SAFETY DEVICE FOR DOUBLE VOLUME EXCHANGE TRANSFUSION

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ABSTRACT

Bilirubin is a yellow breakdown component that is found in the human body due to the decay of red blood cells. Although bilirubin is natural to the body, the concentration can reach levels that are too high for the body to handle, which can then cause harm to the body. These dangerously high concentrations are referred to as Hyperbilirubinemia. Infants are particularly susceptible to Hyperbilirubinemia due to their underdeveloped bodies. When infants are found with too much Bilirubin in their blood, they must undergo treatment to reduce its levels. Most commonly, babies will undergo phototherapy, which is a successful procedure that employs light. If concentrations are too high for phototherapy, the baby will need a double volume exchange transfusion instead. This transfusion removes twice the baby's blood volume with donated blood in order to maximize Bilirubin removed from the body. This procedure is extremely rare, occurring about once every three to five years at a hospital the size of Meriter. When two catheter lines can be inserted into the baby, the procedure has few setbacks and uncertainties. However, if only one catheter can be inserted, then the procedure becomes more complicated for the doctor. These complications are due to the un-intuitiveness of the four-way stopcock design and the complicated stopcock connections. Due to both the rarity and complicated setup of the procedure with a four-way stopcock, the client has asked for a device that will improve both the intuitiveness and safety of this procedure with the four-way stopcock. The device consists of four parts: a base for the stopcock with color coding and rotation directions, an 18 micron blood filter, an air emboli detector, and a counter system to track the amount of blood removed from the baby. To further this project the team will be fabricating the base and counter system, as well as purchasing the filter and detector.

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INTRODUCTION

Background and Motivation

Hyperbilirubinemia, a severe form of Jaundice, is a condition that is caused by high concentrations of a naturally occurring substance called bilirubin. Bilirubin is normally found in low concentrations throughout the blood and is formed as a byproduct when red blood cells break down [1]. As bilirubin builds up in the blood system, it starts to deposit under the fatty tissue and turns the skin yellow. In larger concentrations, it can act as a neurotoxin and ultimately cause seizures and brain damage [2].

Jaundice is normally a harmless, temporary condition that effects up to 50% of newborn babies. Since the liver is responsible for filtering out and eliminating bilirubin, infants, who often have underdeveloped organs, are especially susceptible to Jaundice. However, the bilirubin levels rarely reach threatening concentrations and normally return to normal within a couple of weeks [3]. Although Jaundice does not normally require treatment, if the bilirubin levels continue to rise and Hyperbilirubinemia is reached, immediate medical intervention is needed.

Current Treatments

Currently, there are two main treatments used to treat Hyperbilirubinemia: phototherapy and the double volume exchange transfusion. Phototherapy is the most common treatment, which surrounds the baby with a special wavelength of blue light, usually in the 460-490 nm range [4]. Figure 1 shows a typical Phototherapy bed that is used to administer the treatment to newborns. The wavelength is used because it maximizes the decomposition rate of the bilirubin to a less toxic, water-soluble form that the baby can better eliminate [5]. This procedure is non-invasive, has a very high success rate, and has minimal complications and risks involved.

Figure 0: A phototherapy unit used to to treat Hyperbilirubinemia[7].

The other treatment that is used is a double volume exchange transfusion. This transfusion is reserved for cases where phototherapy has failed to work or where the concentrations of bilirubin are so high that they have to be relieved immediately [6]. In this procedure, an umbilical catheter is inserted into a baby to exchange the baby's blood for donated

blood. In order to maximize the amount of bilirubin that is withdrawn from the baby, they exchange the baby's total blood volume twice. On average, they have to withdraw about 500 mL from the baby and this can take up to 4 hours to complete. An important, and often confusing component of the double volume exchange transfusion is the 4-Way Stopcock (Figure 2). This device is used to connect the syringe (inserted on the top) with the three other ports that consist of the baby's catheter, the donated blood bag, and the waste bag. In order to ensure that the blood makes it to the correct destination, it is vital that the handle only be turned clockwise. This device is rarely seen outside of this procedure and due to the decline in the number of procedures performed, it is a component that commonly leads to doctor insecurity on the setup and execution of the procedure.

