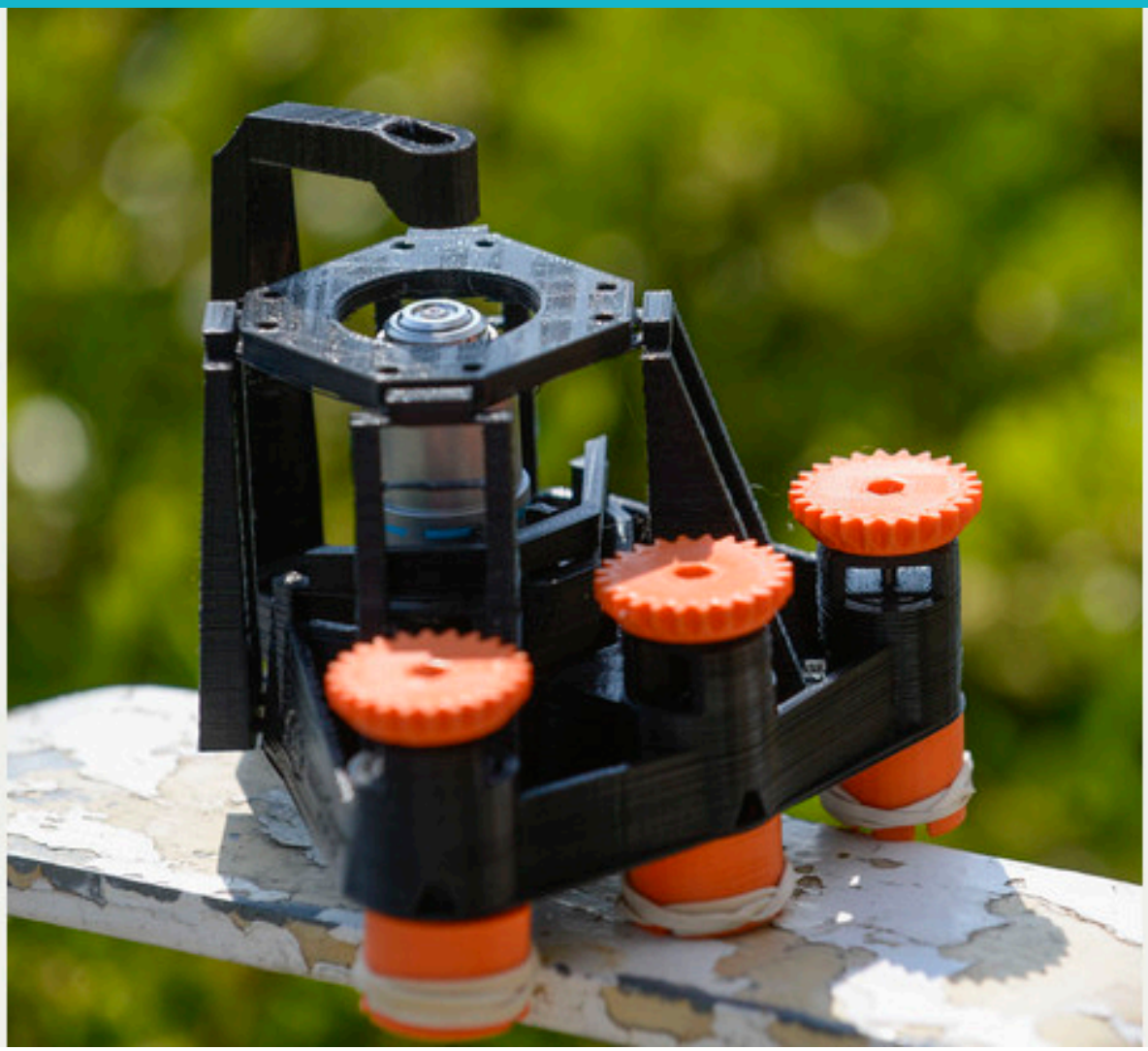
Medical Tools

3D Printing - Product Feasibility Report



envin we start world changing companies

REFAB Dar

Summary

3D printing in the medical space in Tanzania seems to be very feasible. High import prices, unstable supply chains and long lead times are problems health care providers in Tanzania encounter on a daily basis. 3D printing holds the potential to solve or significantly diminish these problems. There are however some specific challenges that have to be dealt with; the lack of approved and high quality designs, insecure regulatory framework and significant material development being the most prominent. This means lengthy clinical trials, field experiments and technological development are needed to take any business to the next step. ReFab Dar is partnering with JHPIEGO, Reflow, Cambridge University and 3D4MD to take those next steps and get a step closer to realizing the potential of this technology for improving the health ecosystem in Tanzania.

