MakBME

Context Based Deign

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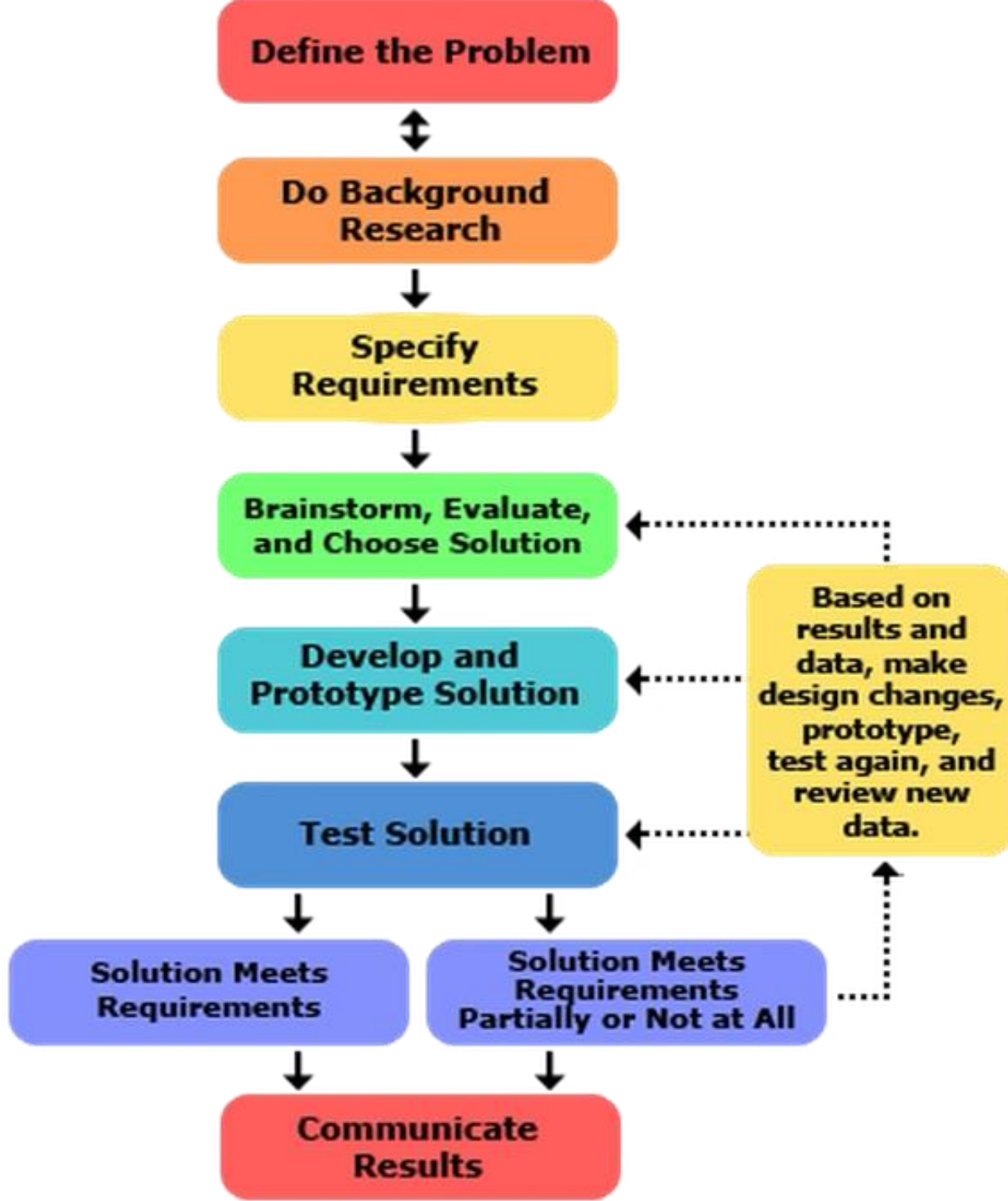
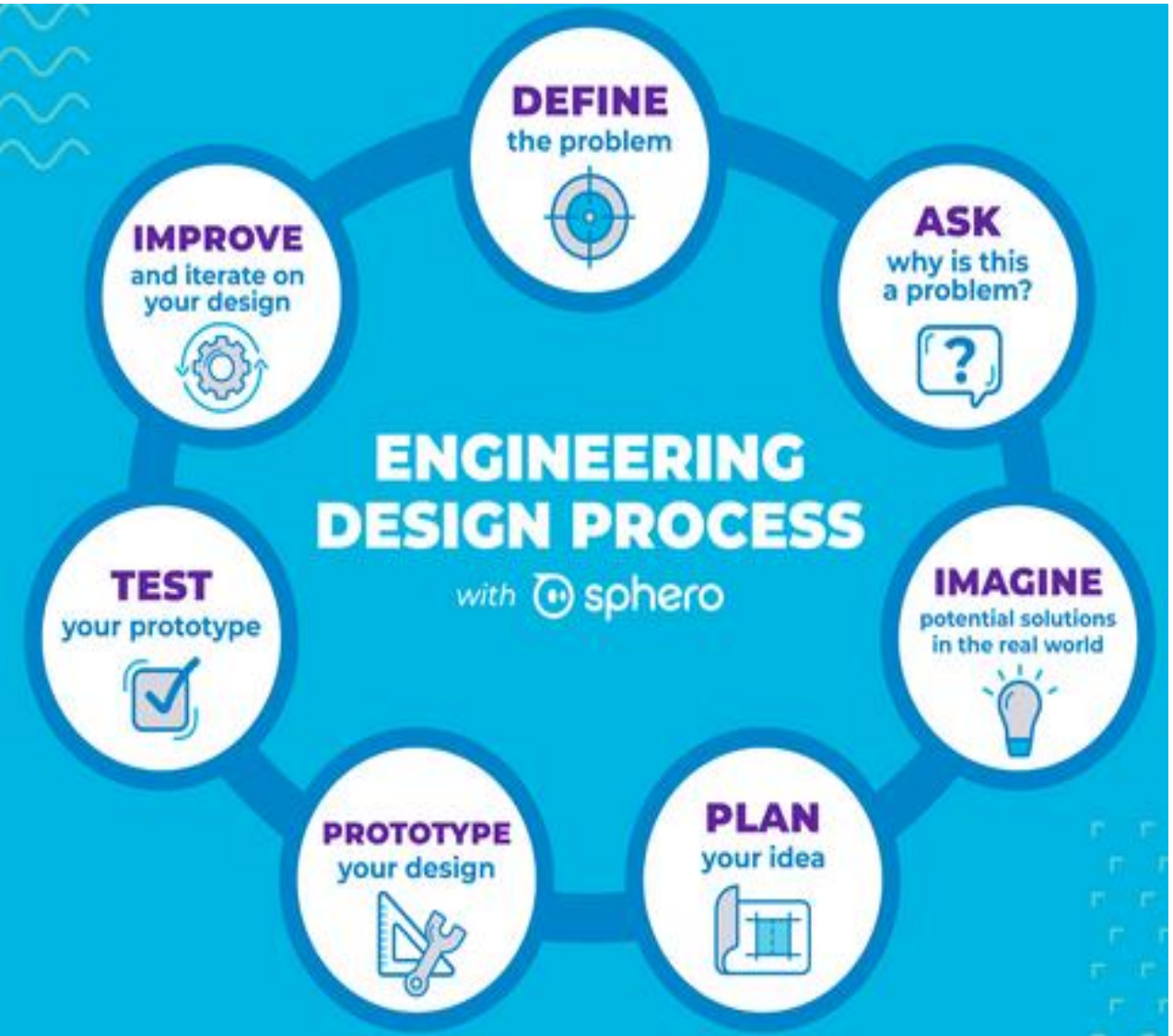
Context based Design

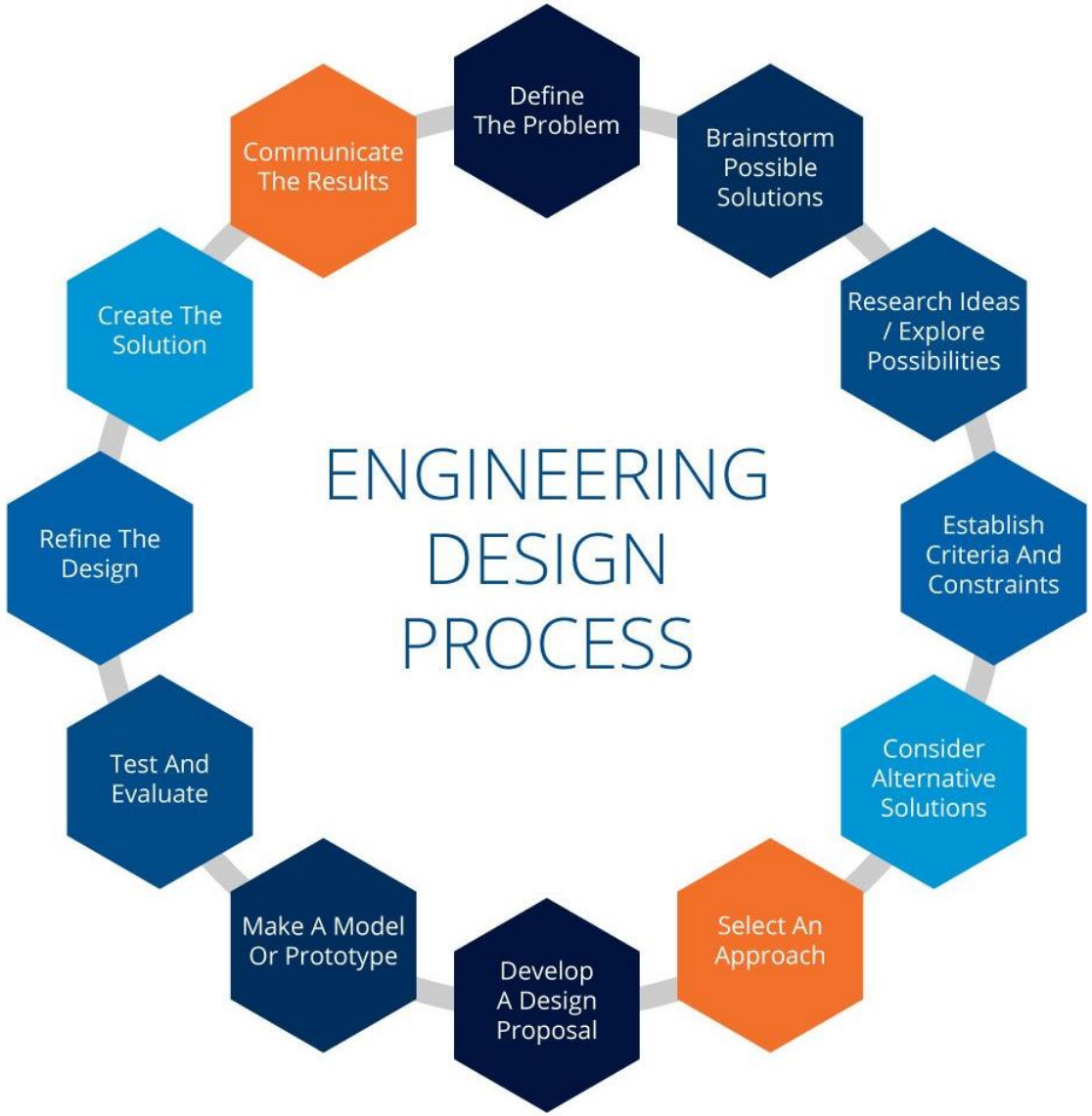
- Impact
- Human Centred Design
- User centred Design
- Systems thinking
- Context based Design is not necessarily equal to Design for LMICs

