

Michigan Department of
Health and Human Services

MICHIGAN NEWBORN SCREENING PROGRAM

Pulse Oximetry Screening for Critical
Congenital Heart Disease

Annual Report 2018

October 2019 Update



Michigan Department of Health & Human Services

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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 600,000 infants in Michigan have been screened for CCHD and approximately 20 cases of CCHD have been detected through screening.

Of the 108,277 infants born in Michigan in 2018 with blood spot screens submitted, 99,228 had pulse oximetry screening values reported. In total, 60 infants failed their pulse oximetry screen, and three were diagnosed with a CCHD. In 2018, 5.5 infants out of every 10,000 screened failed their pulse oximetry screen and one out of every 33,070 screened infants in Michigan was identified with a CCHD through pulse oximetry screening.

Developments occurring in 2018:

- Michigan continued to provide educational opportunities for hospital staff and those serving the homebirth community.
 - Two newborn screening conferences were held in October, one in Detroit and one in Grand Rapids. These conferences were attended by 110 health professionals from 46 different birthing hospitals.
 - Conferences for the midwife community were held in Lansing, Detroit, and Grand Rapids in May. These conferences were attended by 33 midwives.
- NBS personnel continued serving on national work groups, including the NewSTEPs CCHD Technical Assistance (TA) Workgroup.
- NBS personnel presented or participated as an exhibitor at six education events.
- Continuing work:
 - Focus on standardizing the CCHD follow-up process.
 - Work with hospital staff to streamline data submission and minimize errors with reporting.
 - Work to eliminate barriers to pulse oximetry screening for out-of-hospital birth populations .

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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 history of the pulse oximetry screening.
- 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. 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 conditions. Hearing screening is conducted to detect hearing loss in the infant, so that 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 monitor 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 Screening²

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 Michigan's NBS Program added pulse oximetry screening to the mandated screening panel effective April 1, 2014 and recommends the pulse oximetry algorithm endorsed by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children in 2011 (Appendix).⁵

Secondary conditions:

Pulse oximetry screening allows for the detection of secondary conditions, in addition to detecting CCHDs. Secondary conditions are not the target conditions of the pulse oximetry screen, but they are expected to be picked up through screening and can lead to potentially lifesaving care for newborns. There are a multitude of secondary conditions that can be picked up through pulse oximetry screening (Table 2).

Table 2: Secondary Targets for Pulse Oximetry Screening

Secondary Conditions (non-CCHD)	
Hemoglobinopathy	Hypothermia
Infection, Including Sepsis	Lung Disease (Congenital or Acquired)
Noncritical Congenital Heart Defect	Persistent Pulmonary Hypertension
Other Hypoxemic Condition not Otherwise Specified	

Hospitals:

In 2018, Michigan had 83 hospitals with birthing units. Each hospital has a designated NBS coordinator who facilitates the screening process and submission of results. Pulse oximetry screening quality assurance reports were developed at the end of 2017 and were sent to hospitals during the first quarter of 2018. The goal of these quality assurance reports is to help monitor reporting rates, screening metrics, and identify areas of improvement for each hospital. Periodic site visits are also made by the NBS Nurse Consultant to evaluate screening processes and make recommendations for further improvement.

Midwives and Home Births:

There are approximately 42 midwives registered with the Michigan Department of Licensing and Regulatory Affairs. Guidance and individual assistance are provided by the NBS Program to midwives to facilitate meeting program standards. The NBS Program also conducts a loan program that provides midwives with access to pulse oximeters. The goal of 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, as out-of-state infants, who were born at a Michigan hospital, 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 2018 in terms of race, birth weight, gestational age, and birthplace (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 109,179 live births reported as of September 2019 occurring in Michigan in 2018. These blood spot cards were screened for more than 50 different disorders. Pulse oximetry screening results were reported for 90.9% of those with a blood spot submitted (data not shown). Approximately 8.4% (n=9,049 without valid results, n=14 followed incorrect algorithm, n=71 did not receive a proper rescreen, but had a valid first screen) of newborns with blood spot screens submitted in 2018 did not have pulse oximetry screening results.