Introduction

The health supply chain in many developing countries is a critical barrier to receiving timely, quality health services. 3D printing holds the potential of distributed manufacturing, circumventing traditional supply chains. It has the potential to significantly lower distribution and storage costs, solve lead time issues and, if done right, can significantly lower the costs of medical equipment as well.

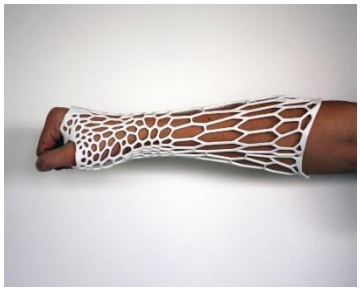
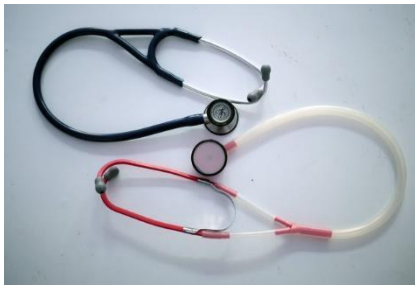




Image sources[1]

In the feasibility study the supply chain problems were investigated and stakeholders were interviewed, with the primary source of information JHPIEGO. A short summary of the problems that were identified in the health supply chain:

- A lack of essential equipment and supplies;
- Complex and costly distribution of equipment prevents clinics close to rural population;
- Lack of diagnostic facilities means a long response time on any diagnostics;
- Long processing time limits the local capability of identifying epidemics at an early stage;
- High distribution and import (tax) costs for almost all equipment;
- High processing cost for medical waste, even for simple clamps as they cannot be processed in-country.

1 http://www.stratasys.com/resources/case-studies/medical/medtronic
http://www.pro3drp.com/?p=955
http://www.huffingtonpost.com/entry/tarek-loubani-3d-printing-stethoscope-gaza_us_55f2f570e4b077ca094ec2f5

Through 3D printing we can circumvent most of these problems by: (1) significantly lowering the cost of equipment, (2) by bringing the product closer to the end user through local manufacturing.

SWOT Analysis Medical Tools

Strengths

- Expensive and inefficient supply chain in the health sector in Tanzania;
- Established and interested partners, low barrier for market testing;
- Local manufacturing circumvents expensive import;
- The use of plastic eases disposal of waste products compared to current expensive medical disposal process;
- Low lead time for production;
- Easily able to upgrade. Design changes can be made anywhere and updated within a day;
- Can be tailored to the context of the environment.

Weaknesses

- Uncertainty around medical approval process;
- Some products need specialized, possibly more expensive, materials. For instance, anti-bacterial or with certain strength properties;
- For some products additional design work needs to be done for it to be suitable for testing;
- Lack of medical framework for locally produced medical equipment might limit adoption rate;
- Problems may arise related to trademark infringement.

Opportunities

- Lack of current regulations and government interference in locally produced medical supplies;
- Increasing investments in the health sector in Tanzania;
- Creating local employment and supply chains.

Threats

- Changing regulations around medical equipment in Tanzania;
- Material development not sufficient to create quality needed;
- Materials testing needs to be done to determine the safety of using the plastic products in reference to leaching of chemicals[2].

2 https://www.choice.com.au/food-and-drink/food-warnings-and-safety/plastic/articles/plastics-and-food, http://www.npr.org/2011/03/02/134196209/study-most-plastics-leach-hormone-like-chemicals

Problem Definition

Neonatal mortality, HIV, malaria and tuberculosis are four of the top 5[3] worrisome health problems in Tanzania. The medical tools presented in this feasibility report are aimed at tackling each of these problems.

In Tanzania, neonatal mortality rate is 26 out of every 1,000 live births. The leading causes of infant mortality are infection, asphyxia, and low birth weight/preterm births. Infections are commonly due to a lack of clean, sanitary medical tools and equipment required for delivery and during the first "golden minute" of life. In this first minute of life, the newborn must be brought in the world in a clean environment and be able to quickly begin to breathe outside the womb if it is to survive. A critical issue is the lack of medical supplies and the understanding of how to use them. Currently medical supplies and tools are often not available to health workers and lay midwives (for the 50+% of women in Tanzania who deliver at home[4]).

