Study Title: Advanced Wireless Sensors for Neonatal Care in the Delivery Room: the AWARD Prospective Multicenter International Study - AWARD Project – Clinical Study

STUDY PROTOCOL

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PROTOCOL

Study Title: **A**dvanced **W**ireless Sensors for Neon**a**tal Ca**r**e in the **D**elivery Room: the **AWARD** Prospective Multicenter International Study.

AWARD Project – Clinical Study

Lead Site:

Principal Investigator/Sponsor-Investigator:

Dr Guilherme Sant'Anna
Research Institute of the McGill University Health Centre
Montreal Children's Hospital
1001 Boul Decarie B06.1274
Montreal, Quebec H3A 2J1

RI-MUHC Co-Investigators:

Dr Wissam Shalish
Robert Kearney PhD
Vivian Azevedo PhD

Participating Site Investigators

- **Daniela Marques MD**, Federal University of Uberlândia (Brazil)
- **Jamil Chagas MD, PhD, Sergio Marba MD, PhD** University of Campinas, UNICAMP (Brazil).
- **Nestor Vain MD**, Hospitals Sanatorio Trinidad Palermo (Buenos Aires, Argentina).
- **Alex Stevenson MBChB MMed (PAeds) Mphil (neonatology)** FACRRM, Consultant Neonatologist
- **Sonia Bandeira MD,** Maputo Central Hospital (Maputo, Mozambique)

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List of Abbreviations and Terminology:

International Liaison Committee on Resuscitation (ILCOR)

Oxygen Saturation (SpO2),

Heart Rate (HR

Skin Temperature (Tskin)

Low and Middle Income Countries (LMIC)

Kangaroo Mother Care (KMC)

Delivery Room (DR)

World Health Organization (WHO)

Sudden Unexpected Postnatal Collapse (SUPC)

Electrocardiography (ECG)

Neonatal Intensive Care Unit (NICU)

Respiratory Rate (RR)

European Society for Paediatric Research (ESPR)

Randomized Controlled Trial (RCT)

1 Introduction and Rationale

1.1 Background

Globally, around 140 million infants are born every year, representing 4 births/second every day. Of these, approximately 10 million infants do not breathe immediately after birth, and 60% require basic neonatal resuscitation. [1,2] The International Liaison Committee on Resuscitation (ILCOR) publishes a consensus on newborn resuscitation science every 5 years and currently recommends monitoring of oxygen saturation (SpO_2), heart rate (HR; monitored by electrocardiography), and skin temperature (T_{skin}) during neonatal resuscitation.[3] Therefore, in the delivery room, the use of expensive and large base monitoring units attached to a power supply is usually necessary. To obtain the signals, wired skin sensors and electrodes are placed on the patient. Altogether, these are barriers for adoption of the ILCOR recommendations due to the lack of portability and the training required for their use in environments with low resources and high number of deliveries.[9] Indeed, many delivery centers in low and middle income countries (LMIC) either do not monitor or use a variety of different systems whose accuracy and safety is unknown (**Figure 1**). The Argentine Pediatrics Society, after evaluating the causes of neonatal deaths of hospitalized newborns, reported that, at the time of death, many newborns were not adequately monitored, , concluding that lack of adequate neonatal vital sign monitoring may contribute to an increase in preventable newborn unexpected catastrophic events leading to death.[10] Furthermore, the necessary equipment is usually in the same room of the mother, demanding close communication within teams and with the family. However, delivery room (DR) technologies should facilitate, rather than impede, family integration and early bonding. Additionally, infants are born with wet skin and a transitioning cardiorespiratory system, but existing monitoring solutions were not primarily designed for resuscitation and may also have a significant delay (up to 1 minute) before displaying data, which can affect critical clinical decisions. As knowledge about the process involving the transition from fetal to neonatal life increases, it is expected that more technologies will evolve for use in the DR. These technologies should be developed for use where the greatest burden of morbidity and mortality exists (LMIC) to have the largest impact in neonatal health care.[1,2]

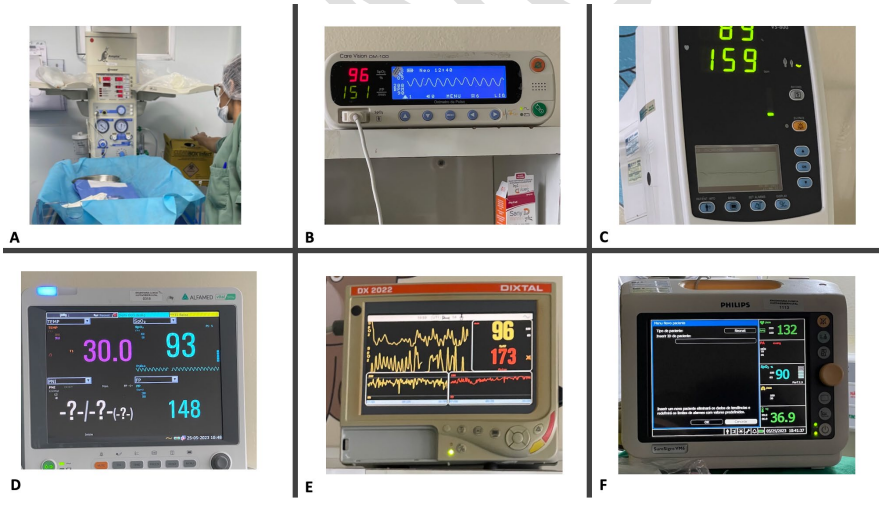

Figure 1. Monitoring in a maternity hospital located in the northeastern region of Brazil. **A** – Delivery room: note lack of monitoring at the resuscitation unit where there are no devices to capture ECG and SpO_2. **B to F** Five different monitoring devices used in the same NICU. All placed on the top of the incubators and using different technologies.

In the majority of infants that do not require resuscitation after delivery, Kangaroo Mother Care (KMC) is a common practice associated with several advantages for maternal and neonatal health and is supported by the World Health Organization (WHO). Skin-to-skin care shortly after birth improves temperature stabilization and facilitates initial breastfeeding. Thus, KMC should start in the obstetrical center.[4-6] However, unsupervised skin-to-skin care may contribute to bedsharing, a practice specifically discouraged by the American Academy of Pediatrics as unsupervised post-partum KMC has been identified as a major risk factor for sudden unexpected postnatal collapse (SUPC), which mostly occurs during the ***first 2 hours of age***.[7] SUPC is an apnea or cardiorespiratory failure occurring in an otherwise-healthy near term or term newborn during the initial skin-to-skin contact, with prone positioning, or with the first attempt to breastfeed. The incidence has been estimated to be between 2.6-133 cases per 100.000 newborns.[8,9,11] Despite educational efforts, falling asleep while breastfeeding or holding a newborn during skin-to-skin care is a hazard after sleep deprivation and/or the use of narcotic analgesics associated with labor & delivery. In over 50% of cases, SUPC occurs following accidental suffocation, and frequently goes unrecognised by parents. For this reason, some health care authorities have recommended development and implementation of safety guidelines in hospitals. Nonetheless, as many as 60% of SUPC cases still occur in centers that have adopted these guidelines.

1.2 Study Rationale

Delivery room and hospital care requires new and advanced technology that can quickly capture and monitor vital signs from birth up to discharge home. Such technology must have several characteristics. It should be small, non-invasive, not require installation of expensive and sophisticated equipment, be easily accessible by health care professionals, affordable, portable, and non-intrusive to promote early and safe skin-to-skin contact between mothers and their newborns. In the hospital setting, a balance is needed between encouraging and supporting a mother while avoiding practices that inadvertently increase the risks to the infant. A number of emerging technologies have been investigated for neonatal vital sign monitoring including camera-based (visible light and infrared thermography), RADAR, Ballistocardiograph, and capacitive ECG.[12-22] Studies were mostly done in the Neonatal Intensive Care Unit (NICU). Camera-based monitoring was examined for HR measurements, but the equipment is expensive, needs to be placed perpendicularly and at a specific distance in front of the infant's face. Additionally, a large band light source is required to uniformly illuminate the selected area on infants in a supine position, allowing direct camera view.[12-14] Camera thermal recordings were investigated for measurements of RR in a control environment with good accuracy. However, thermal imaging is very expensive, sensitive to motion artifacts, and requires wires and cables to connect all the equipment around the infant.[15-17] Ballistocardiography provides unobtrusive measurements of HR and Respiratory Rate (RR) and could be useful for monitoring biological signals without physical limitations.[18] However, signal processing is difficult due to noise, inherent physiological variability, and artifacts. Only one small study was done in neonates and no signal processing improvement was tested in this population. Moreover, it is not usable during KMC since Ballistocardiograph signal was acquired using bed-based load cells. Capacitive sensing of electrocardiographic uses ECG leads embedded on clothes or mattress but requires wires.[19,20] In one study, lead electrodes were connected to a device using shielded wires 2.0m long.[20]

Fortunately, the past decade has seen tremendous breakthroughs in the field of biosensor technology leading to a surge in wireless skin sensors and devices.[23-26] These bio-integrated sensors have been developed and investigated in neonates, providing the prospect of enhancing monitoring capabilities, reducing iatrogenic injuries, and promoting family-centered care, thereby stirring expectations for the use of this technology in the delivery room. A new advanced wireless system was specifically developed for neonates and has the potential to be used immediately after birth as a non-invasive and non-intrusive

system (ANNEArc™ and RAD7 limb sensor SIBEL HEALTH INC, ILLINOIS, USA - Masimo). However, this new technology requires testing in delivery care facilities on a large scale and in different countries, to clearly establish its feasibility, accuracy, and safety. This large prospective study – **the AWARD study** - will use the ANNEArc and RAD7 limb sensor in low-risk infants immediately after vaginal and c-section delivery for the first 2h of age while under parents' care in the obstetrical center.

