



A Proposal for the Engineering World Health Design Competition:
Umbilical Cord Care Kit

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PROBLEM DEFINITION

For the past two years, sub-Saharan Africa had the highest child mortality rate in the world¹. In 2018, 1 in 13 children died in this region before his or her fifth birthday which is sixteen times higher than the ratio in high-income countries¹. In Tanzania specifically, there were over 44,000 neonatal deaths in 2018 alone¹. A source of neonatal infection is the newly cut umbilical cord. Infection of the umbilical cord is known as omphalitis. Omphalitis has an estimated mortality rate of 7%-15%², and in low and middle income countries, there is a greater risk of infection for neonates due to lack of accessibility to healthcare centers and resources such as hospital personnel and equipment.

To combat the high likelihood of infection due to lack of healthcare access, our team proposes the implementation of an umbilical cord care kit. The kit will include the necessary equipment to safely and efficiently cut the umbilical cord while also providing a natural berberine-containing substance in order to prevent infection. Berberine has natural antimicrobial properties that will be utilized in the application of the umbilical cord care kit.

STATEMENT OF IMPACT IN THE DEVELOPING WORLD

Current methods for umbilical cord care in Tanzania commonly include the cutting of the umbilical cord with a razor followed by the tying off of the cord with thread or another material³. Commonly used materials include but are not limited to saliva, breast milk, talcum powder, oil, petroleum jelly, ash, and dirt with saliva being the most commonly used material³. The majority of these products offer little to no antimicrobial properties and increase the risk of contamination which may result in infection. Further, it is observed that in the cases of home births only 10% of births resulted in any sort of substance being applied to the cord with no consistent standard of when the first treatment was applied nor the frequency of application or duration after that³.

This lack of standardized, effective health care administration is a significant factor in the high rates of neonatal sepsis. The implementation of a cost-effective, portable kit will reduce the likelihood of infection while providing a means to standardize the protocol for umbilical cord care in low and middle income countries. Expectant mothers will have the ability to pick up the kit at a local healthcare provider in preparation for childbirth in a setting other than a hospital. This provides women with a peace of mind regarding their newborn's health by giving the opportunity to properly care for the umbilical cord without requiring access to a medical facility.

REQUIRED PERFORMANCE SPECIFICATIONS

The kit must be effective in reducing the rates of neonatal sepsis. To do this, laboratory testing must demonstrate the antimicrobial properties of a berberine-containing substance. The kit itself must also be small enough that it is portable and self-contained. This is to ensure that the kit can be distributed by healthcare centers and then taken with patients to be used in a

different location. This allows for the kit to be more effective in treating patients as there is not mandatory access to a medical facility immediately after birth and the function of the kit may be performed at home or another remote location.

The kit must be low-cost such that the maximum number of kits can be created. The success in distribution of the kit depends on getting it to as many patients as possible and ensuring that the kit is low-cost will allow for the production of far more kits. Finally, the kit must be easy and intuitive to use such that a non-medically trained person can operate it successfully.

IMPLEMENTATION OF PROTOTYPE

Several substances with berberine, which has proven antimicrobial properties, have been tested to demonstrate their antimicrobial effectiveness. Further trials and are currently testing against a common bacteria that leads to infection, *Escherichia coli*. Knowing that the antimicrobial component of the test kit is effective, other items to populate the kit have been selected including sterile clamps, a sterile disposable scalpel, antiseptic wipes, gauze, and a ruler with images to indicate where to cut the cord (**Appendix A**). The selection of these specific items was based on the items being those most familiar to people using the kit that also successfully perform the needed functions. These items can all fit in a standard 7 3/4" x 4 1/2" x 2 1/2" empty plastic first aid kit for distribution. This size is small and light enough for the kit to be portable such that patients can transport the kits from a medical facility.

The team has determined the most effective method of successful operation is involving healthcare providers in the area to teach patients how to use the kit, as this removes any language barriers and cultural discrepancies. At the time of distribution, healthcare providers will be contacted directly and educated so that they may educate users, increasing the effectiveness of the kit.

Finally, the total cost of the kit was kept low as the kit itself and all the items contained within it can be assembled for \$2.82.

PROOF OF PERFORMANCE

Zone of inhibition testing, also called disk diffusion testing, was used to determine the effectiveness of the berberine-containing compounds. The berberine-containing compounds used were goldenseal oil, red clove oil, Oregon grape root oil, and the controls used in the test were bleach and deionized water. The compounds were tested against a common bacteria, *Staphylococcus epidermis*. The results of the tests indicated that the goldenseal oil had antimicrobial properties comparable to that of bleach (**Figure 1**). Further testing of the

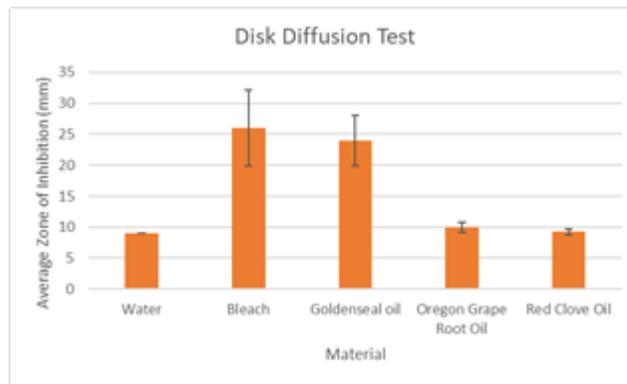


Figure 1: Results of Disk Diffusion Test. The Goldenseal oil is as effective as bleach at inhibited *Staphylococcus epidermis* at levels similar to bleach.

berberine-containing compounds with other bacteria, such as *Escherichia coli*, will be completed to determine which berberine-coating compound will be implemented in the kit.