Asphyxia, one of the leading causes of newborn death, can often be prevented if a skilled health worker provides timely resuscitation during "the golden minute" after birth. While national and regional governments, foundations and other actors in the field are working hard to limit the number of premature deaths, all seem to agree that that a major barrier to sustainability and further scale up of projects is timely procurement of the penguin-shaped nasal aspirators. One of the products which can be 3D printed in the of category medical tools is an infant nasal aspirator (see figure left).

A second important health issue is HIV. In Tanzania, adult HIV prevalence is 5.1% while male circumcision stands at 72%. According to the WHO, there is a growing base of evidence that male circumcision reduces the risk of heterosexually acquired HIV infection in men by approximately 60%.[5] Voluntary medical male circumcision (VMMC) has been identified as an effective measure for HIV prevention (WHO; PEPFAR). Similarly, early infant male circumcision (EIMC) is also recommended to improve hygiene and health from childhood through adulthood. A VMMC programme has been running in Tanzania since 2009, however more than 1m VMMCs are needed to reach the national goal by 2017. The second 3D printed medical tool discussed in this report is a VMMC Prepex[6] device removal circumcision kit, spatula, scissors and forceps. The Prepex device removal kit is currently cost prohibitive. For EIMC, a low cost alternative to the expensive Mogen clamp will be designed and prototyped.

A last area where 3D printing can help to improve health issues is in laboratory diagnosis. In Tanzania, malaria and tuberculosis are still widespread but often the equipment and capacity to

3 https://www.cdc.gov/globalhealth/countries/tanzania/

4 http://www.who.int/pmnch/activities/countries/tanzania/en/index1.html

5 http://www.who.int/hiv/topics/malecircumcision/en/

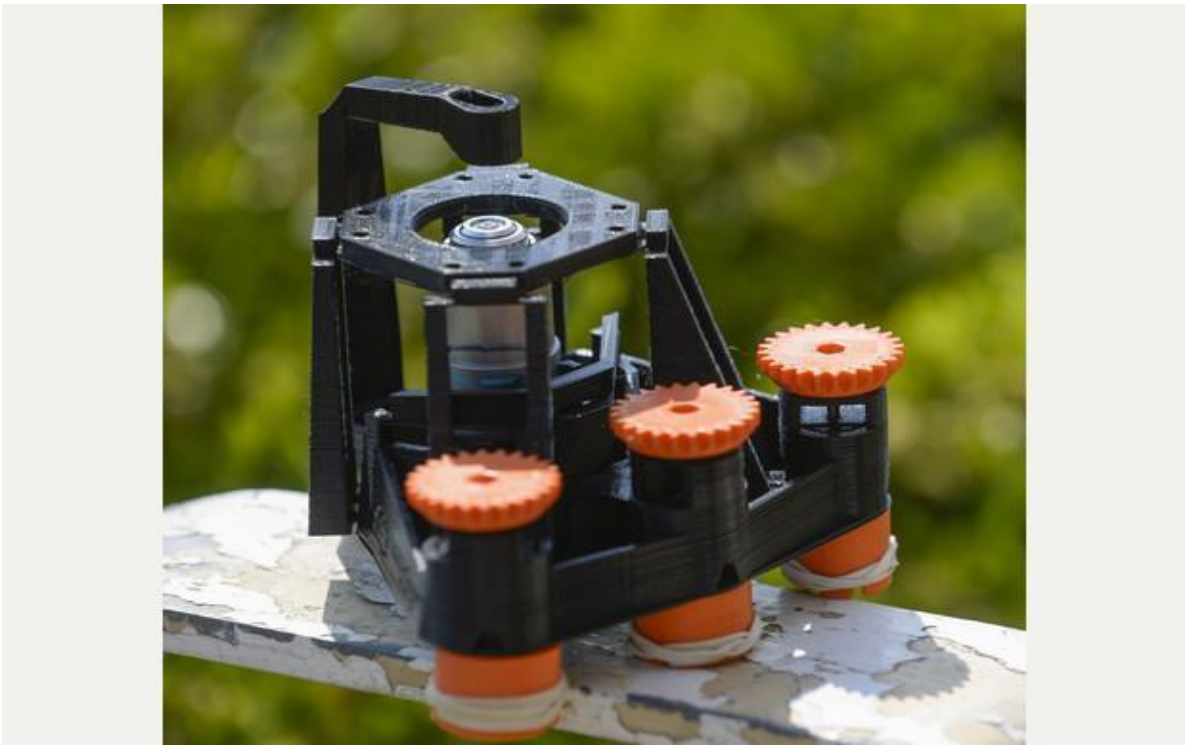
6 http://prepex.com/

conduct confirmatory diagnosis for these diseases, among others, is not adequate. In fact, the current diagnose procedures are extremely inefficient and often rely on government fuel budgets to transport sample slides. This results in significant delays which impact the health of those affected. ReFab dar will test the efficiency and efficacy of the WaterScope microscope to reduce the cost and time involved in disease diagnosis.

