygen-rich blood.

Ebstein's Anomaly

The tricuspid valve does not work properly and causes blood to leak back through the valve, which makes the heart work less efficiently. This defect can lead to enlargement of the heart or heart failure.

Coarctation of the Aortic Arch

The aorta is narrowed, which can cause increased work on the heart and high blood pressure. If severe, it can result in heart failure in infancy as the heart works too hard to get blood through the area of the narrowing.

Interruption of the Aortic Arch

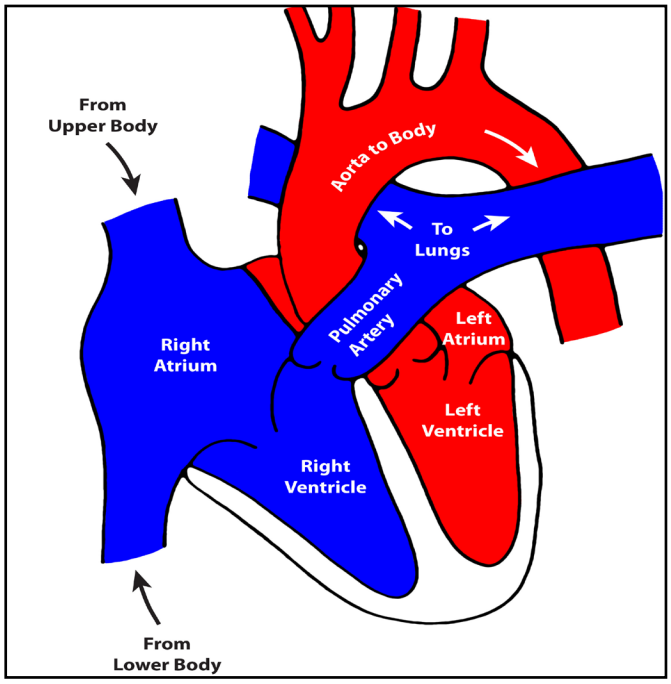
There is an absence or disconnection between the top part of the aortic arch and the lower, descending aorta. This prevents oxygen-rich blood from getting to the rest of the body.

Single Ventricle

Is a group of cardiac defects that share the common feature of having only one of the two ventricles that are of adequate size and function. Additional defects distinguish one single ventricle defect from another.

NOTE: Pulse oximetry may detect other hypoxic cardiac or non-cardiac associated conditions (e.g., persistent pulmonary hypertension and infection).

Normal heart connections AFTER birth



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PULSE OXIMETRY SCREENING & EQUIPMENT

Screening

Screening should be performed with motion-tolerant pulse oximeters that report functional oxygen saturation. Measure oxygen levels on the right upper extremity and either the right or left foot. Measurements may take place at the same time or one immediately following the other.

For more about the importance of newborn pulse oximetry screening visit:

https://www.health.state.mn.us/people/newbornscreening/families/screeningbasics.html#pulseox

Equipment

Birthing facilities are responsible for selecting and securing pulse oximetry equipment for screening newborns for critical congenital heart disease. Some facilities may already have pulse oximetry equipment available. It is important to ensure that the selected equipment is compliant with national standards, including:

- Approval by the Food and Drug Administration (FDA) for use in newborns
- Validation in low-perfusion conditions
- 2% root, mean-square accuracy
- Reporting of functional oxygen saturation

To check that your facility's pulse oximetry equipment meets FDA clearance for use in neonates, follow the instructions below:

- Go to the following link on the FDA website:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

- Enter known information for the pulse oximetry device and/or sensor
  - Enter the name of the oximetry company in the *Applicant Name* field
  - Supply the information you know - some fields may be left blank
- When a list of devices appear, click on the appropriate device for more information
- Additional information about the device will appear, then select *Summary*
- The Intended Use/Indications For Use section will state whether the device is cleared for neonatal use

The following vendors sell pulse oximeters:

- Masimo: https://www.masimo.com/solutions/acute/newborn/cchd/
- Medtronic/Covidien Nellcor: https://www.medtronic.com/covidien/en-ca/products.html

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PROVIDER AND PARENT EDUCATION MATERIALS

The Newborn Screening Program has designed education materials to aid providers in screening, follow-up care, and parent education regarding pulse oximetry and CCHD. The materials listed below and shown in this packet are avaliable to order free-of-charge from the Newborn Screening Program at https://www.health.state.mn.us/people/newbornscreening/materials/education.html

Pulse Oximetry Screening Protocol for Critical Congenital Heart Disease (CCHD) and Tips for Pulse Oximetry Screeners

These handouts are designed to provide a quick reference for screeners when performing pulse oximetry screening. These forms contain a flowchart depicting the recommended pulse oximetry screening protocol in Minnesota, as well as tips for providers on where to place the sensors and how to best communicate screening results with the family. The Newborn Screening Program recommends that nurseries keep a copy of both handouts with each set of screening equipment as a reference for screeners.

