Use of Cord Blood for Admission Lab Testing in High Risk Neonates

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ABSTRACT

Background: As part of their care in the neonatal intensive care unit (NICU) most neonates require routine admission labs, which could equal up to 10% of their total blood volume. This, and the subsequent lab draws while in the NICU can predispose them to anemia and hypovolemia with the possibility of needing blood transfusions.

Local Problem: This QI project is being done in a twenty four bed level three NICU and in a twelve bed labor and delivery (L & D) unit in a major urban medical center in the Mid –Atlantic region. The current practice is to draw admission labs directly from the baby which is not only invasive but also traumatic and expensive considering the supplies used. Participants include registered nurses, neonatal nurse practitioners, neonatologists, laboratory personnel, and information technology staff.

Aim: To implement the feasibility of drawing admission labs from the cord blood as an alternative to the current practice of neonatal phlebotomy. The data collected will be the number of staff who are trained to the number of staff working in the L&D and NICU and the number of samples collected from the cord blood to the number of NICU admissions during this timeframe.

Interventions: The theoretical framework used here was the Plan Do Study Act. All nurses working in the labor and delivery and NICU and all high risk infants between 22 and 42 weeks who were admitted to the NICU were eligible to participate. An evidence based literature review guided improvement of current practice. Unit based practice guideline, power point presentation, competency checklist and data collection tools were prepared for education, training and data collection. Champions were selected and individual and group training sessions were done. Select cord samples were collected and sent to lab.

Results: Education was completed by 80% L & D nurses, and 80% NICU nurses. Samples were collected on 64.47% neonates admitted to the NICU. Based on the posttest administered after the education, 98% agreed that using cord blood for admission labs is safe and reliable and helps prevent pain and other complications.

Conclusion: The procedure has a high degree of usability and staff are continuing to collect samples from cord blood. In this present era where our focus is on quality improvement initiatives, making a wise use of available resources like umbilical cord blood will bring about a better outcome for the sick neonate and cost containment for the patients and their family as well as for the organization where it is implemented. In conclusion, cord sampling as an alternative to neonatal phlebotomy is an easily accessible procedure with the potential to improve the outcome of the sick neonates.

Use of Cord Blood for Admission lab testing in High Risk Neonates

Background and significance of the problem

Globally 15 million babies are born prematurely every year (World health organization (WHO, 2018). Complications related to prematurity are the leading cause of death among children less than five years of age (WHO, 2018). Majority of these deaths could be prevented with current cost-effective interventions (WHO, 2018). There is a 2% increase in preterm births nationally (Centers for disease control (CDC), 2017). In Maryland the percentage of low birth weight births for 2015 was 8.6% compared to the national average of 8.1% (CDC, 2017).

As part of their care in the neonatal intensive care unit (NICU) the very low birth weight (VLBW) neonates require routine admission labs drawn like a type and screen (T&S), complete blood count (CBC) with differential, blood gas, blood culture and a newborn screen (NBS). Their mean phlebotomy loss of almost 1.5 to 4 ml of blood on their first day of life is greater than 10 ml/kg which could equal up to 10% of their total blood volume (Carroll, & Christensen, 2015). This, and subsequent lab draws while in the NICU can predispose them to anemia and hypovolemia with the possibility of needing blood transfusions. (Baer, Lambert, Carroll, Gerday, & Christensen, 2013). Several strategies have been suggested to minimize these phlebotomy losses; one is utilizing umbilical cord blood for admission lab testing (Baer. et al, 2013). Besides reducing need for early transfusions and maintaining a high blood volume with the use of cord blood there was less vasopressor use in the first few days of life (Baer. et al, 2013). Results of CBC drawn from the umbilical cord showed no statistical or clinical difference to that taken directly from the patient (Baer. et al, 2013). A larger volume drawn for blood culture from the cord had the benefit of increased sensitivity (Carroll, P., Nankervis, C., Iams, J., & Kelleher, K.

2012). Type and screen of the cord blood is also widely accepted. (American Academy of Pediatrics (AAP), 2004). Umbilical cord blood is an underutilized resource. Drawing blood cultures as early as possible allows for early initiation of antimicrobial therapy. Cord blood sampling is non traumatic, non-invasive and cost effective. Doing admission labs on the otherwise discarded cord blood decreases the rate of transfusions and other complications (Baer. et al, 2013). Several stakeholders in the obstetric and neonatal areas have expressed interest in collecting cord blood for admission lab testing in the VLBW neonates.

The purpose of this quality improvement DNP project was to implement drawing admission labs from umbilical cord blood as an alternative to neonatal phlebotomy. The anticipated outcome was successful collection of the admission labs from the umbilical cord by the staff and sustainability of the project with ongoing sampling. The data that was measured was the number of staff who were educated about the procedure and the number of samples collected from the cord blood.

Theoretical Framework

The theoretical framework utilized to assist in the translation and implementation of project was the Plan, Do, Study, Act (PDSA) framework. This is a 4 step quality improvement model commonly used in health care to improve a practice or bring about a change (Institute for Healthcare Improvement (IHI, 2016). Originally known as Plan Do Check Act by Shewhart (PDCA), it was modified to the Plan Do Study Act (PDSA) or “Deming wheel” by Edwards Deming (IHI, 2016). The 4 steps are, Plan: develop the initiative, Do: implement the plan, Study: study the result and measure effectiveness, Act: if solution was successful, make further improvements (IHI, 2016). Step 1: Plan: The team should develop a plan to test or observe, to collect data, state the objective of the test and ask questions like, why the change, who will enact

the changes? When and where? What team training and preparation are required? Which patients will be affected and how? What results are expected? What process and outcome measures will be used? How and when will the team be informed of the progress? (IHI, 2016).Step 2: Do: try out the test on a small scale, carry out the test, document problems and unexpected observations and begin analysis of the data (IHI, 2016). Step 3: Study: Analyze the data and study the results. Compare the data analysis to your predictions. Summarize and reflect on what was learned (IHI, 2016). Step 4: Act: refine the change, based on what was learned from the test. After determining the modifications to be made, plan made for the next test and the cycle continued (IHI, 2016).