Healthcare technology continues to advance at remarkable rates, but its assessment lags significantly.[27] The cost of healthcare technology assessment is less than 0.3% of the total amount spent on healthcare, as reported by the Institute of Medicine.[28] Recently, the Neonatal Resuscitation Section Writing Group of the European Society for Paediatric Research (ESPR) published a review on "the newborn delivery room of tomorrow: emerging and future technologies".[9] An online survey reported that funding for development of DR technologies has been poor. Future monitoring of vital signs by using wireless technology was ranked as important or highly important by almost 80% of the respondents. Nevertheless, few studies have properly investigated feasibility, safety, and accuracy of new devices. For healthy near-term and term infants, it is also extremely important to assess if this new technology could help safely promote KMC after delivery, without supervision. This would fulfill a need for enhanced safety measures to prevent catastrophic events such as SUPC, and potentially save thousands of lives per year. Although SUPC is a rare cause of mortality, it deserves attention because it may be largely preventable.

This work may promote and improve monitoring of all neonates immediately after delivery and during unsupervised KMC in the obstetrical center while under parents' care by using a non-invasive, non-intrusive, portable, and low-cost wireless technology. It may also lead to testing of this technology during neonatal resuscitation and prevent deaths related to SUPC in hospitals. Due to the low-cost of implementation and training, this technology could be quickly adopted for widespread use in LMIC.

1.3 Preliminary Data

Over the last 2.5 years our group has conducted a series of studies on the use of wireless technology in preterm and term neonates under the SMART Hospital Project. We started the project by conducting a systematic review of all published literature on wearable devices in neonates[29] and children, followed by a Scoping Review on the use of wireless technology in hospitalized children.[30] After these reviews, we selected a wireless sensor developed by the Laboratory of Prof. John Rogers at Northwestern University optimized & commercialized by Sibel Health, Inc. for evaluation. The safety and accuracy of these sensors were previously investigated in a few neonates for short periods of time, however we felt that healthcare technology assessment in a variety of NICU infants for longer recording periods was necessary.[23,24] To this end, we established a Research & Development collaboration with Sibel Health, Inc. and conducted a *phase 1a* study in our NICU at the Montreal Children's Hospital to evaluate ANNE One® sensors. A hardware/software system called BioDASh was developed for this study by Ikenesia Inc. (https://www.ikinesia.com/; Montreal, Quebec, Canada) to allow simultaneous recording of vital signs from a wired (standard of care) and a wireless system in 25 infants, 8h per day during 4 consecutive days.[31] In order to ensure the research team performing was adequately prepared to perform the Phase 1a study, they participated in training on how to handle, place and remove the wireless sensors prior to the start of data collection. There were no reports or feedback by the research team of any difficulty related placement or removal of the wireless skin sensors. Heart rate, respiratory rate, oxygen saturation, and skin temperature were recorded. Full analysis of the data is underway, with some results presented and published. HR analysis of the first 10 patients enrolled was presented at the Pediatric Academic Society (PAS) meeting in Washington, DC USA (April 27-May 1 2023) showing an excellent agreement between the two systems for HR values.[32] (**Figure 2**).

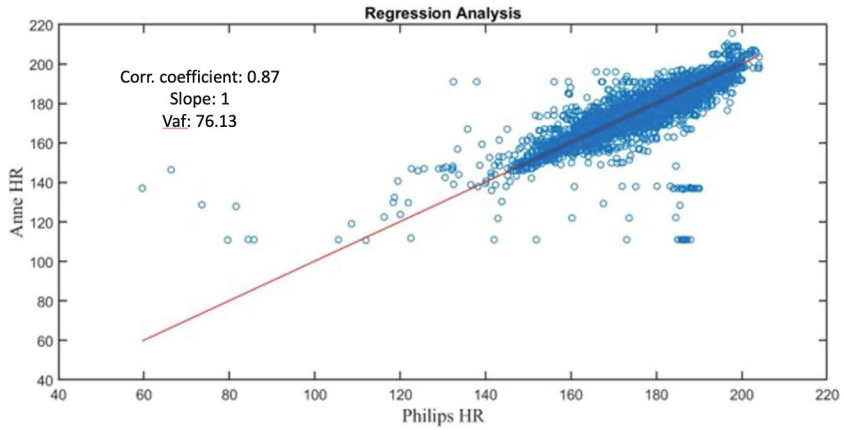

Figure 2. Regression analysis of ANNE One® and Philips HR signals for HR.

This accuracy analysis was recently completed for all 25 infants and confirmed the strong agreement between HR recorded by the wired and wireless systems with ANNE® One, showing a strong potential for wireless monitoring in the NICU[33] (**Figure 3**).

Ongoing work includes the analysis of RR, SpO_2 and T_{skin} signals to evaluate the overall feasibility, reliability, and accuracy of ANNE® One sensors.

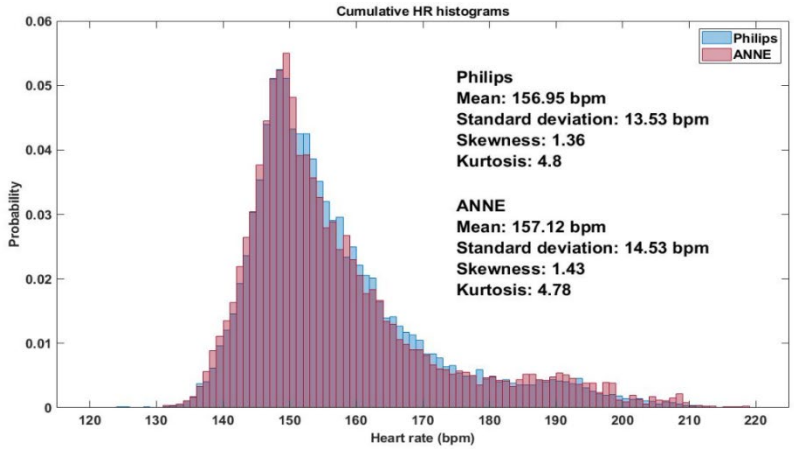

Figure 3. Cumulative histograms of HR recorded with a wired (blue) and a wireless system (red) for a typical subject

Additionally, we developed methods to synchronize and align all signals acquired from the wired and wireless monitors to allow sample-to-sample comparison. [33] (**Figure 4**).

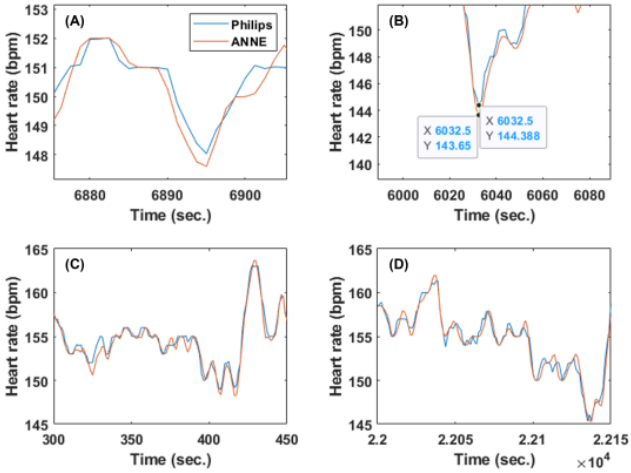

Figure 4. The sample signals following pre-processing, where: (A) the short gap was filled, (B) aligned features share a common time due to resampling, (C) the initial delay was removed, and (D) the signals remain aligned 6 hours later due to drift correction.

More recently, the feasibility of this wireless system was evaluated by correlating periods of missing data in HR with automatically generated alert signals and manually recorded annotations. (**Figure 5**). Gaps in the wireless HR signals were most often linked to Bluetooth disconnections and KMC. Current work is examining the roles of: (1) movement artifact, (2) signal to-noise ratio, as a means to understand problems and improve the feasibility of using a wireless system in the NICU. [34]

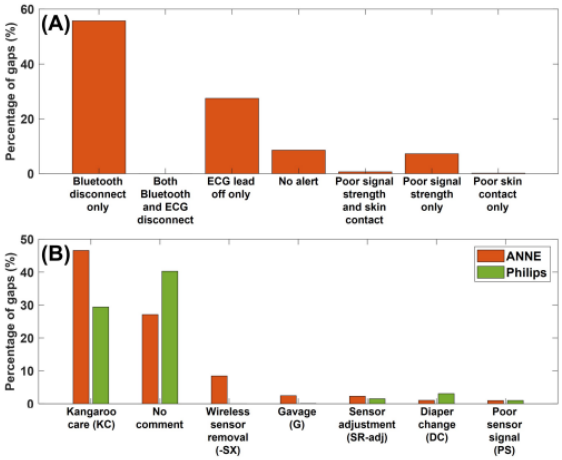

Figure 5. Group results from HR gap classification pertaining to: (A) the correlation of gaps in the wireless system with alert flags, and (B) the correlation of gaps in both the wireless and wired systems with the seven-most prominent comment codes. HR sample coverage = 86%.

Based on these results and on interviews conducted with parents and NICU nurses, Sibel made important modifications to the ANNE One® chest sensor, including its size, shape (configuration), position of the antenna, and type of skin adhesive. The new sensor called ANNE Arc® is now available, has been approved by Health Canada for research (ITA), and will be used in this Study along with the RAD7 Limb Sensor (**Figure 6, Figure 7**). Moreover, a large international survey on the use of wired and wireless technology in the NICU was circulated to HCPs all over the world. Almost 1000 HCPs have replied, and analysis is underway. Finally, in collaboration with researchers at Northwestern University, a wireless acoustic device for

monitoring airflow, breathing efforts and bowel sounds was developed and tested. Results were presented at the PAS meeting in May 2023, and the manuscript was accepted for publication in *Nature Medicine*.[35]

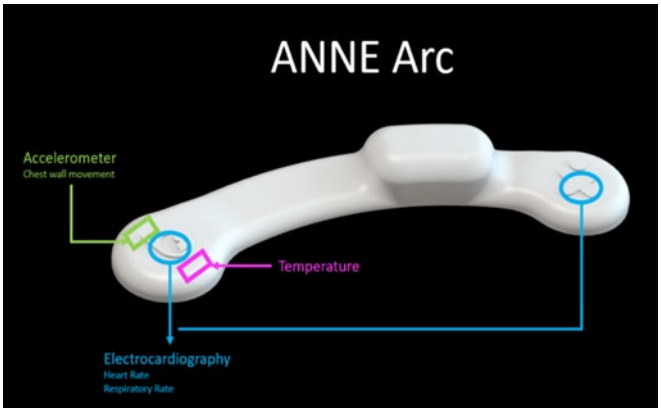

Figure 6. Amplified image of the ANNE Arc sensor. The sensor has 2 ECG leads (HR and RR), a temperature sensor (skin temperature), and an accelerometer (body movements).

