Oxygen Therapy in Malawi: Revising Oxygen Concentrator Filtration and Use for Improved Function in Low-Resource Hospitals

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ACADEMIC ABSTRACT

The quality of healthcare in low-resource countries is often limited by the environment, lack of funds, staff availability, electricity availability, and more. In the words of a Malawian physician, medicine can feel like improvisation, wherein one must make due with available resources rather than desired resources. One prevalent problem among low-resource hospitals is the functionality and longevity of medical equipment. A large percentage of all medical equipment in Malawian hospitals is donated, resulting in a wide spectrum of models, necessary spare parts, and functionality. These machines can break quickly due to heavy use prior to donation, missing user and maintenance manuals, and a lack of replacement parts. Thus, finding necessary life-saving equipment in Malawian hospital wards can be a challenge. One such piece of equipment is the oxygen concentrator, necessary for treatment of respiratory disease, use with CPAP machines, and in the administration of surgical anesthesia. This device fills many roles in low-resource hospitals, but in many Malawian hospitals it is the most frequently malfunctioning piece of equipment.

A survey administered to medical personnel and maintenance personnel in hospitals in Malawi’s Central and Southern Regions isolated some common causes of oxygen concentrator malfunction. Prominent among these were poor oxygen concentrator ventilation and the lack of consumable replacement parts such as the intake bacterial filter. A stand made from locally-sourced materials was developed to encourage better oxygen concentrator exhaust and raise the device out of dust and cleaning fluids on ward floors. Intake bacterial filter alternatives were researched, designed, constructed, and tested, manufactured from housing materials and filter media available in Malawi or continental Africa.

A primary source of difficulty for low-resource hospitals is lack of autonomy, requiring aid from affluent nations to supply equipment and consumable materials. This work suggests that sustainable innovations, such as allowing consumables to be produced in-country, can replace aid with development and create more accessible materials to hospital maintenance personnel. Collaboration with material suppliers and engineers in Malawi can provide sustainable designs and systems to help hospitals access the supplies they need to service oxygen concentrators and other equipment.
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GENERAL AUDIENCE ABSTRACT

The quality of healthcare in low-resource countries is often limited by the environment, lack of funds, staff availability, electricity availability, and more. In the words of a Malawian physician, medicine can feel like improvisation, wherein one must make due with available resources rather than desired resources. One prevalent problem among low-resource hospitals is the functionality and longevity of medical equipment. A large percentage of all medical equipment in Malawian hospitals is donated, resulting in a wide spectrum of models, necessary spare parts, and functionality. These machines can break quickly due to heavy use prior to donation, missing user and maintenance manuals, and a lack of replacement parts. Thus, finding necessary life-saving equipment in Malawian hospital wards can be a challenge. One such piece of equipment is the oxygen concentrator. This device fills many roles in low-resource hospitals, but in many Malawian hospitals it is the most frequently malfunctioning piece of equipment.

A survey was used in hospitals in Malawi’s Central and Southern Regions to collect information on why oxygen concentrators malfunction. Common reported causes of malfunction were oxygen concentrators overheating due to clogged exhaust vents, and the unavailability of necessary disposable filters. A stand made from locally-available materials was developed to improve oxygen concentrator ventilation. Replaceable filter alternatives were researched, designed, constructed, and tested, made from housing materials and filter materials available in Malawi or continental Africa.

A primary source of difficulty for low-resource hospitals is dependence on more developed nations for supplies and aid. This work suggests that designing materials from locally-available materials can lessen this dependency and make necessary medical materials more accessible. Collaboration with material suppliers and engineers in Malawi can provide sustainable designs and systems to help hospitals access the supplies they need to service oxygen concentrators and other equipment.
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Chapter 1: Introduction

To introduce this work, the narrative surrounding the decay of oxygen concentrator maintenance in low-resource hospitals will be explained. Open-ended aid, inefficient donation systems, and the healthcare challenges native to low-resource countries have contributed to this problem, though further investigation in Malawian hospitals revealed ideas of how this problem may be addressed. This work represents initial steps in closing the existing gap in oxygen concentrator function and maintenance.

1.1 Motivation

A 2015 survey by the International Monetary Fund placed Malawi as having the third lowest GDP in the world, at 819 international dollars [6]. Being a low-resource country presents inherent hazards to health such as accidents from underdeveloped infrastructure and burns from the use of fires for heating homes and cooking. However, the CDC also classifies Malawi as a “Malaria Present” transmission area, with 2,905,310 confirmed cases and 4,490 reported deaths due to malaria in 2014 out of a population of 16.7 million [6], [7], [8]. Tuberculosis (TB) and human immunodeficiency virus (HIV) join malaria in the top causes of death in Malawi, and the three diseases combined caused just under 160,000 deaths in 2012 [9]. What’s worse, this high rate of disease is being addressed by a dwindling workforce [10].

For these reasons, Malawi, among other low-resource nations, has long been the recipient of aid and development. Malawi is the country of focus for the technology discussed in this work due to the healthcare challenges it poses.

1.1.1 Open-Ended Aid

In a review of the literature, which can be seen in chapter 2, a pattern emerged in the timing of the provision of oxygen concentrators to hospitals in Malawi by non-profit organizations. Many
organizations, such as the World Health Organization, have initiated programs for providing oxygen concentrators to hospitals in low-resource countries (Table 1). Many of these programs also provided replacement parts and training for hospital maintenance workers so that the lifetime of use for the devices could be extended. However, since many of these programs were implemented in the late 1990s or early 2000s, the lifetimes of the devices, components, and training they provided have begun to decay. The personnel who received use and maintenance training from the providing organizations seem to have largely stopped working at the hospitals and the training was discontinued as the observation periods ended [11]. Similarly, though studies initially included supply of replacement parts, in Malawian hospitals these have depleted completely [12].

Table 1. Non-profit organizations that performed theoretical cost analyses of oxygen concentrators or provided hospitals with devices and evaluated machine performance.

<table>
<thead>
<tr>
<th>Providing Organization</th>
<th>Year</th>
<th>Country</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centre for International Child Health</td>
<td>2001-2007</td>
<td>Papua New Guinea</td>
<td>[16]</td>
</tr>
<tr>
<td>University of Ilorin Teaching Hospital</td>
<td>2002</td>
<td>Nigeria</td>
<td>[17]</td>
</tr>
<tr>
<td>Nuffield Department of Anaesthetics</td>
<td>1995</td>
<td>Egypt</td>
<td>[18]</td>
</tr>
<tr>
<td>Department of Anesthesia, Bir Hospital, Kathmandu, Nepal</td>
<td>1999</td>
<td>Nepal</td>
<td>[19]</td>
</tr>
</tbody>
</table>

Maintenance workers at central hospitals in Blantyre and Zomba elaborated on the issues surrounding donated aid, listing dilemmas such as [12]:
• Lack of spare parts
• Donation of devices across different brands
• Lost or missing user manuals
• No standardized list of what hospitals need
• Language disparity between users and device instructions
• Power conversion from device to wall

These difficulties are not unappreciative of what use can still be obtained from the donated devices [12]. They, however, require the acknowledgement that a number of considerations that have potentially been overlooked in past attempts at aid should be examined before donating medical equipment. Without continued training, devices are being used in the hospitals without primary maintenance, the routine cleaning to be done by device users such as nurses and physicians [12]. Lacking replacement parts, maintenance workers have little resources, both in terms of information and equipment, when attempting to repair defunct machinery.

Another problem resulting from donated medical equipment is what happens to these defunct devices after they are determined as waste. Even fully developed nations have some difficulty managing the disposal of electronics as they gain in popularity and use, and electronic waste is now the fastest growing portion of global municipal waste [20]. Developed nations have specialized facilities and legislation dedicated to managing the disposal of e-waste, which developing nations like Malawi lack [21]. The improper handling of this waste can pose threats to nearby residents, as in the case of an e-waste recycling facility in Guiyu, China [20]. Children in Guiyu showed elevated blood lead levels compared to those of a town farther removed from the facility. It is suspected that water runoff from sites of electronic waste can enter drinking water sites such as rivers or wells and pose possible threats [20], [21]. The situation in developing
countries is worsened by the fact that a large portion of the electronics used are previously owned and donated, and often without prior functionality testing [21]. The result is a high influx of materials that quickly fall out of use. Further, those materials that are donated with full or sufficient functionality may also quickly fall out of use due to poor usage training, a lack of spare parts, or an unsuitability for the environment [12], [22].

1.1.2 Closing the Literature-Time Gap

A literature-time gap is caused both by the institution of programs that donate devices that cannot be indefinitely maintained by the recipient countries, and by the studies seeking to report the “success” of donated materials for a limited research period. This limited time scope saturates the literature with information on how donated devices can be beneficial to developing countries but excludes information on how and when the devices fail. The result in the case of oxygen concentrators has been a wave of donations and studies in the early 2000s, and relative silence since. The most recent study in Table 1 concluded in 2007, one decade ago [16]. Because these programs were not established with a plan for granting eventual autonomy to the hospitals, these hospitals now find themselves with more defunct devices than functioning ones, and no spare parts or maintenance workers trained by the donating institutions [12]. Therefore, self-operating and sustainable changes need to be made to future donation efforts in order to close the literature-time gap and prevent open-ended programs in the future.

1.2 Customer Needs Assessments

Intention to improve the resources of a community are irrelevant without an understanding of community needs. In particular, the opinion of community members is a helpful tool for assessing needs, especially in an area without a wealth of published data such as Malawi. In the case of low-resource hospitals, those community members are the maintenance workers and physicians making
use of resources or experiencing the difficulties caused by their unavailability. Thus, surveys and communication help in understanding community needs, from which further investigation into potential improvements can be performed.

1.2.1 Personal Communication and Survey Results

In May and June of 2016, visits to multiple hospitals in Malawi’s capital city and southern region allowed for personal interviews with members of hospital maintenance personnel, nurses, and physicians. The visited locations can be seen in Figure 1. Subsequently, through Virginia Tech IRB #16-895, surveys were administered via email to 15 contacts from the visited hospitals, with 8 responses, a response rate of 53.33%. The full survey and accompanying protocol, recruitment, and consent documents can be found in the appendices. Personal communication with members of maintenance staff found that the oxygen concentrator was the most frequently malfunctioning category of hospital equipment, though this could be due to any number of unstudied contributing factors like frequency of use over other equipment or greater volume of oxygen concentrators than other pieces of equipment. Furthermore, dysfunctional oxygen concentrators outnumbered all other types of equipment awaiting repair in the maintenance facilities of Zomba.

Figure 1. Hospitals visited in Malawi’s capital and southern region.
Central Hospital in Zomba, Queen Elizabeth Hospital in Blantyre, and the ministry of Health office in Zomba. Highlights of key interviews can be found in Table 2.

Table 2. Highlights of interviews with maintenance ward staff in Malawian hospitals.

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Hospital</th>
<th>Reference</th>
<th>Highlights</th>
</tr>
</thead>
</table>
| Dr. Jonathan Ngoma            | Administration, Physician | Kamuzu Central Hospital | [23]      | - Ongoing population boom, population of 30 million expected in next decade  
- Little access to family planning, surrounding suspicion  
- Some mistrust of healthcare professionals, especially when using methods from “the West”  
- Greatest healthcare challenge in Malawi is human resources: understaffing and how time is used |
| Mr. Sipho Nyasulu             | Administration      | Kamuzu Central Hospital | [24]      | - Greatest healthcare challenge in Malawi is the lack of autonomy  
- Integration of introduced technologies is a challenge  
- User error is common source of machine malfunction |
| Grycian Massa                 | Biomedical Engineer | Kamuzu Central Hospital | [25]      | - Medicine in Malawi feels like improvisation due to lack of resources or technology; can never be sure if things will turn out as hoped  
- Most hospitals have no emergency room or ambulance system |
| Dr. Wilson Ching’ani          | Physician           | Zomba Central Hospital | [26]      | - Regional maintenance at central hospital services 6 district hospitals as well  
- All machines are donated and come with no spare parts or user manuals; would like standardized list of |
| Saidi Moto and Chipilini Khonje | Maintenance staff | Zomba Central Hospital | [12]      |                                                                                                                                              |
equipment requests for donors
- Different equipment requires different first line maintenance, ignored by ward staff
- Wall power voltage differences is a challenge; few devices come with matching voltage to Malawi

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Hospital</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Isobel King</td>
<td>Physician, Administration</td>
<td>Mulanje Mission Hospital</td>
<td>[27]</td>
</tr>
<tr>
<td>Dr. Ben Jacka</td>
<td>Maintenance staff, Physician</td>
<td>Mulanje Mission Hospital</td>
<td>[28]</td>
</tr>
<tr>
<td>Eunice Kanguna</td>
<td>Nursing staff</td>
<td>Domasi Rural Hospital</td>
<td>[29]</td>
</tr>
</tbody>
</table>

- Highest risk factor for any child is death of the mother
- Difficult to implement changes in routine among staff, e.g. temperature monitoring more than 2x/day
- Night staff often sleep during duty
- No electricity on Mondays, use hydro-power and petrol generator

- Greatest healthcare challenge in Malawi is education; people don’t go to hospital until critical condition due to funds or transportation
- Men’s ward typically contains worst situations

- Equipment needs are: oxygen concentrator, glucometer, blankets or space heaters

The needs recorded from personal communication and the quantity of dysfunctional oxygen concentrators led to the implementation of the survey, the purpose of which was to gain an understanding of oxygen concentrator use, malfunction, and repair in Malawian hospitals. The respondents included physicians, nurses, and maintenance workers at the four hospitals shown in Figure 1: Kamuzu Central Hospital, Zomba Central Hospital, Mulanje Mission Hospital, and Domasi Rural Hospital. The survey questions are listed in Table 3.
Table 3. List of questions included on oxygen concentrator questionnaire for hospital personnel.

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Facility:</td>
</tr>
<tr>
<td>Name:</td>
</tr>
<tr>
<td>Which of the following best describes your occupation?</td>
</tr>
<tr>
<td>– Medical doctor</td>
</tr>
<tr>
<td>– Nurse/nurse practitioner</td>
</tr>
<tr>
<td>– Laboratory technician</td>
</tr>
<tr>
<td>– Technical professional (such as engineer, maintenance personnel, etc.)</td>
</tr>
<tr>
<td>– Other</td>
</tr>
<tr>
<td>In which setting do you work?</td>
</tr>
<tr>
<td>– Urban</td>
</tr>
<tr>
<td>– Rural</td>
</tr>
<tr>
<td>– Peri-urban area</td>
</tr>
<tr>
<td>– Transient Location (such as a slum or refugee camp)</td>
</tr>
<tr>
<td>What was the training you received to become a technician?</td>
</tr>
<tr>
<td>Please list the top five challenges you have in your clinical work setting.</td>
</tr>
<tr>
<td>For what purpose do you use an oxygen concentrator?</td>
</tr>
<tr>
<td>How frequently do you use or repair an oxygen concentrator in your work?</td>
</tr>
<tr>
<td>How often is electricity available in the hospital (for using electronic appliances)?</td>
</tr>
<tr>
<td>What are some challenges you have experienced using an oxygen concentrator?</td>
</tr>
<tr>
<td>How frequently do you believe oxygen concentrators should be repaired or maintained?</td>
</tr>
<tr>
<td>What maintenance or repairs do you perform on an oxygen concentrator?</td>
</tr>
<tr>
<td>How often do you change the filters on an oxygen concentrator?</td>
</tr>
<tr>
<td>What would improve the function or use of oxygen concentrators in your facility?</td>
</tr>
<tr>
<td>What part(s) of the oxygen concentrator most frequently need(s) repair or maintenance?</td>
</tr>
<tr>
<td>What are your ideas for improving oxygen concentrator use or function?</td>
</tr>
<tr>
<td>What other comments do you have on oxygen concentrator malfunction, use, or repair?</td>
</tr>
</tbody>
</table>
Kamuzu Central and Zomba Central serve urban areas, while Domasi Rural and Mulanje Mission serve rural areas and in some cases deploy mobile clinics to villages [29]. According to the IRB-approved survey protocol, all responses have been de-identified to specific hospitals and individuals. To begin, demographic data was collected. As can be seen in Figure 2, response from the four hospitals resulted in a nearly even split between urban and rural areas. Availability of staff and materials could potentially vary significantly between these two areas, making data collection from both important. Figure 2 also shows the professions of the survey respondents, broken down between physicians, nursing staff, and technical professionals including electric technicians, engineers, and maintenance staff. Because oxygen concentrator dysfunction affects both the medical personnel using them and the maintenance personnel repairing them,
responses from both were desired. However, different questions appeal to the expertise of different professions, which should be considered in the review of survey data.

To begin from a general standpoint, the survey asked respondents to list the top five challenges they face in their work. Several respondents left spaces blank, resulting in a number of responses less than 40. The results of this question were categorized by theme and can be seen in Figure 3. Of the categories listed in Figure 3, unreliable electricity, lack of spare consumable parts, broken devices, and poor training among staff can all directly affect the use and lifetime of oxygen concentrators. A later question asked what problems specifically relating to oxygen concentrators respondents experienced, the categorized answers to which can be seen in Figure 4. The top complaint listed fell into the category of user error, listed specifically in ways such as “poor patient monitoring” and “no frontline maintenance.” This frontline maintenance is defined by Malawian maintenance professionals as the cleaning to be done in the wards to keep the oxygen concentrator functioning, like keeping the devices away from walls, and cleaning the cabinet filter with water [12]. Secondary maintenance is therefore the repairs that require disassembly of the device such as replacing the intake bacterial filter, rebuilding the compressor, or servicing the sieve beds. It should be noted that complaints of user error were listed by both technical and medical personnel. Following user error, the top complaints were poor oxygen concentration or quality, lack of spare parts, and availability of machines. Some nursing staff
members specifically listed being unable to find a working device when in need of one, a potentially life-threatening occurrence. Oxygen concentrator repair was then addressed, Figure 5 showing responses on believed necessary repair frequency of oxygen concentrators. It should be noted that believed repair frequency was phrased as “How frequently do you believe oxygen concentrators should be repaired or maintained?” in order to understand the beliefs surrounding correct maintenance, not what is practiced. This question aimed to understand what was taught to users and maintenance personnel in training for oxygen concentrator maintenance. More than half of respondents believed oxygen concentrators should be maintained only after they show signs of dysfunction, including technical personnel. One technical professional believed it best to perform checks and preventative maintenance every 4-6 months, while three respondents listed components and specific intervals on which each component should be checked. According to manufacturer information and maintenance
professionals in the United States, this system of component-specifics check is the best method for prolonging the life of an oxygen concentrator [30], [31], [4]. Finally, respondents listed which parts most commonly need repair or replacement, the results of which can be seen in Figure 6. The most listed component was filters, often listed simply as “filters.” Two technical professionals and a physician specified “intake bacterial filters.” Sieve beds and compressors were also listed as problematic, all exclusively by technical professionals. These results affirmed that closing gaps in oxygen concentrator care and environmental could address some of the most widely felt challenges faced by those working in Malawian hospitals. Furthermore, filters were isolated as commonly malfunctioning components of these machines, both by those using and those repairing oxygen concentrators. These results correlated with information from interviews of hospital medical staff, technical staff, and administrators.