Figure 2: Four-way stopcock similar to the one included in the hospital transfusion kit [8].

DESIGN CRITERIA

The design must be sterile, comfortable, compact, and accurate. It cannot interfere with any part of the procedure or compromise the safety of the patient in any way.

Firstly, the device needs to be sterile. In order to meet the standards of Infectious Control at Meriter Hospital, any component of the device that may be exposed to or contact blood must have the ability to be autoclaved in order to prevent cross contamination between patients. Autoclave parameters are normally set at 120°C for at least 30 minutes.

Additional features added to the procedure must be comfortable, portable, and as accurate as possible. Since this is a long procedure, any part of the device that is to be held (such as a new base) must be lightweight and comfortable for the medial personnel to use for up to four hours without adding any additional strain. Any part of the device that cannot be held must be small enough to fit in the bed with the baby or be light enough to be set onto the baby's chest during the procedure. If a counting component is added, it must be reliable in order for it to be used as a reference for the hand written charts. Ideally, it should have a readable accuracy of a minimum of 5 mL.

All components of the design must last throughout the whole procedure, especially those that require power, in order to ensure that it does not malfuction in the middle of the procedure. Any component that is not disposable must also have a shelf life that lasts at least 10 procedures.

Lastly, the device should be safe and comfortable for both the medical personnel and the patient. No component should interfere with the execution of the procedure and the components that are not held during the procedure must not harm the fully conscious baby. The budget given by the client is $500.

Overview of Design Alternatives

The proposed design consists of three main parts: a new base, a counting device, and additional safety devices. The new base will attach to the bottom of the stopcock, locking it into place. Its main function is to provide clarity in order to make the setup and execution of the procedure more intuitive. The second component is some sort of counting device. This will be used as another reference to the doctors as to how much blood has been taken out of the baby. Lastly, additional safety features will be incorporated into the design in order to decrease the most common causes for morbidity and mortality in the infant—blood clots and air emboli.

Stopcock Base Designs

The base design's primary purpose is to clearly identify between the stopcock ports and to provide a comfortable handle for the user. As shown in Figure 3, the top view of the stopcock contains three colors to differentiate between the ports - light blue is to the baby, yellow is to the waste, and red is to the blood. The top also includes a labeled arrow that signifies the correct clockwise rotation of the stopcock. The stopcock is held to the base with adjustable clamps that snap onto the ports of the stopcock. In order to further secure the stopcock onto the base, the white T-shaped block

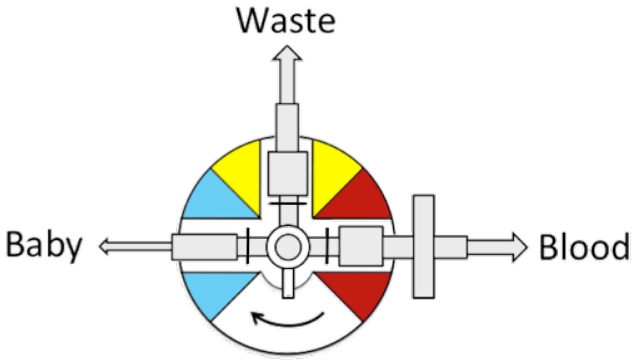

Figure 3: Top view of the stopcock connected to the base. The ports are identified with colors and the arrow ensures counterclockwise rotation of the stopcock.

is indented within the base so that the stopcock can sit within the groove of the base.

Once the top design of the base was finalized, four designs for the bottom were considered (Figure 4). The first design is a round-bottom base, which is a spherical ball approximately the size of a tennis ball (60 mm in diameter). The second design is similar to the first design in that the top is shaped spherically, but with a flat bottom. This bottom allows the base to be set on top of flat surfaces. The third design is a vertical handle, with an approximately 2.5 cm cross-sectional diameter and 10 cm length. Lastly, the fourth design is a loop handle where the user can put their hands through the base. The loop handle has an inner diameter of 9.5 cm on its major axis, and an inner diameter of 5 cm on its minor axis. Its thickness has a cross-sectional diameter of approximately 2 cm. The dimensions decided for these designs were based on research of the human hand. The average length of an adult male hand is 189 mm, the average length of an adult female hand is 172 mm, the average hand breadth for adult males is 84 mm, and the average hand breadth for females is 74 mm [9]. These designs were designed for an average adult male hand so that the final base can be used by both males and females.

