Frugal innovation for low-resource settings

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Hosted by Barbara Catt
Chair, International Federation of Infection Control

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Applied Biomedical Signal Processing and Intelligent eHealth Lab , a multidisciplinary team

Leandro Pecchia
Full Professor in BME
ABSPIE Co-Director

Davide Piaggio
Assistant Professor in BME
ABSPIE Co-Director

Project Administrators

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Post-doc Researchers

Rossana Castaldo
BME
Signal processing/AI

Alessia Maccaro
Philosopher
Medical Devices/ Ethics/Africa

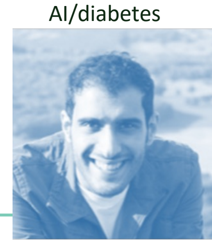
Silvio Pagliara
Electronic Eng
Telemedicine/ Assistive Tech

PhD Students

3-4th y

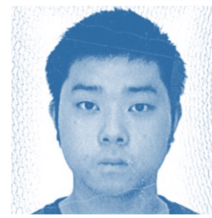
Martina Andellini
BME
HTA of Medical Devices

Owain Cisuelo
Physicist
AI/diabetes



Abdulaziz Almuhini
Medical Engineering
Robots in surgery

3-4th y



Wanzi Su
Computer scientist
Digital health for neurological/ophthal mological diseases and rehab

Zeeshan Raza
Medical doctor
Robots in surgery

2nd y

James Wallace
Mechanical eng.
Frugal engineering

Muhammad Farooq Shaikh
Computer scientist
Digital health for learning disorders

1st y

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About me

Assistant Professor of Biomedical Engineering, University of Warwick, UK
Co-Director, Applied Biomedical Signal Processing and Intelligent eHealth lab
Executive team member, Biomedical Engineering Institute, University of Warwick
Co-Lead, Spotlight on Society and Culture, University of Warwick
Collaborator member, IFMBE HTAD, IFMBE Africa Biomedical Engineering Working Group, and IFMBE Publicity Committee
Councilor, EAMBES

Research interests: medical device design, management, assessment and regulations, frugal engineering, mHealth, additive manufacturing, IPC, ethics, preparedness and governance

Dr Davide Piaggio

Research interest

- Applied *Biomedical signal processing*, *Internet of Things*, *Artificial Intelligence*
- Early-stage *Health Technology Assessment* (HTA) and User Need Elicitation methods
- Medical Device design, regulation, assessment and management (Clinical Engineering)

Main applications:

- Active/healthy ageing, prevent disease or worsening and adverse events in later life
- Disease Management Programs, patient monitoring and telemedicine
- *Medical devices and medical locations* in low-resource settings and LMICs

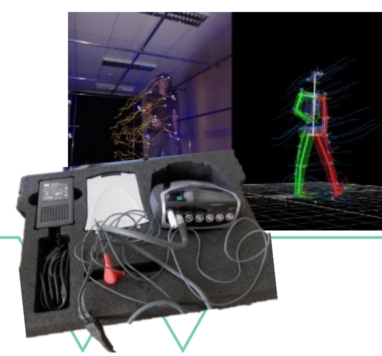
Main Projects

Current projects

1. *2023/2027, WIF, "Novel medical app for the early screening of learning disorders in children"*
2. *2022/2024, Innovate UK, "Intelligent Multimodal Digital Ophthalmic Measuring Device with enabled AI Tele-Ophthalmology"*
3. *2022/2023, Policy support fund, "Pandemic Preparedness: Best and Worst Practices from COVID-19"*
4. *2022/2023, Health GRP, Sustainability across the medical device lifecycle*
5. 2020/2024, *H2020, ODIN Smart Hospital (AI/Robots for Hospitals, COVID-19)*
6. *2020/2023, H2020, GATEKEEPER (AI/IoT for Home Care, COVID-19)*

Former projects

1. *2021/2021. Edwards Lifescience, "HTA of AI-based Medical Devices"*
2. *2021/2021, BT, "5G and well-being monitoring"*
3. *[2020/2022, PandeVita, H2020 call on COVID, EAMBES proj]*
4. 2020/2021, EPSRC, Hypoglicemia via AI and ECG in controlled environment
5. 2020/2022, Wellcome Trust, NoHypoglicemia
6. 2018/2020, GCRF, Medical devices design for Sub-Saharan Africa
7. *2018/2019, EPSRC, Closed-loop control for optimising chemotherapy*
8. *2016/2020, EPSRC IAA, HTA&Design of medical device in low-resource settings*
9. *2015/2016, The Royal Society, Sleep quality & balance*
10. *2014/15, European Commission, MAFEIP tool*



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Learning Outcomes

a. Understand the concept of frugal innovation and its relevance in different contexts
b. Differentiate between low- and middle-income countries and low-resource settings
c. Analyze methods to evaluate the context of use for frugal innovation solutions
d. Identify and apply criteria to make devices more resilient and adaptable to specific contexts of use

How can we improve Medical Devices in Africa?