1.2.2 Fault Tree Analysis

After collecting information from hospital professionals through the survey and personal communication, an analytical approach was warranted to assess potential areas for improvement in oxygen concentrator function and use. Little literature is available on the failure statistics of oxygen concentrators at all, and much less in the largely under-studied environments of Malawian hospitals. Fault tree analysis was performed to delineate the failure possibilities of the device and provide justification for the focus of this thesis, the intake bacterial filter. The fault tree created can be seen in Figure 7.
Figure 7. A fault tree shows the basic failure points of an oxygen concentrator with citations 1 and 2 referring to [31] and [11], respectively.
In Figure 7, the failure cases involving the intake bacterial filter are circled. In addition to the feedback from hospital maintenance workers in Malawi identifying the intake bacterial filter as the most frequently malfunctioning component of the oxygen concentrator, the fault tree in Figure 7 makes a case for the impact the intake bacterial filter can have on the oxygen concentrator. The fault tree has two primary failure modes that can cause a hazard to the patient, compromised oxygen quality and machine failure. A failure of the intake bacterial filter can cause both of these primary failure modes. If the filter is not replaced and is allowed to accumulate too much bacteria and bacteria-laden particles, it can restrict the airflow to the compressor and cause it to overheat and fail, thus causing machine failure [12], [31], [4]. If an attempt is made to clean the bacteria filter, which is warned against by the manufacturer, bacteria can spread from the front end of the filter toward the exit of the filter and become more likely to spread into the device, contaminating the sieve beds [12], [31], [30]. The intake bacterial filter is not manufactured for reuse or cleaning, and is recommended to be replaced after 6-12 months or between patients, as seen in Figure 7 [31] [30]. Thus, it is an important part of keeping the oxygen concentrator working properly. Moreover, of the four filters and sieves participating in the airflow of the oxygen concentrator, the bacterial filter requires the most frequent maintenance without being cleanable, shown in Table 4.

Table 4. All oxygen concentrator filters are listed with their ability to be cleaned and replacement frequency [31], [4], [30].

<table>
<thead>
<tr>
<th>Filter</th>
<th>Cleanable?</th>
<th>Typical Replacement Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cabinet Filter</td>
<td>Yes</td>
<td>Never</td>
</tr>
<tr>
<td>Intake Bacterial Filter</td>
<td>No</td>
<td>6-12 months</td>
</tr>
<tr>
<td>Sieve Beds</td>
<td>No</td>
<td>5 years</td>
</tr>
<tr>
<td>Final Bacterial Filter</td>
<td>No</td>
<td>Never*</td>
</tr>
</tbody>
</table>

*should be replaced only following sieve bed or humidifier malfunction
These requirements and the frequency of failure of the intake bacterial filter led to its selection as a focus of this thesis.

1.3 Thesis Direction

In order to extend the life of oxygen concentrators in Malawian hospitals and break the cycle of donation, dysfunction, and disuse, this thesis proposes changes to both technical components and use.

A literature review will evaluate the current state of healthcare in Malawi, addressing challenges faced by maintenance and medical personnel. The role of the oxygen concentrator in Malawi will be discussed as well as its integration into the fabric of low-resource healthcare. Oxygen concentrator function will be described so that specific areas of improvement can be explored.

Methods for designing improvements to oxygen concentrator function will be explained. Adjustments to both ventilation and bacterial filtration will be described with specific design suggestions and manufacturing instructions. Lastly, a protocol of proper use will be suggested for posting in Malawian hospitals to reduce user error and increase understanding of necessary maintenance and cleaning.

Results for design testing will be presented and subsequently discussed. Finally, conclusions on the efforts presented herein will be drawn along with suggestions for the next steps in expanding this work and improving the lifetime of oxygen concentrators in Malawian hospitals.
Chapter 2: Literature Review

Before steps can be made to address problems in oxygen concentrator function and maintenance, the role of oxygen concentrators in low-resource hospitals must be understood. This chapter explores the general problems that exist in low-resource hospitals as well as how the oxygen concentrator is used, how it works, and how its function can be impacted by the conditions of low-resource hospitals. Additionally, gas filtration will be reviewed before exploring the specific qualities of the oxygen concentrator intake bacteria as well as materials that could potentially be used in alternative filter designs.

2.1 Healthcare Challenges in Low-Resource Communities

Electricity availability is a primary concern in low-resource hospitals. A report by the world health organization published in 2014 found that nationally-representative data on energy availability in developing countries was difficult to find, successfully reporting on only 14 countries [3], [32]. Of those 14 countries, 11 were African nations. Averaged among this pool of African nations, the report found that 26% of health facilities had no access to electricity, shown in Figure 8. Only 34% of African nations with available data reported reliable access to electricity, defined by the WHO as having no power outages longer than 2 hours in a week [3]. Malawi was not among the countries with available data. A Virginia Tech student conducted a survey in 2014 of 36 employees in 8 Malawian hospitals from all three regions of the

![Electricity Availability in African Healthcare Facilities](Image)

Figure 8. Electricity availability in 11 studied African nations, according to a report by the WHO [3].
country. Responses to the question “How many days per week does your hospital have continuous access to electricity?” claimed that 50% of the respondents experience daily electricity availability in their hospitals, with 25% experiencing electricity access 4 or fewer days per week [33].

Potentially as a result of this and other challenges, low-resource hospitals can frequently experience staff shortages and high patient to staff ratios [3]. In a global comparison of physician density, Malawi had 0.018 physicians per 1000 population, making it the nation with the second fewest physicians per population in the world when comparing each nation’s most recent data [34]. Further, low-resource nations tend to have uneven distribution of physicians, favoring urban areas. A literature review published in 2008 regarding this disproportionate provider distribution found extreme examples of this phenomenon in Ghana and Bangladesh, where 87.2% and 35% of physicians practiced in urban areas, though 66% and 85.5% of the population lived in rural communities [35]. In cases such as these, a large portion of the limited supply of healthcare providers cannot be accessed by much of the population. Studies of healthcare worker migration have found trends of small fractions of physicians trained in their home country remaining to practice in that country, such as the 50 Zambian physicians practicing in-country out of over 600 medical graduates [36]. “The medical carousel,” as a paper in the South African Medical Journal terms it, is the phenomenon of physicians seeking practice in countries with higher standards of living, such as Zambian physicians moving to the United Kingdom, UK physicians moving to Canada, and Canadian physicians moving to the United States [37]. This leaves the areas facing the most persistent or widespread medical dilemmas with the least access to care. With this difficulty to staff hospitals, little consideration or resources are left for retraining or evaluating the quality of care provided, leading to additional problems of incorrect diagnosis, outdated procedures, and malpractice [38]. A 2000 study of oxygen therapy in Jaipur found that 35.5%
patients receiving therapy from cylinders actually had no oxygen flowing from the cylinder, with a further 35.2% of oxygen therapy patients receiving flow rates below prescription [39]. This personnel drain from low-resource hospitals is likely due in part to the challenges discussed by the survey respondents reported in chapter 1, along with the occasional inability of hospitals to provide steady payment to employees because of failing healthcare infrastructure [3], [35]. Anecdotal evidence mirroring this trend, an interview with personnel at Domasi Rural Hospital in 2016 revealed that some employees of the hospital had not been paid in a month [29].

Another potential frustration to healthcare workers is the common delay in patients seeking care. In the survey reported in chapter 1, 15% of the top challenges listed by respondents related to a lack of health literacy. Interviewed providers and administrators believed that citizens can lack understanding of how diseases spread and harbor suspicions toward preventative measures such as mosquito netting or medications [29], [23], [24], [40]. Furthermore, after a disease is contracted, patients are delayed in going to the hospital by these suspicions, lack of money, lack of transportation, or even lack of understanding that care is warranted [28], [29]. Providers interviewed claimed that patients often arrived to the hospital after any life-saving measures could be taken, resulting in frustration among the providers [26], [28]. This delay in seeking care comes at more than the potential cost of the patient, as continued exposure of a diseased patient to the general population can promote drug-resistance of the disease [41], [42].

Finally, underpinning the dilemmas already discussed is the lack of funding for healthcare in low-resource communities. As noted in the introduction, in 2015 Malawi had the third lowest GDP in the world [6]. Lacking access to funding results in difficulty retaining hospital personnel, purchasing consumables such as medications, single-use tools, and bandaging, and difficulty acquiring medical machinery. This challenge of acquiring medical devices results in the donation
cycle described in chapter 1, giving hospitals sometimes partially or non-functioning devices that quickly become waste [22].

2.2 Oxygen Concentrator Use in Low-Resource Hospitals

Because of the wider availability of concentrated oxygen in the United States, oxygen concentrators are used almost exclusively for at-home care. Therefore, oxygen concentrators see different use and frequency of use in low-resource environments. Their introduction to low-resource hospitals, application, and response to the environment in Malawi is important initial information for an attempt to improve their function and lifespan.

2.2.1 Comparison to Oxygen Cylinders

Since the chemical discovery of oxygen in 1772 by Swedish chemist Carl Wilhelm Scheele, it has been an integral part of the hospital setting [43]. Patients with difficulty breathing, difficulty transferring sufficient oxygen to their blood, and patients exposed to dangerous gasses are all examples of patients that would require oxygen treatment. Initially, this was delivered via pressurized cylinders. These required refilling at a specialized facility and transport to hospitals or homes for administration to patients, making them inconvenient in settings where oxygen was needed in large volume or where transport was logistically challenging. Further, oxygen cylinders require equipment to regulate flow from the cylinder, which, if broken or missing renders the pressurized cylinders dangerous to operate [44]. The eventual answer to these challenges was the oxygen concentrator, developed in the late 1970s [43].

The oxygen concentrator fills in for these weaknesses of the cylinder, among others, because of its sustainable acquisition of oxygen. The primary descriptor of the oxygen concentrator is a filter. It intakes ambient air and fills a reservoir with over 90% oxygen, though this percentage decreases with increased flow rate [14]. Oxygen concentrators hold great popularity in low-
resource health environments, as there is a high need for oxygen therapy that is unsatisfactorily met by the logistic complications of oxygen cylinders. According to a 2004 study, the main cause of death in children in developing countries was acute respiratory infections (ARI) [13]. These benefits come at some cost, however, such as the reliance of oxygen concentrators on electricity, training required for operation, and specialized maintenance required to maintain oxygen concentrators. Table 5 shows a comparison of oxygen cylinders to oxygen concentrators developed by the WHO.

Table 5. Comparison of oxygen cylinder and oxygen concentrator characteristics adapted from [45].

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Cylinders</th>
<th>Concentrators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital Cost</td>
<td>High including regulator and flowmeter</td>
<td>High</td>
</tr>
<tr>
<td>Running cost</td>
<td>High, particularly with significant leakage</td>
<td>Low if power is inexpensive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High if power is expensive</td>
</tr>
<tr>
<td>Ease of use</td>
<td>Some training required</td>
<td>Considerable training required</td>
</tr>
<tr>
<td>Reliability</td>
<td>Good</td>
<td>Good on selected models</td>
</tr>
<tr>
<td>Physical robustness</td>
<td>Good</td>
<td>Fair</td>
</tr>
<tr>
<td>Regular maintenance</td>
<td>Needed</td>
<td>Needed</td>
</tr>
<tr>
<td>Technical repairs</td>
<td>Needed (e.g. for regulators, to minimize leakage)</td>
<td>Needed (maintenance staff require specialized training)</td>
</tr>
<tr>
<td>Electricity</td>
<td>Not needed</td>
<td>Needed</td>
</tr>
<tr>
<td>Continuity of oxygen delivery</td>
<td>Liable to run out</td>
<td>Good as long as power is available</td>
</tr>
<tr>
<td>Portability</td>
<td>Poor for large cylinders</td>
<td>Good</td>
</tr>
<tr>
<td>Supply system</td>
<td>Transport needed</td>
<td>Transport not needed</td>
</tr>
<tr>
<td></td>
<td>Ordering needed</td>
<td>Ordering not needed</td>
</tr>
</tbody>
</table>
Overall, oxygen concentrators are estimated to be between 25% and 50% more cost-effective than oxygen cylinders in low-resource environments [46]. Thus, despite the accompanying costs of using oxygen concentrators, the transition of low-resource hospitals from cylinders to oxygen concentrators is widespread [16].

2.2.2 Applications

Because of their role as the primary source of concentrated oxygen in Malawian hospitals, oxygen concentrators have a role in nearly every ward. An interviewed physician in Malawi listed the three primary uses of oxygen concentrators in his rural hospital, shown in Table 6.

<table>
<thead>
<tr>
<th>Ward</th>
<th>Uses</th>
</tr>
</thead>
</table>
| Nursery        | - Oxygen support for neonatal patients born with a low Apgar* score and poor oxygen saturation  
                 | - Supplying oxygen to bubble CPAP devices                           |
| Pediatric Ward | - Severe pneumonia                                                   
                 | - Respiratory distress from *Falciparum* malaria                     |
| Adult Ward     | - Bacterial pneumonia                                                
                 | - *Pneumocystis* pneumonia                                           
                 | - Other lung pathologies affecting fingertip oxygen saturation       |

*Apgar score defined as a test performed 1 and 5 minutes after birth to evaluate status after birth [47]

The World Health Organization published a report on a meeting in 2003 concerning the clinical use of oxygen, discussing the epidemiology of conditions requiring the use of oxygen therapy. Overall, the cause for oxygen therapy is hypoxemia, or low blood concentration. The causes of hypoxemia vary by age demographic, as indicated by the interview in Table 6. In neonates,
common respiratory diseases include hyaline membrane disease, pneumonia, and transient tachypnea, with 30 – 40% incidence of hypoxemia [48], [49], [50], [46]. Children experience hypoxemia from acute lower respiratory infection, HIV, and *Pneumocystis carinii* pneumonia, though correlation with the latter two conditions is under-documented [46]. The report stated that there is less incidence of hypoxemia in adult illnesses, though oxygen is frequently used by obstetric departments for complications and procedures relating to birth such as eclampsia and administering epidurals [46]. Surgical departments make use of oxygen therapy both for treatment of post-operative hypoxemia, occurring in 30% of patients, and in the implementation of spinally administered anesthesia [46].

2.2.3 *Environmental Suitability*

There are several drawbacks to the oxygen concentrator for the environment of Sub-Saharan Africa, however, most prominent of which are 1) electricity availability and 2) maintenance. As previously discussed, only 50% of surveyed healthcare workers in Malawi report daily available electricity in their hospitals [33]. Aside from simply needing power to run the oxygen concentrator, the irregularity of available power can cause complications. For example, in a 2014 study comparing oxygen concentrators to the use of a bubble CPAP system to treat neonatal respiratory distress, 40% of the oxygen concentrators observed in the study failed during data collection because of line voltage spikes [51]. However, in settings where electricity is truly scarce, such as in The Gambia where a 2001 study of oxygen concentrator implementation was conducted, alternative methods of power can be employed [14]. This hospital utilized solar panels to power one oxygen concentrator, a system that becomes more cost effective than cylinders provided the panels receive at least 6 hours of sunlight a day and the hospital uses the concentrator for at least 6 full days of 1L/minute flow each month. This is because while the cost of cylinders is tied to the
amount of oxygen used, the cost of oxygen concentrators is independent from the amount of oxygen they produce, increasing their cost effectiveness at high use.

Beyond the potentially negotiable issue of power availability, an important roadblock in the use of oxygen concentrators is their required maintenance. Common malfunctions and important steps to maintain functionality are laid out in Table 7.

Table 7. Listing of commonly dysfunction components or filters in need of regular replacement and their required maintenance.

<table>
<thead>
<tr>
<th>Component</th>
<th>Fault/Decline</th>
<th>Maintenance</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cabinet filter</td>
<td>Accumulation of dust and particulates</td>
<td>Cleaning with soap and water</td>
<td>Once daily [14]</td>
</tr>
<tr>
<td>Intake Bacterial filter</td>
<td>Accumulation of particulates</td>
<td>Full replacement</td>
<td>Every 3 months to yearly (sources vary) [14] [31]</td>
</tr>
<tr>
<td>Sieve beds</td>
<td>Zeolite exposed to heat or moisture</td>
<td>Repair or replacement</td>
<td>When dysfunctional or every 40,000 hours (yearly) [31]</td>
</tr>
<tr>
<td>Compressor</td>
<td>Mechanical error, most commonly with cup seals, flapper valves, or sleeves</td>
<td>Rebuild</td>
<td>When dysfunctional or every 8,750 hours (yearly) [31]</td>
</tr>
<tr>
<td>Exhaust vent</td>
<td>Clogging with dust or particulates</td>
<td>Clearing</td>
<td>When dysfunctional [31]</td>
</tr>
</tbody>
</table>

Aside from the daily or weekly cleaning of the cabinet filter, it can be seen that the regular maintenance of the oxygen concentrator is rather infrequent. However, this infrequency is a potential contributor to the issue of malfunctioning oxygen concentrators, as it may inhibit preventative maintenance. In a recent visit to Malawi, members of Malawian maintenance teams reported that oxygen concentrators were the most commonly malfunctioning piece of hospital equipment in both the cities of Blantyre and Zomba, the two largest cities in the southern region [12]. Figure 9 shows a photo taken in the maintenance department of Queen Elizabeth Hospital in
24

Blantyre Malawi.

2.3 Oxygen Concentrator Function

To best understand the function of an oxygen concentrator it is beneficial to trace the flow of air from the intake to the reservoir and exhaust, based on the format of the typical oxygen concentrator found in Malawi. The most common models in Malawian hospitals are the Newlife Elite and Devilbiss Concentrators, typically with an output of 5 liters of oxygen per minute [31]. A labeled diagram of major external components is shown in Figure 10.

Figure 9. Photo of the Queen Elizabeth Hospital maintenance facility in which 43 dysfunctional oxygen concentrators are pictured [image by P. Muelenaer, June 2016].
Airflow begins by entering through the cabinet filter shown in Figure 10. Located directly above the intake vent, the cabinet filter is a thin layer of foam intended to remove large particulates and dust from the ambient air, as seen in Figure 11. Following the cabinet filter, the air passes through the intake bacterial filter before being compressed by an air compressor and sent through one
of two parallel cylinders. These cylinders are filled with pellets of zeolite and act as sieves to scrub nitrogen out of the air. A four-way valve below the cylinders causes them to alternately pressurize and depressurize, such that one cylinder is pressurized as the other is relieved (Figure 12). In the pressurized state, nitrogen is attracted by the zeolite such that 90% oxygen can flow into the reservoir. Depressurizing the zeolite sieve releases the nitrogen which flows out through the exhaust vent in the bottom of the device [4], [44]. The alternating cylinder
method and intermediary storage in the accumulator tank, shown in Figure 13, allows uninterrupted flow of oxygen to the patient while each cylinder is flushed [44]. The front of the device has a valve for the attachment of a nose catheter or nasal cannula, or to attach an outside vessel such as a humidifier bottle (Figure 10) [31] . The front of the device also typically displays a flow meter so that flow can be monitored [44]. Finally, for ease of mobility around a hospital or home, both of the models discussed here have four casters on bottom corners of the device. Oxygen concentrators require electricity to power the air compressor and rotating four-way valve, requiring 110 V. It is important to note that outlets in Malawi provide 220 V, which requires a converter to achieve compatibility with these common oxygen concentrator models. Figure 14 shows a simplified schematic of oxygen concentrator function and air flow.

![Figure 14. A flow diagram showing ambient air filtered through the cabinet filter and intake bacterial filter, compressed to 140-200 kPa, and separated into nitrogen and oxygen by sieve beds before oxygen is stored in an oxygen reservoir and released to the patient, regulated by a flowmeter [4].](image-url)
2.4 Filter Materials and Alternatives

In order to suggest an alternative design, the beneficial filtration properties of the current industry-produced bacterial filter must be understood. General mechanisms for successful gas filtration, and the strategies used by the current model are important guides to creating a sustainable substitute.

2.4.1 Bacterial Filter Function and Materials

The oxygen concentrator has two bacterial filters, an intake bacterial filter and a final bacterial filter. They are made of the same principal filtration medium, microform borosilicate, but differ in location, housing material, and have different filtration surface areas. In the 5 liter DeVilbiss Compact Oxygen Concentrator, the intake bacterial filter has a filtration surface area of 645.16 centimeters squared, while the final bacterial filter has a filter surface area of 7.2-18 centimeters squared [52]. This difference demonstrates that the intake bacterial filter is intended to filter out the majority of particulates that make it past the cabinet filter. Additionally, the recommended frequency of replacement for the intake bacterial filter is 6 – 12 months, while the final bacterial filter is only recommended to be replaced after a malfunction of the sieve beds or humidifier bottle [31], [4].