Literature Review

The literature review will analyze the evidence supporting the use of cord blood. The evidence summarized in appendix: A, support the use of cord blood for admission labs in the neonates.

The first study reviewed was by Baer et al. (2013). This was a prospective outcome study done in three centers. Cord blood was successfully drawn in 95% of the 96 neonates enrolled. A good matching of cases and controls was utilized based on demographic and severity of illness variables. Fisher's exact test, or a Mann–Whitney U test was used. In a 24 hour period there was an increase in Hemoglobin (Hb) among the cases and a decrease among the controls ($P<0.05$). There was a decrease in the number of cases who had transfusions ($P<0.001$), less use of vasopressors ($P<0.01$) and a decrease in IVH. The authors concluded that cord blood can be used in >95% for drawing admission labs.

The second study reviewed was by Carroll et al. (2012).This was a Cross sectional study of 174 paired samples using the paired t-test and Pearson's correlation coefficient for analysis of the results. There was no difference in the variables used except in the antenatal steroid given to

enrolled and un-enrolled patients. The study compared white blood cell (WBC) count, Hb and platelet count on samples from the cord and neonate and results were similar ($P<0.0001$) showing a high correlation ($R=0.82, 0.72, 0.76$). Minor differences were seen based on the source of sampling. The authors concluded that the cord blood was an acceptable source to test for a complete blood count with differential (CBCD) in the neonates.

This non-randomized trial by Kalathia, Shingala, Parmar, Parikh & Kalathia (2013) done in a tertiary care teaching hospital on 45 newborns, evaluated use of umbilical cord blood culture (UCBC) in diagnosis of neonatal sepsis compared to a neonatal sample. With a sensitivity of 80% and specificity of 91.43% and similar organisms seen in both culture samples the authors stated that UCBC can be reliably used for blood cultures samples.

The objective of the prospective study by Prakash, Decristofaro & Maduekwe (2017) evaluated the use of cord blood to admission CBC in 100 qualifying late preterm neonates. The authors used a two sample t-test or analysis of variance on paired samples. The results of the study did not demonstrate significance even after an unequal variance for differences in the hemoglobin (p=0.002), platelet counts (p=0.43), white cell counts (p=0.2) and absolute neutrophil counts (p=0.01) were taken into consideration which indicated that the neonatal blood sampling for CBC may be replaced with cord blood for admission labs.

A prospective cohort study by Rotshenker-Olshinka, Shinwell, Juster-Reicher, Rosin & Flidel-Rimon (2013) utilized 350 paired samples to evaluate the need for venipuncture. Two-tailed and Pearson correlation coefficients and a McNemar test were used. A p-value of .05 was considered significant. Significant correlation was found for white blood cell (r ¼ 0.683) platelets (r ¼ 0.54) and hemoglobin (r ¼ 0.36). There was a small percentage of contamination in the samples from the cord and peripheral cultures, though there were no positive cultures. The

authors concluded that cord samples for sepsis evaluation may be useful provided there is an adjustment in normal ranges.

The results of all five studies demonstrated support of use of cord blood for admission lab testing in the neonates. The validity of CBC was supported by four of the five studies and two of the studies showed that in paired samples the CBC and differential were equivalent (Baer et al, 2013 & Rotshenker-Olshinka et al, 2013).

Studies conducted by Baer et al, 2013 & Rotshenker-Olshinka et al, 2013 also support use of cord blood for blood culture done under strict aseptic technique. The advantage over direct patient sampling was an increased blood culture volume which increased the sensitivity of the sample. Cord blood has been routinely used for type and screen (Baer et al, 2013). The new born metabolic screening can be done utilizing the cord sample (Baer et al, 2013). Overall the researchers demonstrated a decrease in transfusions, a reduction in intraventricular hemorrhage (IVH), and decreased use of vasopressors with the substitution of cord blood. Though there were minor differences among the studies, overall evidence supports the use of cord blood for admission lab testing.

Project Implementation

The purpose of the quality improvement project is to minimize admission lab sampling directly on the neonate's admitted to the neonatal intensive care unit (NICU). This QI project was done in a 24 bed level 3 NICU and in a 12 bed Labor and delivery unit in a major urban medical center in the Mid –Atlantic region. Internal review board approval was obtained from the school and participating hospital. The participation of the staff in this project was completely voluntary. Inclusion criteria for the cord sampling were all the high risk newborns until 1hour of age admitted to the NICU between 22 weeks and 42 weeks of gestational age born at the

participating institution. Exclusion criteria were the neonates born outside the hospital, placental abruption, and multiple gestation, neonates transferred in from the nursery and those NICU admissions on observation status. The inclusion criteria for the nurse sample was based on the total number of nurses currently working in the two units at the time of project implementation and agreed to participate in the project. Exclusion criteria was those nurses on vacation and those who did not want to participate in the project. There were a total of 30 NICU nurses and 45 L&D nurses which includes the regular and PRN nurses working at the time of the project implementation.

