A Sustainable Engineering Solution for Paediatric Dehydration in Low- Resource Clinical Environments

Ashley R. Taylor
Department of Mechanical Engineering, Virginia Polytechnic Institute and State University, Blacksburg Virginia
ashleyt1@vt.edu

Jeffrey Turovskiy
Department of Mechanical Engineering, Virginia Polytechnic Institute and State University, Blacksburg Virginia
jefft@vt.edu

Benjamin Drew
Department of Mechanical Engineering, Virginia Polytechnic Institute and State University, Blacksburg Virginia
Ben.Drew@trane.com

Dr. Andre Muelenaer
Section of Paediatric Pulmonology/Allergy, Virginia Tech Carilion School of Medicine, Roanoke Virginia
aamuelenaer@carilionclinic.org

Dr. Kerry Redican
Department of Population Health Sciences, Virginia Polytechnic Institute and State University, Blacksburg, Virginia
kredican@vt.edu

Dr. Kevin Kochersberger
Department of Mechanical Engineering, Virginia Polytechnic Institute and State University, Blacksburg,Virginia
kbk@vt.edu

Dr. Lissett Bickford
Department of Biomedical Engineering and Mechanics, Virginia Polytechnic Institute and State University, Blacksburg Virginia
bickford@vt.edu

ABSTRACT: *Engineering efforts in low resource environments pose a unique set of challenges, requiring an in-depth understanding of local needs, comprehensive mapping of community resources, and extensive collaboration with local expertise. The importance of these principles is demonstrated in this paper by detailing the novel design and field demonstration of an affordable, locally manufactured intravenous fluid regulation device. Collaboration with clinical personnel in Uganda and Malawi guided device design. In-country physicians emphasised the need to regulate volume of intravenous (IV) fluid delivered to a paediatric patient without use of electricity. The proposed device regulates IV fluid delivery within ±20 mL of total prescribed dosage, providing a method of reducing fatalities caused by over-hydration in low resource environments; the feasibility of building the device from local resources was demonstrated by a field research team in Malawi. The device was successfully constructed entirely from local resources for a total cost of $46.21 (USD). Additionally, the device was demonstrated in rural clinics where 89 % of surveyed clinical staff reported that they would use the device to regulate IV fluid delivery. This paper emphasises the importance of collaborating with communities for community-based engineering solutions. Mapping community assets and collaborating with local expertise are crucial to success of engineering efforts. Long-term, community-based efforts are likely to sustainably improve health outcomes and strengthen economies of communities worldwide.*

KEYWORDS: Engineering for low resource environments, global health, paediatric dehydration, intravenous fluid volume regulation, community-based solutions

1 INTRODUCTION

As the second leading cause of death in children under five years old, diarrhoea-induced dehydration kills approximately 760,000 children annually (World Health Organisation, 2013). Dehydration related deaths pose the greatest burden in areas where access to water and sanitation resources may be limited. Dehydration is a treatable condition with appropriate medical care, with a recommended treatment of oral rehydration (Rouhani et al, 2011; World Health Organisation, 2013). However, this treatment has several critical limitations; oral rehydration may be too slow to provide adequate hydration for a patient and is not viable when the patient is vomiting. In such instances, intravenous (IV) fluid delivery becomes necessary (Reid and Bonadio, 1996).

Administering IV fluids to paediatric patients remains a challenge in low resource clinical settings. Physicians in resource-limited settings face many challenges, including an unstable electric grid, inadequate equipment, and very high patient-to-staff ratios (Lehmann et al, 2008; Marchal and Kegels, 2003; Vujicic et al., 2004; World Health Organisation and The World Bank, 2015). A recent study found that 82,949 physicians in sub-Saharan Africa are responsible for providing care to 660 million people, resulting in a ratio of 13 physicians per 100,000 people (Hagopian et al, 2004). In 2014, the World Health Organisation estimated that the physician-to-patient ratio in Malawi is approximately 2:100,000, and the nursing ratio is approximately 29:100,000 (World Health Organisation, 2014). In contrast, the United Kingdom and United States have 164 and 279 physicians per 100,000 people, respectively (Hagopian et al, 2004). Intravenous fluid delivery for paediatric patients requires careful monitoring, and in clinical settings that are understaffed, this may not be feasible. Without adequate monitoring by clinical staff, the World Health Organisation does not recommend IV therapy due to the risk of paediatric patients becoming fatally overhydrated (Shah et al, 2015; World Health Organisation, 2005).