The target particle size for filtration by the bacterial filters, particularly the intake bacterial filter, can be determined by understanding the capability of airborne bacteria, or bioaerosols to enter the body via respiration. Generally, particles with a diameter of less than 10 micrometers are thought to be capable of entering the respiratory system via one of two ways. Those particles smaller than 5 micrometers can be carried by inhaled gasses to alveoli and are associated with allergies and lower respiratory infections [53]. Particles larger than 5 microns are too large to
infiltrate through the alveoli and can enter through the mucosa, associated with upper respiratory infections [54], [55].

These bioaerosols, or in fact, particles in any fluid can be removed through filtration, the process of a transport force bringing particles in contact with a medium and attachment forces causing these particles to stick to the medium and leave the stream of transport [56]. There are two primary mechanisms of fluid filtration, membrane filters or depth filters. Membrane filters are synthetically produced through extrusion or casting to produce a thin medium with pores of consistent size and shape [57], [58]. Therefore, absolute ratings can be applied to them as the uniform pores will consistently filter out particles of a specified size, generally to 90% accuracy [57]. Membrane filters are often made from a polymer, though ceramic and metal membrane filters exist at generally greater cost [58]. Depth filters, however, have imprecise, non-uniform structure and instead present an obstacle-laden path for particles to travel through [57]. One of two general categories of depth filters are fiber filters, commonly made by weaving or spinning fibers into cloth or mats [57]. The second type is sintered filters, made by fusing particles into a porous matrix [58]. A common feature of depth filters is using layers of different filtration media to vary obstruction size and properties and increasing the chance of blocking particle paths [56]. Depth filters present a statistical probability of impeding the path of a particle, rather than an absolute guarantee of stopping it by a known, smaller pore size. While this lack of guarantee can seem like a disadvantage of depth filters over membrane filters, most particles are non-spherical and therefore may difficult to assign to a minimum pore size for membrane filtration.

A further aid to bacterial filtration is static charge. Bacteria tend to be negatively charged due to the outer characteristics of their cell walls. Gram-positive bacteria have a thick exterior layer of peptidoglycan which bears negative charge in attached teichoic acids [59], [60]. Gram-
negative bacteria have a much thinner layer of peptidoglycan between two lipid membranes, and therefore receive their negative charge from the lipopolysaccharides in the exterior lipid membrane [61]. Because of this negative charge, filters with static charge have further means of attracting and holding bacteria and bacteria-laden particles. Static charge can be induced in filters through two methods: fibrillation or tribocharging. Fibrillated fibers are made by splitting charged pieces of material into fibers, often polypropylene, while tribocharged fibers require rubbing two materials together [62].

Hydrophobicity is an advantageous characteristic for bacterial filter media. Bacteria can exhibit either hydrophobicity or hydrophilicity, making hydrophobicity not universally advantageous. However, studies of bacteria cell adhesion have shown that hydrophobic bacteria show greater adhesion to hydrophobic surfaces than hydrophilic bacteria do to hydrophilic surfaces, making hydrophobicity a more useful characteristic [63], [64].

The current filter media used in the intake bacterial filters of oxygen concentrators is microform borosilicate glass microfiber. This is made from a spun matrix of the glass microfiber, formed into a mat and then pleated, allowing for greater filtration surface area. In the 5-liter compact oxygen concentrator by DeVilbiss, the filtration surface is approximately 100 square inches [52]. Microform borosilicate glass microfiber is an expensive material as it is synthetically produced, extruded, and spun to a precise matrix [65]. Pricings for the purpose of gas filtration were unavailable from suppliers, but laboratory borosilicate microfiber filters were purchased for the purpose of this work giving a partial idea of cost. For 100 filters of 13.42 square inches, the cost was $66.30, making the cost more than $2 per square inch of media. This was the cost of lower quality microfiber borosilicate, purchased in the country of manufacture. Aside from the high cost of microform borosilicate glass microfiber, none of the suppliers of this media
manufacture in or distribute to the continent of Africa. Thus, both price and availability make it an unrealistic media for use in filter designs for manufacture in Africa [66], [67]. Thus, its mechanism should be understood in order to be modeled by other materials.

Microform borosilicate glass microfiber filters are described as possessing static charge by manufacturers, but it is unspecified how it is manufactured to possess this charge [65]. Foremost, the filtration mechanism of microform borosilicate filters utilizes varied matrix space. The entering side of a filter mat of microform borosilicate glass microfiber is more widely spun than the exiting side, so that particles encounter smaller gaps as they travel through the filter. This ends up functioning like a filter, because as particles aggregate in the close-quarters of the deeper region of the filter, they aggregate into larger blobs of bacteria. These growing clumps of bacteria are therefore squeezed outward into spaces that can accommodate their volume, eventually being wicked toward the exterior of the filter as more particles are blocked by the filter [65]. This allows microform borosilicate glass microfiber filters to hold a greater ratio of particulates per quantity of filtration media than other filter options, according to manufacturers. This mechanism qualifies the industry-produced intake bacterial filter as a depth filter.

Terlux plastic is used for the housing of the intake bacterial filter [52]. Terlux is a moldable plastic, commercially used primarily in north America for manufacturing transparent parts such as intravenous infusion connectors and cosmetic packaging [68]. The properties of Terlux appear irrelevant to the filtration properties of the intake bacterial filter, aside from containing and directing the airflow through the filter media.

2.4.2 Alternative Material Properties

Due to the inaccessibility of microform borosilicate glass microfiber, for both cost and distribution, other, locally-sourced materials should be evaluated for potential as filter media. The
following materials have been selected for study based on key characteristics for both sustainability and filtration effectiveness: availability to Malawi, ease of production or harvesting, cost, hydrophobicity, and/or structure.

Cotton is a primary material worth investigating as a crop grown in Malawi [69]. Cotton has mild hydrophobicity due to a wax coating on the fibers after harvesting, though this is removed during some step of processing [70], [71]. Cotton processing involves ginning to remove seeds and plant material, followed by carding to align the fibers into parallel strands in preparation for spinning into yarn.

Woven cotton fabric is a commodity throughout Malawi, since it is a staple of women’s fashion. Women use approximately 2 by 1 meter rectangles of woven cotton in bright patterns to wear as skirts, dresses, or to carry children on their backs.

Figure 15. Chitenje worn for daily use as (right) well as for religious or political expression (left).

A piece of fabric used for this purpose is called a chitenje, shown in Figure 15 [72]. These fabrics are printed with dyes, likely by screen printing. Specific product data for cotton textiles
manufactured in Malawi and nearby manufacturing nations like Tanzania, are unavailable. However, common treatments for similar cotton fabrics include calendaring, where the fabric is pressed between heated rollers, and chemical finishes to instill color retention, durability, and mild waterproofing [73].

Another plant-based alternative is linen. Linen is made from linseed or flax, which is closest grown to Malawi in Ethiopia [74]. Fibers are harvested from the stems of flax plants and drawn into thread fibers before being woven together to form fabric [75]. Because of similar plant fiber properties to those of cotton, flax fibers are believed to possess mild hydrophobicity as well, though this is likely lessened significantly in the process of spinning and weaving into linen.

Cellulose acetate, the primary component of cigarette filters, is another viable option because of its already proven success as a filter media. Cellulose acetate is formed from the chemical treatment of wood pulp. This process, known as the Dreyfus process, involves the input of chemicals including sulfuric acid, acetic acid, and acetone, and the recovery of the chemical results of these reactions [1], [5]. Figure 16 shows a simplified schematic of this process as described by Celanese, a cellulose acetate manufacturer based in the United States. Cellulose acetate is present in the continent of Africa, though to what degree of availability is unclear.
Cigarettes are manufactured in several sub-Saharan countries, including prominently Zimbabwe and South Africa [76]. However, manufacturing locations of cellulose acetate, as well as finished cigarette filters, are largely undisclosed. However, tobacco is a prominent export of Malawi, making its ties to the cigarette industry strong and potential aids to accessing cellulose acetate or cigarette filters [77]. The in-country production of cellulose acetate is likely an unrealistic option as it is a highly industrial process, requiring large-scale, specialized equipment and bioreactors, as well as a method of recycling chemical byproducts [5]. Cellulose acetate has uses beyond filtration, including recent incorporation in biomedical applications such as drug delivery [78]. This renders its introduction to more parts of the world as a multi-functional advantage.

All of these presented alternative materials are derivatives of cellulose, a primary structural component of green plants. Various plants contain different amounts of cellulose. For example, cotton fibers are 90% cellulose, while wood, the starting component of cellulose acetate, is 50 –
70% cellulose fiber [79]. Cellulose is a primary structural component of the cell wall of plant cells, endowing plant fibers with tensile strength [80]. Cellulose, therefore, is a naturally occurring fiber, and as derivatives of cellulose, the aforementioned materials can be in part harvested, rather than being synthetically created. Cellulose acetate stands alone among these alternative materials as one that 1) takes substantial chemical alterations after harvesting to become a usable filtration product, and 2) is not created for purposes other than filtration. That is to say, cotton, woven cotton, and linen are all currently functional in Africa in roles other than filtration, whereas cellulose acetate is only produced for use in cigarette filters. Despite this drawback, it is designed specifically for filtration, making it a valuable alternative to consider. The various properties and availabilities of each described product can be found in Table 8.

<table>
<thead>
<tr>
<th>Material</th>
<th>Closest manufacture</th>
<th>Price</th>
<th>Hydrophobic?</th>
<th>Multi-fiber structure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cotton, raw</td>
<td>Malawi</td>
<td>$0.52/kg K375/kg</td>
<td>Yes</td>
<td>Spun, random</td>
</tr>
<tr>
<td>Cotton, Woven</td>
<td>Malawi, Tanzania</td>
<td>$4.86/kg K3451/kg</td>
<td>Mildly</td>
<td>Woven</td>
</tr>
<tr>
<td>Linen</td>
<td>Ethiopia</td>
<td>$24.81/kg K17,615/kg</td>
<td>Mildly</td>
<td>Woven</td>
</tr>
<tr>
<td>Cigarette filters (cellulose acetate)</td>
<td>Mozambique, Zimbabwe</td>
<td>$24.90/kg K17,679/kg</td>
<td>Yes</td>
<td>Extruded, random</td>
</tr>
</tbody>
</table>
Chapter 3: Methods and Materials

Three projects represent the engineering advancements undertaken in this work to improve oxygen function in low-resource hospitals, particularly those in Malawi. A ventilating stand was developed to improve oxygen concentrator ventilation and prevent compressor overheating. A sustainable filter was designed using materials available in Malawi or Africa, and tests were performed to evaluate their filtration success and resistance to airflow. Tests were performed on individual materials and combinations of materials. Testing was performed using filter cartridges, evaluating the filter media outside of the housing. Full prototypes were developed to house these cartridges, fit the oxygen concentrator connectivity and mimic the industry-produced filter intake and exhaust ports. Finally, a protocol of proper use was developed to post on oxygen concentrators in low-resource hospitals to promote uniform use and maintenance, regular cleaning, and regular maintenance of the devices.

3.1 Ventilating Stand Development

An accessible step towards extending the life of oxygen concentrators in low-resource hospitals is improving the ability of the device to exhaust nitrogen and circulate cooling air around the compressor. The exhaust vents are on the bottom edges of the device, visible in the diagrams in chapter 2. Thus, a ventilating stand was developed to improve the airflow from the exhaust vents and prevent debris from the floor or corners of the hospital from blocking the vents.

3.1.1 Design Criteria

To begin the design process, a customer needs assessment was performed to determine the criteria that demanded the most focus, as can be seen in Table 9.
Based off of the customer needs assessment, the top three metrics were the mass of the design, its construction or set-up, and waterproofing. The material that seemed to best fit all metrics and needs was polyvinyl chloride (PVC) pipe due to its waterproofing, low mass, high durability, simplistic connective function, and high availability in Malawi. Additionally, using PVC would allow the creation of a design potentially compatible with the work of Sakaramenta, a Malawi-based equipment manufacturer that constructs hospital furniture among other things, often using white piping and simplistic designs [84]. Elaborating on the customer needs assessment, five important inclusions to the design are:

**Dust clogging** – Many hospitals in Malawi have unfinished floors or large outdoor sections, rendering dust on hospital floors a very common problem. Without cleaning, dust can build
up in the interior of the oxygen concentrator cabinet or in the exhaust vents, preventing successful exhaust and effective compressor cooling [31].

_Chlorine resistant_ – Hospital floors in Malawi are often washed with chlorine, and any devices low to the ground could be splashed. Chlorine can enter the oxygen concentrator cabinet through the exhaust vents and corrode the inner components [28].

_Positioning_ – Manufacturers and maintenance personnel recommend keeping oxygen concentrators away from walls, allowing several inches of space from any object or surface to allow effective exhaust from the vents [30], [31].

_Cost_ – Material price is an obvious concern so that the design may be implemented without creating significant additional cost for the hospital, to which many devices are already donated.

_Accessibility_ – To prevent further dependence on developed nation support, the design should be capable of being manufactured in Malawi, and must therefore be constructed from materials available in Malawi.

Based on the above requirements, PVC is further enforced as a viable candidate.

### 3.1.2 Prototype Build

This ventilation stand was designed for the dimensions of the DeVilbiss 5L Compact Oxygen Concentrator, a common model in Malawian hospitals and the model purchased for this work. After several iterations of designs viewable in Appendix H, one combination of pipes and fittings was determined to contain only pieces available in Malawi and accommodate the wheels on the corner of the oxygen concentrator. The orthogonal projections for the stand can be seen in Figure 17.
The stand was constructed from 1-inch diameter schedule 40 PVC pipe and elbow, tee, cross, and cap fittings. It consists of two tiers, a bottom tier for stabilization and a middle tier to support the oxygen concentrator, with an exterior rail rising to keep the oxygen concentrator on the stand. The stand elevates the bottom of the oxygen concentrator 12 inches off of the floor, and has feet that extend outwards and prevent the stand from being pushed less than 4 inches from any wall. Photos of the fully constructed stand can be seen in Figure 18.
The full bill of materials was checked for general availability in Malawi using Appendix F, and can be seen in Table 10. The pricing in Table 10 based on American sales, and could change when purchased in Malawi. The ventilation stand would be introduced to hospitals with training on the purpose of the stand and how to place the oxygen concentrator in the basket. Training will be an important part of integrating the device into hospitals, because it is designed to take away the convenience of pushing the device into a corner, which could be misunderstood and the device modified.

Figure 18. DeVilbiss 5L compact oxygen concentrator on ventilating stand.
Table 10. Bill of materials for ventilating stand.

<table>
<thead>
<tr>
<th>Part</th>
<th>Quantity</th>
<th>Part Cost (USD)</th>
<th>Total Cost (USD)</th>
<th>Photo</th>
</tr>
</thead>
<tbody>
<tr>
<td>1” schedule 40 PVC</td>
<td>13’ 8”</td>
<td>$4.15/10 ft</td>
<td>$5.67</td>
<td></td>
</tr>
<tr>
<td>1” Tee</td>
<td>12</td>
<td>$1.22 ea.</td>
<td>$14.64</td>
<td></td>
</tr>
<tr>
<td>1” Elbow</td>
<td>4</td>
<td>$0.98 ea.</td>
<td>$3.92</td>
<td></td>
</tr>
<tr>
<td>1” Cross</td>
<td>2</td>
<td>$2.78 ea.</td>
<td>$5.56</td>
<td></td>
</tr>
<tr>
<td>1” Cap</td>
<td>4</td>
<td>$0.73</td>
<td>$2.92</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td><strong>$32.71</strong></td>
<td></td>
</tr>
</tbody>
</table>

3.2 Bacterial Filter Redesign and Testing

In order to extend the life of oxygen concentrators beyond the supply of industry-produced replacement intake bacterial filters, options for locally sourced replacements filters were researched. Replacing the current standard made from Terlux plastic housing and microform borosilicate glass microfiber filter media with models manufactured in Malawi would eliminate the practice of using filters past safe bacteria loading and increased pressure drops. The use of
filters past the recommended replacement date runs the risk of overheating the compressor due to restricted airflow through the filter, or to contaminating the airflow by attempting to clean the filter out. By designing a filter that either be refilled with new media, cleaned, or is non-reusable but manufactured locally, the lifetime of oxygen concentrators in low-resource hospitals may be significantly extended.

3.2.1 Design Criteria

The primary criterion of a replacement intake bacterial filter is that it performs the function of the current industry-produced filter. Primarily, that role is to impede the passage of airborne bacteria and bacteria-laden dust particles. This can mean filtering out particles as small as 5 – 10 micrometers. Furthermore, the ability of the new filter to impede small particles must not cause so much of a pressure drop across the filter that the compressor overheats from restricted airflow, or that the filter quickly becomes clogged and restricts airflow.

Second, the new filter must not occupy significantly more volume than the industry-produced filter. Fortunately for the purposes of this re-design, the intake bacterial filter occupies a fairly open space in the oxygen concentrator cabinet, with extra room surrounding all sides of the filter. Therefore, it was unnecessary to match the exact dimensions of the industry-produced filter. The full length of the industry-produced filter is approximately 3.5 inches including the connective exhaust tube, with a width of approximately 1.75 inches and depth of 1.375 inches. The cabinet has a tolerance of approximately 0.5 inches around all sides of the industry-produced intake cabinet filter. The intake of the filter is a hole in the back of the filter fed by ambient air in the cabinet of the oxygen concentrator, while the exhaust is a 0.5-inch diameter pipe extending downward from the filter into a rubber coupling in the center of the floor of the intake bacterial filter cabinet space. This volume and these specifications provide the spatial design limitations.
Finally, the design constraint that diverges from the industry-produced intake bacterial filter is some aspect of sustainability. Three options arise as sustainable potential improvements on the current disposable industry-produced filter:

*Reusable and locally-sourced* – All parts of the filter are manufactured locally and can be cleaned and reused safely after some period. Cleaning and reuse does not compromise the ability of the filter to keep bacteria from the interior of the oxygen concentrator or accumulate pressure drop across the filter media from use to use.

*Refillable* – All parts of the filter are manufactured locally and the filter media inside the filter is removed and disposed of after some period while the external housing is cleaned and refilled with new media. Cleaning and reuse does not compromise the ability of the filter to keep bacteria from the interior of the oxygen concentrator.

*Disposable and locally-sourced* – All parts of the filter are manufactured locally and disposed of after some period and replaced completely.

The above alternatives are listed in order of preference due to environmental impact and ease of use. An entirely reusable filter would require the least materials, labor for manufacturing, transport, and waste. It would, however, still require labor for cleaning and attention to a cleaning schedule, an existing problem with the cabinet filter and thus still not an absolute fix without proper implementation and use. A reusable housing and disposable filter media would require cleaning of the housing and continuous manufacture of filter media. This would necessitate labor on the part of manufacturers and cleaning on the part of hospital maintenance, as well as a continuous cycle of filter media material acquirement and disposal. An entirely disposable filter would also require a continuous system of manufacturing filters and a continuous disposal of spent filters, with a greater volume of material use and produced waste.
Extensive future testing will be required to determine which of these alternatives is possible from the prototype suggested by this work. The common thread among all three alternatives, however, and the keystone in the path toward providing accessible replacement intake bacterial filters, is producing a filter made from resources local to Malawi. The purpose of this bacterial filter redesign is to determine which locally available or Africa-available materials could be used to replace the microform borosilicate glass microfiber currently used inside industry-produced intake bacterial filters.

3.2.2 Design Metrics

The two primary metrics to determine the success of the intake bacterial filter are 1) removal of bacteria and 2) pressure drop across the filter. These two metrics can work at odds to each other, with increased bacteria removal efficiency coming at the cost of restring airflow and increasing the pressure drop of the filter. Thus, the volume and matrix of the filter must strike a balance between these two metrics.