The Design Process

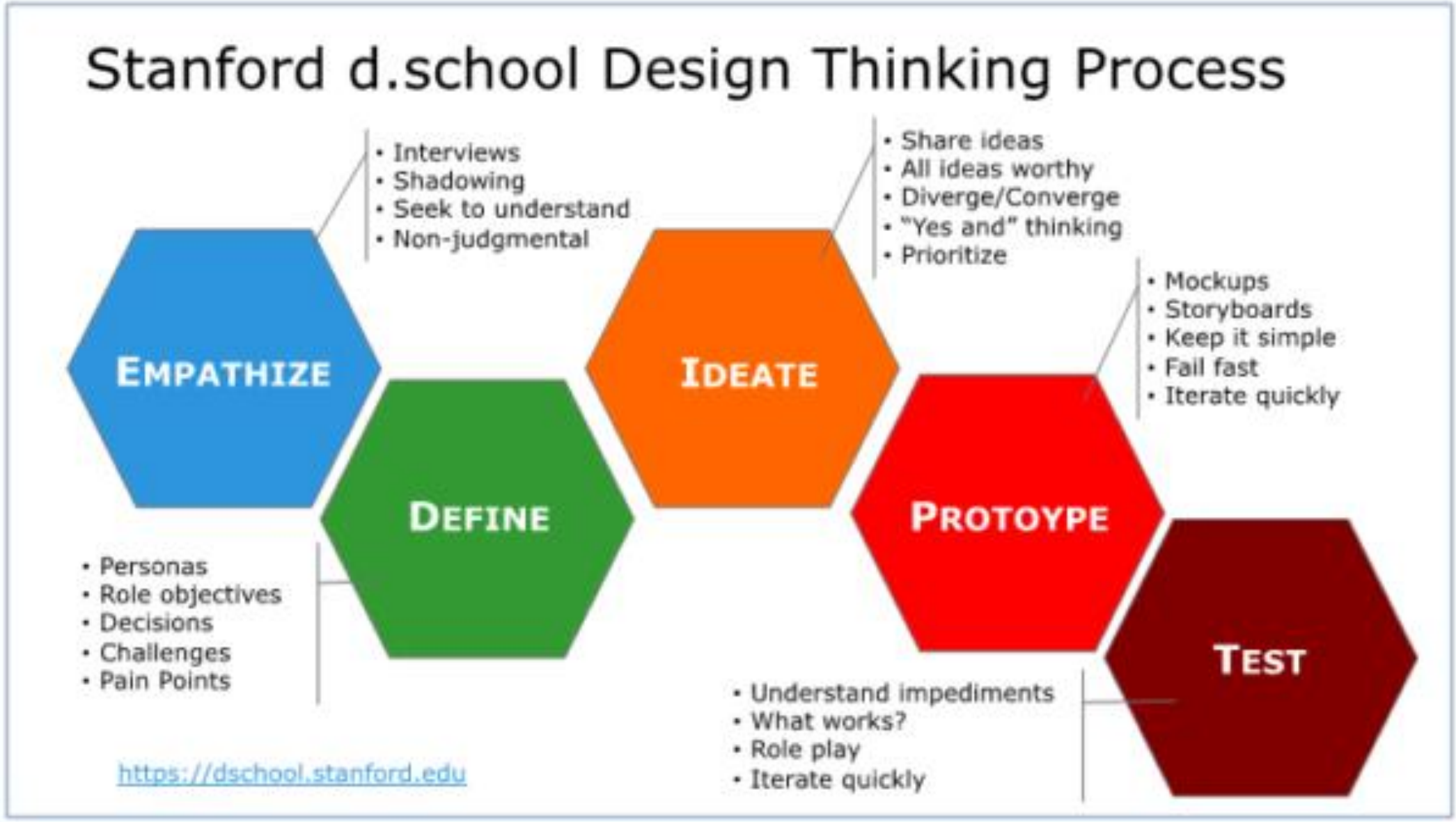

Define the Problem
Do Background Research
Specify Requirements
Brainstorm, Evaluate, and Choose Solution
Develop and Prototype Solution
Test Solution
Based on results and data, make design changes, prototype, test again, and review new data.
Solution Meets Requirements
Solution Meets Requirements Partially or Not at All
Communicate Results

