

Near-Infrared Spectroscopy Monitoring in the Neonatal Intensive Care Unit: Changing provider
comfort and confidence

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Abstract

Purpose: The purpose of this quality improvement (QI) project was to assess provider (MD and Neonatal Nurse Practitioners (NNP)) comfort and confidence with Near-infrared Spectroscopy (NIRS) monitoring on Newborn Intensive Care Unit (NICU) patients when provided with an educational teaching session.

Background and Significance: NIRS data can be used in conjunction with standard vital sign monitoring to help clinicians understand blood flow and metabolic demands of organ systems, particularly cerebral, renal, and mesenteric blood flow patterns. A NICU unit in the northwestern US adopted NIRS use on their patients in 2008, however, NIRS monitoring usage decreased over the past 5 years, citing a lack of continued education and comfort interpreting and managing NIRS monitored patients. One patient was monitored with NIRS in the year prior to the QI project.

Methods: A 5 point Likert-Type survey was designed to examine provider comfort and confidence using and interpreting NIRS on NICU patients. No Cronbach's alpha value exists for the survey as it was purposefully designed for the QI project. An educational presentation on the use and interpretation of NIRS on NICU patients was created and delivered during a formal provider staff meeting. Pre and Post education surveys were distributed electronically to participants and were presented 1 week prior to educational session and 1 month after educational session. IBM SPSS version 23 was used for descriptive statistics, paired *t* tests, and Wilcoxon test. Significance set to $p < 0.05$.

Results: In total, 18 providers ($N=18$) were surveyed, and 13 paired survey results ($n=13$) were received (8 MD and 5 NNP). Paired-samples *t* tests were calculated to compare the mean total score (TS) for pre/post comfort and pre/post confidence. This was a significant improvement for both comfort ($t(11) = -3.13, p=0.010$) and confidence ($t(11) = -3.37, p=0.006$). Wilcoxon test showed a significant increase in the times a provider managed a patient with NIRS ($z=-2.762, p=0.006$). The number NIRS monitored patients increased from one in the previous year to 15 patients in the 5 months of data tracking, a clinically significant increase.

Conclusions: Providing educational session on previously utilized clinical applications can improve providers comfort and confidence and influence their usage in clinical practice. Future continuing education sessions could be designed for different clinical applications in order to keep clinicians abreast of the current evidenced based applications of advanced clinical monitors.

Keywords: NIRS, NICU, Comfort, Confidence, Likert-type survey, Quality Improvement

Neonatal intensive care units help to provide care and support to infants born both prematurely and those with illness or infection. Complex vital sign monitoring is required to maintain homeostasis and indicate times for needed interventions. Routine vital sign monitors may be inadequate at capturing end organ demands in vulnerable neonatal populations. Current noninvasive blood pressure monitoring gives a momentary picture of hemodynamic stability and does not provide continuous moment to moment feedback that a dynamic critically ill neonate can require (Greison, Leung, & Wolf, 2011). Near-infrared spectroscopy monitoring may provide practitioners with additional information to better care for at risk neonatal populations.

Problem Statement

Preterm and vulnerable term infants in neonatal intensive care units (NICU) are at risk for cerebral, renal, and mesenteric hypotension making them susceptible to intraventricular hemorrhage (IVH), feeding intolerance, necrotizing enterocolitis (NEC) and acute renal failure. Current monitoring of standard vital signs may not be capable of accurately identifying this end organ hypoperfusion. Regional saturation monitors, also known as near-infrared spectroscopy monitors (NIRS), are currently available within NICUs to monitor regional saturations across time (Sood, McLaughlin, & Cortez, 2015), however, the medical team in a northwestern city cites a lack of education related to the use and benefits of the monitors preventing them from using them on high-risk NICU patients. Centers across the nation caring for similar acuity infants utilize NIRS monitors on patient populations that are at higher risk for systemic hypotension/hypoxia such as infants with congenital cardiac defects (Chock, Rose, Mante, & Punn, 2016, & Gillam-Krakauer et al., 2013). The SafeBoosC clinical trials established treatment guidelines for the use of NIRS in NICU patients for monitoring cerebral tissue oxygenation (Pellicer et al., 2013) and have been able to show reductions in cerebral oxygen debt

associated with hypoperfusion (Hyttel-Sorensen, et al., 2013). Though exact numbers of infants who experience hypotension is not known given our current monitoring systems, data regarding infants who require blood pressure medications has been researched. Laughon et al. (2010) examined extremely low birth weight infants showed that 90% of 23 week infants and 89% of 27 week infants required some form of blood pressure supportive measures within the first 24 hrs of life. Review of the electronic medical record at the northwestern NICU showed there have been zero prescribed uses of the NIRS monitor for the previous year.

Purpose and Rationale

Currently, a level 4 non-complex cardiac care, non-ECMO NICU in the northwestern United States has NIRS monitors available, however, does not use them because of lack of practitioner education about the benefits and data output generated when monitoring cerebral, renal, and mesenteric regional saturations. The NICU site cares for infants from 22 weeks through post term and utilizes multiple monitors beyond standard vital sign monitoring including amplitude electroencephalogram and transcutaneous carbon dioxide monitoring. Sood, McLaughlin, and Cortex (2015) cited ten different NICU patient groups that use NIRS monitoring including neonates with complex heart disease, preterm infants at risk for patent ductus arteriosus (PDA), and infants at high risk for IVH. Investigating the use of NIRS in the NICU may provide additional data to better support infants at risk for systemic end organ hypoperfusion and guide earlier interventions.

Background/Significance

There are groups of preterm and term infants that are at high risk for shunting blood flow preferentially causing end organ hypo perfusion and hypoxia. The highest risk populations include preterm (infants born less than 35 weeks), infants with cardiac defects, infants who have

experienced intrauterine growth restriction (IUGR) and infants who have experienced hypoxic ischemic events (HIE) (Blackburn, 2013; Gleason & Devaskar, 2012; Lin, Hagan, Fenoglio, Grant, & Franceschini, 2016). These groups of infants could benefit from advanced vital sign monitoring beyond the standard vital signs monitoring done on routine patients in neonatal intensive care units (NICU). Current vital sign monitoring includes heart rate, respiratory rate, oxygen saturation, temperature, blood pressure and pain. Near-infrared spectroscopy offers additional vital sign monitoring by providing regional oxygen saturation data thus giving information on both the blood flow and the metabolic needs of the end organ systems. Liu, Chalak, and Lu (2014) cited that not being able to meet an end organs metabolic demands or a states of end organ hypotension places infants at higher risk for IVH and long-term neurologic deficits. Bozzetti et al. (2016) utilized NIRS to show that IUGR infants continued to shunt blood flow preferentially to their brain over their GI tracts even after birth, a phenomenon not visible to practitioners utilizing routine vital sign monitoring.

In current NICU practice, hypotension is defined as a mean blood pressure less than the infant's gestational age in weeks. This is measured on a peripheral limb with a cuff or centrally with an invasive blood pressure monitoring device such as an umbilical artery catheter. The presence however of a hemodynamically significant patent ductus arteriosus (hsPDA) has the potential to cause decreased the mean blood pressure downstream causing the blood pressure at the level of the kidney to be less than the measured upper limb cuff blood pressure. Blood flow to the end organ systems such as the kidneys cannot be measured by this technique and current practice is to assume that if an infant is making urine then there is adequate blood flow to the kidneys. Similarly, there is no direct measure of cerebral blood flow or cerebral oxygen requirements. Preterm infants are at high risk for intracranial bleeding due to an inability to

autoregulate their cerebral blood pressure as well as the presence of a highly vascular structure known as the germinal matrix (Gleason & Devaskar, 2012). The germinal matrix exists in preterm infants and is often the site for most intracranial bleeds where as in term infants this structure has matured and is much less likely to be at risk for bleeding (Blackburn, 2013).

Near-infrared spectroscopy monitoring has been used in NICU patients as far back as 1985 (Greison, Leung, & Wolf, 2011), however, not until recent SafeBoosC Phase II clinical trials (Riera, et al., 2016) and 2-center randomized controlled pilot study (Pichler et al, 2013) were reference ranges established for infants. NIRS monitors provide real time end organ saturation data allowing practitioners the ability to visualize the impact of interventions on end organ blood flow (Greison, Leung, & Wolf, 2011). Regional saturation information is determined by examining the difference between the arterial and venous oxygenated hemoglobin molecules and the end organ uptake of oxygen also known as metabolic demand (Liao & Culver, 2014). There has been a surge in publications in the last five years pertaining to the use of NIRS monitoring in NICU patients to help better guide both the resuscitation of preterm infants and interventions to protect against end organ hypoperfusion including Pellicer, et al. (2013), Pichler, et al. (2015), and Plomgaard, et al. (2016). Alderliestin et al. (2016) published NIRS reference ranges for both term and preterm infants for the first three days of life enhancing practitioners understanding of how the cerebral oxygen saturation changes overtime in infants. Kenosi et al. (2015) provides an overview of current NIRS research and use in NICU patients as well as suggesting future research regarding cerebral monitoring during the birth process.

