SAFETY DEVICE FOR DOUBLE VOLUME EXCHANGE TRANSFUSIONS

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ABSTRACT

Bilirubin is a naturally occurring substance that is formed as a byproduct when red blood cells decompose. Although it is natural to the body, high concentrations of bilirubin, known as hyperbilirubinemia, can cause severe harm. Infants are particularly susceptible to these high concentrations due to their underdeveloped bodies. If these severe levels are reached, an immediate double volume exchange transfusion is needed. This transfusion removes twice the baby's blood volume with donated blood in order to maximize the bilirubin removed from the body. This procedure is extremely rare, occurring about once every three to five years. In certain cases, only one catheter can be inserted into the baby, which causes complications due to the un-intuitiveness of the four-way stopcock that is used to execute the procedure. Therefore, the client has asked for a device that will improve both the safety of the overall procedure, as well as the intuitiveness of the setup and execution of the four-way stopcock. The team created four improvements to the procedure: a base for the stopcock with color-coding and rotation directions, an 18-micron blood filter, an air emboli detector with an alarm circuit, and a counter system to track the amount of blood removed from the baby. After testing and quantifying the improvements via a survey, it was found that these additional components increased the intuitiveness of the setup by 33.33%, the stopcock comfort by 20%, the stopcock turning by 20%, the accuracy of the blood volume count by 13.33% and the baby's safety by 20%. To further the project, the air emboli detector must be finalized and purchased, the stopcock base has to be fabricated in polypropylene, and the alarm circuit must be scaled to the size of a chip.

TABLE OF CONTENTS

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, immediate medical intervention is needed if the bilirubin levels continue to rise and the baby reaches hyberbilirubinemia.

Current Treatments

Currently, there are two main treatments for Hyperbilirubinemia: phototherapy and the double volume exchange transfusion. Phototherapy is the most common treatment, which surrounds the baby with a 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. This 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 1: 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 must 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, standard practice is to exchange the baby's

total blood volume twice. On average, about 500 mL of blood has to be withdrawn from the baby, which can take up to four hours to complete. An important and often unintuitive component of the double volume exchange transfusion is the four-way stopcock (Figure 2). This device is used to connect the syringe (inserted on the top) with the three other ports that connect to the baby's catheter, the donated blood bag, and the waste bag. In order to ensure that the blood travels 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. Its infrequent use has led to no technological advances in this area and no competitive products exist.

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

DESIGN CRITERIA

In our design, the final device 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.

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. All other components that are not exposed to blood must be safe to use with ethanol, the other sterilization method.

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 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 precision of at least 5 mL.

All components of the design, especially those that require power, must last throughout the whole procedure in order to ensure that the design does not malfunction in the middle of the procedure. Any component that is not disposable must last up to 10 procedures.

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. Lastly, the budget given by the client is $500 to construct and fabricate a device that meets the client's requirements.

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 distinguish the stopcock ports and to provide a comfortable handle for the user. As shown in Figure 3, the top view of the base 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 or with rubber bands. In order to further secure the stopcock onto the base, the white T-shaped block is indented within the base so that the stopcock can sit within the groove of the base.

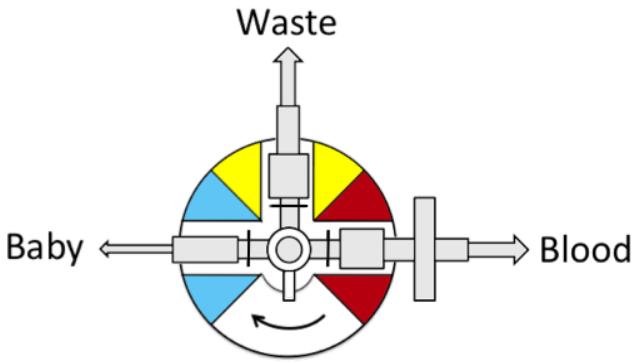

Figure 3: Top view of the stopcock connected to the base. The ports are identified with colors and the arrow ensures counterclockwise rotation of the stopcock.