Because specifics of the intake bacterial filters used in oxygen concentrators are proprietary, published standards for bacterial filters in pulmonary function testing will be used and discussed. These filters function in a comparative way, filtering bacteria from air potentially inhaled by patients when using equipment to test their pulmonary function. The bacterial removal efficiency offered by manufacturers of pulmonary function testing bacterial filters is >99.9% efficiency [62]. Thus the goal standard for bacteria removal efficiency for testing of alternative intake bacterial filter materials is approximately 99%, or complete removal of bacteria. The limitations on pressure drop differ between pulmonary function bacterial filters and the intake bacterial filter of an oxygen concentrator, because the former depends on safe breathing rates of humans, while the latter depends on the intake rate of the oxygen concentrator air compressor [85],
Specific pressure drop across the intake bacterial filter of a functioning oxygen concentrator is unknown to maintenance and homecare providers, though the pressure within the compressor of an oxygen concentrator is published and ranges between 140 and 200 kilopascals [31], [4]. The insubstantial cabinet filter and the intake bacterial filter are the only two components between exterior of the oxygen concentrator and the compressor, making the intake bacterial filter the primary variable in determining if the compressor will have access to enough airflow to avoid overheating [87]. For this reason, the pressure drop across the intake bacterial filter must remain as low as possible, such that there is tolerance for bacteria to accumulate in the filter matrix and still permit sufficient airflow to the compressor. Tests of a new intake bacterial filter for the DeVilbiss 5-liter compact oxygen concentrator using an Extech HD700 Differential Manometer and a Respiration REMstar Pro M Series CPAP machine found a pressure drop of approximately 1.18 kilopascals, making this the pressure drop threshold for the purposes of this work. The protocol for measuring pressure drop in this way can be found in the following sections.

3.2.3 Prototype Development

Based on the justification provided in the literature review, the five materials selected for evaluation were

*Microform Borosilicate*- Primary material in industry-produced intake bacterial filters. Ahlstrom 1610-1050 Borosilicate glass microfiber filter paper of 1.1-micron nominal filtration rating, graded for medium flow and 10.5 centimeters in diameter.

*Cellulose Acetate*- Zen regular cigarette filter tips, approximately 1.48 centimeters in length and 0.73 centimeters in diameter, and Celanese cellulose acetate tow with fibers of 40-micron diameter.
Raw Cotton- organic ginned cotton, no carding or removal of small seeds or plant matter, approximately 40-micron fiber diameter [88].

Woven Cotton- woven and dyed cotton, purchased in Zomba Malawi and made in Tanzania. Production specifications unknown but likely treated with mildly hydrophobic finish [72].

Linen- 100% linen cloth with finished edges produced by “Sew Classic.”

Two filter forms of each material were developed, a single layer and a depth capsule of comparable size to industry produced intake bacterial filters, 3.5 inches (8.89 centimeters) long and 2 inches in diameter (5.08 centimeters). The depth capsules were created by affixing two layers of wide-set plastic mesh on one end of 2 x 3.5 inch PVC cylinders using hot glue. The empty capsule and mesh can be seen in Figure 19. Two layers of the mesh were used because the cellulose acetate filters could fit through the holes of a single layer of mesh. All depth capsule filters except cellulose acetate were made such that the filter media could be placed in and removed from the depth capsule, with one end of the capsule open. This was done so that only 2 or 3 capsules could be used rather than making a new capsule for each of the 15 filters (4 materials and the empty control, each in triplicate). These filters were made by loosely packing a material in the capsule, massing the material, and then placing the material in a new sealable bag. The material, “depth,” number (1 – 3), and mass were then marked on the bag. When being used in the experimentation devices, the capsule was attached to the device using 2 inch PVC coupling. Another layer of plastic mesh
was placed over the open end of the depth capsule before inserting the capsule into the coupling, so as to close off the open end of the filter capsule and completely containing the filter medium within the capsule. The experimenter’s hands were always washed with anti-microbial soap prior to packing any filter material into the depth filter capsule.

The filling of the microform borosilicate depth capsule filters was made by using a precision knife to cut 10.5 cm diameter into approximately 0.5 x 0.5 in square pieces, which were layered into the capsule without any pattern or structure as to fully obstruct any path through the capsule. Each of the three microform borosilicate depth capsule filters contained a total of 25 10.5 cm diameter filters, totaling 2164.75 cm$^2$ filter surface area in the 27.94 cm$^3$ volume.

The linen and woven cotton fillings were made by cutting the fabrics into strips and packing them into the depth filter capsules without any precise folding, so that any path through the capsule would be obstructed. The linen filters contained approximately 30 g of linen, and the woven cotton filters contained approximately 26.5 g of woven cotton each contained in the 27.94 cm$^3$ volume.

Figure 19. Wide-set plastic mesh (top) used to create an end barrier of depth capsule (bottom) while minimally contributing to filtration.
The raw cotton filling was pulled in small pieces from a 1 lb. bundle of raw cotton and placed in the capsule to prevent clumping. Each raw cotton filter contained approximately 3 g of raw cotton contained in the 27.94 cm³ volume of the depth filter capsule.

Because the cellulose acetate depth capsule filters were very precise in composition and cumbersome to make, each of the three cellulose acetate depth capsule filters were filled and then closed off by two layers of mesh on the open side and were thus not refillable like the depth capsules used for the other materials. The cellulose acetate depth capsule filters were made by filling the capsule in layers of upright cigarette filters that formed concentric circles of a total of 37 filters per layer. These layers of concentric circles were found to be the most tightly packed formation that did not deform the filters. The layers were arranged such that any empty space between individual filters in a layer did not overlap with empty space in the neighboring layer, so that no air could pass all the way through the filter without traveling through a cigarette filter.

When placed within the experimentation devices, the single layer filters would be stretched across the end of a 2-inch (5.08 centimeters) diameter PVC pipe, so the primary size constraint was a piece of material larger than a continuous circular surface area of pi inches (7.97 centimeters). Two of the materials, raw cotton and cellulose acetate, were not clearly separated into layers like the fabrics and microform borosilicate filters. Therefore, these were divided into the closest estimation of a single layer by laying them as thinly as possible without creating gaps. These materials were then sandwiched between two layers of wide-set plastic mesh as to keep them together while air was passing through. This 3-layered sheet of mesh, media, mesh, was then laid across the 2-inch diameter PVC pipe in the same way as the fabrics and microform borosilicate filter. Each filter material and type can be seen in Table 11.
### Table 11. Single-layer and depth capsule filter materials and packing.

<table>
<thead>
<tr>
<th>Material</th>
<th>Form</th>
<th>Layer (Surface Area, Thickness)</th>
<th>Depth (Volume, Other Specification)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microform Borosilicate</td>
<td></td>
<td>(7.97 cm², 0.77 mm)</td>
<td>(27.94 cm³, 2164.75 cm² SA)</td>
</tr>
<tr>
<td>(primary industry material)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulose Acetate</td>
<td></td>
<td>(7.97 cm², 0.88 mm)</td>
<td>(27.94 cm³, 222 filters)</td>
</tr>
<tr>
<td>Woven Cotton</td>
<td></td>
<td>(7.97 cm², 0.43 mm)</td>
<td>(27.94 cm³, ~26.5 g)</td>
</tr>
</tbody>
</table>
After initial testing on each material in single-layer and depth capsule form, prototypes were developed using combinations of materials to mimic the funneling properties of microform borosilicate. Each combination utilizes a random or spun material, cellulose acetate or raw cotton, for the statistical advantage of the random construction in impeding particles. This was then combined with a woven material, linen or woven cotton, for the advantage of the tight weave in restricting particle paths. Thus, 4 combinations arose, as seen in Table 12.

Table 12. Material combinations combining randomly spun material and woven material.
These filters were fabricated using 2.5-inch long pieces of 2-inch diameter schedule 40 PVC. This length was used, as opposed to the 3.5-inch long pieces used for the single material depth capsule filters, to mimic the volume inside the machine-fit prototypes discussed in section 3.4. The ends were capped with two layers of mosquito netting, also to mimic the design of the machine-fit prototypes. Each combined material filter was produced in duplicate for testing.

3.2.4 Experimental Design

Two experiments were designed to evaluate the pressure drop and bacteria removal efficiency across each filter medium.

PVC pipe of 2-inch diameter (5.08 centimeters) was used to create a wind-tunnel across which the filter layer or depth cartridge was placed, connected by 2-inch PVC couplings. The leads of the Extech HD700 Differential Manometer were placed on either side of the filter through ¼-inch diameter holes drilled in the PVC. Airflow was produced by the Respironics REMstar Pro M Series CPAP at a constant rate of 12 cmH₂O (1.1768 kPa), connected to the PVC tunnel by respirator tubing and a PVC reducer. The manometer was connected to a computer running the Extech HD700 recording software so that pressure drop across each filter was recorded into an Excel file. The pressure drop testing apparatus can be seen in Figure 20.
Each filter material and form was tested in triplicate. Recording using the manometer was initiated, the CPAP machine was turned on after eight seconds, and then allowed to run for one minute before the CPAP machine was turned off.

The manometer recording was then stopped after the pressure reading stabilized. After each prototype filter was tested, a new, clean intake bacterial filter was tested in the same way using the same CPAP machine and manometer. Because of the intake and exhaust holes of the industry

Figure 20. Evaluation and recording of pressure drop across each material.

Figure 21. The industry-produced intake bacterial filter testing for comparison to prototype filters.
produced, filter, the connectivity was altered. However, as in the case of the prototype filters, the cross-sectional areas of the pressure measurement points were equivalent in the industry produced filter pressure drop test. The industry produced filter test set-up can be seen in Figure 21. The manometer evaluated pressure according to the following calculation

\[ \Delta P = P_1 - P_2 \]

with pressure recorded according to the diagram in Figure 22.

![Figure 22. Pressure diagram for pressure drop testing](image)

Because all of the materials were compressible except for the cellulose acetate cigarette filters, and of varied density, the pressure drop data was also used as a method of achieving comparable quantities of filter material in each depth capsule, in addition to a constant volume of 27.94 centimeters squared. For example, when building the first prototype depth capsule filters, the guiding principle was to “loosely pack” each filter. However, loosely packed raw cotton came to approximately 3 grams, while loosely packed linen was approximately 30 grams. Despite the wide variation in masses for these original quantity guesses, many of the initial prototypes achieved very similar pressure drop measurements to the industry-produced filter. The two outliers with lower pressure drop measurements were the cellulose acetate filter and the woven cotton filter.
The cellulose acetate filter content was invariable because it was packed with individual cigarette filters. They were essentially incompressible so more could not be added to bring it to a comparable pressure drop measurement. The amount of woven cotton in the woven cotton depth capsule filters could be added to, however. The content was increased to approximately 25.6 grams, and the pressure drop across this second iteration was very similar to those of the other prototypes and the industry-produced filter.

Once the depth capsule filters achieved comparable pressure drop measurements, they were tested for bacteria removal efficiency. This test was performed after the pressure drop testing so that the airflow through the filters during the pressure drop testing could act as a means of blowing existing bacteria out of the filters. The bacteria removal efficiency testing was performed by using human exhalation to aerosolize bacteria. The exact quantity and type of bacteria typically present on human breath varies from person to person due to diet, intolerances, and more [89]. The amount typically exhaled has not been conclusively quantified as it is nearly impossible to distinguish exhaled bacteria and bacteria-laden particles from bacteria and particles re-suspended from the act of exhalation on the environment and ambient air [90]. However, literature supports that both bacteria and spores are carried in human exhalation, and that these bacteria can be incubated at human body temperature and observed [90].

The objective of the test apparatus was to project human breath through a test filter onto a petri dish for a constant time at a constant distance from the dish across all trials. Therefore, a tube was created out of PVC piping. A 1 x ¾ inch reducer coupling was fitted into a 2 x 1-1/4-inch reducer coupling to represent the mouth piece. These were then connected to a 5-inch long 2-inch diameter PVC using a 2 inch coupling. A ¼ inch diameter hole was drilled into the middle of the length of the 2-inch diameter pipe through with an anemometer lead could project into the airflow.
in the pipe. The 2-inch diameter pipe was connected to a 5-inch long, 4-inch diameter PVC pipe by a 4 x 2-inch reducer coupling. Holes of 1/8 inch were drilled evenly spaced around the 4-inch diameter to allow the air to exhaust. The device stood upright on a horizontal surface with the end of the 4-inch diameter pipe flat against the surface. Petri dishes of 3.54 inches (9 centimeters) would be placed on the horizontal surface under the 4-inch diameter outlet. Single-layer filters were placed between the exiting end of the 2-inch diameter PVC pipe and the 4 x 2-inch reducer coupling, kept taught by the tension caused by pipe sliding tightly into the reducer coupling. The full structure 15 3/8 inches with 9 inches between the exiting side of the filter and the petri dish.

In the case of depth-capsule filters, the depth capsule was connected to the exiting side of the 2-inch diameter PVC pipe with a 2-inch coupling, and fitted into the 4 x 2-inch reducer coupling. This added 3.5 inches to the length of the full structure, totaling 18 7/8 inches but retaining a distance of 9 inches between the exiting side of the filter and the petri dish. Both the single-layer and the depth capsule forms of the bacteria

Figure 23. The single-layer (left) and depth capsule (right) devices for bacteria projection onto a petri dish.
projection device can be seen in Figure 23.

All bacteria testing and handling was done in the lab of Dr. Biswarup Mukhopadhyay on Virginia Tech’s campus. The depth capsule filters were evaluated first, and all depth capsule filters were tested on the same day. The test procedure began with rinsing all PVC components individually, including the empty depth capsule filter cartridges, in a dilute bleach solution of 1:15 bleach to water. The components were then rinsed with water and air-dried in a high-temperature incubator. The filter cartridge was then filled with the previously aliquoted filter material, or in the case of cellulose acetate, one of the premade closed filter capsules was used. The PVC parts were then reassembled as described above.

The plates used were poured by the author and a member of the Mukhopadhyay lab a week prior to testing. The plate media solution was created by heating 100 milliliters of DI water, and adding 10 g/L NaCl, g/L yeast extract, 10 g/L tryptone, and 15 g/L agar. This solution was then autoclaved for 20 minutes before being poured into plates and then refrigerated until the day of use. All plates were allowed to warm to room temperature before use.

Before each test, the plate being breathed onto was marked with the material being tested, the type of filter being tested (layer or depth), the number of the filter (1-3), the experimenter’s initials, and the date. The plate was then opened and placed under the bacteria projection device. For the depth-capsule filters, the experimenter exhaled into the mouthpiece for two minutes. The manometer was used to quantify the pressure incident on the filter before, throughout, and after the breathing period and this data was recorded to an excel file using the Extech HD700 manometer software. Breathing was performed by inhaling through the nose and using a glottal stop in the throat so no air from the tube was aspirated and no negative pressure was produced in the tube. The experimenter’s lips formed a seal with the mouthpiece throughout every test so that all air was
projected through the tube. The experimenter fasted prior to all bacteria testing as to not affect the bacteria content of the exhaled air.

Three individual depth-capsule filters, numbered one 1-3, were tested for each material, microform borosilicate, cellulose acetate, woven cotton, raw cotton, and linen. Three trials of empty filter capsules were tested as a control. Therefore 6 filter materials were tested in triplicate, totaling 18 trials. All parts of the bacteria projection tubing were cleaned with the bleach solution, rinsed, and dried between every test. The 18 resulting plates were placed in an incubator at 36.5 °C for 48 hours before the colonies were counted and photographed.

The same procedure was followed the following day for the single-layer filters, however with breathing performed for 30 seconds rather than 2 minutes as to not overwhelm the dish with bacteria. The experimenter fasted prior to testing for the single-layer filter testing. A number of test irregularities occurred during single-layer filter testing, documented in Table 13.

<table>
<thead>
<tr>
<th>Filter identity</th>
<th>Test irregularity</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose Acetate Layer 1</td>
<td>Manometer software glitch approximately 30 seconds into breathing period</td>
<td>Immediate pause of test, restarted with new petri dish</td>
</tr>
<tr>
<td>(CAL 1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microform Borosilicate Layer 1</td>
<td>Pressure on filter caused filter to break during testing, detected by sudden</td>
<td>Fully performed test and restarted with new filter and new petri dish</td>
</tr>
<tr>
<td>(MBL 1)</td>
<td>drop of incident pressure</td>
<td></td>
</tr>
<tr>
<td>Microform Borosilicate Layer 2</td>
<td>Inserting filter and 2-inch PVC pipe into reducer coupling cause filter to tear</td>
<td>Fully performed test and restarted with new filter and new petri dish</td>
</tr>
<tr>
<td>(MBL 2)</td>
<td>detected by consistently lower incident pressure</td>
<td></td>
</tr>
</tbody>
</table>
The results of the single-layer bacteria testing can be seen in chapter 4. The single layer test was intended as a backup incase bacteria was unable to penetrate the depth capsules, however, because the single-layer testing appeared less effective than the depth capsule testing, single layer testing was not continued.

After colonies were counted in the depth capsule filter petri dishes, the plates were placed in a 65 °C incubator for 20 minutes to heat shock the samples and activate any spores on the plates. They were then incubated in 36.5 °C for 24 hours before being re-counted and photographed. All dish photographs can be seen in Appendix G.

A second round of testing was then performed using a different protocol in order to either reinforce the results from the previously described bacteria testing or attain more robust results. A potential area for improvement on the first round of testing was the projection of air onto the surface of a prepared petri dish. This limits bacteria growth to the surface of the agar. Additionally, the air was projected from the filter into the 4-inch diameter PVC chamber, of which the petri dish occupied the bottom. The air moved around the chamber and eventually out through the 4 vent holes. Thus there was little control over where the air was flowing, and only a portion of it was presumed to come in contact with the petri dish.

Therefore, the second round of bacteria testing utilized liquid lysogeny broth (LB), which is identical to the contents of the agar plates with the omission of the agar, the solidifying agent. Air passing through the filter would be projected into a test tube containing LB and bubble through the LB so that all the air came in contact with the growth media, and thus, so did the hypothetical bacteria carried by the air. The liquid LB would then be spread onto agar plates such that the agar absorbed the inoculated LB, and any microorganisms in the liquid LB could grow throughout the volume of the agar. In preparation for testing, 30 test tubes were filled with 2 milliliters each of
LB to allow 20 for testing and 10 extra tubes. These were autoclaved on a liquid cycle prior to testing. Additionally, 50 plates were poured with sterilized agar LB for spreading.

A new test apparatus was required for this second round of testing. In order to only expose the liquid LB to microorganisms carried on the air from the filters, the air projection tube must end in a straw or tube that could project into the liquid after being sterilized in an autoclave. Pasteur pipettes were selected to fill this role. Thus, a way to funnel air into the Pasteur pipettes was also required. Because PVC has a melting temperature of approximately 160 °C, with decomposition beginning at approximately 140 °C and a gravity cycle of an autoclave reaches a maximum temperature of approximately 121°C, PVC 2 inch-diameter schedule 40 caps were selected for this role [91, 92].

Because the tip needed to be sterile for each test, twenty individual tips were prepared, with several extras in case of breaks or errors in experimentation. Each tip was constructed by drilling a hole in the center of the PVC cap using a .266-inch drill bit, so that the hole would be slightly smaller than the diameter of the widest part of the Pasteur pipette. The bulb of a pipette was then cut down shorter so that it would protrude approximately ½ inch into the cap. The pipette was then slid through the interior side of the hole in the cap, so that the stem protruded out of the bottom of the cap, and the hole caught the pipette as the stem widened into the bulb. The connection was then secured.

Figure 24. Autoclave-safe tips for bacteria testing made from PVC caps and Pasteur pipettes.

on both sides with autoclave tape, as seen in Figure 24. The tips were then wrapped individually in aluminum foil, marked with autoclave tape, and autoclaved on a gravity cycle.