Products

3D printing holds the promise of changing various supply chains around products. Together with partners we've focused in on three of them which are aimed at solving the problems outlined above.

1. 3D Printed Microscope - Diagnosis of Malaria and TB



The WaterScope microscope was developed by Cambridge University as part of their I-team project in developing water testing methods. The WaterScope is largely 3D printed. As part of the ReFab Dar project the microscope will be tested for finding bacteria in water supplies, Tuberculosis and Malaria diagnosis. The Waterscope microscopes incorporates a Raspberry Pi, camera and internet connectivity so samples can be send to remote diagnostic centers digitally. This would solve the logistic and time issues of sending physical samples to a central location and could potentially offer diagnostic centers closer to clients.

The cost calculations of the microscope are summarized in the table below. Diagnostic Microscopes, if purchased from abroad, currently cost around $1500-2000 excluding shipping costs according to JHPIEGO procurement. Estimates show that the model proposed in this section has the potential to

produce it for $250-300 including hardware, software and printing. There is a clear price advantage in using 3D technology to print parts of the microscope.

Hardware	**Quantity**	**Price ($)**
M3 nuts (Brass)	3	0,9
25mm M3 Hexagon-head screw	3	0,9
M3 Washer	3	0,9
8mm M3 screws	2	0,6
Elastic bands, No. 32	6	0,6
Total		**3,9**
Electronics		**Price ($)**
White LED, 3mm diameter, 15 degree beam angle	1	2
60 Ohm resistor	1	0,3
Jumper wires with female header pin connectors	1	1
Raspberry Pi	1	50
Raspberry Pi Camera Module	1	30
Wireless module	1	10
Total		**93,3**
3D printed Production		**Total Cost**
Microscope Body	1	$18,43
Tilted Feet	2	$1,11
Untilted Feet	1	$0,55
Optic module - pilens	1	$1,11
Optic module - picam cover	1	$0,37
Camera Lens remover - lens remover	1	$0,37
Camera Lens remover - board gripper	1	$0,18
Large gear	3	$3,32
Illumination arm and rear foot	1	$0,92
Sample clip	2	$0,37
Spacer for actuating gear	1	$0,18
Total	15,00	$26,91
Total hardware	$3,90	
Total Electronics	$93,30	
Total 3D printed parts	$26,91	
Assembly labor	$7,50	
Total Production Cost	**$131,61**	

SWOT analysis Microscope

Strengths

- Digital transfer of images allows for centralized disease identification. Additionally, this would ease the early identification of an epidemic;
- Significantly lower production cost;
- Low lead times compared to import;
- Specialized updates and adaptable designs;
- Easy access to spare parts and local production means local knowledge for repairs;
- Significantly reduce storage costs;
- Limiting distance and simplifying distribution prevents loss and theft of products.

Weaknesses

- Untested in the field;
- Unfamiliarity with digital technology by lab users;
- Needs external device to read data;
- Needs locally trained technicians to produce.