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 in which 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 handbreadth for adult males is 84 mm, and the average handbreadth 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.

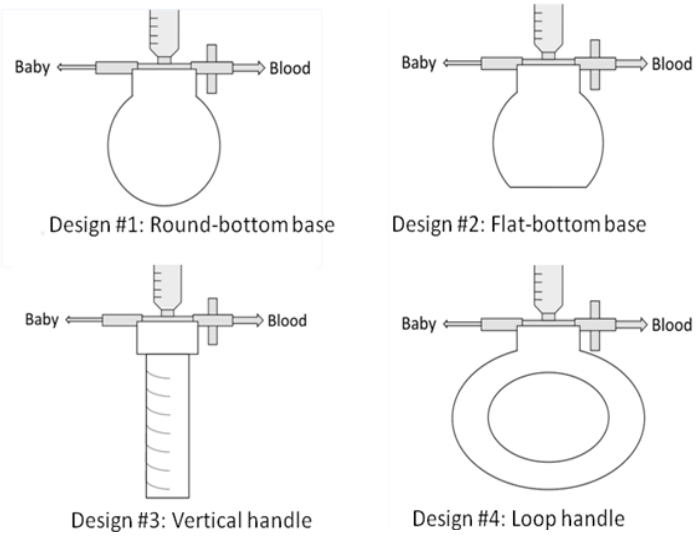

Figure 4: Side view of base designs, which include the round-bottom base, the flat-bottom base, the vertical handle, and the loop handle.

Evaluation of Stopcock Base Design Alternatives

In order to choose the final design, a design matrix was created that rated each base 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 since the transfusion procedure is two to four 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 considered 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 completely redesign the waste container.

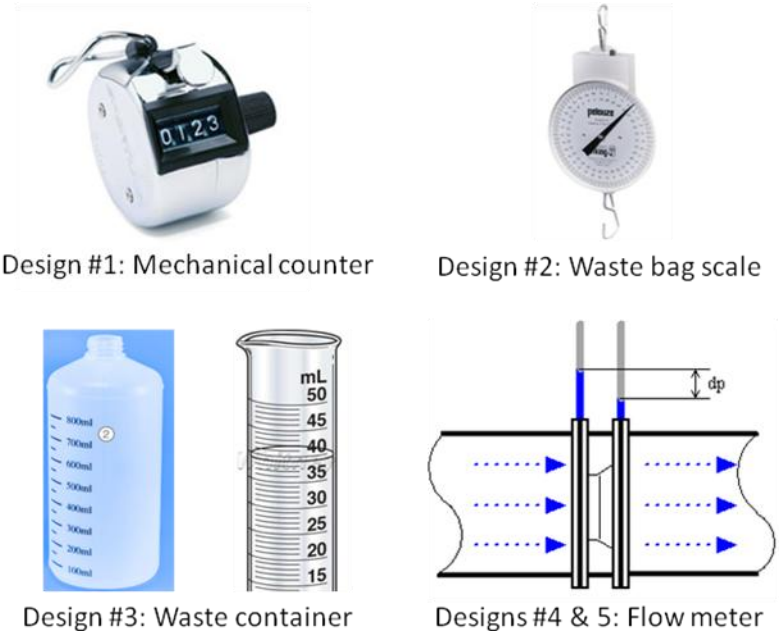

Figure 5: Conceptual designs for the counter system, which include the mechanical counter, the waste bag scale, the waste container, and the flow meters [10][11][12][13][14].

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 in-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 a waste bag scale. These components are to be an addition to the transfusion kit that the hospital already uses. Our main goal for this semester was improvement of both the safety and intuitiveness of the double volume exchange transfusion.

