Applications for the March 2017 intake will close on 1 November 2016

A full application comprises of

- this online application form
- your application video not longer than 5 minutes
- your resume
- Please use no more that 1500 characters per essay question
- 1) Tell us about the world as you see it.

(A description of the status quo and context in which you will be working)

I work in one of the richest hospitals in the world – an academic hospital in Canada – and one of the poorest – Al Shifa hospital in the Gaza strip. I worked during crises in both, and felt critical differences between the two worlds when it came to lifesaving medical devices. The high cost of modern diagnostic and therapeutic medical devices renders them inaccessible to many providers in the developed world, where there may be fewer devices than are needed. In low- and middle-income communities, however, devices are often completely unavailable. Put academically, this results in a lower standard of care for people served by these institutions compared to richer ones. Put emotionally, that's me and my colleagues unable to care for our patients like we know we should.

The senselessness of this disparity is obvious when examining one of the pillars of medical practice: the stethoscope. This simple instrument has undergone little innovation in design or fabrication in the past century – certainly since Dr. David Littmann patented his model in 1963. Despite this, the field's gold standard Littmann Cardiology III stethoscope still costs several hundred US dollars. This cost is a barrier even in the developed world. In Gaza, it meant that we had to put our ears to patients' chests to hear their breaths.

This state of affairs grows from a culture that stifles dissemination and innovation in favour of patents and profit, leading to unnecessary disenfranchisement and poor health.

2) What change do you want to make in the world?

(A description of what you want to change about the status quo, in the world, your personal vision for this area)

I want to end the asymmetry of care by giving health care providers access to high quality medical equipment at low cost using an open access model.

I want to create the medical devices to make that possible, and get them certified by regulatory authorities in developed countries so that people everywhere can feel confident in them.

I want doctors, nurses, students and others to help by changing their relationships from consumers of medical devices to participants and creators.

I want to prove that open medical hardware is not only viable, but the best approach to creating and disseminating off-patent devices.

3) What do you believe has prevented this change to date?

(Describe the innovations or questions you would like to explore during the fellowship year)

I see three historical barriers to this change. The largest was the lack of affordable and accessible prototyping and production equipment. Even a decade ago, it would have been impossible for a small-scale researcher or clinician like me to prototype and test a piece of medical equipment. Production therefore required complex knowhow, institutional partnerships and funding. This requirement adds cost and complexity, reducing the incentives for cheap and low-margin devices. This barrier is currently melting away.

Another barrier is the expensive and time-consuming research and development required for medical devices. The use of medical devices to make lifesaving decisions means that they must be developed and tested to the highest clinical, technical and ethical standards. This generally relegates R&D to academics, who are disproportionately rewarded for novel research that generates high-impact publications rather than mundane infrastructural work. The pool of researchers able and willing to work on low-cost open-source medical devices is therefore small. This barrier is inherent to working on medical devices.

A final major barrier to the use of open hardware medical devices is negotiating the regulatory environment. Licensing devices is expensive and tedious, and negates the ability to self-produce devices by individuals and small groups. Several thoughtful approaches exist for negotiating these problems, but it is unclear how well they will survive over time.

4) What are you going to do to get there?

(A description of what you actually plan to do during the year)

Our team created an open access 3D-printed stethoscope as a mature proof-of-concept for the open source medical hardware model. This stethoscope is based on a design whose patent expired decades ago, and costs USD\$2.83, a small fraction of the USD\$250 gold standard.

During the year, I will oversee the creation and dissemination of open source stethoscopes in both Canada and the Gaza strip, distributing them to physicians and nurses as kits rather than assembled products. In Canada, my institution (London Health Sciences Centre) will pay for the material cost of production. In Gaza, the ten thousand stethoscopes required for the strip will take several years to produce using the limited 3D printers available and will need funding by donations and grants.

I intend to complete an open source pulse oximeter that costs USD \$25 to produce (the gold standard Nellcor costs ~USD\$1000). I collaborate with Dr. Hanan Anis, an engineering professor at University of Ottawa and founder of the uOttawa Makerspace. Through a makerspace competition, we have a preliminary arduino-based design that we are refining to be accurate, safe and reliable (see: https://github.com/GliaX/oximeter). Once the device is ready, we must validate it on human volunteers, an experiment for which we received ethics approval (https://clinicaltrials.gov/ct2/show/NCT02846974). Regulatory approval follows.