Design Cycle

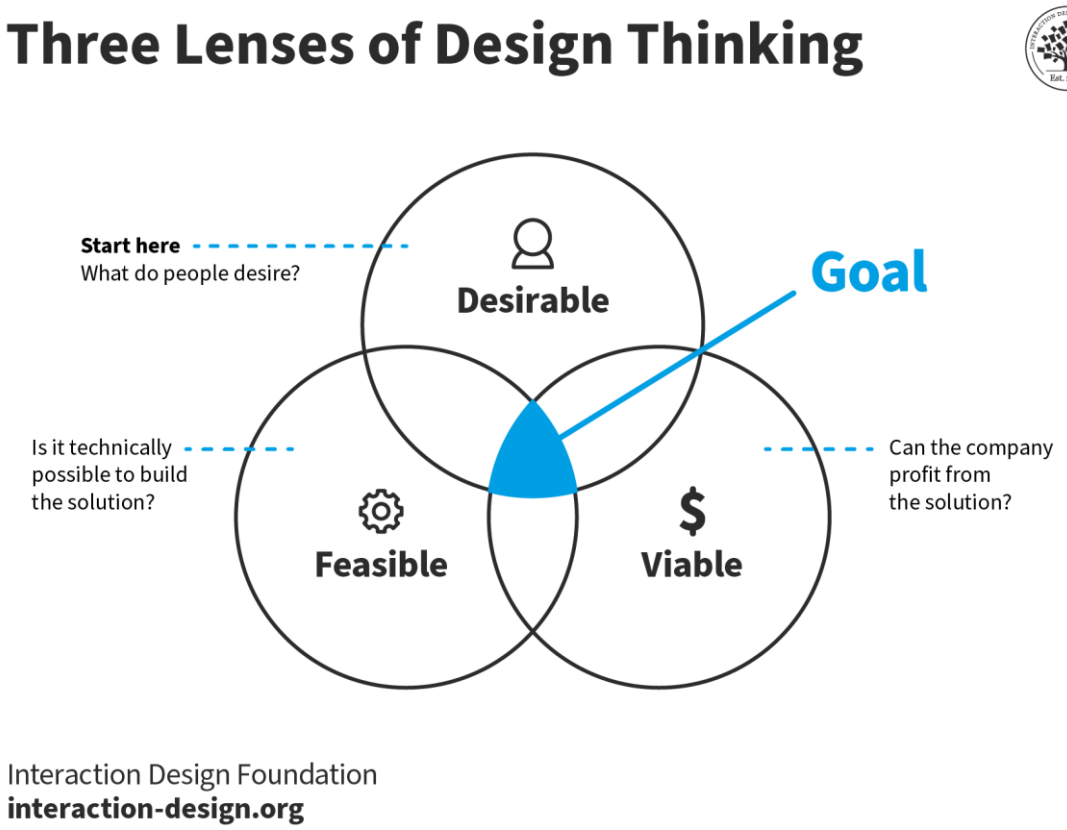




Design Thinking

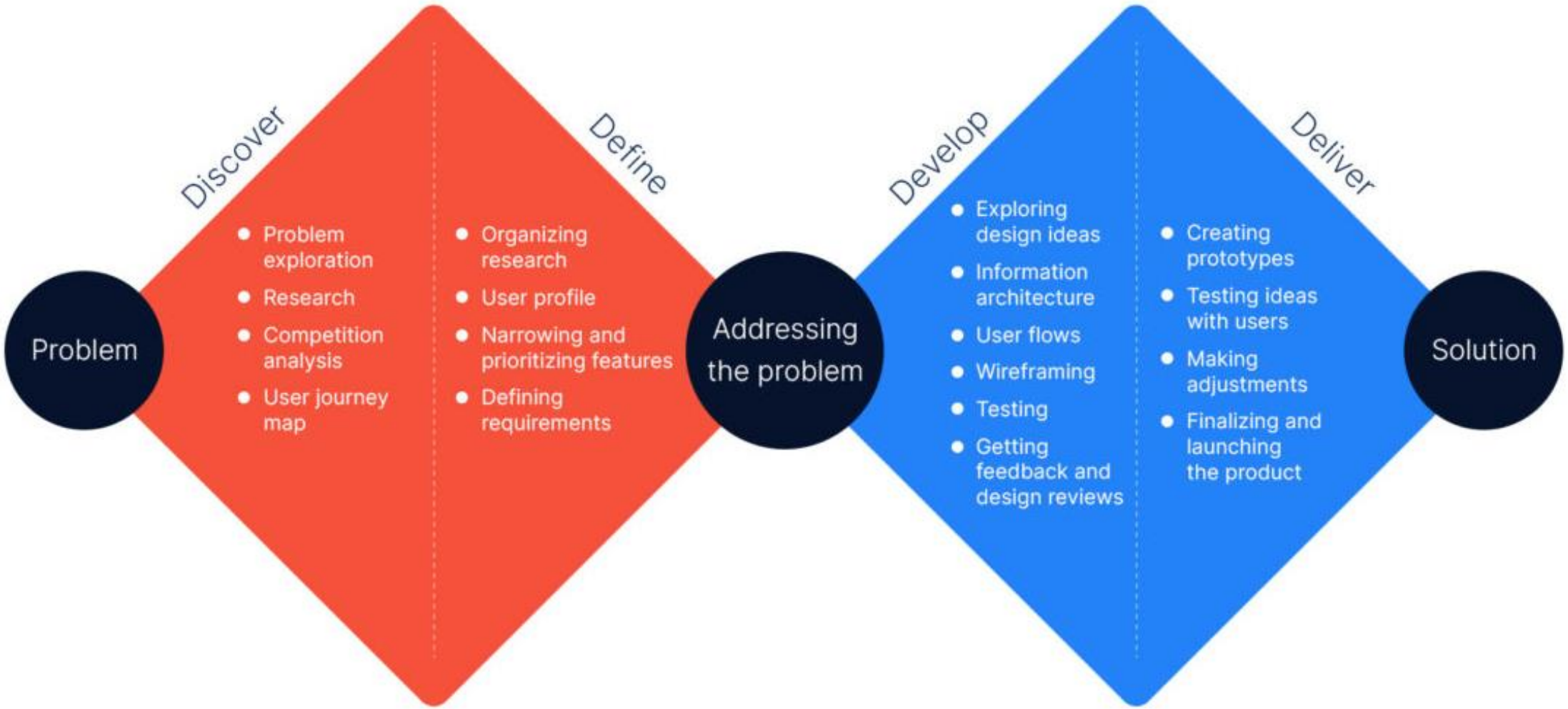


The End Goal of Design Thinking: Be Desirable, Feasible and Viable



The design thinking process aims to satisfy three criteria: desirability (what do people desire?), feasibility (is it technically possible to build the solution?) and viability (can the company profit from the solution?). Teams begin with desirability and then bring in the other two lenses.

4 Phases of Double Diamond Model

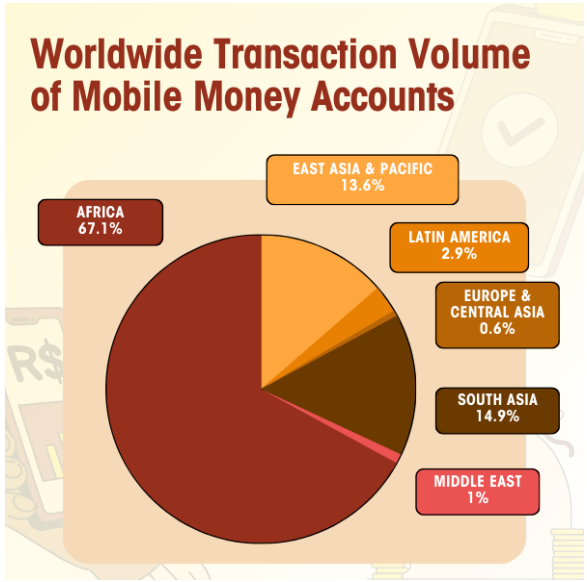


Strategic Phase

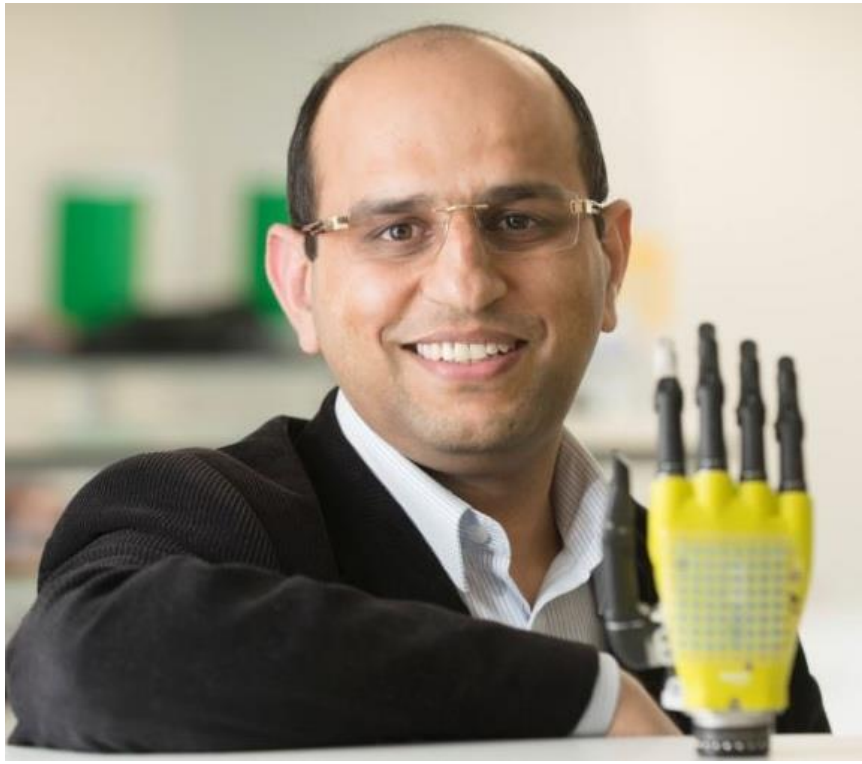
Creative Phase

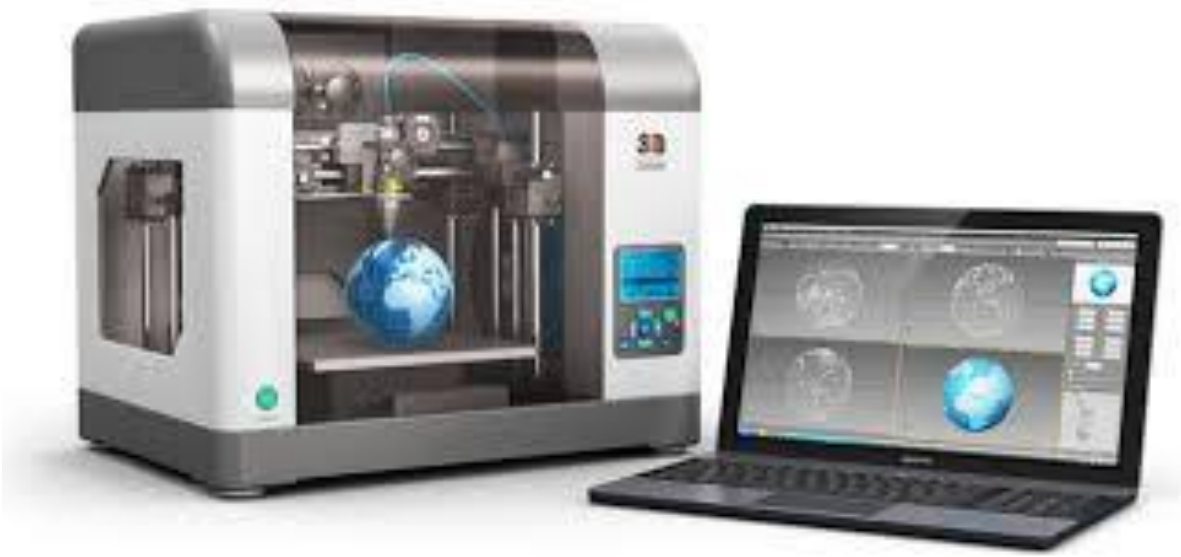
LMICs inspired technologies

- m-banking


Worldwide Transaction Volume of Mobile Money Accounts
EAST ASIA & PACIFIC 13.6%
AFRICA 67.1%
LATIN AMERICA 2.9%
EUROPE & CENTRAL ASIA 0.6%
SOUTH ASIA 14.9%
MIDDLE EAST 1%


diamedica
glostavent
Scavenger





Techno, Infinix, Itel

Solar Power

CARE Solar Suitcase

Key attributes for context based design

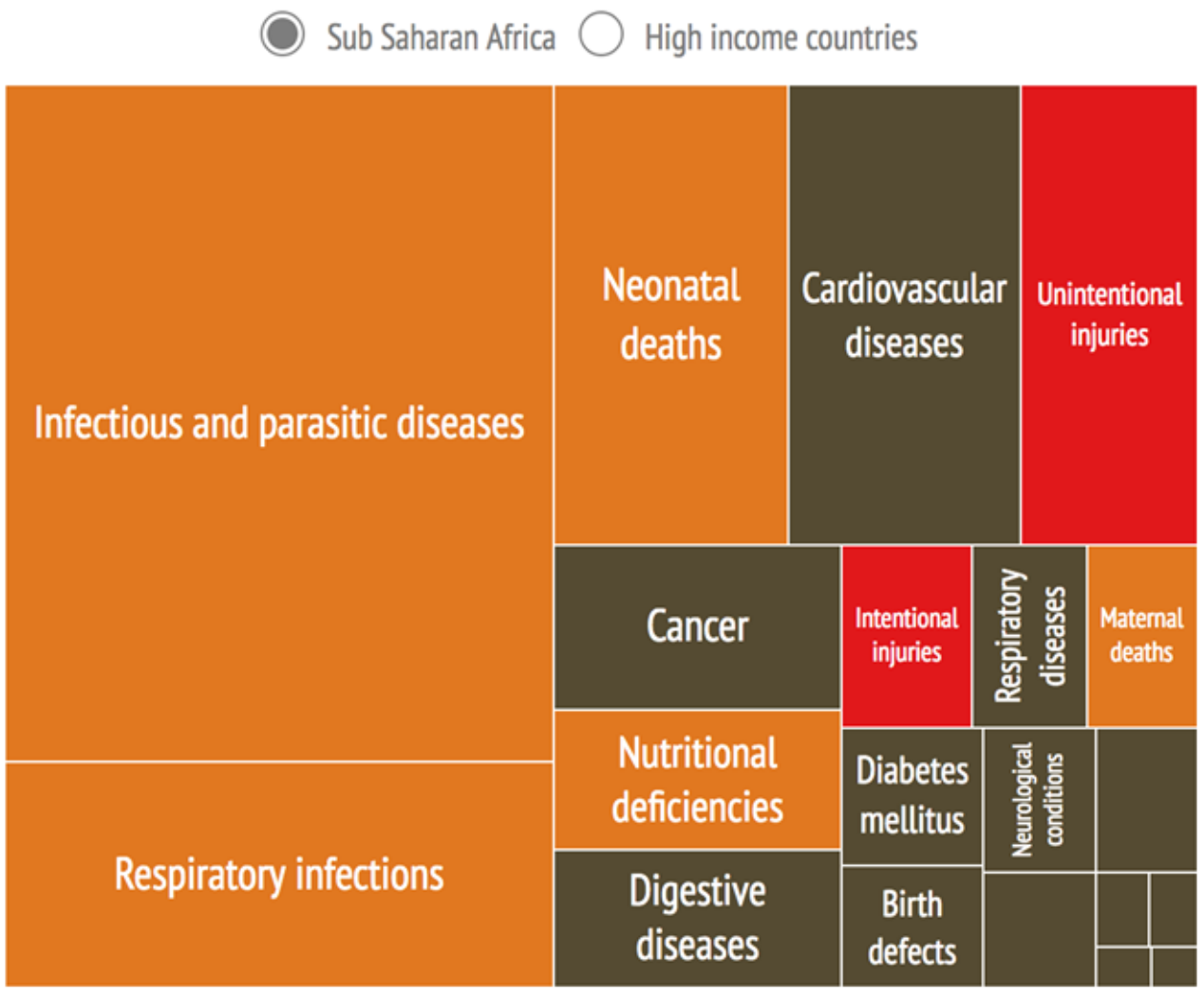
- Clearly defone the need – clearly define the context
- Enablers - identify ‘all’ stakeholders
- Support systems
  - Policy
  - Priority areas
    - SDG list, local Gov
- A lot on HFE
  - Human factors
  - Environmental context