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Improve medical device effectiveness and safety in Africa requires interdisciplinarity.

We focused on:

- Design
- Regulation
- Management
- Assessment

8 field studies in 24 months: Benin, Ethiopia, South Africa, Nigeria, Uganda

Go to **vevox.app**

Enter the session ID:
181-342-959

Or scan the QR code

Join: **vevox.app** ID: **181-342-959**

In your opinion, which is the percentage of donated medical devices in Sub-Saharan Africa?

1. <25%

   0%

2. 50%

   0%

3. 75%

   0%

4. >75%

   0%

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In your opinion, which is the percentage of donated medical devices in Sub-Saharan Africa?

1. <25%

2. 50%

3. 75%

4. >75%

In Sub-Saharan Africa 80% of the available medical devices are donated

70% of them are broken or
non-functional because of different reasons

Join: **vevox.app** ID: **XXX-XXX-XXX**

What's wrong in this picture?


AMBULANCE

Medical location and medical device assessment in Uganda and Benin

Field study to identify the conditions of equipment, healthcare facilities and capacity in Sub-Saharan hospitals:

- Uganda (3 hospitals)
- Benin (3 hospitals)

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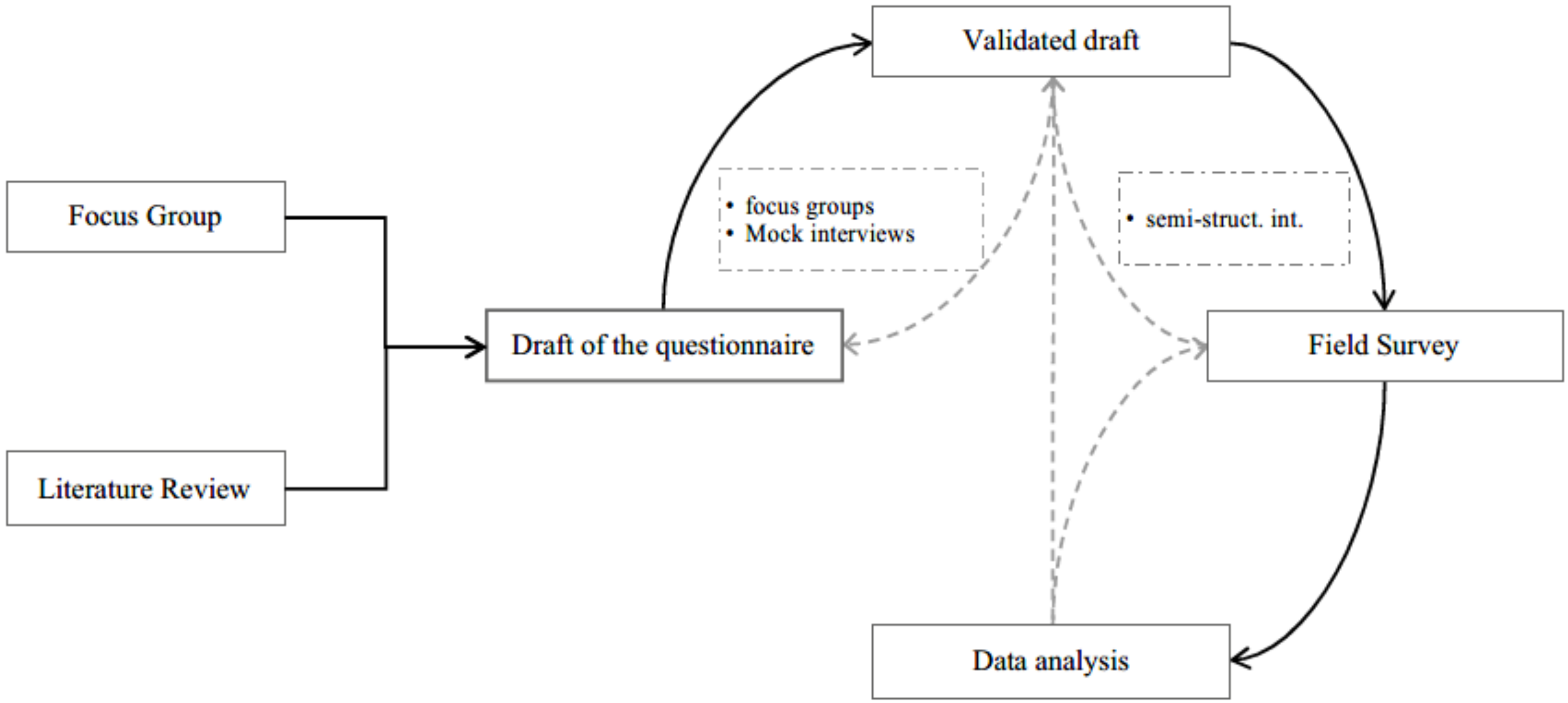
Centro E. Piaggio
bioengineering and robotics research center