Problem Statement

This inquiry has lead to the clinically relevant PICO question, "In Neonatologists and Neonatal Nurse Practitioners, does providing education on the use and interpretation of Near-

Infrared Spectroscopy monitoring on Newborn Intensive Care Unit patients affect their comfort and confidence using and ordering NIRS and the frequency of ordering the intervention compared to no formal education"?

Search Strategy

Searches were conducted utilizing Cumulative index of nursing and allied health literature (CINAHL), PubMed, and the Cochrane Library. Keywords of NICU, Newborn, infant, neonate, NIRS, near infrared spectroscopy, INVOS, monitoring, intervention, and education were used. Initial CINAHL results (Appendix A) for search terms Infant or neonate and INVOS or NIRS or near infrared spectroscopy produced 1,675 results and PubMed (Appendix B) provided 55 results. Cochrane library (Appendix C) initial search for infant produced 40,087 results and was further narrowed using infant and NIRS or INVOS to 47 results. No initial limiters were placed on the search results and no publication data limit. Further combining search terms together produced 46 results through CINAHL (Appendix A), 55 results through PubMed (Appendix B), and 47 results through Cochrane Library (Appendix C). One hundred and forty eight studies were identified and duplicates were removed. Elimination criteria were implemented including publication within the last 10 years, available in English, and full text available. Thirty-nine studies were then selected for review.

Primary preference was given to studies of either systematic reviews or randomized controlled trials. One systematic review and three randomized controlled trials are included in the evaluation table (Appendix D). Multiple non-systematic reviews of the current use of NIRS in the NICU were excluded though they provided background to the current uses and implantation of NIRS protocols in neonatal care. The table (Appendix D) discusses the purpose and significant findings of 10 of the 39 reviewed studies. The findings help establish how NIRS

monitoring is currently utilized in NICU patients and additional research being done with NIRS monitoring.

Critical Appraisal and Synthesis

Ten studies were included in this literature review; all studies were evaluated using the rapid clinical appraisal tool from Melnyk and Fine-Overhold (2015) and their results are presented in an evidence table for analysis (Appendix D). Included are two randomized controlled trials (RCT), one extension of data gathered during an RCT, one systematic review (SR), one prospective observational trial (POT), one non-aprori retrospective study (NPRS), two observational cohort studies (OCS), one prospective observational study (POS), one case control (CS), and one prospective case-control study (PCCS). The levels of evidence include one level one, three level two, three level three, two level four and one level six, based on Melnyk and Fine-Overhold (2015) classification of evidence, providing a range of study designs. Sample sizes varied from 3 to 999 participants and the SR examined 229 studies. The ten studies provided a good representation of current use of NIRS in NICU patients and provide reference curves for the use NIRS on both term and preterm infants. The studies provide the clinical background for addressing the PICO question explored in this examination. A synthesis table (Appendix E) was created to illustrate the pertinent findings noted in the evidence table (Appendix D).

All ten studies were published in the last five years and all completed within the NICU setting. Most studies were published in Europe, with two studies being multicenter trials. Homogeneity was noted in the demographics across studies with participants being both term and preterm infants with similar ranging birth weights. APGAR scores assigned to patients at both one and five minutes were homogenous across the sample.

The study findings included establishing rScO₂ reference plots for both term and preterm infants from birth through transition and birth through first 72 hrs of life, a reduction in overall oxygen debt (cerebral), the ability to monitor for hsPDA, and visualization of the physiologic response of the mesenteric artery velocity in relation to feeding. Prior to rScO₂ reference plots being created clinicians interpreted NIRS data from unpublished reference ranges that were established on well term infants. Cerebral oxygen debt, defined as the time spent outside of expected rScO₂ saturations ranges during newborn transition, was shown to be reduced when resuscitation team members were able to view the real time NIRS monitoring data. The hemodynamic status of an infant's PDA was shown to be able to be monitored with NIRS by utilizing a ratio between simultaneously measured rScO₂ and rSmO₂ values. Lastly, rSmO₂ monitoring was able to show the physiologic response feeding had on the blood flow to an infant's gastrointestinal tract by monitoring the regional saturation and ultrasound velocity of the mesenteric artery.

The primary variables measured included measurement of three different NIRS values, rScO₂, rSrO₂, and rSmO₂, the time domain, and detection of hemodynamically significant PDA. Moderate homogeneity exists between the period analyzed across studies ranging from birth to transition through birth to 72 hrs. All nine studies utilized INVOS monitors for data measurement making for consistent comparison across studies. No validity or reliability was stated for the INVOS measurements.

Conclusions about Evidence

Evaluation of the synthesis table (Appendix E) shows that NIRS monitoring provides actionable data for clinicians when used on a variety of NICU patients. NIRS can be utilized to monitor infants during birth transition, prompting clinicians to add or remove respiratory support

in response to cerebral saturations. This can help reduce oxygen debt, an important concept for preterm infants with reduced cerebral auto-regulation of blood flow and blood pressure.

Reducing the oxygen debt has the potential to then reduce IVH rates leading to better overall neurologic outcomes though this potential has not yet been fully studied by utilizing the NIRS monitor.

NIRS provides clinicians the ability to monitor physiologic parameters including the status of an infant's PDA, potentially saving the patient financially by reducing the frequency of screening echocardiograms. The PDA status is monitored by measuring a ratio of the rScO₂ and rSmO₂, giving medical providers' additional information on cerebral oxygen debt and abdominal blood flow patterns.

The creation of gestational age specific reference plots for expected rScO₂ values over time provides guidance to both medical staff and nursing for managing patients and interventions. The SafeBoosC clinical trial (Riera, et al., 2016) established intervention guidelines for saturations outside of the reference values and has been shown to reduce overall oxygen debt and improve outcomes.

Though these highlighted clinical applications do not directly answer the PICO question they provide the fundamental background for the current usefulness of NIRS in NICU patients. Providing this NIRS background data, in conjunction with education on NIRS management, to the medical team in the Northwestern NICU should assist in making a change in clinical practice and ordering of NIRS monitoring.

Theoretical Framework

Near-infrared spectroscopy monitoring is a measure of a physiologic response to changing conditions within the body, however, Kurt Lewin's Change theory was chosen as a

conceptual framework to guide this project as the focus is on changing the behaviors of the participants. For this project, the participants are the medical team in the Northwestern NICU and the behavior is the utilization of NIRS monitoring on their patients.

Change theory is a three-step process involving unfreezing, moving, and refreezing to change behaviors and three major concepts driving forces, restraining forces and equilibrium (Polt & Beck, 2015). Lewin discussed driving forces that influence organizations towards change and restraining forces to remain the same, keeping the organization in a state of equilibrium (Polt & Beck, 2015 & Lewin's Change theory, n.d.). Unfreezing of a behavior must first take place in which a new solution is found, then the influencing forces must be addressed, before movement can happen on the behavior. Refreezing takes place when the new behavior is integrated into practice creating a new state of equilibrium in the system.

The current state of equilibrium in the Northwestern NICU is one of little to no use of NIRS on high risk neonates. To shift this to the goal of increased utilization the staff will need to be willing to unfreeze, accept the education, and refreeze by integrating NIRS into their practice. Key stake holders have been identified and have assisted in creating buy-in from the rest of medical staff to overcome increase the driving force to moving. An educational intervention is being proposed with a goal of decreasing the restraining forces that can negatively affect the movement. Assessing the refreezing process and establish the use of NIRS in the NICU will be done by a pre-and post-educational session surveying to assess the providers change in comfort and behavior prescribing the use of NIRS.

Evidence Based Practice Model

Rosswurm and Larrabee (1999) evidenced based practice (EBP) model was chosen to guide the implementation of the evidence. The model (Appendix F) involves six steps from

exploring a clinical gap to maintenance of the intervention. Rosswurm and Larrabee EBP model was chosen primarily for its focus on integration and maintenance of change beyond the initial change process. Review of the Northwestern NICU's electronic medical record (EMR) shows no orders for the use of NIRS monitoring, even with three dedicated monitors available for NICU patients, showing the gap in clinical practice. The lack of education was cited as the problem leading to the practice gap that linking the problem to the intervention laid out in step two of the EBP model. Buy in from the medical team has been established, and best evidence was reviewed and synthesized (Appendix E) relating to the use of the NIRS in NICU patients. Going forward education will be designed and presented to the medical staff and the bedside RNs on use and management of NIRS for at risk NICU patients.