Do's and Don'ts for Pulse Oximetry Screening

This handout provides a quick reference of best practices for pulse oximetry screening. The Newborn Screening Program recommends that nurseries keep this form with each set of screening equipment for screeners as a reference at all times.

Provider Fact Sheet: Did Not Pass Pulse Oximetry Screen

This fact sheet is designed for providers to reference when they encounter positive (did not pass) pulse oximetry screens. The fact sheet outlines recommended follow-up evaluation and testing, how to communicate test results with the infant's family, and potential NICU issues. It also includes a clinical summary of CCHD and a list of additional resources for both parents and providers.

Pass Result: Pulse Oximetry Screen Result Notification

This result notification sheet should be given to the family of each infant with a passing result immediately following pulse oximetry screening. In addition to explaining the newborn's result, the handout also outlines what signs parents should be aware of after they take their newborn home that could indicate a possible CCHD not detected by screening.

Did Not Pass Result: Pulse Oximetry Screen Result Notification

This result notification sheet should be given to the family of each infant with a not-passing result immediately following the pulse oximetry screening. In addition to explaining the newborn's result, the form outlines what parents can expect to happen next and provides additional resources for the family.

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PULSE OXIMETRY SCREENING PROTOCOL FOR CRITICAL CONGENITAL HEART DISEASE

Newborn Prescreen Checklist

- ☐ At least 24 hours of age

If being discharged before 24 hours of age, screen as close to discharge as possible

- ☐ Breathing room air
- ☐ Pediatric probe on right hand and either foot
- ☐ No clinical signs or prenatal ultrasound findings of CCHD; cardiac evaluation is preferred over screening in these situations

Less than or equal to 89% in right hand OR foot?

Yes → **FAIL**

No ↓

Greater than or equal to 95% in hand AND foot?

No ↓

Is this the newborn's 2nd screen?

Yes → **FAIL**

No ↓

RESCREEN REQUIRED
Repeat the pulse oximetry screen in one hour.

Yes ↓

Less than or equal to 3 percentage points difference between hand and foot?

No → **FAIL**

Yes → **PASS**

FAIL

- Notify the medical provider of the failed screen and the need for further evaluation.
- Consult with a pediatric cardiologist.
- Evaluate the infant for other causes of the low oxygen saturation (e.g., infection, pulmonary hypertension, pneumonia).

PASS

- Notify the medical provider of the passed screen. Infant could still have cardiac disease.
- Signs and symptoms of CCHD can include rapid breathing, cyanosis, fatigue, poor feeding, and poor weight gain.
- Regardless of passing result, if any of these clinical results are present, proceed with cardiac evaluation.

Remember

Report results to the Newborn Screening Program. All results should be reported electronically using MNScreen or through secure fax.

A text-alternative Pulse Oximetry Screening Protocol for Critical Congenital Heart Disease can be found on page 14.

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TIPS FOR PULSE OXIMETRY SCREENERS

Prepping Families for CCHD Screening

Where do I place the sensor?

Either foot

Wrap the sensor around the outer area of either foot. Place the light emitter on the top of the foot with the photodetector directly opposite of it. The tape/ wrap should be secured around the foot.

Right hand

Wrap the sensor around the outer aspect of the right hand. Place the light emitter on the top of the right hand with the photodetector directly opposite of it. The tape/wrap should be securely wrapped around the hand.

What do I say to the families?

Screen

We are going to screen your baby for critical congenital heart disease using a fast and painless test called pulse oximetry. The test will only take a few minutes, and it checks the oxygen level in your baby's blood.

Pass

Your baby had a normal oxygen level when we performed the pulse oximetry screen. No further testing is needed at this time. Since screening does not detect all heart defects, it is important for you to know what symptoms to look for in the future. Watch your baby's H.E.A.R.T.: Heart rate (too fast or too slow?); Energy (overly sleepy or fussy?); Appearance (pale or blue skin?); Respiration (breathing too fast or too slow?); Temperature (cold to the touch?).

Repeat Screen

Your baby's oxygen level was lower than we'd like when we performed the pulse oximetry screen, so we will recheck it again in about an hour.

