CRITICAL CONGENITAL HEART DEFECTS (CCHD) AND PULSE OXIMETRY SCREENING

Medtronic
Further, Together

In Canada, 1 out of every 100 babies is born with critical congenital heart defects (CCHD).[1]

CCHD AND PULSE OXIMETRY

In September 2011, the United States Department of Health and Human Services approved adding screening for critical congenital heart defects (CCHDs) with pulse oximetry to the Recommended Uniform Screening Panel.

In the United States, about 4,800 (or 11.6 per 10,000) babies are born every year with CCHDs. These babies are at significant risk if this condition goes undiagnosed.[1] Since 1993, Nellcor™ pulse oximetry technology has been utilized on more than 33,000 newborns spanning five separate clinical studies evaluating the use of pulse oximetry for critical congenital heart disease screening.[2-6] Using Nellcor pulse oximetry has been shown to be a simple and economical tool to aid healthcare providers in CCHD screening.[6]

The seven classifications for CCHDs are:

1. Hypoplastic left heart syndrome
2. Pulmonary atresia (with intact septum)
3. Tetralogy of Fallot
4. Total anomalous pulmonary venous return
5. Transposition of the great arteries
6. Tricuspid atresia
7. Truncus arteriosus

PULSE OXIMETRY SCREENING

At 24 to 48 hours of age, or just prior to discharge if less than 24 hours of age, a series of pulse oximetry readings are taken to determine the amount of oxygen in a baby's blood and the baby's pulse rate. Low levels of oxygen in the blood can be a sign of a CCHD.[1]

Kemper Recommended Screening[7]:

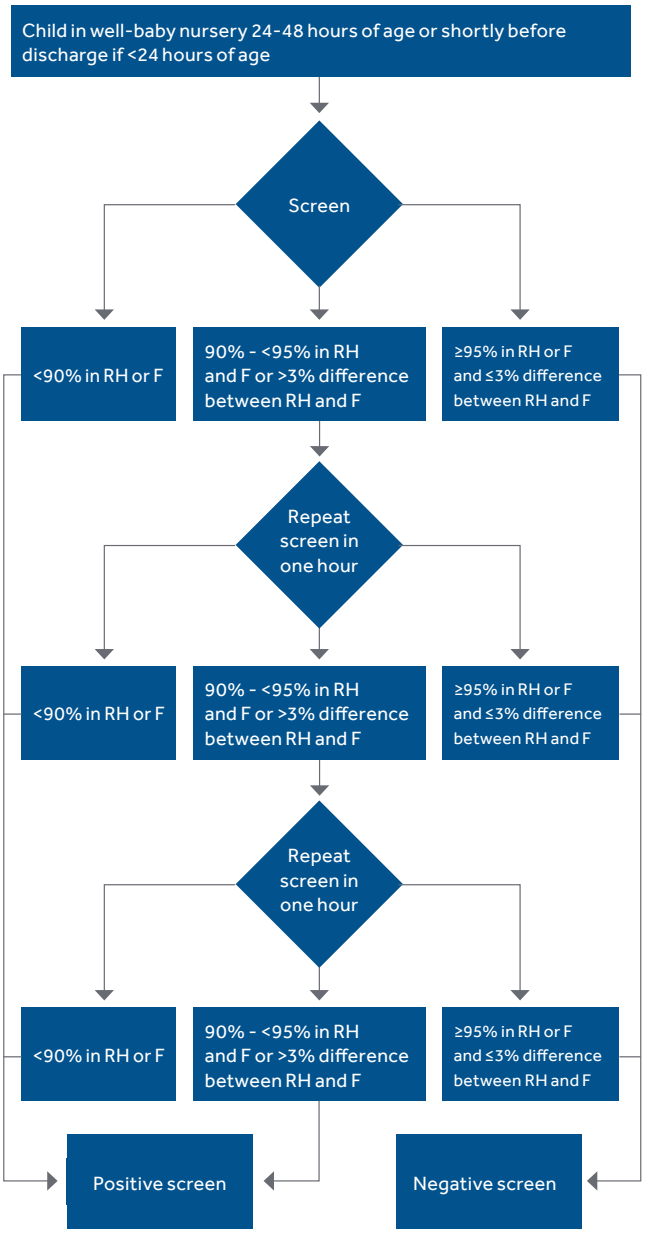
- **SpO_2 readings from the right hand (pre-ductal) and either foot (post-ductal) in parallel or in sequence**
- **Protocol:**
  - <90% is an automatic positive screen
  - 90% to <95% in both extremities on three measurements, separated by one hour = positive screen
  - >3% difference in SpO_2 between right hand and foot on three measurements, separated by one hour = positive screen
  - ≥95% in right hand or foot and ≤3% difference between right hand or foot is an automatic negative screen

PRE-DUCTAL

POST-DUCTAL

"Any 'hospital-grade' pulse oximeter that is cleared by the FDA for use in neonates is suitable for CCHD screening. It is important that the entire system is designed and cleared to work together, from the sensors that are designed for use in the neonate population, to the pulse oximeter. Reusable pulse oximetry sensors are also a viable solution, as long as the proper cleaning protocols are practiced."

–Alex R. Kemper, MD, MPH, MS, Duke University Medical Center



PULSE OXIMETRY SCREENING RESULTS

Both health care providers and families must understand the rationale for and limitations of pulse oximetry monitoring to detect CCHD, including the important understanding that a negative screening result does not exclude the possibility of CCHD or other congenital heart disease. If the results are positive, it means that the baby's test results showed low levels of oxygen in the blood, which can be a sign of a CCHD, and further testing is needed.