Though robust IV delivery systems, such as electronic infusion pumps and burettes, have been designed for clinical settings in developed nations, appropriate and affordable solutions for resource-limited environments remain sparse (Oden et al, 2010; Shah et al, 2015). One successful design was presented in 2015 by Rice University's Beyond Traditional Borders program; the proposed device was designed for use in low-resource settings and is able to function without access to the electric grid or consumables (Shah et al, 2015). The development of this device was a leap in technology innovation for the developing world; however, the cost ($80 for the proposed device) may be improved by designing technology that does not use steel or aluminum, which may be prohibitively expensive (Shah et al, 2015).

Designing for low resource settings poses a set of diverse challenges for engineers and requires an extensive understanding of the collaborating community, locally available resources, and cultural values (Black, 1999; Malkin, 2007; Mohan, 2014). For sustainable medical solutions, device designs should utilise local materials to enable local maintenance and repair (Malkin, 2007; Schumacher, 1973). Additionally, locally-manufactured devices may promote empowerment and independence of communities instead of dependence on medical device donations. Designing for low resource settings must also consider local constraints, such as an unstable electric grid. Mapping community assets is also critical for designing in resource-limited clinical settings; maintenance personnel and local masons are invaluable resources in the design process and may provide essential knowledge on availability of local materials and manufacturing processes (Black, 1999; Mohan, 2014).

2 PRELIMINARY DESIGN OF IV REGULATION SYSTEM

The following section outlines the design process for the IV fluid regulation device.

2.1 Identification of Clinical Need and Design Requirements

In order to design a robust IV fluid regulation system for low resource clinical settings, it was first necessary to seek a comprehensive understanding of system requirements. Clinicians in rural Uganda expressed the original need, and clinicians in rural Malawi expressed similar needs. Clinics in Malawi and Uganda exhibit many differences, including varying patient-to-staff ratios, healthcare system structures, and availability of resources, such as pharmaceuticals and medical equipment. However in both locations, clinicians

Table 1: Intravenous fluid regulation system design requirements

Functionality of Device	Performance of Device	Construction of Device
Device can be operated mechanically	Device dispenses volumes of fluids within 10 % of total fluid volume to be delivered to the patient	Device is built from locally available materials and tools
Device stops fluid flow independently of clinician intervention	Device dispenses accurate fluid volume ranges between 0 to1000 mL	
Device alerts caregiver of completion of fluid delivery		

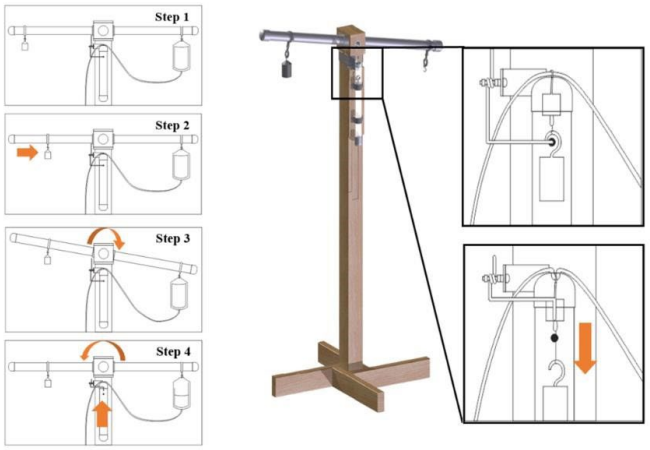

Figure 1: Diagram of system design. Starting at equilibrium (Step 1), the counterweight is adjusted towards the centre (Step 2) and the system shifts out of equilibrium (Step 3). As fluid empties from the bag, the system returns to equilibrium (Step 4), which activates the cut-off. Inside the cut off is a small mass suspended by the wire trigger and tied on a string to a hook. When the cut-off is activated, the wire trigger releases the mass, and the resulting downward force pulls on the hook, creating a kink in the tubing. This kink in the tubing restricts fluid flow.

expressed similar key challenges associated with working in low resource environments; these shared challenges in Uganda and Malawi formed the design requirements for the IV fluid regulation system. Among the challenges identified were an unstable electric grid, shortage of staff, and lack of spare or replacement parts to repair equipment. Table 1 shows design requirements developed in response to insight from clinicians in low resource settings. One of the most critical design requirements was for the device to be manufactured entirely from local resources to enable local maintenance and repair.

