



Michigan Newborn Screening



Michigan Newborn Screening Program

Pulse Oximetry Screening for Critical Congenital Heart Disease

2023 Annual Report
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Executive Summary

The critical congenital heart disease (CCHD) annual report provides an overview of the pulse oximetry screening portion of the State of Michigan Newborn Screening (NBS) Program, including screening methods, metrics and quality assurance information.

The Michigan NBS Program began in 1965 with one disorder and has since grown, adding many new disorders to the screening panel. Pulse oximetry screening for CCHD became a mandatory component of the screening panel on April 1, 2014. Since the screening mandate was implemented, about 982,000 infants in Michigan have been screened for CCHD and 34 cases of CCHD have been detected through screening.

Of the 98,225 infants born in Michigan in 2023 with blood spot screens submitted, 90,712 had a completed pulse oximetry screen. Of the 55 infants who failed their pulse oximetry screen, one was diagnosed with a CCHD. In 2023, five infants out of every 10,000 screened failed their pulse oximetry screen, and one out of every 90,712 infants born in Michigan who had a valid pulse oximetry screen was identified with a CCHD.

Developments occurring in 2023

Michigan continued to disseminate findings to committees, providers and partners at both the state and national level:

- Presentation at Association of Public Health Laboratories (APHL) Continuous Quality Improvement Conference.
- Presentation at APHL Newborn Screening and Genetic Testing Symposium.

NBS personnel continued to conduct trainings related to pulse oximetry screening:

- Virtual conference for hospital staff.

NBS personnel presented or participated as an exhibitor at numerous education events, including:

- Six Michigan Department of Health and Human Services (MDHHS) Virtual Baby Fairs.
- 2023 Maternal Infant Health Summit.
- Michigan American Academy of Pediatrics 73rd Annual Conference.
- Partners in Pediatric Care.
- Cristo Rey Community Center Baby Fair.
- 2023 WIC Conference.
- 2023 Maternal Infant Health Summit.

New screening developments:

- The NBS Program continued partnership with the Michigan Birth Defects Registry (MBDR) on a cooperative grant agreement through the Centers for Disease Control and Prevention. A portion of the cooperative agreement strictly focuses on CCHDs and works to better link MBDR records with individual-level screening results and data.
- The NBS Program continued work on a quality improvement project that they received funding for in 2022. The project was aimed at increasing pulse oximetry screening reporting rates among home births. The NBS Program used a multi-pronged approach to improve CCHD screening rates among the homebirth community in Michigan by establishing a foundation for educating home birthing attendants on CCHD screening, increasing reporting rates by promoting the pulse oximeter loan program, and promoting use of the eReports™ online module for reporting CCHD screening results.
- The NBS Program received funding through the Unite Newborn Screening Learning Community, a partnership with the Association of Public Health Laboratories and National Center for Hearing Assessment and Management. As part of this learning community, Michigan's NBS and Early Hearing Detection and Intervention (EHDI) Programs came together to develop a training for birthing attendants. A survey was developed to evaluate if collaborative efforts enhance NBS knowledge among community birth providers in Michigan.

Continuing work:

- Improving CCHD reporting rates by following up with hospitals and midwives on cases where a blood spot screen was submitted, but no pulse oximetry screening results were reported. Hospital reporting rates are also tracked monthly, and additional follow-up is given to hospitals reporting below 85%. Technical assistance is provided to underperforming hospitals.

This report provides an overview of Michigan’s pulse oximetry screening program for critical congenital heart disease (CCHD), which is a component of Michigan’s Newborn Screening (NBS) Program. The report includes methods for screening and submission of results, screening performance metrics and quality assurance information.

This report is intended to provide:

- An introduction to the pulse oximetry screening process and the history behind it.
- Pulse oximetry screening performance metrics.
- Quality assurance information.

What is newborn screening?

NBS is the process of identification of adverse health conditions and implementation of treatment in newborns before the onset of disease processes in the individual. Screening is conducted shortly after birth, confirmatory testing is used when necessary, and treatment of the disorder is administered in a timely fashion. Proper use of NBS minimizes the risk associated with disease, reduces the possibility of long-term sequelae and aims to increase the quality of life of any non-treatable diseases. Potential outcomes of disorders on the NBS panel include neurological impairment and damage, intellectual disability, organ damage including the liver, eyes, or spleen and even death if not detected early.

