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MONTREAL
CHILDREN'S
HOSPITAL
(MUHC)

NICU RESEARCH STUDIES

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NICU - MONTREAL CHILDREN'S HOSPITAL

DOPAMINE VS NOREPINEPHRINE

Hôpital de Montréal
pour enfants
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Montreal Children's
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Project Title: Dopamine vs. Norepinephrine for Hypotension in Very Preterm Infants with Late-onset Sepsis: A National Comparative Effectiveness Research (CER) Project

Type of study: National comparative effectiveness research (CER) study

Investigators: Dr. Gabriel Altit (MUHC), Dr. Marc Beltempo (MUHC) & External PIs

Clinical Research Coordinator: Daniela Villegas M (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Fluid-unresponsive hypotension needing cardiotropic drug treatment is a serious consequential complication in very preterm neonates (gestational age ≤ 32 weeks) with suspected late-onset sepsis (LOS), defined for this study as culture-positive or negative bloodstream infection or necrotizing enterocolitis (NEC) occurring >48 hours of age. In Canada, ~ 250 very preterm neonates receive cardiotropic drugs for LOS related fluid-unresponsive hypotension every year. Of these, $\sim 35\text{--}40\%$ die. Although the underlying pathophysiology is predominantly vasodilatory shock, unlike for adult patients, there is little evidence to inform practice.

Aim of the study: To compare the relative effectiveness and safety of pharmacologically equivalent dosages of dopamine versus norepinephrine for primary pharmacotherapy for fluid-unresponsive hypotension in preterm infants born ≤ 32 weeks gestational age with suspected LOS.

Summary of intervention: The attending team will determine the adequacy of circulation and need to initiate, escalate, as well as patient's readiness to wean and/or discontinue treatments. However, all patients deemed circulatory insufficient will receive fluid therapy either Dopamine or Norepinephrine (minimum 10–20 cc/kg).

Inclusion criteria:

- Infants born GA ≤ 32 weeks and > 48 hours of life.
- Infants receiving primary vasopressor therapy with Dopamine or Norepinephrine in the context of suspected late-onset sepsis or NEC with systemic hypotension.

Exclusion criteria:

- Infants with known chromosomal or genetic anomalies.
- Infants receiving primary therapy with agents other than Dopamine or Norepinephrine.

More information:

<https://www.neocardiolab.com/research-recherche/dopamine-vs-norepinephrine-cer-study>



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Mount Sinai Hospital
Joseph & Wolf Lebovic Health Complex



THE DOXA TRIAL

Project Title: Doxapram versus Placebo Study in Premature Infants: A Double-blind Multicenter Randomized Study.

Type of study: Double-blind Multicenter Randomized international Study.

Investigators: Dr. Wissam Shalish (MUHC), Dr. Marc Beltempo (MUHC) & External PIs.

Clinical Research Coordinator: Daniela Villegas M (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Preterm infants often suffer from apnea of prematurity (AOP; a cessation of breathing) due to immaturity of the respiratory system. AOP can lead to oxygen shortage and a low heart rate which might harm the development of the newborn, especially the central nervous system. In order to prevent oxygen shortage, infants are treated with non-invasive respiratory support and caffeine. Despite these treatments, many preterm newborns still suffer from AOP and need invasive mechanical ventilation. Doxapram is a respiratory stimulant that has been administered off-label to treat AOP.

Aim of the study: The main objective of the trial is to investigate if Doxapram is safe and effective in reducing the composite outcome of death or neurodevelopmental impairment at 2 years corrected age as compared to placebo.

Summary of intervention: All babies will receive an intravenous (IV) infusion (into the vein) of a glucose 5% solution with or without the study drug (babies in the placebo group will receive glucose 5% without the study drug added). The study drug/placebo will be administered through an IV for at least the first 24 hours. After this period, if the baby does not have an IV anymore, the study drug/placebo can be administered through a tube in the baby's stomach called a gastric tube. The baby will be treated with the study drug/placebo until the apneas have reduced in frequency and severity compared to when the study drug/placebo was initiated. Alternatively, if apneas persist and invasive ventilation is required, the study drug/placebo will be stopped. Finally, between 18-24 months, the parents will be asked to complete a questionnaire for the baby either by phone or during the standard of care visit with the baby's doctor.

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Inclusion criteria:

- Gestational age at birth < 29 weeks
- Caffeine therapy, adequately dosed
- Optimal Non-invasively supported with nasal Continuous Positive Airway Pressure (CPAP) or ventilation ((S)NIPPV, NIV-NAVA, BIPAP/Duopap, SIPAP)
- Persistent apneas despite optimal caffeine and non-invasive respiratory therapy, that are close to requiring intubation and invasive ventilation as judged by the attending physician.

Exclusion criteria:

- Use of theophylline
- Chromosomal defects.
- Major congenital malformations that: compromise lung function, result in chronic ventilation; increase the risk of death or adverse neurodevelopmental outcome (congenital cerebral malformations, chromosomal abnormalities);
- Palliative care or treatment limitations because of high risk of impaired outcome.

More information:

<https://clinicaltrials.gov/study/NCT04430790>



THE EMBLEM STUDY

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Project Title: Early-life MRI biomarkers of longer-term respiratory morbidity in infants born extremely preterm (EMBLEM)

Type of study: Multicentric Observational Prospective Study

Investigators: Dr. Gabriel Altit (MUHC), Dr. Larry Lands (MUHC), Dr. Andreea Gorgos (MUHC), Dr. Zonah Khumalo (MUHC) & External PIs.

Clinical Research Coordinator: Daniela Villegas M (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Bronchopulmonary dysplasia (BPD) is a chronic lung disease of prematurity associated with multi-system morbidity, including neurodevelopment, that continues into adulthood. Lung disease is not easily predicted using traditional definitions of BPD; better measures are needed to define lung disease early in life and predict long-term outcomes. Pulmonary vascular changes are suspected to contribute to morbidity. Novel imaging modalities, including phase-resolved functional lung (PREFUL) and ultra-short echo time (UTE) magnetic resonance imaging (MRI), can evaluate pulmonary parenchyma and vasculature and their interplay with high resolution.

