Official Title: Compare the Q-Cup With Other Umbilical Cord Blood Collection Techniques

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Study Title: Compare Q-Cup with other umbilical blood collection techniques for umbilical cord blood collection and transfer to laboratory tubes: A Feasibility Study

Principal Investigator: Sireesha Reddy, M.D., M.S.

Co- Investigator: Michael Schaffer, M.D. and Zuber D. Mulla, MSPH, PhD

I. Abstract:

Currently there is no standardized method of collecting and transferring umbilical cord blood to laboratory vacuum tubes. Current methods are messy and may require needles to draw the blood presenting risk of blood exposure and percutaneous injury to obstetrical personnel. A safer, more efficient method of collecting cord blood is needed. We propose to use our Q-Cup technology for collecting cord blood. Our Q-Cup device is a two-piece injection molded blood collection and transfer device that enables safe and easy collection of blood from the newborn's umbilical cord and readily transfers the blood into a laboratory vacuum tube. The device consists of a collection cup with a wide opening to easily collect blood from the umbilical cord and a guide tube with a recessed needle which is attached to the collection cup. The operator is enabled to fill the required vacuum containing tubes in a clean, quick, efficient and safe manner by simply inserting the vacuum tube into the guide tube of the Q-Cup. As a result, there is less risk of blood exposure and percutaneous injury and blood is collected more efficiently. This device allows the practitioner to collect and transfer umbilical cord blood: without the need for removing the stopper from the vacuum tube (reducing mess and contamination) and without the need for a syringe and exposed needle (reducing injury and infection).

II. Background

Approximately 4 million babies were born in the United States in 2015.[1] Umbilical cord blood (UBC) collection is a routine hospital procedure done to evaluate a newborn's health after the birth of the fetus. UBC is tested to measure bilirubin levels, blood gases, blood sugar levels, blood types, complete blood counts, and platelet counts. [2] UBC is collected by either draining the blood into the collection vial, milking the umbilical cord of blood, or extracting the blood by injecting a needle with a syringe. The Center for Disease Control (CDC) estimates 5.6 million workers in the health care industry are at risk of occupational exposure to bloodborne pathogens. [2-5] Occupational exposure during umbilical cord blood collection may occur due to the great deal of blood and amniotic fluid present at the time of delivery. This fluid causes the physician to have a slippery grasp on the umbilical cord and vials for collection. These methods pose a risk of exposing Labor and Delivery staff to blood borne diseases. The drainage and milking method can lead to an increased amount of spilled blood while the extraction method may lead to accidental needle sticks. Exposure to bloodborne pathogens may be amplified when the umbilical cord is engorged with blood and as the needle is inserted in the cord, splatter may occur. [6-8]The Needlestick Safety and Prevetion Act was signed into law on November 6, 2000 in which employees were required to implement safer medical devices. [5]l Many patents have been obtained for umbilical cord blood collection devices[3,7,9], however, there has not been a standardized method of collecting and

transferring umbilical cord blood to the laboratory vacuum tubes. The goal of this project is to prove the feasibility of using the Q-Cup, a patent pending disposable, two-piece blood collection and transfer device for safely and efficiently collecting umbilical cord blood and transferring it into laboratory vacuum tubes.

III. Objective

The overall objective of this project is to prove the feasibility of using a two-piece umbilical blood collection and transfer device for safely and effectively collecting umbilical cord blood and transferring the blood into a laboratory vacuum tube. Also we will assess provider satisfaction, safety, ease of use, length of procedure comparing passive flow into blood tubes and the Q-cup technology. The Q-Cup technology can take part in the effort to reduce occupation exposures including percutaneous exposures during labor and delivery in general and by studying specifically the heretofore neglected category of umbilical cord blood collection and transfer. Our efforts in this area will help focus attention on this previously ignored domain and help establish a standard of care and safety during this frequent procedure.

IV. Hypothesis

We hypothesize the Q-Cup will be a more effective transfer method than current practices utilized for umbilical cord blood collection.