Di Pietro, Licia, Davide Piaggio, Iyabosola Oronti, Alessia Maccaro, Roland C. Houessouvo, Daton Medenou, Carmelo De Maria, Leandro Pecchia, and Arti Ahluwalia. "A framework for assessing healthcare facilities in low-resource settings: field studies in Benin and Uganda." Journal of Medical and Biological Engineering 40, no. 4 (2020): 526-534.

Questionnaire development



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Results from the field studies

Country	Uganda	Uganda	Uganda	Benin	Benin	Benin
Hospital	**H1**	**H2**	**H3**	**H4**	**H5**	**H6**
Colonoscope	0	1	0	0	0	0
Mammograph	0	0	1	0	0	0
CT-scanner	0	1	1	0	0	0
Gastroscope	0	1	2	0	0	0
Infant reanimation centre	0	0	1	0	1	1
X-Ray Machine	1	3	1	1	1	1
Ambulance	0	3	1	2	0	2
Defibrillator	2	4	NA	3	2	0
Ventilator ICU	0	4	8	0	2	1
Hemocytometer	1	4	1	8	4	1
Ultrasound machine	0	8	2	4	2	3
Oxygen systems/cylinders	10	10	1	0	0	0
Syring pump	0	8	0	2	8	8
Autoclave for sterilisation	2	8	10	2	4	1
Operating theatre with basic equipment	3	8	3	8	3	2
Suction pump	1	8	10	0	8	1
Infant warmer	0	8	8	4	8	0
Anasthetic machine	1	10	8	0	2	8
Fetal monitor	1	8	10	0	8	2
Neonatal incubator	8	10	1	3	4	4
ECG machine	0	4	8	10	8	2
Patient monitor	1	10	10	10	8	10
Scale for adult	0	10	10	10	10	10
Scale for newborns	0	10	10	10	10	10
Pulsoximeter	2	10	10	10	10	10
Thermometer	8	10	10	10	10	10
Blood pressure machine/cuff	10	10	10	10	10	10

Di Pietro, Licia, Davide Piaggio, Iyabosola Oronti, Alessia Maccaro, Roland C. Houessouvo, Daton Medenou, Carmelo De Maria, Leandro Pecchia, and Arti Ahluwalia. "A framework for assessing healthcare facilities in low-resource settings: field studies in Benin and Uganda." Journal of Medical and Biological Engineering 40, no. 4 (2020): 526-534.

Visual inspections, electric safety measures (protective earth, insulation resistance, and leakage currents)

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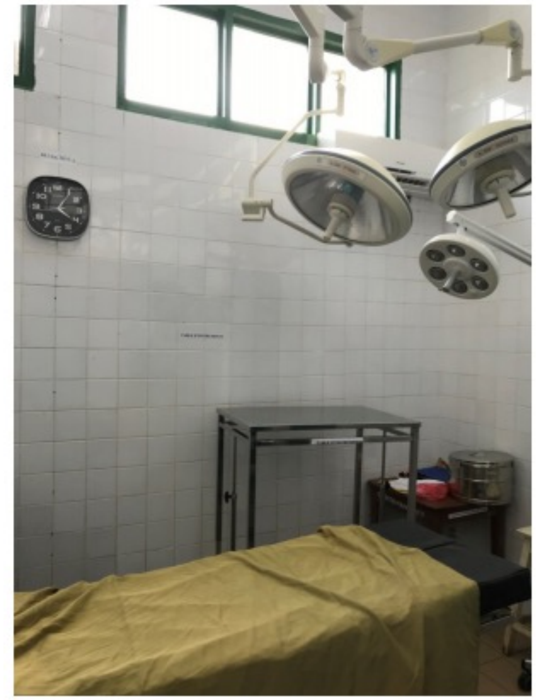

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Electrical access, reliability, and safety