Three different screens are administered to the newborn to reduce the likelihood of these outcomes occurring. Blood spots are collected from infants in the first days of life to screen for metabolic disorders, hemoglobinopathies, endocrine disorders, lysosomal storage disorders, and other genetic conditions. Hearing screening is conducted to detect hearing loss in the infant, so that treatment and intervention may be started promptly. Pulse oximetry screening is used to evaluate the oxygen saturation of blood in the extremities of the newborn to detect potential heart defects, specifically critical congenital heart defects.

What are CCHDs?

Approximately one in 100 babies is affected by a congenital heart defect (CHD), making CHDs rank among the most prevalent birth defects.¹ Pulse oximetry screening has been shown to detect some forms of CHDs based on low oxygen saturation and, more specifically, has been able to detect more serious abnormalities categorized as CCHD.² It is imperative that CCHDs be detected as early as possible to reduce the risk of circulatory collapse and death.

What is pulse oximetry screening?

Pulse oximetry screening sends red light and infrared light through the hand and foot of the infant and measures the amount of each type of light absorbed to detect the amount of oxygen in the blood. Low oxygen saturation in the blood signifies that there may be a problem with the heart and circulatory system. Pulse oximetry screening targets identification of 12 specific CCHDs (Table 1).

Table 1. Primary Targets for Pulse Oximetry Screening

Critical Congenital Heart Disease	
Coarctation of the Aorta	Tetralogy of Fallot
Double-Outlet Right Ventricle	Total Anomalous Pulmonary Venous Return
Ebstein’s Anomaly	D-Transposition of the Great Arteries
Hypoplastic Left Heart Syndrome	Tricuspid Atresia
Interrupted Aortic Arch	Truncus Arteriosus
Single Ventricle	Pulmonary Atresia

Pulse Oximetry Screening Background

Pulse oximetry screening was officially recommended by the U.S. Department of Health and Human Services Secretary in 2011 as an important tool for detecting CCHDs in asymptomatic newborns.³ Studies have shown the benefit of pulse oximetry screening in improving CCHD detection rates.⁴ The State of Michigan NBS Program added pulse oximetry screening to the mandated screening panel effective April 1, 2014. Michigan’s NBS Program recommends the pulse oximetry algorithm endorsed by the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children in 2011 (Appendix).⁵

Hospitals

In 2023, Michigan had approximately 80 hospitals with birthing units. Each hospital has a designated NBS coordinator who helps facilitate the screening process and submission of results. Pulse oximetry screening quality assurance reports were developed at the end of 2017 and have been sent to hospitals since the first quarter of 2018. The goal of these quality assurance reports is to help monitor reporting rates, screening metrics and areas of improvement for each hospital. Periodic site visits are also made by NBS Program staff to evaluate screening processes and make recommendations for further improvement.

Midwives and Home Births

There are approximately 80 midwives registered with the NBS Program in Michigan. Guidance and individual assistance are provided to midwives to facilitate meeting program standards. Midwives may borrow pulse oximeters through the NBS Program. The goal for this program is to alleviate a cost barrier for midwives while elevating pulse oximetry screening rates in the out-of-hospital birth population.

This section describes the process in which infants are screened and the methods to calculate a) the total number of newborns eligible for screening, b) the demographic characteristics of the newborns, c) total number of infants who failed their pulse oximetry screen, d) screening performance metrics, and e) quality assurance indicators.

Screening reporting methods

For each birth, hospital staff have three options for submitting the pulse oximetry screening results to the NBS Program. They may enter the individual-level screening results into a web-based reporting system (eReports®, Revvity, Inc.). Hospitals also have the option to use a secure file transfer service (FTS) to send a file of screening results to the NBS Program. The final option is to upload information using Health Level Seven (HL7), which is an instantaneous information upload system. Midwives have the option of submitting results electronically via eReports® or by sending the results on paper forms to the NBS Program.

Pulse oximetry screening results for total number of newborns eligible for screening

Vital records data collected by the Division for Vital Records and Health Statistics at MDHHS were used to determine the total number of live births eligible for screening.

Total number of newborns with CCHD identified by pulse oximetry screening

The MDHHS laboratory information management system (Revvity, Inc.) was used to identify individuals who failed their pulse oximetry screens. CCHD cases referred to in this report must be a) identified by NBS through pulse oximetry screening and b) Michigan residents.