Purpose Statement

The purpose of this quality improvement (QI) project was to increase provider (doctors and neonatal nurse practitioners) comfort and confidence using, interpreting, and ordering near-infrared spectroscopy (NIRS) monitoring on neonatal intensive care (NICU) patients. The providers will benefit from the project by gaining improved knowledge leading to potentially improved health outcomes for the patients in their care. The goal of the project is to see an increase in the providers comfort and confidence and see an increase in the utilization of NIRS in the NICU.

Methods

Intuition review board (IRB) approval was applied for and granted from Arizona State University and the northwestern NICU hospital to conduct the QI project. The QI project was conducted at a single NICU site that cares for infants from 22 weeks through post term with a wide range of children's specialty services. The NICU has a max census of 64 patients and an

average daily census of 30-35 patients. The NICU had adopted the use of NIRS ~10 years ago and the QI project required no financial budget as the NICU already owns the NIRS monitors to be utilized for patient monitoring.

Eighteen doctors and NNPs were recruited for the project. The project design was an interventional education session with a pre and post intervention survey and usage tracking of clinical orders for a 3 month period, however, the tracking phase was extended to 5 months. The primary investigator was the only team member supporting the project and was available to support the providers by phone and in person.

An educational session was designed and delivered to the providers by the primary investigator. The session consisted of a PowerPoint, handouts, and question and answer period. The educational session was delivered during a medical staff meeting and the materials used were then distributed to the staff for review via their work emails.

A 5-point Likert-type survey was created and then distributed to the NICU providers using a Google form (Appendix F). The survey contained consent to participate in the project, a unique reproducible identifier for the provider to fill out for pairing pre and post surveys, demographics questions (job role, years in role, years at northwestern NICU), and 13 questions on the use and interpretation of NIRS. The same survey was used pre and post educational session to measure the change in the providers. Two primary concepts were explored were comfort and confidence using, ordering, and interpreting NIRS data. No Croanbach's alpha value exists for the survey as it was specifically designed to assess the providers comfort and confidence using NIRS. No established survey tool was found specifically designed for the content examined in this QI project.

Surveys were distributed to the participants through their work email accounts via a web link to the survey. The primary investigator was the only person with access to the online survey results. The results were then converted to an Excel spreadsheet and printed to be stored by the primary investigator. No provider identifiers were collected beyond the unique reproducible identifier used to pair pre and post educational surveys in order to maintain participant anonymity and each participant provided their consent to participate in the project with each survey they filled out.

The pre survey was distributed 7 days prior to the educational session and responses were accepted until the day of the educational session. The post survey was distributed to the participants one month after the educational session and responses were accepted for a 10 day period.

The one month period following the educational session was noted to have a lower than normal census in the NICU prompting the investigator to modify the original QI plan. The lower than normal census period resulted in no NICU patients being considered for monitoring causing there to be no potential change to be measured by some of the survey questions. To account for this period of low census the tracking period was extended from 3 months to 5 months and an abbreviated survey was created to reevaluate three survey questions. The abbreviated survey was distributed 4 months after the educational session and responses were accepted for 2 weeks.

The survey results were validated and entered into IBM SPSS version 23 for analysis. Demographic data was analyzed with descriptive statistics. NIRS frequency survey questions were analyzed using a Wilcoxon analysis. The comfort and confidence concepts were analyzed using mean total score paired *t* tests. The significance was set to $p < 0.05$.

The usage data tracked included the gestational age of the NICU patient at birth and at time of NIRS ordering, the sites monitored with NIRS, and the length of time the patient was monitored. This information was gathered from the electronic medical record and was recorded in an Excel spreadsheet and printed to be stored by the primary investigator. The pre intervention data was examined for the 1 year period before the project and the post intervention data was tracked for a 5 month period. No patient identifiers were collected during the project in order to protect the identity of the patients monitored with NIRS.

Outcomes

Eighteen NICU providers completed the initial pre survey (8 MD/10 NNP) and 13 providers completed the post education survey (7 MD/8 NNP). The samples were paired using a unique reproducible identifier made by the provider at the time the survey for a total of 13 paired surveys. Additionally 16 providers completed the abbreviated surveys and those results were then paired to the pre educational survey results.

Descriptive statistics on the providers including their role in the NICU (MD or NNP), the years they have been in that role and the number of years they have been with the Northwestern NICU. The 13 providers (61% MD/ 39% NNP) had worked in their role on average 11.25 years (sd=5.8) with a range of 0.1-20 years. Significance for parametric and non-parametric statistics was set to $p < 0.05$.

A Wilcoxon test examined the results of three survey questions; how frequently providers ordered NIRS, how frequently providers managed NIRS and how frequently providers managed NIRS ordered by another provider. A significant difference was found in the results for the how frequently providers managed patients with NIRS with the result of ($z = -2.762, p = 0.006$) between the pre intervention survey results and the abbreviated survey results given at 4 months.

Providers stated that they managed patients more frequently after the educational session with NIRS in place. No significant difference was found the providers response to the frequency which they ordered NIRS ($z=1.51$, $p=0.132$) and how frequently they managed NIRS ordered by another provider ($z=-1.01$, $p=0.314$).

Paired-samples t test was calculated to compare the mean total score for pre survey for both comfort and confidence to the mean total score post survey. The pre education mean total score for comfort was 8.77 ($sd=2.62$) and the mean total score post education was 12.85 ($sd=4.52$). The pre education mean total score for confidence was 12.33 ($sd= 4.54$) and the mean total score post education was 16.42 ($sd=5.38$). A significant increase was noted for both comfort ($t(11)=-3.13$, $p=0.010$) and confidence ($t(11)=3.37$, $p=0.006$) at one month after educational session.

The clinical use of NIRS in the NICU changed considerably from the 1 year prior to educational session with one patient monitored in that time and 15 patients monitored during the 5 months of data tracking. Patients who NIRS was used on during the 5 months of data tracking ranged from 24 weeks to 36 weeks with 10 of 15 patients monitored less than 27 weeks gestation. Cerebral and Renal monitoring was used in 13 of 15 patients and renal monitoring only in 2 of 15 patients. Patients were monitored from 1 day to 15 days with one patient actively being monitored at the time data tracking was completed.

Discussion

The QI project did result in a statistically significant improvement in the providers comfort and understanding using, interpreting, and ordering NIRS on NICU patients as measured by the pre/post survey results. These findings, however, should factor in that they survey was purposefully created for this project and does not have an established Cronbach's alpha

coefficient for validation. The survey questions were designed to assess the providers on topics related to NIRS use and interpretation and reviewed by the primary investigator and DNP mentor. The post education survey was given 1 month after the teaching session in order to allow the providers time to review the material covered and use the NIRS on patients they felt could be monitored. Of far greater importance than the statistical significance was the change in clinical practice with 15 patients monitored with NIRS during the 5 months of data tracking, an increase from 1 patient monitored in the previous year. Additionally the patient population being monitored was a significant shift from historical use in the Northwestern NICU with 10 of 15 patients being less 27 weeks or less gestation. Previously only term infants with mature skin were monitored and now the use of Mepitel skin barrier product between the sensor and the infant's skin. The Mepitel barrier has helped alleviate some of the concern from providers regarding how tacky the sensors are when using them on preterm infants with fragile skin (McNeil, Gatenby, McElroy, & Engelhardt, 2010).

Though specific diagnoses were not tracked on patients who NIRS was ordered on, the investigator did notice three particular patient groups that were being monitored. This was based on interactions with the ordering providers as well as the questions being asked about patient conditions and NIRS probe site selection. The three groups were patients who were being observed for the presence of a hemodynamically significant PDA (hPDA), patients nearing red blood cell (RBC) transfusion criteria established by the unit specific transfusion algorithm, and preterm infants during the initial transition to extrauterine life. These are three groups that are found in the current literature and in NIRS clinical trials. Chock, Rose, Mante, and Pun (2016) published their findings related to the use of NIRS to monitor an infant for hPDA and cited a 81% sensitivity and 77% specificity for infants with hPDA when the infants rSO₂ was less than

66%. This is valuable to the clinical setting as pediatric echocardiograms are a costly intervention not available at all hospital settings, however, clinical judgments on treating a hPDA should not be made on the rSO₂ NIRS alone. The SafeBoosc clinical guideline by Plomgaard et al. (2016) discusses different interventions for when cerebral NIRS values are less than the expected range and this was given to the medical staff during the educational teaching session. One of the interventions discussed was examining a patient's hematocrit and considering a RBC transfusion if the values were consistently lower than expected (Plomgaard et al., 2016). The improvement in the cRSO₂ values when noted by the providers was often discussed with the investigator when reviewing the patient's time with NIRS in place.