Additional resources

If families are requesting additional information, please direct them to the Minnesota Department of Health Newborn Screening Program Information webpage https://www.health.state.mn.us/people/newbornscreening/program/about.html

Did not pass

Your baby's oxygen level was low when we performed the pulse oximetry screen. Your baby's care team needs to follow-up right away to find out why the oxygen level was low. Sometimes a low oxygen level is a sign of health problems. If there is a problem, it is best to figure it out before your baby goes home.

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DO'S & DON'TS OF PULSE OXIMETRY

DO'S

- Screen while the newborn is awake and calm, if possible. Use a new, clean sensor for each infant.
- Make sure that the skin is clean and dry before placing the sensor on the newborn. It is okay to screen if the baby is jaundiced.
- Use the correct sites for screening: right hand and either foot.
- Align the emitter with the detector.
- Use confidence indicators to ensure an accurate r

DON'TS

- Use an adult pulse oximetry clip to screen an infant.
- Attempt to obtain a reading on the same extremity where the blood pressure cuff has been placed.
- Perform the screen in bright or infrared light. It is okay to cover the sensor with a blanket to block the light in order to ensure accuracy.
- Use tape or your own hand to hold the sensor against the infant's skin.

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SCREENER KNOWLEDGE ASSESSMENT

1 Pulse oximetry screening will detect all forms of congenital heart disease:

a. True

b. False

2 The following can affect the accuracy of a pulse oximetry reading:

a. Movement

b. Cold extremities or shivering

c. Crying

d. Bilirubin lamps or surgical lights

e. All of the above

3 One clean, disposable pulse oximetry probe can be used on up to five newborns:

a. True

b. False

4 To ensure the accuracy of a pulse oximetry reading, screeners should:

a. Look at the waveform displayed on the monitor; if the waveform is asymmetrical and choppy or it is a flat line, the pulse oximetry reading is most likely accurate.

b. Look at the waveform displayed on the monitor; if the waveform is symmetrical and does not have motion artifact (i.e., is not jumping up and down), the reading is most likely accurate

c. Both a and b are correct

d. Both a and b are incorrect

5 If a newborn fails the pulse oximetry screening, you should not perform a re-screen:

a. True

b. False

6 All of the following can affect the accuracy of the pulse oximetry reading **except**:

a. Placing the pulse oximetry probe on the same extremity from which you are taking the newborn's blood pressure

b. Performing the pulse oximetry screen while the infant is crying

c. Using a clip on the finger of the infant

d. Jaundice

7 The following criteria would **exclude** an infant from being screened:

a. Gestation age greater than 35 weeks

b. Presence of dysmorphism or a known genetic syndrome that requires cardiac evaluation

c. Normal vital signs while in the newborn nursery

d. Age greater than 24 hours

8 The screening guidelines outlined in the protocol state that pulse oximetry should be performed on:

a. The right hand

b. The left hand

c. Either foot

d. Both a and c

d. Both b and c

9 Pulse oximetry screening should be performed when the infant is what age?

a. Less than 8 hours

b. Between 8 and 24 hours

c. At least 24 hours

Answers can be found on page 13 of this packet.

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PROVIDER FACT SHEET
Did Not Pass Pulse Oximetry Screen

Action required

Today you should take the following recommended actions:

- Echocardiogram
- Physical examination
- Perfusion check (blood pressure and pulses x4 extremities)
- Arterial blood gases
- ECG

If the cardiac evaluation is of concern for CCHD, immediately refer the infant to pediatric cardiology and transfer to NICU. If CCHD is not identified, initiate sepsis/respiratory evaluation.

Sepsis/respiratory evaluation may include:

Examinations

- Physical examination
- Axillary temperature
- Lumbar puncture
- Chest X-ray

Labs

- Blood culture
- C-reactive protein
- Blood glucose

False positives

Pulse oximetry screening result can be impacted by performing the screen before 24 hours of life or while the infant is asleep.

Review with family

Healthy newborns may have low oxygen levels. However, low oxygen levels may also be a sign of CCHD or other conditions such as breathing problems or infections. More testing is needed to determine why a low oxygen level was detected.

NICU issues

Newborns in the NICU often require oxygen supplementation, which may impact the timing and/or results of the pulse oximetry screen.

Clinical summary & expectations

Congenital heart defects are the most common group of birth defects. CCHD refers to those structural malformations requiring surgical or catheter intervention within the first year of life. Signs and symptoms of CCHD can include rapid breathing, cyanosis, fatigue, poor feeding, and poor weight gain. Failure to detect CCHD, or late detection, may lead to significant morbidity or death.