Stopcock Base

The base is the main component to improve the intuitiveness of the four-way stopcock and increase the comfort for the user. The ports of the stopcock are identified via labels etched into the top and with colored rubber bands to secure the stopcock on the base. Although

Figure 7: A SolidWorks® top view of the final base to be fabricated in polypropylene.

the top of the base was initially designed to have adjustable clamps to snap the stopcock into the base, the team decided it was not a feasible option because the strength of polypropylene was unknown, and clamps made out of different materials were not compatible with an autoclave. The top of the base also has an etched arrow to ensure clockwise rotation of the stopcock (Figure 7).

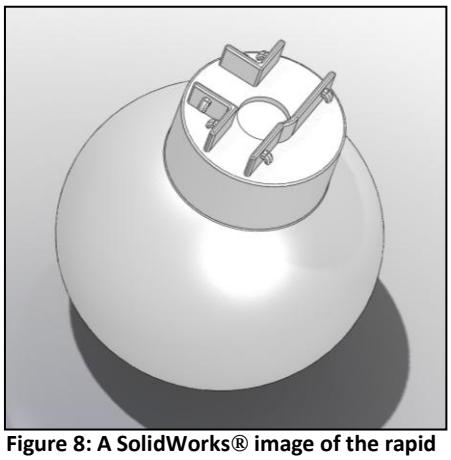

Figure 8: A SolidWorks® image of the rapid prototype base in ABS.

The base is to be made entirely out of polypropylene, a strong plastic that can withstand high pressure and temperatures, to ensure that it can be autoclaved in between patients and procedures. However, because of budget constraints (the polypropylene base was quoted to approximately $500), the current base is a rapid prototype fabricated at the University of Wisconsin-Madison (Figure 9). The base top has a radius and height of 0.02 m and the base bottom has a radius of 0.04 m. The base bottom has hollow middle with wall thickness of 1 cm to decrease the amount of material and cost in fabrication.

Blood Clot Filter

In order to help increase the safety of the procedure, the team has chosen an 18-micron blood filter to prevent blood clots from reaching the baby (Figure 9). This filter is 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, and thus, is easy to obtain.

Figure 9: An 18-micron blood filter [15].

Air Emboli Detector & Alarm Circuit

In order to prevent air emboli from entering the baby, the team chose the AD 9 sensor from Introtek (Figure 10). This sensor fits around an extension line connecting the stopcock to the catheter in the baby. Utilizing ultrasound technology, each time air passes through the line, a light on the detector changes from green to red, alerting the user to stop

Figure 10: AD9 sensor from Introtek that uses ultrasonic technology to detect air emboli in a line [16].

before the air reaches the baby. However, the sensor could not be obtained at this time because the standard IV tubing is not compatible with this device. More information is discussed in the future considerations section.

Although the sensor provides a great safety improvement to detecting harmful air emboli in the tubing, watching for a light to flash is unrealistic in a hospital setting. Therefore, an audible alarm circuit was constructed to complement the detector (Figure 11).