Prospectively, only time will tell if the increased utilization of NIRS in the Northwestern NICU will continue or if it was a direct result of the QI project and support being provided to the medical providers. The NICU has a history of increased utilization of NIRS monitoring following educational presentations, however, their utilization decreased overtime. Lewin's Change Theory was chosen with the hopes of being able to change the clinical practice and then refreeze it into place. Additional educational "check in's" may help the providers with questions and allow for further discussion on the current research on NIRS use in NICUs, helping to sustain the change long term (Silver et al., 2016). The health information technology (HIT) department working within the NICU is currently working with the electronic medical record (EMR) to have data flow directly from the NIRS monitor into the patients record, eliminating the bedside nurses from having to enter the values hourly. This advance will aid in decreasing data being missed and allow the providers to see remotely what the min to min graphically representation of NIRS data looks like. This will decrease the frequency in which providers will have to come to the patient's bedside to review the NIRS trends.

Limitations

The limitations of this QI project include its single site design with a provider group that had previous history using the NIRS monitors. The survey used to assess for change in the providers comfort and confidence was designed specifically for this project and does not have a Cronbach's alpha coefficient to report for validity of the survey findings. Lastly the investigator does work in the NICU as a bedside RN and was responsible for providing care to some of the patients being monitored with NIRS, however, while working as the bedside RN refrained from suggesting or discussing NIRS monitoring on other patients with the providers unless asked by the provider specifically, as to prevent creating bias in the frequency of NIRS orders.

Conclusion

This QI project focused on educating the providers on the current evidence and research into NIRS use on NICU patients while also supporting the clinicians when managing patients with NIRS monitoring in place. The Northwestern US NICU had already invested capital budget into the purchase of three NIRS monitors, however, was not utilizing them for their patients. The educational session provided did show a significant change in the providers comfort and confidence on NIRS and a significant increase in the clinical utilization of NIRS monitoring was noted. This project highlighted how revising previously abandoned clinical tools and monitors with new evidence can change provider practice, a very good reason for providers to attend continuing education seminars and conferences. Just as Kenosi, Naulaers, Ryan, and Dempsey (2014) titled their article, the future looks brighter for cerebral oxygenation monitoring in preterm infants.

Dissemination of Project Plan

The project results were presented in poster format at ASU to DNP nursing faculty and students. Completed DNP project poster was shared with the Northwestern NICU department staff with a review of the project results. There is no further presentation or publication plan at this time.

Moving forward, alerts have been set for NIRS and NICU on PubMed, Cochrane Library, and CINAHL in order to keep abreast of the new research published on NIRS use. The publications will be reviewed and additional teaching sessions

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Appendix A

Database Search Strategy

CINHAL Plus with full text



Searching: CINAH L Plus with Full Text | [Choose Databases](#)


Suggest Subject Terms

Select a Field (optional) ▾ Search Clear ?

AND ▾ Select a Field (optional) ▾

AND ▾ Select a Field (optional) ▾ + -

[Basic Search](#) [Advanced Search](#) [Search History ▾](#)



Search History/Alerts

[Print Search History](#) | [Retrieve Searches](#) | [Retrieve Alerts](#) | [Save Searches / Alerts](#)

<input type="checkbox"/> Select /deselect all	Search with AND	Search with OR	Delete Searches	Refresh Search Results
Search ID#	Search Terms	Search Options	Actions	
<input type="checkbox"/> S7	S s4 AND intervention	Search modes - Boolean/Phrase	View Results (46) View Details Edit	
<input type="checkbox"/> S6	S S4 AND education	Search modes - Boolean/Phrase	View Results (5) View Details Edit	
<input type="checkbox"/> S5	S S2 AND NICU	Search modes - Boolean/Phrase	View Results (3) View Details Edit	
<input type="checkbox"/> S4	S S2 AND monitoring	Search modes - Boolean/Phrase	View Results (400) View Details Edit	
<input type="checkbox"/> S3	S S2 AND education	Search modes - Boolean/Phrase	View Results (20) View Details Edit	
<input type="checkbox"/> S2	S (infant or neonate or newborn) AND (NIRS or INVOS) OR near infrared spectroscopy	Search modes - Boolean/Phrase	View Results (1,672) View Details Edit	
<input type="checkbox"/> S1	S near infrared spectroscopy AND (infant or neonate or newborn)	Search modes - Boolean/Phrase	View Results (286) View Details Edit	

Appendix B

Database Search Strategy

PubMed

The screenshot shows a PubMed search interface. At the top, the search bar contains the query: "(Infant or neonate or newborn) and (NIRS or INVOS or near infrared spectroscopy) and NICU". The search results show 55 items. Below the results, there is a section for "Search Details" which includes a "Query Translation" box containing a complex Boolean search string. Below the query translation, there is a "Result:" section showing "55". A "Stopword(s) Ignored:" section lists "and". A "Translations:" section contains a table with the following data:


Term	Translation
Infant	"infant"[MeSH Terms] OR "infant"[All Fields]
neonate	"infant, newborn"[MeSH Terms] OR ("infant"[All Fields] AND "newborn"[All Fields]) OR "newborn infant"[All Fields] OR "neonate"[All Fields]
newborn	"infant, newborn"[MeSH Terms] OR ("infant"[All Fields] AND "newborn"[All Fields]) OR "newborn infant"[All Fields] OR "newborn"[All Fields]
near infrared spectroscopy	"spectroscopy, near-infrared"[MeSH Terms] OR ("spectroscopy"[All Fields] AND "near-infrared"[All Fields]) OR "near-infrared spectroscopy"[All Fields] OR ("near"[All Fields] AND "infrared"[All Fields] AND "spectroscopy"[All Fields]) OR "near infrared spectroscopy"[All Fields]
NICU	"intensive care units, neonatal"[MeSH Terms] OR ("intensive"[All Fields] AND "care"[All Fields] AND "units"[All Fields] AND "neonatal"[All Fields]) OR "neonatal intensive care units"[All Fields] OR "nicu"[All Fields]

Appendix C

Database Search Strategy

Cochrane Library

Wiley Online Library



Trusted evidence.
Informed decisions.
Better health.

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Search Search Manager Medical Terms (MeSH) Browse

To search an exact word(s) use quotation marks, e.g. "hospital" finds hospital; hospital (no quotation marks) finds hospital and hospitals; pay finds paid, pays, paying, payed)

[Add to top](#) [View fewer lines](#)

⊖	+	#1	safeboosc:ti,ab,kw (Word variations have been searched)	S	7
⊖	Edit	+	#2	infant	40087
⊖	Edit	+	#3	infant and near-infra-red	3
⊖	Edit	+	#4	neonate and monitoring	219
⊖	Edit	+	#5	NIRS	251
⊖	Edit	+	#6	<u>NIRS</u> or INVOS	275
⊖	Edit	+	#7	neonate and <u>NIRS</u> or INVOS	47
⊖	+	#8		M	N/A

[Clear Strategy](#) [Search Help](#) Highlight orphan lines

Save strategy

Appendix D

Evaluation Table

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
<p>Alderliesten, Dix, 2015, Reference values of rScO₂ during first 3 days of life in preterm neonates.</p> <p>Country: The Netherlands Wilhelmina Children's Hospital Level III NICU</p> <p>Funding: Fellowship from RFF, ERC</p> <p>COI- None disclosed</p>	<p>Physiologic Framework</p>	<p>Quantitative</p> <p>Observational cohort Study</p> <p>Purpose: Establish rScO₂ reference values/tables for preterm infants for first 3 days of life</p>	<p>n= 999 preterm infants (M 539 / F 460)</p> <p>GA <32 weeks</p> <p>Mean 28.7 SD 1.96</p> <p>IC - born < 32 weeks with PC between 1/2005 - 9/2013</p> <p>EC - CM/SGA or severe congenital malformations, missing data sets</p> <p>DD - BW, APGAR score, hsPDA, presence of IVH, Mortality</p>	<p>Variable of interest: rScO₂ over time</p> <p>Measured for first 72 hrs after birth</p>	<p>INVOS 4100 or 5100 with small adult electrode</p> <p>Data collected from birth through first 72 hrs.</p> <p>Sensor on forehead with elastic bandage.</p> <p>Mean value for 1 hr periods were analyzed. Small sample (n=16) with neonatal sensor for conversion data</p>	<p>Linear, squared, and polinomial models to find best fit for both rScO₂ and cFTOE.</p>	<p>Creation of reference curves for GA in 2 week increments for both rScO₂ and cFTOE for first 72 hr of life</p> <p>Similar results to other similar studies for reference ranges</p>	<p>Level IV</p> <p>Strength: Large sample size, establish, similar results to other studies</p> <p>Weakness: Use of adult sensor, only <32 week infants</p> <p>Highly applicable to practice, education on normal expected ranges for given GA and time.</p> <p>Conclusion: Good references for use of NIRS in practice on preterm infants through</p>

