CCHD Screening Newsletter 2017-1

February 10, 2017

Update on CCHD pulse oximetry screening phased roll-out

NSO will be taking a **phased roll-out approach** to CCHD screening. Beginning in February and March, 14 hospitals, 6 midwifery practices, and a maternal and newborn clinic will send CCHD pulse oximetry screening data to NSO (Phase 1). We'll be working with these sites to get feedback and input on the data collection card, recommended protocols, education materials, pulse oximeters, and all other CCHD screening material and tools and will make any required adjustments in time for the next phase of the roll-out.

All other organizations will be beginning their NSO CCHD screening during Phase 2 (starting in June 2017), with the goal of having all organizations screening by December 2017. We are asking your organization to **let NSO know the timeframe** (June to December) in which you intend to begin to screen for CCHD by pulse oximetry as part of the provincial initiative. CCHD data collection cards will be available to order in time for your Phase 2 start time, and we will send launch kits containing material to support your organization's education needs with your target launch date in mind.

Protocols to support CCHD screening for babies born out-of-hospital or who are discharged early from hospital are currently in development. **NSO is recommending that affiliated hospitals, midwifery groups, and postnatal clinics collaborate on their implementation plan for CCHD screening**; particularly related to a smooth consultation process for those infants who have positive CCHD screens that occur in

*What are some next steps if you are an **organization starting in Phase 2**?*

- Consult the education material on the NSO website, including the 'Are you ready?' checklist for guidance. Review the screening process, proposed workflows, and supporting materials.
- Respond to this newsletter with your target start date (between June and December 2017)

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Equipment

NSO has made a list of standards for pulse oximeters and probes to meet for use for CCHD screening.

1. Pulse oximeters must report functional oxygen saturation (SpO_2).
2. Pulse oximeters must be motion-tolerant.
3. Pulse oximeters must be validated by the manufacturer for use in low perfusion conditions
4. Pulse oximeter must have an indicator of signal reliability (e.g. plethysmograph (pleth) line or waveform, audible heartbeat, or signal indicator).
5. Probes must be designed for use for neonatal patients.
6. Pulse oximeters must have built in quality assurance and/or system validation checks.
7. Pulse oximeters must be cleared by Health Canada and/or the U.S Food and Drug Administration for use in newborns and conform to relevant standards (FDA guidance document 1605: Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff).

If your organization does not have sufficient equipment that meet these requirements, support for hospitals, community clinics and midwives for initial purchase of pulse oximeters and probes will be available. More information on the purchasing process will be coming in time for the Phase 2 launch.

Please contact us by email at NSOCCHD@cheo.on.ca if you have any questions or concerns about implementing CCHD screening or the equipment standards.

Thank you for your time, contributions and continued support of this initiative! We're looking forward to hearing from you.

Newborn Screening Ontario, CCHD Screening Implementation Team

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