Aim of the study: To validate MRI biomarkers of pulmonary parenchymal and vascular abnormalities as predictors of respiratory morbidity and neurodevelopmental impairment (NDI) in infants born extremely preterm.

Summary of intervention: At baseline (36 weeks PMA), babies will undergo Phase-resolved functional lung and Ultra-short echo time MRI, echocardiogram, lung function (oscillometry) and lung ultrasound. We will evaluate 4 MRI biomarkers of pulmonary parenchymal and vascular structural disease. The primary outcome will be severe respiratory morbidity, evaluated up to 18 months CA through questionnaire every 3 months and chart review.



Inclusion criteria:

- Infants born at <29 weeks gestation.
- <36 weeks PMA at the moment of interventions.

Exclusion criteria:

- Known interstitial lung disease, congenital lung anomaly, ciliary dysfunction, immunodeficiency, cystic fibrosis, neuromuscular disease, or structural heart disease (other than atrial septal defect/hemodynamically insignificant ventricular septal defect/patent ductus arteriosus).
- Genetic syndrome or congenital anomaly.
- Contraindications for MRI or transport.
- Invasive or non-invasive ventilation that cannot be safely removed for MRI.
- Current respiratory infection.
- Family cannot speak English/French.
- Transferred to another hospital prior to baseline study visit.
- Not receiving follow-up at one of the study centres.

More information:

<https://www.neocardiolab.com/recherche-recherche/emblem-study>



DREAM 2.0

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Project Title: Detection of respiratory events using acoustic monitoring in extremely preterm infants (DREAM 2.0)

Type of study: Single-center observational prospective study

Investigators: Dr. Wissam Shalish(MUHC), Dr. Guilherme Sant'Anna(MUHC), Dr. Robert Kearney.

Clinical Research Coordinator: Ana Saavedra Ruiz (email: ana.saavedra.ruiz@muhc.mcgill.ca)

Background: Premature infants are often prone to respiratory problems because their lungs and central nervous system are not yet fully developed. When infants forget to breathe, or when the flow of air into their lungs is diminished, their heart rates and oxygen levels may briefly drop. These cardiorespiratory events (CREs) are very common in infants born prematurely and have been associated with long-term complications. CREs can take many forms, with each type requiring a specific kind of treatment. Unfortunately, the clinical methods used today cannot adequately detect, describe, or differentiate between these types of events. Consequently, research is being conducted with the aim of developing tools that can provide a more detailed account of babies' breathing and better monitor cardiorespiratory events.

Aim of the study: To evaluate the accuracy and clinical acceptance of acoustic monitoring for detecting and differentiating respiratory events in extremely preterm infants.

Summary of intervention: Patients' cardiorespiratory signals will be measured using different devices (reference standard vs current standard vs acoustic sensor) for 3 hours at four time-points. Likewise, Healthcare Providers (HCPs) will take part in an interview to explore and assess their perspectives on the current limitations and clinical acceptance of using an acoustic sensor.

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Inclusion criteria:

- **Infants:** gestational age < 29+0 weeks, and off respiratory support at the time of study recording.
- **HCPs:** directly involved in caring for an infant participating in the study.

Exclusion criteria:

Infants with known major congenital anomalies or deemed clinically unstable for the study.

More information:

<https://www.smarthospitalproject.com/>



PARENTAL ENGAGEMENT AND WELL-BEING IN THE NICU

Project Title: Optimizing Parental Self-Efficacy in the Neonatal Intensive Care Unit: Implications on Child Care and Parenting Quality

Type of study: Multicentric Observational Prospective Study
Investigators: Dr. Tina Montreuil & internal MUHC co-investigators/collaborators.

Clinical Research Coordinator: Chloé Gratton (email: chloe.gratton@mcgill.ca)

Background: Many NICU parents feel overwhelmed and inadequately prepared to care for their often high-risk, premature infant, particularly regarding making decisions about complex medical care issues. NICU clinicians have identified the urgent need for improved mental health and emotional support for NICU parents facing these difficult challenges. The promotion of parental engagement and attachment with their infant once discharged, is a crucial component to ensure a successful transition to home and to prevent readmission. Self-efficacy and parental beliefs of competence in managing parental tasks has been thought to act as a protective factor for both parent and child's emotional well-being. It is therefore important that parents receive adequate support, particularly in the NICU, so they can in turn have the emotional availability and parenting competence to help their child thrive.

Aim of the Study: The purpose of this study is to identify the specific psychosocial and emotional needs of parents with newborns in the NICU to better understand the factors associated to parental engagement in the NICU given its implications on child care and parenting quality.

Summary of Intervention: Participants will be asked to complete a set of self-administered questionnaires pertaining to parental engagement and self-efficacy within the NICU and will be invited to take part in a qualitative interview about their experience as a parent in the NICU.

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Childhood Anxiety and Regulation of
Emotions (C.A.R.E.) Research Group

Inclusion criteria:

- Parent of a child admitted to the Montreal Children's Hospital NICU.
- Ability to read and write in English or French.
- Have a RAMQ card.

More information:

For more information, please contact the clinical research coordinator.



RESET-PDA

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Project Title: REdefining the Significance and Treatment threshold for PDA in preterm neonates (RESET-PDA)

Type of study: Multicentric Observational Prospective Study

Investigators: Dr. Gabriel Altit (MUHC) & External PIs

Clinical Research Coordinator: Daniela Villegas M (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Prior studies on the reliability of targeted neonatal echocardiography (TNE) in extremely low gestational age neonates (ELGANs) with a patent ductus arteriosus (PDA) have been limited to a single-center setup and an evaluation of pre-defined images by a small set of study observers. To facilitate large multicenter prospective studies, the reliability of collecting comprehensive TNE measures across centers needs to be established.

Aim of the study: To investigate the interobserver reliability of echocardiography measures of PDA size/shunt volume, left ventricular (LV) function and dimensions among TNE-Neonatologists.