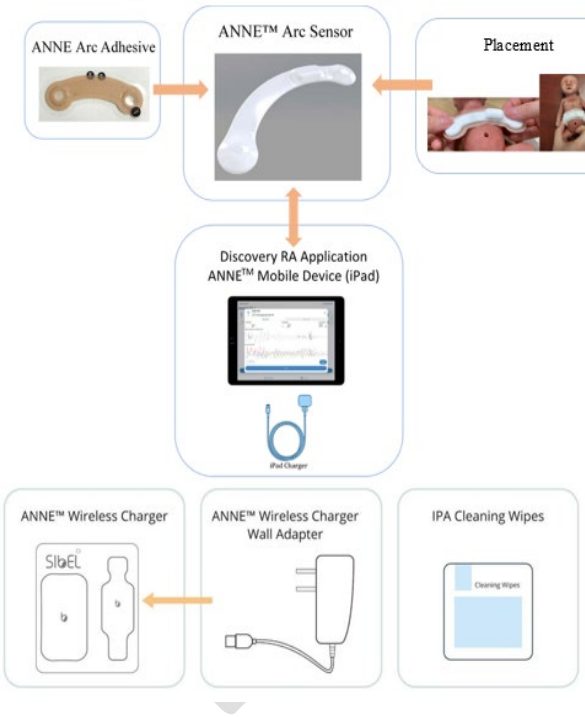

Figure 7. Overview of the ANNE Arc system showing all components, including the adhesives, correct placement on the chest, and the wireless charger.

2 Study Hypothesis, Aims and Purpose

2.1 Hypothesis

Is a new advanced and non-intrusive wireless skin sensor system feasible, safe, and accurate for monitoring infants immediately after birth and for the first 2h of age, while in the obstetrical center and under unsupervised parents' care in high, lower, and middle income countries

2.2 Aims

Healthcare technology assessment is the multidisciplinary evaluation of medical technologies with regard to **feasibility, safety, efficacy**, indications for use, cost, and cost-effectiveness. A complete assessment should explore the scientific, ethical, economic, and social reasons for adopting a technology and it may influence the quality of service and distribution of resources.

In this multicenter study, we aim to assess the first 3 important criteria.

Aim 1 – To determine the **feasibility** of using a wireless system immediately after delivery and for the first 2h of age, while in the obstetrical center under unsupervised parents' care. The following outcomes will be measured for both wired and wireless systems:

a. Percentage of time for which HR, RR, SpO_2 and T_{skin} data are displayed.
b. Occurrence of gaps in signal detection/recordings (% and length).
c. Causes of the gaps in signal detection/recordings.
d. Descriptive analysis of user surveys and their satisfaction with the wireless system.

Aim 2 - To investigate the **safety** of using this wireless system immediately after delivery and for the first 2h of age. The following outcomes will be measured for both wired and wireless systems:

a. Skin score to be determined by a blinded dermatologist using de-identified pictures of the skin after removal of the sensors of each system.
b. Pain scale to assess any discomfort or pain during the removal of the sensors.
c. Clinically significant events detected by the wired system (HR < 100 bpm or SpO2 < 80%) but missed by the wireless system.

Aim 3 – To assess the **accuracy** of this wireless system in measuring HR, RR, SpO_2 and T_{skin} signals compared with the "standard of care" wired system. The following outcomes will be computed:

a. Correlation coefficient
b. Slope
c. Variance accounted for
d. Bias

Further subgroup analyses will be conducted to assess for systematic differences in feasibility, safety, and accuracy of the wireless system between the following:

- High vs. Low and Middle income countries
- Female vs. Male subjects
- Term vs. Preterm (born < 37 weeks gestational age) infants
- C-section vs. Vaginal delivery

- Skin pigmentation

2.3 Purpose

The main objective of the AWARD Project – Clinical Study is to evaluate the use of advanced wireless sensor technology to monitor neonates after birth in low-risk infants immediately after vaginal and c-section delivery for the first 2h of age while under parents' care in the obstetrical center.

Reliable and low-cost wireless monitoring that could be used immediately after delivery would promote widespread adoption of neonatal resuscitation recommendations in LMIC, improve detection of vital signs quickly after delivery and during early unsupervised KMC, and optimize neonatal care in the obstetrical centers or during hospital stay, to prevent cases of instabilities and catastrophic events after birth, such as SUPC and its associated high mortality.

This work will promote and improve monitoring of all neonates immediately after delivery and during unsupervised KMC in the obstetrical center while under parents' care by using a non-invasive, non-intrusive, portable, and low-cost wireless technology. Potentially leading to testing of this technology during neonatal resuscitation and preventing deaths related to instabilities and catastrophic events after birth, such as SUPC in hospitals in both HIC and LMIC. Since the technology can be implemented at a low-cost as compared to standard of care wired neonatal vital signals, it can be quickly adopted for widespread use in hospitals worldwide, in particular for improving access to neonatal vital sign monitoring technology in LMIC.

3 Study Design

3.1 Study Design

Prospective International Study involving 6 centers located in 5 different countries on 3 continents. In this cohort study, all data will be collected prospectively. The focus of this study is the use of a new wireless technology for monitoring vital signs, from birth up to 2h of age, compared to data obtained from a standard-of-care wired system (**Figure 8**).

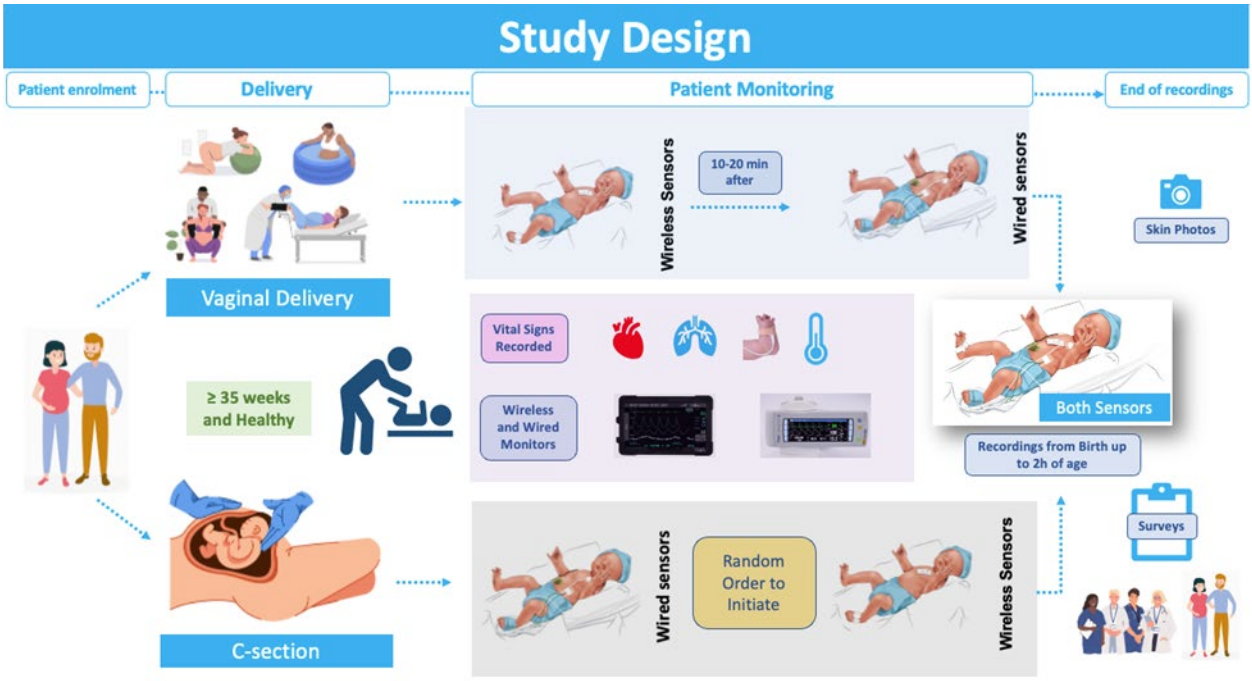

Figure 8. Study design illustration

3.2 Rationale for Study Design

The most powerful method to assess healthcare technology is the prospective, randomized controlled trial (RCT). However, RCTs are difficult to perform and expensive. Moreover, the success of RCTs requires a fundamental transformation in how they are designed, conducted, monitored, adapted, reported, and regulated, to generate the best evidence. Recently, advances in wearable technologies, data science and machine learning have begun to transform evidence-based medicine, offering a glimpse into a future of next-generation 'deep' learning medicine, which includes wearable technologies. Hence, before a RCT can be properly designed and performed, a prospective cohort study comparing 4 vital signals obtained from each patient, using wired and wireless technologies, can provide important and necessary insight on feasibility, safety, and accuracy. This will be paramount for the optimal design of a future trial.