Key: **AGA** – Appropriate for Gestational age, **BP** - Blood pressure, **BPD** - Bronchopulmonary displasia **BS** – Brain sparring, **BW** - Birth weight, **cFTOE** - cerebral fractional tissue oxygen extraction, **CM/SGA** - Cardiac malformation or severe chromosomal abnormalities, **COI** - Conflicts of interest, **CSOR** – cerebral / splanchnic oxygenation ratio, **DD** - Demographic data, **DV**-dependent variable, **EC** - Exclusion criteria, **EEG** - Electroencephalographic, **ERC** - European Research Council, **F** - Female, **GA** - Gestational Age, **HR** - Heart rate, **hsPDA** - hemodynamically significant patent ductus arteriosus, **IC** - Inclusion criteria, **IUGR** – Intrauterine Growth Restricted, **IV**- independent variable, **IVH** - Intraventricular hemorrhage, **M** - Male, **mFTOE** – Mesenteric fractional tissue oxygen extraction, **MV** - Mechanical ventilation, **N**-number of studies, **n**- number of participants, **NEC** - Necrotizing Enterocolitis, **NIH** – National Institutes of health, **NIRS** - Near infrared Spectroscopy, **PC** - Parental Consent, **PNA** - Post natal age, **RDS** - Respiratory distress syndrome, **REF** - Research Foundation Flanders, **ROP** - Retinopathy of Prematurity **rScO₂** - regional cerebral oxygen saturation, **rSrO₂** - regional renal oxygen saturation, **rSmO₂** – Regional mesenteric oxygen saturation, **SD** - Standard Deviation, **SMAV** - Superior Mesenteric artery velocity, **T** - Time,

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis (stats used)	Findings/ Results	transition Level/Quality of Evidence; Decision for practice/ application to practice
<p>Bozzetti (2016), rScO2 and rSmO2 in IGUR preterm infants</p> <p>Country: Italy, San Gerardo Hospital</p> <p>Funding: None</p> <p>COI: None stated</p>	<p>Physiologic Framework</p>	<p>Quantitative</p> <p>Prospective Case-control Study</p> <p>Purpose: Examine BS in IGUR infants by measuring regional saturations</p>	<p>n=20, 10 IUGR preterm infants 10 AGA preterm infants (GA 29-33 weeks)</p> <p>DD: GA, Gender, BW, APGAR, Prenatal steroids, hsPDA, IVH (BW only significant difference between groups (p=0.05))</p> <p>EC: CM/SGA, Perinatal asphyxia with multi-organ failure, skin disease at probe site</p>	<p>IV1- rScO2 for IUGR infants IV2- rSmO2 for IUGR infants IV3- rScO2 for non-IUGR infants IV4- rSmO2 for non-IUGR infants</p> <p>DV1- T0 (12.3 hr ±4.4 hr) DV2- T1 (62.7 hr ± 4.0 hr)</p>	<p>NIRS data from INVOS 5100 placed infra-umbilical and forehead. Measured in first 24 hrs and again at 48-72 hrs</p>	<p>Student's <i>t</i>-test for continuous variables, Man-Whitney U two sided, Kuskal-Wallis, and fisher's exact / chi-squared</p>	<p>CSOR of IV1 and IV2 at DV1 (p<0.001)</p> <p>IV1 > at DV1 than DV2 (p<0.001)</p> <p>cFTOE for IV1 at DV1 and DV2 (p<0.001), no difference in mFTOE (p not reported)</p> <p>CSOR for IV3 and IV4 at DV1 and DV2 (p<0.001)</p> <p>IV2 and IV4 at DV1 and DV2 (p<0.001) for both rSmO2 and mFTOE</p>	<p>Level of evidence: Level 4</p> <p>Strengths: preselected infants for study based on ultrasound data. Two paired groups reflective of population difference in question</p> <p>Weakness: Small sample size and limited timeframe of measurement</p> <p>Application to practice: Good for monitoring differences in IUGR patients blood flow patterns to not push feeds to quickly post birth</p> <p>Conclusion:</p>

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								Helps establish awareness of continued BS post birth and feeding considerations with continued BS effect
Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & interventions studied	Measurement/ Instrumentation	Discussion of case studies	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Cerbo (2012). rScO2 and rSmO2 in sick preterm infants Country: Italy, Fondazione IRCCS, San Matteo Funding: No funding stated COI: No conflict of interest stated	Physiologic framework	Quantitative Case review of 3 preterm infants and use of NIRS monitoring Purpose: review of use of NIRS in clinical practice with different patient diagnosis	n= 3 GA #1= 24 week M infant GA #2= 28 week F infant GA #3= 30 week M infant DD: HR, BP, pulse ox, rScO2 and rSmO2 Single center findings	Variables: rScO2 and rSmO2 Treatments: PDA ligation, UVC extravasations monitoring	NIRS measurement of rScO2 and rSmO2 with INVOS 5100	Case #1: Preterm infant noted to have CSOR difference suggestive of PDA, required ligation Case #2: Preterm infant with atrial tachyarrhythmia shown to have PDA requiring ligation Case #3: Infant with UVC infiltrate noted with change in rSmO2	Discussion of NIRS data findings prior to, during, and after PDA ligation with overall increase in rScO2 noted when duct was closed NIRS data trended to show worsening hsPDA and changes during surgical closure Discussion of rSmO2 response with abdominal infiltration of umbilical catheter	Level of evidence: Level VI Strengths: Shows use of NIRS in different disease process Weakness: Small number of cases, not easily reproducible Application to practice: Additional ways NIRS can be used to monitor disease processes Conclusion: Limited generalizability to populations

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								without reproducibility of case study results
Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
<p>Chock (2016) NIRS for Detection of hsPDA.</p> <p>Country: USA, Stanford University Medical center, Luciel Packard Children's Hospital</p> <p>Funding: no support</p> <p>COI - None stated</p>	<p>Physiologic framework</p>	<p>Quantitative</p> <p>Non a-priori retrospective study</p> <p>Purpose: Determine if NIRS monitoring can show the presence of hsPDA with confirmation by Cardiac Echo</p>	<p>n= 47 (M 15 / F 32)</p> <p>GA <29 weeks with NIRS monitoring between 9/2013-8/2015, Normal routine monitoring of rScO2 and rSrO2 done on patients of this GA</p> <p>DD - GA, BW, Race, PNA, use of vasopressors, MV</p>	<p>IV- rScO2 and rSrO2 values measured at 6 days of life</p> <p>DV- Presence of hsPDA by cardiac Echo</p>	<p>NIRS monitoring of both rScO2 and rSrO2 with INVOS 5100 Cardiac Echos performed on any suspected infant with hsPDA without influence of rScO2 or rSrO2 data and read by Peds Cardiology without knowledge of any rScO2 or rSrO2 data</p>	<p>Fisher's exact test w/Freeman-Halton extension, Kruskal-Wallis for nonparametric with Bonferroni correction</p>	<p>rSrO2 less an 66% correlated with hsPDA (p=0.03), rScO2 was not significantly different between confirmed hsPDA and non hsPDA (p=0.24), rScO2 to rSrO2 ratio higher with hsPDA (p=0.007)</p>	<p>Level IV</p> <p>Strength: Measured when hsPDA plays a physiologic role</p> <p>Weakness: Small sample size</p> <p>Applicable to clinical practice as a non invasive tool to monitor for hsPDA without added cost of Cardiac Echo</p> <p>Conclusion: Small study size, good consistent result when confirmed by Echo</p>
Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for