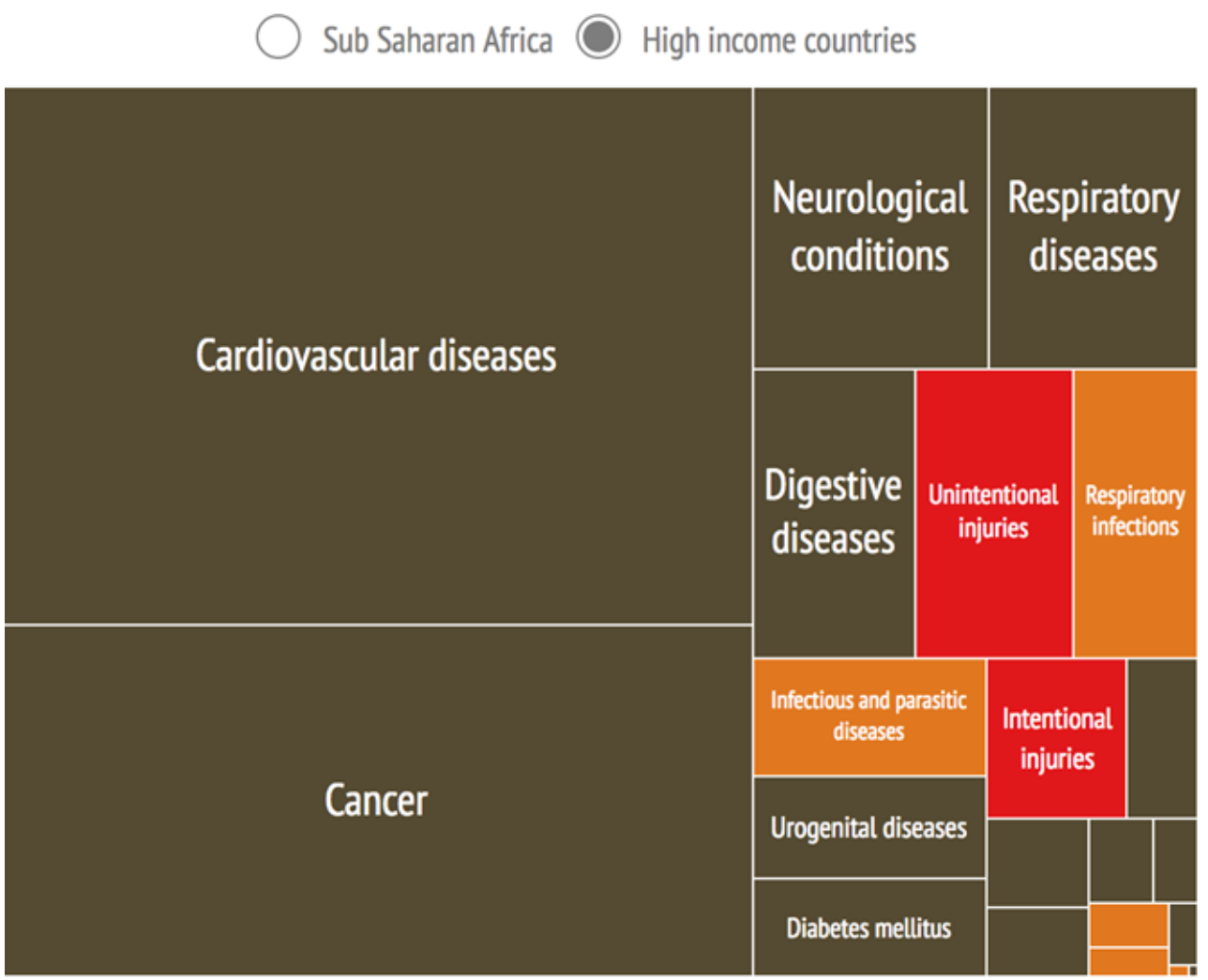
Understanding the Context

Introduction- Sub Saharan Africa (SSA): the context

- Bears 24% of the world's burden of disease
- Has less than 1% of the global financial resources
-
- Very limited human resources
- World's poorest region
- Fertility rates are among the highest in the world.
- Will more than double in population by 2050, fror 1.1 billion to 2.4 billion

Global Disease burden

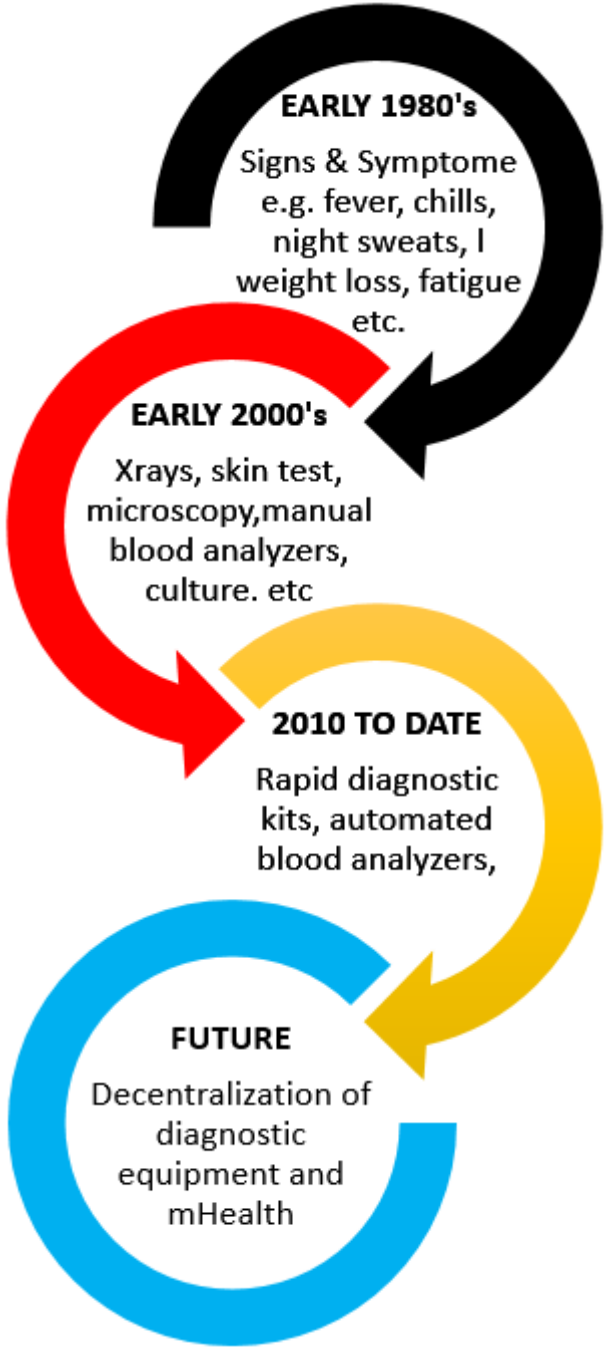




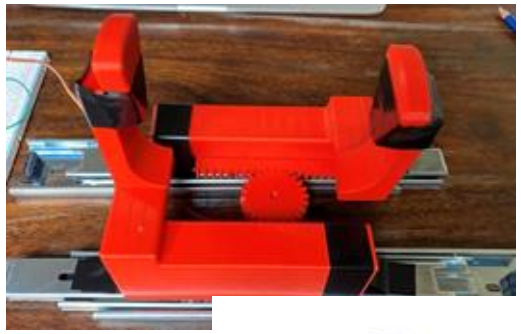
Design for context at Makerere

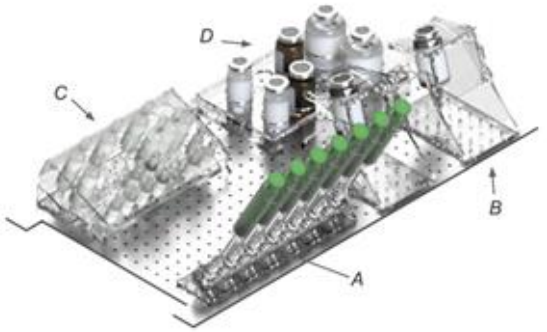
Global trend in Healthcare technology

- **Initially it was based on physician's experience**
  - In SSA it is still the case
  - The challenge is there isn't enough
- **The equipment became sophisticated**
  - Huge need of input by skilled technicians
  - Currents creates many challenges in LMICs
- **Decentralisation of healthcare**
  - Task shifting, lack of skilled personnel
  - Aging population in HICs
  - POC, RDTs, mHealth, telemedicine etc



