

Team LowCostomy: EWH Proposal

Problem Definition

High-quality colostomy bags found on the market today are expensive and unavailable to those in less developed countries⁵. Many patients in Sub-Saharan Africa resort to homemade solutions such as duct taping plastic bags to their stomas (the part of the intestine which protrudes from the abdomen). Such methods often cause leakage, foul odors, discomfort, and further health complications which disrupt daily life and their overall quality of life. As a team, we decided the four main design criteria for the LowCostomy bag include being low cost, odor-proof, anti-leak, and durable. We produced a bag made of readily available materials including components which the user could construct themselves to further reduce manufacturing costs. This resulted in a colostomy bag of beeswax, resin, fabric, plastic water-bottles and plastic bags, which still passed a 3-day durability test, a time comparable to the status quo.

In choosing the bag design, we tested a variety of materials by placing liquified dog feces in the bag and having the participants rate the scent intensity radiating from each bag type on a five-point Likert Scale. The results showed that the triple layered plastic bag and a full plastic water bottle were effective odor proof solutions, which, when combined with comfortability tests, resulted in us choosing three 500mL plastic bags, ironed together to make one bag with increased durability and odor proof qualities. The top inch of the bags is left un-ironed. The top half of a recycled water bottle is slipped into the mouth of bag, just deep enough so one of the thin layers at the top can be folded over the neck of the bottle and cinched in place with the cap. Leaving the top inch un-ironed supports our patients' needs, because if there is any damage to one layer in the middle of the day, it can easily be swapped out for the next layer without needing to replace the whole bag. For extra security, a second water bottle is used as a "cuff" which wraps around the device, sandwiching the bag between the two plastic bottles. A hole is cut through both bottles and the bag, creating a completed colostomy bag. We tested how leakproof the design was by putting 500 mL of water in the bottle/bag assembly without a hole cut for the stoma. We identified 0 mL of leakage out of the bag and bottle screw connection, including when turned upside down out of the seal with the bottle cap. Additional leakage testing is being conducted using a model stoma and peristaltic pump. A body wrap with an extruding pocket is used to secure the completed bag to the abdomen. The LowCostomy Bag scarf is designed to be used, washed, and reused countless times before disposal.

The final aspect of the LowCostomy Bag is the beeswax buffer, which sits between the device and the skin, to replace the expensive 'putty/barrier rings' currently used. Beeswax was chosen because of its accessibility in Sub-Saharan Africa and its anti-bacterial, anti-fungal,² and antioxidant³ properties. The beeswax is mixed with pine resin to increase its malleability and adhesive qualities. It is then molded into a donut shape and placed on the stoma hole of the LowCostomy Bag. We are currently testing with a stoma model to determine the appropriate concentration of resin in the beeswax, and to ensure the shape of the stoma does not affect the leakproofness.

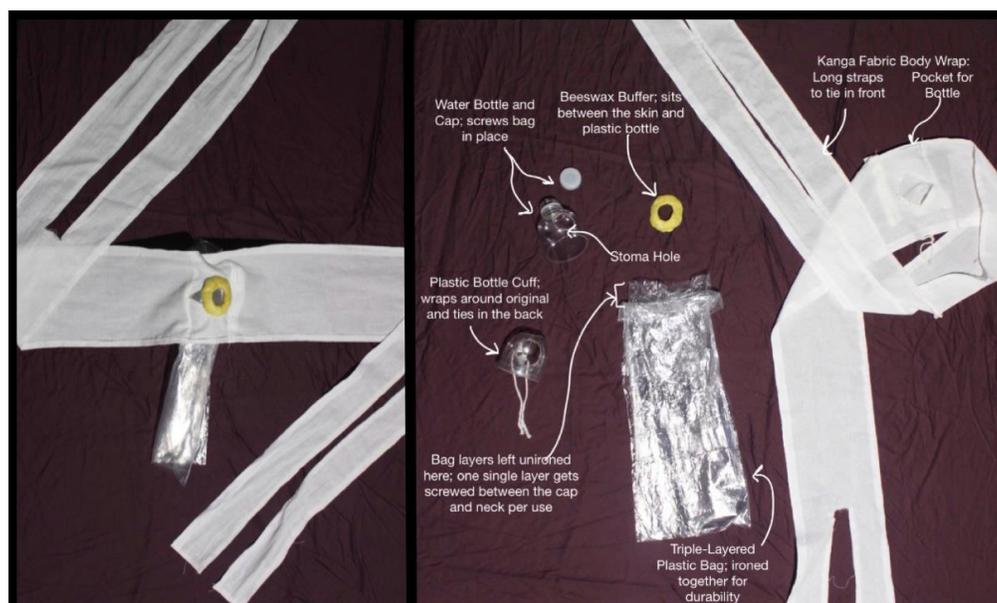


Figure 1: Parts and Assembly of LowCostomy Bag

Statement of Impact in a Developing World

Colorectal cancer plagues another 1.2 million people annually as the third most common cancer worldwide, causing 600,000 deaths per year^{1,3}. The incidence values for colorectal cancer in Sub-Saharan Africa are increasing annually at an average rate of 4%². Common treatment for those diagnosed with any stage of colorectal cancer is to receive surgical intervention, commonly a colostomy. Additionally, Ethiopia alone has 33.95 surgical admissions per 100,000 population per year with 10.3% being due to trauma and intestinal obstructions⁴. Despite the rampant and increasing number of cancer and intestinal trauma patients who receive colostomies, there has yet to be an affordable colostomy bag created for the low-to-medium income patients for post-surgical living in limited-resource countries. This is precisely the demand that the LowCostomy colostomy bag aims to meet.

Surgical procedures impact one's ability to monetarily provide for themselves and their families; in fact, a staggering economic productivity loss of \$12.3 trillion (about \$38,000 per person) due to poor provision of surgical care in low-to-middle income countries was projected for the period between 2015 and 2030⁵. With major health disparities among mortality rates and treatment options/availability, action must be taken to remedy the lack of healthcare equity in low-resource areas^{1,4}. With these shortcomings in mind, the LowCostomy bag was designed to improve the quality of life for colostomy patients in low-resource settings.

Our device, "an ostomy pouch plus accessories", is a Class 1 medical device according to the FDA. Thus, we will not be required to follow through with a PMA.⁴ Additionally, our device is 510(k) exempt as a colostomy bag is considered a "personal use device," one of the listed exemptions.⁵ We are currently finalizing IRB submission forms with our PI to formally test the irritability of the beeswax resin combination on skin. After completion of this testing, we will need a 21-CFR Part 807 to approve our manufacturing. Our team will then proceed to conducting clinical trials in Tanzania. While the details of such trials have not been firmly established, we will need to obtain federal IRB approval as well as IRB approval in Tanzania through Duke University Medical Center. Our final goal is to become a legally approved, non-profit organization.

A unique aspect of the LowCostomy Bag is that most of its pieces can be handmade to lower the cost of the product. For instance, the idea of a handsewn body scarf was inspired by typical Kanga fabric and the way it is handcrafted into Sub-Saharan African clothing by its wearers. If consumers are capable of fabricating their own scarves, this piece of the LowCostomy Bag needn't be purchased and can be reused until worn out. In future, we must decide which components of our bag should be handmade, and which should be manufactured, and hence determine the true cost of our produce. Additionally, we will decide whether the beeswax and resin will be sold premixed.

References:

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