3.3 Detailed Study Design

3.3.1 Study Sites

The AWARD Clinical Study will take place at obstetrical centers in hospitals in Canada, South America, and Africa. The McGill University Health Centre (RVH, MCH) will be the lead site (Dr Guilherme Sant'Anna, Sponsor-Investigator) the other sites are as follows:

South America

Brazil:

i. Hospital de Clínicas de Uberlândia
Department of Pediatrics, Neonatal Division, Federal University of Uberlândia
Av. Pará, 1720 - Umuarama, Minas Gerais, 38405-320, Brazil.

ii. Hospital da Mulher Jose Aristodemo Pinotti State University of Campinas –CAISM
University of Campinas – UNICAMP
R. Alexander Fleming, 101 - Cidade Universitária, Campinas - São Paulo, 13083-881, Brazil.

Argentina:

i. Hospitals Sanatorio Trinidad Palermo, San Isidro and Ramos Mejía
Department of Pediatrics and Newborn Medicine
Av. Rivadavia 13280, Ramos Mejía, Buenos Aires, Argentina.

Africa
Zimbabwe:

i. Mbuya Nehanda Hospital
University of Zimbabwe College of Health Sciences
3 Allan Wilson, Harare, Zimbabwe.

Mozambique:

i. Maputo Central Hospital
1653 Avenida Eduardo Mondlane, Maputo, Mozambique.

The study will begin at the MUHC prior to initiating at the participating sites. The participating sites will be initiated within 6 months after lead site to allow for any necessary revisions to the protocol, recruitment strategy and data collection based performing the study at the MUHC. As well as to ensure that the required research agreements, regulatory and ethics approvals are in place for each participating site.

3.3.2 Population and Eligibility Criteria

3.3.2.1 Study Population

Infants born by vaginal or C-section delivery at any of the participating sites, with ≥ 35 weeks of gestational age and judged clinically stable immediately after birth.

The number of patients expected at each site and any potential limitation is outlined on the table below:

Sites	Total Deliveries	Expected Meet Criteria	Refusal to Consent	Research team not available	Poor quality data	Potentially included for study
Royal Victoria Hospital (Lead Site)	3,300	2,805	1,042	841	280	642
UNICAMP	2,500	2,125	1,062	637	212	214
Uberlandia	2,200	1,870	935	561	187	187

Sanatorio Trinidad Palermo Hospital (3 units)	5,200	4,420	2,210	1,326	442	442
Mbuya Nehanda Hospital, Harare, Zimbabwe	11,128	9,458	4,729	2,837	945	947
Maputo Central Hospital- Mozambique	8,812	7,490	3,745	2,247	749	749
TOTAL	**33,140**	**28,168**	**13,723**	**8,449**	**2,815**	**2,823**

Infants born at ≥ 35 weeks of gestational age and judged clinically stable immediately after birth are expected to represent 85% of all deliveries. Of those, 49% are anticipated to refuse consent, 30% are anticipated to be excluded due to unavailability of the research team (night and weekend deliveries), and 10% are anticipated to be excluded due to poor quality of data recordings. This leaves 10% (n=2,823) of infants that could be eligible for the study.

3.3.2.2 Eligibility Criteria

Inclusion Criteria
Infants born by vaginal or C-Section delivery at any of the participating centers, with ≥ 35 weeks gestational age and judged clinically stable immediately after birth.*
Exclusion Criteria
Skin abnormality that precludes sensors placement.
Infants born at <35 weeks gestational age
Clinically unstable infants born at ≥ 35 weeks **

*Clinically stable immediately after birth will be defined for the purposes of this Study as neonates not requiring neonatal resuscitation as determined by the MUHC "Neonatal Resuscitation within the Birthing Centre Working Protocol" (Appendix 3)

** Clinically unstable immediately after birth will be defined for the purposes of this study any neonate requiring interventions in accordance with MUHC MUHC "Neonatal Resuscitation within the Birthing Centre Working Protocol" (Appendix 3).

3.3.3 Study Interventions

Each newborn enrolled in the Study will be monitored simultaneously by both the standard of care (control) wired vital sign monitoring system (Infinity M540 monitor, Draeger, Germany) and the wireless monitoring system (intervention) (ANNE Arc chest sensor , SIBEL Health, Illinois, USA and Limb sensor (RAD7, Masimo) (Figure 9).

Both monitoring systems, will simultaneous record heart rate, respiratory rate, oxygen saturation, and skin temperature for the first 2h of age.

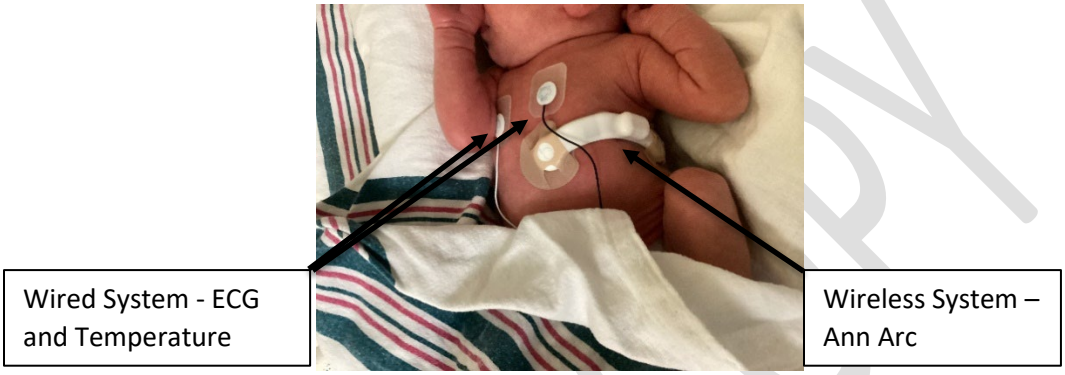

Figure 9. Monitoring systems – ECG and temperature

Figure 10. Monitoring Systems – SpO2

All materials and equipment required for the conduct of the study will be provided to the participating sites by the lead site. All research team members at all sites will be trained on the placement and removal of the wireless and wired monitoring including appropriate cleaning and disinfecting protocols. Training on the use of the BioDash system will also be provided as part of the study training at all sites.

Vital Sign Monitoring:

If a baby is born via:

1. *Vaginal Delivery*: Following normal, vaginal delivery, the wireless skin sensor monitoring system (Anne Arc & RAD7 Limb,Sibel Health Inc - Masimo) will be immediately placed on the newborn. In order to promote the standard practice of bonding between newborn and mother the standard of care wired monitoring system (Infinity Monitor, Drager) will be placed on the newborn after 10-20 min of age.

2. *C-section*: Immediately before birth, the infant will be randomized for the type of monitoring system to be applied first: a) the wireless sensors (Anne Arc & RAD7 Limb,Sibel Health Inc - Masimo) or b) standard of care wired system (Infinity Monitor, Drager). In order to promote the standard practice of bonding between newborn and mother the second monitoring system will be placed on the newborn after 10-20 min of age.

3.3.4 Data Collection

The Study research team at each site will collect standard demographic and clinical information from mothers and newborns as described in the Data Collection Form (see Appendix 1) during the 2hrs of vital sign recording (see Figure 11 below). With a stopwatch, a designated trained research team member(s) will time the recording as the period (sec.) that elapses from the application of the leads until the first display of data on the monitors, for all the sensors of both systems. Data will be continuously recorded while the mother/caregiver provides routine care. Annotations as described in the Data Collection Form will be documented by the research team regarding movements, breast-feeding attempts, cleaning/drying, patting, etc. (see Appendix 1). The vital signs data displayed on the monitors will only be visible to designated research team member(s), and all alarms will be turned off so as not to disturb parents and newborn. Any clinically relevant changes observed in vital sign parameters will be communicated by the research team member(s) to the obstetrical/neonatal team. A clinically relevant event is defined as follows: HR < 100 bpm or SpO2 <85% (after the first 10 minutes of life) with sinusoidal wave as detected on either monitoring system during the course of the 2hr continuous monitoring. If the neonate requires any intervention to reverse instability, such as oxygen therapy and ventilator support, data collection will end but the data collected up to that time point will be included. The participating baby will not be withdrawn from the study.

The following data will be collected:

- *Skin assessment:* In order to assess the safety of the wireless skin sensors, photographs of the infant's skin will be taken before device placement and after device removal. Each participating site will send de-identified digital photos coded (with the participant's study code) to the dermatologist for blinded assessment using the skin score (Neonatal Skin Condition Score - NSCS) as described in the Data Collection Form.
    - Neonatal Skin Condition Score (NSCS)[37]: Photographs of the infant's skin at the site of device placement for both the chest and limb skin sensors will be taken prior to device

placement and following device removal. These photographs will then be scored by a dermatologist using the NSCS. Scores range from 3 (intact skin condition) to 9 (very poor skin condition).

- Skin Pigment: Previous research has highlighted the challenges of some pulse oximeters in providing accurate readings for skin with darker pigmentation and as a result has emphasized the need to investigate the performance of pulse oximeters for different skin tones[38,39]. The infant's skin color will be recorded using the adapted Munsell System Soil Color Chart (2009 Revision, Munsell Color, Grand Rapids, Michigan), Hue7.5YR to investigate impact of skin pigmentation on pulse oximetry accuracy. This scale has previously been used in research on neonates[40].

- *Pain Assessment:* As well, neonatal pain will be assessed throughout the sensor removal process. The pain scale (NIPS) will be completed by the study team member at the time of sensor removal and entered into REDCAP.

  - Neonatal Infant Pain Scale (NIPS)[36] : At the time of device removal, the researcher will complete the NIPS to ensure removal of adhesive does not cause significant discomfort to the patient. The scale consists of 6 items. Scores range from 0 to 7, with scores greater than 3 indicating presence of pain. This scale has been widely validated for the assessment of acute pain in neonates. This scale will be included in the Data Collection Form.

- *Surveys:* In order to assess feasibility on the use of wireless sensors to monitor babies after birth, a survey will be conducted to get the opinions of parents and Health Care Professionals involved in the care of the baby and mother. The survey will be presented in hard copy form as well as through REDCAP.

  - Parent Survey: Parents of the participating infant will be asked to complete a short survey to after the sensors of both systems are removed. The survey will be coded with the study code assigned to the participating infant, no personal health information or personal information will be asked of the parent for the completion of the survey. (See Appendix 2).