The full testing apparatus consisted of a ring stand suspending the pipe assembly over a test tube stand, which held the LB test tube being inoculated. A timer was used to ensure breathing into the tube was only performed for 2 minutes. The manometer anode was placed in the same hole in the pipe as in the first round of bacteria testing, and was connected to a laptop for pressure recording. All PVC parts were bleached prior to every test, and a new pipette/PVC tip was used for every test. A single test began with removing the aluminum foil from the PVC portion of the autoclaved tip only, leaving the pipette stem covered and therefore sterile. Duct tape was then used to attach the PVC cap to the filter being tested to achieve an airtight seal. The filter was then placed up into the coupling being held by the ring stand, thus connecting it to the tube with the manometer hole and mouthpiece. The test tube of LB being used was then placed in the test tube stand below the suspended tip. The timer was set to 2 minutes, and a front-facing camera phone was aimed toward the test tube so the tube could be observed while blowing into the mouthpiece. The aluminum foil was then removed from the pipette

Figure 25. Pasteur pipette stem lowered into liquid LB so air could bubble through the media.
stem and the cap removed from the test tube, so the ring stand arm could be lowered and the pipette tip placed in the LB, as shown in Figure 25. The manometer software recording was initiated, and after 8 seconds, the 2-minute timer was started and breath was exhaled into the pipe. The camera was monitored and breathing modified so the test tube did not bubble over. After 2 minutes was over, breathing into the pipe was stopped and the manometer software was allowed to record until it reached 145 seconds of data. The data recording was stopped and the ring stand arm was raised so that the test tube could be capped and labeled. The pipe tip was set aside and the filter put in a clean re-sealable bag. All parts of the pipe assembly were cleaned with bleach and dried before set-up for the next test began. After all filters were tested, the pipette/PVC pipe tips were autoclaved and discarded. The full experimental set-up is shown in Figure 26.

![Figure 26. Experimental set-up allowing air to be bubbled through liquid growth media.](image)

This second round of testing was performed on the combined-material test filters in double, capsule depth filters 1 and 2 of each individual test material (microform borosilicate, cellulose acetate,
woven cotton, raw cotton, and linen) as well as two empty filter cartridges. This resulted in a total of 20 trials.

Post testing processing consisted of spreading and incubating all plates, as well as heat-shocking half of the plates. To spread the plates, 100 microliters from an inoculated LB tube were pipetted onto a labeled plate. The plate was placed on a small turn table, and a glass spreader, cleaned with ethanol that was subsequently burned off, was then used to spread the LB evenly on the surface of the agar as the plate rotated. This was done until all liquid had been absorbed by the agar and no longer pooled on the surface. One plate was prepared from each inoculated tube and incubated at 36.5 °C to support bacterial growth. The inoculated tubes of LB were then incubated at 65 °C to heat shock them and activate any spores in the liquid. Another labeled plate was then spread from each of the heat shocked tubes and incubated at 36.5 °C. All 40 plates were observed after 24 and 48 hours of incubation, and were documented and photographed. All petri dish photos can be seen in Appendix G.

3.3 Sustainable Bacterial Filter Prototype

The application of the previously described pressure drop and bacteria testing was to recommend a fully fleshed-out sustainable intake bacterial filter design, validated by entry-level testing. After bacteria and pressure drop testing, the final step was to determine an easily manufactured, low cost housing design that would fit within the machine and match the connectivity of the industry-produced intake bacterial filter. The design recommended here is not fully validated or ready for implementation in hospitals.

3.3.1 Design Criteria

After bacterial testing determined options for the inside of the sustainable filter, the housing was designed to fit the oxygen concentrator to determine that an easily fabricated housing was
possible. As with the stand, PVC was determined to be the most appropriate and convenient material, if components that fit the machine could be found.

Unfortunately for the purposes of this work, every oxygen concentrator model has a slightly different intake bacterial filter with a different shape and path. Thus, the prototype recommended here may not fit every oxygen concentrator model. This is relevant to the environment of Malawian hospitals because as discussed in Chapter 2, devices of all brands and models can be donated through hospital donation programs. The industry-manufactured intake bacterial filter of the DeVilbiss 5L Compact Oxygen Concentrator purchased for this work is pictured in Figure 27. The DeVilbiss 5L Compact Oxygen Concentrator is a commonly appearing model in Malawian hospitals, however, leading to its selection as the model for this work.

The intake of the filter in Figure 27 is an approximately 0.25-inch diameter tunnel in the back of the device, opening opposite of the exhaust, pictured. The tunnel ends in a small layer of foam approximately 0.25 inches thick, emptying into the lower empty space in Figure 27. Air would then filter through the pleated microform borosilicate, which is fastened to the inside of the housing with an adhesive akin to hot-glue. The other side of the microform borosilicate was another open cavity, ending with another 0.25-inch thick layer of foam leading to the 0.5-inch diameter exhaust visible in Figure 27. Each part of this flow and material pattern would be modeled in the prototype.
3.3.2 Prototype Build

From initial comparison, 2-inch diameter PVC pipe and fittings appeared to most closely fit the exterior dimensions of the industry-produced intake bacterial filter. Several reducer bushings were required then to reduce the 2-inch diameter PVC to the 0.5-inch diameter PVC that would fit in the rubber bushing that connected the intake bacterial filter exhaust to the air compressor tubing. This rubber coupling can be seen in Figure 28.

A 2-inch diameter cap was chosen over a less robust test cap to form the opposite end of the filter prototype. After the selection of these fittings, the remaining space in the filter cabinet allowed for one 2-inch diameter coupling to connect the cap to the bushings. A section of 2-inch diameter pipe was required to connect the cap to the coupling. The maximum length of 2-inch diameter pipe that would be fully covered by the cap and the coupling was used. The full prototype construction can be seen in Figure 29.
As described in section 3.3.3, four different types of combined-material filters were developed. Figure 29 shows the location of each category of filter material in the prototype. In place of the foam used after the intake and prior to the exhaust in the industry-produced filter, mosquito netting was used. The intake bacterial filters of different oxygen concentrator models use a closely woven plastic mesh in place of these foam layers, making mosquito netting a comparable locally-sourced substitution for this component.

To fabricate the prototype filters, PVC cutters were used to cut the 2-inch and 0.5-inch pipe sections to size. A 0.25-inch diameter hole was drilled in the top of the cap adjacent to one side wall so the hole was not blocked by the ceiling of the filter cabinet. Two layers of mosquito netting was affixed to the interior end of the 0.5-inch pipe as well as to one end of the 2-inch diameter pipe using hot glue. All pieces of the prototype were then cleaned with bleach. Filter media were
then placed in their respective cavities in quantities of proportional mass to those used in the single material depth capsule filters fabricated for pressure drop and bacteria testing, as seen in the following calculations:

**Cellulose Acetate – 1.75-inch pipe**

\[
\frac{3.5\text{"}}{222\text{ filters}} = \frac{1.75\text{"}}{x}, \quad x = 111\text{ filters}
\]

**Raw Cotton – 1.75-inch pipe**

\[
\frac{3.5\text{"}}{3\text{ g}} = \frac{1.75\text{"}}{x}, \quad x = 1.5\text{ g}
\]

**Linen – 0.75-inch deep 2” x 1” bushing interior**

\[
\frac{3.5\text{"}}{30\text{ g}} = \frac{0.75\text{"}}{x}, \quad x = 6.43\text{ g}
\]

**Woven Cotton – 0.75-inch deep 2” x 1” bushing interior**

\[
\frac{3.5\text{"}}{26.5\text{ g}} = \frac{0.75\text{"}}{x}, \quad x = 5.68\text{ g}
\]

One layer of mosquito netting was then affixed on the open end of the 2-inch PVC pipe section, and the full assembly was pushed together until all components were fully fitted, and the cap and coupling were flush together. Each type of filter can be seen in Figure 30.
After fabrication, pressure drop across the prototype filters was tested using a similar set-up to the depth capsule and single layer test filters. The testing apparatus can be seen in Figure 31.

Results from bacteria and pressure drop testing would be used to determine the value of pursuing more robust validation of these prototypes for eventual implementation in hospitals.
3.4 Protocol of Proper Use

In order to increase general understanding of proper maintenance and use of oxygen concentrators, a one-page concise guide was created. This idea was originally proposed by Dr. Ruth Shakespeare, Mulanje Mission Hospital’s management team medical director. She proposed posting a one-page guide on every piece of equipment in the hospital so the same protocol was followed by all personnel. This section offers a protocol of proper use for the oxygen concentrator and potential methods for effective implementation of the protocol.

3.4.1 Protocol Content

The following page shows the one-page content of the suggested protocol of proper use. It has separate instructions for personnel using the device for patient therapy, and for maintenance personnel repairing and maintaining the device. All steps for medical personnel are numbered or lettered to help employees follow them in a uniform order. The protocol includes some weekly maintenance intended for medical personnel to perform, described by maintenance personnel as “front-line” maintenance, so the devices receive preventative maintenance and have to be removed from the wards for maintenance less frequently. The maintenance suggested on this protocol of proper use are hypothetical and can be adjusted at the discretion of hospital administrators. The interval suggested, however, is supported by manufacturers and maintenance personnel in the United States and should be retained if the specific days are modified. The maintenance protocol suggested is simply a schedule of maintenance and checks, rather than an in-depth guide and is not intended as a substitute for training or maintenance manuals. A serif-free font was used for ease of readability.
Protocol of Proper Use

Oxygen Concentrator

Operation – Medical Personnel

1. Preparation
   a. Ensure the oxygen concentrator is plugged in, using a voltage adapter and voltage stabilizer if available
   b. Place the oxygen concentrator at least 2 feet away from any walls, and away from visible dust or debris
   c. Ensure the humidifier bottle is filled with clean water between the “min” and “max” fill lines
   d. Check the back of the device for the cabinet filter, and open the filter door to check for the intake bacterial filter – both must be present during use

2. Use
   a. Connect the humidifier bottle
   b. Connect the nasal cannula or mask to the oxygen concentrator and check the tubing for kinks
   c. Switch the power switch to “on”
   d. Set the flow meter on the front of the device to the prescribed flow
   e. Place the outlet of the cannula in a cup of water and check that bubbles are created, signaling airflow
   f. Place the cannula or mask on the patient
   g. Monitor the patient so that they receive oxygen for the prescribed amount of time

3. Maintenance
   a. Remove the cabinet filter every Monday morning and clean with soap and water before drying and replacing in the machine
   b. Clean the humidifier bottle and refill with clean water every Monday, Wednesday, and Friday.
   c. When cleaning the ward, cover the oxygen concentrator with a cloth or tarp and keep it clear of any cleaning materials

Repair – Maintenance Personnel

Intake Bacterial Filter – Replace every 6-12 months, when available
Sieve Beds – Service every 40,000 hours of operation
Final Bacterial Filter – Replace after sieve bed rupture or humidifier bottle spill
Compressor – Rebuild every 8,750 hours or yearly, whichever occurs first

Check oxygen concentration whenever being serviced – Write date of check and oxygen percentage on tape and place on the front of the device
3.4.2 Implementation

The protocol of proper use is intended to be posted in a visible location on or near every oxygen concentrator. Because some hospitals share oxygen concentrators between multiple wards, it would ideally be fixed onto the oxygen concentrator. Repairs often occur in a maintenance facility on the hospital campus, rather than in the wards. Thus, making sure the protocol is attached to the device will allow both medical and maintenance personnel to refer to it without having to transport the protocol with the oxygen concentrator. Laminating the page, if possible, would also help to protect it from wear and tear as the oxygen concentrator is used, repaired, and moved. Because the front of the oxygen concentrator is the location of the flow meter, on/off switch, connector for the cannula and humidifier bottle, and shelf for the humidifier bottle, the protocol of proper use would likely have to be placed on the side or rear of the device below the cabinet filter.

Training should accompany the implementation of the protocol of proper use, both to introduce the protocol and refresh personnel on oxygen concentrator use and maintenance. Going through each step on the protocol with medical personnel will allow training recall as the protocol is referred to during oxygen concentrator use. Translating each written step into an action during training will help to ensure that steps in the protocol are interpreted uniformly by medical personnel. Training will also reinforce to medical personnel that the protocol incorporates some maintenance into the duties of medical personnel. This may be a new responsibility to some medical personnel, according to maintenance workers interviewed [12].

Maintenance personnel should receive repair training with the introduction of the protocol of proper use so that the schedule of repairs and checks is understood and interpreted uniformly. Further, training should incorporate taking inventory of consumables, calculating how many cycles of replacements are available, and organizing restocking if necessary and possible.
Chapter 4: Results

This chapter presents the results of all building and testing, showing accompanying photographs, and graphs. Results are discussed superficially but left for fuller interpretation and discussion in chapter 5.

4.1 Ventilating Stand Assessment

Despite achieving general fit to the oxygen concentrator, the ventilating stand should be evaluated for successes as well as potential improvements. The primary drawback of the device is potential difficulty placing the oxygen concentrator in the stand. The model for which this stand was designed, the DeVilbiss 5L Compact Oxygen Concentrator, weighs approximately 36 pounds. The device must be lifted approximately 22 inches from the ground, over the lip of the top of the stand, before being lowered 8.5 inches into the “basket.” This is further complicated by the cord protruding from the back of the device. The cord is surrounded by stabilizing plastic, extending approximately 1-inch perpendicular to the back of the stand, 1.5 inches from the bottom of the device. By lowering the back edge of the oxygen concentrator into the stand before the front end, this can be mitigated, but requires using one hand to lift the

Figure 32. The oxygen concentrator in the ventilating stand, with the cord protruding left of the center support.
device and one to guide it into the stand basket. This can be a challenging maneuver depending on the strength of the person lifting the oxygen concentrator. This action must be repeated in reverse to free the oxygen concentrator from the stand. This difficulty removing the device from the stand can be beneficial in the implementation of the stand, however, so that the oxygen concentrator cannot be moved easily from the stand to a more convenient position that is worse for ventilation. The wheels must also be rotated so they point toward the center of the device before the oxygen concentrator can be lowered into the stand “basket.” The rear of the oxygen concentrator in the ventilating stand can be seen in Figure 32.

Another potential drawback of the ventilating stand is the presence of the feet extending from the center of each bottom edge of the stand. These were intentionally incorporated into the design to prevent the stand from being pushed against a wall or into a corner, preventing sufficient airflow. However, these do present potential trip hazards to someone operating or walking near the stand.

The stand succeeds in lifting the oxygen concentrator exactly 12 inches from the ground. The feet will not allow the stand to be pushed closer than 4 inches to any upright surface, and also provide stability to the stand. Because the compressor, the heaviest component in the oxygen concentrator, is placed on the floor of the cabinet of the device on the motor mounts, the oxygen concentrators center of gravity is near the bottom of the device. Because the stand has a basket that rises 7 inches above the bottom of the device, the majority of the weight of the oxygen concentrator is cradled by this basket, preventing tipping during normal operation. Additionally, the stand lifts the casters of the oxygen concentrator off of the floor, preventing mobility. This is a success in that it prevents the oxygen concentrator from being pushed into a location with poorer ventilation, such as closer to a wall, giving the stand and the oxygen concentrator a beneficial permanence.
This does present a challenge if the device needs to be moved from ward to ward, however. These successes and drawbacks can be found, summarized, in Table 14.

<table>
<thead>
<tr>
<th>Successes</th>
<th>Drawbacks</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 12-inch lift from floor</td>
<td>- Difficult loading</td>
</tr>
<tr>
<td>- Resistance to unnecessary removal from stand</td>
<td>o High upper lip</td>
</tr>
<tr>
<td>- Feet give 4-inch spacing from walls</td>
<td>o Little tolerance for rear cord</td>
</tr>
<tr>
<td>- Resistance to unnecessary repositioning</td>
<td>- Potential tripping hazard- feet</td>
</tr>
<tr>
<td></td>
<td>- Limited mobility</td>
</tr>
</tbody>
</table>

4.2 Material Filtration Evaluations

To understand the potential filtration capabilities of each alternative material, each material was tested for pressure drop and bacteria removal efficiency, in both single layer and depth format, in triplicate.

4.2.1 Pressure Drop Results

To get the most basic understanding of each material’s resistance to airflow, a single layer of each material was suspended across the cross-section of a pipe and pressure was measured on either side of the material. Figure 33 shows the averaged results for each material for the entire recording period in the single layer test. Figure 34 shows the mode for each material’s averaged trials, and Figure 35 shows the standard deviation of the three trials of each material. These triplicate trials were necessitated by the potentiality for differences in pressure drop caused by different arrangements of the “loose” materials, cellulose acetate and raw cotton.
Figure 33. Pressure recordings for no filter (Blank), cellulose acetate (CA), microfiber borosilicate (MB), woven cotton (WC), raw cotton (RC), and linen (L). Recording period included 8 seconds of no airflow, initiation of CPAP machine to 12 cmH₂O, one minute of constant flow, ceasing airflow, and then stabilization at zero flow.

Figure 34. Mode of trials averaged across materials.
Microfiber borosilicate created the largest pressure drop, maintaining an approximately 1.16 kilopascals pressure difference. Woven cotton, raw cotton, and linen created pressure differences under 0.25 kilopascals, with cellulose acetate and the blank control creating negligible pressure drop. Standard deviation calculations in Figure 35 show little variation between different filters of each material, with the greatest difference occurring between trials of linen filters. It should be noted that values of 0 standard deviation for cellulose acetate and microfiber borosilicate are due to limited instrument precision, achieving negligible deviation rather than true lack of deviation between filter models.

The same test and calculations were performed for depth capsule filters for comparison to the industry-produced filter. However, adjustments were made after preliminary pressure drop testing in an attempt to normalize depth capsule content by both volume and pressure drop. The preliminary testing results can be seen in Figure 36.

![Figure 35. Standard deviation of trials averaged across each material.](image)
The results shown in Figure 36 indicated that microfiber borosilicate, raw cotton, and linen depth capsule filters produced comparable pressure drop readings to the industry produced filter at the initial masses selected. Cellulose acetate and woven cotton produced lower pressure differences. The cellulose acetate filter could not be altered because of the definite form of the cigarette filters. However, the mass of woven cotton used in the woven cotton depth capsule filter could be increased to increase the pressure drop across the filter and make it comparable to the other filters. This was achieved in the second iteration of pressure drop testing, the results of which can be seen in Figures 37, 38, and 39.

Figure 36. Initial pressure recordings for no filter (Blank), cellulose acetate (CA), microfiber borosilicate (MB), woven cotton (WC), raw cotton (RC), and linen (L). Recording period included 8 seconds of no airflow, initiation of CPAP machine to 12 cmH₂O, one minute of constant flow, ceasing airflow, and then stabilization at zero flow.
Figure 37. Pressure recordings for an industry-produced filter (industry) no filter (Blank), cellulose acetate (CA), microfiber borosilicate (MB), woven cotton (WC), raw cotton (RC), and linen (L). Recording period included 8 seconds of no airflow, initiation of CPAP machine to 12 cmH₂O, one minute of constant flow, ceasing airflow, and then stabilization at zero flow.
Figures 37 and 38 show that all filter alternatives except for cellulose acetate created pressure drops within 0.027 kilopascals of the industry-produced intake bacterial filter. Microfiber borosilicate produced the exact same pressure drop as the industry-produced filter, the primary filter medium of which is microfiber borosilicate, which serves as a reassuring check. Standard deviation values in Figure 39 show that the cellulose acetate filters produced the most widely varying pressure drops, likely because overlap between the cigarette filters can differ between
filters and create significant change in the amount of continuous open space available for air to pass through.

4.2.2 *Bacterial Filtration Assessment Results*

Bacteria testing for the single-layer filters yielded entirely null results. After 48 hours of incubation, no colonies were visible on the plates and the plates were discarded. Speculation as to why this occurred can be found in chapter 5. Results of bacteria testing for the depth capsule filters after 48 hours of incubation can be found in Table 15.