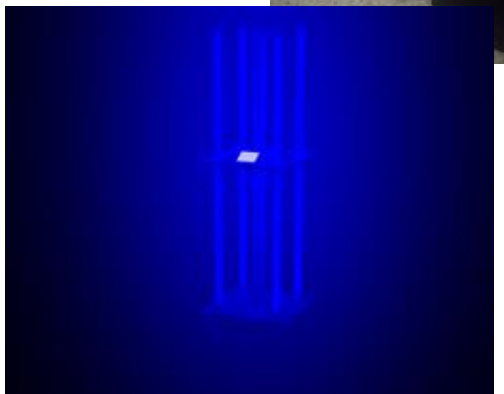
And even more Devices





Plus more

Lumenda



matica
play the math

Some of our Devices

PPH-Belt

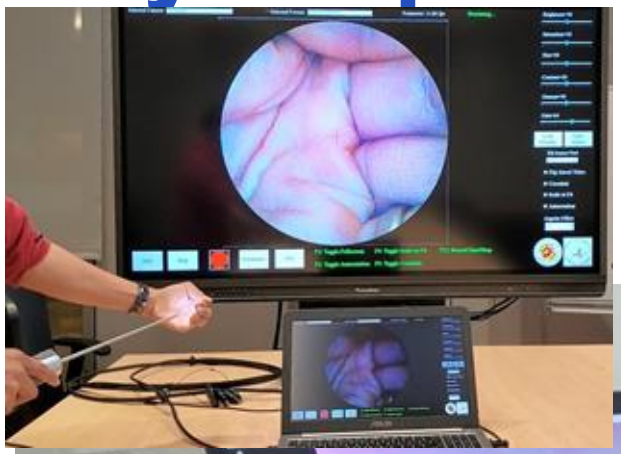
Fit-for-purpose hand

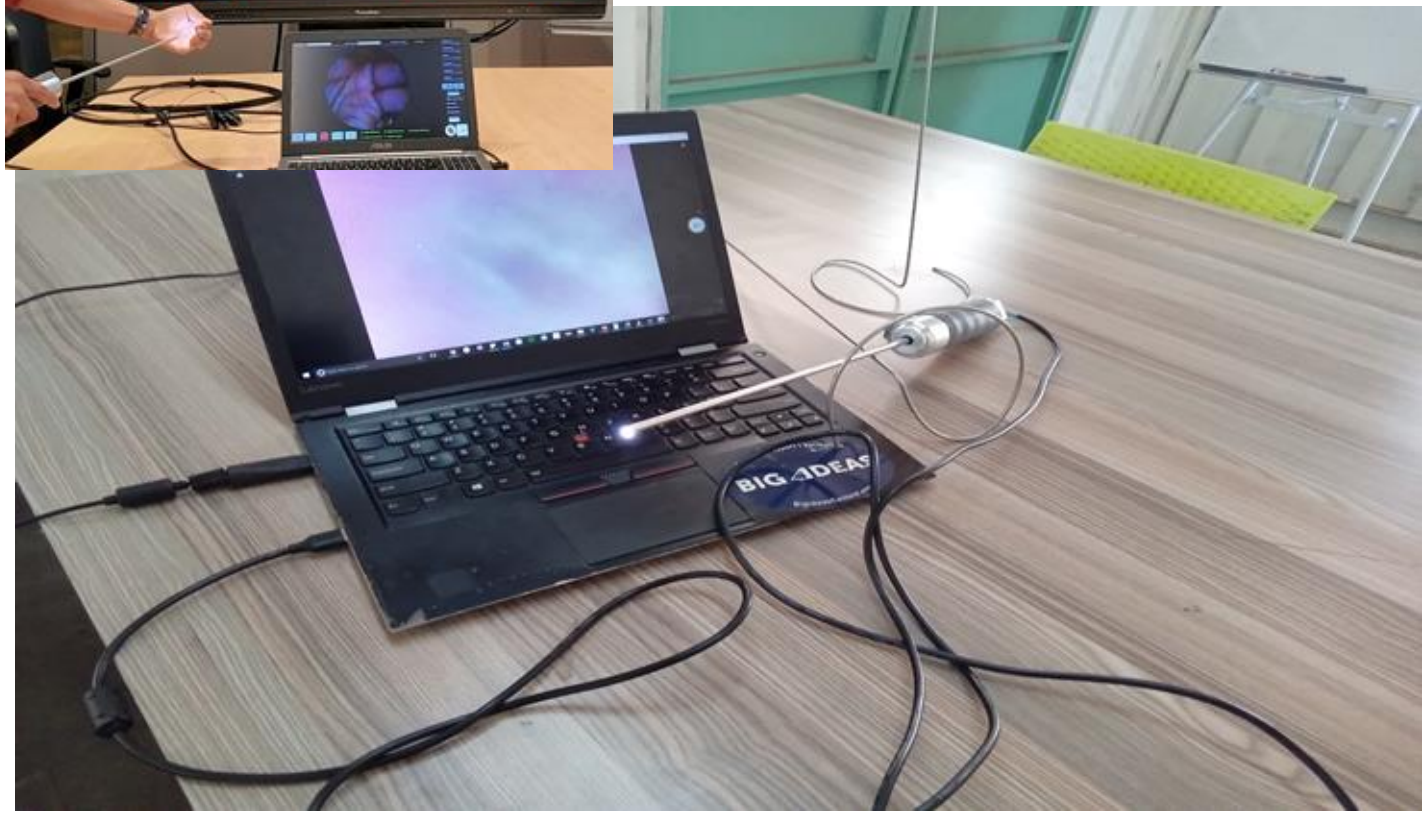
EPED Strip

Other devices

Gastro- Bag

KeyScope - Laparoscope





Context based design papers

Prosthetics services in Uganda : a series of studies to inform the design of a low cost, but fit-for-purpose, body-powered prosthesis

Kenney, LPJ, Ssekitoleko, R, Chadwell, AEA, Donovan-Hall, M, Morgado Ramirez, D, Holloway, C, Graham, P, Cockroft, A, Deere, B, McCormack, S, Semwanga, A, Gizamba, H and Kalibbala, M 2019, **Prosthetics services in Uganda : a series of studies to inform the design of a low cost, but fit-for-purpose, body-powered prosthesis** , Working Paper, World Health Organisation.

PDF - Accepted Version
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Official URL: https://www.fit4purposeprosthetics.org/publication...

Abstract

The majority of people with upper limb absence (PWULA) live in lower, or middle-income countries (LMICs). However, efforts to develop improved prostheses have largely focused on electrically powered devices, sustainable deployment of which, in LMICs, is difficult. In the 'Fit-for-purpose, affordable body-powered e UK, Uganda and Jordan are developing mechanically-operated prostheses, optimised for LMICs, and establishing local evaluation. Here we first report on preliminary studies aimed at grounding the project in the reality of current prosthetics ople with limb absence in Uganda. Finally, we outline our ongoing work in the context of our findings. In our first two studies we

prosthesis

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3D Printing in LMICs: Functional Design for Upper Limb Prosthetics in Uganda

by Ali Hussaini [1], Peter Kyberd [2], Benedict Mulindwa [3], Robert Ssekitoleko [3], William Keeble [4], Laurence Kenney [5,*] and David Howard [6]

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2 Institute of Orthopaedics and Musculoskeletal Sciences, Royal National Orthopaedic Hospital, University College London, Royal National Orthopaedic Hospital, Brockley Hill, Stanmore HA7 4LP, UK
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4 Faculty of Technology, University of Portsmouth, Portsmouth PO1 2UP, UK
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6 School of Science, Engineering and Environment, University of Salford, Salford M5 4WT, UK
* Author to whom correspondence should be addressed.

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(This article belongs to the Special Issue 3D Printing Strategies for Limb Prostheses)

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The Usability, Acceptability, and Performance of the Maternal PPH Wrap Device in Controlling Postpartum Hemorrhage: A Pilot Study at Kawempe National Referral Hospital, Uganda

SOLOMON C. OWINO[1], MAUREEN D. ETUKET[1], OWEN MUHIMBISE[1], MARTIN KIWANUKA[1], BERYL N. ARINDA[1], DENIS MUKIIBI[1], NOAH KIWANUKA[2], ROBERT T. SSEKITOLEKO[1], (Member, IEEE), AND SAM ONONGE[3]

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(Solomon C. Owino, Maureen D. Etuket, Owen Muhimbise, Martin Kiwanuka, Beryl N. Arinda, and Denis Mukiibi contributed equally to this work.) CORRESPONDING AUTHOR: S. ONONGE (sononge2006@yahoo.com)

This work was supported in part by the Grand Challenges Canada under Grant R-ST-POC-1808-17001 (https://www.grandchallenges.ca/grantee-stars/1808-17001/) and in part by the Big Ideas Competition at the University of California Berkeley, USA (https://bigideascontest.org/projects/the-first-aid-post-partum-haemorrage-belt-makerere-university/).

This work involved human subjects or animals in its research. Approval of all ethical and experimental procedures and protocols was granted by the School of Medicine Research and Ethics Committee (SOMREC), Makerere University, under Application No. REC REF 2019-129, and also by the Kawempe National Referral Hospital and the Uganda National Council of Science and Technology (UNCST).

This article has supplementary downloadable material available at https://doi.org/10.1109/TEHM.2022.3197688, provided by the authors.

ABSTRACT Timely intervention for atonic postpartum hemorrhage (PPH) significantly reduces the incidence of death from PPH. However, technological solutions geared towards this have not received substantial adoption by the health community in sub-Saharan Africa due to limiting factors such as; cumbersome application, being costly, requiring skilled personnel, needing cold chain storage, and the associated side effects. This pilot study aimed to assess the usability, acceptability, and performance of the Maternal PPH Wrap, a first-aid device designed to control atonic PPH after childbirth. Forty subjects were recruited for the study. Twenty of these were women who sought maternity care at Kawempe National Referral Hospital (KNRH). The women wore the device for 120 minutes while their vitals were recorded every 20 minutes. The device's acceptability and performance were evaluated on the women. The remaining twenty were licensed midwives working at KNRH. The device's usability was assessed on all the midwives recruited for the pilot study using a usability questionnaire. There was a non-significant reduction in blood loss associated with the use of the Maternal PPH Wrap alongside the standard of care as opposed to the standard of care alone. This reduction in blood loss was detected between the 80th and 120th minute of the device application onto the mothers. The acceptability and usability scores from the study participants also scored favorably. The Maternal PPH Wrap demonstrated potential to control PPH and product satisfaction, and these results will support the device's redesign leading into a phase I clinical trial.

INDEX TERMS Medical device, obstetric first-aid, pilot study, postpartum hemorrhage, uterine atony.