Summary of intervention: Four distinct, clinically relevant, and pragmatic postnatal age specific prediction models will be developed using the main study outcome, based on age of PDA evaluation after birth: (1) 1-3 days, (2) 4-7 days, (3) 8-14 days and (4) 15-28 days. Postnatal-age specific models provide a more homogeneous population for modelling and may be more applicable to clinical practice. For each model detailed clinical and imaging data from echocardiography evaluations, which identify a PDA and occur in the respective timeframe will be abstracted and included in the model.



Inclusion criteria:

- GA $\leq$ 27 weeks + 6 days at birth.
- Echo with PDA diameter $\geq$ 1.50 mm in the first 28 days after birth.

Exclusion criteria:

- Major congenital anomaly/genetic syndrome.
- Structural congenital heart disease other than small VSD (< 2 mm) or secundum ASD (irrespective of size).

More information:

<https://www.neocardiolab.com/research-recherche/reset-pda-study-protocol>



SAVING BABIES

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Project Title: Sonographic Assessment Validation study for Neonatal Global health improvement

Type of study: Multicentric prospective study

Investigators: Dr. Gabriel Altit (MUHC), Dr. Michelle Ryan (MUHC), Dr. Pia Wintermark (MUHC), Dr. Wadi Mawad (MUHC), Dr. Elisa Ruano Cea (MUHC) & External PIs

Clinical Research Coordinator: Daniela Villegas M (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Recently, wireless handheld ultrasound devices have been developed, primarily for use in adults, with some applications in older pediatric patients. However, these ultrasound solutions have not yet been validated for specific use in the neonatal context. The validation of these devices represents a unique opportunity to enhance diagnostic capabilities and monitoring at a lower cost. However, it is crucial to thoroughly assess the reliability of these devices before introducing them globally into neonatal care and research.

Ultrasound is a non-invasive and radiation-free imaging technique. It enables visualization of cardiac, vascular, cerebral, abdominal, and pulmonary structures. Its use is fundamental for the diagnosis, monitoring, targeted management, and adjustment of treatments in newborns facing postnatal complications.

Aim of the study: To validate the accuracy and reliability of measurements obtained using the hand-held ultrasound probe relative to those obtained using the standard of care advanced ultrasonography: Cardiac, lung and intracranial measurements.

Summary of intervention: Newborns of various gestational and chronological age, with various baseline diagnosis, will be recruited and scanned for lung, head, heart ultrasound using the golden standard ultrasound machine, and with the hand-held ultrasound. At a later stage, two blinded data extractors will be quantifying right and left cardiac function, lung scores, and intracranial bleed grading on the 2 modalities. Inter-rater and intra-rater variability analysis will be done. Correlation between the values and diagnosis of the two hand-held results will be compared to those of the standard ultrasound.



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Inclusion criteria:

- Newborns ranging from 23 weeks to 41 weeks + 6 days of GA.
- Newborns admitted to the NICU or nursery

Exclusion criteria:

- Infants with known genetic anomalies, congenital brain, heart, or lung defects, or those isolation for COVID-19 precaution will be excluded from the study.

More information:

<https://www.neocardiolab.com/research-recherche/saving-study>



SNAP-PY

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Project Title: Staphylococcus aureus Network Adaptive Platform trial in Paediatric and Youth (SNAP-PY)

Type of study: Multicentric phase III trial.

Investigators: Dr. Jesse Papenburg (MUHC).

Clinical Research Coordinator: Rim Nazar
(email: rim.nazar@muhc.mcgill.ca)



Background: SNAP-PY is a multinational (Global lead, Melbourne AUS), pragmatic, phase 4* open-label adaptive platform randomized control trial evaluating treatments for Staphylococcus aureus bacteremia (SAB) in neonates, infants, children and adolescents.

*In Canada, the only aspect of the trial considered to be phase 3, is the addition of cefazolin to vancomycin or daptomycin for the treatment of methicillin-resistant S. aureus (MRSA).

Treatment interventions: Depending on the antibiotic susceptibility profile of the causative S. aureus isolate, participants will be randomly allocated to receive the following antibiotic(s):

Silo	Antibiotic Backbone Domain
MSSA	(Flu)cloxacillin vs Cefazolin
MRSA	Vancomycin/Daptomycin vs Vancomycin/Daptomycin plus Cefazolin

Aim of the study: Primary objective is to examine the effect of the above treatment interventions on all-cause mortality at 90 days in patients with SAB.

Secondary objectives, to examine the effect of the treatment interventions on several secondary endpoints including:

- pediatric composite outcome (any of: 90-day mortality, microbiological treatment failure, new foci of infection, prolonged (>30d) total index hospitalization)
- mortality (at days 14, 28, and 42 after platform entry)
- hospital length of stay
- treatment failure and complications (e.g., diagnosis of new foci or C. difficile diarrhea)
- health economic costs (activity level of child; return to work for caregiver)

Tertiary objectives is to establish a biobank of S. aureus isolates and patient samples linked to clinical outcomes to elucidate the host- and pathogen-specific mechanisms that underlie responses to different therapies.

Inclusion criteria:

- Staphylococcus aureus complex grown from > 1 blood culture (BC).
- Admitted to participating hospital at anticipated time of eligibility assessment AND is <18 years of age

Exclusion criteria:

- Time of anticipated platform entry is >72 hours post collection of the index BC
- Polymicrobial bacteremia, defined as more than one organism (at species level) in the index BCs or in any subsequent BC reported between the collection of the
- index BC and platform eligibility assessment, excluding those organisms judged to be contaminants by either the microbiology laboratory or treating clinician.
- Known previous participation in the randomized SNAP platform.
- Known positive BC for S. aureus (of the same silo: MSSA or MRSA) between 72 hours and 180 days prior to the time of eligibility assessment.
- Treating team deems enrolment in the study is not in the patient's best interest 6. Treating clinician believes that death is imminent and inevitable.
- Patient is for end-of-life care and antibiotic treatment is considered not appropriate.
- Patient has died since the collection of the index blood culture

More information:

<https://www.snaptrial.com.au/>



THE BCPAP STUDY

Hôpital de Montréal
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Project Title: The use of bubble continuous positive airway pressure in premature infants: acoustics as a metric of effective pressure delivery.