### Table 15. Bacteria colony numbers for depth capsule filter bacteria testing after 48 hours of incubation.

<table>
<thead>
<tr>
<th>Material</th>
<th>Bacteria Colonies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Plate 1</td>
</tr>
<tr>
<td>Blank</td>
<td>0</td>
</tr>
<tr>
<td>Cellulose Acetate</td>
<td>0</td>
</tr>
<tr>
<td>Microfiber Borosilicate</td>
<td>0</td>
</tr>
<tr>
<td>Woven Cotton</td>
<td>0</td>
</tr>
<tr>
<td>Raw Cotton</td>
<td>2</td>
</tr>
<tr>
<td>Linen</td>
<td>0</td>
</tr>
</tbody>
</table>

This test resulted in little bacteria growth, though it can be noted that both cellulose acetate and linen yielded no bacteria growth. However, raw cotton yielded more colonies than the blank, calling into question the validity of the test. The plates were then heat-shocked and incubated for another 48 hours, after which colonies were recounted, specifically looking for the addition of
spores, which can appear much smaller than colonies. Table 16 shows tentative counts of spores and colonies after heat-shocking.

Table 16. Bacteria colonies and tentative counts of spores after 48 hours of incubation, heat-shocking, and a subsequent 48 hours of incubation.

<table>
<thead>
<tr>
<th>Material</th>
<th>Bacteria Colonies and Spores</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Plate 1</td>
</tr>
<tr>
<td>Blank</td>
<td>0 col.</td>
</tr>
<tr>
<td></td>
<td>6 spores</td>
</tr>
<tr>
<td>Cellulose Acetate</td>
<td>0 col.</td>
</tr>
<tr>
<td></td>
<td>4 spores</td>
</tr>
<tr>
<td>Microfiber Borosilicate</td>
<td>0 col.</td>
</tr>
<tr>
<td></td>
<td>3 spores</td>
</tr>
<tr>
<td>Woven Cotton</td>
<td>0 col.</td>
</tr>
<tr>
<td></td>
<td>1 spore</td>
</tr>
<tr>
<td>Raw Cotton</td>
<td>3 col.</td>
</tr>
<tr>
<td></td>
<td>0 spores</td>
</tr>
<tr>
<td>Linen</td>
<td>0 col.</td>
</tr>
<tr>
<td></td>
<td>7 spores</td>
</tr>
</tbody>
</table>

The suspected spores were then observed after 24 more hours of incubation and appeared to exhibit little growth. This cast doubt on whether they were indicative of microorganisms or imperfections of the agar, warranting subsequent testing in the form of the liquid LB test described in chapter 3.

The results of the liquid LB tests after 48 hours of incubation are summarized in Table 17.
Aside from potential contamination of one plate, essentially zero bacterial growth was observed in the plates in the form of colonies or spores. No trends could be observed from the data. However, it is noteworthy that the results of the liquid LB testing and the previous iteration of bacteria testing are similar despite designing the liquid LB test to be more robust and increase exposure to microorganisms.

4.3 Prototype Filtration Evaluations

After developing prototype options in the model of multi-material depth filters and the funnel-form of the industry-produced microform borosilicate glass microfiber filter, these combinations required similar testing to the single-material test filters. To review from chapter 3, this was done in two forms. The first was the full prototypes made to fit the oxygen concentrator, tested to see how both the filter media and the intake and exhaust holes affected pressure drop. One of each of the four types was fabricated and tested for pressure drop. The second form is the combined material “test” filters. These had the same contents as the full prototype filters, but rather than the full machine-fitting housing were each contained in a single piece of 2-inch diameter PVC
for compatibility with the bacterial testing apparatus. Two of each of the four material combinations was fabricated and tested for both pressure drop and bacteria removal efficiency.

### 4.3.1 Pressure Drop Results

Pressure drop across the full, machine-fitting prototypes is shown in Figure 40. Because one of each type of filter was fabricated, averaging was unnecessary. The modes of each test can be found in Figure 41.

![Pressure Drop - Full Prototypes](image)

*Figure 40. Pressure recordings for an industry-produced filter (Industry), cellulose acetate and linen (CA/L), raw cotton and linen (RC/L), cellulose acetate and woven cotton (CA/WC), and raw cotton and woven cotton (RC/WC). Recording period included 8 seconds of no airflow, initiation of CPAP machine to 12 cmH2O, one minute of constant flow, ceasing airflow, and then stabilization at zero flow.*
Each filter prototype produced a very similar pressure drop, all of which were within 0.01 kilopascals of the new industry-produced intake bacterial filter. Pressure drop recordings across the combined material “test” filters can be seen in Figure 42. Accompanying modes and standard deviations can be found in Figures 43 and 44.

Figure 41. Mode of each filter alternative.
Figure 42. Pressure recordings for cellulose acetate and linen (CA/L), raw cotton and linen (RC/L), cellulose acetate and woven cotton (CA/WC), and raw cotton and woven cotton (RC/WC). Recording period included 8 seconds of no airflow, initiation of CPAP machine to 12 cmH₂O, one minute of constant flow, ceasing airflow, and then stabilization at zero flow.

Figure 43. Mode of trials averaged across materials.
All pressure drop modes were within 0.2 kilopascals of each other, with the greatest pressure drop occurring across the raw cotton and linen filter. The standard deviation data in Figure 44 shows the greatest deviation among the cellulose acetate and linen filters, though all standard deviations were below 0.15.

### 4.3.2 Bacterial Filtration Assessment Results

The combined material test filters were evaluated for bacteria removal capabilities solely through the liquid LB method. The results of this testing can be found in Table 18.

#### Table 18. Bacterial growth after 40 hours of incubation in plates for liquid LB bacteria testing for depth capsule filters.

<table>
<thead>
<tr>
<th>Material</th>
<th>Bacteria Colonies and Spores</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tube 1</td>
</tr>
<tr>
<td></td>
<td>Regular</td>
</tr>
<tr>
<td>Cellulose Acetate/Linen</td>
<td>0</td>
</tr>
<tr>
<td>Raw Cotton/Linen</td>
<td>0</td>
</tr>
<tr>
<td>Cellulose Acetate/Woven Cotton</td>
<td>6</td>
</tr>
<tr>
<td>Raw Cotton/Woven Cotton</td>
<td>0</td>
</tr>
<tr>
<td>Blank</td>
<td>0</td>
</tr>
</tbody>
</table>
Though more bacteria grew in these plates than the single material liquid LB tests, no significant trend can be observed. However, the combination of raw cotton and woven cotton was the only combination to elicit no bacterial growth.
Chapter 5: Discussion

Results of all prototype building and testing are discussed herein with reference to results presented in chapter 4. All parts of this work represent preliminary steps toward improvements to oxygen concentrator function and use and therefore require further consideration in order to progress toward implementation.

5.1 Ventilating Stand

To discuss the success of the ventilating stand design is to acknowledge the current struggle of culture taking place among hospital administration in Malawi. Despite any amount of positive intentions held by hospital employees, in certain cases, communication, culture, and the challenges of low-resource medicine prevent the administration of the highest quality of care. One such case is the use of oxygen concentrators. Misunderstandings of proper use allow the machines to be pushed up against walls to clear more space, inhibiting ventilation, or they can come in contact with corrosive cleaning materials during routine cleaning. Cultural roadblocks significantly inhibit nighttime monitoring of patients, sometimes creating situations in which wards are entirely unsupervised. Understaffing inhibits continuous monitoring of patients on oxygen therapy, allowing nonfunctional machines to be used despite producing no oxygen flow.

Therefore, part of the purpose of the ventilating stand is to inconvenience hospital personnel, disallowing the machine from being pushed against surfaces or go unnoticed. Thus, some of the important success of the stand will always be mutually responsible for some of the drawbacks discussed in section 4.1. Those conditions acknowledged, there are areas of potential improvement for the design. Creating some sort of structural allowance for the cord projecting from the back of the oxygen concentrator when loading it on the stand would prevent bending of the cord, a potential cause of eventual wear.
Another structural drawback of the device is the large number of pieces required for manufacturing. Accommodating for the location of the casters on the bottom of the oxygen concentrator and providing a “basket” to support the bottom of the device called for the use of many fittings, requiring many cuts when preparing the PVC pipe for assembly. In total, 28 individual pieces of PVC pipe and 22 fittings are used to create the stand. Additionally, the cost of PVC fittings is higher than that of PVC pipe, making the high number of fittings a large portion of the cost of the stand. A favorable alternative design would produce the same structural security and meet the same requirements of lifting and spacing the oxygen concentrator from the floor and walls while requiring fewer fittings and individual pieces. Further, a design that could be adapted to fit the multiple models of oxygen concentrators used in low-resource hospitals would be an ideal solution, rather than requiring a new design for each model.

5.2 Material Filtration

Testing of both pressure drop and bacteria removal efficiency represented the first steps in validating the suggested filter alternatives. Both pressure and bacteria testing did not indicate failure of the tested filter alternatives to perform to the level of the industry-produced filter, but robustness of the tests was called into question by uncertain results. More sophisticated testing would be required to draw more certain comparisons between the tested filter alternative materials and the industry-produced filter.

5.2.1 Pressure Drop

The pressure drop testing across the single layer filters was primary to understand the air permeability of each material when a uniform surface area was compared. These showed that microfiber borosilicate caused by far the most obstructive to airflow, with the other filter alternatives creating very little pressure drop. The results of pressure drop testing for the single-
material depth capsule filters were very similar to that across the industry-produced filter with the exception of cellulose acetate. This represents a success in the first step of alternative filter design—determining that similar volumes of more accessible materials can have similar effect on airflow to that produced by the industry-produced filter. However, this test could be improved upon to draw more reassuring conclusions. A bubble CPAP machine was used to create airflow for pressure drop testing, which produced air at an output 12 cmH₂O, or 1.18 kilopascals. This was done because the available manometer could measure a maximum pressure difference of 2 pound-force per square inch, or 13.7895 kilopascals. More realistic to application in an oxygen concentrator would be using a similar compressor to that inside the concentrator, producing an intake pressure of 140 – 200 kilopascals. This more realistic test could show how the filter media changes in higher airflow velocities; a real possibility since the media of the test filters was simply placed in the test capsules, not fixed to the inside walls. Yet, by measuring the pressure drop across the test filters in the same method as the industry-produced filter, even at a lower airflow velocity than that inside the oxygen concentrator, a valuable comparison was achieved. The pressure drop created by linen, raw cotton, and woven cotton filters were so similar to that created by the industry-produced filter and microfiber borosilicate that they cannot be parsed for a best alternative. However, the cellulose acetate filters’ averaged mode pressure drop of 0.967 kilopascals, provided it produces sufficient bacteria removal efficiency, would be the most favorable of the group. A lower pressure drop is desirable because pressure drop will rise as bacteria and particulates are trapped by the filter, eventually becoming too restrictive to allow sufficient airflow to the compressor. A lower initial pressure drop theoretically allows longer use before becoming blocked enough to require replacement.
5.2.2 Bacterial Filtration

The plates breathed on in the single-layer filter tests yielded no colonies across all 18 plates. These were very surprising results to both the experimenter and the members of the Mukhopadhyay lab, who helped setting up the experiment and interpreting results. The most likely cause for these results is that exhalation, or at least that of the experimenter, has low bacterial content. Additionally, the single-layer filters were only breathed through for 30 seconds, rather than 2 minutes as in the capsule depth filters. These were done differently for fear that with less filter media to trap bacteria, the plates for the single-layer test could be overwhelmed with too many colonies to count if they were breathed on for the full 2 minutes. Pilot testing of just one raw cotton single-layer filter yielded 8 bacterial colonies after 30 seconds of breathing, indicating it would be an appropriate amount of breathing for the full test. However, as stated in chapter 3, the single layer test was performed as an introductory test, in case the depth capsule filters trapped all bacteria and showed no results. The single-layer test turned out to be a weaker indicator of bacteria removal efficiency than the depth capsule test, so it was not repeated.

On the surface and according to members of the Mukhopadhyay lab who assisted with bacterial testing, the initial depth capsule filter bacteria tests, in which breath was projected onto solid plates, seem to indicate that all depth capsule filters aside from raw cotton are successful in trapping bacteria. They almost entirely prevented bacteria from reaching the plates and producing colonies. The questionable aspect of the test results is the response in the blank test cases. The blank filters acted as a control - they should show the most bacteria because none of it could be stopped by filter media. However, the blank plates showed only 1 colony in the dry plates tests, an equal number to that in the microfiber borosilicate plates and the woven cotton plates. Most of all, the raw cotton plates showing 8 colonies while the control showed 0, indicates a failure of the
control. The test indicates linen and raw cotton have the best bacteria removal efficiency, allowing 0 colonies to grow. However, these results cannot be taken as a strong validation because the control plates did not grow the most bacteria. In an effort to see more bacterial growth, the plates were all heat shocked and recounted for spores. These results, if counted correctly, were somewhat more informative as they resulted in higher numbers of colonies and spores to compare. However, the blank filter plates still did not have the most growth, making the success of the test still questionable. It is possible that the filters were seeded with bacteria that was subsequently projected onto the plate by the airflow caused by exhalation, causing the higher number of bacteria in some filters than in the blank cases. However, all filters were prepared from bleached PVC, with cleaned hands, and were stored in new airtight bags before use. Additionally, all filters were tested for pressure drop before they were tested for bacteria removal efficiency. This was done in order to get the pressure drop reading before any of the filter matrix was occupied by particulates caused by the bacteria removal test. However, it also served to blow through the filters and hopefully clear out bacteria trapped inside the filter. Thus, all filters were prepared to be as clean as possible before they were tested in the bacterial tests. Another speculation was that some bleach from the cleaning that occurred between every test was projected onto the plates, killing any bacterial growth on the plates. However, every part of the apparatus was entirely rinsed with water after bleaching and entirely dried, minimalizing this risk. Therefore, in the face of these precautions, the results of the test remain somewhat anomalous.

Thus, the second round of testing was performed where air was bubbled through liquid LB. This was viewed as a more robust test because all air exhaled through the filters would come in contact with the growth media. These tests were performed for the same amount of time and with the same rigorous cleaning protocol as the dry plate tests. However, these tests showed less
bacterial growth than the dry plate tests, with only one plate yielding colonies. These are arranged solely around the edge of the plate, appearing to be caused by contamination during spreading rather than from bacterial inoculation of the liquid LB. None of the bacterial growth occurred in the plates created from the blank control, giving this test similarly questionable validity to the dry plate test. These results indicate there likely isn’t enough bacteria in the challenge, or the airflow entering the filter, to penetrate the filter and create informative results. A potential cause for less bacteria growing in the liquid LB test than in the solid plate test is the pressure of exhalation used in each test. Peak pressure created from each breath in the dry plate tests was always between 0.3 kilopascals and 0.5 kilopascals, according to manometer data. However, the tubes of liquid LB could bubble over if too much air was projected through them at one time or too fast. Thus, exhalation was regulated by how much the liquid was bubbling in the liquid LB tests, creating peak breath pressures between 0.15 and 0.3 kilopascals, exhaled more slowly. Therefore, even though all exhaled air passed through the growth media, less air was likely projected in the 2-minute breathing period. Potentially, the full contact of air to growth media was unable to make up for this decrease in the quantity of air passing through the filters or the pressure at which it was projected.

These tests should be improved upon by using a filter challenge with a known bacterial content. The addition of flow control would also help to apply a more uniform challenge. Pulmonary filters can be tested using a nebulized suspension of micro-organisms, managed by a device created by Henderson and adapted by Druett [62], [93], [94]. This method was investigated for use in this work, however it would require expensive equipment and breath was determined a more accessible way to aerosolize bacteria. Yet, the results of these bacterial tests show that
validation using a more sophisticated method such as the Henderson and Druett method is warranted for moving forward.

5.3 Prototype Filters

The pressure drop and bacterial penetration tests were performed for the combined material test filters, and pressure drop was evaluated for the full machine-fitting prototypes. The validity and results of each tests are discussed in these sections.

5.3.1 Pressure Drop

Similar to the results of the single material depth capsule pressure drop tests, the full, machine-fitting prototypes produced very similar pressure drop to that of the industry produced filter, in all cases within 0.01 kilopascal of that created by the industry-produced filter. It would be similarly beneficial to test these prototypes in higher pressure tests, however these contained more internal structure and would likely show less change when filtering higher velocity airflow. The similarity in pressure drop between the pressure drop of these prototypes and the industry produced filter provides an initial validation before bacteria removal efficiency is compared. Another important note from creating the prototype filters is knowledge that a filter housing can be manufactured from components available in Malawi, another important initial validation.

5.3.2 Bacterial Filtration

As discussed in section 4.2.2, the dry plate bacterial testing showed inconclusive results, and thus were not performed on the combined material test filters. The liquid LB test results show mostly growth-free plates, rendering the results similarly inconclusive. The same blank trials used for comparison to the single material depth capsule tests were used to compare to these combined material trials. While cellulose acetate/Linen grew 2 colonies in one plate, raw cotton/linin grew
2 in one plate, and cellulose acetate/woven cotton grew 6 in one plate, no colonies were grown in plates from the blank tests, again calling into question the validity of the test. Also questionable is that no correlation can be seen between the single material depth capsule tests and the combined material tests. Theoretically, the best performing individual materials should yield the best performance when combined. However, though raw cotton showed by far the most growth in the dry plate tests, combined material filters containing raw cotton produced less growth than those in which the raw cotton was replaced by cellulose acetate. The lack of correlation between different tests further support the necessity for more robust testing, like that discussed in section 4.2.2.

5.4 Protocol of Proper Use

The protocol of proper use is limited in its description of a fully functioning oxygen concentrator with all necessary accompanying parts. As discussed by interviewed physicians in Malawi, much of medicine in low-resource hospitals is improvisational—missing parts are substituted creatively, or physicians make do with partially functioning equipment. Thus, the concern is that if the protocol of proper use describes parts and conditions that cannot be used or adhered to, members of medical staff will grow accustomed to ignoring it. One of the benefits of using a set, posted protocol is the mutual understanding of how machines are being used and serviced by all members of the medical and maintenance staff. For example, maintenance personnel know that nurses are cleaning the cabinet filter daily, and nurses know that the sieve beds are being serviced regularly to provide medical-grade oxygen. Thus, implementing the protocol of proper use requires an understanding that the guidelines should be followed as closely to as possible, with administrative and training personnel continuously referring to it as an important tool.
Chapter 6: Conclusions and Future Work

This chapter presents the conclusions of this work and suggests the next steps in implementing the devices and protocol developed. Furthermore, this chapter discusses methods of organizing manufacturing and training, both important elements of creating truly sustainable devices. Much of improving oxygen concentrator use and function requires the creation of sustainable systems, rather than sustainable devices alone. Therefore, the true completion of this work will require collaboration with partners in-country to create autonomous systems of hospital supply and organize training. This collaboration is what will allow this work to break the cycle of aid and create lasting development in its place.

6.1 Ventilating Stand Feedback and Production

Because a largely satisfactory stand has been designed, the next step is to demonstrate the stand to different members of the hospital team and record their feedback. As was done for devices developed by TEAM Malawi in 2016, multiple hospitals should be visited in Malawi demonstrating the stand. Members of nursing staff, maintenance staff, cleaning staff, and physicians should be interviewed for feedback on the stand. Additionally, they should be asked to demonstrate implementation, such as placing the device in the stand and removing it. They should also be asked if they could explain the stand to others and demonstrate its use to insure perpetuity of understanding. Following general approval from hospital employees, manufacture of the stand in Malawi can be considered.

For manufacturing purposes, partnerships with institutions in Malawi will ensure its availability and sustainability.Partnering with Sakaramenta would be ideal, as they are currently established as providers of hospital furniture. Another possible partnership is with the Polytechnic in Malawi, with whom Virginia Tech Engineering and TEAM Malawi has a developing
partnership. These partnerships could also bring about suggested changes to the stand design. If these changes are significant and impact the use of the stand, another prototype should be developed and demonstrated in hospitals again. This system of development and demonstration can be used to ensure that the final stand is the most appropriate design for use in hospitals and for local manufacture.