Clinical and translational impact statement
The clinical evaluation results show that the Maternal PPH Wrap can control PPH in mothers after birth at health centers, during transportation, and delays in receiving treatment at referral hospitals.

No Access

The lived experience of people with upper limb absence living in Uganda: A qualitative study

Dafne Zuleima Morgado Ramirez, Brenda Nakandi, Robert Ssekitoleko, Louise Ackers, Erisa Mwaka, Laurence Kenney, Cathy Holloway and Maggie Donovan-Hall

Published Online: 20 May 2022

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Technology focus for Makerere University

- Biomaterials and drug delivery
- Point-of-care diagnostics
- Biomedical Imaging
- Data analytics and AI

Our PhD students at CWRU

Opolot Einyat Emmanuel
PhD Student at Case Western Reserve University

Polymer-based drug delivery systems

Solomon Oshabahebwa PhD Student at Case Western Reserve University- USA

Developing a portable device for sickle cell diagnostics

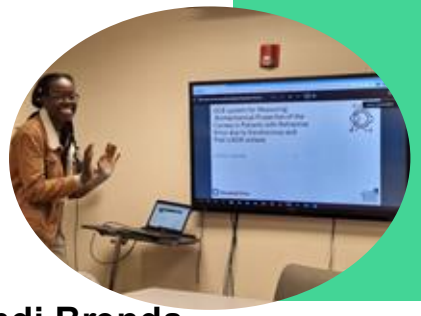
Zoe Sekyonda PhD Student at Case Western Reserve University- USA
Optical detection and monitoring of haemoglobin variants

Lydia Akino PhD Student at Case Western Reserve University- USA

Treatment of Atrial Fibrillation using an optical guided technology.

Bakwatanisa Bosco
PhD Student at Case Western Reserve University

Optical Coherence Tomography



Nakandi Brenda
PhD Student at Case Western Reserve University

Measuring the biomechanics of the cornea in patients with Keratoconus

Calvin Abonga
PhD Student at Case West Reserve University

Microfluidics | Biosensors | Point-of-Care Devices | Microfabrication

Stephen Tasobya
PhD Student at Case Western Reserve University

Imaging and Data Analytics

NIH Fogarty

5D43TW012260-04

"Strengthening Research Capacity in Innovative Global Health Technologies for Non-Communicable Diseases in Uganda" (SIGHT).

Other PhD Students from MakBME

Henry Kiwumulo
PhD Student at Makerere University - Uganda

Nanotechnology magnetic guided targeted drug delivery.

Martin Kiwanuka
PhD Student at University of Singapore

Mechanobiology.

Catherine Namayega
Medical image inferencing and AI. PhD fellow –UCT South Africa

Maureen Etuket PhD Student at Stellenbosch University SA
Industrial Engineering and Device Translation

Martha Mulerwa
PhD Student at University of Salfor

Artificial Wrist Design for ADLs

Yvonne Tusiimire
PhD Student at Makererere

Nanotech encapsulated Plasters for wound Healing

Beryl Arinda Ngabirano
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Tissue Engineering

Context Based Design: Systems thinking

Evaluating Translational bottlenecks - Regulations

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ORIGINAL ARTICLE

The Evolving Landscape of Medical Device Regulation in East, Central, and Southern Africa

Sarah Hubner, Caroline Maloney, Sarah Dunn Phillips, Pratik Doshi, Julius Mugaga, Robert Tamale Ssekitoleko, Jenna L. Mueller and Tamara N. Fitzgerald

Global Health: Science and Practice March 2021, 9(1):136-148; https://doi.org/10.9745/GHSP-D-20-00578

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Mini Review

28 July 2022

10.3389/fmedt.2022.952767

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Rossella Di Bidino, Agostino Gemelli University Polyclinic (IRCCS), Italy

Qingyu Cui, University of California, Los Angeles, United States

Robert T. Ssekitoleko, rssek@gmail.com

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25 May 2022

Review of investigational medical devices' clinical trials and regulations in Africa as a benchmark for new innovations

Brian Matovu[1], Mercy Takuwa[1], Charles Norman Mpaata[1], Fiona Denison[2], Noah Kiwanuka[1], Steff Lewis[4], John Norrie[4], Sam Ononge[5], Owen Muhimbise[1], Sharon Tuck[4], Maureen Dimitri Etuket[1] and Robert T. Ssekitoleko[1]*

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ORIGINAL RESEARCH article

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This article is part of the Research Topic

Medical Device Innovations and Clinical Trials in Africa

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Systems and processes for regulation of investigational medical devices in Uganda

Charles Norman Mpaata[1], Brian Matovu[1], Mercy Takuwa[1], Noah Kiwanuka[2], Steff Lewis[3], John Norrie[3], Sam Ononge[4], Sharon Tuck[3], Maria Wolters[5], Marc Demulliez[6] and Robert T. Ssekitoleko[1*]

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Brian Matovu, [1] Mercy Takuwa, [1] Charles Norman Mpaata, [1] Fiona Denison, [2] Noah Kiwanuka, [3] Steff Lewis, [4] John Norrie, [4] Sam Ononge, [5] Owen Muhimbise, [1] Sharon Tuck, [4] Maureen Dimitri Etuket, [1] and Robert T. Ssekitoleko[✉1],

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Abstract

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TYPE Original Research
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Systems and processes for regulation of investigational medical devices in Uganda

Charles Norman Mpaata[1], Brian Matovu[1], Mercy Takuwa[1], Noah Kiwanuka[2], Steff Lewis[3], John Norrie[3], Sam Ononge[4], Sharon Tuck[3], Maria Wolters[5], Marc Demulliez[6] and Robert T. Ssekitoleko[1]*

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Background: In many parts of the world, medical devices and the processes of

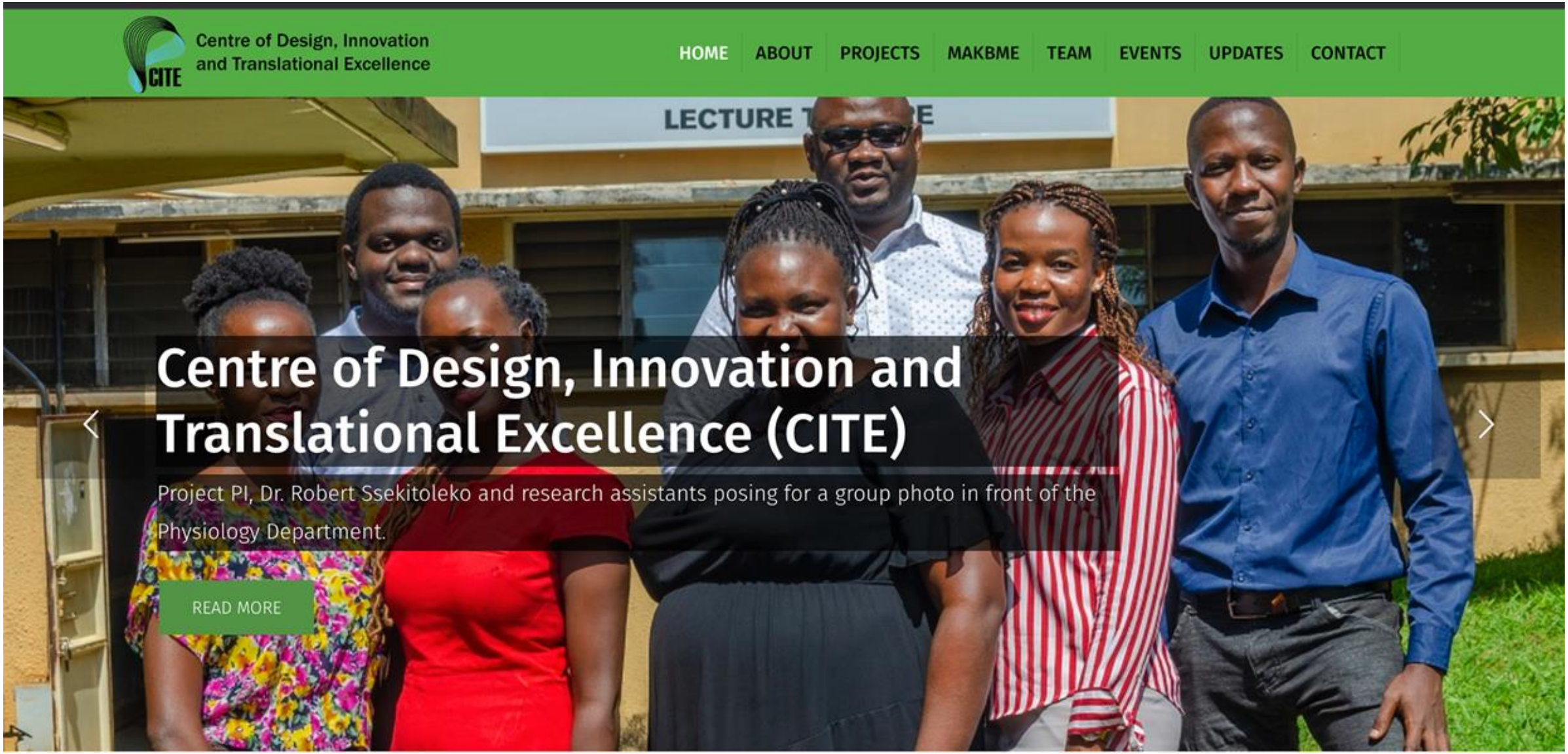
Matovu et al. BMC Research Notes (2023) 16:262
https://doi.org/10.1186/s13104-023-06541-6