Table 2 reports the demographic and perinatal characteristics of Michigan residents born in 2018 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 birthweight ($> 2,500$ g). Overall, 8.4% of infants were admitted to a NICU or SCN, 8.4% were low birthweight, and 8.0% 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 3: Demographic and Perinatal Characteristics of Infants born in Michigan with a Valid Pulse Oximetry Screen, 2018

Race	Column Total		Nursery Type						Birthweight (g)		Gestational Age (wks.)	
			Regular Hospital		NICU/SCN		Non-Hospital		<2500		<37	
	N	%	N	%	N	%	N	%	N	%	N	%
White	62,102	62.6	57,074	91.9	4,603	7.4	425	0.7	4,367	7.0	4,469	7.2
Black	17,441	18.1	15,093	86.5	2,345	13.5	3	0.0	2,352	13.5	2,037	11.7
Multi-Racial	6,389	6.4	5,880	92.0	482	7.5	27	0.4	486	7.6	475	7.4
Other	7,444	7.5	6,988	93.9	450	6.1	6	0.1	538	7.2	440	5.9
Missing	5,767	5.8	5,315	92.2	445	7.7	7	0.0	598	10.4	487	8.4
Total:	99,143*	100.0	90,350	91.1	8,325	8.4	468	0.5	8,341	8.4	7,908	8.0

* 9,049 newborns were missing valid screening results, 14 did not follow the Michigan Algorithm while screening, and 71 newborns were missing proper rescreens.

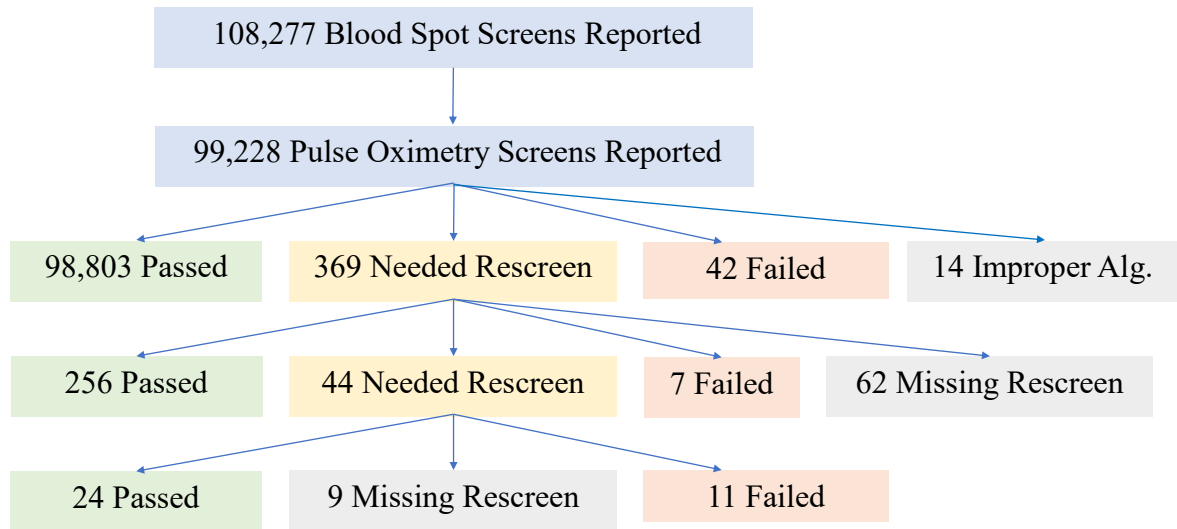


Figure 1: Pulse Oximetry Screening Outcome Information of Michigan Infants, 2018

Pulse oximetry screening outcome information

Figure 1 shows the breakdown of screening outcomes for Michigan in 2018. In total, of the 99,228 infants who had valid pulse oximetry screening results submitted, 60 infants, or 0.6%, failed their pulse oximetry screen, while 99,083 infants passed their screens (Table 3). A total of 71 infants were missing rescreens and 14 infants had screens that did not follow Michigan’s screening algorithm. These 85 infants were excluded from Table 3. All racial groups had at least 99.9% of babies with a valid outcome from the pulse oximetry screen pass their screen, with a total of 99,124 infants, or 99.9%, passing their screens (Table 3).

