

Executive Summary

The objective of this project is to improve the maintenance of the cold chain in developing countries. A quarter of all children born each year are not immunized against common and preventable diseases during their first year of life [1]. By increasing vaccine delivery, a greater number of lives will be saved. The process to deliver these life saving vaccines is both a technological and logistical problem. Our project created a device that is able to keep vaccines, blood and test samples within the narrow temperature range of 2°C to 8°C.

Clinical Need

In the current vaccine supply chain, the “cold chain”, passive temperature stabilization relies on insulated vaccine carriers storing ice packs, or cold boxes, but poor design often renders vaccines impotent due to freeze damage. Also, in developing countries there are similar difficulties maintaining the cold chain for blood and test samples. Our device will address the need of maintaining the proper temperature range as vaccines, blood and test samples are transported from the local district hospitals like Bayalpata Hospital to rural towns and villages.



Description of Market

THE CUSTOMERS

As an investment in health, immunization is widely regarded as a “best buy”, since it protects individuals and populations at low cost, but also provides a platform for delivering other health interventions, such as vitamin A supplementation [3]. The primary responsibility for ensuring sufficient financing for immunization services rests with governments of LMICs (Low and Middle-Income Countries, as recognized by WHO); however, since national governments alone may not be able to provide all of the required funding, it is a shared responsibility of the central government, district governments, and communities to identify and mobilize the necessary resources to sustain safe and effective immunization services [4].

END USERS

Carriers/Clinicians that are delivering the vaccines to the remote villages and towns within their district. Our device is aimed at the final step in maintaining the cold chain.

MARKET SIZE

In 2003 alone, vaccines are estimated to have prevented two million diseases and 600,000 deaths [1]. However, at the same time, it is estimated that 27 million children and 40 million women were not vaccinated [5]. The need for the delivery of vaccines will always be present along with the need for the delivery of blood and test samples.

DISTRIBUTION

Our product will be distributed through the governments and world health organizations. Many world health organizations focus on immunization and also many governments believe vaccines are the best buy when it comes to healthcare.

Description of Design

Functional Goal: The goal of our project is to create a backpack that is capable of accurately maintaining an internal temperature of 2 – 8° Celsius over the course of 3 hours. It will be used for the transportation of blood or vaccines and will that operate on minimal electrical energy.



Main Chamber

- Multiple layers of insulation to minimize temperature changes within internal box.
- Temperature within actively monitored by two probes
- Aluminum chamber allows for air and heat circulation to prevent uneven heat distribution

Cold Chamber

- Isolated from main chamber by multiple layers of insulation
- Holds ice to provide absorb heat from main chamber when needed

Temperature Control System

- Determines temperature of main chamber using two probes in different locations
- If temperature is too high turns on fans circulation air between cold and main chambers
- After temperature returns to acceptable ranges, turns off fans.

Backpack Straps

- Provides sturdy frame to maintain the structural integrity of the backpack
- Evenly distributes weight of pack on shoulders, chest, and waist reducing discomfort
- Lightweight



Novelty

Current Cold Chain Devices

- No regulation of temperature, which leaves vaccines vulnerable to temperatures outside the recommended range of 2°C to 8°C
- Require carrying by hand or over one shoulder for upwards of 6 hours

PoCo DeCo

- Maintain temperature between the required range of 2°C to 8°C
- Hands-free carrying with the added support of both a waist and chest strap
- Added user friendly features like real time temperature readings

Product Cost

Components	Price per item	Total Cost
Insulated Box	\$5.49	\$7.98
Insulation	\$2.00	\$2.00
Backpack (Fabric)	\$4.00	\$4.00
Backpack Frame	\$5.00	\$5.00
Temperature Probe	\$1.20	\$2.40
USB Microcontroller	\$16.00	\$16.00
Temperature Display	\$1.56	\$1.56
Acrylic Sheet	\$3.50	\$3.50
PVC Tubing	\$1.50	\$1.50
Aluminum Sheet	\$2.00	\$2.00
Total Cost of Product		\$45.94

Regulatory Pathway

- Class I Device
 - Not intended to support or sustain life
 - Low potential for harm
- Exempt from 510(k) and PMA
- Does not require FDA clearance before marketing

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References

- [1] Vaccines: Handled with Care. (2004). New York, New York: The United Nations Children Fund
- [2] A vaccine cold chain freezing study in PNG highlights technology needs for hot climate countries (2007)
- [3] Vaccines as a global imperative--a business perspective (2011)
- [4] Immunization Essentials: A Practical Field Guide. In I. D. Office of Health, and Nutrition, Bureau for Global Health, U.S. Agency for International Development (USAID) (Ed.): USAID.
- [5] Estimating the costs of achieving the WHO-UNICEF Global Immunization Vision and Strategy, 2006±2015 (Vol. 86).