The key stakeholders in this QI project were the nurse managers and nurses from NICU and L&D, others stakeholders were the neonatologists, obstetricians, and staff from the laboratory, blood bank, and personnel from the education and information technology department. Starting end of August to end of September 2018, educational materials to include the video and power point were emailed to all nurses. Individual and group training sessions were held at this time and meetings with the stakeholders to address questions and concerns. As staff were not able to access you tube video due to restrictions on the hospital computers, emails were sent to education department to add the educational materials on to ‘Health stream’ thus making it accessible to all. Also, it was easier to keep track of who all accessed the presentation through ‘Health stream’. Permission was obtained from the neonatologist to collect the newborn screen.

After discussion with the nurse managers from both the units on who and how the samples will be collected, email was sent out to all the nurses in L&D and NICU specifying the procedure for the sample collection and dispatch. The project leader randomly came in on off days and while on duty to check compliance and reminded staff in the L&D on the sample

collection process, thus ensuring project functionality. She also reminded NICU nurses of their part in the sample collection process. The project leader continued to provide education in the L&D regarding the change in procedure and the rationale for the same. She assessed the project frequently using the PDSA framework to maintain the flow and functionality. In general, the nurses in the L&D were successfully accessing the cord or placenta to draw samples of the ordered labs. The implementation took place from first week of October to the 10thDecember 2018.

Data collection was through prospective samples collected on cord blood obtained from a segment of the umbilical cord. The samples were labelled with a computer generated label and sent to the lab for analysis. On a data collection tool de-identified patient data was recorded with details on patient demographics, birth weight, gestational age and type of sample collected. To maintain confidentiality the data tool was kept in a locked cabinet in the NICU. During the second and third week of December final data extraction was done. Data from 'Health Stream' was entered on an excel spread sheet with details on who all completed the educational modules, the tests and procedure evaluation. Data was analyzed on a weekly basis using simple descriptive statistical analysis.

Report of changes in practice made

The implementation of this QI project brought about a practice change in the structure and process of certain admission labs being done on neonates being admitted to the NICU. As agreed by the managers from both the units, for a potential NICU admission, the L&D nurse collected the cord samples and handed over at least 0.5mls of blood to the NICU nurse, who filled the New born screen (NBS) document, signed it and took back the form for dispatch to the state lab. Through 'Health Stream' the project leader was able to keep track of those who

completed the education module. Initially education was focused both on the L&D and NICU staff, but since L & D nurses were primarily drawing the cord blood, education was more focused on the L&D department. Despite the refocus, the educational modules remained available to the NICU nurses as well. Majority of Nurses from NICU and L&D completed the education on drawing umbilical cord samples. Details as in table 3.0. The L&D nurses perfected the procedure and were successfully collecting samples when required.

Description of the results of the data analysis and outcomes

At the time of this project implementation there were 75 nurses in total in the L&D and NICU. Table 1.0 gives details of nurses who completed the education. Education was completed by 36/45 (80%) L & D nurses, and 24/30 (80%) NICU nurses. Among the 36 staff from L&D who completed the education 28, held full time positions and 8 held per diem positions. Of the 24 NICU nurses who completed the education 22 held full time positions and 2 held per diem positions. Table 2.0 indicates the demographics of the 49 neonates who had cord samples drawn and the 76 neonates who were admitted to the NICU during the time of project implementation.

A pretest and posttest were given to assess the knowledge level pre and post implementation. Scores of greater than 96% on the posttest attempted by 80% of nurses from both units proved that education did make a difference. Table 3.0 gives details of the pretest and posttest with the scores. Total number of admissions to the NICU during the 10 week period of the project was 76. Number of samples drawn from the cord blood were 49 (64.47 %). Figure 1.0 gives a comparison of samples drawn each week to the number of admissions each week. The remainder n=27 (35.52 %) did not have samples drawn as they were initially admitted on observational status or transferred in from the nursery. Samples were drawn on 27 male infants

and 22 female infants. The ethnicity of those infants on whom the samples were drawn was 11 Asians, 18 whites, 11 African Americans, 8 Hispanics and 4 with no nationalities listed.

Discussion

Most neonates require admission labs to be drawn on admission to the NICU. This iatrogenic blood loss can predispose the VLBW neonates to anemia and hemodynamic instability with the possibility of needing blood transfusion during their first week of life. The purpose of this QI initiative was to implement admission labs drawn on cord blood of neonates admitted to the NICU. Data measured was the number of staff who completed the education and the number of neonates who had samples drawn from the umbilical cord.

It was a challenge to implement a QI project within a 10 week frame to bring about a practice change. Particular strengths of the project were a very supportive clinical site representative and support from the staff in the 2 units, especially the labor and delivery nurses. A few nurses from both units were enthusiastic about the change in practice, they acted as champions and helped with the implementation of the project.

The project was successfully designed and implemented using the PDSA framework. The project itself met the goal of successful education of the L&D staff who have perfected the procedure of collecting samples from the placental vein or umbilical cord. Education was completed by 80% of nurses working in the NICU and L&D. Based on the posttest administered after the education, 98% agreed that using cord blood for admission labs is safe and reliable and helps prevent pain and other complications.