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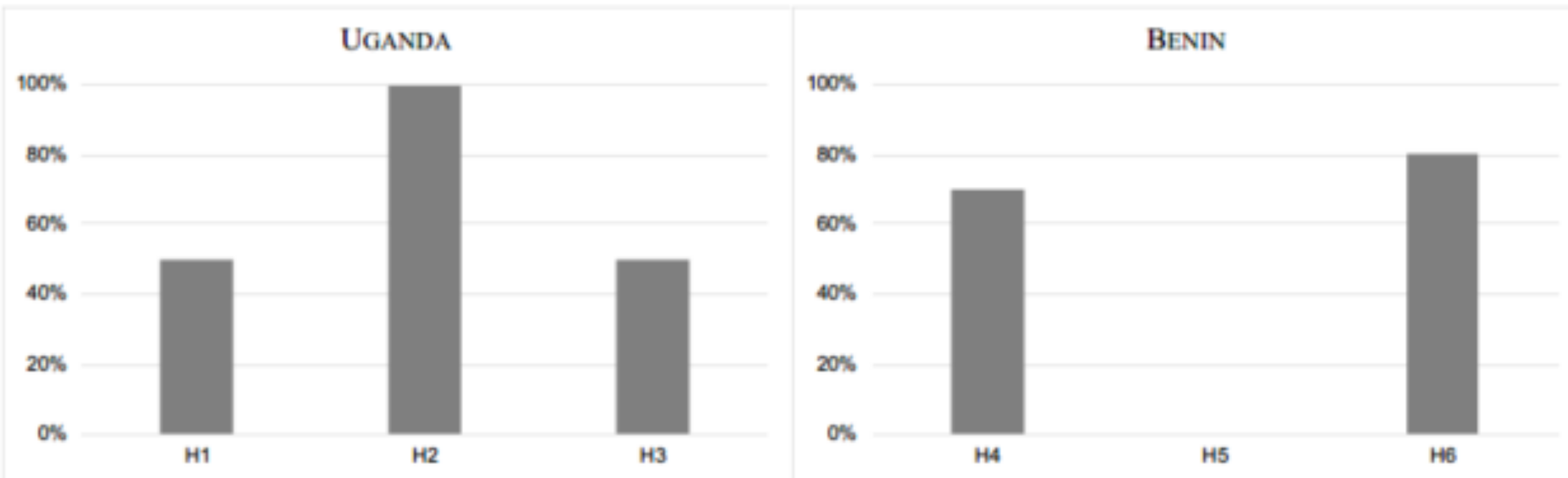
Table 2 Summary of the information and the ratings of the electrical access, reliability, and safety

Hospital	Power outages per month	Rating of the access to the main source of electricity	Rating of the quality and reliability if the electricity of the facility	Available and functional systems for electrical safety	Rating of the electrical safety in the facility	Rating of the compatibility of the working voltage and frequency required for the MDs and those available at of the facility
H1	4–6	Acceptable	Poor	EG	Poor	Good
H2	1–3	Acceptable	Very good	EG, EN, IT	Good	Very good
H3	1–3	Good	Acceptable	EG, EN, IT	Very good	Good
H4	10+	Poor	Poor	EG, EN	Acceptable	Poor
H5	10+	Good	Poor	EG, EN, IT	Acceptable	Very good
H6	10+	Acceptable	Acceptable	EG, EN	Good	Very good

EG electrical grounding, *EN* equipotential node, *IT* isolation transformer

Di Pietro, Licia, Davide Piaggio, Iyabosola Oronti, Alessia Maccaro, Roland C. Houessouvo, Daton Medenou, Carmelo De Maria, Leandro Pecchia, and Arti Ahluwalia. "A framework for assessing healthcare facilities in low-resource settings: field studies in Benin and Uganda." Journal of Medical and Biological Engineering 40, no. 4 (2020): 526-534.

Compatibility between the plugs of donated MDs and the local sockets



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Insulation/distance from undue noise, dust, foul odors, and smoke

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Table 3 The ratings of the insulation or distance of the structures from undue noise, dust, foul odors and smoke

Hospital	Undue noise	Smoke	Dust	Foul odours
H1	Very poor	Very poor	Very poor	Very poor
H2	Very poor	Very poor	Very poor	Acceptable
H3	Very poor	Very poor	Very poor	Very poor
H4	Acceptable	Acceptable	Poor	Acceptable
H5	Good	Good	Acceptable	Good
H6	Good	Poor	Acceptable	Good

Di Pietro, Licia, Davide Piaggio, Iyabosola Oronti, Alessia Maccaro, Roland C. Houessouvo, Daton Medenou, Carmelo De Maria, Leandro Pecchia, and Arti Ahluwalia. "A framework for assessing healthcare facilities in low-resource settings: field studies in Benin and Uganda." Journal of Medical and Biological Engineering 40, no. 4 (2020): 526-534.