BMC Research Notes

RESEARCH NOTE Open Access

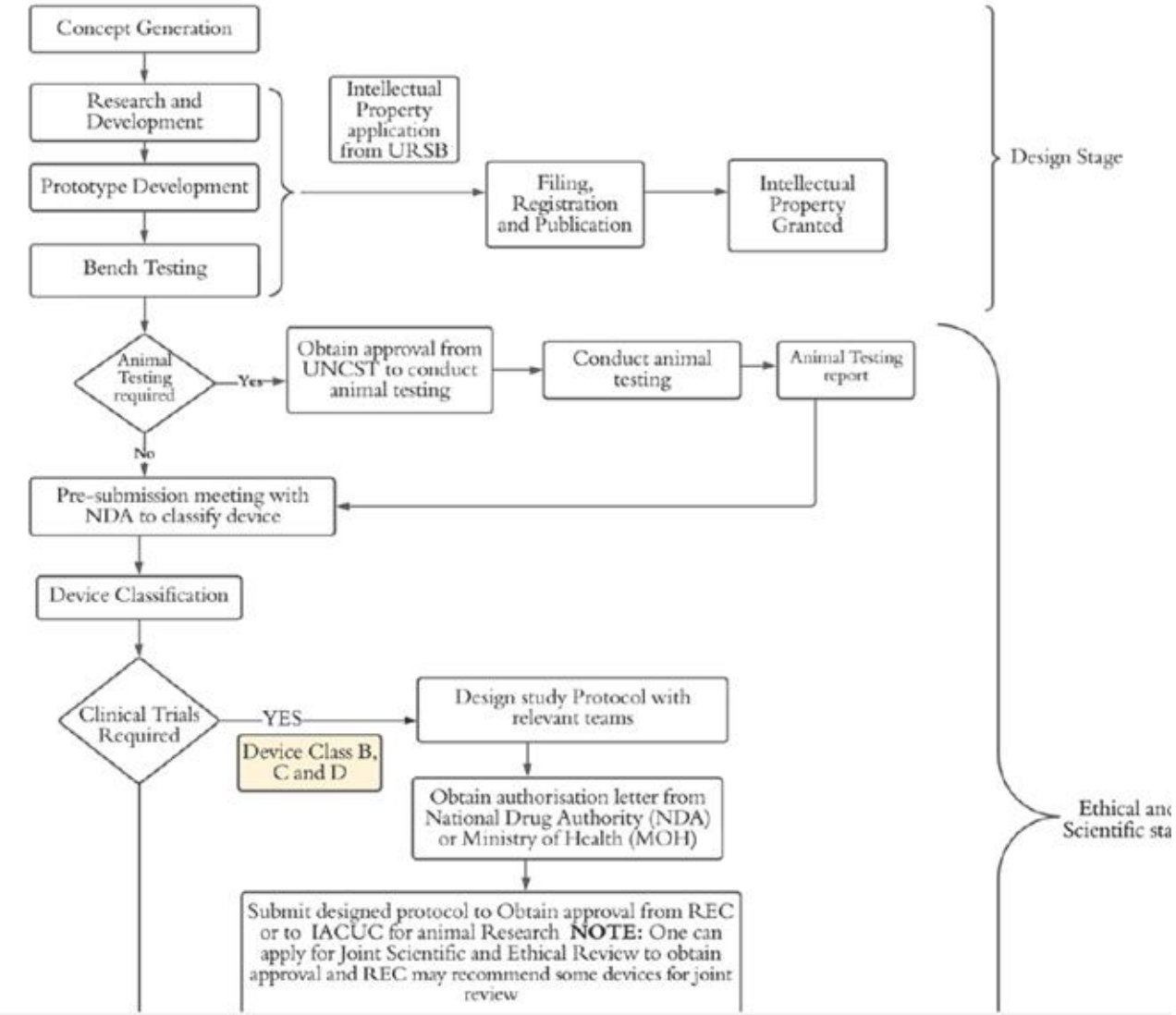
Translating medical device innovations to market - a Ugandan perspective

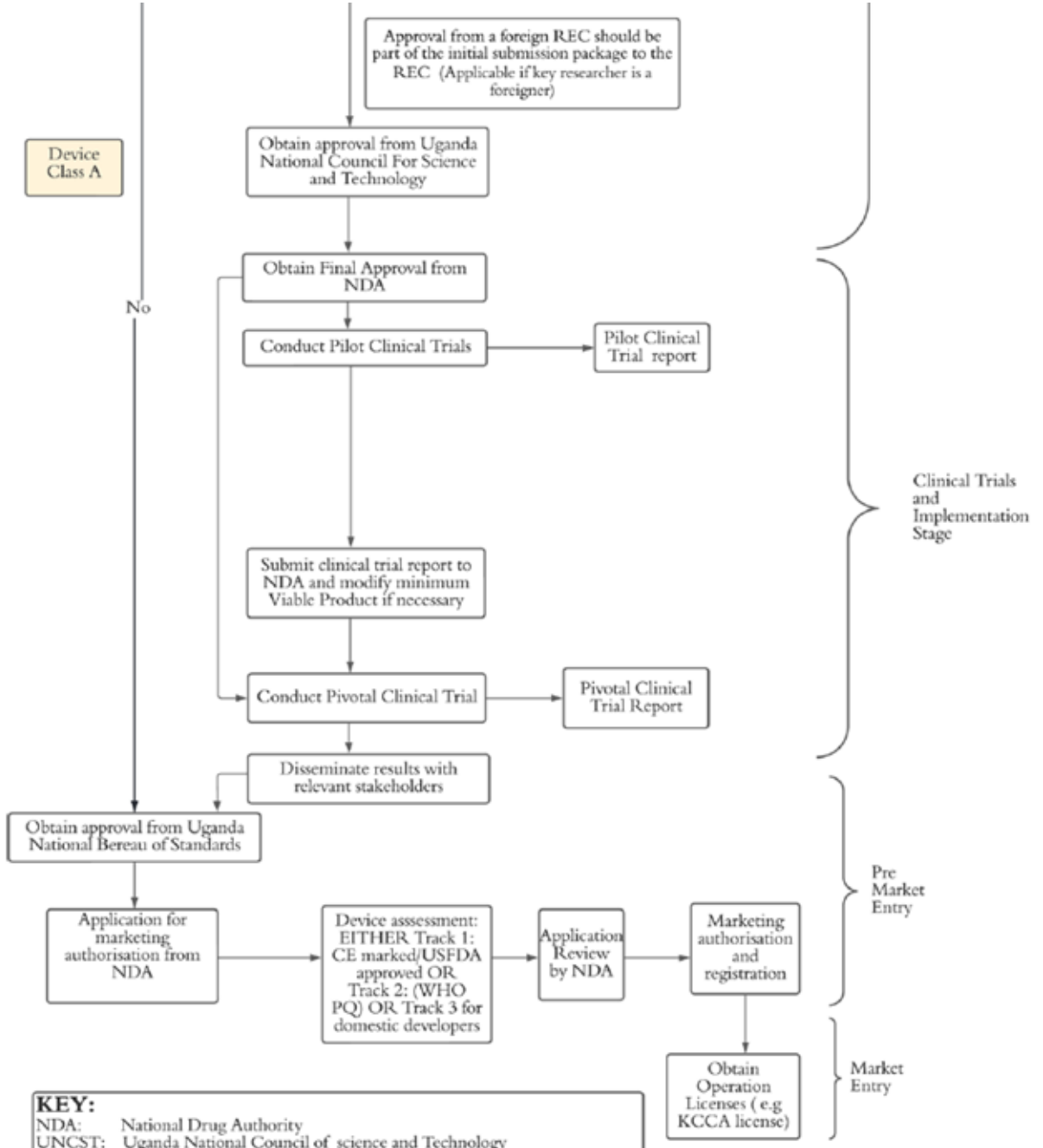
Brian Matovu[1], Jackline Winfred Baluka[1], Mercy Takuwa[1], Lucy Kevin Namuli[1], Charles Norman Mpaata[1], Julius Mugaga[1], Benedict Mulindwa[1], Racheal Nalwoga[1], Maria K Wolters[2] and Robert Tamale Ssekitoleko[1]*



https://cite.ug/

Regulatory Pathway for Medical Devices in Uganda
Developed by Center for Innovation, Design and Translational Excellence(CITE) (Under Makerere University Biomedical Engineering Unit)





KeySuite Manufacturing, Testing, Regulatory Approval, and Business Development Model in Uganda

Dr. Robert Ssekitoleko- Makerere University Biomedical Research Center, Kampala

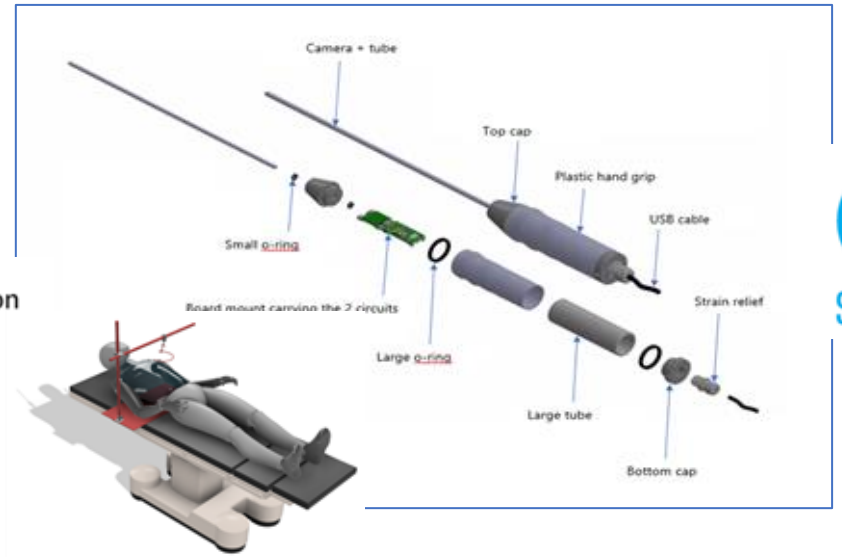
Regulatory Arm

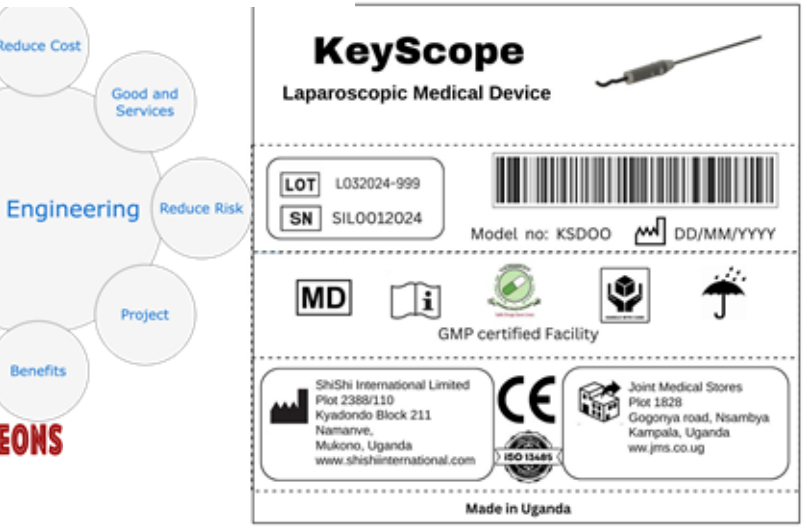
Local GMP by National Drugs Authority

ISO 13485:2016 By KGS
Notified body accredited by SAPHRA in South Africa

CE Mark with Consultation from Altagena Ltd

Stakeholders





Manufacturing Arm

Local Manufacturing

ShiShi Int. Ltd

Setting up Premises

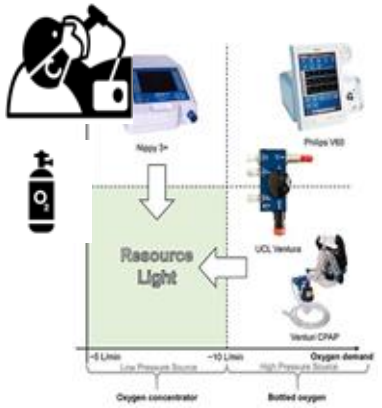
- Local and International Supply chain established.
- Manufacture close to 50 units in Year 1:SOW2