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								practice/ application to practice
Gillam-Krakauer (2013). Correlation of rSmO2 with Superior mesenteric artery velocity Country: USA, Vanderbilt Children’s Hospital Funding: Grand from Vanderbilt Institute for clinical and translational research, unrestricted technology grant from Somanetics, NIH grant COI: Unrestricted Somanetics grant	Physiologic framework	Quantitative Prospective Observational single-center trial Purpose: Determine if variations in rSmO2 measured by NIRS correlated with measured variations in superior mesenteric artery velocities.	n=18 (M 9, F 9) GA: 25 – 31 weeks Attrition: 28% (18/25) IC: GA 23 6/7 to 30 6/7 weeks, < 1500 g, < 14 days of age, tolerating enteral feeds 10-20 ml/kg/day EC: CM/SGA, IUGR, Gastrointestinal anomalies, pressor support within 24 hrs, severe jaundice, hx necrotizing enterocolitis DD: GA, BW, Gender, Race, APGAR, PNA, Days to full feeds	rSmO2 data and the corresponding superior mesenteric artery velocity in three intervals around feeding for three consecutive days Higher superior mesenteric artery velocity would correlate with increased blood flow to the abdominal viscera	rSmO2 with INVOS 5100 with neonatal sensor placed midline below the umbilicus, measured just prior to starting feeding, 10 mins after feeding, and 60-120 mins after feeding completed. Doppler ultrasound of SMAV (systolic, diastolic and mean) by Siemans Acuson Sequoia measured just prior to starting feeding, 10 mins after feeding, and 60-120 mins after feeding completed. Total of 9 ultrasound measurements, around 3 different feedings	Spearman’s rank correlation, Wilcoxon test, and Kruskal-Wallis	Kruskal-Wallis on rSmO2 and Dopplar flow measures were not significantly different from day 1 to day 3. Not significant in pre feeding or 60-120 mins post feeding (p=0.068, 0.062, and 0.53 for systolic, diastolic, and mean pre feeding) Significant difference in 10 mins post feed in all SMAV (p=0.013, 0.015, and 0.005)	Level of evidence: Strengths: Weakness: Small sample size, Application to practice: Limited beyond continued focus on variability in NIRS data being more clinically important Conclusion: Provides jumping off point for further research
Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for

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								practice/ application to practice
<p>Hyttel-Sorensen (2015). rScO2 in Phase II clinical trial</p> <p>Country: 8 European countries (retrieved from British medical journal)</p> <p>Funding: Unrestricted grant from Danish Council for Strategic research</p> <p>COI: None stated</p>	<p>Physiologic Framework</p>	<p>Quantitative</p> <p>Phase II randomised, blinded, feasibility trial</p> <p>Randomization by computer generated allocation sequence</p> <p>Purpose: test the SafeBoosc recommendations for reduction in rScO2 burden in multiple centers</p>	<p>n= 166 infants</p> <p>Intervention group: 86 (M 44, F 51)</p> <p>Control group: 80 (M 34, F 43)</p> <p>DD: BW, GA, Sex, prenatal steriods, length (time) of rupture of membranes, presence of chorioamnionitis, APGAR, Umbilical artery pH</p> <p>IC: At least 12 weeks preterm, establish rScO2 within 3 hrs of birth with PC</p> <p>EC: Inability to place rScO2 within 3 hrs, no NIRS monitor available, no PC, decision for no life support measures</p> <p>Power of 95% with sample size of 166 estimated</p> <p>Attrition: 4% (6/166)</p>	<p>IV1- rScO2 data visible to medical staff</p> <p>IV2- rScO2 not visible to medical staff</p> <p>DV- Cerebral oxygen burden (hypoxia or hyperoxia)</p>	<p>NIRS data from INVOS 5100c with adult sensor measuring rScO2 from 3 hrs through 72 hrs after birth. INVOS were blinded by being placed in a box or in a research specific screen mode</p>	<p>Specific statistical analysis tests were not discussed. Cited as utilizing two sided tests with P of 0.05 and mixed modeling for continuous variables and ordinary logistic regression for binary and ordinal outcomes</p>	<p>IV1 to DV (p<0.001) when compared to IV2 to DV, primary reduction in hypoxia</p> <p>DD were not significant between IV1 and IV2</p> <p>No secondary measures were significant between IV1 and IV2</p>	<p>Level of evidence: Level II</p> <p>Strengths: Large multicenter RCT utilizing established interventional guidelines</p> <p>Weakness: First study of its kind with infants, no discussion of stats analyzed</p> <p>Application to practice: shows the importance of utilizing interventions to reduce rScO2 oxygen debt when monitoring with NIRS</p> <p>Conclusion: Good evidence for the use of NIRS to reduce potential harmful oxygen debt and use of clinical treatment recommendations</p>

Key: **AGA** – Appropriate for Gestational age, **BP** - Blood pressure, **BPD** - Bronchopulmonary displasia **BS** – Brain sparing, **BW** - Birth weight, **cFTOE** - cerebral fractional tissue oxygen extraction, **CM/SGA** - Cardiac malformation or severe chromosomal abnormalities, **COI** - Conflicts of interest, **CSOR** – cerebral / splanchnic oxygenation ratio, **DD** - Demographic data, **DV**-dependent variable, **EC** - Exclusion criteria, **EEG** - Electroencephalographic, **ERC** - European Research Council, **F** - Female, **GA** - Gestational Age, **HR** - Heart rate, **hsPDA** - hemodynamically significant patent ductus arteriosus, **IC** - Inclusion criteria, **IUGR** – Intrauterine Growth Restricted, **IV**- independent variable, **IVH** - Intraventricular hemorrhage, **M** - Male, **mFTOE** – Mesenteric fractional tissue oxygen extraction, **MV** - Mechanical ventilation, **N**-number of studies, **n**- number of participants, **NEC** - Necrotizing Enterocolitis, **NIH** – National Institutes of health, **NIRS** - Near infrared Spectroscopy, **PC** - Parental Consent, **PNA** - Post natal age, **RDS** - Respiratory distress syndrome, **REF** - Research Foundation Flanders, **ROP** - Retinopathy of Prematurity **rScO2** - regional cerebral oxygen saturation, **rSrO2** - regional renal oxygen saturation, **rSmO2** – Regional mesenteric oxygen saturation, **SD** - Standard Deviation, **SMAV** - Superior Mesenteric artery velocity, **T** - Time,

								from SafeBoosc
Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Interventions used during RCT	Measurement/ Instrumentation	Impact on practice	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
<p>Pellicer (2013), SafeBoosc Phase II RCT treatment guideline</p> <p>Country: Spain (La Paz University Hospital)</p> <p>Funding: Danish Council for Strategic Research</p> <p>COI: None stated</p>	<p>Physiologic Framework</p>	<p>Quantitative Systematic Review</p> <p>Purpose: Describe the rational for the treatment guideline and the algorithm for the interventions per SafeBoosc</p>	<p>N= 229 initial studies, 61 directly relevant to treatment guideline and 9 RCT's</p> <p>SafeBoosc is a randomized clinical trial involving premature infants from birth through the first 72 hrs of life examining rScO2 values measured by NIRS</p>	<p>Cardiovascular status review</p> <p>Oxygen Transportation</p> <p>Respiratory Status</p> <p>Blood Glucose management</p>	<p>Recommendations based on level of evidence from I to III with Level I being from RCT and Level III being opinions from respected authorities</p> <p>Recommendations based on quality of evidence from good to fair to poor and net benefit to health outcomes from substantial to zero/negative.</p> <p>MeSH terms searched through PubMed: Neonate, NIRS, cerebrovascular circulation, BP, hypotension, dopamine, dobutamine, epinephrine, anemia, blood</p>	<p>Provides background for interventions recommended by SafeBoosc RCT</p>	<p>All recommendations have at least a Level II study supporting and a minimum of small to substantial net benefit</p>	<p>Level of evidence: Level I</p> <p>Strengths: Provided rational for clinical interventions</p> <p>Weakness: Some recommendations are only weakly supported by research</p> <p>Application to practice: Highly applicable if monitoring rScO2 in preterm infants</p> <p>Conclusion: Good for basis of interventions used to correct rScO2 outside of expected ranges</p>