  - Health Care Professional Survey: HCPs involved in the care of the infant and mother after birth will be asked to complete a short survey after the sensors of both systems are removed in order to assess how the HCPs felt about the wireless skin sensors as compared to their experience of the standard of care wired monitoring system. (See Appendix 2).

<u>REDCAP</u>

Clinical data, images, information as described in the Data Collection Form (Appendix 1) and Survey (Appendix 2) responses will be entered into a REDCAP database hosted at the RI-MUHC through the CORD platform. A service agreement has been entered into with CORD and the Principal Investigator for the REDCAP database set up and support for the study's data management. Each participating site will be provided access to the study REDCAP database at the RI-MUHC and be responsible for entering their site's

data into REDCAP. Participating sites will be expected to sign a site user agreement before permitting access to REDCAP. The HCP and parents will be provided a link to the survey in REDCAP or a hard copy depending on their preference and/or the preference of each participating site. The sites will be asked to send their a copy of each completed Data Collection Form and a hard copy of the survey in order to query and ensure compliance and consistency in the conduct of data collection and data entry on a monthly basis. No site will be able to access another site's individual site data and will only have access to REDCAP for their site. The de-identified study database will only be accessible to the lead site and all analysis of the study data collected in REDCAP will be done by RI-MUHC study team members. Results will be shared with the participating sites on an ongoing basis for training purposes as well as to support the drafting and submission of manuscripts, abstracts, and presentations as the study progresses.

BIODASH

The research team will use the data collection software system called Biosensors Data Aggregation and Synchronization (BioDASh) developed by the Smart Hospital Project team in collaboration with iKinesia Inc. (Montreal, CANADA) to stream, visualize, and log data all in real-time from the standard of care wired monitoring system and the wireless monitoring system into a single study laptop (Figure 10) . Data from all monitoring devices will be aggregated and synchronized for display and logged into files for eventual offline analysis. See Figure 10 below for the BioDASh high-level system architecture and components. The BioDASh application is designed not to interfere with the patient monitor and will not store any protected health information. The streamed data logged by the application will be stored locally on the study laptop until the end of the recording period when it will be uploaded to a secure DropBox™ professional account created for the study by the Principal Investigator as well as a hard drive which will be kept in a locked cabinet in a room to which only RI-MUHC study personnel will be granted access. The data from all sites captured by BioDash will be uploaded to the secure DropBox™ professional account created for the study as well as a hard drive which will be kept in a locked cabinet in a room to which only study personnel will be granted access The BioDash system as well as all the required devices will be provide to all participating sites by the Principal Investigator. All participating site study personnel will receiving training on proper

placement of the sensors and wires, all data capturing systems and proper study conduct by the Principal Investigator and designated lead site study personnel.

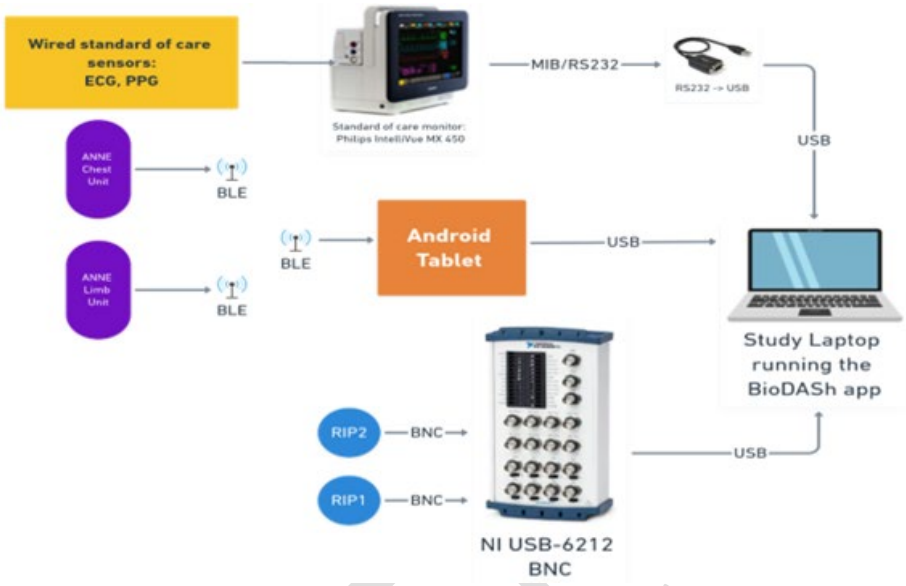

Figure 11. BioDASh system architecture and components

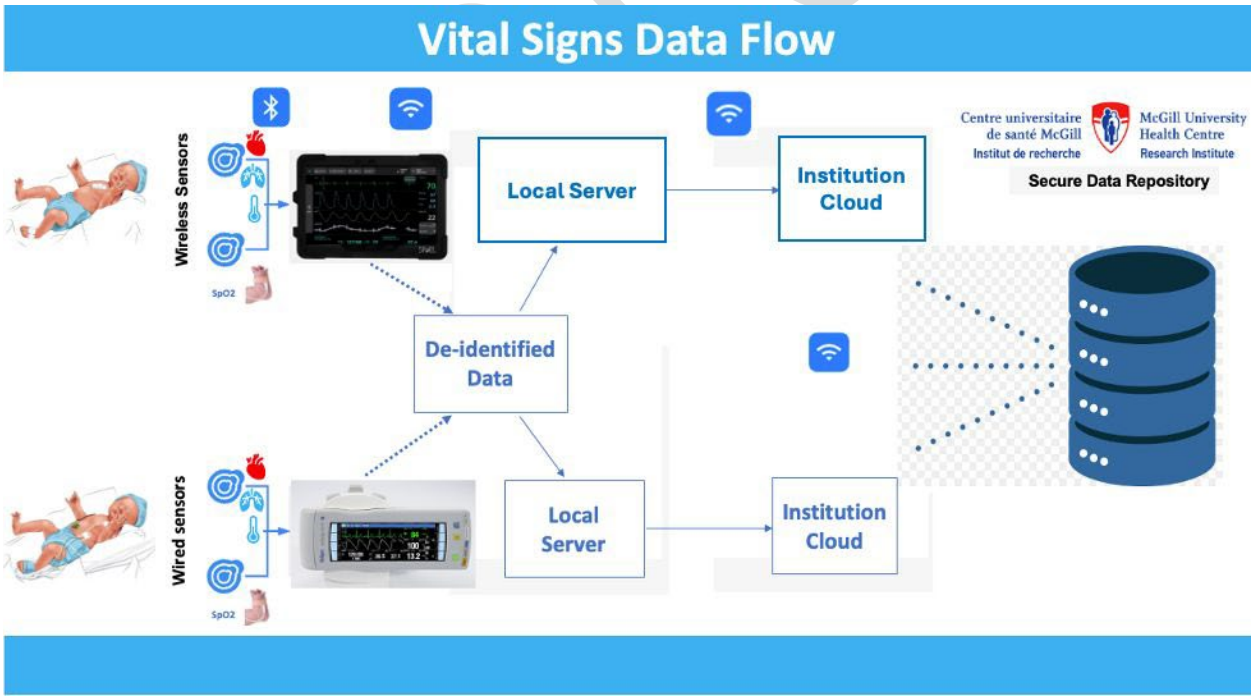

Figure 12. Data obtained from each monitoring system will be de-identified and on a secure local server and then to a cloud before it is downloaded onto a secure data repository at the RI-MUCH for investigators' assessment.

3.3.5 Confidentiality and Protection of Personal Health Information

Participant's personal health information and medical information collected for the purposes of this study will be de-identified or anonymized. Participants will be identified with a unique participant Study code to ensure confidentiality. The key to the unique participant Study code will be kept in a secure file under the supervision of the Principal Investigator (hard copy) and password protected under the Principal Investigator control (electronic copy). All de-identified signal recording data, including annotations, recorded via the BioDash application will be transferred to the secure Dropbox ™ professional account. Each member of the research team will be granted access to the Drobox through their own account with individually assigned login and passwords. Additionally, this data will be uploaded to a hard drive which will be kept in a locked office cabinet to which only members of the research team will have access to.

Information collected via the paper data collection form and paper survey will be transcribed and uploaded to both the secure Dropbox™ professional account as well as Research Electronic Data Capture (RedCap) system. Skin photographs will be edited to remove identifying information (eyes, face, identifying medical tags) and then uploaded to both the secure Dropbox and RedCap data storing systems.

Each participating site will only provide de-identified data in the same manner as described in the protocol and approved by their local regulatory authorities and institutions. Any local requirements will be addressed within the individual site protocols, consents and site agreements. All applicable laws, regulations and guidelines related to data collection, storage, confidentiality, transfer and use will be adhered to as required.

As part of the Smart Hospital Project, this Study and potential future research studies to improve the quality, accuracy and efficiency of monitoring neonates admitted in the NICU, the participants' information may be shared with academic or commercial third parties and used by the research team in other related research studies. Any use of the RI-MUHC and participating site's data in future research studies will be approved by competent research ethics boards and no data that could identify the participant will be shared. Participants at all participating sites will be asked to consent to the sharing of their data collected during this study as well as for use in future research in the field of neonatal care and monitoring. The participants' data will be kept confidential to the extent required by applicable laws. The research agreements with the participating sites will include all the terms and conditions required for the use and sharing of the data from participating sites.

4 Statistical Analysis and Rationale

Sample size: The proposed sample size is 100 newborns/site (n=600) to be recruited over 2 years from start of the Study at each site.