6.2 Filter Redesign Validation and Implementation

As referenced in chapter 5, the next step for validating the content of the sustainable filter design presented in this work is sophisticated testing. Pressure testing performed in this research suggests that it is possible to design a filter of similar dimensions to the industry-produced filter that creates similar pressure drop. The next question is whether the quantity of material producing that pressure drop is sufficient to achieve <99.9% bacteria removal efficiency. Attempts were made to measure the bacteria removal efficiency of these filter prototypes, but the difficulty of aerosolizing bacteria resulted necessitated somewhat primitive initial testing. However, using a challenge with unknown bacteria content led to inconclusive test results. As suggested in chapter 5, using a bacteria aerosolizing method such as that developed by Henderson and Druett would allow the use of a challenge with a controlled bacteria density. This bacterial density could be adjusted until comparable quantities penetrate the test filters and appear in the control. Further, lifetime testing to assess the amount of safe use before filter failure should be performed. This is necessary to provide a recommended replacement time for the redesigned filter. A further option that should be noted is the option of incorporating a pre-filter that can be more easily cleaned in order to preserve the full redesigned filter. In the event that the lifetime is short and the redesigned filter would need frequent replacement, this is an option to be explored. A validated design would be presented to
the Ministry of Health in Malawi for further discussions on approval for medical use, implementation, and distribution.

Once a filter design is selected, manufacturing would need to be arranged for the filter to truly be sustainable. As mentioned in section 6.1, the Polytechnic in Malawi has a growing partnership with Virginia Tech and TEAM Malawi, and could be used as a connection to manufacturing opportunities in-country. Because the filter alternatives developed in this work are made from PVC materials available in Malawi, the housing could be created without necessitating ordering. However, if cellulose acetate or linen are part of the selected final design, these would require regular ordering from other African nations to maintain a steady supply. Supplies made in Africa are still more accessible than supplies made outside of the continent, representing an improvement over the Terlux and microform borosilicate glass microfiber standard. Once acquisition and manufacturing are arranged, quality control will need to be integrated into the production line. These tests will need to validate the success of the filters in preventing bacteria-size particle flow while producing low pressure drop, similar to the validations this work seeks to achieve. However, these will need to be performable in the environment of Malawi, without neutralizing the sustainability efforts made by the filter, such as using outsourced or expensive quality testing equipment.

6.3 The Future of the Oxygen Concentrator in Malawi

Though this work focuses on the development of a ventilating stand, sustainable intake bacterial filter, and protocol of proper use, much more can be done to improve the longevity of oxygen concentrators in Malawi, and indeed, all medical equipment. Many of the concerns expressed in the interviews performed for this work can be mitigated through administrative actions. The donation of many different models of each device causes difficulty for personnel
using medical equipment and maintaining it. As suggested by Howie et al., donation management committees can be formed to create databases of desired equipment models, advertise the greatest equipment needs, and manage reorder of consumables or test equipment [22]. The formation of such committees may be difficult in understaffed circumstances, but could be developed over time. A single committee could serve several rural hospitals the way central hospital maintenance departments service surrounding hospitals. These committees could ease many of the difficulties felt by maintenance departments and medical personnel, and even improve the quality of care provided in hospitals by ensuring that equipment is best understood and maintained by hospital maintenance departments.

Regular training is another important component of extending the life of equipment and ensuring the provision of the highest quality of care. Training managers could be established to schedule regular equipment maintenance and use training so that even experienced personnel stay up to date. Further, the training programs implemented by donating organizations like those discussed in chapter 1 could coordinate with a training manager to ensure that training continues even after the donating body lessens or removes its presence in the hospital. A single training manager could service several hospitals if transportation and communication supported it.

Finally, as begun in this work, creating more sustainable consumable materials can help maintenance departments extend the life of equipment. Allowing hospitals to order replacement parts made in Malawi will allow more reliable stock of consumables to develop, support manufacturers and suppliers in Malawi, and overall promote the self-reliance of hospitals in Malawi. Further, having more available consumables will allow maintenance personnel and medical personnel to rely more on engineering and medicine and less on improvisation, providing more reliable care.
The oxygen concentrator has drastically increased the availability of oxygen while reducing its cost in low-resource hospitals. However, due to the environments of low-resource hospitals and the inaccessibility of replacement parts, the oxygen concentrator is not living up to its fullest quality of oxygen and longevity of use. By organizing donation procedures, maintaining current training, and engineering adaptations and consumables to fit the environment of low-resource hospitals, the oxygen concentrator can continue to improve the quality of care provided to patients in need of life-saving oxygen therapy.
REFERENCES


68. Styrolution Terlux 2802 HD MABS, in Material Property Data. MatWeb.
Appendix A: Oxygen Concentrator Assessment

Malawi O$_2$ Concentrator Questionnaire

Virginia Tech Department of Mechanical Engineering

Name of Facility: ________________________________________________________

Which of the following best describes your occupation?

___ Medical doctor
___ Nurse/nurse practitioner
___ Laboratory technician
___ Technical professional (such as engineer, maintenance personnel, etc.)
___ Other___________________________

In which setting do you work?

___ Urban
___ Rural
___ Peri-urban area
___ Transient location (such as a slum or refugee camp)

What was the training you received to become a technician?

___ Technical school: Which school did you attend _________________________
   Do you have a certificate? __________________________
___ University degree: Which university did you attend? _________________________
   What is your degree? ______________________________
___ Other training, __________________________________________________

Please list the top five challenges you have in your clinical work setting.
1. 
2. 
3. 
4. 
5. 

For what purpose do you use an oxygen concentrator?
How frequently do you use or repair an oxygen concentrator in your work?

How often is electricity available in the hospital (for using electronic appliances)?

What are some challenges you have experienced using an oxygen concentrator?
1.
2.
3.
4.
5.

How frequently do you believe oxygen concentrators should be repaired or maintained?

What maintenance or repairs do you perform on an oxygen concentrator?

How often do you change the filters on an oxygen concentrator?

Cabinet filter:

Bacterial filter:

Zeolite sieve:

What would improve the function or use of oxygen concentrators in your facility?
What part(s) of the oxygen concentrator most frequently need(s) repair or maintenance? Circle all that apply

- Meter
- Oxygen reservoir
- Output valve
- Bacterial filter
- Zeolite filter
- 2-way valve
- Zeolite filter
- Compressor
- Exhaust vent

What are your ideas for improving oxygen concentrator use or function?

What other comments do you have on oxygen concentrator malfunction, use, or repair?
Appendix B: Virginia Tech IRB 16-895 Research Protocol

Once complete, upload this form as a Word document to the IRB Protocol Management System: https://secure.research.vt.edu/irb

Section 1: General Information

1.1 DO ANY OF THE INVESTIGATORS OF THIS PROJECT HAVE A REPORTABLE CONFLICT OF INTEREST? (http://www.irb.vt.edu/pages/researchers.htm#conflict)

☐ No
☐ Yes, explain:

1.2 IS THIS RESEARCH SPONSORED OR SEEKING SPONSORED FUNDS?

☐ No, go to question 2.1
☐ Yes, answer questions within table

<table>
<thead>
<tr>
<th>IF YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide the name of the sponsor [if NIH, specify department]:</td>
</tr>
</tbody>
</table>

Is this project receiving or seeking federal funds?

☐ No
☐ Yes

If yes,

Does the grant application, OSP proposal, or “statement of work” related to this project include activities involving human subjects that are not covered within this IRB application?

☐ No, all human subject activities are covered in this IRB application
☐ Yes, however these activities will be covered in future VT IRB applications, these activities include:
☐ Yes, however these activities have been covered in past VT IRB applications, the IRB number(s) are as follows:
☐ Yes, however these activities have been or will be reviewed by another institution’s IRB, the name of this institution is as follows:
☐ Other, explain:

Is Virginia Tech the primary awardee or the coordinating center of this grant?

☐ No, provide the name of the primary institution:
☐ Yes
Section 2: Justification

2.1 DESCRIBE THE BACKGROUND, PURPOSE, AND ANTICIPATED FINDINGS OF THIS STUDY:

The purpose of this study is to assess the use and function of oxygen concentrators in low-resource hospitals. Specifically, this research aims to identify specific components of oxygen concentrators that can be improved upon for future use. Subsequently this research aims to identify areas in which a protocol for proper use could improve the quality of primary maintenance being performed on oxygen concentrators in clinical environments.

2.2 EXPLAIN WHAT THE RESEARCH TEAM PLANS TO DO WITH THE STUDY RESULTS:

For example - publish or use for dissertation

From the study results, the aim is to redesign oxygen concentrator components from locally resourced and longer lasting components, reducing the maintenance need in low-resource hospitals. Additionally, based on the results regarding routine maintenance, a protocol of proper use will be produced to clarify use and maintenance procedures that will improve the function and life of the machine.

Section 3: Recruitment

3.1 DESCRIBE THE SUBJECT POOL, INCLUDING INCLUSION AND EXCLUSION CRITERIA AND NUMBER OF SUBJECTS:

Examples of inclusion/exclusion criteria - gender, age, health status, ethnicity

The subject pool includes clinical and maintenance personnel in Malawi, Africa, limited to 30 participants.

3.2 WILL EXISTING RECORDS BE USED TO IDENTIFY AND CONTACT / RECRUIT SUBJECTS?

Examples of existing records - directories, class roster, university records, educational records

☐ No, go to question 3.3
☐ Yes, answer questions within table

IF YES

Are these records private or public?
☐ Public
☐ Private, describe the researcher’s privilege to the records:

Will student, faculty, and/or staff records or contact information be requested from the University?
☐ No
3.3 DESCRIBE RECRUITMENT METHODS, INCLUDING HOW THE STUDY WILL BE ADVERTISED OR INTRODUCED TO SUBJECTS:

Recruitment will be done in-person in Zomba, Mulanje, Domasi and Blantyre in Malawi, Africa. This will be done in hospitals and hospital-affiliated maintenance centers. Additionally, email will be used to request survey participation from personnel at the aforementioned hospitals and maintenance centers provided they cannot be reached in person.

3.4 PROVIDE AN EXPLANATION FOR CHOOSING THIS POPULATION:

Note: the IRB must ensure that the risks and benefits of participating in a study are distributed equitably among the general population and that a specific population is not targeted because of ease of recruitment.

Clinical and maintenance personnel in low-resource healthcare environments have insight to the use and improvement of medical devices in those environments.

Section 4: Consent Process

For more information about consent process and consent forms visit the following link:
http://www.irb.vt.edu/pages/consent.htm

If feasible, researchers are advised and may be required to obtain signed consent from each participant unless obtaining signatures leads to an increase of risk (e.g., the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting in a breach of confidentiality). Signed consent is typically not required for low risk questionnaires (consent is implied) unless audio/video recording or an in-person interview is involved. If researchers will not be obtaining signed consent, participants must, in most cases, be supplied with consent information in a different format (e.g., in recruitment document, at the beginning of survey instrument, read to participant over the phone, information sheet physically or verbally provided to participant).

4.1 CHECK ALL OF THE FOLLOWING THAT APPLY TO THIS STUDY’S CONSENT PROCESS:

☐ Verbal consent will be obtained from participants
☐ Signed consent will be obtained from participants
☒ Consent will be implied from the return of completed questionnaire. Note: The IRB recommends providing consent information in a recruitment document or at the beginning of the questionnaire (if the study only involves implied consent, skip to Section 5 below)
☐ Other, describe:

4.2 PROVIDE A GENERAL DESCRIPTION OF THE PROCESS THE RESEARCH TEAM WILL USE TO OBTAIN AND MAINTAIN INFORMED CONSENT:

4.3 WHO, FROM THE RESEARCH TEAM, WILL BE OVERSEEING THE PROCESS AND OBTAINING CONSENT FROM SUBJECTS?
4.4 WHERE WILL THE CONSENT PROCESS TAKE PLACE?

4.5 DURING WHAT POINT IN THE STUDY PROCESS WILL CONSENTING OCCUR?
Note: unless waived by the IRB, participants must be consented before completing any study procedure, including screening questionnaires.

4.6 IF APPLICABLE, DESCRIBE HOW THE RESEARCHERS WILL GIVE SUBJECTS AMPLE TIME TO REVIEW THE CONSENT DOCUMENT BEFORE SIGNING:
Note: typically applicable for complex studies, studies involving more than one session, or studies involving more of a risk to subjects.

☑ Not applicable

Section 5: Procedures

5.1 PROVIDE A STEP-BY-STEP THOROUGH EXPLANATION OF ALL STUDY PROCEDURES EXPECTED FROM STUDY PARTICIPANTS, INCLUDING TIME COMMITMENT & LOCATION:

This study involves administering a survey on the faction and repair of oxygen concentrators. Should you choose to participate, you will be asked to review your interaction and understanding of oxygen concentrators and provide feedback using the survey. This research does not involve using oxygen concentrator on yourself or on another person. The survey should only be completed once and there is no time limit for its completion. It should take no more than 15 minutes to complete and can be completed at the participant’s convenience.

5.2 DESCRIBE HOW DATA WILL BE COLLECTED AND RECORDED:

Data will be collected and recorded using both paper surveys administered in person and electronic surveys completed however is most convenient to the participant and send back via email.

5.3 DOES THE PROJECT INVOLVE ONLINE RESEARCH ACTIVITIES (INCLUDES ENROLLMENT, RECRUITMENT, SURVEYS)?

View the “Policy for Online Research Data Collection Activities Involving Human Subjects” at http://www.irb.vt.edu/documents/onlinepolicy.pdf

☐ No, go to question 6.1
☑ Yes, answer questions within table
IF YES

Identify the service / program that will be used:

- [ ] www.survey.vt.edu, go to question 6.1
- [ ] SONA, go to question 6.1
- [ ] Qualtrics, go to question 6.1
- [ ] Center for Survey Research, go to question 6.1
- [x] Other

IF OTHER:
Name of service / program: email, for recruitment purposes
URL: N/A
This service is…

- [ ] Included on the list found at: http://www.irb.vt.edu/pages/validated.htm
- [ ] Approved by VT IT Security
- [ ] An external service with proper SSL or similar encryption (https://) on the login (if applicable) and all other data collection pages.
- [x] None of the above (note: only permissible if this is a collaborative project in which VT individuals are only responsible for data analysis, consulting, or recruitment)

Section 6: Risks and Benefits

6.1 WHAT ARE THE POTENTIAL RISKS (E.G., EMOTIONAL, PHYSICAL, SOCIAL, LEGAL, ECONOMIC, OR DIGNITY) TO STUDY PARTICIPANTS?

The survey requires minimal risks or discomfort. No physical risk or discomfort is associated with the data collection procedure, and the lack of a time limit should remove emotional distress associated with completing the survey.

6.2 EXPLAIN THE STUDY’S EFFORTS TO REDUCE POTENTIAL RISKS TO SUBJECTS:

Emotional stress is reduced by removing a time limit from the survey completion

6.3 WHAT ARE THE DIRECT OR INDIRECT ANTICIPATED BENEFITS TO STUDY PARTICIPANTS AND/OR SOCIETY?

There are no individual benefits associated with the study. Larger benefits associated are aiding in the development of oxygen concentrators more appropriate for low-resource hospital environments and a protocol to improve their maintenance and function.

Section 7: Full Board Assessment

7.1 DOES THE RESEARCH INVOLVE MICROWAVES/X-RAYS, OR GENERAL ANESTHESIA OR SEDATION?

- [x] No
7.2 DO RESEARCH ACTIVITIES INVOLVE PRISONERS, PREGNANT WOMEN, FETUSES, HUMAN IN VITRO FERTILIZATION, OR INDIVIDUALS WITH MENTAL DISORDERS?

☐ Yes, answer questions within table

☐ No, go to question 7.3

IF YES

<table>
<thead>
<tr>
<th>This research involves:</th>
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</thead>
<tbody>
<tr>
<td>□ Prisoners</td>
</tr>
<tr>
<td>□ Pregnant women</td>
</tr>
<tr>
<td>□ Fetuses</td>
</tr>
<tr>
<td>□ Human in vitro fertilization</td>
</tr>
<tr>
<td>□ Individuals with a mental disorder</td>
</tr>
</tbody>
</table>

7.3 DOES THIS STUDY INVOLVE MORE THAN MINIMAL RISK TO STUDY PARTICIPANTS?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily activities or during the performance of routine physical or psychological examinations or tests. Examples of research involving greater than minimal risk include collecting data about abuse or illegal activities. Note: if the project qualifies for Exempt review (http://www.irb.vt.edu/pages/categories.htm), it will not need to go to the Full Board.

☐ No

☐ Yes

IF YOU ANSWERED “YES” TO ANY ONE OF THE ABOVE QUESTIONS, 7.1, 7.2, OR 7.3, THE BOARD MAY REVIEW THE PROJECT’S APPLICATION MATERIALS AT ITS MONTHLY MEETING. VIEW THE FOLLOWING LINK FOR DEADLINES AND ADDITIONAL INFORMATION:
http://www.irb.vt.edu/pages/deadlines.htm

Section 8: Confidentiality / Anonymity

For more information about confidentiality and anonymity visit the following link:
http://www.irb.vt.edu/pages/confidentiality.htm

8.1 WILL PERSONALLY IDENTIFYING STUDY RESULTS OR DATA BE RELEASED TO ANYONE OUTSIDE OF THE RESEARCH TEAM?

For example – to the funding agency or outside data analyst, or participants identified in publications with individual consent

☐ No

☐ Yes, to whom will identifying data be released?

8.2 WILL THE RESEARCH TEAM COLLECT AND/OR RECORD PARTICIPANT IDENTIFYING INFORMATION (E.G., NAME, CONTACT INFORMATION, VIDEO/AUDIO RECORDINGS)?

Note: if collecting signatures on a consent form, select “Yes.”
**IF YES**

Describe if/how the study will utilize study codes:

- **If applicable, where will the key [i.e., linked code and identifying information document (for instance, John Doe = study ID 001)] be stored and who will have access?**

  Note: the key should be stored separately from subjects’ completed data documents and accessibility should be limited.

  The IRB strongly suggests and may require that all data documents (e.g., questionnaire responses, interview responses, etc.) do not include or request identifying information (e.g., name, contact information, etc.) from participants. If you need to link subjects’ identifying information to subjects’ data documents, use a study ID/code on all data documents.

---

8.3 HOW WILL DATA BE STORED TO ENSURE SECURITY (E.G., PASSWORD PROTECTED COMPUTERS, ENCRYPTION) AND LIMITED ACCESS?

Examples of data - questionnaire, interview responses, downloaded online survey data, observation recordings, biological samples

Once surveys are completed, data will be entered into a spreadsheet in a password protected computer, after which paper copies will be destroyed and electronic responses deleted.

8.4 WHO WILL HAVE ACCESS TO STUDY DATA?

- Research team

8.5 DESCRIBE THE PLANS FOR RETAINING OR DESTROYING STUDY DATA:

- Paper copies of the survey will be shredded and electronic responses will be deleted.

8.6 DOES THIS STUDY REQUEST INFORMATION FROM PARTICIPANTS REGARDING ILLEGAL BEHAVIOR?

- No, go to question 9.1
- Yes, answer questions within table

**IF YES**

Does the study plan to obtain a Certificate of Confidentiality?