Other projects in various stages include an openly licensed lifelike hand prosthetic and an open ECG.

5) What challenges or uncertainties do you expect to face?

Three challenges might sink this project. The most important is whether openly created medical devices can maintain the expected high standards and reliability even when created by people in other parts of the world who might not be directly connected to the device's creators. If the answer is "no", this is a fundamental and ultimately fatal flaw in the project, as it would reduce the impact of the project to only a handful of places or people.

Practically, most knowledge on biomedical device creation, validation and regulation is locked up in the traditional medical device manufacturing industry. It has been a challenge to find and develop a cadre of engineers with both the practical and philosophical traits needed to work on a project such as this. This challenge will be solved over time as the feasibility of the idea is proved. However, it means uncertain timelines in the meantime, as a large amount of time and energy is spent seeking suitable engineers. One solution has been to turn to academic engineers such as Dr. Hanan Anis, but this solution has obvious problems.

Regulatory hurdles are another problem. I'm trying to deal with this by starting with simple (class I) devices and moving up until we reach the most difficult devices (class IV). However, regulation for

medical devices is notoriously arcane and might require significant and unexpected effort to satisfy.

6) What part does openness play in your idea?

Openness is the foundation of this idea, not an optional component.

In academic terms, our work depends on "green" open access - openly published patent information, previous research and collaboration from physicians and researchers. In technological terms, we chose a stack that is dogmatically Free/libre, not just open source. There are philosophical reasons for this,

but the practical advantages are real and drive the decision.

This means we can create devices by taking the hard work of others and building or innovating, rather than starting from scratch. For the stethoscope, we benefit from over a hundred years of patents and research, but also from Josef Prusa openly distributing his 3D printer design that we can create in Canada or Gaza from easily available parts. For the pulse oximeter, we also benefit from the accumulated work

on Arduinos.

There is no way to tailor our devices to all use-cases. Releasing devices openly means that users in other parts of the world with sometimes radically different needs can modify the device as they see fit.

This idea is not only impractical, but impossible without being Free.

In terms of philosophy, releasing all devices as Open Hardware License / GPLv3 compliant means we are creating devices and a culture independent of our future selves and temptations. If I should sink into the sea or sell out, others can pick up relevant parts of the work and continue them. This is not an inno-

vation of my duties as an academic physician, but a realization of them.

7) Does your idea/project have a name?

Yes

Project/Idea Name: Glia: High-quality low-cost open-access medical hardware

8) Have you started implementation of the idea? Yes

9) How have you funded your initiative in the past? Self funded Other: I received two small grants from the University of Western Ontario's medical school for two student summer internships. These grants paid for small stipends for the students during the summer. 10) Who are your current or potential key partners? 11) Do you intend to implement the idea as a for profit or not for profit initiative? Not for profit 12) Where will you be based during the fellowship? Base Country: Canada (8 months) / Palestinian Territories (4 months) Base City: London (Canada) / Gaza City 13) Where will you implement your idea? Same as above 14) Do you have an online presence? Yes Please Provide Links to your Web Presence/s 15) Does the idea/project have an online presence? Yes Please Provide Links to your Project/Idea's Web Presence/s **Upload Resume** PDF file is preferable.

Link to your video

Vimeo or YouTube preferable. Facebook or Dropbox links not accepted

I acknowledge that:*

This video is purpose made for this application.

This video link points to a video available on a video hosting service like Vimeo or YouTube.

16. Have you applied for a Shuttleworth Foundation Fellowship in a previous round?

No

15. How did you hear about the Shuttleworth Foundation Fellowship Program?

Current/Past Fellow

On the web

I acknowledge that:*

I have read and understood the Foundation Privacy Policy: https://shuttleworthfoundation.org/privacy/ I have read and understood the Terms and Conditions of the website: https://shuttleworthfoundation.org/terms/ I am above the age of majority in my country of residence and can legally enter into contracts. I understand that the Foundation will require all intellectual property created as part of the Fellowship to be openly licensed. I understand that if my project has a for-profit element, the Foundation will ask for an equity stake based on the investment made. I understand that if my application is incomplete in any way, it will not be reviewed. It will be excluded for this round.

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