Screening metrics

Two different screening metrics that can help evaluate a screening test are positive predictive value and false positive rate. The positive predictive value is the number of infants confirmed with CCHD divided by the number of infants who failed the pulse oximetry screen, expressed as a percentage. The false positive rate is defined as the number of infants with false positive screens divided by the number of infants screened expressed as a percent. Ideal screening tests have a high positive predictive value (perfect = 100%) and a low false positive rate (perfect = 0%). This ideal screening test would correctly identify all cases of a disorder with no false positives.

Quality assurance

Quality assurance (QA) data were obtained from the laboratory information management system. The QA indicators focus on time of birth to pulse oximetry screen, time between pulse oximetry screen and reporting of results to the NBS Program, compliance with the NBS pulse oximetry screening algorithm, and whether screens were missed. Table 2 describes each of the QA metrics and how the metrics are calculated. Other QA indicators look at reasons for a missed screen, including prenatal CCHD diagnosis, postnatal CCHD diagnosis, infant distress, infant transfer to a different hospital, refusal of screening procedures, infant death, and being referred for further examination to a practitioner.

Screening Results

The Michigan NBS Program received blood spot cards for approximately 98% of the 98,225 live births occurring in Michigan in 2023. These blood spot cards were screened for more than 55 different disorders. Pulse oximetry screening results were reported for 93.9% of those with a blood spot card submitted.