Type of study: Observational Prospective Study

Investigators :Dr. Wissam Shalish, Dr. Robert Kearney & Dr. Guilherme Sant'Anna & External PIs

Clinical Research Coordinator: Ana Saavedra Ruiz (CUSM) ana.saavedra.ruiz@muhc.mcgill.ca

Background: Infants born prematurely have lungs that are not fully developed and therefore require some form of respiratory support, such as bubble CPAP (bCPAP). The pressures delivered by the bCPAP device along with the vibrations of the bubbles can help lungs grow. For the bCPAP to work as intended, the prongs need to be placed adequately in the nares. Nevertheless, oftentimes the prongs get displaced, or the infants open their mouths, making the pressure less able to reach the lungs. Unfortunately, there are currently no methods for continuously monitoring the delivery of pressure from the bCPAP system to the infant's lungs. This means that different healthcare professionals to make sure the bCPAP is working as intended frequently check the infant. Likewise, when the bCPAP system is not bubbling, the infant might need some help to adjust their prongs or their position because they might not be receiving the desired CPAP pressures.

Aim of the study: To use the acoustic properties of the bubbling sounds (loudness and frequency of the sounds) to estimate the pressure being delivered by the CPAP system in preterm neonates.

Summary of intervention: Patients included in the DREAM study will be monitored and their vital signals measurements will be acquired using different devices by the research team for different durations, depending on the group.

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Inclusion criteria:

- Infants on bCPAP with gestational age < 32+0 weeks.
- PMA between 28+0 and 36+6 weeks and PNA greater than 168 hours (7 days) at the time of the study.
- On bCPAP device with binasal prongs at the time of the study.
- Receiving bCPAP levels of 5 to 7 cm H₂O with gas flows between 6L/min and 10L/min at the time of the study.

Exclusion criteria:

- Infants with known major congenital anomalies, heart disorders, or neuromuscular disease.
- Infants receiving ventilator-derived CPAP or CPAP via a nasal mask interface at the time of the study.
- Infants receiving inotropes, narcotics or sedative agents at the time of the study.
- Infants deemed clinically unstable for the study by the attending neonatologist.



THE COMET TRIAL

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Project Title: Cooling in Mild Encephalopathy trial.

Type of study: Prospective multi-centre open label two-arm randomised controlled trial with masked outcome assessments.

Investigators : Dr. Jarred Garfinkle, & Dr. Marc Beltempo.

Clinical Research Coordinator: Charlotte Serrano (CUSM) charlotte.serrano@mail.mcgill.ca

Background: Hypoxic-ischemic encephalopathy (HIE) occurs in newborns following perinatal asphyxia and can lead to long-term neurodevelopmental impairment. Therapeutic hypothermia is the standard treatment for moderate to severe HIE, where it has been shown to reduce mortality and neurodevelopmental disability. However, infants with mild HIE are currently not routinely treated with cooling, despite evidence suggesting that some of these infants may still experience cognitive and developmental impairments later in childhood. The safety, efficacy, and cost-effectiveness of therapeutic hypothermia in infants with mild encephalopathy remain uncertain, prompting the need for a randomized controlled trial.

Aim of the study: To determine whether whole-body therapeutic hypothermia improves neurodevelopmental outcomes in neonates with mild hypoxic-ischemic encephalopathy compared with normothermia.

Summary of intervention:

Experimental Group: Infants randomized to the intervention receive; Whole-body therapeutic hypothermia. target temperature: 33.5°C for a duration of 72 hours. Initiated within 6 hours after birth and followed by gradual rewarming (approximately 0.5°C per hour) until normothermia is reached.

Control Group:

Infants randomized to the control group receive: Standard care with normothermia, temperature maintained in the normal physiological range (approximately 36.5–37.5°C). No therapeutic cooling. Both groups receive standard neonatal intensive care management, including monitoring, respiratory support if needed, and neurological evaluation.



Inclusion criteria:

- Gestational age ≥ 36 weeks
- Age ≤ 6 hours at randomization
- Evidence of perinatal asphyxia (metabolic acidosis, low Apgar score, or need for resuscitation)
- Mild encephalopathy on standardized neurological examination (modified Sarnat staging)
- Normal or mildly abnormal aEEG background without seizures.

Exclusion criteria:

- Moderate or severe encephalopathy
- Clinical or electrographic seizures prior to enrollment
- Abnormal aEEG pattern suggesting moderate/severe HIE
- Major congenital anomalies
- Life-limiting conditions
- Infants already receiving therapeutic hypothermia before enrollment.

More information:

<https://clinicaltrials.gov/study/NCT05889507>



THE MVP TRIAL

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Project Title: Manual T-piece Versus Ventilator Positive Pressure Ventilation During Resuscitation of Extremely Premature Neonates

Type of study: Cluster crossover randomized controlled trial

Investigators: Dr. Marc Beltempo

Clinical Research Coordinator: Charlotte Serrano (CUSM) charlotte.serrano@mail.mcgill.ca

Background: Extremely premature infants often require positive pressure ventilation (PPV) immediately after birth to establish lung aeration and stabilize breathing. While T-piece resuscitators are commonly used for neonatal resuscitation, they provide limited feedback on ventilation delivery and may lead to variability in pressures and ventilation quality, potentially increasing the need for endotracheal intubation, which carries additional risks. An alternative approach is ventilator-derived PPV (V-PPV) delivered through a neonatal ventilator using nasal intermittent positive pressure ventilation (NIPPV) mode, which may offer more precise control of ventilatory parameters and improve stabilization of extremely premature infants in the delivery room.

Aim of the study: To compare manual T-piece resuscitation versus ventilator-derived positive pressure ventilation during the initial resuscitation of extremely premature neonates and determine whether ventilator-based PPV improves clinical outcomes.