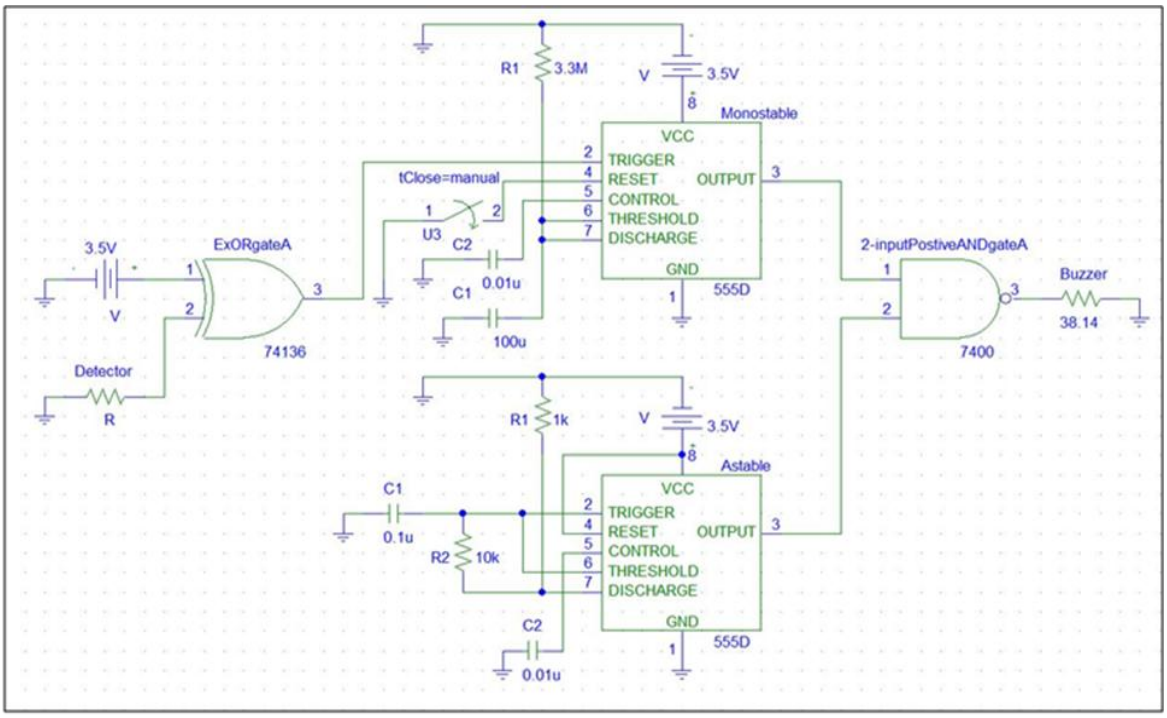

Figure 11: Schematic of the audible alarm system generated on PSPICE.

When air is detected in the sensor, the sensor outputs a temporary square wave that peaks at +4.5 V and returns to equilibrium at 0 V once the air has passed through the sensor. The circuit takes the output of the detector and converts it to an audible sound via a buzzer that lasts up to six minutes, long enough to alert the medical personnel. The buzzer can also be easily reset with a switch. Adding this alarm system greatly improves the safety factor for detecting air during transfusions. With this alarm circuit, doctors can focus on the procedure without constantly watching the line for air.

Counter System

Figure 12: The scale to weigh the waste bag for an accurate measurement to blood withdrawn [17].

The counter system is an additional safety feature that allows the medical personnel to know exactly how much blood they have withdrawn from the baby. Each time blood is infused or removed from the baby, one of the nurses is in charge of hand recording those values on a chart. This method is not appropriate and not error-free, infusing more blood than withdrawn, or vice versa, is harmful to the baby. The counter system added is essentially a scale that can weigh the waste bag and its content in grams (Figure 12). By using the simple conversion 1g = 0.943 mL of blood, the amount of blood that is drawn from the baby can be easily obtained by subtraction the weight of the empty waste bag from the weight of waste bag at any point during the procedure. This can be used as a reliable checking mechanism for the manual chart.

ERGONOMICS

The double volume exchange transfusion can take up to four hours to complete, and the stopcock is small and rather cumbersome to hold and turn. The flat-bottom base design maximizes the number of ways that the user can hold the stopcock. In addition, the spherical shape of the bottom was designed to fit the average male hand and keeps the hand and wrist in a neutral position. Moreover, the flatness of the base gives the user the ability to set it down, making the base a handheld device or a support feature for the stopcock. This versatility increases the ergonomics of the base and helps keep the user 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. The blood clot filter can be disposed and replaced before each procedure, and the air emboli detector, alarm circuit, and the counter system can be sterilized with ethanol since they do not come in contact with the blood.

Testing Procedure

The testing of our final design was performed at the Simulation Center at Meriter Hospital in Madison, Wisconsin (Figure 13). The set up simulated the same conditions as the transfusion procedure except water dyed with red food coloring was used instead of blood, and a simulation baby was used instead of a real patient. Three medical personnel, including the client, and each team member tested the system for the intuitiveness of the four-way stopcock, comfort, accuracy, safety, and ease of use. The medical personnel experienced with the procedure provided feedback via a survey (Appendix D) to quantitatively analyze the success of our design.