2.2 Consideration of Community Assets and Local Resources

To achieve a design that is sustainable in low-resource areas, engineers must consider available local resources for their designs. By using only local parts, engineered products can be manufactured and maintained efficiently. Designs should also consider the manufacturing capabilities of the area. Precision machining and injection molding are rarely available and usually are prohibitively expensive. Thus, designs that are limited to locally available materials and manufacturing create a sustainable product that can succeed in low resource environments. To meet these criteria, the proposed device was originally designed using only materials found in local North American hardware stores, which are comparable to materials available in hardware markets in Malawi and Uganda. Additionally, the device was constructed by hand exclusively using simple hand tools. Building and construction materials are abundant in many low resource areas; markets are often filled with items ranging from PVC and metal hardware to rope and wire. Hand tools are also in abundance in areas that do not have consistent access to an electric grid.

2.3 Proposed Device for IV Fluid Volume Regulation

The IV fluid volume regulation device is shown in Figure 1. The device utilises a simple lever-based counter-balance methodology to dispense a defined amount of IV fluid to a patient. The user adjusts the position of a fixed-mass counterweight to set the desired volume. The IV bag will be suspended at a fixed distance from the lever pivot. As fluid is drained from the IV bag, the lever arm rotates in the counterclockwise direction.

The counterweight distance (d) for a given mass of fluid can be determined from the following (Equation 1):

$$d_{cw} = \frac{\left(m_{IV} - \rho V_{dosage} + m_{offset}\right) * d_{IV}}{m_{cw}} \quad (1)$$

where:

m_{IV} is the initial mass of the IV bag;

ρ is the IV fluid density;

V_{dosage} is the target volume of fluid to be dispensed;

d_{IV} is the distance between the IV bag and the lever pivot (centre of device);

m_{cw} is the mass of the counterweight; and

m_{offset} is a linear offset term accounting for the friction in the pivot bearing and the force required to trigger the fluid cut off mechanism.

Equation 1 was used in the design of the IV fluid regulation system and is provided above as a starting point for calibration of the device in the field. As explained in section 2.3.2, the device can be calibrated without precise measurements of the mass of the IV bag and the linear offset term. Estimates for the counterweight position at each dosage increment can be made based on Equation 1, visually represented by Figure 2. Adjustments must be made accordingly to the counterweight position of each device during calibration to account for the varying offset in the system.

2.3.1 System Cut-off

The mechanism for stopping the fluid flow is enclosed inside a vertical polyvinyl chloride (PVC) pipe mounted onto the system support (Figure 1). Inside the pipe is a hook created from looping wire through a dowel rod, which is tied with a string to a small mass. The mass is an eyebolt holding up a stack of washers. The hook is pulled through a hole in the centre of a PVC end cap, and the IV tubing rests under the hook. The mass is suspended by a thick wire that

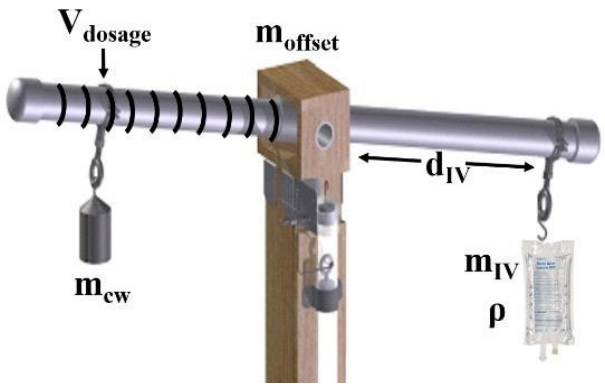

Figure 2: The device utilises a simple lever-based counter-balance methodology to dispense a defined amount of fluid to the patient

acts as the trigger for system cut-off. This wire is looped around a bolt on the side of the system support and bent up to rest under the equilibrium position of the counterweight side of the lever arm. When the system approaches equilibrium, the lever arm rotates until it comes into contact with the trigger wire, applying enough pressure to rotate it out of position. When it rotates, it releases the mass inside the PVC pipe. The mass falls and applies a downward force to the hook, which gets pulled through the hole in the PVC end cap, pulling the IV tubing with it. The downward motion of the hook creates a kink in the tubing, which stops the flow of fluid. The system cutoff is shown in Figure 1. The cut-off mechanism meets the design criteria in Table 1 that states "device alerts caregiver of completion of fluid delivery". The alert accomplished by the cut-off mechanism is two-fold; first, an audible alert is given when the counterweight falls, and second, a visual alarm is accomplished when the cutoff mechanism is open upon completion of IV fluid dosage delivery.