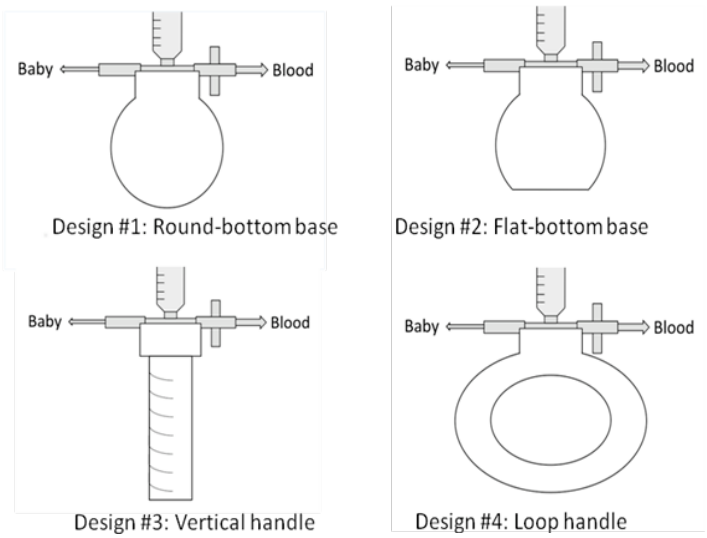

Figure 4: Side view of base designs, which include the round-bottom base, the flat-bottom base, the vertical handle, and the loop handle.

Evaluation of Stopcock Base Design Alternatives

In order to choose the final design, a design matrix was created that rated each reservoir design alternative on seven criteria: comfort, stability, versatility, weight, occupied space, and ease of fabrication. The design matrix for the four possible base designs is shown in Table 1. The more significant criteria were weighted more heavily, and the total weight of all criteria sum to 100.

Table 1: The design matrix for the bottom of the base, which includes the round-bottom, flat-bottom, vertical handle, and loop handle designs.

Criteria	Weight	Round-bottom	Flat-bottom	Vertical handle	Loop handle
Comfort	30	25	20	17	16
Stability	25	14	21	9	12
Versatility	20	16	15	5	18
Weight	10	2	4	9	6
Occupied space	10	7	8	5	3
Ease of fabrication	5	4	4	5	1
Total	**100**	**68**	**72**	**50**	**56**

Comfort was given the highest weight because the transfusion procedure is 2 to 4 hours long. The user must be comfortable with the base for the entirety of the procedure. Along those same lines, stability is also a key factor because the base should be able to sit on a surface in case the user decides to set the base down. With this criterion, the flat-bottom base design outweighs the rest because of the flat bottom incorporated into the design. The other designs do not have the proper center of gravity or the proper weight distribution to keep the base and stopcock system upright without support.

Versatility was next in weight, which was defined as the variety of ways the base could be held. The loop handle was speculated to have the most versatility because the user has flexibility with the loop. The round-bottom and flat-bottom received a lower score because even though the position of the grip can be shifted around the base, the user's wrist is limited to the same position. Lastly, the vertical handle received the lowest score because it allows no variability.

The weight and occupied space criteria were determined based on the amount of material and the size of the base, respectively. Since the base is to be fabricated out of polypropylene, the material for all four bases is the same. Therefore, the weight is a direct function of the amount of material used in the design. This leads to the vertical handle being the lightest and the round-bottom being the heaviest. The occupied space is a function of its size and how much space each design requires. Since the round-bottom and flat-bottom are most compact, they received the highest scores for occupied space. The loop handle received the lowest score.

The final criterion was ease of fabrication, which received the lowest weight. The loop handle is by far the hardest to fabricate because of the hollow middle and large surface area. All in all, the flat-bottom base received the highest score and will be the pursued design.