An advantage seen in collecting samples from the cord, was a large amount of blood could be collected and sent in a timely manner, thus minimizing the amount drawn from the baby. Samples were drawn in 64.47% of neonates being admitted to the NICU. Data from this QI

initiative does support the feasibility of drawing admission labs from the cord blood. In previous studies the feasibility of drawing admission labs from the cord blood was seen in 95% of VLBW deliveries where it was attempted, thus validity of the technique (Baer et al, 2013). Similar results were seen where this approach was implemented in three Intermountain Health Care NICU's where cord blood was used instead of direct phlebotomy (Baer et al, 2013).

Almost all the nurses in the labor and delivery unit have been successfully collecting samples from the placental or cord blood. Easy access to a noninvasive procedure and making use of cord blood which is otherwise discarded. A large amount of sample can be collected for almost all the admission labs in a timely manner. A large amount of blood remains in the cord even after cord clamping and milking. With training on the technique of accessing the cord a sufficient amount of blood can be collected for all the tests (Baer et al, 2013). There is also a benefit in terms of cost and the resources used (Baer et al, 2013). The nurses collected samples for blood type and coombs, blood gases and new born metabolic screen.

The main limitation was the lack of initial buy in due to concerns for false positive blood culture samples. Initially the neonatologists were not supportive but with the help of the clinical site representative, permission was obtained from the neonatologist to draw specific samples. Institutional review board approval was obtained both from the school and the site of implementation prior to initiating this QI project. A meeting was held with the managers from both the L& D and NICU units to specify how, and who will collect and send the newborn screen, and nurses from both units were made aware of the same.

Another limitation was a resistance to change. Resistance to change is seen with most implementation of practice changes. In order to overcome this, the project leader would suggest an interactive session with the staff and stakeholders involved to help with sustainability of the

practice change. Such a session would be of benefit to the institution, by making use of underutilized resources especially with the economic challenges most organizations are facing today (Bruckman, 2008).

The time period of 10 weeks to educate and bring about awareness and complete the educational module was also limited. Initially the educational module and video were emailed to all the staff, but due to restrictions in the hospital computers the video on drawing cord samples could not be accessed. The project leader was able to get help from the educational department and IT department to have the educational module and video posted on 'Health Stream' thus making it accessible to all. It was also convenient to keep track of who all completed the activity on 'Health Stream'.

Another limitation was, this was a convenience sample based on who was working at the time of the potential births and who was willing to collect the samples, and obtain an adequate sample. The project leader sent out emails every 2 weeks reminding staff and encouraging them to continue collecting the samples. It was preferable to have the samples collected as soon as possible after delivery to minimize chances of clotting. So infants who were initially sent to NICU for observation sometimes had to be under observation status for up to 6 hours and later got admitted to the NICU. These neonates were ineligible for placental lab draws. Other reasons when a sample could not be collected was inadequate blood from the placenta of extremely low birth weight babies, emergency or stat deliveries, outside or emergency department deliveries and multiple deliveries. In these situations, blood had to be drawn directly from the neonate by an arterial, venous or capillary draw.

Conclusion

Utilizing the plan do study act framework, the project leader successfully educated and implemented drawing neonatal new born screening and other labs from the cord blood. The process of collecting admission labs from the cord blood has a high degree of usability; besides being noninvasive the procedure has several benefits for those neonates especially the VLBW who are being admitted to the NICU. This procedure is becoming more popular with some institutions across the country successfully doing the procedure for several years.

Currently staff are continuing to collect samples from the cord blood. For the sustainability of the QI initiative, meetings with the clinical site representative and other stakeholders about the progress and results may be helpful. Champions or advocates to continue education, training and reminding staff to collect samples will also help with sustainability.

Umbilical cord blood is an underutilized resource which is otherwise wasted. Evidence supports its use for all the admission labs. Performing other quality improvement initiatives will be beneficial. Suggested next steps would be to form a dedicated multidisciplinary committee with permission of the neonatologists and administration, selecting a group of dedicated champions, providing education and training on strict aseptic technique, especially while drawing blood culture samples; these are future proposals for a practice change. The NICU nurses and practitioners should be dedicated to draw blood culture and other samples to minimize chances of contamination.

In the present era where our focus is on quality improvement initiatives, making a wise use of available resources like umbilical cord blood will bring about a better outcome for the sick neonate and cost containment for the patients and their family as well as for the organization where it is implemented. Cord sampling as an alternative to neonatal phlebotomy is an easily accessible procedure with the potential to improve the outcome of the sick neonates.

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Table: 1
Table of the number of nurses who completed education on cord blood sampling in the labor delivery and neonatal intensive care units

	Labor delivery	Neonatal Intensive Care Unit
Total number of nurses in the unit	n=45	n=30
Nurses who completed education	n=36	n=24
Completed working full time	n=28	n=22
Completed working per diem	n=8	n=2
Did not complete	n=9	n=6

Table: 2

Table indicates the demographics of n=49 neonates who had cord samples drawn. Total admissions to the NICU during the implementation period n=76

Characteristics		N	Percentage
Total admissions to the NICU		76	
Neonates who had samples drawn on cord blood		49	64.47%
Clotted samples/ Neonates admitted from New born nursery/ Admitted for observation only		27	35.52%
Demographics / Variables :			
Gender			
	Males	27	55.1%
	Females	22	4.89%
Race			
	Whites	11	22.44%
	African Americans	18	36.73%
	Asians	11	22.44%
	Hispanics	5	10.2%
	Others not listed	4	8.16%
Mode of Delivery			
	Cesarean sections	24	48.95%
	Vaginal deliveries	25	51%
Gestational Age			
	25 to 37 weeks	21	42.85%
	37 to 42 weeks	28	57.14%
Birth weight			
	< 2000gms	9	18.36%
	> 2000gms	40	81.63%