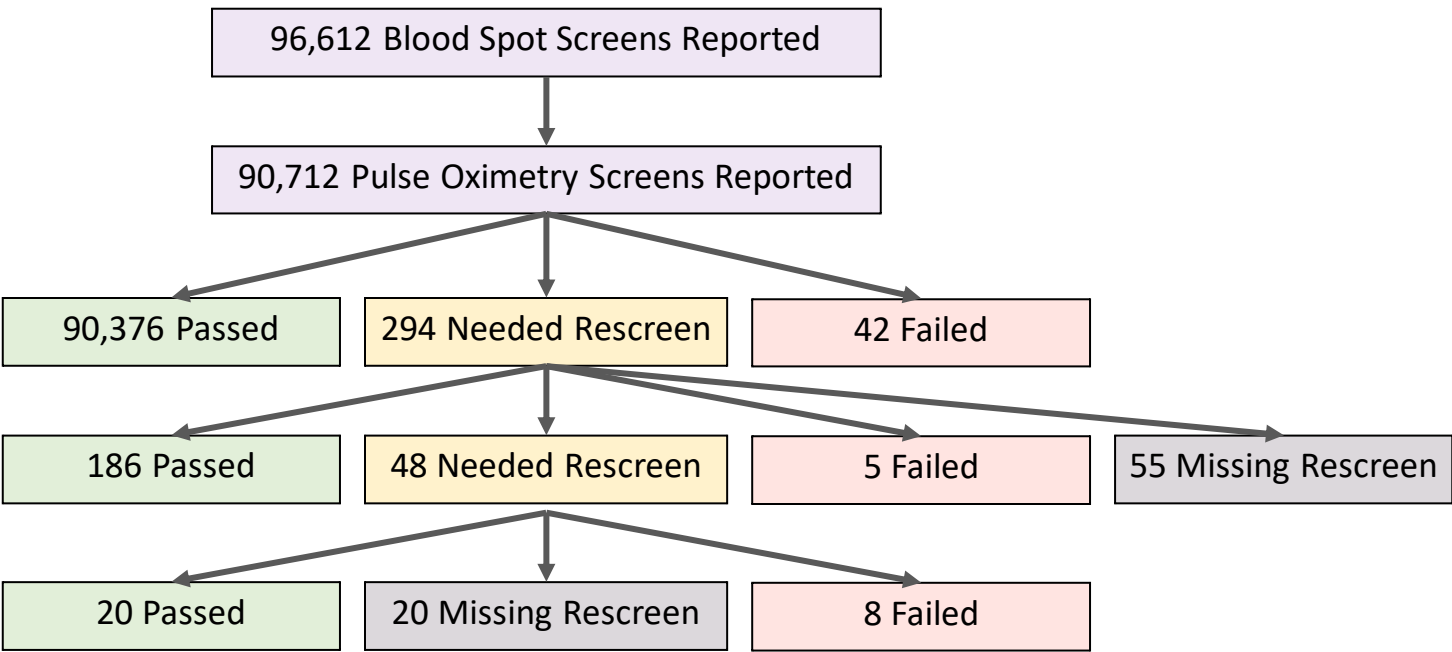


Figure 1. Pulse Oximetry Screening Outcome Information of Michigan Infants, 2023

Pulse oximetry screening outcome information

Figure 1 shows the breakdown of screening outcomes in Michigan in 2023. In total, of the 90,712 infants who had valid pulse oximetry screening results submitted, 55 infants, or 0.06%, failed their pulse oximetry screen, while 90,582 infants passed their screens (Figure 1). A total of 75 infants were missing rescreens.

Reasons for not completing screens

Of the 5,900 infants with no pulse oximetry screening values, 4,225 had no pulse oximetry screening information reported, while 109 infants had results reported as the screen being missed. The most prevalent reason for not completing a screen was being transferred between facilities (n=463) followed by receiving an echocardiogram (n=424) . A total of 71 infants had a prenatal diagnosis of a CCHD and ten infants had a postnatal diagnosis of a CCHD. Furthermore, 260 infants were reported as being in distress, 224 were referred for further testing, 70 had parents who would not permit screening, and 44 infants expired before screening could occur.

Screening metrics

One confirmed case of CCHD was detected after the infant failed their pulse oximetry screen. Pulse oximetry screening in Michigan in 2023 had a positive predictive value of 1.8% and a false positive rate of 0.06%. In addition to the one infant who failed their screen and were diagnosed with a CCHD, 13 infants were incidentally diagnosed with a secondary condition following a failed screen. Secondary conditions are comprised of 14 conditions including non-critical congenital heart defects, persistent pulmonary hypertension, and other hypoxic conditions not otherwise specified.

Quality Assurance Information

This section includes quality assurance (QA) information about pulse oximetry screening. These indicators are included in quarterly reports distributed to hospitals.

Table 2. Indicators and Performance Goals for Pulse Oximetry Screening, Michigan, 2023

Metric	Description
Percent Screened	Calculated by dividing the number of newborns with a right hand and foot pulse oximetry screen results reported to the NBS Program by the total number of newborns with a bloodspot screen. Target = 95%.
Percent Reported on Time	Calculated by dividing the number of newborns with a right hand and foot pulse oximetry screen reported to the NBS Program within 10 days of the screen date by the total number of newborns with a bloodspot screen. Target = 90%.
Percent Timely Screened	Calculated by dividing the number of newborns with a right hand and foot pulse oximetry screen conducted between 20 and 28 hours after birth by the total number of newborns with a bloodspot screen. Target = 90%.

Performance Indicators

Performance indicators were calculated for the entire 2023 birth year. Neonatal Intensive Care Unit (NICU) or Special Care Nurseries (SCN) births are excluded from these calculations.

Table 3. Performance Indicators for Pulse Oximetry Screening in Well Baby Nurseries, Michigan, 2023

	Total Blood Spots (N)	Reported Screens (n)	Percent Reported (%)	Screens Reported On-Time (n)	Percent Reported On-Time (%)	Timely Screens (n)	Percent Timely Screens (%)
State of Michigan	83,846	81,962	97.8	58,665	70.0	78,769	96.1

Overall, 97.8% of babies born in well baby nurseries in 2023 had pulse oximetry values reported to the NBS Program. Exactly 70 percent of the babies had their first screen reported to the NBS Program within 10 days, and 96.1% had the pulse oximetry screen conducted between 20-28 hours of life.

Conclusions

NBS is a critical public health program that protects the lives of newborns in our state. One crucial piece of this program is pulse oximetry screening for CCHD. Of the 90,712 infants screened for CCHD in 2023, 55 failed their pulse oximetry screen and one confirmed with a CCHD after a failed screen. An additional 13 babies were incidentally diagnosed with a secondary condition. Since the pulse oximetry screening mandate was implemented on April 1, 2014, approximately 540 newborns have failed their pulse oximetry screen, leading to 34 CCHD diagnoses through the end of 2023. The NBS Program is continually expanding and growing, allowing for screening procedures to be refined to better protect the health of Michigan infants.

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Figure 2. Michigan Algorithm for Pulse Oximetry Screening