Figure 13: Testing of the procedure with our modifications at the Meriter Simulation Center.

Testing Results and Discussion

The Counter System

The team initially tested a diet scale already available to the team for preliminary data on its compatibility and accuracy with the waste bag. However, the waste bag could not fit on the scale bowl and caused the bag to crease. This crease prevented liquid from flowing to the bottom of the bag and therefore did not fully register on the scale even though the scale itself was accurate to the mL mark when tested without the waste bag. This error prompted the team to continue research that led to the incorporation of the current scale.

The current scale was tested outside of the Simulation Center for accuracy in four different trials (Figure 14).

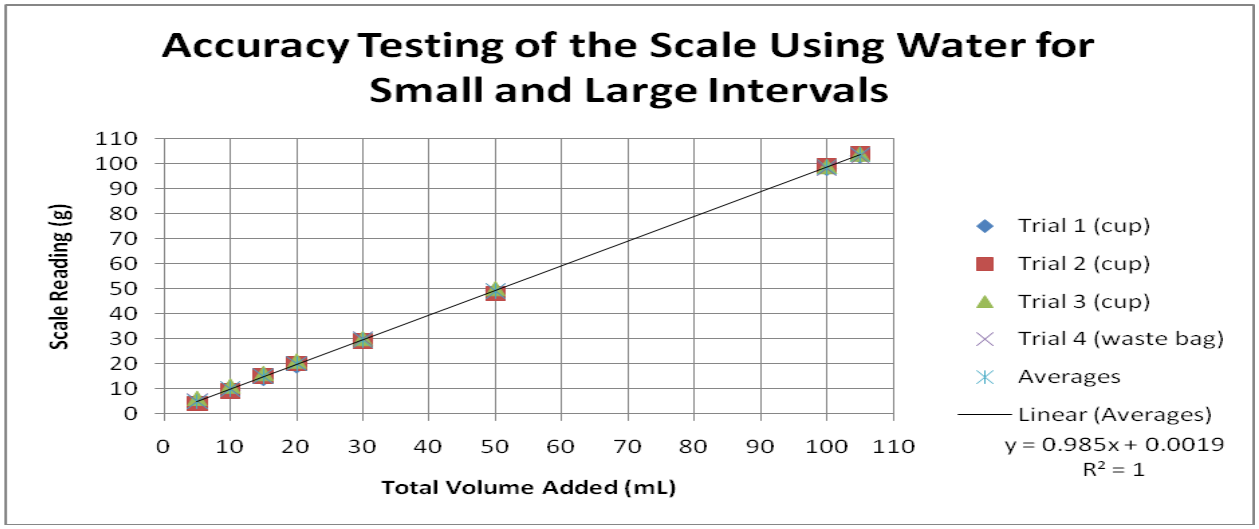

Figure 14: Data from accuracy testing shows that the scale follows a liner regression with an R-squared value of 1.

The R – squared value is one, which indicates that the scale is very accurate on average. Out of the four conducted trials, the one that used the waste bag instead of the cup was the most accurate. That trial had exact reading from 5 mL through 30 mL. Testing also revealed that the scale is quick to automatically shut down. In order to keep the volume accurate for the procedure, the mass of the empty waste bag in the position it will be for the procedure will need to be measured and recorded before the transfusion begins. During the procedure if the doctor wishes to check the volume of blood removed, he/she will then turn on the scale and mass the partially full blood bag. The empty waste bag is subtracted from the mass and then multiplied by 0.943 to convert from grams to milliliters of blood.