Table: 3

Table indicates pretest and post test results of the nurses who attempted it. N= 41 attempted pretest and N=60 attempted the posttest

Questions	Pretest	Right Answers	Posttest	Right Answers
Using placental or umbilical cord blood for NICU admission labs is safe and reliable.	N=41/75 (54.7%)	N=35/41 (85.3%)	N=60/75 (80%)	N=59/60 (98.3%)
Using placental or umbilical cord blood can be done with delayed cord clamping and/or umbilical cord blood banking.	N=41/75 (54.7%)	N=36/41 (87.8%)	N=60/75 (80%)	N=58/60 (96.7%)
Premature infants are at risk for hypotension, IVH and anemia from iatrogenic blood loss from NICU admission labs.	N=41/75 (54.7%)	N=41/41 (100%)	N=60/75 (80%)	N=58/60 (96.7%)
Using placental or umbilical cord blood for NICU labs helps prevent pain.	N=41/75 (54.7%)	N=38/ 41 (92.7%)	N=60/75 (80%)	N=59/60 (98.3%)
Using placental or umbilical cord blood for NICU labs helps prevent frequent blood transfusions.	N=41/75 (54.7%)	N=38/41 (92.7%)	N=60/75 (80%)	N=59/60 (98.3%)
Obtaining placental or cord blood for NICU labs is complicated and time consuming	N=41/75 (54.7%)	N=38/41 (92.7%)	N=60/75 (80%)	N=59/60 (98.3%)

Comparison of umbilical cord samples collected to the weekly admissions:

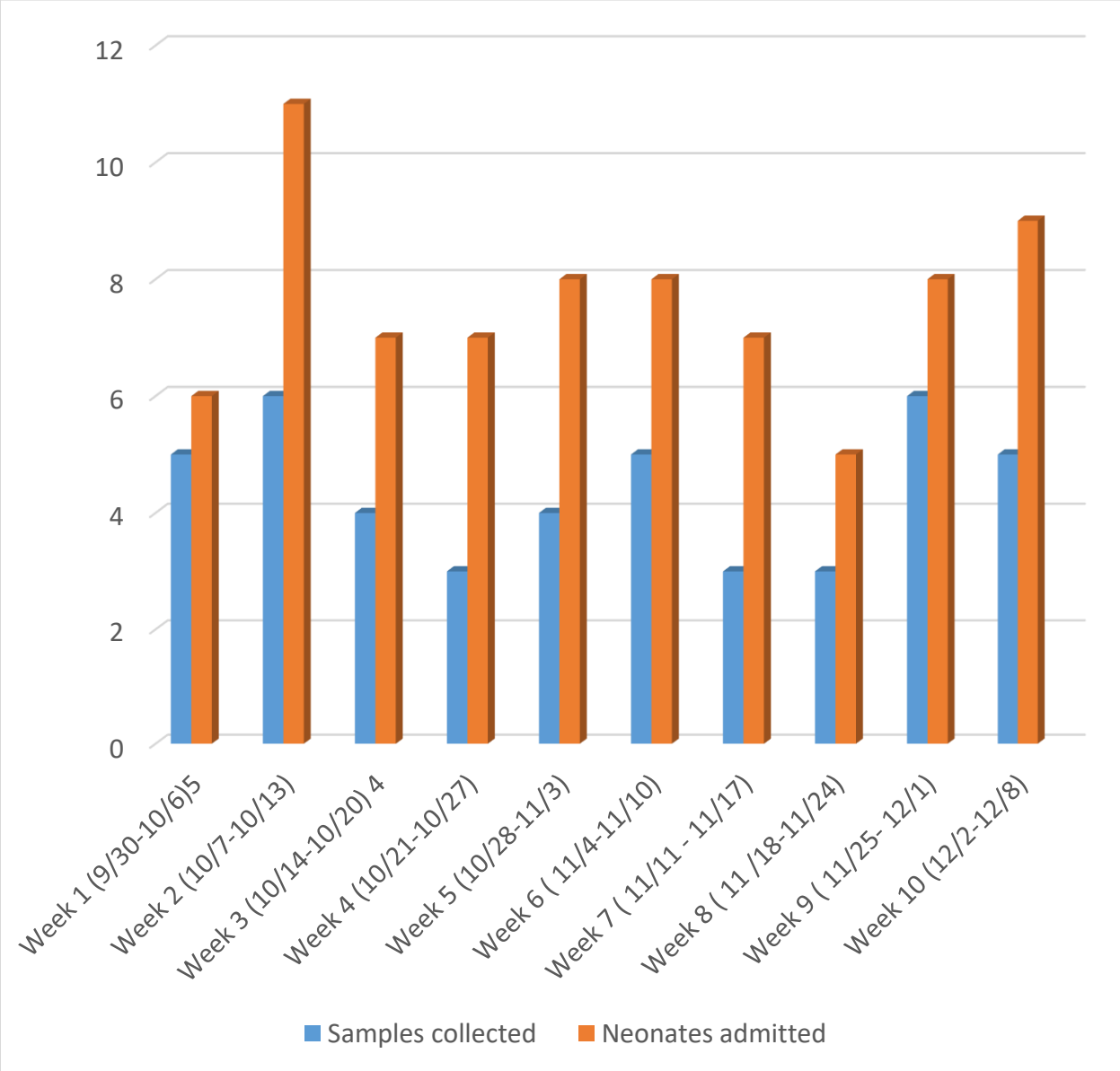

Figure 1: showing comparison of neonates on whom cord samples were collected weekly to the total neonates admitted. Moving the pointer over each bar shows the week of implementation on the 'X' axis and the value indicating number of neonates admitted on the 'Y' axis.