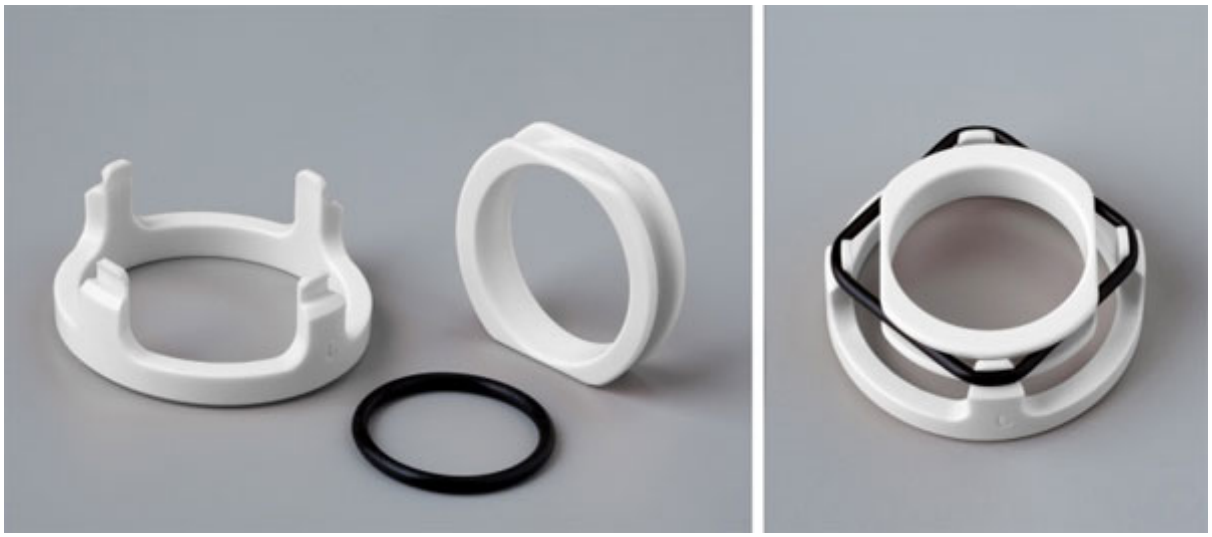
Opportunities

- Growing need for early epidemic diagnosis;
- Field testing for the microscope for utilization in finding bacteria in water and for diagnosis of malaria and TB;
- Assisting government to explore relevant regulation pertaining to 3D printed medical devices and paving a way for future entrepreneurs to follow when entering the market

Threats

- There are no regulations that detail how medical supplies created in Tanzania are to be tested. There are regulations for the importation and approval of imported medical supplies which are then processed by the Tanzania Food and Drug Administration (TFDA)

2. Circumcision Kit- Medical Toolkit



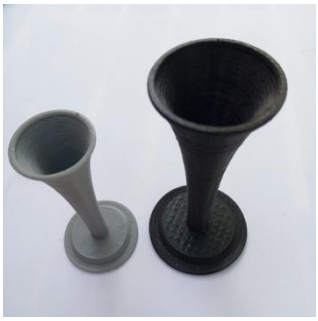
In Tanzania, circumcision is a right of passage for some tribes and in others is not culturally practiced. Circumcision is done traditionally in a village environment, although in recent years public health campaigns have made great strides in improving the safety of the procedure. The Prepex device is an innovation which allows a man to be circumcised without an operation nearly pain free. The device cuts off the blood flow to the foreskin, so it becomes necrotic and is easily removed. The entire process takes one week. The Prepex device is low cost, but the tools required for the application and removal of the device are not. The circumcision kit as a whole is aimed at preventing the spread of HIV among adults and reduces infection due to unsterilized tools being used for circumcision in rural areas. The kit comprises of a Prepex device, spatula, sponge stick, scissors and forceps. A PrePex Removal kit currently would cost $30, excluding shipping costs. While precise estimates of the costs are not clear yet, it is expected to be more cost-effective than the current solution.

Products [7]	**Total cost**
Circumcision Kit - Spatula	$0,31
Circumcision Kit - Scissors	$3,24
Circumcision Kit- Sponge Stick	$3,24
Circumcision - Forceps	$0,40
Circumcision Kit- Mogen clamp device	$4,87
TOTAL COST	$12,06*

*No design files are available online, price calculations have been done through a estimate of weight. Might vary with redesign and development

7 Cost calculations based on plastic and time utilized to create other medical products during prototyping

3. Natal Health Kit- Medical Toolkit


The Natal Health kit is a distributed manufacturing product that eases access to natal health care product, especially in rural regions. ReFab Dar is currently testing the specific content of the kit, in the latest iteration it consists of:

- Pinard Horn
- Umbilical clamp
- Hemostat
- Forceps
- Needle Driver
- Newborn Nasal Aspirator

ReFab Dar has prototyped these products, and although some of them would be sufficient, the lack of medical knowledge behind designs commonly found on the internet and lack of clinical field testing limits product utilization. This is why for the next steps ReFab Dar is partnering with 3D4MD through their Medical Makers community. 3D4MD is a Canadian based organization with the mission to make 3D printable medical supplies to deliver healthcare in the most challenging places, to those who need it the most. They are specifically looking at taking the 3D printed process through FDA approval processes and creating high quality designs that are clinically tested.

One specific request from JHPIEGO is a newborn nasal aspirator. Currently there are no design files online for a 3D printed nasal aspirator. Clogged nasal passages can interfere with babies' ability to feed, and in very young newborns, their ability to breathe. According to World Health organization modeled estimates for Tanzania, 79% of newborn deaths are due to three main causes: infections including sepsis/pneumonia (29%), birth asphyxia (27%); and complications of preterm birth (23%)[8].