Contractual Manufacturing

Council for Scientific and Industrial Research

Translation of the LeVe CPAP system to Uganda for local production, maintenance, and clinical use

Dr Robert Ssekitoleko[1], Brian Matovu[1], Kigenyi Douglas[1], Dr Edith Namulema[2], Ms Racheal Musasizi[2], Dr William Davis-Birch[3], Dr Ian Waters [3], Prof Peter Culmer[3], Prof Nik Kapur[3]



1. The need…


THE ENGINEER

NEWS IN-DE

News Medical & healthcare Covid-19

'Frugal innovation' yields low-cost CPAP breathing device

2. A frugal solution

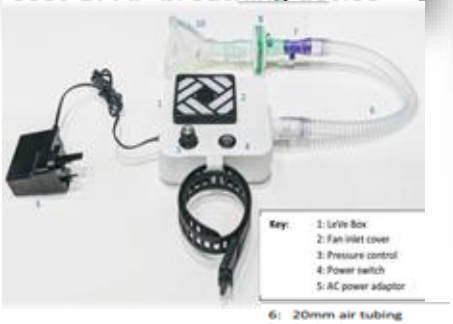
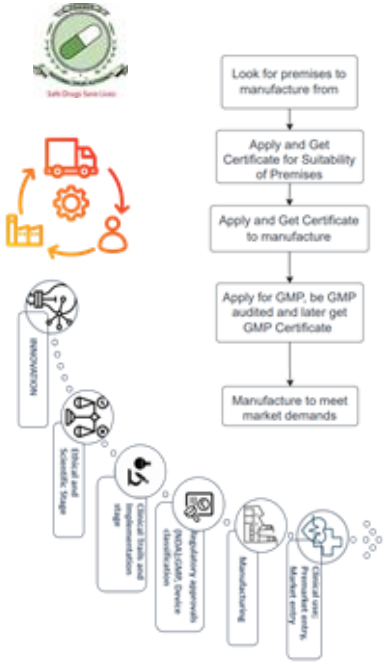


Figure 2: Complete LeVe System

3. Collaboration with Mengo Hospital

4. Clinical Evaluation

5. Translation for local production and clinical use



6. Planned activities

CITE- Proposed Manufacturing Center- Kasangati Annex

https://shishiinternational.com/

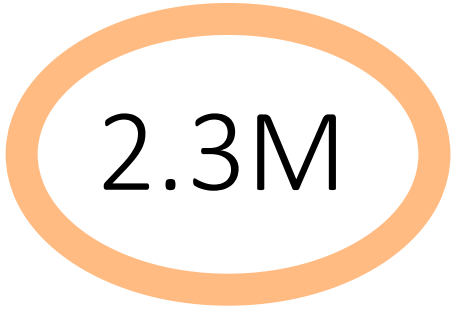
ShiShi

INNOVATIONS IN GLOBAL SURGERY

[1]School of Biomedical Sciences, Makerere University, Uganda
[2]Mengo Hospital, Uganda
[3]School of Mechanical Engineering, University of Leeds

Some Case studies

Neonatal Hypothermia-Key Statistics



Neonatal deaths occur annually worldwide. [1]

of deaths happen in LMICs.[2]

risk of neonatal death for every **1ºC** drop.[3]

Prevalence in Uganda.[4]

1 IN 40 Secs

Every **40** seconds, **1** premature baby dies.[5]

40% from 4Hrs

At **Kawempe National Referral Hospital**, **40%** of newborns in the NICU are preterm, most brought in an ambulance from over **4 hours** away.[6]

"Saving preterm infants by preventing hypothermia during life-saving transportation."

Device Description & Innovation

Device Overview:

- Temperature **36.5-37.5°C** for over 24 hrs.
- Adjustable
- Portable
- Safe
- low Cost

Innovation/Key Features:

- Thermoregulated warming system
- Carriage and Protection system
- Sensor , logging and user alert system
- Locally sourced and manufactured

NeoNest prototype – a portable preterm infant warmer.

"Saving preterm infants by preventing hypothermia during life-saving transportation."

Clinical Benefits to Healthcare Providers/Patients

Reduced **Hypothermia Cases** during transport

Reduced **neonatal mortality rates i**n resource-limited settings

Ease of use for non-specialist caregivers.

Easy **repair and maintenance**

Use Cases/Applications

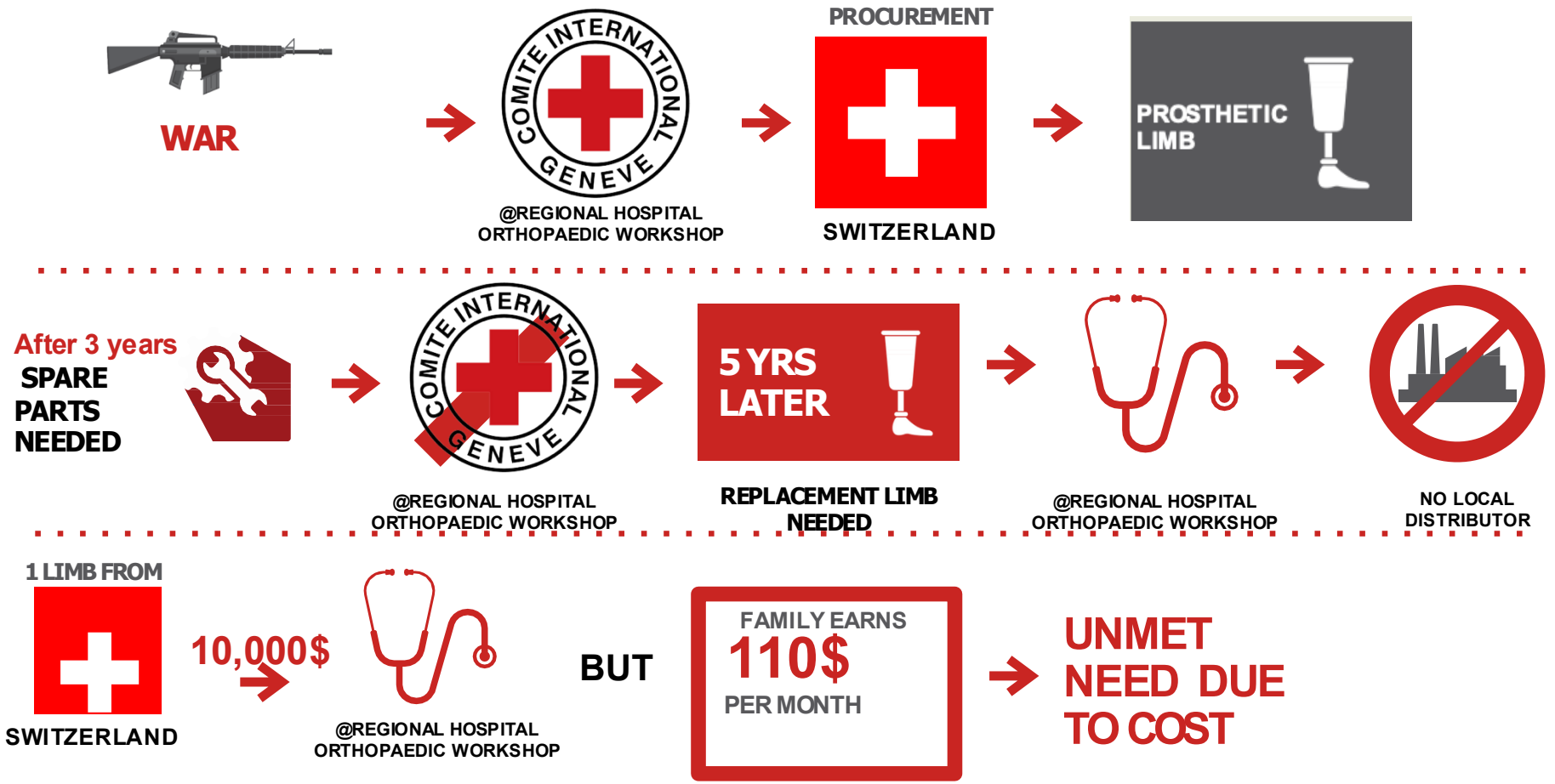
Hours-long Transport of preterm Infants in rural areas.

Complement **Kangaroo mother care**

Ward-ward transportation in Referral Hospitals and Clinics.

Rural Health Facilities.

A Typical Case Scenario for prosthetics



The lived experience of people with upper limb absence living in Uganda: A qualitative study

Dafne Zuleima Morgado Ramirez, Brenda Nakandi, Robert Ssekitoleko, Louise Ackers, Erisa Mwaka, Laurence Kenney, Cathy Holloway and Maggie Donovan-Hall

Published Online: 20 May 2022

Co-design, co-selection workshops

- Two co-design activities in the form of a 2-Day workshop (5 months in between) were organized locally in Uganda.

3D printing

- An efficient fabrication route to meet the constraints within the iterative design approach of the co-design activities

Engaging industrial partners

- Industry consultants from Fillauer TRS, USA, to gain insight on structuring co-design activity questions.

Co-design

- Used a discrete choice approach to encourage the users to explore the trade-offs between function and appearance.
- 21 co-designers (12 males, 9 females)
- Selection from a combination of functional and cosmetic devices

Fit-for-purpose hand