Appendix: A
Evidence Rating Table

Author, Year	**Study Objective/Intervention or Exposures Compared**	**Design**	**Sample (N)**	**Outcomes Studied (How measured)**	**Results**	**Level and Quality of Evidence**
Baer, V.L., Lambert, D.K., Carroll, P.D., Gerday, E., & Christensen, R.D. (2013).	This study was to measure the feasibility of obtaining the initial lab tests from the fetal blood from the placenta and to test the hypothesis that this results in higher hemoglobin and fewer erythrocyte transfusions in the first week after birth.	Multicenter prospective outcome study	This large multicenter trial enrolled N=96 VLBW patients and successfully obtained umbilical cord blood for admission laboratory testing in N=91.	Cases and controls were matched 1:1 on the basis of birth weight±200 grams, gestational age±2 weeks, gender, and severity of illness (SNAPPE II) scores±10 and maternal receipt of antenatal steroids. Blood hemoglobin concentrations measured at the time of delivery were compared with repeat values obtained 12 to	In 91 of 96 VLBW neonates (95%) the initial blood tests were successfully obtained with this method. The success rate was not diminished by delayed cord clamping or cord milking, as it was successful in 35 of 36 (97%) such instances. Cases and controls were well matched on demographic and level of illness comparisons. The cases showed an increase with hemoglobin for up to 24hrs while the controls showed a decrease ($P<0.05$). In the week following birth fewer cases received vasopressors ($P<0.01$) and erythrocyte transfusions ($P<0.001$). The authors concluded that in >95% cases admission labs can be done on the	III A

				24 h later. This study showed a decrease in erythrocyte transfusions, decreased intraventricular hemorrhage and decrease in the use of vasopressors.	umbilical cord blood.	
Carroll, P., Nankervis, C., Iams, J., & Kelleher, K. (2012).	This study was to support the hypothesis that a complete blood count (CBC) with manual differential from umbilical cord blood is equivalent to a CBC with manual differential obtained from the neonate on admission	Cross sectional study of paired samples of cord blood and direct patient testing.	174 paired umbilical cord blood and admission blood samples from infants <35 weeks gestation.	Paired t-test and Pearson's correlation coefficient were the primary statistical tools used for data analysis. . Each infant enrolled had paired samples of cord blood and admission blood sent to the laboratory for CBC/diff analysis.	Cord and admission blood white blood cell (WBC) count, hemoglobin and platelet count all significantly (P<0.0001) correlated with paired neonatal samples (R=0.82, 0.72, 0.76). Admission blood WBC count fell within the variation of WBC count values from currently accepted neonatal admission blood sources. Cord blood hemoglobin was not clinically different than admission hemoglobin (1.0 g dl^{-1}). Cord blood platelet counts were not different from admission blood platelet counts (5800 cells per μl, P=0.23). The immature to total	III A

					granulocyte ratio was not different between samples (*P*=0.34).	
Kalathia, M. B., Shingala, P. A., Parmar, P. N., Parikh, Y. N., & Kalathia, I. M. (2013)	The authors evaluated use of Umbilical cord blood culture (UCBC) in diagnosis of neonatal sepsis as compared to peripheral venous blood culture.	Non randomized well-designed controlled trial	N=45 This study was done in tertiary care teaching hospital during May-June 2012. A total of 45 newborns with presence of two or more risk factors of sepsis were included.	Blood sample from placental end of umbilical cord was collected and cultured. Primary outcome was diagnosis of neonatal sepsis by use of umbilical cord blood sample as compared with venous blood sample. Secondary outcome was to compare organisms identified by UCBC and venous blood culture.	A total of 24.44% (11 out of 45) high-risk newborns had positive UCBC. A total of 17.8% (8 out of 45) newborns had positive blood culture report. Organisms grown in UCBC were *Pseudomonas* (45%, 5 out of 11), *Acinetobacter* (27.27%, 3 out of 11), *Escherichia coli* (18.18%, 2 out of 11), and *Klebsiella* (9%, 1 out of 11). UCBC was stated as a good method for diagnosis of neonatal sepsis among high-risk newborns as compared to venous blood culture with a sensitivity of 80% and specificity of 91.43%. Organisms grown were comparable to blood culture samples.	III B
Prakash,N., Decristofaro,J., & Maduekwe,E.T. (2017, April 10)	The objective of the study was to evaluate the use of umbilical cord blood as an alternative to admission CBC in qualifying well	Prospective study where paired blood samples	N=100	Paired umbilical cord and admission blood CBC samples were compared using	There was no significant difference in the Hgb concentrations whether drawn from the artery or vein with p=0.002,there was no significant difference in	III B