Counter System Designs

The second component of our design is the counter system that will help keep track of the amount of blood withdrawn from the baby. During the entire procedure, the baby's vitals are recorded frequently, including the amount of blood withdrawn. Therefore, the counter system can reduce the amount of work for the medical personnel performing the procedure and serve as a safety check.

The team's first idea was to use a mechanical counter and variations of the mechanical counter to implement into the design. However, after extensive research, it was decided that a mechanical counter may not suffice, and that other alternative designs need to be considered. This led to four proposed concepts for the counter system that includes a mechanical counter, a waste bag scale, a waste container, and a flow meter. These concepts are illustrated with representative images in Figure 5.

The first design is a mechanical counter, which uses gears and a tally clicker to increase the count. The mechanical counter would count the number of revolutions of the stopcock, and one revolution would correspond to 5 mL withdrawn from the baby. The second design, the waste bag scale, records the weight of the waste bag, either by hanging the waste bag, or by placing the waste bag on top of the scale. The third design is to

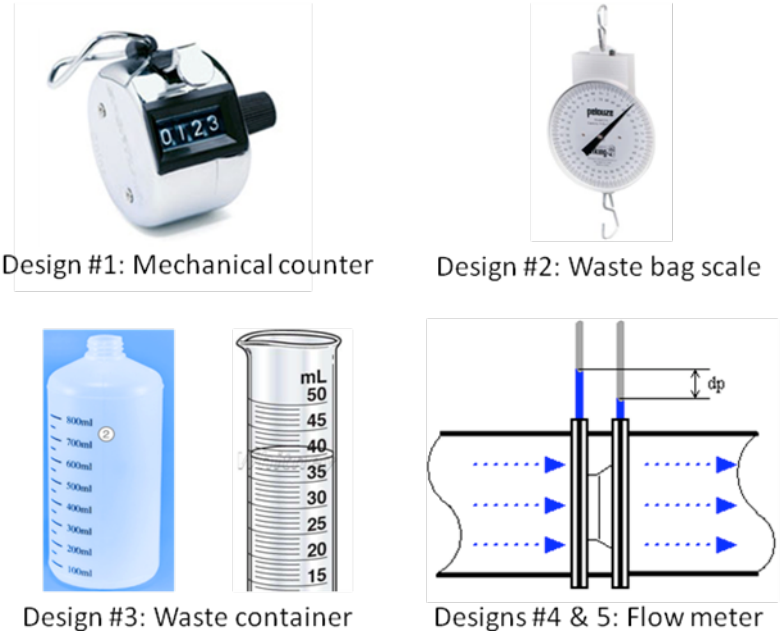

Figure 5: Conceptual designs for the counter system, which include the mechanical counter, the waste bag scale, the waste container, and the flow meters [10] [11] [12] [13] [14].

completely redesign the waste container. Currently, the waste bag is a two-liter bag that is not designed specifically for the double volume exchange transfusion (Figure 6). Since the procedure only expels approximately 500 mL of blood overall, the two-liter bag is not necessary. Therefore, the goal of design three is to redesign the waste container to hold a volume more suitable for the procedure and be accurate to the 5 mL mark. The fourth and fifth designs are both types of flow meters but are located in different parts of the stopcock system. The syringe flow meter will be attached between the syringe and the stopcock with a luer-lock mechanism. Similarly, the line flow meter will be attached between the line to the waste bag and the stopcock.

Figure 6: The current waste bag from the double volume exchange transfusion kit.

Evaluation of Counter System Design Alternatives

A design matrix was created to aid in making the decision between the five alternative counter system concept designs. The matrix was weighted on six different criteria, with the client's most important criterion of accuracy most heavily weighted. The criteria from heaviest to least amount of weight are as follows: accuracy, sterilization, size, feasibility, shelf life, ease of fabrication, and cost (Table 2).

Table 2: Counter system design matrix, which includes the mechanical counter, the waste bag scale, the waste container, the syringe flow meter and the line flow meter.