2.3.2 Construction and Calibration

The original prototype of the system was built exclusively using materials sourced from domestic (North American) hardware stores. This allowed the design to focus on simple yet robust methods for the system to accomplish necessary functions. The main body of the device was originally assembled from timber. PVC pipes and fittings allowed for smooth rotational motion and sturdy connections. Nuts, bolts, washers, and wire were used for smaller components. A simple construction allowed for easy repair or replacement if components were to break.

Once a new system is built, the following process can be used to calibrate it for use. The calibration equation (Equation 1) will calculate the relative distances from the counterweight to the centre of rotation that bring the system to equilibrium at various delivered dosages. For example, if 100 mL dosages are desired, the distances corresponding to 100 to 1000 mL should be calculated at 100 mL increments. It is important to note that the counterweight adjustment (shown by adjacent lines in Figure 2) is the same length for each increment of 100 mL dosage; however, this length may differ from device to device depending on the materials used in its construction.

To calibrate a new device, several test trials should be performed. The distances calculated from Equation 1 are to be measured and marked on the lever arm (Figure 3a). Three initial trials are to be performed at 100, 200, and 300 mL, respectively. After each trial, the amount of fluid drained from the IV should be measured, and the system should be set up again to continue draining into the same container. Then, the actual delivered dosages may be compared to the intended dosages. If too much fluid is being dispensed, the markings should be adjusted away from the centre of rotation (Figure 3b); if too little fluid is being dispensed, the markings should be adjusted towards the centre (Figure 3c). This process can be repeated for dosages of 400, 500, and 600 mL. If finer adjustment is required, repeat the process again for dosages of 700, 800 and 900 mL. With this process, only one bag must be utilised in order to accurately calibrate the system.

2.4 IV Fluid Dosage Testing

To ensure safety, the device was pilot tested for accuracy and reliability to demonstrate the proof of concept of the system and obtain pertinent standard deviations as a baseline. Full 1000 mL IV bags were drained by increments of 100 mL for a total of ten target volumes (100 mL, 200 mL, 300 mL, etc.); subsequently, the volumes of fluid dispensed at each increment were recorded. This procedure was repeated five times to provide five data points at each target fluid volume. Testing was conducted at the highest possible flow rate, with the standard IV bag roller clamp fully open. Additional testing was conducted at a slower flow rate (50 mL/hr) to ensure device functionality across a range of flow rates. It is important to note that flow rate is controlled independently of the IV fluid regulation device using a standard roller clamp; the device only regulates the volume of IV fluid to be delivered. The height of the device can be adjusted to meet the needs of individual hospitals. If the height of the device is adjusted, the calibration procedure (section 2.3.2) should be repeated.

Comparing experimental volume delivery results to the projected volume delivery results found during calibration, the uncertainty associated with each target volume, as well as uncertainty in the overall system, was determined. Statistical methods (standard error and student's t-distribution) were used to quantify uncertainties and develop appropriate confidence intervals. Based on discussions with clinicians, the device must regulate fluid deliver within 10 % of total fluid volume to be delivered to the patient.

A 99 % confidence interval and standard error were formed for each target volume. It is important to note that the total error at each interval is a combination of the total system error, most specifically in the cut-off mechanism, and any error that arises due to the placement of the counterweight. The overall system standard error was ±20 mL at a 99 % confidence interval, falling within the acceptable range

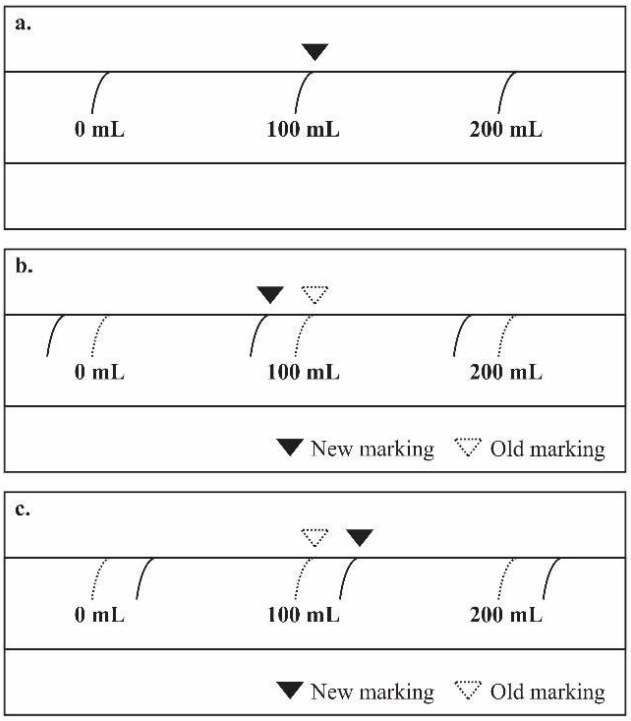

Figure 3: The calibration process for a newly built system

of ±30 mL. As shown in Figure 4, a linear relationship was found between the volume of fluid dispensed and the distance of the counterweight from the zero position. Figure 4 also reflects the consistency of fluid volume delivered at each counterweight position.

