

Michigan Department of  
Health and Human Services

# MICHIGAN NEWBORN SCREENING PROGRAM

Pulse Oximetry Screening for Critical  
Congenital Heart Disease

Annual Report 2021

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## Executive Summary

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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 800,000 infants in Michigan have been screened for CCHD and 23 cases of CCHD have been detected through screening.

Of the 102,965 infants born in Michigan in 2021 with blood spot screens submitted, 94,384 had a completed pulse oximetry screen. Of the 46 infants who failed their pulse oximetry screen, three were diagnosed with a CCHD. In 2021, four infants out of every 10,000 screened failed their pulse oximetry screen and one out of every 31,342 infants born in Michigan who had a valid pulse oximetry screen was identified with a CCHD through pulse oximetry screening.

### **Developments occurring in 2021:**

Michigan continued to disseminate findings to committees, providers, and partners.

NBS personnel continued serving on national work groups, including:

- Critical Congenital Heart Disease (CCHD) Data Response Team.
- Health Information Technology (HIT) Association of Public Health Laboratories (APHL) Workgroup.
- Education and Training Workgroup for the Advisory Committee on Heritable Disorders in Newborns and Children.

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

- Livingston County Baby Fair.
- Five MDHHS Virtual Baby Fairs.
- 2021 Michigan WIC Training and Educational Conference.
- 2021 Maternal and Infant Health Summit.
- 2021 Newborn Screening Midwife Updates.
- 2021 Newborn Screening Conference.

New screening developments:

- The NBS Program partnered 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.

Continuing work:

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

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## I. Introduction

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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, 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.<sup>1</sup> 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.<sup>2</sup> 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

| <b>Critical Congenital Heart Disease</b> |   |
|--|---|
| 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.<sup>3</sup> Studies have shown the benefit of pulse oximetry screening in improving CCHD detection rates.<sup>4</sup> 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).<sup>5</sup>

**Hospitals:**

In 2021, 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.

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## II. Methods

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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®, Perkin Elmer Life Sciences, 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 statistics 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 (PerkinElmer Life Sciences, 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.



### III. Screening Results

The Michigan NBS Program received blood spot cards for more than 99% of the 104,104 live births occurring in Michigan in 2021. These blood spot cards were screened for more than 50 different disorders. Pulse oximetry screening results were reported for 91.6% of those with a blood spot card submitted.

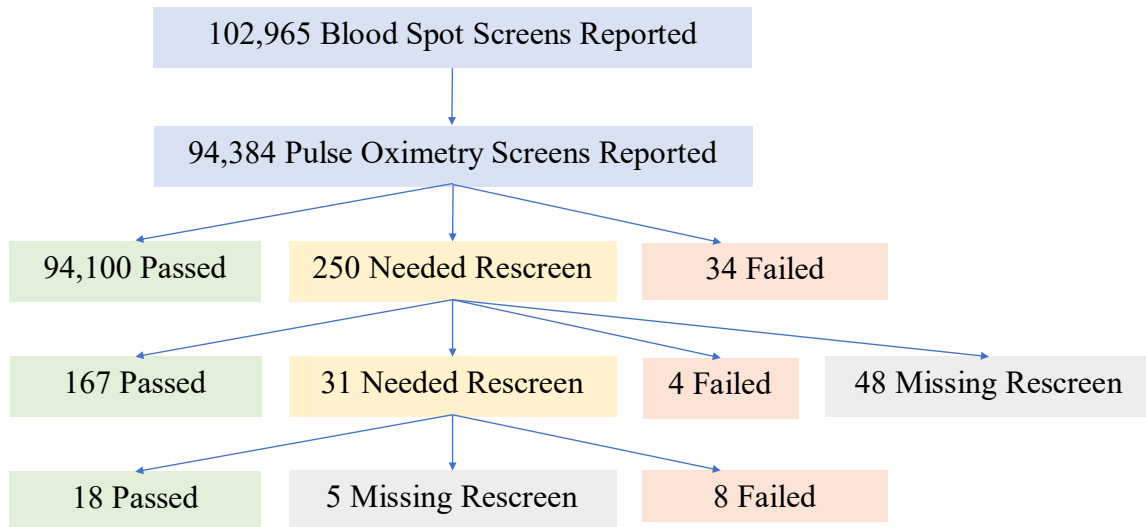


Figure 1: Pulse Oximetry Screening Outcome Information of Michigan Infants, 2021

#### Pulse oximetry screening outcome information

Figure 1 shows the breakdown of screening outcomes in Michigan in 2021. In total, of the 94,384 infants who had valid pulse oximetry screening results submitted, 46 infants, or 0.05%, failed their pulse oximetry screen, while 94,100 infants passed their screens (Figure 1). A total of 53 infants were missing rescreens.