There is currently little to no effort to provide a full umbilical cord care kit to low-resource settings. There are cord care powders available, but there is not an extensive kit that includes everything needed to cut the cord and clean it daily until it falls off. This provides a superior solution to umbilical cord care for mothers in low-resource settings who may not have the means of traveling to a hospital for childbirth. The team's umbilical cord care kit is small, portable, inexpensive, and provides a simple but effective means of umbilical cord care following childbirth.

BUSINESS PLAN

Market

The kit will be marketed to healthcare clinics in developing countries, specifically Tanzania. Tanzania has a tiered healthcare system that includes national hospitals, district hospitals, healthcare centers, and dispensaries. Healthcare centers and dispensaries are located in the most rural areas of Tanzania, and these locations will be the main market for the distribution of the kit because expectant mothers in these areas are unable to travel to healthcare centers at short notice.

Funding and Sales

The funding for the umbilical cord care kit will come from partnering with various non-profit organizations focused on global health. The organizations partnered with will cover the cost of creating and shipping the kit. The team will also apply for grants through the National Institutes of Health focused on global health initiatives. The approximate cost of each kit is \$2.83. The greatest cost associated with the project is the shipping of the kit, and the approximate cost of shipping 250 kits from South Carolina would be approximately \$4000.

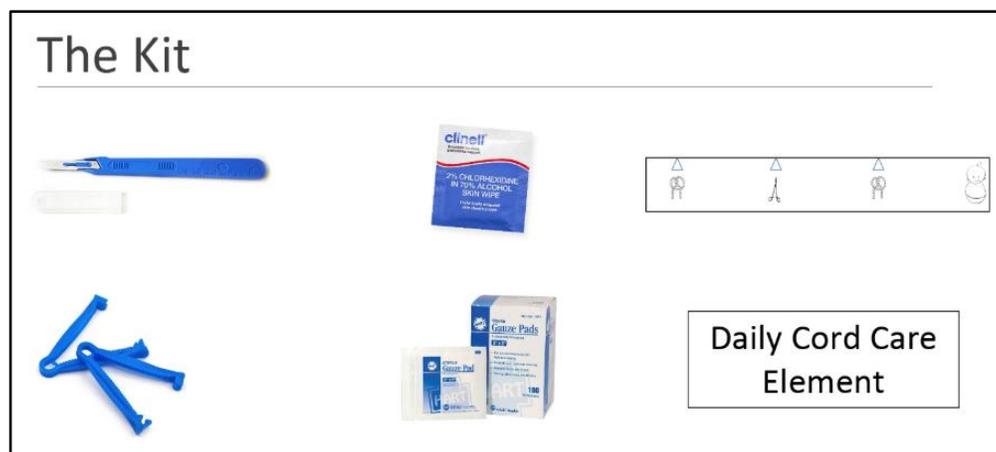
Manufacturing and Distribution

The umbilical cord care kit will be assembled in the United States and shipped to healthcare providers in low-and-middle-income countries, specifically Tanzania. In Tanzania, the kits would initially be given to healthcare centers and dispensaries. The kits would then be distributed to expectant mothers when they visit their healthcare provider during their pregnancy. The healthcare provider would then instruct the expectant mothers how to properly use the kit as well. This increases the effectiveness of the kit as the mothers will be taught how to use it by people that they trust and know.

Regulatory/IP

The team will not seek a patent for the technology. The umbilical cord care kit will be classified as a Class I device by the FDA, and will undergo the corresponding regulatory pathway to production.

APPENDIX



Appendix A: Materials included in the kit. The kit includes a scalpel to cut the cord and a wipe to pretreat the area. The clamps and bandage for after cutting the cord. There is a pictographic ruler to show where the clamps and cut occurs relative to the baby's belly. Finally, there is a daily cord care element comprised of a temperature stable antimicrobial agent, goldenseal oil.

REFERENCES

- [1] Hug, L., Sharrow, D., & You, D. (n.d.). *Levels & Trends in Child Mortality: Report 2019*. UN Inter-agency Group for Child Mortality Estimation.
- [2] Güvenç H, Aygün AD, Yaşar F, Soylu F, Güvenç M, Kocabay K. Omphalitis in term and preterm appropriate for gestational age and small for gestational age infants. *J. Trop. Pediatr.* 1997 Dec;43(6):368-72.

[3] Coffey, P., & Brown, S. (2017). Umbilical cord-care practices in low- and middle-income countries: a systematic review. *BMC Pregnancy And Childbirth*, 17(1). doi: 10.1186/s12884-017-1250-7