BME 301: BIOMEDICAL ENGINEERING DESIGN

PRODUCT DESIGN SPECIFICATIONS

– THE UMBILICAL TEAM –

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Project Title: Umbilical Cord Model for Umbilical Vein Catheterization Training *(Project Number: 22 / Code: umbilical)*

Initial Problem Statement

The American Academy of Pediatrics Neonatal Resuscitation Program (NRP) is required training for thousands of physicians and medical staff who attend the delivery of newborns. Placement of an intravenous catheter in the umbilical vein of the cord stump in a distressed newborn is one way to provide life-saving medication and is a skill that is essential to the NRP course. Hands-on training in the placement of an umbilical venous catheter has received increased attention and emphasis since the 2005 update of the NRP course. Currently, two models for hands-on training are available. Some companies make newborn models for CPR that also have artificial umbilical cords (eg. Laerdal). These models appear to inadequately mimic placement in a real cord and are very expensive. Alternatively, the American Academy of Pediatrics recommends using sections of an umbilical cord obtained after delivery. The cord section is placed in a glass baby bottle with part of the nipple cut off so the cord extends about 1/2 an inch from the top of the nipple. While this model has the advantage of using a real cord, the cord is secured poorly and thus does not adequately mimic placement in a newborn. The goal of this project would be to create an inexpensive and disposable model that would be a vast improvement over the "baby bottle" model for teaching and could be patented and marketed to the over 25,000 individuals in the US who teach NRP.

During the first semester of this project, the umbilical team designed two working models, the "cord-in-gel" and "sphygmomanometer". Both models had good tensile test assessments and limited but promising side-by-side comparisons of catheterization success. Additional design work is needed for both models before consideration of patent and production. The superior model needs to be identified, and the materials and construction process need to be refined for bulk manufacturing. The mold for the "cord-in-gel" model needs additional design work with alterations to mimic the course of the umbilical vein in the body and modifications to ensure correct placement of the cord in the gel and exit of the cord end to a reservoir. The "sphygmomanometer" model was created from a blood pressure cuff and purchased materials. This model needs to be designed from appropriate materials with a built-in "cuff". The design for the support system for both models will need to be altered accordingly. In addition, part of the design goals will include work with human cords to determine if cord orientation, storage (eg.

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freezing), or fixation affect the model. Ultimately, we will have physicians test the models side by side to gather data for the possible patenting of this product through WARF, including success of catheterization, biosafety, and infection control data.

Revised Problem Statement

The superior model has been identified as the sphygmomanometer (or cuff) model. The design focus now lies on the creation of an external support that incorporates the cuff model and mimics the infant's abdomen. As umbilical vessels themselves will be used to simulate the systemic blood vessels upon the umbilical cord's entry beyond the umbilicus, the course of the umbilical vein in the abdomen needs not be mimicked. Manufacturability of the entire model must be considered as a design constraint. At the end of the semester, a manufacturing package that encompasses all pertinent information required for a manufacturer's assessment should be prepared. This includes testing results as mentioned in the initial problem statement.

Client Requirements

- Fresh human umbilical cords are to be used within 1 to 2 days before significant postnatal deterioration begins and renders the cords unsuitable for handling.
- The umbilical cord should be well stabilized and be able to withstand the mechanical forces involved during catheterization training.
- At least 2 cm of the umbilical cord should extrude from the surface of the model, while 5 cm of it should be embedded within the model to simulate the systemic blood vessels.
- A variety of cord sizes must be accommodated.
- A blood reservoir should be included to contain blood-mimicking solution that can be drawn to verify catheter depth during catheterization training.
- The external support of the stabilizing mechanism should mimic the infant's abdomen in terms of dimensions and weight, and its texture must resemble human soft tissue and be opaque.
- Materials should be disposable to ensure biosafety, but should at least be durable for the period of usage.
- The final product must be user-friendly and require minimal or no preparatory work by the user.
- The model should perform better than existing models and must be manufacturable in a standard production line.

Design Requirements (for External Support)

1. Physical & Operational Characteristics:

a. **Performance Requirements:** The external support must mimic the infant's abdomen in terms of dimensions, weight and texture, and incorporate the cuff model without compromising the stability of the umbilical cord.

b. **Safety:** Materials used in the entire model must be disposable since physical contact with human tissues is anticipated. Additionally, the model must not contain sharp edges, or any mechanisms that permit skin contact with human tissue during usage. Expected device failures must not endanger the user.

c. **Accuracy & Reliability:** The dimensions and weight of the external support should be within 10% from those of an average healthy infant. Texture mimicry will be assessed using compliance testing, but the acceptable accuracy has yet to be determined. Methods and materials employed to construct the external support must optimize reproducibility to reduce variance among the products at both design and manufacturing stages.

d. **Life in Service:** Each usage should last for at least 2 hours between opening of the packaging and disposal of the product.

e. **Shelf Life:** At least 2 years of storage is expected since the NRP training occurs at least 45 times a year.

f. **Operating Environment:** Normal clinical or laboratory environment.

g. **Ergonomics:** The model should require minimal or no preparation on the user's part. During usage, the user must be sufficiently "convinced" by the abdominal mimicry, and the catheter should be inserted at least 5 cm into the umbilical vein to be considered successful.

h. **Size:** Assuming that the "abdomen" is roughly rectangular, the external support should be around 30 cm by 15 cm by 5 cm, and contain a cylindrical hole of 1.75" in diameter to incorporate the cuff model.

i. **Weight:** Between 1 kg to 2 kg, considering the average weight of a newborn is 3.4 kg and the abdomen is approximately 30% of the body weight.

j. **Materials:** One fresh human umbilical cord per use, but may be sectioned such that 2 to 4 products share the same cord. Soft elastomers or other low-density polymers will be considered to mimic the texture of the infant's abdomen.

k. **Aesthetics, Appearance & Finish:** The model must resemble an infant's abdomen primarily in terms of texture. Color will be of secondary concern.

2. Production Characteristics:

a. **Quantity:** 1 reproducible model by the end of the semester. Target production quantity at the manufacturing stage will be determined later.

b. **Target Product Cost:** Raw materials should cost less than $90 for 1 product. Target production cost at the manufacturing stage will be determined later.

3. Miscellaneous:

a. **Standards & Specifications:** The design and construction of the model must comply with manufacturing standards and the NRP guidelines.

b. **Customers:** Any clinical institution that is involved in the NRP umbilical vein catheterization training.

c. **Patient-Related Concerns:** The donor of the umbilical cords must remain anonymous to the designers and users of the model.

d. **Competition:** The recommended baby bottle model currently used in NRP. Commercial products include "Baby Umbi" from Laerdal.