The expected mean and standard deviation are required for estimating the mean effects which is used to determine the absolute precision. In our first study with wireless sensors (see preliminary data) or *phase 1a*, 100 patient recordings (25 infants x 4 days) were expected but only 96 were obtained, resulting in a 4% drop-out rate. Further, the average coverage across wired HR signals was 98.7±2.2%, while that of wireless signals was 85.3±14.3%. Assuming a two-sided significance of 0.05, a study power of 0.9, and accounting for the drop-out rate of 0.04 in all calculations, we can expect an effect size of 2.7% in HR coverage, with the selected sample size of 600 infants. In the case of SpO_2 monitoring, the average coverage was 93.9±6.3% in the wired system and 66.5±20.8% in the wireless. In our proposed study, we

can thus expect a difference of 3.46% in SpO_2 coverage. For the statistical measures used to assess the agreement between the wired and wireless vital signals, the average findings from *phase 1a* are reported in the Table. Using the same parameters listed previously, the margin of error expected for each statistical measure in the proposed study can be found.

Statistical measure		Correlation coefficient, *C*	Proportionality constant, *k*	Variance accounted for (VAF)	Mean difference (bias), $\underline{d}$
Average result in *phase 1a*	Heart rate (HR)	0.96 ± 0.03	1.00 ± 0.00	91.5 ± 6.5%	0.04 ± 0.32 bpm
	Oxygen saturation (SpO_2)	0.53 ± 0.23	1.01 ± 0.01	18.9 ± 20.8%	1.43 ± 1.4%
Expected margin of error	Heart rate (HR)	0.01	0.00	1.24%	0.06 bpm
	Oxygen saturation (SpO_2)	0.04	0.00	3.97%	0.26%

Statistical analytical approach: Descriptive analyses will first be applied to the demographic data. Accuracy analysis of the wireless system to capture the vital signs will be done by using a statistical measure of the strength of a linear relationship between the two systems (correlation coefficient), a measurement of the steepness of this correlation (slope), the ratio of explained and target variance (variance accounted for), and a Bland-Altman plot analysis to evaluate *bias* between the mean differences and estimate an agreement interval.

Each participating site has the facilities and capacity to provide the estimated number of infants to establish feasibility, safety, and accuracy of the device. The wireless device sensors and system being used in the study is approved by Health Canada for research on neonates. Each site will obtain approval from their local and country specific health authorities, as required.

5 Ethical, Legal and Regulatory Considerations

5.1 Recruitment plan and consent of participants

At each participating site, the local research team will meet with the obstetrical team to identify potential candidates for participation in the study. Following that, eligible patients will be approached early in their labor stage to assess willingness to participate. If consent is obtained, the research team members will follow the course of the delivery. At the time of birth, infants will only be included if ≥ 35 weeks of gestational age and clinically stable as determined by the attending pediatrician. Written consent will be obtained from parents prior to enrollment. The study protocol has been designed respecting the special moment around birth. Hence, parents will be approached and receive explanation about the study design before delivery and given ample time to make an informed decision. Families will be able to withdraw from the Study at any time. However, any data collected up to date of withdrawal will not be destroyed in order to maintain the integrity of the study design. No further data will be collected once a participant is withdrawn from the Study.

As the study is not a randomized clinical trial a Data Safety and Monitoring Committee (DSMC) will not be established. However, interim evaluations for safety will be done by the lead site after 200 and 400 patients have been studied to review data related to safety, including skin lesion, pain scores, and HCPs survey responses. Any adverse event or evidence of discomfort during monitoring, including placement and removal of sensors (expected to be negligible) will be recorded and reported to the local investigator and the Principal Investigator at the lead site.

Recruitment material in the form of posters and brochures will be provided to all the sites explaining the Study and how to get additional information if interested.

5.2 Regulatory and Legal Considerations

The Sponsor-Investigator Dr. Guilherme Sant'Anna will lead this multicenter prospective study at the lead site with co- investigators Dr. Wissam Shalish and Robert Kearney PhD. As Principal Investigator/Sponsor-Investigator Dr Sant'Anna's responsibilities include all aspects of study design, education and training on the study, study conduct, data analysis, student supervision, and preparation of the data for presentation and publication, regulatory oversight and overall responsibility for the conduct of the study at all participating sites. The lead site Principal Investigator is responsible for ensuring the study is conducted according to professional standards relating to the proper conduct of research such as ICH-Good Clinical Practice guidelines and Health Canada regulations and ISO guidelines for Class II device studies. The lead site Study personnel will provide support with regulatory and research ethics board approvals at the participating sites, as well as comprehensive training on the protocol, monitoring systems, data collection and data management.

The participating Site Investigator(s) will be responsible for ensuring the proper conduct of the study at their center, accurate data collection and management, and timely transfer of data to the lead site. They will also present the study to their faculty, their NICU personnel, their Obstetric division personnel, and help facilitate communication between sites.

With the support and expertise of the RI-MUHC Capture and Optimization of Research Data (CORD) Unit, data collection, management, and a REDCap study database will be set up at the RI-MUHC. Input from the participating sites will ensure a comprehensive, secure, and user-friendly data capture and analysis strategy is implemented for all study sites. The CORD platform and the Principal Investigator entered into a service agreement for the cost of the CORD services and support.

Prior to initiating the Study at participating sites, the RI-MUHC and Principal Investigator will enter into inter-institutional research collaboration agreements with each participating site. These site agreements will establish the responsibilities of both the lead site and the participating sites. The agreement will include the budget for each participating site and collaboration terms. The agreements will ensure data shared with the lead site is in accordance with applicable legal frameworks for the security, privacy, and confidentiality of the health information of the study participants. These agreements will also ensure that the participating sites comply with all regulatory guidelines, standard operating procedures, and the requirements of their particular countries and institutions, including obtaining REB and local regulatory approvals before initiating the study at their respective institutions.

The protocol will be made publicly available at **clinicaltrials.gov** before initiation of the study at the lead site. Informed consents have been prepared by the lead site Study team and will be shared with the participating sites and translated to their respective languages.

Principal Investigator as Sponsor will retain all source documents and study related documents for 15 years as required by Health Canada. Sponsor will maintain the right to monitor and audit participating sites as required by ICH-GCP including access to all study related essential documents including source documents.

6 Publication Policy

It is expected that this research study will result in one or more multi-center publications. The Principal Investigator retains the right to publish the results independently and at his discretion. No site can publish any publication, including but not limited to a publication in the form of a presentation, abstract, protocol, poster or manuscript without the consent of the Principal Investigator. However, once the study is complete and the first multicenter manuscript is published sites may publish results of their site study data independently. All publications and presentations by any site must be sent to the Principal Investigator, who maintains the ability to comment and request confidential information to be removed, prior to submitting for publication. All site publications must acknowledge the Smart Hospital Project, authorship will be according to ICMJE guidelines and all publications will acknowledge the funding support as follows:

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APPENDIX 1

The AWARD Project - Data Collection Form

Date of the study (YYYY-MM-DD):

Start time (HH:MM):

End time (HH:MM):

1. PATIENT INFORMATION

Patient ID (code)*	Sex	Type of delivery	Gestational age (at birth)	Time of birth (HH:MM)	Birth weight (grams)	APGAR score (1, 5 and 10')	Munsell Scale Score
R-_____	☐ M ☐ F	☐ Vaginal ☐ C-section	__weeks __days				

2. PAIN ASSESSMENT

Score:

Facial Expression	
0 – Relaxed muscles	Restful face, neutral expression
1 – Grimace	Tight facial muscles, furrowed brow, chin, jaw, (negative facial expression – nose, mouth, brow)
Cry	
0 – No cry	Quiet, not crying
1 - Whimper	Mild moaning, intermittent
2 – Vigorous Cry	Loud scream; rising, shrill, continuous (Note: silent cry may be scored if baby is intubated as evidenced by obvious mouth and facial movement.)
Breathing Patterns	
0 – Relaxed	Usual pattern for this infant
1 – Change in Breathing	Indrawing, irregular, faster than usual, gagging, breath holding
Arms	
0 – Relaxed/Restrained	No muscular rigidity, occasional random movements of arms
1 – Flexed/Extended	Tense, straight legs; rigid and/or rapid extension/flexion
Legs	
0 – Relaxed/Restrained	No muscular rigidity, occasional random movements of legs
1 – Flexed/Extended	Tense, straight legs; rigid and/or rapid extension/flexion

State of Arousal	
0 – Sleeping/Awake	Quiet, peaceful, sleeping, or alert random leg movement
1 – Fussy	Alert, restless, thrashing
TOTAL	

*__R__=Royal Victoria Hospital; **U** = UNICAMP; B = Uberlandia; **S** = Sanatorio Trinidad Palermo Hospital; **M** = Mbuya Nehanda Hospital (Harare, Zimbabwe); **N** = Neocare Baby Hospital (Harare, Zimbabwe); **C** = Maputo Central Hospital (Mozambique); **T** = Hospital Sanatorio Trinidad Palermo; **V** = Hospital Ramos Mejía; **H** = Hospital of Newborn Medicine (Buenos Aires, Argentina)

3. MONITORING INFORMATION

Order of monitoring (w = wired, s = wireless) ; i.e. 1w,2s	
Placement of **limb wired sensor**, if applicable (RA = right arm, LA = left arm, RL = right leg, LL = left leg)	
Placement of **vital signs wired sensors**, if applicable (C = chest, B = back)	
Number of wired leads	
Placement of **limb wireless sensor**, if applicable (RA = right arm, LA = left arm, RL = right leg, LL = left leg)	
Placement of **vital signs wireless sensors**, if applicable (C = chest, B = back)	
Operator/nurse responsible for placement of monitors	

4. VITAL SIGNS MONITORING LOG

		0 (Baseline)	15	30	45	60	75	90	105	120
Time										
Heart rate (bpm)	**Wired**									
	Wireless									
Respiratory rate	**Wired**									
	Wireless									

(breaths per minute)										
Oxygen saturation (SpO2)	**Wired**									
	Wireless									
Axillary temperature (˚C)										
Newborn Location (k = kangaroo care, c = in bed, ma = mother arms, fa = father arms, o = other, specify)										
Newborn Position (s = supine, p = prone, side line =sl, o = other, specify)										