The Modified Procedure

A survey that compares the procedure before and after our modifications using a 0 or 5 point scale was compiled to quantitatively analyze the success of our design. The results from three medical personnel experienced in the transfusion can be found in Appendix E. The results of the survey showed that the base increased the intuitiveness of the four-way stopcock setup as well as the comfort and ease of use of the stopcock. The counter system was shown to improve the accuracy of the blood volume count and the overall safety of the baby was improved as well (Figure

15). The intuitive setup, stopcock comfort, stopcock turning, accurate blood volume, and baby safety improved by 38%, 20%, 20%, 13.33% and 20% respectively.

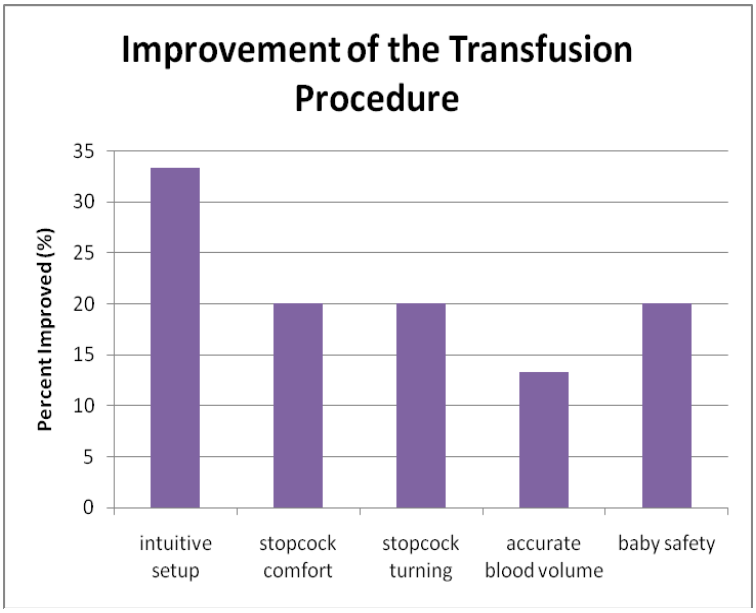

Figure 15: The comparative results of the survey from the original procedure to the procedure with the team design showed a minimum of 13.33% improvement in all major design criteria.

The results from the surveys gave an average score of 4.33 for overall improvement considering 5 as the best possible score. This indicated a large improvement from the original procedure seen by the personnel. The five design criteria considered in the survey all had improvement and it was then calculated to see how each of these criteria contribute to the overall 4.33 improvement rating (Figure 16).

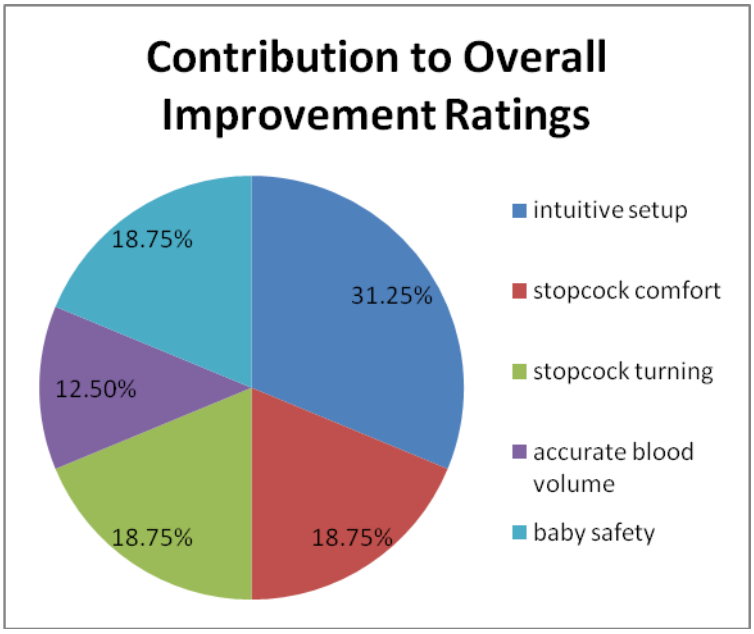

Figure 16: The contribution of each criterion to the improvement of in the procedure. The intuitive setup contributed the most to the overall 4.33 improvement rating.