Table 4: Pulse Oximetry Screening Outcomes of Infants Born in Michigan, by Race, 2018

Race	Column Total		Outcome			
			Pass		Fail	
	N	%	N	%	N	%
White	62,102	62.6	62,058	99.9	44	0.0
Black	17,441	17.6	17,437	100.0	4	0.0
Multi-Racial	6,389	6.4	6,388	100.0	1	0.0
Other	7,444	7.5	7,437	99.9	7	0.0
Missing	5,767	5.8	5,763	100.0	4	0.1
Column Total:	<i>99,143*</i>	<i>100.0</i>	<i>99,064</i>	<i>99.9</i>	<i>60</i>	<i>0.1</i>

*9,049 newborns were missing valid screening results, 14 did not follow the Michigan Algorithm while screening, and 71 newborns were missing proper rescreens.

Reasons for missed screens

Of the 9,049 infants with no pulse oximetry screening values, 7,481 had no pulse oximetry screening information reported, while 1,568 infants had results reported as missing. The most common reason for missing a screen was receiving an echocardiogram (n=493), followed by missing a screen without a reason given (n=394), and the infant being transferred between facilities (n=380). A total of 93 infants had a prenatal diagnosis of a CCHD and 24 infants had a postnatal diagnosis of a CCHD reported to the NBS Program. Of the 1,568 infants who had a screen reported as missing, 90 infants were reported as being in distress, 53 were referred for further testing, 16 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 for 2018 had a positive predictive value of 5.0% and a false positive rate of 0.06%. In addition to the three infants who failed their screen and were diagnosed with a CCHD, five infants were incidentally diagnosed with a secondary condition. Examples of secondary conditions include hypothermia, lung disease, infection, 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 5: Indicators and Performance Goals for Pulse Oximetry Screening, Michigan, 2018

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 2018 birth year. NICU or SCN births are excluded from these calculations.

Table 6: Performance Indicators for Pulse Oximetry Screening in Michigan, Well Baby Nurseries, 2018

Total Blood Spot Screens (N)	Reported Pulse Oximetry Screens (n)	Percent Reported (%)	Screens Reported On-Time (n)	Percent Reported On-Time (%)	Timely Screens (n)	Percent Timely Screens (%)
94,844	89,948	94.8	59,313	62.5	79,825	84.2

Overall, 94.8% of babies born in well birth nurseries in 2018 had pulse oximetry values reported to the NBS Program. Just under two-thirds of the babies (62.5%) had their first screen reported to the NBS Program within 10 days and 84.2% 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 part of this program is pulse oximetry screening for CCHD. Of the 99,143 infants screened for CCHD in 2018, 60 failed their pulse oximetry screen and three confirmed with a CCHD after a failed screen, while five babies were diagnosed with a secondary condition. Since the pulse oximetry screening mandate was implemented on April 1, 2014, approximately 300 newborns have failed their pulse oximetry screen, leading to 20 CCHD diagnoses. The NBS Program is continually expanding and growing, allow for screening procedures to be refined to better protect the health of Michigan infants.