5. COMMENTS LOG

Comments	0 (Baseline)	1	2	3	4	5	6	7	8
Time **wired** Monitor									
Time **wireless** Monitor									
Location of newborn (k = kangaroo care, b = in bed)									
Time (clock)									
Position of newborn (s = supine, p = prone, side line =sl)									
Time (clock)									

Muscle tone (normal = n, hypotonic = hypo, hypertonic = hyper)									
Time (clock)									
Quality of reading (N/A = no issue, A = presence of artifact, P = poor signal capture)									
Time (clock)									
Interventions performed during recording (N/intervention)									
Time (clock)									
Sensor disconnection (N/reason*)									

6. COMMENTS LOG – CODE WORDS (for redcap)

Event	Drop-Down Code	Details
Kangaroo Care = KC	KC start	Start of kangaroo care
	KC end	End of kangaroo care
Nursing Care = NC	NC check	Quick nurse check (may open incubator, no real manipulation of infant)
	NC start	Routine care, that is longer than quick check, includes diaper change, feeding, etc)
	NC end	End of routine care procedures
Parent Care = PC	PC start	Holding baby, changing diaper, umbilicus care, bath time
	PC end	End of parent care procedures
Breastfeeding = BF	BF start	Start of breastfeeding
	BF end	End of breastfeeding
Repositioning = R	R supine	Baby repositioned to supine
	R prone	Baby repositioned to prone
	R Side	Baby repositioned to side
	E end	Exam end

xEvent Other	EO *[specify]*	Other relevant event not accounted for by annotations list please specify
Sensors (both) = S	SR start	Sensors removed for
	SR end	Sensors placed back
Chest Sensor = C	CR start	Chest sensor removed for exam
	CR end	Exam over chest sensor placed back on
	CA	Chest sensor readjustment
Limb Sensor = L	LR start	Limb sensor removed
	LR end	Limb sensor back on
	LA	Limb sensor readjustment
	LX	Limb sensor falling off [ES1]
	LH right	Limb location change – now on right hand
	LH left	Limb location change – now on left hand
	LF right	Limb location change – now on right foot
	LF left	Limb location change – now on left foot
Drager Electrodes = E	ER start	Electrodes removed
	ER end	Electrodes back on
	EA	Electrodes readjusted/moved
Massimo Oximeter = O	OR start	Oximeter removed
	OR end	Oximeter back on
	OA	Oximeter readjusted
	OH	Oximeter moved to hand
	OF	Oximeter moved to foot
Temperature and Humidity	T ( ) H ( )	Temperature and humidity recording

7. ADDITIONAL OBSTETRICAL INFORMATION

Maternal age	
Gesta / Para / Abortion (G/P/A)	
Medications during pregnancy	
Medications during delivery	
Pre-eclampsia	
Diabetes	
Infection	
Use of forceps during delivery (Y/N)	
Use of vacuum extraction (Y/N)	

8. ADVERSE EVENTS RELATED TO MONITORING

WIRED SENSORS	
☐ None ☐ Skin irritation: ( ) Chest or ( ) Limb ☐ Skin erosions: ( ) Chest or ( ) Limb ☐ Skin bleeding: ( ) Chest or ( ) Limb	
Skin photos: ☐ Chest ☐ Limb	Neonatal Skin Condition Score (NSCS)* Chest: Limb:
WIRELESS SENSORS	
☐ None ☐ Skin irritation: ( ) Chest or ( ) Limb ☐ Skin erosions: ( ) Chest or ( ) Limb ☐ Skin bleeding: ( ) Chest or ( ) Limb	
Skin photos: ☐ Chest ☐ Limb	Neonatal Skin Condition Score (NSCS)* Chest: Limb:

Treatment required: ☐ Yes: ( ) No

Chest Neonatal Skin Condition Score (NSCS)* will be done by a blinded dermatologist at the end of the AWARD project.

Signature of data collector: _____ Date (YYYMMDD):_____

Appendix

(photos)

APPENDIX 2

PARENT SURVEY

Subject ID:

( ) Mother ( ) Father ( ) Other: _____

Section 1: Your experience with the Wired Monitoring

1. How satisfied are you with the system?
    a. Very dissatisfied
    b. Dissatisfied
    c. Neutral
    d. Satisfied
    e. Very satisfied

1. What are your concerns? (Mark all that apply - multiple choices are permitted)
    a. Problems with the stickers on my baby's skin
    b. Too many stickers on my baby's skin
    c. Too many wires around my baby
    d. Difficult to touch my baby because of the stickers and wires
    e. The stickers, wires and monitors are concerning
    f. No concerns
    g. Other (please specify):

1. The monitors and wires interfere with my ability to do skin-to-skin (Kangaroo) care:
    a. Strongly disagree
    b. Disagree
    c. Neutral
    d. Agree
    e. Strongly agree

1. What kind of problems have you seen with the use of the wired monitoring system? (Mark all that apply - multiple choices allowed)
    a. Skin lesions associated with chest adhesives
    b. Skin lesions associated with the limb probe
    c. Pressure sore associated with chest adhesives
    d. Pressure associated with the limb probe
    e. Fear of handling my baby because of the multiple wires and cables
    f. Wires tangled around the baby chest or limbs
    g. Wires soiled – requiring replacement or cleaning
    h. Cables soiled – requiring replacement or cleaning
    i. Installation time
    j. Wires disconnected
    k. Cables disconnected

l. Other:

1. The adhesives, sensors, wires, and monitors, can prevent me from bonding with my baby:
    a. Strongly disagree
    b. Disagree
    c. Neutral
    d. Agree
    e. Strongly agree

Section 2: Your experience with the Wireless Monitoring

1. What is your opinion about the use of a new wireless technology to monitor your baby's vital signs?

Chest sensor

a. Strongly oppose
b. Somewhat oppose
c. Neutral
d. Somewhat favor
e. Somewhat favor
f. Strongly favor

Limb sensor

a. Strongly oppose
b. Somewhat oppose
a. Neutral
c. Somewhat favor
d. Somewhat favor
e. Strongly favor

1. I am worried about the safety and the accuracy of the new wireless technology.

Chest sensor

a. Strongly disagree
b. Disagree
c. Neutral
d. Agree
e. Strongly agree

Limb sensor

a. Strongly disagree

b. Disagree
a. Neutral
c. Agree
d. Strongly agree

1. What are your main concerns with the implementation of a new wireless technology in the Delivery Room? (Mark any that apply - multiple choices permitted)

Chest Sensor

a. Accuracy (good and reliable data)
b. Challenges using sensors
c. Safety of stickers used to apply sensors
d. Size of the sensors
e. Weight of the sensor
f. Battery life of wireless sensors
g. No concerns
h. Other (please specify):

Limb Sensor

a. Accuracy (good and reliable data)
b. Challenges using sensors
c. Safety of stickers used to apply sensors
d. Size of the sensors
e. Weight of the sensor
f. Battery life of wireless sensors
g. No concerns
h. Other (please specify):

1. What do you think might be the impact of a wireless system on bonding between parents and their babies?
   a. Strongly negative
   b. Negative
   c. Neutral
   d. Positive
   e. Strongly positive

1. What do you think might be the impact of a wireless system on your baby's hospital experience? (Mark any that apply - multiple choices permitted)
   a. Easier Kangaroo care (KC) initiation
   b. Increase the amount of time on KC
   c. Reduce discomfort

d. Decrease pain
e. Better sleep
f. Newborn safety
g. None
h. Other (please specify):

1. Any additional comment (s):

HEALTH CARE PROFESSIONAL'S SURVEY

Subject ID:

( ) Neonatologist ( ) Neonatal Fellow ( ) Pediatric Resident

( ) Registered Nurse ( ) Neonatal Nurse Practitioner

( ) Respiratory Therapist

( ) Other: _____

Years of experience: ( ) < 2 years ( ) 2-5 years ( ) 6-10 years ( ) > 10 years

Section 1: Current State of Monitoring with Wires and Cables

1.How satisfied are you with the use of monitoring system with wires and cables immediately after birth and up to 2h of age in the DR?

a. Very dissatisfied
b. Dissatisfied
c. Neutral
d. Satisfied
e. Very satisfied

2. What are your main concerns with the monitoring system with wires and cables? (Mark any that apply - multiple choices permitted)
    a. Inaccurate readings
    b. False alarms
    c. Issues associated with adhesion of the sensors (heat generation or pressure and skin irritation)
    d. Too many sensors applied to the skin
    e. Too many wires around the baby
    f. Difficult to handle the baby because of the multiple wires and cables
    g. The sensors, wires and cables are intimidating to the parents
    h. I do not have concerns
    i. Others (please specify):

3. What are the main benefits of using a wired and cable monitoring system immediately after birth and up to 2h of age in the DR? (Mark any that apply - multiple choices allowed)
    a. Easy to use
    b. Various functions in this system were well integrated
    c. Quickly to learn how to use
    d. Fast speed of data display
    e. There are no benefits

f. Others (please specify):

4. How confident are you with the use of monitoring system with wires and cables immediately after birth and up to 2h of age in the DR?
    f. Not confident
    g. Somewhat not confident
    h. Neutral
    i. Somewhat Confident
    j. Confident

5. What kind of problems did you see by using the current standard monitoring system in healthy babies immediately after birth and up to 2h of age in the DR? (Mark any that apply - multiple choices permitted)
    a. Skin lesions associated with ECG adhesives
    b. Skin lesions associated with the oxygen saturation sensor
    c. Pressure sores associated with ECG adhesives
    d. Pressure sores associated with the oximeter sensors
    e. Parents afraid to handle their baby because of the multiple wires and cables
    f. Wires tangled around the baby's chest or limbs
    g. Wires soiled – requiring replacement or cleaning
    h. Cables soiled – requiring replacement or cleaning
    i. Wires disconnected
    j. Cables disconnected
    k. Other:

6. List any other perceived benefits and disadvantages of the system:

Section 2: Wireless Monitoring System in the Delivery Room

7. What is your attitude towards the use of this new wireless chest sensor technology in the Delivery Room?
    a. Very skeptical
    b. Skeptical
    c. Neutral
    d. Optimistic
    e. Very optimistic

8. What is your attitude towards the use of this new wireless limb sensor technology in the Delivery Room?
    a. Very skeptical
    b. Skeptical
    c. Neutral
    d. Optimistic
    e. Very optimistic

9. What is your level of concern regarding the safety and accuracy of using this new wireless chest sensor technology, immediately after birth and up to 2h of age in the DR?
    a. Very concerned
    b. Somewhat concerned
    c. Neutral
    d. Somewhat concerned
    e. Not concerned at all

10. What is your level of concern regarding the safety and accuracy of using this new wireless limb sensor technology, immediately after birth and up to 2h of age in the DR?
    a. Very concerned
    b. Somewhat concerned
    c. Neutral
    d. Somewhat concerned
    e. Not concerned at all

11. What are your main concerns, if any, with the implementation of this new wireless technology in the Delivery room, regarding the chest sensor? (Mark any that apply - multiple choices permitted)
    a. Accuracy (good and reliable data)
    b. Challenges related to “user-friendliness” of technology
    c. Safety
    d. Size of the sensors
    e. Weight of the sensor

f. Battery life
g. Radio frequency radiation
h. Other (please specify):

12. What are your main concerns, if any, with the implementation of new wireless technology in the Delivery room, regarding the limb sensor? (Mark any that apply - multiple choices permitted)
    a. Accuracy (good and reliable data)
    b. Speed of data display
    c. Challenges related to “user-friendliness” of technology
    d. Safety
    e. Size of the sensors
    f. Weight of the sensor
    g. Battery life
    h. Radio frequency radiation
    i. Other (please specify):

13. What do you think it might be the impact of a using a wireless system immediately after birth and up to 2h of age in the DR, on some outcomes?
    a. Improve kangaroo care (KC) experience
    b. Increase the amount of time on KC
    c. Reduce discomfort
    d. Decrease pain
    e. Better sleep
    f. Newborn safety
    g. None
    h. Other (please specify):

14. Any additional comment (s)?:

APPENDIX 3

Neonatal Skin Condition Score (NSCS)

Dryness	**Score**
1 = Normal, no sign of dry skin.	
2 = Dry skin, visible scaling.	
3 = Very dry skin, cracking/ fissures.	
Erythema	
1 = No evidence of erythema.	
2 = visible erythema, <50% body surface.	
3 = Visible erythema, > 50% body surface.	
Break down/Excoriation	
1 = None evident.	
2 = Small, localized areas.	
3 = Extensive	
TOTAL SCORE	

Directions for Use:

- To identify a Neonatal Skin Condition Score (NSCS), choose the description that best fits the neonate's skin related to dryness, erythema, and break down / excoriation and assign the number most appropriate per description.
- Each section is given a score from 1 to 3.
- The "perfect" score using the NSCS is 3; the worst score is 9.

APPENDIX 4

Neonatal Infant Pain Scale(NIPS)

The NIPS (Lawrence et al., 1993)

Pain Assessment Tools
Neonatal/Infant Pain Scale (NIPS)
(Recommended for children less than 1 year old) - A score greater than 3 indicates pain

Pain Assessment		Score
Facial Expression		
0 – Relaxed muscles	Restful face, neutral expression	
1 – Grimace	Tight facial muscles; furrowed brow, chin, jaw, (negative facial expression – nose, mouth and brow)	
Cry		
0 – No Cry	Quiet, not crying	
1 – Whimper	Mild moaning, intermittent	
2 – Vigorous Cry	Loud scream; rising, shrill, continuous (Note: Silent cry may be scored if baby is intubated as evidenced by obvious mouth and facial movement.	
Breathing Patterns		
0 – Relaxed	Usual pattern for this infant	
1 – Change in Breathing	Indrawing, irregular, faster than usual; gagging; breath holding	
Arms		
0 – Relaxed/Restrained	No muscular rigidity; occasional random movements of arms	
1 – Flexed/Extended	Tense, straight legs; rigid and/or rapid extension, flexion	
Legs		
0 – Relaxed/Restrained	No muscular rigidity; occasional random leg movement	
1 – Flexed/Extended	Tense, straight legs; rigid and/or rapid extension, flexion	
State of Arousal		
0 – Sleeping/Awake	Quiet, peaceful sleeping or alert random leg movement	
1 – Fussy	Alert, restless, and thrashing	

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APPENDIX 5

Neonatal Resuscitation within the Birthing Centre

Working Protocol

Identification of cases or situations when to call 'NICU'

The goal is to anticipate any identifiable situation that may require neonatal resuscitation team presence prior to the delivery of the newborn in a timely fashion.

The neonatal resuscitation team is composed of neonatologist, respiratory therapist, NICU resuscitation nurse and NICU on call personnel (nurse practitioner, NICU pediatric resident, fellow or clinical assistant) and their spectralink numbers are listed as follows:

Neonatologist- 25643

NICU on call personnel- 25645

Respiratory therapist- 25646

NICU Resuscitation nurse- 25647

*NICU fellow may be called at 25644 depending on the availability.

Role within the Birthing Centre

One professional within the birthing center needs to be assigned to each baby to be born. This person needs to be able to initiate resuscitation as per NRP guidelines.

If a situation is identified prior to labor, during labor and delivery or after birth that will require the presence of resuscitation team, the nurse taking care of the mother should call the NICU team member at " 25645. The nurse should be able to pass on the information regarding the situation, background information on the pregnancy and the presence of any complication, mode of delivery, level of urgency along with anticipated level of priority to the NICU covering person. Based on the priority level, the NICU person will mobilize the rest of resuscitation team members (i.e. RT, Resuscitation nurse or neonatal attending). Please see below the priority level, required neonatal staff and indications. In the event an emergency situation arises that will require emergent resuscitation of the newborn, the OB team members should press the "code pink button" in the labor room. The code pink button is linked to the spectralink numbers of the resuscitation team members.

"Code Pink"- may be called when a fetus or a neonate has a **perceived potential** or **documented need** for resuscitation. This may include, but is not limited to apnea or bradycardia unresponsive to stimulation, ineffective respiration or gasping with or without bradycardia, cyanosis, cardiac arrest or delivery of a neonate not making

appropriate transition and needing urgent intervention and supportive care. Unexpected delivery of a newborn outside the birthing center – warrants a code pink.

Level of Priority and Required Neonatal Staff

Priority 1: Pediatric resident/ NNP/ clinical assistant or fellow on call, NICU resuscitation nurse, neonatal RT, and neonatologist on call

Priority 2: Pediatric resident/NNP/clinical assistant or fellow on call, NICU resuscitation nurse and neonatal RT

"Code Pink" – Pediatric resident/ NNP/ clinical assistant or fellow on Call, NICU resuscitation nurse, RT and neonatologist

ISBAR Communication Tool for Calling

Neonatal Resuscitation Team

NEONATAL RESUSCITATION

Identification	Identify yourself
Situation	✓ Why is neonatology being called? ✓ Briefly state the problem, what it is, when it started, and how severe
Background	✓ Gestational age ✓ Prenatal complications, presence or absence of ✓ Major anomalies ✓ Labor complications, fetal heart rate category ✓ Membranes: Intact, ruptured Fluid: clear, cloudy, meconium
Assessment	✓ Level of risk to the baby ✓ Plan for delivery: Vaginal or C-section, level of urgency
Recommendation	✓ Categorize level of priority level anticipated, inform the neonatal resuscitation team ✓ Specify the location of delivery

Indications for NICU Presence at Delivery		
Code Pink **(press code pink button)** **Neonatologist : 25643** **NICU on call: 25645** **RT: 25646** **Res Nurse:25647** **Fellow: 25644***	NICU resident/NNP/clinical assistant or fellow on call NICU ressuscitation nurse Neonatal RT Neonatologist *Denotes presence on availability	• A fetus or neonate has a perceived potential or documented need for emergent resuscitation. • Unanticipated delivery in the antepartum unit on D-6 or outside birthing center
Priority 1 **Call NICU on Call first at 25645**	NICU resident/NNP/clinical assistant or fellow on call NICU resuscitation nurse Neonatal RT Neonatologist	• Preterm delivery < 32 weeks • Delivery of any newborn expected to require full resuscitation (vasa previa, cord prolapse, placental abruption, uterine rupture, fetal anemia) • The presence of fetal malformation with the potential of needing neonatal resuscitation (heart, lung, abdominal, cranio-facial or any other potentially impairing breathing) • Hydrops • Delivery of a fetus of questionable viability

Priority 2 **Call NICU on Call first at 25645**	NICU resident/NNP/clinical assistant or fellow on call NICU ressuscitation nurse Neonatal RT ± Neonatologist	• • Preterm delivery; GA 32-35 weeks • Stat, **Priority 1** C-section • Severe oligohydraminos or polyhydraminos • Newborn unexpectedly receiving positive pressure ventilation (hypotonic with decreased respiratory effort-) • Multiple birth < 35 weeks GA • Oligohydramnios and the presence of other anomalies • Non reassuring fetal heart tracing - severe decelerations • Multiple birth > 35 weeks • Chorioamnionitis (maternal fever >38.0˚C with two of the following findings: fetal tachycardia, maternal tachycardia, foul smelling discharge, uterine tenderness, leukocytosis WBC >15 000) • Shoulder dystocia • Meconium staining of amniotic fluid • Respiratory distress (abnormal breathing) at birth • General anesthesia • Maternal BMI > 40 • Any other issue at the discretion of the LDR nurses/OB Physician/Anesthesiologist • Baby more than 35 weeks of gestation but less than 2300 grams • Unexpected finding that does not require resuscitation • Instrumental delivery/vaginal breech delivery • Maternal narcotic administration within 2 hours of delivery

APPENDIX 6 -Munsell Scale