3 EVALUATION IN LOW-RESOURCE CLINICAL SETTINGS

After the device was constructed and calibrated, field-testing and demonstration was conducted in the southern region of Malawi, located in sub-Saharan Africa. In preparation for travel, it was necessary to modify the design slightly upon realisation that wood materials for the base of the device were not readily available. Instead, the team constructed the base from PVC pipes, which also improved sterility of the device since PVC can be easily cleaned with a sterilising solution.

3.1 Building the Device from Local Resources

Working with the in-country PVC manufacturer and distributor, the field research team constructed a device entirely from local resources, shown in Figure 5. The mass of the constructed device was approximately 9 kilograms. The base shown in Figure 5 is approximately 0.8 metres wide with a depth of 0.45 metres. The total height of the constructed device was approximately 1.8 metres, and the length of the lever arm was approximately 1.1 metres.

It was necessary to modify the design of the cut-off mechanism in the device. The original bent wire trigger was replaced with a pin inserted through the vertical piece of PVC to suspend the small dropping mass. This pin was tied by a string to the rotating arm near the stationary IV bag. The length of the string is determined so that the pin is pulled out of place just as the system reaches the equilibrium position.

Table 2 provides an itemised list of local resources used for in-country design as well as an image of the final device. The total cost of building a single IV regulation device in southern Malawi amounted to $46.21 (USD). It is important to note that the cost of building a single device is significantly greater than the unit cost of building many devices, since the cost of PVC components decreases as the purchase quantity increases. Additionally, there may be some variability in pricing of the device due to the inconsistent pricing of parts in local hardware markets. Future work will include fabrication of multiple devices in-country, enabling the determination of

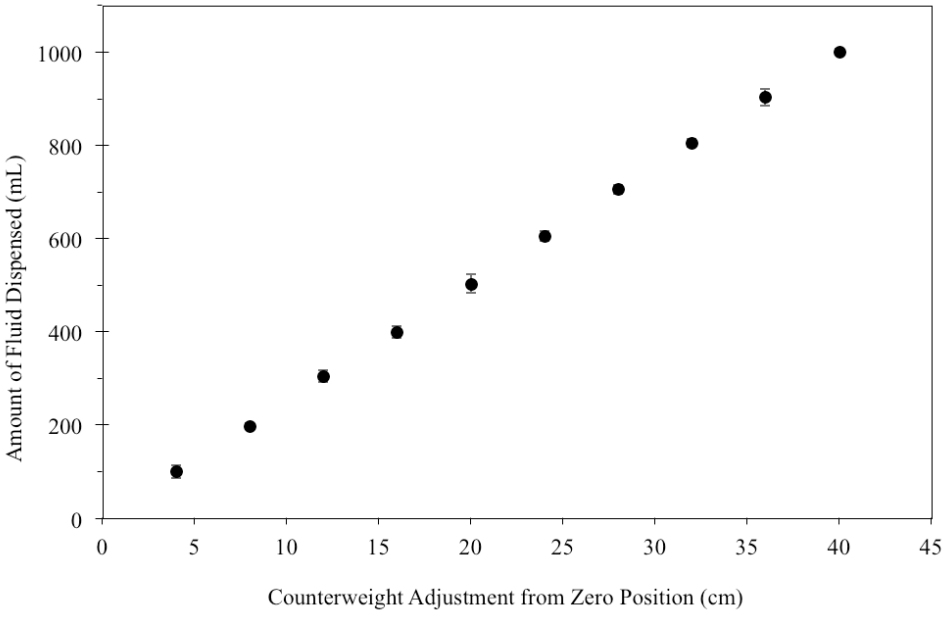

Figure 4: Average dispensed volumes in millilitres (mL) plotted against counterweight adjustment in centimetres (cm) with error at 99 % confidence level.