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					transfusion, CO2, RDS, PDA, and treatment			
Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
<p>Pichler, Binder (2013) Reference ranges for rScO2 and cFTOE during neonatal transition</p> <p>Country: Austria, Royal Alexandra Hospital</p> <p>Funding: Jubiläumfond, Österreichische National-Bank</p> <p>COI: No conflict stated</p>	<p>Physiologic framework</p>	<p>Quantitative</p> <p>Prospective Observational Study</p> <p>Purpose: determine range values for rScO2 during neonatal transition using NIRS</p>	<p>n= 381 neonates (82 Term vaginal delivered, 272 term Cesarean delivered, 27 preterm Cesarean delivered)</p> <p>DD: BW, GA, Apgars, SpO2, HR</p> <p>EC: Vacuum assisted or forceps assisted delivery, Respiratory support during transition</p> <p>Setting: Medical university of Graz between 1/2009 - 8/2012</p> <p>Attrition: none, analysis done for only those who had complete data sets</p>	<p>IV1- rScO2 IV2- cFTOE DV- Time Birth through 15 mins</p>	<p>Invos 5100 monitor with neonatal sensor placed on left frontoparietal forehead, secured with strap</p> <p>Measurements started at 2 mins of age and continued for 15 mins during transition</p>	<p>Least mean squares for rScO2 and cFTOE and linear mixed modeling with first order autoregressives covariance structure for overall effects and differenced between groups</p> <p>P value set to 0.05</p>	<p>Stats for HR and SpO2 differences min by min for three population groups</p> <p>rScO2 at 4 and 5 mins for vag term deliveries was higher than Cesarean term (p = 0.003)</p> <p>Four rScO2 vs time graphs and four cFTOE vs time graphs</p> <p>Two tables with 10th, 50th, and 90th percentile for rScO2 and cFTOE</p>	<p>Level of evidence: Level IV</p> <p>Strengths: Large sample size, Multiple gestations, Establish normal transition data set</p> <p>Weakness: Limited to 15 mins of transition, minimal vaginal preterm infants,</p> <p>Application to practice: Assist with guiding normal transition in delivery room</p> <p>Conclusion: Helps establish base knowledge of use during transition and expected data</p>

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								points/goals for normal transition
Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
<p>Pichler (2016), rScO2 to guide oxygen delivery 2 center RCPT</p> <p>Country: Austria, Medical University of Graz</p> <p>Funding: None stated</p> <p>COI: No conflicts stated</p>	<p>Physiologic Framework</p>	<p>Quantitative</p> <p>Multicenter Randomized controlled Pilot Feasibility trial</p> <p>Randomized by sealed envelope opened just before birth</p> <p>Neonatology staff in NICU was blinded to whether NIRS was visible to resuscitation team on delivery of infant</p>	<p>Two sites: Graz, Austria and Edmonton, Alberta CA</p> <p>n= 60, 30 at each site, 15 in Control group and 15 in intervention group, (M - 32, F - 28)</p> <p>DD: GA, BW, APGAR, Sex, Mortality, IVH rates, NEC rates, ROP, BPD</p> <p>IC: PC, < 34 weeks, choice to provide life support</p> <p>EC: Congenital malformation or no life support</p> <p>Attrition: 0/60</p>	<p>IV 1-rScO2 visible to resuscitation team</p> <p>IV 2 - rScO2 not visible to resuscitation team</p> <p>DV- Oxygen debt defined as hypoxia or hyperoxia during resuscitation as measured by cerebral NIRS</p>	<p>IVOS 5100 with cerebral monitor placed on Left forehead and covered with hat. Continuous data was recorded and means for each min were calculated for HR, Saturation, and rScO2. Delayed cord clamping was done between 30 to 60 seconds for eligible infants.</p> <p>Data was collected for the first 15 mins after birth</p>	<p>Chi Squared, Fisher exact test for discrete variables, t test or Mann-WhitneyU for continuous variables.</p> <p>Group differences with Mann-Whitney U</p> <p>Mean values expressed in models and P<.05 for statistical significance</p>	<p>No significant DD differences</p> <p>IV1 vs IV2 on DV Reduction in cerebral oxygen debt (p=.028) for patients who had complete data sets available for analysis</p> <p>IV1 vs IV2 on DV for all patients not significant (p=.107)</p> <p>Teams with visible NIRS were able to add/wean resp support reducing cerebral hypoxia quicker</p>	<p>Level of evidence: Level II</p> <p>Strengths: Showed reduction in oxygen debt during resuscitation, multiple centers</p> <p>Weakness: Small sample size, Not significant result on whole of data set</p> <p>Application to practice: Could help guide resuscitation of known NICU admits</p> <p>Conclusion: Good application of NIRS similar to SafeBoosC clinical trial</p>

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Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
<p>Plomgaard (2016) SafeBoosC II RCT: treatment guided by NIRS reduces cerebral hypoxia</p> <p>Country: 6 European countries (retrieved from Pediatric RESEARCH)</p> <p>Funding: Danish Council for Strategic Research</p> <p>COI: No authors cite conflicts</p>	<p>Physiologic framework</p>	<p>Quantitative</p> <p>Extension of original RCT</p> <p>Purpose: Extend the findings of initial RCT to examine the effect on cerebral hypoxia by EEG</p>	<p>n= 158 in RCT, 133 for analysis in subgroup of EEG recording, 123 for blood biomarker analysis</p> <p>DD: BW, GA, Twin delivery, APGAR, Antinatal steriods,</p> <p>Setting: NICU in 6 different European countries</p> <p>Attrition: 16/158 (10%), 8 died before 64 hr mark, 8 did not have EEG</p>	<p>IV1- NIRS visible</p> <p>IV2- Control group without NIRS</p> <p>DV1- EEG</p> <p>DV2- Blood Biomarker</p>	<p>EEG at 64 hrs of age by amplitude-integrated EEG at P3 and P4 locations with 120 mins of recording time</p> <p>Blood biomarkers at 6 hrs and 64 hrs, 1 ml per collection, markers S100β, BFABP, and Neuroketal examined</p>	<p>EEG examined for normality, multiple regression modeling of estimated means</p> <p>Biomarkers with logarithmic transformation, linear mixed modeling analysis and unstructured covariance matrix. Mann Whittney U for non normal distributed data</p>	<p>No significant changes noted between IV1 and IV2 on DV1 or DV2</p> <p>The use of cerebral NIRS did not have an effect on the EEG or blood biomarkers for cerebral damage</p>	<p>Level of evidence: Level II</p> <p>Strengths: Data found during RCT, well designed multicenter trial, multiple data variables analyzed</p> <p>Weakness: EEG and biomarkers are not established markers for brain injury</p> <p>Application to practice: Additional justification for use of clinical guideline</p> <p>Conclusion: The SafeBoosC treatment guideline did not have a negative</p>

Key: **AGA** – Appropriate for Gestational age, **BP** - Blood pressure, **BPD** - Bronchopulmonary displasia **BS** – Brain sparring, **BW** - Birth weight, **cFTOE** - cerebral fractional tissue oxygen extraction, **CM/SGA** - Cardiac malformation or severe chromosomal abnormalities, **COI** - Conflicts of interest, **CSOR** – cerebral / splanchnic oxygenation ratio, **DD** - Demographic data, **DV**-dependent variable, **EC** - Exclusion criteria, **EEG** - Electroencephalographic, **ERC** - European Research Council, **F** - Female, **GA** - Gestational Age, **HR** - Heart rate, **hsPDA** - hemodynamically significant patent ductus arteriosus, **IC** - Inclusion criteria, **IUGR** – Intrauterine Growth Restricted, **IV**- independent variable, **IVH** - Intraventricular hemorrhage, **M** - Male, **mFTOE** – Mesenteric fractional tissue oxygen extraction, **MV** - Mechanical ventilation, **N**-number of studies, **n**- number of participants, **NEC** - Necrotizing Enterocolitis, **NIH** – National Institutes of health, **NIRS** - Near infrared Spectroscopy, **PC** - Parental Consent, **PNA** - Post natal age, **RDS** - Respiratory distress syndrome, **REF** - Research Foundation Flanders, **ROP** - Retinopathy of Prematurity **rScO2** - regional cerebral oxygen saturation, **rSrO2** - regional renal oxygen saturation, **rSmO2** – Regional mesenteric oxygen saturation, **SD** - Standard Deviation, **SMAV** - Superior Mesenteric artery velocity, **T** - Time,

								effect on EEG of preterm infants
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Appendix E

Synthesis Table

	Alderliesten	Bozzetti	Cerbo	Chock	Gillam-Krakauer	Hyttel-Sorensen	Pellicer	Pichler, Binder	Pichler	Plomgaard
Year	2015	2016	2012	2016	2013	2015	2013	2013	2016	2016
RCT						X			X	X (Extension)
NPRS				X						
POT					X					
SR							X			
OCS	X									
POS								X		
PCCS		X								
CS			X							
N	999	20	3	47	18	166		381	60	158
Ns							229			
Demographics										
GA range, (Mn)	24-31 (28.7)	29-33 (31 1/7)		25-28	25-31 (28)	25-27 (26)		34-40 (29.5)		(24.4-27.6)
BW range, (Mn)	0.770-1.375	1.157		0.66-1.038	(1.203)	0.410-1.33		2.259-3.386 (1.35)		0.41-1.33
Mn APGAR at 1,5 mins	7, 8	-, 9			7,8			9, 10	6, 8	
Setting										
NICU	X	X	X	X	X	X	X	X	X	X
United States				X	X					
Spain							X			
Europe						X (8 countries)				X (6 countries)
Austria								X	X	
Italy		X	X							
Netherlands	X									
Findings										
Creation of reference ranges	X	X						X		
Reduction in oxygen debt						X			X	
No negative impact to infant										X
Able to monitor for hsPDA			X	X						
Physiologic response					↓ post feed					
Measurement Interval										
Birth - Transition								X	X	
Birth - 72 hrs	X					X	X			X
Measurement device										
Invos used	X	X	X	X	X	X		X	X	X
Independent variables										
rScO2	X	X	X	X		X		X	X	X
rSrO2				X						
rSmO2		X	X		X					
cFTOE								X		