#### Reasons for missed screens

Of the 8,554 infants with no pulse oximetry screening values, 6,754 had no pulse oximetry screening information reported, while 313 infants had results reported as the screen being missed. The most prevalent reason for missing a screen was being transferred between facilities (n=477) followed by receiving an echocardiogram (n=418). A total of 86 infants had a prenatal diagnosis of a CCHD and 18 infants had a postnatal diagnosis of a CCHD. Furthermore, 246 infants were reported as being in distress, 96 were referred for further testing, 121 had parents who would not permit screening, and 25 infants expired before screening could occur.

#### Screening metrics

Three confirmed cases of CCHD were detected after infants failed their pulse oximetry screen. Pulse oximetry screening in Michigan in 2021 had a positive predictive value of 6.5% and a false positive rate of 0.04%. In addition to the three infants who failed their screen and were diagnosed with a CCHD, nine 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.

## IV. 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, 2021

| 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 = 90%.                           |
| 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 2021 birth year. NICU or SCN births are excluded from these calculations.

Table 3: Performance Indicators for Pulse Oximetry Screening in Michigan, Well Baby Nurseries, 2021

|                   | 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 | 89,566                | 85,519               | 95.5                 | 66,678                       | 74.4                         | 80,609             | 90.0                       |

Overall, 95.5% of babies born in well birth nurseries in 2021 had pulse oximetry values reported to the NBS Program. Close to three quarters (74.4%) of the babies had their first screen reported to the NBS Program within 10 days and 90.0% had the pulse oximetry screen conducted between 20-28 hours of life.

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## V. Conclusions

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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 94,384 infants screened for CCHD in 2021, 46 failed their pulse oximetry screen and three confirmed with a CCHD after a failed screen. An additional nine babies were incidentally diagnosed with a secondary condition. Since the pulse oximetry screening mandate was implemented on April 1, 2014, approximately 430 newborns have failed their pulse oximetry screen, leading to 32 CCHD diagnoses through the end of 2021. 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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## VI. References

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1. 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. *Pediatrics*. 2009;201(5):447-458. <https://pediatrics.aappublications.org/content/124/2/823>. Accessed January 8, 2018.
2. Screening for Critical Congenital Heart Defects. Centers for Disease Control and Prevention (CDC). Website. <https://www.cdc.gov/ncbddd/heartdefects/screening.html>. Updated January 8, 2018. Accessed January 18, 2018.
3. Sebelius K. Letter to R. Rodney Howell, M.D [Internet]. <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/reports-recommendations/response-congenital-cyanotic.pdf>. Published [2011]. Updated [September 21, 2011]. Accessed [January 18, 2018].
4. Granelli A, Wennergren M, Sandberg K, et al. Impact of Pulse Oximetry Screening on the Detection of Duct Dependent Congenital Heart Disease: a Swedish Prospective Screening Study in 39,821 Newborns. *British Medical Journal*. 2009;338:a3037. <https://www.bmj.com/content/338/bmj.a3037>. Accessed March 22, 2018.
5. Kemper AR, Mahle WT, Martin GR, et al. Strategies for Implementing Screening for Critical Congenital Heart Disease. *Pediatrics*. 2011;128(5): e1259-e1267. <http://pediatrics.aappublications.org/content/128/5/e1259>. Accessed March 22, 2018.
6. MacDorman MF, Mathews TJ, Declercq E. "Trends in Out-of-Hospital Births in the United States, 1990-2012." NCHS Data Brief, No. 144. Hyattsville, MD: National Center for Health Statistics. 2014. <https://www.cdc.gov/nchs/data/databriefs/db144.pdf>. Accessed March 22, 2018.
7. Marin JA, Hamilton BE, Osterman MJK, Driscoll AK, Mathews TJ. Births: Final Data for 2015. *National Vital Statistics Reports*. 2017; 66(1): 9, Supplemental Table I-12. [https://www.cdc.gov/nchs/data/nvsr/nvsr66/nvsr66\\_01.pdf](https://www.cdc.gov/nchs/data/nvsr/nvsr66/nvsr66_01.pdf). Accessed March 22, 2018.

## VII. Appendix

### Michigan Algorithm for Pulse Oximetry Screening

