**Reusable Blood Transfusion Sets**

**Collaboration with Pothawira**

Pothawira (Safe Haven) Christian Mission Organisation, based in Salima, Malawi, serves the community by providing housing, healthcare, education, and economic sustainability projects. The campus includes a medical clinic, birthing center, primary school, and a home for 124 orphaned children. Recently, funds were raised, and plans were made to open a new surgical center in 2025. This is crucial as the only other surgical center in the region, Salima District Hospital, has just two OR rooms, neither adequately equipped for optimal surgical procedures and insufficient to serve the needs of 800,000 people.

**Blood Donation**

Pothawira’s new surgical center will be equipped with a blood bank. Blood donation is a critical issue in Malawi, as the Salima District Hospital blood bank frequently lacks sufficient supply. Patients are required to bring a family member with the same blood type to be on standby for potential transfusions. This challenge is exacerbated when blood-giving sets are unavailable, as the Malawi Government provides a limited supply of these sets to the local hospital, but more are needed to reach the demand. This unfortunately leads to situations where necessary blood cannot be provided during surgery.

**Needs Statement**

The current method for blood transfusions at the Pothawira Surgical Center in Salima, Malawi, relies on on-site blood gathering, testing, and donation from a patient’s family member with the same blood type. The clinic lacks the ability to store blood donations and frequently runs out of necessary equipment for blood transfusions, leading to critical delays in patient care. The local population, which includes over 800,000 residents, is in urgent need of reliable and efficient transfusion methods. There is a need for affordable, reusable, and sterilizable blood-giving sets and a blood-warming device that can safely warm stored blood to the optimal transfusion temperature. These devices must be durable, compatible with existing equipment, and made from locally available materials to ensure sustainability, improving patient outcomes, and meeting the operational demands of the new blood bank and surgical center opening in 2025.

# Part 3:

**Design criteria**

1. **Sterilizable (Must Have)**

*Justification*: The blood-giving sets must be made with components that can withstand sterilization procedures used at the clinic (e.g., high-temperature cleaning). The blood-warming device must also be sterilizable to maintain safety in blood handling and administration.

*Verification*: We will test the device's components by subjecting them to multiple cycles of sterilization (e.g., autoclaving at 121°C for 30 minutes) and evaluating their structural integrity, material degradation, and cleanliness. Each component will undergo at least 50 sterilization cycles to verify long-term usability without degradation (21).

1. **Locally available resources**

*Justification*: The device should be made from materials that are available or easily accessible in Malawi to ensure long-term sustainability and reproducibility. This will reduce dependency on external suppliers and allow local healthcare providers to maintain and replicate the device.

*Verification*: A conversation will be conducted with local suppliers and healthcare providers in Malawi to confirm the availability of materials needed to manufacture the devices.

1. **Cost under $100 for blood-giving sets**

*Justification*: The cost of the devices must meet the budgetary constraints of the clinic and the Malawian healthcare system. These numbers are safe upper limits for cost, given by our sponsor. The affordability will ensure that the devices can be widely used and sustained in the resource-limited setting.

*Verification*: A cost analysis will be conducted by sourcing material quotes from local and international suppliers, along with labor costs. We will ensure the final production cost remains within the specified range.

1. **Air-tight seal***Justification*: The blood-giving sets must maintain an air-tight seal to prevent contamination and ensure the safe transfer of blood. This is essential to avoid infection risks and maintain the integrity of blood during transfusion.

*Verification*: We will test the air-tightness by applying water or air pressure to the system and ensuring no leaks occur under typical use conditions. The system will also be tested under vacuum conditions to simulate blood flow during transfusion.

1. **Reusable, Durability to withstand 200 uses***Justification*: The blood-giving sets must be reusable and durable enough to withstand multiple sterilization cycles and uses without degrading. This will ensure that the investment in each set maximizes its long-term use and reduces the need for frequent replacements.

*Verification*: The devices will undergo mechanical fatigue testing by simulating repeated use, including sterilization cycles, disassembly, and reassembly.

1. **Portability and easy-to-use design***Justification*: The device should be portable and easy to use by healthcare workers with minimal training. This will facilitate use in various settings within the clinic and ensure the device can be employed efficiently during emergency situations.

*Verification*: The device’s portability will be verified by ensuring it weighs less than 2 kg and can be easily transported by a single healthcare worker between rooms. Ease of use will be validated through usability tests where healthcare workers will be able to set up the device within 10 minutes and operate it effectively after no more than 30 minutes of training.

1. **Mechanical robustness and resistance to mechanical stress***Justification*: The devices must be able to withstand rough handling, transport, and drops in a busy clinic environment without breaking or malfunctioning. According to *WHO* standards, medical devices in resource-limited settings must be rugged and able to withstand rough handling, transport, and frequent use. This ensures longevity and reduces the cost of repairs or replacements.

*Verification*: The devices will be subjected to mechanical stress tests, including drop tests from 1 meter and impact resistance tests. Components will also be tested for fatigue by applying repeated pressure and strain.

1. **Compact design for storage**

*Justification*: The blood storage device must be of comparable shape and size to existing blood bags to fit seamlessly into the current blood storage infrastructure at the clinic. This ensures compatibility with existing refrigeration and storage systems, reducing the need for modifications or additional storage solutions.

*Verification*: We will compare the dimensions of the blood storage device to standard blood bags (approximately 10-15 cm in width and 20-25 cm in length) and test its fit in clinical storage units. The device must occupy the same space as a typical blood bag in refrigerators and storage racks used at the clinic, ensuring it integrates smoothly with the current setup.

1. **Community Comfortability**

*Justification*: The blood-giving set must be as non-intimidating as the current disposable sets to ensure patient comfort and acceptance, supporting a smooth transition and consistent use.

*Verification*: Surveys will compare patient comfort levels using a Likert scale, assessing the new set against existing disposable sets. Usability tests will gauge willingness and preference through direct comparison feedback.