Summary of intervention: Experimental Group
Infants receive: Ventilator-derived positive pressure ventilation (V-PPV)

Control Group

Infants receive:

Manual T-piece positive pressure ventilation.



Inclusion criteria:

- Gestational age 25+0 to 28+6 weeks
- Planned to receive full resuscitation at birth (not comfort care only)
- Require positive pressure ventilation within the first 10 minutes after birth, as determined by the resuscitation team.

Exclusion criteria:

- Outborn birth status
- Resuscitation performed in unusual locations outside the delivery room (e.g., emergency department or antenatal ward)
- Major congenital or chromosomal anomalies
- Established spontaneous breathing without the need for PPV

More information:

<https://clinicaltrials.gov/ct2/show/NCT05196646>



THE NEURO-NQI

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Project Title: The NeuroNQI Pilot study: Effects of a Nurturing and Quiet Intervention (NeuroN-QI) on Preterm Infants' Neurodevelopment and Maternal Stress and Anxiety

Type of study: A Randomized Clinical Trial

Persons Responsible: Dr. Gabriel Altit (MUHC) and Dr. Marylin Aita (Sainte-Justine Hospital)

Clinical Research Coordinator: Charlotte Serrano (email: charlotte.serrano@muhc.mcgill.ca)

Background: The current state of knowledge reveals that the development of the brain of preterm babies is influenced by specific neonatal experiences during hospitalization, such as environmental sensory stimulation (light and noise), as well as proximity to mothers. However, there is a lack of evidence regarding the benefits that could be associated with the combination of care interventions to improve the health outcomes of preterm infants and their mothers, and in particular the development of the brain of infants during their hospitalization in the neonatal unit.

Aim of the study: To assess the feasibility and acceptability of a developmental care intervention including periods of nurturing between mothers and their infant (skin-to-skin contact/ Kangaroo care and auditory stimulation) to promote physical and emotional proximity and a quiet period (controlled light and noise levels and olfactory stimulation in incubators) and to estimate the effect of this intervention on infants' neurodevelopment as well as on maternal stress and anxiety.

Summary of intervention: Acquire light and noise measurements while kangaroo care is being done by the mother by using a photometer and a sonometer respectively.

Inclusion criteria:

- Infants born between 26 and 33 6/7 weeks.

Exclusion criteria:

- Birth defects or genetic disorders.
- An intraventricular hemorrhage >grade II.
- Receive analgesics or paralyzing agents.

Mothers exclusion criteria:

- <18 years of age, have a physical condition that does not allow kangaroo care, alcohol misuse, chose formula or mixed feeding; do not speak, read or write French or English.

More information:

<https://www.neocardiolab.com/rese-arch-recherche/neuron-qi-project>



THE PEACE STUDY

Project Title: Post-Extubation Assessment of Clinical stability in Extremely Preterm Infants (PEACE)

Type of study: Multiple center prospective observational study

Persons Responsible: Dr. Wissam Shalish, Dr. Guilherme Sant'Anna, Dr. Robert Kearney & External PIs

Clinical Research Coordinator: Ana Saavedra Ruiz (CUSM)
ana.saavedra.ruiz@muhc.mcgill.ca

Background: Almost all extremely preterm babies admitted to the NICU need a breathing tube connected to a ventilator to help them breathe after birth. The process of transitioning from invasive respiratory support (through a breathing tube) to non-invasive respiratory support (through a nasal mask or nasal prongs), also known as extubation, is a critical milestone in these babies. However, following extubation, these babies commonly have some form of clinical instability, including increased oxygen needs, increased work of breathing, and frequent cardiorespiratory events (where they have pauses in breathing, drops in their heart rate, and drops in their oxygen saturation). Also, a subset of these infants fail their extubation attempt and require re-insertion of the breathing tube, also known as reintubation. For these reasons, it is important to understand better why these fragile babies develop clinical instability and require reintubation.

Aim of the study: By collecting more detailed information about your baby's well-being, To evaluate the feasibility and acceptance of a multimodal monitoring system that integrates clinical data and biomedical signals during the post-intubation period in a cohort of extremely preterm infants.

Summary of intervention: Once the infant is deemed ready for extubation by the clinical team, clinical and physiological data (heart rate, breathing movement, oxygen saturation, brain and intestinal oxygenation) will be acquired continuously from 1-hour pre-extubation until 168 hours (7 days) post-extubation using different devices.

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Inclusion criteria:

- Birth weight < 1000g and gestational age < 28+0 weeks.
- Received mechanical ventilation within the first 72h of life.
- Undergoing their first planned extubation within the first 6 weeks of life.

Exclusion criteria:

- Congenital anomalies and congenital heart disorders.

More information:

<https://clinicaltrials.gov/study/NCT06037083>



THE PERSPECTIVE OF PARENTS

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Montreal Children's
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Project Title: Perspectives of Parents and Healthcare Professionals on Cardiorespiratory Events in Extremely Preterm Infants: A Qualitative Descriptive Study.

Type of study: Qualitative descriptive study

Persons Responsible: Dr. Wissam Shalish, Dr. Sylvie Lambert

Clinical Research Coordinator: Ana Saavedra Ruiz (CUSM)
ana.saavedra.ruiz@muhc.mcgill.ca

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Background: Extremely preterm infants frequently experience cardiorespiratory events—episodes of apnea, bradycardia, and/or desaturation— due to immaturity of the lungs and respiratory control centers. These events are often distressing for both families and clinical staff. Healthcare providers in the NICU, including neonatologists, neonatal nurse practitioners (NNPs), nurses, and respiratory therapists (RTs), play a critical role in recognizing and managing these events, as well as in supporting and communicating with families. However, there may be variation in how providers interpret the clinical significance of these episodes and communicate this information to parents. Thus, it is important to explore parents' and healthcare providers' perspectives on these events and the communication practices surrounding them, to identify potential gaps and areas for improvement in parent support and care delivery.

Aim of the study: To gain a deeper understanding of the perspectives of both parents and Healthcare Providers (HCPs) regarding cardiorespiratory events in extremely preterm infants to identify areas where communication and support can be improved, ultimately enhancing the care provided.