Criteria	Weight	Mechanical Counter	Waste bag scale	Waste container	Syringe flow meter	Line flow meter
Accuracy	25	22	20	18	23	23
Sterilization	25	8	23	23	8	15
Size	20	10	15	16	13	18
Feasibility	10	6	9	8	5	3
Shelf Life	10	6	8	9	4	5
Ease of Fabrication	5	1	5	4	1	3
Cost	5	2	4	4	2	1
Total	**100**	**55**	**84**	**82**	**56**	**68**

Among the top weighted criteria are accuracy and sterilization. Since this counter system is to serve as a safety check, the team decided that accuracy should be given the largest weight. The flow meters scored the highest because they can provide an exact volume that passes through. The waste container, however, can only be accurate to the 5 mL marking, and depending on the angle of reading, can provide a different reading for each person.

Sterilization was given the same weight as accuracy because the counter must be autoclave compatible to prevent cross-contamination between patients. This criterion was one of the limiting factors for incorporating the design into our system. In order to be autoclaved, the device must withstand a temperature of 121°C. Because of this, only the waste container can operate after autoclaving. The waste bag scale scored just as high because it does not come in direct contact with blood and thus does not need to be autoclaved. The mechanical counter and the flow meters both involve circuitry that fails after exposure to high temperatures. They also must be autoclaved due to their close proximity to the blood.

The size is another important factor because the device must be small enough to hold or place near the baby. Since the waste bag scale and the waste container are not directly involved with the stopcock setup, the two designs received the highest scores because size is not a factor when far from the baby.

Feasibility is the practicality of the design. The waste bag scale is the most practical and easiest to implement because it does not directly involve the blood, unlike the others. The flow meters would require the most research and testing to make sure that they would be compatible with blood and with the low flow rates.

Shelf life is how well the device would last, and the ease of fabrication and cost are criteria that factor into our labor. As shown in Table 2, the waste bag scale and the waste container scored much higher than the rest. However, because the designs only differ by 2 points, the team decided to further investigate and research the two designs before arriving at a final decision.

Final Design

Based on our design matrices and our preliminary research, the four components chosen for our final design are the flat-bottom base with the color coded top, an 18 micron blood filter, an air emboli detector and either the waste bag scale or the new waste container. These

components are going to be an addition to the transfusion kit that the hospital already uses. Our main goal for this semester is improvement of both the safety and intuitiveness of the double volume exchange transfusion.

The base is the main component to improve the intuitiveness. The top of the base will be the anchor for the stopcock and act as a resource to increase doctor confidence in the procedure and the setup. The base will be made entirely out of polypropylene, a very strong plastic that can withstand high pressure and temperatures, to ensure that it can be autoclaved in between patients and procedures. The counter system will be incorporated into the waste bag. Depending on future research, the waste bag in the kit will either be replaced or it will be incorporated with a scale during the procedure.

The team has chosen an 18 micron blood filter shown in Figure 7. This filter will be directly attached between the blood bag line and the blood bag stopcock port. This particular blood filter was chosen because the hospital already uses it in the Neonatology Intensive Care Unit (NICU) as a part of a different procedure. This filter will help to reduce the number of blood clots that can potentially enter the baby. In order to prevent air emboli from entering the baby, the team has also chosen the AD 8 sensor from Introtek seen in Figure 7. This sensor will fit onto the extension line connecting the stopcock to the catheter in the baby. Every time air passes though the line towards the baby, a light on the sensor changes from green to red. The team plans to add an alarm circuit as an addition to the sensor so that every time the light changes red, an alarm will warn the doctor to immediately stop the procedure and remove the air from the line. This additional alarm circuit will allow the doctors to focus on the procedure without constantly watching the line for air emboli.

