

Michigan Department of
Health and Human Services

MICHIGAN NEWBORN SCREENING PROGRAM

Pulse Oximetry Screening for Critical
Congenital Heart Disease

Annual Report 2020

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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, quality assurance information, and implications.

The Michigan NBS Program began in 1965 with one disorder and has grown since, 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, around 700,000 infants in Michigan have been screened for CCHD and approximately 20 cases of CCHD have been detected through screening.

Of the 102,204 infants born in Michigan in 2020 with blood spot screens submitted, 66 failed their pulse oximetry screen, and five were diagnosed with a CCHD. In 2020, seven infants out of every 10,000 screened failed their pulse oximetry screen and one out of every 18,348 infants born in Michigan who had a valid pulse oximetry screen was identified with a CCHD through pulse oximetry screening.

Developments occurring in 2020:

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

Michigan continued to conduct trainings with hospitals.

- NBS conferences for hospital staff were held virtually on three different dates. Updated information was presented on pulse oximetry screening for CCHD.

NBS personnel continued serving on national work groups, including:

- The Association of Public Health Laboratories (APHL) Critical Congenital Heart Disease Data Response Team.

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

- Kalamazoo Baby and Children's Fair.
- Lansing Baby Fair (Virtual).
- MDHHS Virtual Baby Fair.

New screening developments:

- Screening follow-up for out-of-hospital births was further standardized.

Continuing work:

- Continued work to increase reporting rates, provide technical assistance, improve quality, and promote the pulse oximeter loan program was conducted.

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Acronym Key

Acronym	Name
CCHD	Critical Congenital Heart Disease
CHD	Congenital Heart Disease
MDHHS	Michigan Department of Health and Human Services
NBS	Newborn Screening
NICU	Neonatal Intensive Care Unit
PCP	Primary Care Physician
QA	Quality Assurance
SCN	Special Care Nursery

I. Introduction

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 1 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 critical congenital heart disease (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 2020, Michigan had 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.

II. Methods

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.

Demographic characteristics:

The demographic characteristics are presented for Michigan residents who received a pulse oximetry screen in Michigan. This report focuses on this population. Out-of-state infants born at Michigan hospitals are often followed up and diagnosed elsewhere. Screening information, including demographic information and screening outcomes, was obtained from NBS records.

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 4 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

Demographic characteristics of screened newborns

This section describes the population of screened infants born in 2020 in terms of race, birth weight, gestational age, and birth place (hospital nursery, NICU/SCN, or non-hospital). These data are helpful in understanding the epidemiology (distribution of disease among the population in Michigan) of CCHD covered in the subsequent sections of the report.

The Michigan NBS Program received blood spot cards for more than 99% of the 102,768 live births occurring in Michigan in 2020. These blood spot cards were screened for more than 50 different disorders. Pulse oximetry screening results were reported for 89.8% of those with a blood spot submitted (data not shown). Approximately 9.0% (n=9,071 without information submitted, n=12 followed incorrect algorithm, n=71 did not receive a proper rescreen) of newborns with blood spot screens submitted in 2020 did not have valid pulse oximetry screening results. The final 1.5% of infants did not receive a pulse oximetry screen, but had a valid reason for the screen not being conducted or were designated as a missed screen by hospital staff.

Table 2 reports the demographic and perinatal characteristics of Michigan residents born in 2020 with a pulse oximetry screen reported. As indicated in Table 2, most in-state infants screened were white, born in a well birth nursery of a hospital, full term (≥ 37 weeks gestational age), and normal birth weight ($> 2,500$ g). Overall, 8.0% of infants were admitted to a NICU or SCN, 8.3% were low birth weight, and 7.9% were born preterm (< 37 weeks). Black infants were over-represented in the NICU/SCN population, in the low birthweight population, and the preterm population. White infants were overrepresented in the out-of-hospital birth population.

Table 2: Demographic and Perinatal Characteristics of Infants born in Michigan with a Valid Pulse Oximetry Screen, 2020

Race	Column Total		Nursery Type						Birth Weight (g)		Gestational Age (wks.)	
			Regular Hospital		NICU/SCN		Non-Hospital		<2500		<37	
	N	%	N	%	N	%	N	%	N	%	N	%
White	57,780	63.0	52,711	91.2	4,322	7.5	747	1.3	3,937	6.8	4,126	7.1
Black	14,953	16.3	13,100	86.6	1,825	12.2	28	0.2	2,062	13.8	1,781	11.9
Multi-Racial	6,539	7.1	6,052	92.6	428	6.5	59	0.9	482	7.4	519	7.9
Other	7,058	7.7	6,624	93.9	422	6.0	12	0.2	590	8.4	427	6.1
Missing	5,326	5.8	4,966	93.2	339	6.4	21	0.4	491	9.2	392	7.4
Total:	<i>91,656*</i>	<i>100.0</i>	<i>83,453</i>	<i>91.1</i>	<i>8,087</i>	<i>8.0</i>	<i>867</i>	<i>1.0</i>	<i>7,562</i>	<i>8.3</i>	<i>7,654</i>	<i>7.9</i>

* 9,071 newborns were missing valid screening results, 1,068 newborns had a reason for not being screened designated, 12 newborns were not screened following the Michigan algorithm, and 71 newborns were missing proper rescreens.