- No
- Yes (Note: participants must be fully informed of the conditions of the Certificate of Confidentiality within the consent process and form)

For more information about Certificates of Confidentiality, visit the following link:

http://www.irb.vt.edu/pages/coc.htm
Section 9: Compensation

For more information about compensating subjects, visit the following link:
http://www.irb.vt.edu/pages/compensation.htm

9.1 WILL SUBJECTS BE COMPENSATED FOR THEIR PARTICIPATION?

☐ No, go to question 10.1
☐ Yes, answer questions within table

<table>
<thead>
<tr>
<th>IF YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the amount of compensation?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WILL compensation be prorated?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes, please describe:</td>
</tr>
<tr>
<td>☐ No, explain why and clarify whether subjects will receive full compensation if they withdraw from the study?</td>
</tr>
</tbody>
</table>

Unless justified by the researcher, compensation should be prorated based on duration of study participation. Payment must not be contingent upon completion of study procedures. In other words, even if the subject decides to withdraw from the study, he/she should be compensated, at least partially, based on what study procedures he/she has completed.

Section 10: Audio / Video Recording

For more information about audio/video recording participants, visit the following link:
http://www.irb.vt.edu/pages/recordings.htm

10.1 WILL YOUR STUDY INVOLVE VIDEO AND/OR AUDIO RECORDING?

☐ No, go to question 11.1
☐ Yes, answer questions within table

<table>
<thead>
<tr>
<th>IF YES</th>
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</thead>
<tbody>
<tr>
<td>This project involves:</td>
</tr>
<tr>
<td>☐ Audio recordings only</td>
</tr>
<tr>
<td>☐ Video recordings only</td>
</tr>
<tr>
<td>☐ Both video and audio recordings</td>
</tr>
</tbody>
</table>

Provide compelling justification for the use of audio/video recording:

How will data within the recordings be retrieved / transcribed?
How and where will recordings (e.g., tapes, digital data, data backups) be stored to ensure security?

Who will have access to the recordings?

Who will transcribe the recordings?

When will the recordings be erased / destroyed?

Section 11: Research Involving Students

11.1 DOES THIS PROJECT INCLUDE STUDENTS AS PARTICIPANTS?

☑ No, go to question 12.1
☐ Yes, answer questions within table

IF YES

Does this study involve conducting research with students of the researcher?

☐ No
☐ Yes, describe safeguards the study will implement to protect against coercion or undue influence for participation:

Note: if it is feasible to use students from a class of students not under the instruction of the researcher, the IRB recommends and may require doing so.

Will the study need to access student records (e.g., SAT, GPA, or GRE scores)?

☐ No
☐ Yes

11.2 DOES THIS PROJECT INCLUDE ELEMENTARY, JUNIOR, OR HIGH SCHOOL STUDENTS?

☑ No, go to question 11.3
☐ Yes, answer questions within table

IF YES

Will study procedures be completed during school hours?

☐ No
☐ Yes

If yes,

Students not included in the study may view other students’ involvement with the research during school time as unfair. Address this issue and how the study will reduce this outcome:
Missing out on regular class time or seeing other students participate may influence a student’s decision to participate. Address how the study will reduce this outcome:

Is the school’s approval letter(s) attached to this submission?

☐ Yes
☐ No, project involves Montgomery County Public Schools (MCPS)
☐ No, explain why:

You will need to obtain school approval (if involving MCPS, click here: [http://www.irb.vt.edu/pages/mcps.htm](http://www.irb.vt.edu/pages/mcps.htm)). Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should accompany the approval request to the IRB.

11.3 DOES THIS PROJECT INCLUDE COLLEGE STUDENTS?

☐ No, go to question 12.1
☐ Yes, answer questions within table

IF YES

Some college students might be minors. Indicate whether these minors will be included in the research or actively excluded:

☐ Included
☐ Actively excluded, describe how the study will ensure that minors will not be included:

Will extra credit be offered to subjects?

☐ No
☐ Yes

If yes,

What will be offered to subjects as an equal alternative to receiving extra credit without participating in this study?

Include a description of the extra credit (e.g., amount) to be provided within question 9.1 (“IF YES” table)

Section 12: Research Involving Minors

12.1 DOES THIS PROJECT INVOLVE MINORS (UNDER THE AGE OF 18 IN VIRGINIA)?

Note: age constituting a minor may differ in other States.

☐ No, go to question 13.1
☐ Yes, answer questions within table
### IF YES

**Does the project reasonably pose a risk of reports of current threats of abuse and/or suicide?**

- [ ] No
- [x] Yes, thoroughly explain how the study will react to such reports:

*Note: subjects and parents must be fully informed of the fact that researchers must report threats of suicide or suspected/reported abuse to the appropriate authorities within the Confidentiality section of the Consent, Assent, and/or Permission documents.*

---

**Are you requesting a waiver of parental permission (i.e., parent uninformed of child’s involvement)?**

- [ ] No, **both** parents/guardians will provide their permission, if possible.
- [ ] No, **only one** parent/guardian will provide permission.
- [ ] Yes, describe below how your research meets **all** of the following criteria (A-D):
  - **Criteria A** - The research involves no more than minimal risk to the subjects:
  - **Criteria B** - The waiver will not adversely affect the rights and welfare of the subjects:
  - **Criteria C** - The research could not practicably be carried out without the waiver:
  - **Criteria D** - (Optional) Parents will be provided with additional pertinent information after participation:

---

**Is it possible that minor research participants will reach the legal age of consent (18 in Virginia) while enrolled in this study?**

- [ ] No
- [ ] Yes, will the investigators seek and obtain the legally effective informed consent (in place of the minors’ previously provided assent and parents’ permission) for the now-adult subjects for any ongoing interactions with the subjects, or analysis of subjects’ data? If yes, explain how:

*For more information about minors reaching legal age during enrollment, visit the following link: [http://www.irb.vt.edu/pages/assent.htm](http://www.irb.vt.edu/pages/assent.htm)*

*The procedure for obtaining assent from minors and permission from the minor’s guardian(s) must be described in **Section 4** (Consent Process) of this form.*

---

### Section 13: Research Involving Deception

For more information about involving deception in research and for assistance with developing your debriefing form, visit our website at [http://www.irb.vt.edu/pages/deception.htm](http://www.irb.vt.edu/pages/deception.htm)

**13.1 DOES THIS PROJECT INVOLVE DECEPTION?**

- [x] No, go to question 14.1
- [ ] Yes, answer questions within table
Section 14: Research Involving Existing Data

14.1 WILL THIS PROJECT INVOLVE THE COLLECTION OR STUDY/ANALYSIS OF EXISTING DATA DOCUMENTS, RECORDS, PATHOLOGICAL SPECIMENS, OR DIAGNOSTIC SPECIMENS?

Please note: it is not considered existing data if a researcher transfers to Virginia Tech from another institution and will be conducting data analysis of an on-going study.

☐ No, you are finished with the application
☐ Yes, answer questions within table

IF YES

From where does the existing data originate?

Provide a detailed description of the existing data that will be collected or studied/analyzed:

Is the source of the data public?

☐ No, continue with the next question
☐ Yes, you are finished with this application
Will any individual associated with this project (internal or external) have access to or be provided with existing data containing information which would enable the identification of subjects:

- **Directly** (e.g., by name, phone number, address, email address, social security number, student ID number), or
- **Indirectly through study codes** even if the researcher or research team does not have access to the master list linking study codes to identifiable information such as name, student ID number, etc.
- **Indirectly through the use of information that could reasonably be used in combination to identify an individual** (e.g., demographics)

☐ No, collected/analyzed data will be completely de-identified
☐ Yes,

If yes,

Research will not qualify for exempt review; therefore, if feasible, written consent must be obtained from individuals whose data will be collected/analyzed, unless this requirement is waived by the IRB.

Will written/signed or verbal consent be obtained from participants prior to the analysis of collected data? -select one-

---

This research protocol represents a contract between all research personnel associated with the project, the University, and federal government; therefore, must be followed accordingly and kept current.

Proposed modifications must be approved by the IRB prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects.

Do not begin human subjects activities until you receive an IRB approval letter via email.

It is the Principal Investigator's responsibility to ensure all members of the research team who interact with research subjects, or collect or handle human subjects data have completed human subjects protection training prior to interacting with subjects, or handling or collecting the data.

----------END----------

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Appendix C: Virginia Tech IRB 16-895 Recruitment Materials

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
Informed Consent for Participants
in Research Projects Involving Human Subjects

Title of Project: Oxygen Concentrator Maintenance Assessment

Investigator(s): Kevin Kochersberger, Ph.D.  kbk@vt.edu/540-231-5589
Lauren Cashman, BS  lcashman@vt.edu/757-771-4753

Recruitment Materials

Recruitment for this research will be conducted in-person in the cities of Blantyre, Mulanje, Domasi, and Zomba in Malawi, Africa, as well as via email to contacts in the same cities. The location of the research will be at hospitals and maintenance facilities in these locations. Recruitment will occur at a time convenient to the participants and with no time restriction as to avoid emotional distress.

Suggested recruitment script:
“Hello- my name is ______________ and I am a researcher with Virginia Tech. We are working to understand the role of oxygen concentrators in Malawian hospitals and how they are used, maintained, and repaired. Would you be willing to read over the informed consent document and consider participating in our study?”
Appendix D: Virginia Tech IRB 16-895 Consent Form

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
Informed Consent for Participants in Research Projects Involving Human Subjects

Title of Project: Oxygen Concentrator Maintenance Assessment

Investigator(s): Kevin Kochersberger, Ph.D. 
Lauren Cashman, BS

kbk@vt.edu/540-231-5589
lcashman@vt.edu/757-771-4753

I. Purpose of this Research Project

The purpose of this study is to assess the use of oxygen concentrators in low-resource hospitals as well as their malfunction, repair, and maintenance. Based on prior collaboration in hospitals in the Southern region of Malawi, oxygen concentrators frequently fall into disrepair. Understanding why these machines malfunction, how they are repaired, and what regular maintenance they receive will help in mitigating this issue. This research will be used to improve design of oxygen concentrators for low-resource environments, and may be used for publication purposes. The subject pool includes clinical personnel in Malawi, Africa.

II. Procedures

This study involves administering a survey on the function and repair of oxygen concentrators. Should you choose to participate, you will be asked to review your interaction and understanding of oxygen concentrators and provide feedback using the survey. This research does not involve using oxygen concentrator on yourself or on another person. The survey should only be completed once and there is no time limit for its completion. It should take no more than 15 minutes to complete and can be completed at your convenience.

III. Risks

The survey requires minimal risks or discomfort. No physical risk or discomfort is associated with the data collection procedure, and the lack of a time limit should remove emotional distress associated with completing the survey.

IV. Benefits

There are no individual benefits associated with the study. Larger benefits associated are aiding in the development of oxygen concentrators more appropriate for low-resource hospital environments and a protocol to improve their maintenance and function. No offer or guarantee of benefits is being made to encourage you to participate.
V. Extent of Anonymity and Confidentiality

Anonymity and confidentiality are important to this research. No identifying information will be collected, and survey data will be collected without identifying information associated. Only members of the research team will have access to the data, which is de-identified. The Virginia Tech (VT) Institutional Review Board (IRB) may view the study’s data for auditing purposes. The IRB is responsible for the oversight of the protection of human subjects involved in research.

VI. Compensation

No compensation will be earned for involvement in this research.

VII. Freedom to Withdraw

It is important for you to know that you are free to withdraw from this study at any time without penalty. You are free to refrain from answering any questions you choose or refrain from responding to what is being asked of you without penalty.

Please note that there may be circumstances under which the investigator may determine that a subject should not continue as a subject.

VIII. Questions or Concerns

Should you have any questions about this study, you may contact one of the research investigators whose contact information is included at the beginning of this document.

Should you have any questions or concerns about the study’s conduct or your rights as a research subject, or need to report a research-related injury or event, you may contact the VT IRB Chair, Dr. David M. Moore at moored@vt.edu or (540) 231-4991.

IX. Subject's Consent

I have read the Consent Form and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent:

Consent to participate in this study is implied with return of completed questionnaire.
Appendix E: Enlarged Fault Tree

[Diagram of a fault tree with nodes such as Hazard to Patient, Machine Failure, Compressor Failure, Power Failure, Overloading, Cooling Filter Failure, Exhaust Vent Obstruction, Recommended 2", distance from walls or objects [1], Overdue Compressor Rebuild, Recommended compressor rebuild every 6,700 hours [1], Electronics Failure, Power Supply Failure, Airflow Restriction, Filter Obstruction, Failure to replace intake bacterial filter, Recommended replacement every 6-12 months, and ideally between patients [1].]
Appendix F: Malawian PVC Distributor Pricing

Taken with permission of collector [33].

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“Pricing of PVC from Polyplast Inc. located in Blantyre, Malawi, July 2015. Note: PN4, PN6, PN10, etc. are “classes” of PVC and refer to the wall thickness of the pipe (see Table, page 7). Prices listed are in Malawian Kwacha (check online for most recent exchange rate, varies from 300-500 MKW per 1 US dollar). Left column is OD in mm. Prices listed are for lengths of 6 meters. Can also buy in lengths of 3 meters.” [33]
### Short Radius Bends

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### MALE Adaptors

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Features
- Strong, UV Stabilized and Long Lasting
- Hygienic and Non-Toxic
- High Resistance to Acids and Chlorides
- Light Weight and No Maintenance
- Extremely Low Thermal Conductivity
- Easy Installation and Handling
- Insulation is Required for Exterior Applications
- Tolerates High Pressure and Temperature (100°C)
- Negligible Pressure Drop
- Eco-Friendly and Not Harmful to Human Health - Food Grade
- Noise free at High Flow Rates
- Extensive Saving in both Time and Labour during Plumbers
- No Calcification and Sedimentation
- No Rust, No Scaling Down and Resistant to Abrasion - Corrosion
- Widely used in European and Developed Countries
- No Bacterial or Fungal Growth and No Contamination
- Long Life and Competitively Priced
- Approved by Water Quality Institution of 16 Countries across the World

Field of Applications
- Potable Water Pipe for Hot & Cold Water Installations
- i.e., in Residential Buildings, Hospitals, Hotels, Office and School Buildings
- Pipe Networks for Compressed Air Plants
- Pipe Networks for Swimming Pool Facilities
- Pipe Networks for Solar Plants
- Pipe Networks in Agricultural and Horticulture
- Pipe Networks for Rainwater Utilization Systems
- Ideal in Textile, Sugar and Paper Industries
- Ideal for Transportation of Aggressive Fluids like Chemicals, Acids, Lyes etc.
- Suitable in Food, Beverage and Dying Industry in place of SS and all Pipes

Property and Cost Analysis

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>CPVC</th>
<th>GL</th>
<th>Copper</th>
<th>S. Steel</th>
<th>PBT Pipe</th>
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<td>Cost</td>
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Popular Sizes

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<th>PN16 kg/cm²</th>
<th>PN10 kg/cm²</th>
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GI Pipes After 10 Years

Authorised Distributor / Dealer
### PP-R FITTINGS

#### Ball valve with brass ball (cold water)

<table>
<thead>
<tr>
<th>Code</th>
<th>Size/mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>KHW01A</td>
<td>20</td>
</tr>
<tr>
<td>KHW02A</td>
<td>25</td>
</tr>
</tbody>
</table>

#### Ball valve with plastic ball (cold water)

<table>
<thead>
<tr>
<th>Code</th>
<th>Size/mm</th>
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<tbody>
<tr>
<td>KH01A</td>
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<td>KH02A</td>
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<tr>
<td>KH03A</td>
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<tr>
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</tr>
<tr>
<td>KH06A</td>
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#### Ball valve with brass ball (hot water)

<table>
<thead>
<tr>
<th>Code</th>
<th>Size/mm</th>
</tr>
</thead>
<tbody>
<tr>
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<td>KHW02A</td>
<td>25</td>
</tr>
<tr>
<td>KHW03A</td>
<td>32</td>
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</tbody>
</table>

#### Ball valve with brass ball (hot water)

<table>
<thead>
<tr>
<th>Code</th>
<th>Size/mm</th>
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</thead>
<tbody>
<tr>
<td>KH01A</td>
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<td>KH02A</td>
<td>25</td>
</tr>
<tr>
<td>KH03A</td>
<td>32</td>
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</table>

#### Stop valve

<table>
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<td>KH02</td>
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</tr>
<tr>
<td>KH03</td>
<td>32</td>
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<tr>
<td>KH04</td>
<td>40</td>
</tr>
<tr>
<td>KH05</td>
<td>50</td>
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<td>KH08</td>
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</tr>
<tr>
<td>KH09</td>
<td>130</td>
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#### Double union ball cock

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<tr>
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<tr>
<td>KH203</td>
<td>12</td>
</tr>
<tr>
<td>KH204</td>
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#### Single union female threaded ball cock

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<td>KH302</td>
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#### Concealed valve

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<td>KH02A</td>
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</tr>
<tr>
<td>KH03A</td>
<td>32</td>
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#### Elbow ball valve

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</table>

#### Coupling ball valve

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#### PVC PP-R PIPE CUTTER

<table>
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<tbody>
<tr>
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#### Water pressure test pump

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<tbody>
<tr>
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#### PP-R HDPE welding machine

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</thead>
<tbody>
<tr>
<td>KL01</td>
<td>30</td>
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</tbody>
</table>

**Specifications:**
- **Specification:** 16-32mm
- **Limited power:** 20V/40A x 5Hz
- **Rated power:** 600W
- **Rated temperature:** 280 ± 5°C
- **Rated power:** 700-1500W

**Other Information:**
- **Certification:** Various certifications

---

**Polyplast Ltd**
MC 194 Chiramba Industrial Area, Blantyre, Malawi
sales@polyplastmw.com
Tel: +265 1111 666837/917312
Fax: +265 111 664535
www.polyplastmw.com
Appendix G: Petri Dish Photographs

Single material depth capsule filters – projection onto solid plates, pre-heat shock

Blank, plate 2
Microfiber borosilicate, plate 2

Woven cotton, plate 3
Raw cotton, plate 1

Raw cotton, plate 2
Raw cotton, plate 3
Single material depth capsule filters – projection onto solid plates, post-heat shock

Blank, plate 1

Blank, plate 1

Blank, plate 3

Cellulose acetate, plate 1

Cellulose acetate, plate 2

Cellulose acetate, plate 3
Microfiber borosilicate, plate 1

Microfiber borosilicate, plate 2

Microfiber borosilicate, plate 3

Woven cotton, plate 1

Woven cotton, plate 2

Woven cotton, plate 3
Single material depth capsule filters – bubbling through liquid LB, heat shocked

Microfiber borosilicate, tube 1

Combined material depth capsule filters – bubbling through liquid LB, not heat shocked

Cellulose acetate and linen, tube 2

Cellulose acetate and woven cotton, tube 1

Combined material depth capsule filters – bubbling through liquid LB, heat shocked

Raw cotton and linen, tube 2
Appendix H: Preliminary Sketches

PVC stand prototype

H 24.5"
W 13.5"
D 12"

1 foot of lift

1/30/2017
Single layer

- Single "layer" of each medium
- For CA + cotton, use wide mesh to sandwich "1 layer"
- SA is area inside tube: \( \pi \)

Volume capsule

- 2" PVC, 3.5" long
- Held by wide mesh on either side
- Placed in petri-tube with coupling

5 media
1. Linen
2. Woven cotton
3. Raw cotton
4. Microfiber borosilicate
5. Cellulose acetate
6. Control - blank

6 media, 3 trials each
- \( \times 2 \) (layer, volume)
- = 36 plates
6/16/2017

Diagrams:
- Top view of an object labeled with dimensions: 3.5 inches.
- Side view of an object labeled with various components:
  - Hole
  - Inset cap w/ mosquito net
  - Cleaned cotton
  - Woven cotton
  - Mosquito net
  - Reducer

Details:
- 2" cap
- 2" capping
- 2'x1" bushing
- 1" x 1/2" bushing
- Tip of expansion repair thing 1/2"

- "Random" arrangement layer
- "Woven" layer
- Linen or WC

Legend:
- CA
- LC
- WC
- BC
- BC
machine-fit prototype

inside

mosquito netting x2
random 1.75"
cellulose acetate
or raw cotton

linen or woven cotton

mosquito netting x2