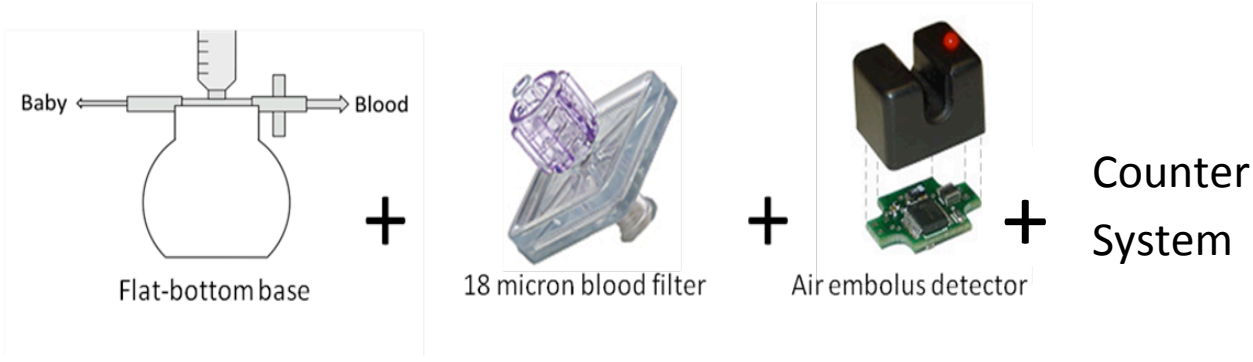

Figure 7: The four additional components to the transfusion kit, which include the flat-bottom base, the 18 micron filter, the air emboli sensor, and the undetermined counter system [15] [16].

Ergonomics

The double volume exchange transfusion can take up to four hours to complete. The stopcock is small and rather cumbersome to hold and turn. The flat-bottom base has been designed to maximize the number of ways that the doctor can hold the stopcock. The flatness of the base also gives the doctor the ability to set it down. This versatility increases the ergonomics of the base and helps keep the doctors more comfortable during this long procedure.

Ethical Considerations

The main ethical consideration for this project is that no blood can be cross-contaminated between patients. In order to ensure that no blood is transferred, the entire device must be able to be sterilized. The base will be made of polypropylene, which is a sturdy plastic that can withstand high temperatures and pressures. These specific plastic properties will allow the base to be autoclaved between procedures. Currently the team is unaware and researching whether the sensor will need to be autoclaved or if a common ethanol wipe-down will be sufficient for sterilization before a procedure.

Future Work

Looking forward to the rest of the semester, most of the effort will be committed to fabricating and testing the final product. The flat-bottom base, counter circuit, and alarm circuit will all have to be fabricated and then tested. The filter can be purchased individually from the kit that the hospital currently has from Utah Medical [17]. The air emboli sensor will be purchased from Introtek and the team-built alarm system will then be connected and tested together. Finally, the entire double volume exchange transfusion with the new components will be tested at the Simulation Center of Meriter Hospital. The fabrication and testing of the design are elaborated on in the following sections.

Fabrication Process

There are a number of design pieces that cannot be purchased and therefore have to be fabricated by the team. These design components include both the flat-bottom base and the alarm system circuit. Potentially the counter system will need some degree of fabrication, but due to

the fact that the counter system has not been finalized, the extent of fabrication needed for that component is unknown.

In order to fabricate the stopcock, a SolidWorks® file will be created for the base. The clamps that the team has chosen to use to secure the stopcock to the base can be found from McMaster-Carr, who provides SolidWorks® files for nearly all their parts. The team hopes to attach the SolidWorks® of the clamp directly to that of our base. To do this, we have to make sure that the polypropylene will have enough flexibility to have the stopcock ports forced through the clamp openings without breaking. As long as the polypropylene is equipped to handle this force, the team will then be sending out the part to a company like Proto Labs that can manufacture the part. The company will then send out the finished part and the base will be complete. If we find out that the clamps will not be functional when made out of polypropylene, there is an alternative option to buying straps that can be autoclaved and attaching them to the base part fabricated by the company.

The communicator and BWIG team member have had some correspondence with a sales application engineer at Introtek in order to gain information about designing and fabricating an alarm system that is compatible with the air emboli sensor. The sensor has a HCMOS output that the circuit can be connected to. The sales application engineer suggested that the alarm system be composed of a simple comparator circuit to drive an audible alarm such as a Sonalert. There has been some basic outreach to campus faculty in order to gain some help and expertise on how to build the alarm system from these components.