The current design used for Helping Babies Breathe campaign[9] with JHPIEGO is the Laerdal company's penguin. The device is designed to clear babies' airways and is made of one piece of silicone making it easy to clean and durable, able to withstand hundreds of uses. The difficulty with

8 http://www.who.int/pmnch/countries/tanzaniamapstrategic.pdf

9 http://www.helpingbabiesbreathe.org/docs/An%20intro%20to%20HBB.pdf

the Laerdal devices is not the quality, but the supply chain required for them to reach Tanzania and to be delivered to the medical centers in need. As ~~it is understood that~~ the first "golden minute" of life is critical, facilities waiting on these medical supplies are incurring unnecessary neonatal mortality.

An estimate of the costs of the natal health kit proposed are summarized in the table below.

Products	Total cost	Current Price*1
Natal Health Kit - Pinard Horn	$3,89	$5,50
Natal Health Kit - Umbilical Clamp	$1,99	$0,50
Natal Health Kit - Hemostat (2)	$6,64	$6
Natal Health Kit - Forceps (2)	$2,77	$2,90
Natal Health Kit - Needle Driver	$2,43	$6,75
Additional Items		
Alcohol swabs	$ 0,50	$ 0,50
Blood cloths	$ 0,25	$ 0,25
Gloves	$ 0,20	$ 0,20
Hand sanitisers	$ 0,25	$ 0,25
Soap	$ 0,25	$ 0,25
Carrying Case	$ 2,00	$ 2,00
Total	$ 3,45	
Total Cost	$ 21,17	$25,10
Nasal Aspirator Estimate*2	$5,90	$4,50
Total cost including aspirator	$27,07	$29,60

**1 Current prices were based on stainless steel comparison. Current plastic alternatives do not have sufficient quality for field use. Significant redesign and material needed to make plastic 3D printed parts competitive*

**2The nasal aspirator cost calculation is based on the weight of current aspirators, significant redesign needed to be cost-competitive and user friendly*

Cost analysis shows the natal health kit generally is not cost-competitive to the base price of a mass produced health kit. These prices exclude however the transport and shipping and the significant effort needed and cost involved to get it from HQ to remote rural areas. Nonetheless, price calculations do show that to create healthy business on health kit the advantages to supply chain and distribution should outweigh the likely higher cost of a 3D printed product. Redesigns to make the product more suitable for 3D printing could improve the functionality.

SWOT Analysis for Medical Toolkits

(Natal health kit with Nasal Aspirator and Circumcision kits)

Strengths

- Plastic recycling easier and more affordable that other medical waste;
- Low lead time due to the flexibility of the 3D printing process;
- Easy adaptability of products to local needs due to no cost in changing product setup;

- Simplified distribution and supply leading to low storage and distribution costs;
- 3D printing is a simplified process, compared to other production processes and relatively easy to teach.

Weaknesses

- Significant design work has to be done to create market ready products as current designs and plastic materials are not built to last;
- Very limited field test of current product;
- Limited regulation framework may cause delay in adaptation;
- Technical design and production skills limited to a few select people, additional education may be needed.

Opportunities

- Lack of regulation may provide a lower barrier to market entry;
- Helping to prevent unnecessarily morbidity and mortality in previously under served areas.

Threats

- Early regulation or policy preventing adoption, especially by state clinics;
- Insecurity of regulation could prevent future growth investments;
- Legal framework around patents and copyright in the 3D printing process unclear. This could possible lead to patent infringements.

Challenges & Next Steps

While 3D printing medical tools has high potential, some important challenges remain. First of all, the tools will have to undergo a medical approval process. There is currently no regulatory framework in Tanzania for medical supplies produced in-country. A second important challenge regards the materials used for the tools. Some products may need specialized and more expensive materials such as antibacterial. In addition, some products require a lot of additional design work in order for it to be suitable for testing. This means that the development of the tools (even just prototypes) will be lengthy. Lastly, the lack of a medical framework for locally produced medical equipment may limit the adoption rate of the tools, however useful.

To address these challenges, Refab Dar is partnering and collaborating with Voices of Africa Foundation, Reflow, JHPIEGO and 3D4MD. These will be important for the pilot programme where the products will be tested. The next major steps include testing the materials and finalizing the designs of the products in preparation for market experiments.


REFAB Dar
envi


STICLab
THE HOUSE OF INNOVATION


COSTECH


blogi