Summary of intervention: We will recruit parents and healthcare providers who have witnessed and treated clinically significant cardiorespiratory events. Parents will participate in individual interviews, while HCPs will take part in focus groups. We will then bring both groups together for a deliberative dialogue to explore shared perspectives and priorities and identify recommendations.

Inclusion criteria:

- Parents of infants with GA $\leq$ 28+0 weeks and PMA up to 36+6 weeks, who have witnessed their infants experience at least one clinically significant cardiorespiratory event since hospitalization.
- HCPs (registered nurses, respiratory therapists, neonatologists, and neonatal nurse practitioners), who are directly involved in the care of extremely preterm infants (GA $\leq$ 28 weeks) and the treatment of severe cardiorespiratory events during NICU hospitalization.

Exclusion criteria:

- Parents of infants with known major congenital anomalies, congenital heart disorders, or neuromuscular disease.
- HCPs who do not work with extremely preterm infants and are on extended leave or unavailable during the study period.

More information:

<https://www.smarthospitalproject.com/>



THE PURPOSE STUDY

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Project Title: PurPOSE Study – Point of Care
Ultrasound in Congenital Diaphragmatic Hernia:
Predicting Outcomes and Success of Extubation

Type of study: Prospective observational study.
Persons Responsible: Dr. Gabriel Altit (MUHC) Other
MUHC Collaborators, & External PIs
Clinical Research Coordinator: Daniela Villegas M.
(email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Children with congenital diaphragmatic hernias are more likely to have been born with organs displaced in the chest leading to the need for certain surgical interventions or close monitoring. It is known that some of these children are born with heart and lung problems. We believe that chest ultrasound (with images from the lung and the heart), an imaging modality that is done without radiation, may already predict those babies that may have more complications or more problems before discharge from the hospital. Due to this hypothesis, we aim to assess if chest ultrasound on the first day of life and just before extubation may help better predict those that will have major issues as well as predict the successful extubation.

Aim of the study: To analyze chest ultrasound of the lung and the heart in order to better understand the impact of CDH after birth, and before extubation.

Summary of intervention: Ultrasound of the chest will be done on the first day of birth, as well as repeated in the hours prior to the planned extubation.

Inclusion criteria:

- Males and females less than 24 hours of life.
- Diagnosis of CDH (prenatally diagnosed).
- Gestational age ≥ 34 weeks.

Exclusion criteria:

- Prematurity (<34 weeks).
- Bilateral CDH.
- Postnatal diagnosis / outborn infants.
- Cyanotic congenital heart disease or complex non-cyanotic defects (excluding a patent ductus arteriosus (PDA), atrial septal defect (ASD) or ventricular septal defect (VSD)).
- Major congenital anomaly (such as brain or airway/lung malformation) or prenatally known genetic syndrome.
- Infants unable to recruit prior to cannulation on ECMO.

More information:

<https://www.neocardiolab.com/research-recherche/ongoing-research-projects-projets-de-recherches-en-cours#h.vj39ehkxolkt>



THE SANE-03 THE SILDENAFIL STUDY

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Project Title: Treatment of Neonatal Encephalopathy with Oral Sildenafil Suspension to Repair Brain Injury Secondary to Birth Asphyxia: A Phase 2 study

Type of study: Randomized, double-blind, placebo-controlled clinical trial

Persons Responsible: Dr. Pia Wintermark

Clinical Research Coordinator: Joseph Zepeda
(Email: joseph.zepeda@affiliate.mcgill.ca).

Background: The phase II study will be a double-blind, randomized placebo-controlled trial that will be started at the Montreal Children's Hospital and will be extended to other sites. Neonates will be randomized to receive either (1) sildenafil (experimental group) or (2) placebo (control group) twice a day for seven days (from day 2 of life to day 9 of life). The allocation ratio for the study will be 2:1, to allow for the assessment of the efficacy of sildenafil with a larger number of neonates. We will explore the change in the severity of brain injury determined by MRI between days 2, 10 and 30 of life. We will compare the MRI scores of brain injury severity on days 10 and 30 of life with baseline (day 2 of life) using the Wilcoxon signed-rank test. We will follow these babies at 18 and 36 months.

Aim of the study:

Primary Objective:

-Determine if sildenafil decreases brain injury

Secondary objectives:

- Further assess safety of sildenafil
- Determine if sildenafil improves cardiopulmonary hemodynamics
- Determine if sildenafil improves neurodevelopmental outcome
- Determine if sildenafil decreases neuroinflammation.

Summary of intervention: Neonates will be randomized to receive either sildenafil (experimental group) or placebo (control group) twice a day for seven days.

Inclusion criteria:

Male and female neonates meeting the criteria for induced hypothermia:

- Gestational age ≥ 36 weeks and birth weight ≥ 1800 g.
- Evidence of fetal distress, i.e., history of an acute perinatal event.
- Cord pH ≤ 7.0 or base deficit ≤ -16 mEq/L.
- Evidence of neonatal distress, such as an Apgar score ≤ 5 at 10 minutes, postnatal blood gas pH obtained within the first hour of life ≤ 7.0 or base deficit ≤ -16 mEq/L, or a continued need for ventilation initiated at birth and continued for at least 10 minutes.
- Evidence of moderate to severe neonatal encephalopathy by an abnormal neurological exam and/or an amplitude-integrated electroencephalogram (aEEG).
- They will receive whole-body cooling to an esophageal temperature of 33.5°C , initiated within the first 6 hours of life, continued for 72 hours, and then they will be slowly rewarmed using standard protocol.
- Evidence of brain injury on a brain magnetic resonance imaging (MRI) performed on day 2 of life.

Exclusion criteria:

- Neonates with complex congenital heart disease.
- Neonates with cerebral malformations.
- Neonates with genetic syndrome.
- Neonates with intraventricular and/or intraparenchymal hemorrhage on MRI performed on day 2 of life.

More information:

<http://www.neobrainlab.org>



THE SMART DASHBOARD

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Project Title: Development of a Smart Dashboard for the Neonatal Intensive Care Unit (NICU): A Usability Evaluation Study with NICU Parents.