The new stopcock base alone accounts for 68.75% of the total improvement rating. The medical personnel also gave the aesthetics of the base an overall average rating of 4.33 on the same 0 to 5 scale. It was mentioned by two of the medical personnel during their own testing of the procedures that the base now prevents incorrect turning of the stopcock. This is because the syringe itself is used to turn the stopcock and if it is turned counterclockwise, the syringe will unscrew from the stopcock all together.

SEMESTER SUMMARY

The proposed timeline from the beginning of the semester can be found in the appendix. The timeline was mostly followed, with the exception that prototype design, prototype fabrication, and testing started later than projected. Moreover, the project's need for products manufactured by other companies prompted the team to continue research throughout the semester. Complications that hindered project progress include difficulties with tubing for the air embolus detector and high cost of the polypropylene base.

The expenditures for this project are summarized in the appendix. With the initial budget of $500, the team spent only $103.70. Although the cost of the polypropylene base and air embolus detector sum to a value greater than the given budget, the added safety greatly outweighs the cost, especially since the air embolus detector is versatile and can be applied to other procedures in the hospital. The team spent a total of approximately 250 hours on the project.

FUTURE WORK

Although considerable effort was put into creating a system fully ready to be used in a clinical setting, there is future work remaining before the system is ready for use. Currently, the stopcock base is a rapid prototype fabricated with ABS. This material is not autoclave compatible and will start to degrade when cleaned with an ethanol solution. This makes the current base unacceptable for close work with blood and for use on several patients. The team has been working with a CNC machining company called Firstcut that can take the SolidWorks® file that the team created of the base and print it in polypropylene. Polypropylene was chosen because it is a plastic that can endure the high temperature and pressures of an autoclave and ethanol will not cause it to degrade. The final stopcock base has labeled ports and a directional arrow added to the top of the base (Figure 7). These labels have been engraved into the base because the company cannot print in various colors and polypropylene does not react desirably with glues and markers.

This base was not purchased from Firstcut by the team because of the high pricing. The stopcock base that the team had printed for a prototype was quoted from Firstcut for $497 to be made from polypropylene. The newly added detail will only increase the pricing. Due to the expense, which would consume the entire semester budget, the team did not purchase the base and has given the client the SolidWorks® file so that she may have the base printed if desired.

The team was also unable to purchase the air emboli sensor from Introtek due to complications that arose throughout the semester. The team initially worked with the client to find an tubing extension for the catheter that would allow the sensor to be used for several different procedures in the hospital. This tubing was sent into the company in New York after a few shipping complications. The company then told the team that the tubing was too fragile for the sensors and very late in the semester suggested the team use MasterFlex 4mm OD soft silicone tubing. This tubing has no connectors or compatible with male or female luers. To make it compatible with the stopcock and the catheter two barbed adapters, one for the female luer and one for the male luer, must also be purchased (Figure 17).

Figure 17: Male luer adapter (left) and female leur adapter (right) [19].

These adapters and the tubing need to be purchased and tested for compatibility with the four-way stopcock and the catheter line. All three can be purchase from Cole-Parmer. The female adapter, male adapter, and tubing are parts MK-45500-04, MK-45503-04, and SI-96410-16 respectively. As long as the tubing can properly work with the system, a sample of the tubing can be sent in for testing at Introtek, who can then create a sensor specifically for Meriter Hospital. Once the client has the sensor, she can then also decide if she would like the alarm circuit created by the team to be miniaturized onto a chip so that it is not cumbersome during the procedure.

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APPENDIX

Appendix A: Product Design Specifications

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 waste taken from the baby, 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

Appendix B: Semester Schedule/Timeline

Table 1: Semester Schedule/Timeline. Colored coding indicates the projected timeline at the beginning of the semester. The check marks indicate when each task was completed.