Electrical safety measurements in Benin

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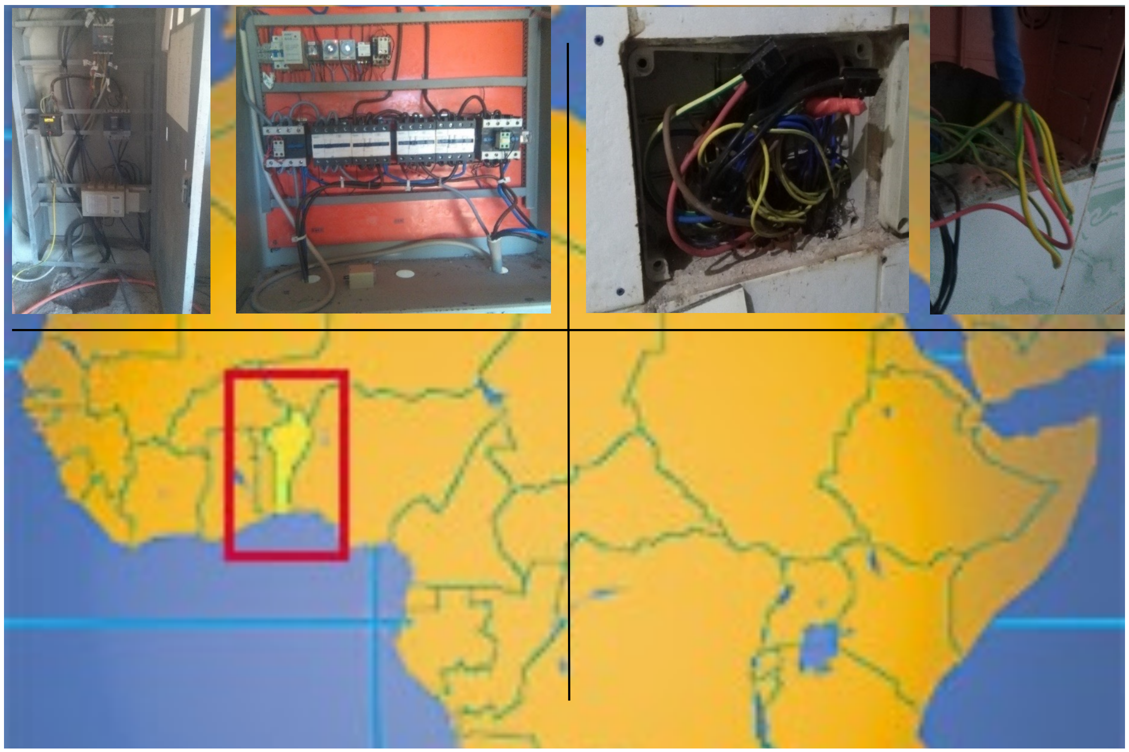
Table 5 The report of the electric safety measurements done in Benin (H4, H5, H6)

Hospital	Equipment	Protective earth (ohm)	Insulation					Leakage current	
			Mains-PE	AP-PE	Mains-AP	Mains-NE	AP-NE	Equipment	AP
Hôpital la croix	Patient monitor	1.23[a]	Infinite	98.4	Infinite	Infinite	98.2	0.2	7.7
Chu d'abomey Calavi	ECG Schiller AT 102	0.126[a]	Infinite	96.2	Infinite	Infinite	96.2	0.1	20.7
	Patient monitor[b]	1.7[a]	Infinite	Infinite	Infinite	Infinite	Infinite	0.5	3.8
	Bionet fetalcare ECG	0.34[a]	Infinite	Infinite	Infinite	Infinite	Infinite	0.65	0.5
Chu Suru-Lére	Biobase Centrifuge	0.125[a]	Infinite	Infinite	Infinite	Infinite	Infinite	0.5	NA
	Mindray Bs200 Analyzer	0.633[a]	Infinite	Infinite	Infinite	Infinite	Infinite	34.2	NA
	Heamatology analyser	0.073	Infinite	Infinite	Infinite	Infinite	Infinite	0.2	NA
	Sysmex coagulation system	0.166[a]	Infinite	Infinite	Infinite	Infinite	Infinite	0.7	NA
	Patient monitor	NC	Infinite	99.5	Infinite	Infinite	Infinite	0.9	8
	Aspel ECG	NC	Infinite	Infinite	Infinite	Infinite	Infinite	0.2	18.6

The protective earth resistance should not be greater than 0.1 ohm for these devices according to IEC60601-1

Medical Locations: (4 hospitals)



Medical Locations: (4 hospitals)

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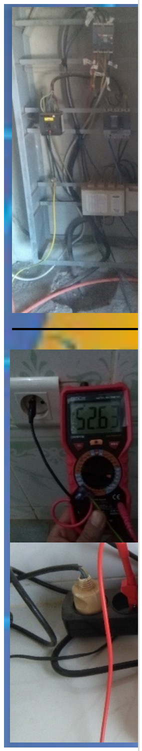