Pulse oximetry screening is used to detect CCHD. The primary targets of the screen include:

- Hypoplastic left heart syndrome
- Pulmonary atresia
- Tetralogy of Fallot
- Total anomalous pulmonary venous return
- Transposition of great arteries
- Tricuspid atresia
- Truncus arteriosis

Pulse oximetry may detect additional heart defects not listed above.

Most infants with CCHD need surgery within the first year of life. However, each infant with CCHD will require a unique treatment plan developed for their particular heart defect.

Resources for parents and providers

Centers for Disease Control and Prevention
https://www.cdc.gov/heart-defects/

Children's National Medical Center
https://www.childrensnational.org/get-care/

American Heart Association
www.aha.org

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PASS RESULT
Pulse Oximetry Screen Result Notification

Your baby ***passed*** the pulse oximetry screen

The pulse oximetry screen detected normal oxygen levels in your baby's blood. This means that your baby did not show signs of critical congenital heart disease (CCHD). **No further testing is needed at this time.**

What is critical congenital heart disease (CCHD)?

Congenital heart defects are the most common group of birth defects. Heart defects cause problems with the structure of the heart or the way blood flows through it. CCHD refers to heart defects that need to be addressed early to help prevent other health problems.

Why is screening for CCHD important?

While prenatal ultrasounds may detect some cases of CCHD, not all can be detected before birth. Without screening shortly after birth, babies with CCHD are sometimes sent home without care because they appear healthy. At home, these babies can develop serious health problems and often require emergency care. If CCHD is detected early, however, infants can be treated and lead healthier lives.

What happens next?

Pulse oximetry screening ***does not*** detect all cases of CCHD. It is important for your baby to receive regular checkups with a primary care provider and for you to watch your baby's H.E.A.R.T. for signs of CCHD.

Heart rate - beating too fast or too slow?

Energy - overly sleepy or fussy?

Appearance - pale or blue skin?

Respiration - breathing too fast or too slow?

Temperature - cold to the touch?

It is important to contact your baby's primary care provider or the hospital right away if your baby has any symptoms listed above.

If you have additional questions about pulse oximetry screening, please contact us.

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DID NOT PASS RESULT
Pulse Oximetry Screen Result Notification

Your baby ***did not pass*** the pulse oximetry screen

What is critical congenital heart disease (CCHD)?

Congenital heart defects are the most common group of birth defects. Heart defects cause problems with the structure of the heart or the way blood flows through it. CCHD refers to heart defects that need to be addressed early to help prevent other health problems.

Why is screening for CCHD important?

While prenatal ultrasounds may detect some cases of CCHD, not all can be detected before birth. Without screening shortly after birth, babies with CCHD are sometimes sent home without care because they appear healthy. At home, these babies can develop serious health problems and often require emergency care. If CCHD is detected early, however, infants can be treated and lead healthier lives.

How are babies screened for CCHD?

Babies are screened with a simple test called pulse oximetry. Pulse oximetry is a quick and painless procedure that uses sensors placed on the baby's skin (typically the hand and foot) to determine the amount of oxygen in the blood.

What does it mean if my baby did not pass the pulse oximetry screen?

It means that the screen detected low oxygen levels in your baby's blood. Low oxygen levels can be a sign of CCHD or other conditions such as breathing problems or infections. More testing is needed to find out why a low oxygen level was detected.

What happens next?

Before you and your baby go home, your baby's care provider will arrange for further testing and evaluation to determine if your baby has CCHD.

Further testing may include a repeat pulse oximetry screen, an echocardiogram (an ultrasound of the heart), an electrocardiogram (tests the electrical activity of the heart), and/or a chest x-ray. If you are at a hospital that cannot provide this additional testing, your baby may need to be transferred to a hospital that can.

If any of the results from the additional testing are of concern for CCHD, then your baby may need to see a pediatric cardiologist. A pediatric cardiologist is a doctor that specializes in problems with the heart of infants, children, and adolescents. If you are at a hospital that does not have a pediatric cardiologist, your baby may need to be transferred to a different hospital that has a pediatric cardiologist on staff.

What is the treatment for CCHD?

Babies with CCHD typically need surgery within the first year of life. Each baby with CCHD will require a unique treatment plan developed for their particular heart defect.