	appearing late preterm neonates admitted to the neonatal intensive care unit	were collected from all well appearing late preterm infants.		a two sample t-test or analysis of variance with an unequal variance for differences in the hemoglobin, platelet counts, white blood cell counts and absolute neutrophil counts.	the platelet counts with p=0.43,the mean value of WBC difference between artery and vein was p=0.2,the paired difference in ANC was larger in females than males p=0.01.Overall there was no significant statistical or clinical difference in the cord and admission blood testing suggesting that the admission blood CBC may be replaced with an umbilical cord blood CBC.	
Rotshenker-Olshinka, K., Shinwell, E.S., Juster-Reicher, A., Rosin, I. & Flidel-Rimon, O. (2013).	This study was done to evaluate the need for a venipuncture, by comparing routine tests done for early neonatal sepsis in paired samples from umbilical cord and peripheral venous blood drawn during the first hours after birth in both preterm and term infants.	prospective cohort study	N=350 paired samples	Paired t-test and the non-parametric Wilcoxon test used to determine whether the differences between infant and cord blood test results were significant. The correlation between the results was examined using Pearson	Significant correlation between umbilical cord and peripheral venous samples was found for white blood cell (WBC; r ¼ 0.683) and platelets (PLT) (r ¼ 0.54). Correlation for hemoglobin was lower (r ¼ 0.36). No cases of early neonatal sepsis were detected. However, contamination rates were 12% in umbilical cord blood and 2.5% in peripheral venous blood cultures. WBC rose after birth and the 90th percentile rose from 22 500 in umbilical cord blood to 29	IV B

				correlation coefficients. For the qualitative approach, McNemar test was used. All tests were two-tailed and a 5% p-value was considered statistically significant.	700 in peripheral blood. Screening for sepsis with umbilical cord CBC may be useful provided normal ranges are adjusted accordingly.	

Appendix: B

Rating System for Hierarchy of Evidence

Level of the Evidence	Type of the Evidence
I (1)	Evidence from systematic review, meta-analysis of randomized controlled trails (RCTs), or practice-guidelines based on systematic review of RCTs.
II (2)	Evidence obtained from well-designed RCT
III (3)	Evidence obtained from well-designed controlled trials without randomization
IV (4)	Evidence from well-designed case-control and cohort studies
V (5)	Evidence from systematic reviews of descriptive and qualitative studies
VI (6)	Evidence from a single descriptive or qualitative study
VII (7)	Evidence from the opinion of authorities and/or reports of expert committees

Melnyk, B.M. & Fineout-Overholt, E. (2014). *Evidence-based practice in nursing & healthcare: A guide to best practice* (3rd ed.).

New York: Lippincott, Williams & Wilkins.

Rating Scale for Quality of Evidence

A: High – consistent results with sufficient sample, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific literature

B: Good – reasonably consistent results; sufficient sample, some control, with fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence

C: Low/major flaw – Little evidence with inconsistent results; insufficient sample size; conclusions cannot be drawn

Newhouse, R.P. (2006). Examining the support for evidence-based nursing practice. *Journal of Nursing Administration, 36*(7-8), 337-4

Appendix: C

Draft of practice guidelines for the use of umbilical cord blood for admission lab testing in the neonates.

As part of their care in the neonatal intensive care unit (NICU) the VLBW neonates require routine admission labs drawn like a type and screen, complete blood count (CBC) with differential, blood gas, blood culture and a metabolic screen. Their mean phlebotomy loss of almost 1.5 to 4ml of blood on their first day of life is greater than 10ml/kg which could equal to 10% of their total blood volume (Carroll, & Christensen, 2015). This, and the subsequent lab draws while in the NICU can predispose them to anemia and hypovolemia with the possibility of needing blood transfusions. (Baer, Lambert, Carroll, Gerday, & Christensen, 2013). Several strategies have been put forward to minimize these phlebotomy losses, one is utilizing umbilical cord blood for admission lab testing (Baer. et al, 2013).Besides reducing need for early transfusions and maintaining a high blood volume with the use of cord blood there was less vasopressor use in the first few days of life (Baer. et al, 2013).Results of CBC drawn from the umbilical cord showed no statistical or clinical difference to that taken directly from the patient(Baer. et al, 2013). A larger volume drawn for blood culture from the cord had the benefit of increased sensitivity (Carroll, P., Nankervis, C., Iams, J., & Kelleher, K. 2012).Type and screen on the cord blood is also widely accepted. (AAP, 2004).Umbilical cord blood is an underutilized resource. By obtaining an adequate sample immediately by a less skilled person helps the practitioner to dedicate their expertise to the sicker patients. Drawing blood culture as early as possible allows for early initiation of antimicrobial therapy. Cord blood sampling is non traumatic and non-invasive. Multiple peripheral attempts is not only painful but also expensive considering the supplies used. Therefore doing admission labs on the otherwise discarded cord blood decreases the rate of transfusions and its associated side effects in the VLBW. (Baer. et al, 2013).

Current Practice:

Admission labs are done on the premature and other high risk babies admitted to the NICU through an arterial, venous, heel stick or through an UAC/UVC.

Proposed change in practice:
Draw all admission labs CBC differential, blood culture, metabolic screen, blood gas, type and screen, chromosome analysis from the umbilical cord without causing a huge blood loss in the baby.

Goal of present practice: Avoid direct sampling from the neonate. The maternal fetal circulation is separated by a semipermeable membrane through which nutrition is provided to the feto-placental circuit(Caroll,2015).The blood in the umbilical cord reflects the fetal blood and doing the admission labs on this otherwise discarded cord blood can decrease the need for transfusions.