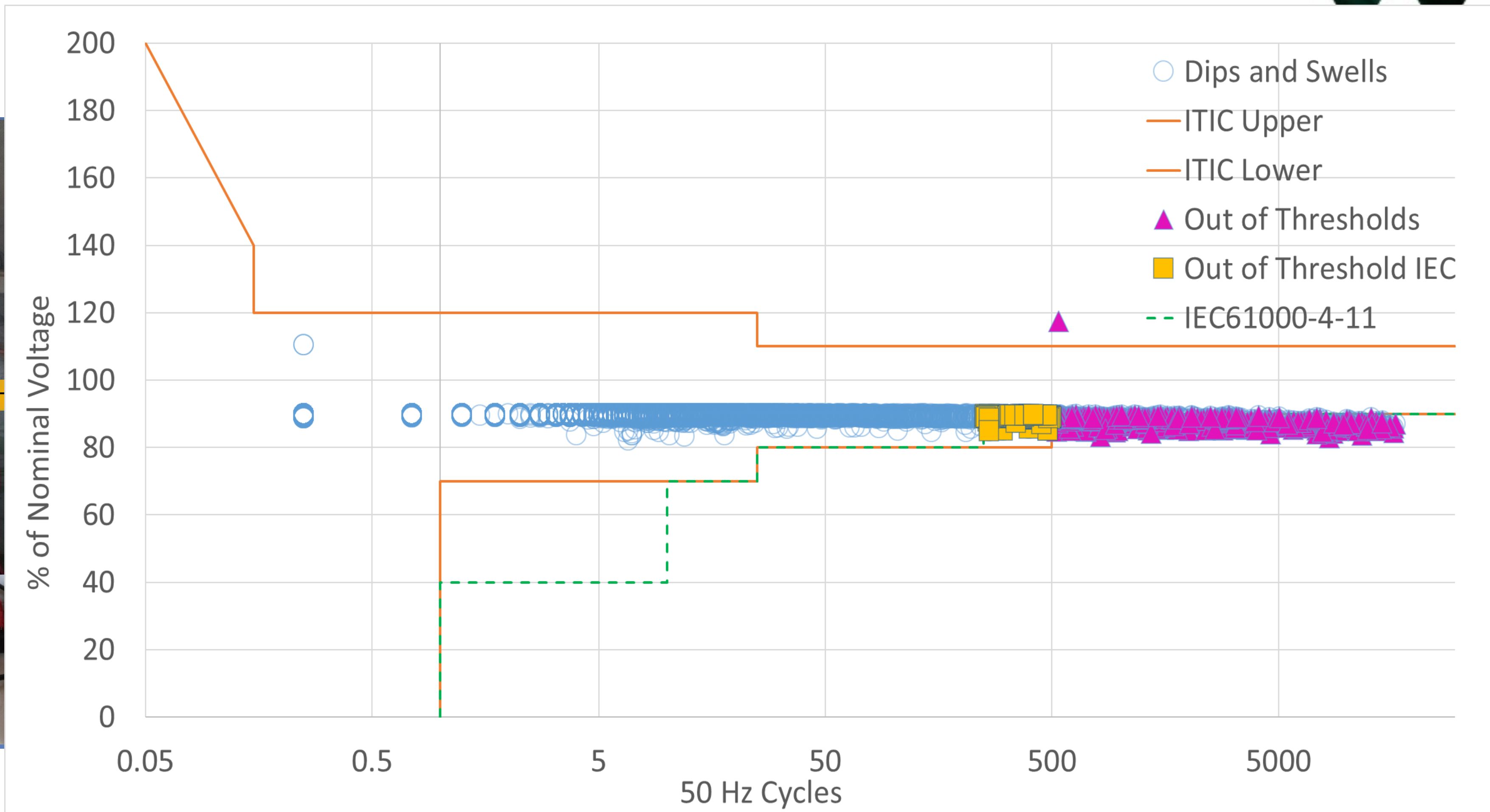

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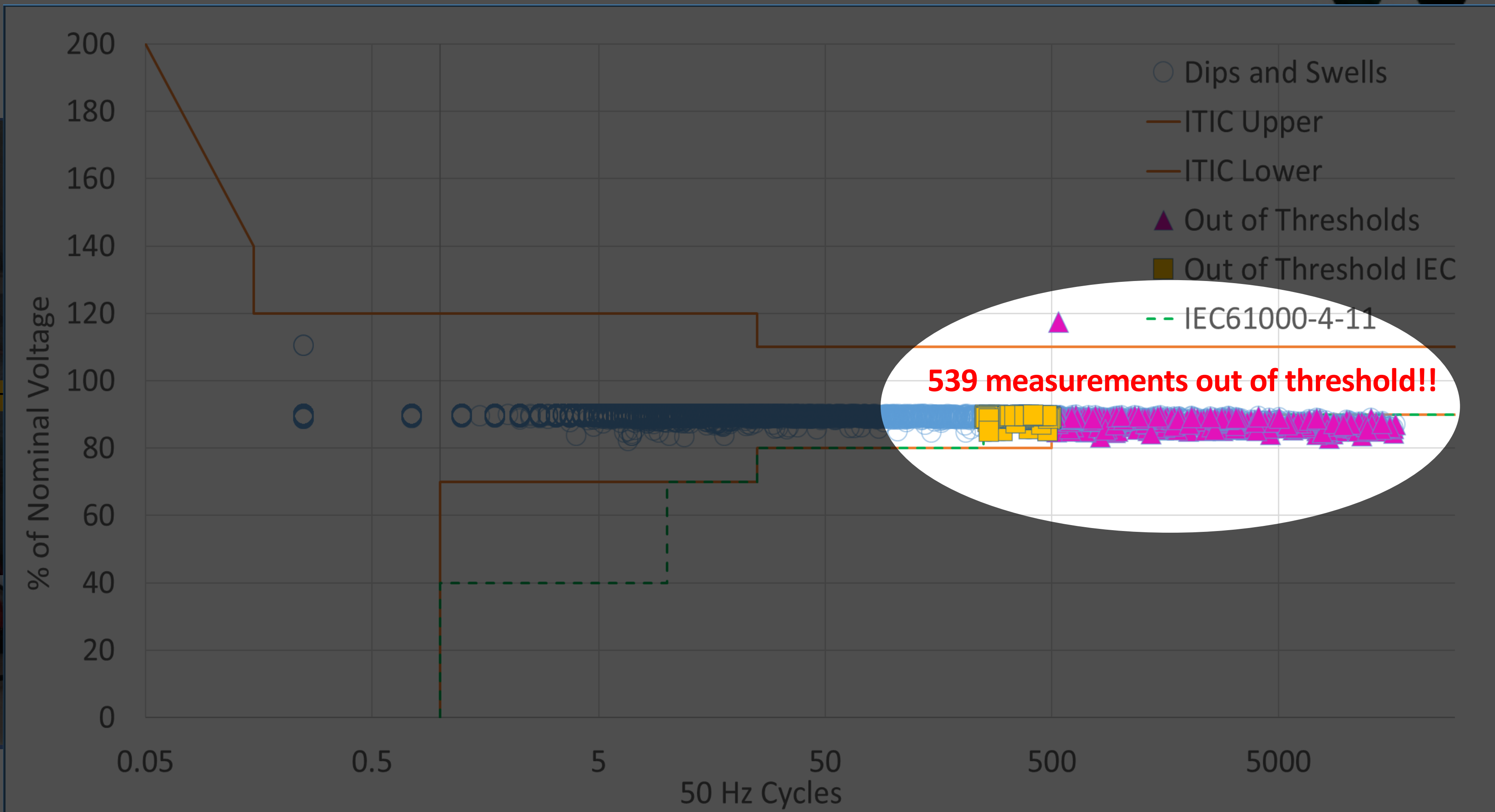

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Out of our field studies, we conducted a SWOT analysis…

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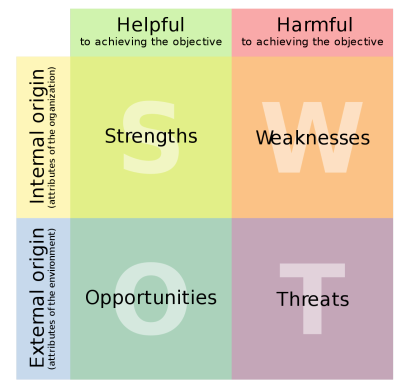
WEAKNESSES

Extremely limited-resource country	30 poorest countries in the world
Insufficient number of medical doctors	1.5/10 000 pop. Benin (28/10 000 pop. U.K.)
Poor infrastructures (electrification rate)	38% pop. Covered (1.7 out of 7 quality)*
Heterogeneous distribution of resources	Mainly capital/Poor supply chain

STRENGTHS

Huge diffusion of mobile phones	82% of the pop. Benin
Young population	65% of the pop. is under 25 in Benin
Resilient healthcare operators	Flexible, proactive and adaptable
Fast Growing BME School	...