Table 2: Cost of manufacturing single device in southern Malawi

Material Type	Quantity	Total cost of materials ($USD)[1]
PVC T-Joint	10	$14.78
90° PVC Elbow	2	$2.19
PVC Unions (Double Sockets)	4	$1.15
3 metre length of 40 mm PVC pipe	2	$10.39
6 metre length of 32 mm PVC pipe	1	$6.58
1 metre length wire	1	$2.22
Washers	30	$6.67
Dowel	1	$1.11
2 metre length string	1	$1.11
Total cost of device in southern Malawi		**$46.21**

Notes:
1. Prices from PVC distributor and manufacturer in Blantyre, Malawi. Materials purchased in Malawian Kwacha (MKW). Conversions to USD based on conversion rate 1 USD = 450 MKW.

a median price of the device and reducing uncertainty on price variability.

Several challenges arose when fabricating the device from local resources. First, design modifications were necessary as a result of availability of local materials and tools. An unstable electric grid made using power tools for fabrication infeasible; instead, hand-powered tools were necessary to build the device. Lastly, inconsistent availability of parts in local hardware markets created challenges for fabrication; this was mitigated, largely, by collaborating with in-country PVC distributors.

Figure 5: IV fluid regulation device constructed in southern Malawi. Photo taken in Mulanje, Malawi

3.2 Evaluation of Clinical Feasibility and Local Acceptance

The field research team also evaluated the clinical feasibility and local acceptance of the device. The Virgina Tech research team conducted demonstrations of the device three clinical settings in southern Malawi. Clinical staff provided feedback on the device demonstration through a qualitative survey. In an effort to elicit transparent feedback and respect cultural differences in comfort with direct speech, clinical staff provided anonymous feedback through the aforementioned survey. The survey was approved by the Virginia Tech Institutional Review Board as well as by the hospital administrators of collaborating institutions in-country. Nurses and maintenance personnel piloted the survey with help from a public health colleague in Malawi.

Twenty-nine clinical staff provided feedback on device usability in low-resource clinical settings. All respondents (100 %) reported that the device was "easy to use", and most respondents (93 %) reported that the device was "easy to clean". When asked about feasibility of the building the device locally, 57 % of respondents reported that the device could be easily "manufactured using local resources". Of surveyed clinical staff, 89 % reported that they would use the device to regulate IV fluid delivery for paediatric patients. However, none of the respondents (0 %) reported that the device was "easy to move around as needed". The general consensus was that the size of the device needed to be reduced. Several clinical staff also commented that the device should be more portable to allow for easy transition from one bedside to another.

4 CONCLUSIONS AND RECOMMENDATIONS FOR FUTURE WORK

In conclusion, the proposed IV regulation system offers a feasible solution for safely treating paediatric dehydration in low-resource clinical settings. Through collaboration with in-country clinical personnel, a thorough understanding of needs was developed to guide device design. The proposed device regulates IV fluid delivery within ±20 mL, providing a safe and reliable method of preventing fatalities caused by over-hydration.

Field testing and demonstration in Malawi confirmed the feasibility of building the device locally. The field research team successfully constructed the device entirely from local resources. Cost of building the device in-country was $46.21 USD. Additionally, 89 % of surveyed clinical staff reported that they would use the device to regulate IV fluid delivery. Clinical staff recommended that the size of the device be reduced and the portability of the device be improved.

This work has several limitations. First, life-cycle testing to determine durability and reliability of the device was not fully completed before demonstration in Malawi. The original prototype device was tested for 7 months prior to demonstration in Malawi, and the device constructed in Malawi was demonstrated for 2 weeks. During demonstrations, fatigue effects on device performance were not apparent. However, further testing on multiple devices should be conducted to quantitatively determine device durability and reliability over a longer period of time (including consecutive days, weeks, and months) to fully examine the long-term accuracy and reliability of the system. This long-term testing must be done at the work site with equipment developed using local resources, such that meaningful data can be obtained and a possible preventative maintenance schedule developed. Additionally, this study did not include a training program for clinical staff on device use or device fabrication. Future work will include a formal training program and an evaluation for training on utilisation of device and fabrication of device. Long-term, this work aims to enable local masons to fabricate the devices independent of research team.

Field testing of the device in-country emphasised the importance of collaborating with communities for community-based engineering solutions. Constructing the device in country was successful, thanks to the insight and expertise of local hardware store owners. The importance of mapping community assets should not be underestimated for humanitarian engineering efforts. Designs that incorporate or exclusively use local resources are likely to promote empowerment of communities and decrease community dependence on medical device donations. Long-term, community-based solutions that incorporate local resources are likely to improve health outcomes and strengthen economies of communities worldwide.

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