*Pulse oximetry screening can be an effective tool in identifying CCHDs, but there still could be instances of false positives and negatives.

NELLCOR™ PULSE OXIMETRY

For more than 25 years, clinicians have been using Nellcor pulse oximetry technology. We have a full offering of pulse oximetry sensors and monitoring platforms, which can be used as tools for CCHD screening. Our technology features SpO_2 and pulse rate. accuracy during low perfusion and motion conditions[12], as well as unsurpassed LoSat expanded accuracy claims. With LoSat functionality, you can accurately monitor your patients in lower saturation ranges unlike other pulse oximeters.

NELLCOR™ BEDSIDE RESPIRATORY PATIENT MONITORING SYSTEM†*

PERFORMANCE

MEASUREMENT RANGE

SpO_2: 1% to 100%

Pulse rate: 20 to 250 beats per minute (bpm)

Pulse amplitude: 0.03% to 20%

ACCURACY††

Saturation (% SpO_2 ± 1 SD)

70% to 100% ± 2 digits; ± 3 digits (Motion)

60% to 80% ± 3 digits

Low perfusion: 70% to 100% ± 2 digits

Pulse rate: 20 to 250 bpm ± 3 digits

Low perfusion: 20 to 250 bpm ± 3 digits

† Refer to the Nellcor™ Bedside Respiratory Patient Monitoring System operator's manual for complete descriptions, instructions, warnings, cautions and specifications. Specifications are subject to change without notice.

NELLCOR™ BEDSIDE SpO_2 PATIENT MONITORING SYSTEM†*

PERFORMANCE

MEASUREMENT RANGE

SpO_2: 1% to 100%

Pulse rate: 20 to 250 beats per minute (bpm)

Pulse amplitude: 0.03% to 20%

ACCURACY††

Saturation (% SpO_2 ± 1 SD)

70% to 100% ± 2 digits; ± 3 digits (Motion)

60% to 80% ± 3 digits

Low perfusion: 70% to 100% ± 2 digits

Pulse rate: 20 to 250 bpm ± 3 digits

Low perfusion: 20 to 250 bpm ± 3 digits

† Refer to the Nellcor™ Bedside SpO_2 Patient Monitoring System operator's manual for complete descriptions, instructions, warnings, cautions and specifications. Specifications are subject to change without notice.

NELLCOR™ PORTABLE SpO_2 PATIENT MONITORING SYSTEM, PM10N

PERFORMANCE

DISPLAY RANGE

SpO_2: 0% to 100%

Pulse rate: 20 to 250 beats per minute (bpm)

ACCURACY††

Saturation (% SpO_2 ± 1 SD)

70% to 100% ± 2 digits

60% to 80% ± 3 digits

Low perfusion: 70% to 100% ± 2 digits

Pulse rate: 20 to 250 bpm ± 3 digits

Low perfusion: 20 to 250 bpm ± 3 digits

† Refer to the Nellcor™ PM10N pulse oximeter operator's manual for complete descriptions, instructions, warnings, cautions and specifications. Specifications are subject to change without notice.

REUSABLE SOLUTION

ADH-A/N

D-YS

DISPOSABLE SOLUTION

MAXN

††Adult and neonate specifications are shown for the Nellcor™ MAX-A and MAX-N sensors with OxiMax™ technology. Saturation accuracy will vary by sensor type. Refer to Nellcor Sensor Accuracy Grid Card for details.

GLOSSARY

Hypoplastic left heart syndrome: A birth defect that affects normal blood flow through the heart. As the baby develops during gestation, the left side of the heart does not form correctly.[1]

Pulmonary atresia: A congenital heart disease where the pulmonary valve does not form properly. As a result, blood from the right side of the heart cannot go to the lungs to pick up oxygen.[8]

Tetralogy of Fallot: A birth defect that affects normal blood flow through the heart. It is made up of the following four defects of the heart and its blood vessels[1]:

1. A hole in the wall between the two lower chambers—or ventricles—of the heart. This condition also is called a ventricular septal defect.
2. A narrowing of the pulmonary valve and main pulmonary artery. This condition also is called pulmonary stenosis.
3. The aortic valve, which opens to the aorta, is enlarged and seems to open from both ventricles, rather than from the left ventricle only, as in a normal heart. In this defect, the aortic valve sits directly on top of the ventricular septal defect.
4. The muscular wall of the lower right chamber of the heart (right ventricle) is thicker than normal. This also is called ventricular hypertrophy.

Total anomalous pulmonary venous return (TAPVR): In TAPVR, oxygenated blood returns from the lungs back to the right atrium or a vein flowing into the right atrium and not to the left side of heart. Blood circles to and from the lungs and never gets out to the body.[9]

Transposition of the great arteries (TGA): TGA occurs when the two main arteries going out of the heart—the pulmonary artery and the aorta—are switched in position, or "transposed."[1]

Tricuspid atresia: Normally, blood flows from the body into the right atrium, then through the tricuspid valve to the right ventricle and on to the lungs. If the tricuspid valve does not open, the blood cannot flow from the right atrium to the right ventricle. Blood ultimately cannot enter the lungs, where it must go to pick up oxygen (become oxygenated).[10]

Truncus arteriosus: Truncus arteriosus is a rare type of congenital heart disease in which a single blood vessel (truncus arteriosus) comes out of the right and left ventricles, instead of the normal two (pulmonary artery and aorta).[11]

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