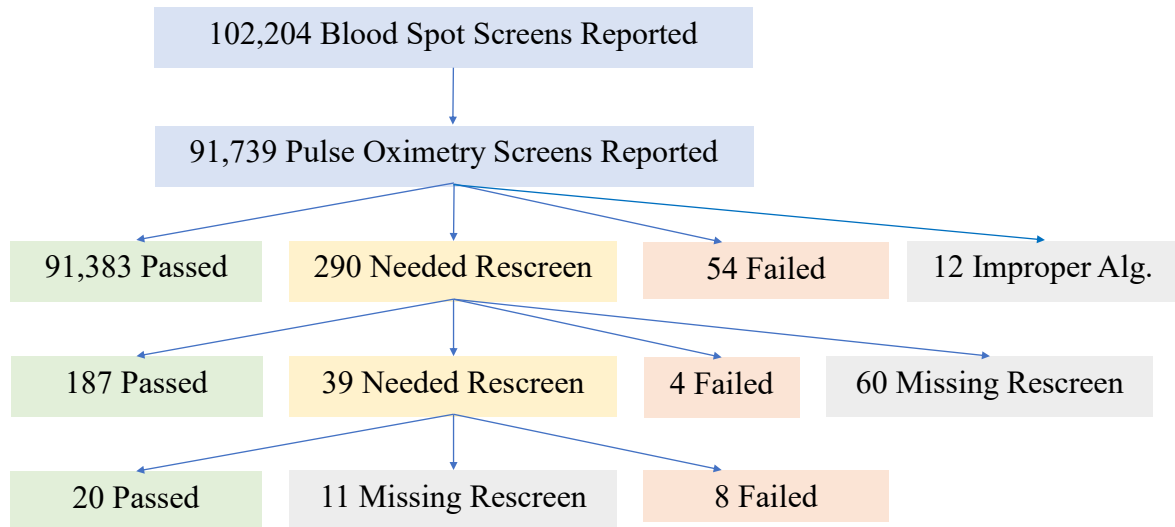


Figure 1: Pulse Oximetry Screening Outcome Information of Michigan Infants, 2020

Pulse oximetry screening outcome information

Figure 1 shows the breakdown of screening outcomes in Michigan in 2020. In total, of the 91,739 infants who had valid pulse oximetry screening results submitted, 66 infants, or 0.1%, failed their pulse oximetry screen, while 91,590 infants passed their screens (Figure 1). A total of 71 infants were missing rescreens and 12 infants had screens that did not follow Michigan's screening algorithm. While these babies did have screens reported, they did not have valid pulse oximetry screening results.

Reasons for missed screens

Of the 10,497 infants with no pulse oximetry screening values, 9,071 had no pulse oximetry screening information reported, while 358 infants had results reported as the screen being missed. The most prevalent reason for missing a screen was receiving an echocardiogram (n=322) and the infant being transferred between facilities (n=328). A total of 71 infants had a prenatal diagnosis of a CCHD and six infants had a postnatal diagnosis of a CCHD. Furthermore, 142 infants were reported as being in distress, 71 were referred for further testing, 101 had parents who would not permit screening, and 27 infants expired before screening could occur.

Screening metrics

Four confirmed cases of CCHD were detected after infants failed their pulse oximetry screen. Pulse oximetry screening in Michigan in 2020 had a positive predictive value of 7.6% and a false positive rate of 0.07% as all diagnosed CCHDs failed their pulse oximetry screen. In addition to the four infants who failed their screen and were diagnosed with a CCHD, eight 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 3: Indicators and Performance Goals for Pulse Oximetry Screening, Michigan, 2020

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 2020 birth year. NICU or SCN births are excluded from these calculations.

Table 4: Performance Indicators for Pulse Oximetry Screening in Michigan, Well Baby Nurseries, 2020

	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	89,353	83,433	93.4	66,078	74.0	78,198	87.5

Overall, 93.4% of babies born in well birth nurseries in 2020 had pulse oximetry values reported to the NBS Program. Close to three quarters (74.0%) of the babies had their first screen reported to the NBS Program within 10 days and 87.5% had the pulse oximetry screen conducted between 20-28 hours of life.

V. Conclusion

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 91,739 infants screened for CCHD in 2020, 66 failed their pulse oximetry screen and five confirmed with a CCHD after a failed screen. An additional eight babies were incidentally diagnosed with a secondary condition. Since the pulse oximetry screening mandate was implemented on April 1, 2014, approximately 400 newborns have failed their pulse oximetry screen, leading to 29 CCHD diagnoses through the end of 2020. The NBS Program is continually expanding and growing, allowing for screening procedures to be refined to better protect the health of Michigan infants.

The Michigan Department of Health and Human Services will not exclude from participation in, deny benefits of, or discriminate against any individual or group because of race, sex, religion, age, national origin, color, height, weight, marital status, partisan considerations, or a disability or genetic information that is unrelated to the person's eligibility.

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VII. Appendix

Michigan Algorithm for Pulse Oximetry Screening