Procedure for Umbilical cord blood sampling:
Gather all supplies • Clean gloves • Sterile gloves • Sterile gauze • Betadine sticks • Alcohol swabs • 18 g needle • 10 ml syringe • Blood transfer device • 25 g needle • Blood culture bottle

• Type and screen tube • CBC with diff tube • Newborn screen card ,Optional tube for chromosomes

- Delayed cord clamping should still occur
- Remind the delivering provider to clamp the distal end of the cord
- Dry the placenta / cord insertion site with gauze
- Perform hand hygiene and don sterile gloves
- Swab the base of the cord insertion site
- Swab 3 times on the placenta up to 8-10 cm of cord
- Allow to dry 60 seconds
- Cleanse with alcohol swab
- Grasp the umbilical cord
- Insert 18 g needle into umbilical vein
- Insert bevel down • 6-8 cm above insertion site
- Aspirate 10 ml of blood
- Remove needle from syringe
- Wipe blood culture bottle with alcohol
- Transfer 1-2 ml blood into culture bottle
- Transfer proper volume of blood into tubes Type and screen , CBC with diff , Chromosomes, Drip blood onto metabolic screen spots , Label all specimens and send to lab
- Multiple births may be differentiated with clamps • one clamp for baby A • Two clamps for baby B • Three clamps for baby C

Appendix: D
Competency checklist:

	competent	**Needs to repeat**
Gathers all supplies Clean gloves • Sterile gloves • Sterile gauze • Betadine sticks • Alcohol swabs • 18 g needle • 10 ml syringe • Blood transfer device • 25 g needle • Blood culture bottle • Type and screen tube • CBC with diff tube • Newborn screen card ,Optional tube for chromosomes		
Remind OB to do delayed cord clamping		
Reminds the delivering provider to clamp the distal end of the cord		
Dries the placenta / cord insertion site with gauze		
Performs hand hygiene and dons sterile gloves		
Swabs the base of the cord insertion site		
Swabs 3 times on the placenta up to 8-10 cm of cord		
Allows to dry 60 seconds		
Cleanses with alcohol swab		
Grasps the umbilical cord		
Inserts 18 g needle into umbilical vein		
Inserts bevel down • 6-8 cm above insertion site		
Aspirates 10 ml of blood		
Removes needle from syringe		
Wipes blood culture bottle with alcohol		
Transfers 1-2 ml blood into culture bottle		
Transfers proper volume of blood into tubes		
Drips blood onto metabolic screen spots		
Labels all specimens and send to lab		

Appendix: E
Project Curriculum

Topic: Umbilical cord blood as an alternative to neonatal phlebotomy for admission lab testing

Objectives:

Describe benefits of using umbilical or cord blood for admission labs in the preterm neonates

Describe the risk factors associated with direct blood sampling from the neonates for admission labs.

Describe the process of sample collection from the umbilical cord or placenta.

Requirements for successful completion:

- Complete the online module , competency checklist and the post test

Schedule	The quality improvement project is anticipated to be implemented over a 10 week period from October to the middle of December 2018.
Starting end of August to end of September 2018.	Select 4-6 champions, project leader trains and tests proficiency of champions. On line module made available for learning. Meet with remaining clinical staff and explain why the change is necessary and address all questions and concerns, Train all NICU staff nurses. The champions will be divided into two shifts and have flexible shifts to assist with staff training and getting them competency checked. All completed competency checklists will be dated and signed and placed in each staff member's competency assessment folder. Collaborate with IT technician to have data entry sets in EHR if site requires it.
Starting October 2018 to 2nd week of December 2018	Initiate drawing admission labs on the cord blood, Meet with champions weekly to identify barriers. Address concerns and modify curriculum as needed. Compliance can be monitored by performing random chart checks and attending random deliveries. Champions will train new staff members or those who were on vacation as needed.
In November 2018	Continue with the implementation process. Meet with champions biweekly to identify problems. Compliance can be monitored by performing random chart checks and attending random deliveries. New staff members are trained and competency checked as needed.
By 2nd week of December 2018	Final meeting with champions to evaluate project implementation. Extract final data from data collection tools. Extend final appreciation to the Clinical site representative and all the stakeholders. Meet with hospital statistician to analyze and interpret data.
Beyond December 2018	Sustainability of this project. Staff continue to successfully draw admission labs on the cord blood.

Appendix: F

Tool for Data Collection

Infant Characteristics	N	Mean+/- SD	*P* Value
Time of Birth			
Birth weight in grams(mean +/- SD)			
Gestational age in weeks(mean +/- SD)			
Preterm			
Term			
Post Term			
Mode of Delivery:			
Vaginal			
Instrumental			
Caesarean			
Singleton delivery			
Five –minute Apgar score			
0-3			
4-6			
>7			
Tests done:			
ABG			
VBG			
Blood culture			
Metabolic screen			
CBC with Diff			
Chromosome analysis			
Type and screen			
Time when sample collected			
Insufficient sample			
Not correctly labelled			
Admission blood not sent			
Clotted sample			
Time of cord clamping after birth			
Staff characteristics			
Completed online training module			
Competency checked			
On vacation/PRN			
Completed post test			
Completed evaluation tool			

Appendix: G
University of Maryland Institutional Review Board Approval

From: CICERO@som.umaryland.edu <CICERO@som.umaryland.edu>
To: "rgeorge@umaryland.edu" <rgeorge@umaryland.edu>
Sent: Tuesday, July 31, 2018, 11:22:06 AM EDT
Subject: Research is Not Human Subjects Research

Not Human Subjects Research (NHSR) Confirmed

To: Ronie George

Link: HP-00082012

An IRB Analyst has reviewed the information provided and has determined that the project meets the definition of *Not Human Subjects Research* (NHSR). IRB oversight is not required and no further actions are required.

Description:

Submission Title: Umbilical cord blood for admission lab testing: NDNP 811

POC: Claire Bode

Please contact the HRPO at 410-706-5037 or HRPO@umaryland.edu if you have any questions.

University of Maryland, Baltimore

Template: HP_NHSR Confirmed