IV. Study Design and Procedures

a. Setting. University Medical Center at El Paso Labor and Delivery unit.

b. Target Population. This study will consent OB patients to use the Q-cup, however, the actual feasibility project and evaluation of the Q-cup will be conducted by healthcare providers.
    a. Providers (Certified Nurse Midwives, Residents, Medical Doctors) employed at the Texas Tech University Health Sciences Center El Paso
    Blood transfer method: Blood will be collected as a standard of care from the expelled umbilical cord.
    b. Patients delivering at University Medical Center
    Patients with established care at Texas Tech University Health Sciences Center El Paso and who will be delivering their baby at University Medical Center will be recruited to participate in this study. Their expelled umbilical cord blood will be used to test the Q-cup device. Inclusion criteria will include: women over 18 years of age, in their third trimester of pregnancy and receiving their prenatal care with a TTUHSC El Paso provider.

c. Procedure:
    a. Providers:
        i. Delivery providers will be added to the research protocol. The research personnel will introduce and train the use of the blood collection methods

to the delivery providers; Providers will be trained on the Q-cup collection and review the standard collection currently used (drain umbilical cord blood into the vial). This project will not have an impact on direct patient care. At the time of delivery, the Q-cup will be provided to the provider in a sterilized bag. The bag is opened and the vacuum tube with needle is inserted into the barrel of the Q-cup.

ii. The expelled umbilical cord is usually clamped after delivery.

iii. The clamp is then opened and the blood specimen is drained into the blood vial or will be drained into the Q-cup.

1. If the Q cup is involved, then an additional step will be to use vacuum pressure to push the blood specimen into the vacuum collection tube.

iv. The tube is rinsed in saline and sent to the lab for standard of care.

v. The provider will fill out a data sheet to assess safety, ease of use, and length of procedure. The provider will also fill out a survey to assess their satisfaction and other questions on blood collection techniques comparing the standard method, passive flow to the Q-cup technique.

b. Patients

i. Patients will be recruited at the TTUHSC EP OBGYN Clinic. The clinical personnel will introduce the study to the potential participant. If the participant would like to hear more information, research personnel will be called to explain in more detail, assess eligibility, and describe the consent process.

ii. If the patient would like to participate in the study and meets eligibility, she will be asked to sign a consent form and will be randomly placed into the control or study (Q-cup) group. Participant will be given a laminated card to pack in her hospital bag directing her to take this card with her to the hospital when she goes into labor.

1. The card will indicate to hospital staff that she is participating in the study.
2. The participant will give the card to her assigned nurse who will inform the providers on duty about the participant.
3. The card will indicate if the participant is in the control or study (Q-cup) group.

iii. Eligibility states the participant must be pregnant in their third trimester since the actual feasibility of the Q-cup will take place when the baby is delivered and cord blood is collected. Due to this, all participants in the study are expected to be admitted to the hospital. When participants are admitted to the hospital to deliver their baby, this will not be considered an unanticipated event.

iv. At the time of delivery, umbilical cord blood will be collected and sent out to the lab for standard testing.
    1. If the participant is in the control group, umbilical cord blood will be collected per the hospital standard.
    2. If the participant is in the study group, umbilical cord blood will be collected with the Q-cup.
v. This research study will not collect any of the participant's specimens for research purposes.

V. Data analysis: Anticipating the average lengths of cord blood collection with the standard method is 15 seconds and 30 seconds with the Q-cup, we will need 30 subjects total. 15 in the Q-cup arm of the study and 15 in the comparison group (for a two-sided two-sample t-test with 80% power, an alpha of 0.05, and a common standard deviation of 14 seconds). Data will be entered into REDCap by research personnel and will be analyzed using SAS 9.3. Data will be coded appropriately for missing information as 999, and "not applicable" sections as 88. Additionally, frequencies and tabulations will be created from the collected data.

VII. References

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