C- country, CS- Case study, hsPDA - hemodynamically significant patent ductus arteriosus, IUGR - Intra Uterine Growth Restricted, Mn- mean, N- number of subjects, NPRS- Non a-priori retrospective study, Ns - Number of studies, NICU- neonatal intensive care unit, OCS- Observational cohort study, RCT - Randomized controlled trial, PCCS - Prospective case-control study, POT - Prospective Observational Trial, POS - Prospective Observational Study, R- range, rScO2 - regional cerebral oxygen saturation, rSmO2 - regional mesenteric oxygen saturation, rSrO2 - regional renal oxygen saturation, SMAV - Superior mesenteric artery velocity, SR- systematic review

	Alderliesten	Bozzetti	Cerbo	Chock	Gillam-Krakauer	Hyttel-Sorensen	Pellicer	Pichler, Binder	Pichler	Plomgaard
Independent variables										
Cont.										
IUGR		X								
Non-IUGR		X								
Dependent variables										
Oxygen Debt						X			X	
hsPDA presence				X						
SMAV					X					
Time (post birth)	X	X						X		
EEG variance										X
Blood Biomarkers										X

C- country, CS- Case study, **hsPDA** - hemodynamically significant patent ductus arteriosus, **IUGR** - Intra Uterine Growth Restricted, **Mn**- mean, **N**- number of subjects, **NPRS**- Non a-priori retrospective study, **Ns** - Number of studies, **NICU**- neonatal intensive care unit, **OCS**- Observational cohort study, **RCT** - Randomized controlled trial, **PCCS** - Prospective case-control study, **POT** - Prospective Observational Trial, **POS** - Prospective Observational Study, **R**- range, **rScO2** - regional cerebral oxygen saturation, **rSmO2** - regional mesenteric oxygen saturation, **rSrO2** - regional renal oxygen saturation, **SMAV** - Superior mesenteric artery velocity, **SR**- systematic review

Appendix F

Rosswurn and Larrabee EBP model

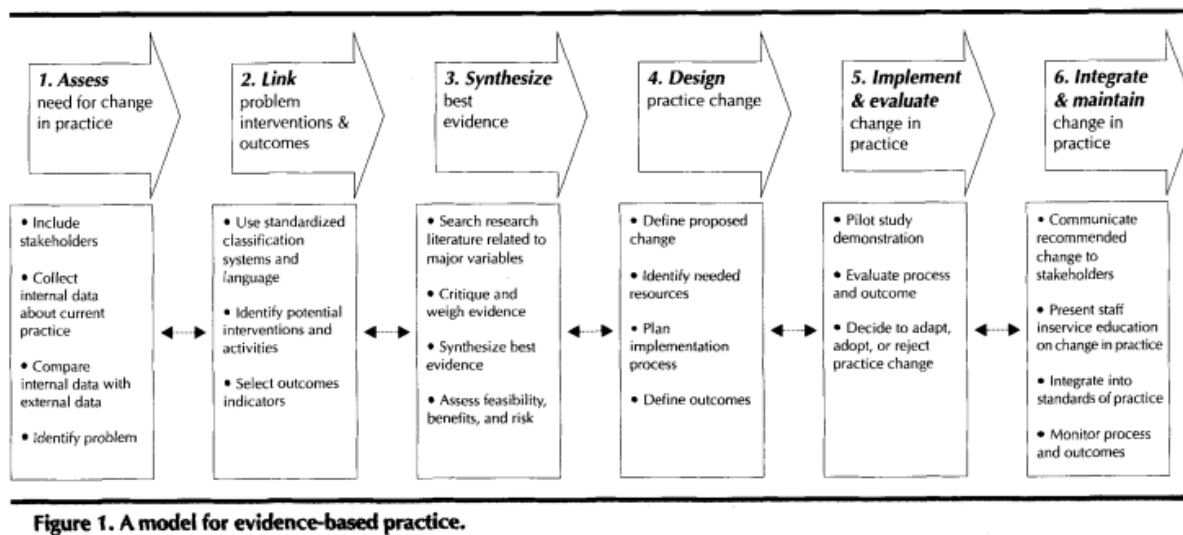


Figure 1. From Rosswurn, M. & Larrabee, J. (1999). A model for change to Evidence-Based practice. *Journal of Nursing Scholarship*.31:4, 317-322.

Appendix G

Survey to assess Provider Comfort and Confidence

Near-Infrared Spectroscopy monitoring for NICU patients

Study Information and Informed consent:

This survey was produced by Danlal Zeppelin NNPS, Arizona State University. This survey is being presented to you to assess your comfort and understanding of Near-Infrared Spectroscopy Monitoring (NIRS) use in the NICU. This project is being conducted to examine changes in your comfort and understanding after being presented with an educational session and your potential benefit is an increase in understanding. I (Dan Zeppelin) will be delivering your educational session and this survey will be presented ~1 week prior to the educational session and again 1 month after the educational session to examine for any changes in understanding and comfort. Additionally NIRS orders will be tracked for a ~4 month period to examine any change in clinical practice.

I (Dan Zeppelin) am a NNPS under the direction of Professor Joan Newby DRN in the College of Nursing and Health Innovation at Arizona State University am conducting a doctoral project to examine medical providers comfort and understanding utilizing Near-Infrared Spectroscopy monitoring (NIRS) in the Newborn Intensive Care Unit (NICU). I am inviting your participation which will involve pre and post educational session surveys taking approximately 10 minutes each and an education session taught by myself (Dan Zeppelin) lasting approximately 20 minutes with additional time for questions. Your participation is voluntary and you have the right to not answer questions and stop participation at any time without penalty. The potential benefit from participating is an increase in your knowledge regarding NIRS use and there are no foreseeable risks or discomforts to your participation. Survey responses will be kept confidential without the use of personal identifiable information and may be used for presentations and publication. If you have any questions concerning the research study, please contact the research team at: (Dan Zeppelin 612-201-8513 or Joan Newby 602-509-7512). If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Office of Research Integrity and Assurance, at (480) 965-6788. Please let me know if you wish to be part of the study.

1. Please create a anonymous reproducible identifier

Pick the name of your first car and the last four digits of your phone number. For example, if my first car was a Volvo and my phone number was 123-456-7890 then I would put volvo7890

2. I consent to participating in this project as outlined above.

Mark only one oval.

- Yes
 No

3. Role in NICU

Mark only one oval.

- Doctor
 Nurse Practitioner

4. Years of experience in current role

5. Years working for In current role

6. How frequently have you ordered NIRS monitoring on an NICU patient since EPIC go live

Mark only one oval.

- Zero times
- 1 - 2 times
- 3 - 4 times
- 5 - 6 times
- > 6 times

7. How frequently have you managed a patient with NIRS monitoring in place since EPIC go live

Mark only one oval.

- Zero
- 1 - 2 patients
- 3 - 4 patients
- 5 - 6 patients
- >6 patients

8. How frequently have you managed a patient with NIRS monitoring in place ordered by a colleague

Mark only one oval.

- Never
- Once
- 2 - 3 times
- 4-5 times
- > 5 times

9. How comfortable are you ordering NIRS in EPIC

Mark only one oval.

	1	2	3	4	5	
Not comfortable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very comfortable

10. How comfortable are you in reviewing nurse charting of NIRS data in EPIC

Mark only one oval.

	1	2	3	4	5	
Not comfortable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very comfortable

17. How comfortable are you utilizing NIRS for Infant resuscitation

Mark only one oval.

1 2 3 4 5

Not comfortable Very comfortable

18. How comfortable are you interpreting NIRS data when utilizing on a HIE patient

Mark only one oval.

1 2 3 4 5

Not comfortable Very comfortable

19. How confident are you understanding the difference between rCSO₂ and cFTOE

rCSO₂ means cerebral regional saturation and cFTOE means cerebral fractional tissue oxygen extraction

Mark only one oval.

1 2 3 4 5

No confidence Very confident

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