VI. References

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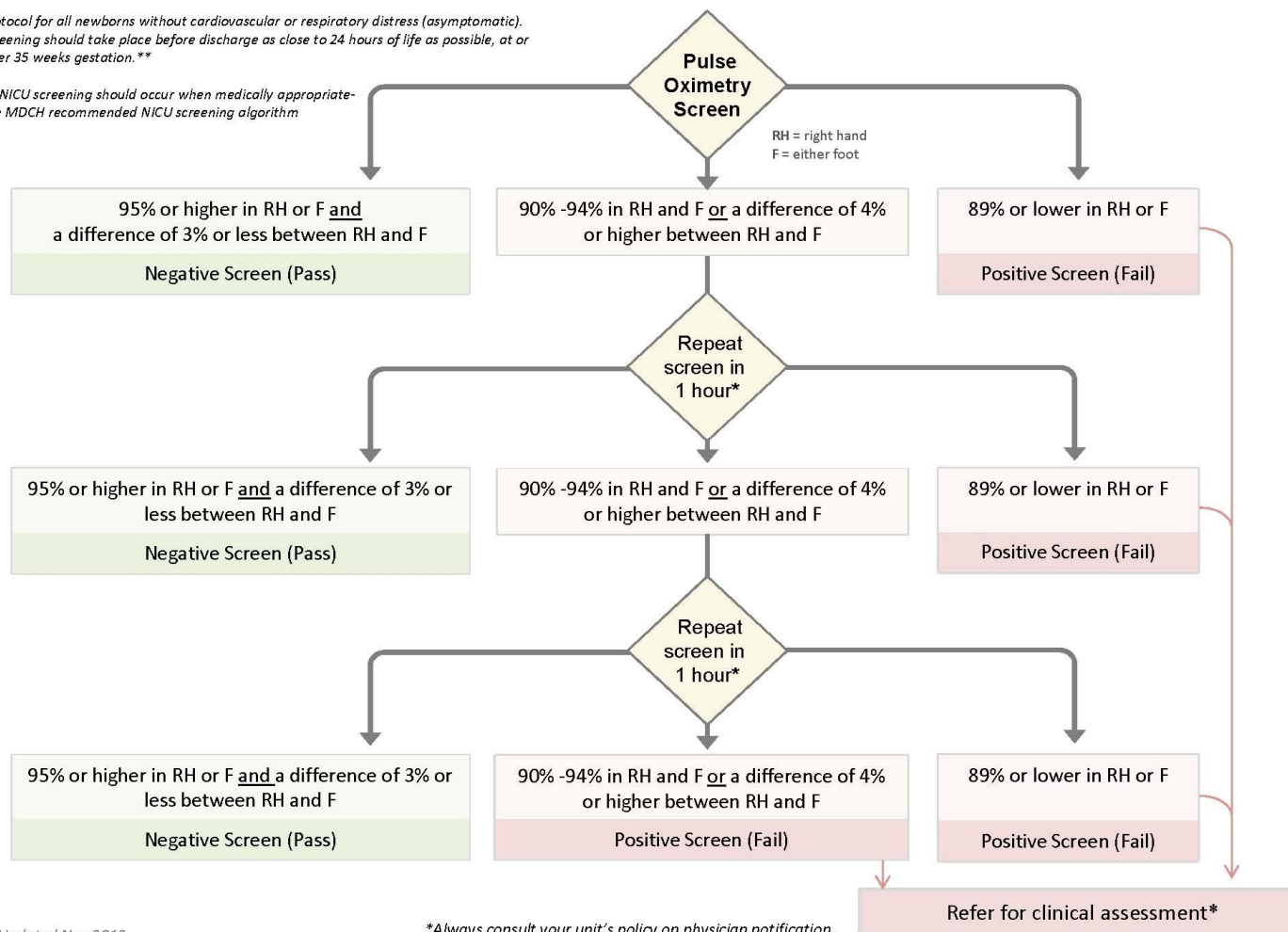
VI. Appendix

Michigan Algorithm for Pulse Oximetry Screening

Michigan Algorithm for Pulse Oximetry Screening

*Protocol for all newborns without cardiovascular or respiratory distress (asymptomatic). Screening should take place before discharge as close to 24 hours of life as possible, at or after 35 weeks gestation.***

*** NICU screening should occur when medically appropriate- See MDCH recommended NICU screening algorithm*



Updated Nov 2013

*Always consult your unit's policy on physician notification.