Testing

The testing of the device will occur in multiple steps. First to be tested will be the sensor alarm system and the counting system. If the device includes the waste bag scale, it will be tested by adding 5 mL increments into the waste bag and ensuring that the scale is sensitive enough to accurately tell how much blood in weight and/or volume is in the waste bag. If instead the new waste container is chosen, then the accuracy of the container will be tested in 5 mL increments. The client has asked that a new container be accurate to at least 5 mL if possible and said that a 1 mL accuracy would be ideal.

The air emboli detector with the attached alarm system circuit will also need to be tested immediately. The sensor will be connected to the extension tubing and dyed water will be passed

through the tubing. When an air bubble is created in the line, the sensor LED must turn red and the alarm must sound. Different sized bubbles will be tested to find a more precise limitation to the size of air emboli that the sensor can detect. When all of these components work, the entire device will be taken to Meriter for testing.

The client has access to the Simulation Center of Meriter Hospital. All of the additional components to the transfusion kit will be added for a test run of the entire double volume exchange transfusion procedure. The hospital will provide either a fluid that is similar in viscosity to blood or donated blood that is expired and cannot be used on patients for this procedure test. The entire four-hour transfusion will not be tested but there will be enough blood increments used to test the stability of the stopcock in the base, the base comfort, the accuracy of the counter, and the accuracy of the air emboli detector and alarm. Any problems that occur during this simulation will influence the final product and changes necessary will be fixed or recommendations will be given to the client for future work.

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APPENDIX

Transfusion Device: Product Design Specifications
February 11, 2011
Client: Julie Kessel, M.D.
Team: Clara Chow, Rachel O'Connell, Ashley Mulchrone
Advisor: Paul Thompson

Problem Statement

A double volume exchange transfusion is a procedure in which a baby's entire blood volume is exchanged twice in order to clear the blood of bilirubin and prevent brain damage in newborn babies. Since the procedure is not done frequently due to the increase of phototherapy treatments, neonatologists are thereby less experienced with this procedure. The goal is to improve the safety of the transfusion by designing a device that can eliminate incorrect use of stopcock, count the number of revolutions, and differentiate between the stopcock connections.

Client Requirements

- Device that ensures accurate use
- Easily identifiable tubing connections for both the 3-way and 4-way stopcock
- If not disposable, must be able to be autoclaved
- Portable and needs to be placed near baby

Design Requirements

1. Physical and Operational Characteristics
    a. *Performance requirements:* Device must enhance and make the transfusion process more efficient. Should be easy to use and intuitive despite infrequent usage (once every 3 to 5 years). Can be used during the procedure as well as during training.
    b. *Safety*: Must be safe to use in a clinical environment and should decrease the morbidity and mortality of the exchange transfusion.
    c. *Accuracy and reliability:* Should allow the user to only turn the stopcock one direction and count the number of revolutions accurately.
    d. *Life in Service/Shelf Life:* Should last the duration of the transfusion (2 to 4 hours). If not disposable, the device would ideally last for 10 transfusions.
    e. *Operating Environment:* Indoor clinic, hospital, or laboratory. Operated between 20-25°C. Pressure and moisture should not affect operation.
    f. *Ergonomics:* Should be comfortable for the user and easy to handle. Force exerted by user should be less than 10 N.
    g. *Size:* Needs to be portable and small enough to be handheld or placed near baby. Should be no bigger than 500 cm^3.
    h. *Weight:* 1 kg or less.
    i. *Materials:* The device will incorporate the stopcock, syringe, and IV tubing. Material needs to be able to be sterilized.

j. *Aesthetics, appearance, and finish:* Should be presentable in a hospital setting.

2. Production Characteristics
    a. *Quantity:* One prototype as a proof of concept.
    b. *Target Product Cost:* System less than $500.

3. Miscellaneous
    a. *Standards and Specifications:* Meets FDA standards for a Class II medical device.
    b. *Customer:* To be used at Meriter Hospital as a teaching tool and for clinical practice.
    c. *Patient-related concerns:* Apart from general transfusion safety requirements, there are no special considerations for the device.
    d. *Competition:* There are no similar devices in the market and no foreseeable competition due to infrequency of the procedure