Summer Research Training Program
2019 Project Description - Hemodialysis

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Project Title: Development of a high-quality, low-cost, open-source hemodialysis machine. Phase I: Device design & prototype development

Project Description – include background, hypothesis, proposed methodology, and expected outcomes (one page maximum; you may attach a page to this form):

Background

Hemodialysis uses an artificial kidney machine that receives waste-filled blood from a patient's bloodstream, filters it, and returns the filtered blood back to the patient's body. Hemodialysis is essential for ensuring that patients with end-stage kidney disease can survive. Low-resource settings such as rural parts of Ontario & other parts of Canada, developing countries and conflict zones are characterized by limited access to medication, equipment, supplies and devices, and in these environments hemodialysis machines are used far beyond their usable life, providing lower-quality dialysis for patients who suffer severe health consequences over time.

In addition to being very inexpensive (target price $500 USD as compared to $15,000 USD for premium brands), this device will have another very important feature: The ability to accept disposable circuits from any manufacturer. By being compatible with multiple brands of disposables, the device will be more affordable and accessible in low-resource settings. In low-resource locations where the supply of disposable circuits is unreliable, it will allow for a single machine to substitute for several.

We will collaborate with engineers from the Department of Mechanical Engineering at the University of Sheffield (UK) and IRNAS (Slovenia) to create this high quality, professional-grade hemodialysis device ready for testing. All design documents and source code will be accessible in an open-access repository. Using current rapid prototyping technologies such as 3D printing, we believe it is possible to create an inexpensive dialysis device that meets or exceeds the gold standard.

The goal of this project is to design a dialysis device that costs less than USD$500 to build and is approved by Health Canada. The completed device will be released under Open Hardware License (OHL), such that hospitals and ministries of health in rural and impoverished communities in Canada and internationally would have easy access to these devices.

Hypothesis

This project relies on two pillars: the use of 3D printers and other rapid prototyping technology; and leveraging Open Access and Open Source principles and devices to decrease development costs and disseminate results to stakeholders.

This model has been proved with a simple medical devices (stethoscope & tourniquet) and a more complex device (pulse oximeter). The main question of our research is: Can the successful model that developed, validated and deployed a low-cost stethoscope also be used to develop more complex devices such as a dialysis device?

Methodology

Background literature review. A background literature review will be conducted to ascertain the current status of dialysis devices and gather all available engineering designs that are openly available or usable. This review will involve:

- Literature review
- Patent search
- Grey literature review
- Interviewing industry engineers involved in creating, repairing and maintaining hemodialysis devices.

Needs assessment. A needs assessment will be conducted based on the background literature and surveys to ministries of health in low-resource settings to prioritize the development goals for the device. This will help ascertain the minimum viable product for the project. Design considerations include: cost, availability of parts, ease of construction, quality, ease of maintenance, and ease of use.

User-centric design. Using a methodology called *Agile development*, we will co-develop a prototype with end-users. This prototype can then be entered into a validation trial to ensure that it is non-inferior to current premium brand devices.

Preliminary engineering work is being carried out for the dialysis device by engineering students at Sheffield University, under careful guidance of Dr. Beverley Gibbs, Director of Mechanical Engineering. The team at Sheffield is currently taking on four different perspectives of this project: technology review from the perspective of low-resource settings, design specification for low-resource settings, design maintainability in low-resource environments, redesign options for consumable system elements. The work by the team at Sheffield will be done over the 2018-19 school year.

Timeline

Literature review: June – September 2019
Needs assessment: June – September 2019
Device design: August – December 2019
Device 1st prototype constructed: January – August 2020
Plan for validation & calibration study: June – December 2020
Ethics submission: June – December 2020

Expected Outcomes

Glia's stethoscope and tourniquet have already made a significant impact. Replicating this success with a low-cost hemodialysis machine will provide kidney patients around the world with access to one of the most essential medical devices. The availability of specifications for generic manufacturers to manufacture devices and the subsequent downward price pressure on premium brand manufacturers will increase the standard of care even in areas where our device is not directly available. It will also allow low-income communities to save costs while maintaining equivalent quality of care.

In the developing world, availability of a low-cost hemodialysis machine will allow ministries of health and hospitals to forgo rationing of devices and provide them to hospitals and clinics, multiplying the availability dramatically. In addition, a hemodialysis machine that is universally compatible with branded disposables means that low-resource communities can use available consumable materials, essentially commodifying the otherwise costly disposable circuits.

In broader terms, providing communities with open-access, low-cost medical device designs fosters a culture of self-reliance and sustainability. If low-resource communities can access the equipment they need via an open-access model, they feel more encouraged to troubleshoot problems, customize designs to meet their needs and share their findings with others. The ability to share successes in an open-access market allows medical and technical communities to work together, avoiding duplication of work and long feedback cycles.

Research Environment - Description of the number of research personnel, size of lab, etc.:

Tarek Loubani, Associate Professor in the Division of Emergency Medicine, Department of Medicine.
Carrie Wakem, Project Manager
Melanie Columbus, Research Coordinator
Alex Pavlosky, Research Assistant
Emily Stephenson, Research Assistant
Luka Mustafa, Engineer, Inštitut za razvoj naprednih aplikativnih sistemov Rače (IRNAS)
Dr. Beverley Gibbs, Director of Mechanical Engineering, Sheffield University

This research will be based in the Emergency department at LHSC, primarily at the Victoria campus. Research in the emergency department is conducted via the Western University Emergency Medicine Research Centre, which is coordinated by Dr. Melanie Columbus and directed by Dr. Jon Dreyer.

Expected Objectives/Accomplishments for Student for Year 1:

- Understand and familiarize with the philosophy of Free/Open hardware as a model of improving access to health
- Investigate what work has already been done that can be built upon
- Acquire access to appropriate ISO documentation and resource the international standards
- Consider the different types of end-users for the device and make a plan for their needs, such as those in low-resource and low-income communities
- Consider end-user experience in design, such as; using materials and building equipment that are easy to source in low resource settings and creating a device that resembles and operates as existing devices do today
- Consider the most appropriate device design for communities that have low-access to device disposables

Expected Objectives/Accomplishments for Student for Year 2:

- Act as a liaison between Glia team and engineers in construction of device that functions mechanically and electronically
- Ensure this device is low-cost, easy to use, and widely-accessible
- Meet regulatory requirements for Health Canada
- Collaborate with engineers to produce a usable prototype ready for clinical trials
- Help to prepare plan for calibration and validation study