Type of study: Multi-center qualitative study.

Persons Responsible: Dr. Guilherme Sant'Anna

Clinical Research Coordinator: Alyssa Maximov
(email: alyssa.maximov@muhc.mcgill.ca)

Background: Advances in neonatology and intensive monitoring technologies have significantly improved outcomes for newborns cared for in Neonatal Intensive Care Units (NICUs). However, parents' experiences and relationships with their infants are now recognized as essential factors during a NICU stay. The NICU environment can create high levels of stress for parents due to caregiving limitations, reliance on healthcare staff, and concerns about their baby's condition. To improve family-centered care, tools such as healthcare dashboards—like the proposed Smart Dashboard—aim to support decision-making and enhance the NICU experience for families.

Aim of the study:

This study aims to evaluate the usability and impact of the Smart Dashboard, a family-centered monitoring tool designed for NICU settings. It seeks to reduce parental stress and improve communication by allowing parents to access simplified, real-time health data and care updates for their babies. Researchers will assess how easy and useful the tool is for parents through tasks, questionnaires, and interviews, focusing on satisfaction, learnability, and user experience.

Summary of intervention: This research study will take place at the Simulation Room of the Smart Hospital Project (downtown Montreal). Parents' participation in this research study will require 1 visit to the Simulation Room of the Smart Hospital Project and will last approximately 1.5 hours. Parents will be asked to complete a 3 questionnaires and participate in a semi-structured interview about their NICU experience. They will also be facing a camera during their interactions with the Smart Dashboard to track where you look. The camera does not record their face; it only fixes their eye and draws lines as their eyes move. This will allow us to understand the complexity of the Smart Dashboard's design.

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Inclusion criteria:

Parents or caregivers to ≥ 1 infant(s) admitted to the NICU for > 5 days at time of recruitment OR

- Parents or caregivers to ≥ 1 infant(s) at the NNFU clinic at time of recruitment (after a NICU admission ≤ 12 months) OR
- Healthcare Providers working at the MCH NICU for at least 3 months

AND over the age of 18 years

AND literate in English or French

Exclusion criteria:

- Parents or caregivers to ≥ 1 infant(s) admitted to the NICU for < 5 days at time of recruitment
- Parents or caregivers to ≥ 1 infant(s) at the NNFU clinic at time of recruitment (after a NICU admission > 12 months)
- Any family determined by an attending physician or bedside care team to be experiencing too much stress (e.g., terminally ill infants)
- Healthcare Providers working at the MCH NICU for less than 3 months.

More information:

<https://www.smarthospitalproject.com/>



THE UNICORN STUDY

Project Title: Understanding Infant Cerebral growth & Outcome Research in Neurodevelopment (The UNICORN study)

Type of study: Prospective observational study

Persons Responsible: Dr. Marie Brossard Racine, PhD
Other contact: Sarah Palmis, PhD (email: sarah.palmis@mail.mcgill.ca) & Camille Héguy (email: camille.heguy@mail.mcgill.ca)

Background: Thanks to improved health care, most babies born preterm or with a congenital heart defect (CHD) grow up to be independent adults and have satisfying lives. However, some may develop functional difficulties during childhood and adolescence. However, the relationship between these difficulties and brain development remains poorly understood. This information could help us identify sooner the children who will be facing challenges so we can react promptly. Overall, a better understanding of these will guide the development of targeted interventions and help us provide better support to babies and their families.

Aim of the study: This research study seeks to better understand brain growth and child development during the first 2 years.

Summary of intervention: Perform magnetic resonance imaging and/or age-appropriate neurodevelopmental evaluations following discharge (starting at term equivalent for the preterm born babies or post-open heart surgery for the babies with CHD) and every season (~3 months) during the first 12 corrected age. Also, perform age-appropriate evaluations only every 6 months during the second year of life.

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RESEARCH LABORATORY

Inclusion criteria:

Babies born preterm :

- Infants born ≤ 37 weeks gestational age at the Montreal Children's Hospital.

Babies with CHD:

- Infants with CHD who underwent open heart surgery utilizing cardio-pulmonary bypass during the first six months of life.

Exclusion criteria:

- Presenting with brain malformation or severe brain injury detected by bedside ultrasound
- Congenital infection, genetic syndrome, or documented chromosomal anomaly

More information:

<https://www.abcdresearch.ca/projects>



THE WHEAT INTERNATIONAL TRIAL

Project Title: WithHolding Enteral Feeds Around Packed Red Cell Transfusion (WHEAT)

Type of study: Randomized controlled, unblinded, multicentric trial.

Persons Responsible: Dr. Marc Beltempo (MUHC) & other external PIs

Clinical Research Coordinator: Daniela Villegas M. (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Necrotizing enterocolitis is a serious complication related to prematurity. Almost 5% of infants born at <30 weeks gestation will develop necrotizing enterocolitis which can lead to death or long-term health and developmental problems among survivors. Red blood cell transfusion has been suggested as a possible factor that contributes to the risk of necrotizing enterocolitis. This transfusion-associated necrotizing enterocolitis may also be more severe with higher mortality. The majority of preterm infants born <30 weeks (60% to 90% have at least one transfusion) will require at least one transfusion during admission. Stopping milk feeds for a short period of time (12h) during red blood cell transfusion may reduce the risk of necrotizing enterocolitis by decreasing postprandial mesenteric. However, due to a lack of good-quality evidence, there is no consensus regarding the optimal feeding strategy during a blood transfusion.

Aim of the study: Compared with continuing feeds, withholding feeds during each packed red cell transfusion after randomization will reduce the incidence of NEC occurring after the first packed red cell transfusion.

Summary of intervention: Babies will be randomized before receiving a blood transfusion to stopping feeds during transfusions or continuing feeds during transfusions.

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Inclusion criteria:

- Preterm birth at <30+0 weeks of gestational age.

