Product Design Specification Report
Probiotics Delivery Device

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Problem Statement

Dr. Nasia Safdar, of the UW-Madison Department of Medicine, researches the use of probiotics. Currently, she is researching the efficiency of the probiotic lactobacillus GG in preventing *s. aureus* infections when the probiotics are applied to the interior nasal passage. A device to deliver the probiotic to the inside of the nose is needed to perform clinical trials with the probiotic. The delivery device should allow the accurate delivery of one billion viable lactobacillus GG organisms to the nose. Also, a solution in which to suspend and deliver the bacteria to the nose needs to be found. The lactobacillus GG should live inside the nasal passage for at least one day to allow for daily application of the probiotic.

Client requirements

- Deliver probiotics to anterior nasal passage
- Probiotics to be delivered are the bacteria lactobacillus GG (trade name: Culturelle)
- Accurate and repeatable delivery of 10 million to one billion organisms
- Solution needs to be found to suspend bacteria in
    - Biocompatible with human patients
    - Solution must allow bacteria to live for up to 2 weeks
    - Solution must keep bacteria from overgrowing
    - No food for bacteria will be present
- Daily application: the bacteria must live in the nose for a minimum of 1 day
- Delivery device will need to be able to be refrigerated
- Delivery device should be opaque to keep out light that would promote bacteria growth
- Weigh less than 0.25 kg
- Dimensions less than 7 cm x 7 cm x 2 cm
- Delivery device must prevent insertion of delivery device further than 1-2cm into the nasal passage
- Material of delivery device must not harm user and must be non-abrasive
- Material must not degrade with constant use
    - Lifetime is 2 weeks
    - Use daily
- Material must withstand refrigerated storage conditions
    - 4-5^{o}C
    - 50% humidity

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The device will be used daily to deliver the dosage of between 10 million and 1 billion bacteria. The device and bacteria suspended in a solution must allow the bacteria to survive for up to 2 weeks. The device must have ability to secure bacteria inside to prevent contamination of outside surfaces or of bacteria itself.

b. *Safety*: This device must not endanger the user. There must not be toxic materials or sharp edges within the device. There should not be any pathological concerns due to fluids escaping the delivery device. Neither the solution, nor the delivery device should cause harm to the patient.

c. *Accuracy and Reliability*: This device should accurately deliver between 10 million and 1 billion organisms. This delivery should be precise and repeatable for daily delivery up to 14 days. The solution should not cause the bacteria to die or grow excessively.

d. *Life in Service*: The device should have repeatable delivery procedures for 2 weeks. The materials should uphold their features to allow for multiple deliveries of probiotics. The solution should not allow excessive growth or death of bacteria for 2 weeks.

e. *Shelf Life*: The materials of the model should not degrade over time in refrigerated storage for 2 weeks. The solution should not allow bacteria to die within 2 weeks. The solution will be made up to a week before the patient receives it. For the clinical trials, this is a feasible time period because the people in charge of the clinical trial will be packaging the gel themselves. The patient will have it for up to a week for use; the total shelf life is 2 weeks.

f. *Operating Environment*: There will be one device per patient. The delivery will be performed at ambient conditions. The storage will be at 4-5 ^{o}C in a refrigerator.

g. *Ergonomics*: Delivery device should only be used to deliver the prescribed probiotics and should be discarded after use. The probiotic may be discarded in regular trash out of reach of children. The probiotics should be taken only in prescribed dose.

h. *Size*: The device should not exceed a size of 7 cm x 7 cm x 2 cm.

i. *Weight*: The delivery device with the probiotics suspended in the solution should weigh less 0.25 kg.

j. *Materials*: Materials must be safe for use with humans. Any material used should not pose a health risk. Non-radioactive, non-flammable, and non-corrosive materials should be used. Material must not degrade when introduced to the nasal passage. The solution must not be harmful to the bacteria or patient.

k. *Aesthetics, Appearance, and Finish*: The device should be pleasing to the eye. The finish should be smooth and clean looking.

2. Production Characteristics

a. *Quantity*: One device is required at this time. However, since the device is to be used on a large scale clinical trial, additional models should be able to be available.

b. *Target Product Cost*: The target manufacturing cost for the product is $10 per delivery device. This target cost includes the bacteria and the solution. The target cost is based on a mass production of the device; the first device will have a target cost of under $150 for the lab supplies, solutions, culture media, and bacteria (the lab is fully equipped and some culture media and solutions will be used from the current stock).

3. Miscellaneous

a. *Standards and Specifications*: This device will require approval by the FDA if this product with the delivery device is mass produced for market use after the clinical trials take place since it will be used with patients. Currently, the device falls under Class I classification and does not require any premarket notification to the FDA regarding the device.

b. *Customer*: The delivery device should adhere strictly to the basic requirements of delivering bacteria to the nasal passage of the patient. The device and the bacteria should be used as prescribed.

c. *Patient-related concerns*: The delivery device will come in contact with patients and therefore should not cause harm to the patient. The patient should not be made sick by the materials of the device or its probiotic contents. Patient confidentiality should be maintained while building and testing the delivery device.

d. *Competition*: There are many types of products that focus on delivering fluid solutions to the nose. Three examples are Afrin, Flownase, and Bactroban. There is not a marketed ointment or sprayer specifically for delivering probiotics to the nasal passage.