Resources for parents

American Heart Association: www.heart.org

Lasting Imprint: www.lastingimprint.org

Mended Little Hearts: www.mendedhearts.org

The Children's Heart Foundation: www.childrensheartfoundation.org

More questions about pulse oximetry screening? Feel free to call the Minnesota Newborn Screening Program at 651-201-3548 or visit us online at https://www.health.state.mn.us/people/newbornscreening/index.html

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FAMILY STORIES

Gratitude Amidst the Grit

Samarra and Aldo share their journey when their son's heart condition was detected after birth through newborn screening. Through the highs and lows of those first few days as parents, Samarra and Aldo reflect on their appreciation of screening and the support they found in each other.

Greta Great Heart

Steve and Karin discuss the delivery of their daughter, Greta, who shortly after birth was found to have a life-threatening heart defect through newborn pulse oximetry screening and the strong girl she has become today as a result of this experience.

Like Lions

A simple pulse oximetry screen prompted doctors to check Aria for a heart defect shortly after she was born. Listen to her mother, Melia, and grandmother, Julie, talk about the strength Aria has shown and everything they went through as she fought for her life.

Interested in more inspiring stories like these? Visit https://www.health.state.mn.us/people/newbornscreening/families/minnestories/index.html

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SCREENER ASSESSMENT
Multiple Choice Answers

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a. True

(b.) False

2 The following can affect the accuracy of a pulse oximetry reading:

a. Movement

b. Cold extremities or shivering

c. Crying

d. Bilirubin lamps or surgical lights

(e.) All of the above

3 One clean, disposable pulse oximetry probe can be used on up to five newborns:

a. True

(b.) False

4 To ensure the accuracy of a pulse oximetry reading, screeners should:

a. Look at the waveform displayed on the monitor; if the waveform is asymmetrical and choppy or it is a flat line, the pulse oximetry reading is most likely accurate.

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a. Placing the pulse oximetry probe on the same extremity from which you are taking the newborn's blood pressure

b. Performing the pulse oximetry screen while the infant is crying

c. Using a clip on the finger of the infant

(d.) Jaundice

7 The following criteria would **exclude** an infant from being screened:

a. Gestation age greater than 35 weeks

(b.) Presence of dysmorphism or a known genetic syndrome that requires cardiac evaluation

c. Normal vital signs while in the newborn nursery

d. Age greater than 24 hours

8 The screening guidelines outlined in the protocol state that pulse oximetry should be performed on:

a. The right hand

b. The left hand

c. Either foot

(d.) Both a and c

d. Both b and c

9 Pulse oximetry screening should be performed when the infant is what age?

a. Less than 8 hours

b. Between 8 and 24 hours

(c.) At least 24 hours

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PULSE OXIMETRY SCREENING PROTOCOL FOR CRITICAL CONGENITAL HEART DISEASE

Text Alternative

CCHD Newborn Prescreen Checklist

- At least 24 hours of age
  - If being discharged before 24 hours of age, screen as close to discharge date as possible
- Breathing room air
- Pediatric probe on right hand and either foot
- No clinical signs or prenatal ultrasound findings of CCHD; cardiac evaluation is preferred over screening in these situations

Outline of Pulse Oximetry Screening Protocol for CCHD Flowchart

An infant fails pulse oximetry screening if any of the following are true:

- The oxygen saturation is less than or equal to 89% in right hand or foot
- The oxygen saturation is less than 95% in hand and foot and this is the infant's 2nd screen
- The oxygen saturation is greater than or equal to 95% in hand and foot but the difference in percentage points between hand and foot is greater than 3 percentage points, and this is the infant's 2nd screen

An infant passes pulse oximetry screening if any of the following are true:

- The oxygen saturation is greater than or equal to 95% in the hand and foot and the percentage point difference between the hand and foot is less than or equal to 3 percentage points

A pulse oximetry rescreen is required if either of the following is true:

- The oxygen saturation is 90-94% and this is the infant's 1st screen
- The oxygen saturation is greater than or equal to 95% in the hand and foot and the percentage point difference between the hand and foot is greater than 3 percentage points and this is the infant's 1st screen
- Signs and symptoms of CCHD can include rapid breathing, cyanosis, fatigue, poor feeding, and poor weight gain.

If an infant fails pulse oximetry screening:

- Notify the medical provider of the failed screen and the need for further evaluation
- Consult with a pediatric cardiologist
- Evaluate the infant for other causes of the low oxygen saturation (e.g., infection, pulmonary, hypertension, pneumonia)

If an infant passes pulse oximetry screening:

- Notify the medical provider of the passed screen - the infant may still have cardiac disease
- If clinical signs or prenatal diagnosis of CCHD are present, proceed with a cardiac evaluation

Remember

- Report results to the Newborn Screening Program
- All results should be reported electronically or through secure fax

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