Exclusion criteria:

- Packed red cell transfusion with concurrent enteral feeds prior to enrolment (*infants who have received a packed red cell transfusion while nil-by-mouth or minimal enteral nutrition (<15 ml/kg/days feeds) are eligible).
- Infants where enteral feeding is contraindicated in the first 7 days after birth [e.g. Major congenital abnormality of the GIT].
- Previous episode of NEC or SIP prior to first packed cell transfusion.

More information:

<http://neoepoch.com/wheat-trial>



THE WIRELESS aEEG

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Montreal Children's
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Project Title: TEvaluating a wireless aEEG device in the Neonatal Intensive Care Unit

Type of study: Single center prospective observational study

Persons Responsible: Dr. Guilherme Sant'Anna, Dr. Jarred Garfinkle.

Clinical Research Coordinator: Alyssa Maximov (email: alyssa.maximov@muhc.mcgill.ca)

Background: An amplitude integrated electroencephalogram (aEEG) is a test used to detect problems related to electrical activity of the brain. aEEGs are standard of care to diagnose a multitude of neurologic disorders in neonates (e.g. seizures, intraventricular hemorrhage and encephalopathy) through the evaluation of brain wave patterns. Currently, aEEG monitoring requires constant, wired attachment to a power supply and hardware, which can limit the patient's ability to move without making the aEEG difficult to interpret. aEEG monitoring requires many electrodes to be applied over a large area on the baby's head.

The purpose of this research study is to compare a wireless aEEG device using non-invasive sensors, to the standard aEEG wired electrodes connected by wires to the monitors.

Aim of the study: This study aims to 1) optimize these devices for use in NICU patients, 2) demonstrate safety, reliability, and accuracy of these devices for continuous NICU aEEG signal measurements, and 3) demonstrate that these devices are preferred by patients and parents to current aEEG devices. Once validated, such sensors could fundamentally change the way patients are monitored by aEEG in the NICU, allowing wireless, continuous, real-time detection of brain wave activity in NICU patients, and reducing limitations in mobility and access by staff and caregivers.

Summary of intervention: A member of the research team will set up the study equipment AFTER completion of the clinically indicated aEEG. Up to 4 leads will be placed on the baby's head using medical grade skin adhesive. The wireless aEEG device will remain in place for up to 2 hours. A small power source connected to the electrodes will be placed on the baby's body, and a computer/tablet will be placed in the patient's room to receive the aEEG signals wirelessly.

Two wireless electrocardiogram (ECG) sensors will be applied on the chest to capture heart rhythm. Once the data collection period is complete and the wireless aEEG sensor has been removed from the participant's head, the parents/caregivers and HCPs of the participant will be asked to complete a short questionnaire to evaluate their opinion on the traditional wired aEEG system, and on the new wireless aEEG device.

Inclusion criteria:

- Participants must be admitted to the NICU and are being monitored with an aEEG as part of their standard of care. Patients can be term or pre-term but must be under 29 days of age.
- HCP must be in the circle of care of the participant at the time of data collection.

Exclusion criteria:

- Anyone with a skin abnormality that would potentially increase the risk of device use will be excluded.
- Any infants 29 days or older will be excluded.
- Any patient or family determined by an attending physician or bedside care team to be too unstable (patient) or experiencing too much stress (family) will not be approached for recruitment.

More information:

<https://www.smarthospitalproject.com/>

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THE WIRELESS NIRS

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Project Title: Evaluating a wireless NIRS device in the Neonatal Intensive Care Unit

Type of study: Single center prospective observational study

Persons Responsible: Dr. Guilherme Sant'Anna,
Dr. Gabriel Altit

Clinical Research Coordinator: Alyssa Maximov (email: alyssa.maximov@muhc.mcgill.ca)

Background: Near-infrared spectroscopy (NIRS) is a test commonly used in the NICU to monitor oxygen levels and blood flow in the brains of newborns (e.g. those with congenital heart defects, birth asphyxia, etc.) by measuring how light is absorbed by brain tissue. Currently, NIRS monitoring requires constant, wired attachment to a power supply and hardware, which can limit the patient's ability to move.

Aim of the study: By applying a new wireless non-invasive NIRS sensor on the participant's forehead slightly above or below the standard NIRS, the research study aims to compare this wireless non-invasive NIRS sensor to the standard NIRS wired device connected to the monitors by a cable.

Summary of intervention: A member of the research team will set up the study equipment during the period in which the baby is monitored with the clinically indicated NIRS. One small, soft and flexible sensor will be placed on the baby's forehead in parallel to the current wired NIRS device using medical grade skin adhesive. The wireless NIRS device will remain in place for 4 consecutive hours, over 2 consecutive days. As with all sensors on the baby, they will be removed, the skin condition will be checked, and the device will be reapplied by the research team with every care (approximately every 3 hours). A computer/tablet will be placed in the patient's room to receive the NIRS signals wirelessly. Once the data collection period is complete and the wireless NIRS sensor has been removed from the participant's forehead, the parents/caregivers of the participant will be asked to complete a short questionnaire to evaluate their opinion on the traditional wired NIRS system, and on the new wireless NIRS device.

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Inclusion criteria:

- Infants admitted to the NICU with a gestational age of ≥ 32 weeks at the time of the monitoring, and undergoing monitoring with the INVOS wired NIRS system.
- HCPs: directly involved in caring for an infant participating in the study.

Exclusion criteria:

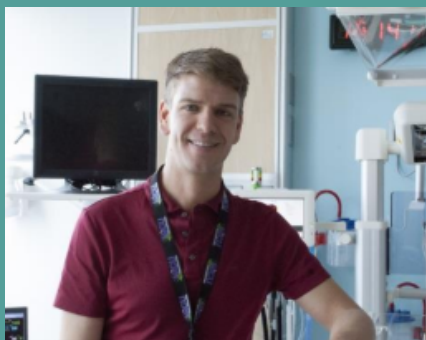
- Infants with a skin abnormality that would potentially increase the risk of injury.
- Patient too unstable or family experiencing too much stress as determined by an attending physician or bedside care team to not be approached for recruitment.

More information:

<https://www.smarthospitalproject.com/>



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