Tasks	Jan		February				March				April				
	21	28	4	11	18	25	4	11	18	25	1	8	15	22	29
Research		✔	✔	✔	✔	✔	✔	✔	✔	✔		✔	✔	✔	
Brainstorming			✔	✔	✔	✔									
PDS		✔	✔												✔
Prototype Design						✔	✔	✔	✔	✔					
Prototype Fabrication										✔	✔	✔			
Testing											✔	✔	✔		
Meeting with Client		✔	✔			✔	✔						✔		✔
Team Meeting	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔		✔	✔	✔
Presentation						✔	✔							✔	✔
Written Reports						✔	✔					✔		✔	✔
Peer/Self Evaluations							✔								✔

Appendix C: Expenses

Table 2: Total expenses spent by the team throughout the semester.

Item	Cost (dollars)	Date Purchased
Mechanical tally counter	$10.54	2/20/11
Express mail for tubing	$18.30	3/23/11
Buzzer for alarm circuit	$6.19	3/27/11
Scale	$25.50	4/8/11
Bowl for scale	$8.06	4/17/11
Rubber bands	$1.36	4/18/11
Poster	$33.75	4/25/11
TOTAL	**$103.70**	

Appendix D: Survey

Double Volume Exchange Transfusion Survey
April 2011

What is your position at the hospital? _____

What role(s) have you done in the transfusion procedure?_____

How many times have you performed the transfusion procedure? *Please circle one.*

0 1 to 5 6 to 10 10+

For the following questions please rate the transfusion before and after the improvements that the BME team has developed for the procedure. Consider 5 the best and 0 the worst and please circle one number.

	Before	After
How intuitive is the four-way stopcock setup?	0 1 2 3 4 5	0 1 2 3 4 5
How comfortable is it to use the four-way stopcock?	0 1 2 3 4 5	0 1 2 3 4 5
How easy it to turn and use the four-way stopcock?	0 1 2 3 4 5	0 1 2 3 4 5
How confident are you during the transfusion that the count for volume removed from the baby is accurate?	0 1 2 3 4 5	0 1 2 3 4 5
How safe do you believe the procedure to be for the baby?	0 1 2 3 4 5	0 1 2 3 4 5
Overall, do you feel that the suggested improvement make the procedure safer for the baby and easier for the doctors and nurses?	NA	0 1 2 3 4 5

Do you have any further comments? *Feel free to include suggestions, concerns, and questions.*

Thank you for your participation and feedback. We hope you enjoy the improvements!

Clara, Rachel, and Ashley

Figure 1: The survey that was given to medical personnel at Meriter Hospital that were experienced in the Double Volume Exchange Transfusion.

Appendix E: Testing Results

Final Scale Testing

Table 3: Table showing the results from the scale testing when different amounts of water were added.

	Trial 1 (cup)	Trial 2 (cup)	Trial 3 (cup)	Trial 4 (waste bag)	
total mL added	scale reading	scale reading	scale reading	scale reading	average
5	4	4	6	5	4.75
10	9	9	11	10	9.75
15	14	15	16	15	15
20	19	20	21	20	20
30	29	29	30	30	29.5
50	49	48	50	49	49
100	98	99	99	98	98.5
105	103	104	104	103	103.5

Survey Results

Table 4: Table showing the results from the survey that was administered to the medical personnel at the hospital. This table represents the before and after difference for each of component of the procedure.

	Intuitive Setup	Stopcock Comfort	Stopcock Turning	Accurate Blood Volume	Baby Safety
Staff 1	1	0	0	0	0
Staff 2	0	0	0	0	1
Client	4	3	3	2	2
Averages	1.667	1	1	0.667	1
Individual Improvement	33.33	20	20	13.33	20
Contribution	31.25	18.75	18.75	18.75	18.75

Table 5: Table showing the results of the survey questions on a scale from 0 to 5. The purple cells indicate the client's answers.

Do you find the stopcock base aesthetically pleasing?				
4	4	5	Average:	4.33
Overall, do you feel the suggested improvement make the procedure safer for the baby and easier for the doctors?				
4	4	5	Average:	4.33