

## Collection of Critical Congenital Heart Disease (CCHD) pulse oximetry screening information by Newborn Screening Ontario (NSO)

### Background

At the request of the Ministry of Health and Long-Term Care (MOHLTC), NSO is overseeing CCHD screening by pulse oximetry for all newborns in Ontario. Screening for CCHD will be implemented across Ontario in a staged roll-out through 2017. CCHD pulse oximetry screening uses a point of care test, performed at the bedside ideally when the infant is between 24 and 48 hours of age. The test is done by taking a pulse oximetry measurement from the infant's right hand and either foot and evaluating the results using an algorithm. CCHD screening is a shared responsibility between NSO, hospitals, midwifery practices, and newborn health care providers; together they form the circle of care for CCHD screening. This collaboration is essential to the success and quality of the screening program.

It is a responsibility of newborn health care providers (HCPs) to ensure that all infants born in Ontario are offered CCHD screening by pulse oximetry. Parents may decline screening, and HCPs should discuss this decision with parents and document dissent by parents. While there is no formal province-wide mechanism to document consent, NSO and the MOHLTC have taken steps to provide educational materials for parents to enable them to make informed decisions for their infants, and NSO has created a decline/deferral form for CCHD screening that is a part of the newborn screening card. A decision to decline CCHD screening is documented in the baby's medical records and/or on the newborn screening card. Information for parents and guardians on NSO's protection of privacy and confidentiality practices is available on the tear-off parent information sheet of the newborn screening card and on the Newborn Screening Ontario website.

After screening, the HCP records the pulse oximetry values and screening results on the newborn screening card and sends the card to NSO. Newborn screening cards are generally received the day after they have been shipped to NSO and CCHD screening results are entered into the information system the day they are received. For infants who are screened within the recommended time frame and whose newborn screening cards are shipped to NSO in a timely manner, NSO will receive CCHD screening results when the infant is approximately 3 to 4 days of age.

According to the timeline of CCHD presentation, the number of babies remaining asymptomatic will decline over the first week of life. However, there are those who will remain asymptomatic and would still benefit from a screen (if they were missed) or a corrected interpretation (if an error in evaluation had occurred). Primary care providers of infants who were not screened would also benefit from the knowledge that their patient had not been screened by pulse oximetry.

The CCHD Disease-Specific Working Group, a group of subject matter experts from across Ontario including paediatricians, neonatologists, and paediatric cardiologists, in coordination with NSO, have established these uses for the pulse oximetry screening information collected by NSO.



**NSO will use this information to:**

Primary uses

- A. Ensure that systems are in place to support submitters (hospitals, birthing centres, midwifery practices, and other organizations offering newborn screening) such that all infants have access to CCHD pulse oximetry screening according to Ontario standards. Using the pulse oximetry screening data received, NSO will identify and follow up on cases to:

i. Reduce risk in interpretation

NSO will identify cases where there has been a misinterpretation of the screening algorithm. This includes cases where the result should have been 'REFER' but a 'PASS' result was documented, and cases where the result should have been 'REPEAT' but a 'PASS' result was documented (See CCHD screening algorithm for more details). Given these scenarios, NSO will contact the submitter who performed the screen to inform them of the error, and the submitter will contact the family of the infant who was screened. These are considered alert cases and the workflow will be initiated on the same day that CCHD screening results are received by NSO.

ii. Reduce risks related to the screening algorithm

NSO will identify cases where the provincial algorithm has not been followed. An example of this would be the case where a pulse oximetry measurement has only been taken on one limb and the result cannot be evaluated (ie. one documented SpO2 value above 89 %. See algorithm for further details). Given this scenario, NSO will contact the submitter who performed the screen to inform them of the error, and the submitter will contact the family of the infant who was screened. This is considered an alert case and the workflow will be initiated on the same day that CCHD screening results are received by NSO.

iii. Reduce risk of missed screens

NSO will identify cases where a CCHD screen has not been done. This includes cases where NSO has received an infant's dried blood spot sample, but no CCHD screening results, and cases where NSO has received an alert from BORN Ontario of a potential missed screen. Given these scenarios, NSO will contact the submitter to inform them of the potential missed screen, and the submitter will contact the family of the infant. The recommendation will be for the infant to have a pulse oximetry screen done if they are under 7 days of age. In cases where the infant is not screened, the infant's primary health care provider will be informed.





Information that a CCHD screen may have been missed could become available to NSO as early as 3 days after birth (as soon as a dried blood spot sample is received), and missed screen follow up workflow could then be initiated. Follow-up actions from NSO for missed screens will be implemented once all submitters have begun pulse oximetry screening for CCHD within their organizations, and are projected to be in place by January 2018.

iv. Interpret screening results for other conditions and coordinate follow up between multiple health care providers

NSO will identify cases where CCHD screening results may have an impact on the results or follow up of an infant for another NSO target disease, or vice versa. Some diseases on the blood spot screening panel may be related to a cardiac condition or cardiac surgery. This information is useful in the interpretation of screening results.

In addition, when an infant is being referred to a Regional Treatment Centre (RTC) as screen positive for a disease detected through blood spot screening, it is important to communicate a screen positive CCHD result and where the infant is being followed. Specialists at the RTC will be able to coordinate care and follow up with the health care providers already involved with the family and infant.

B. Assure the quality of and evaluate the provincial program.

- Evaluate the recommended screening protocol and algorithm.
- Evaluate the performance of the Ontario-wide CCHD screening program.
- Enable health care providers to improve care by providing information on screening outcomes, and by allowing for comparison with benchmarks or other health care providers in the province. Submitters will receive feedback on their screening outcomes using quality indicators such as infant age at time of test, CCHD screens performed, and CCHD screens performed that follow the recommended algorithm. The report will also provide submitters with comparison to provincial trends and best practice standards for the reported quality indicators.
- Identify areas where CCHD screening best practice needs reinforcement and communicate this appropriately.

Secondary uses

- A. Develop and maintain CCHD pulse oximetry screening standards and guidelines, as well as educational materials.





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- Continuously improve CCHD screening standards and guidelines.
  - Develop educational tools and strategies to support Ontario-wide CCHD screening.
- B. Conduct research following the rules set out in Ontario's *Personal Health Information Protection Act, 2004* to contribute to further understanding of CCHD pulse oximetry screening procedures, policies, and overall program outcomes. All research must be approved by the CHEO Research Ethics Board.