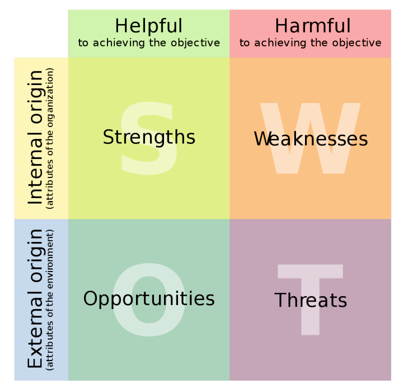
*http://reports.weforum.org

OPPORTUNITIES

- Fast growing market of medical devices (15% per year)
- Limited (no) inertia to the adoption of technologies
- Flexible/adaptable workers (e.g. New healthcare professions are easier to estabilish than in EU)
- Homogeneous platform for mobile phones (everything is Android based, not Apple...)
- Good coverage of wireless telecom.

THREATS

- Pro-tempore solutions become permanent
- Huge brain drain of (specialised) personnel
- Empowered operators will never be medical doctors!!



Summary information about Uganda and Benin

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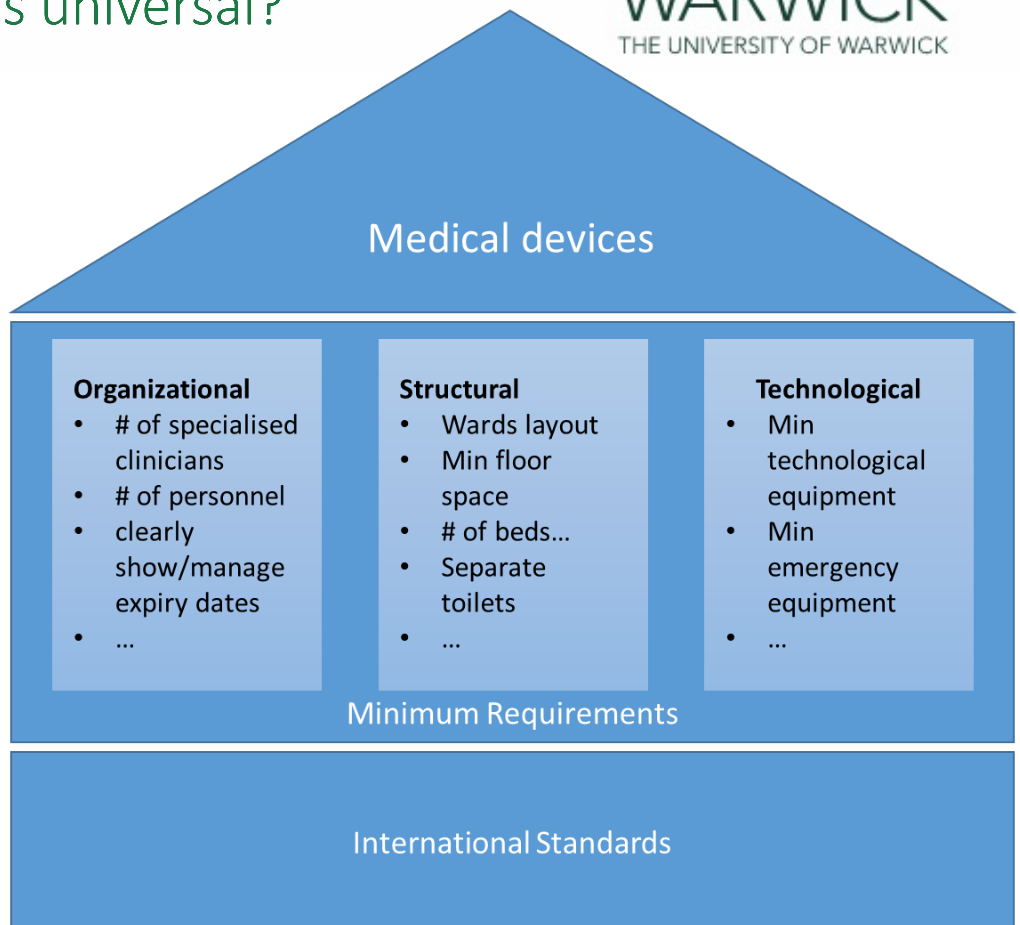
	Uganda	Benin	Italy
Area	241,037 km^2	114,763 km^2	301,338 km^2
HDI	0.528	0.520	0.883
Population	42.86 million	11.49 million	60.48 million
GNI	620$	870$	34,456$
HIV[a] prevalence	5.7% (15–49 years old)	1.13% (15–49 years old)	0.3% (15–49 years old)
Life expectancy at birth	60 years	62 years	83 years
Percentage of the population using an improved drinking water source	79%	77.9% (rural and urban)	100%
Physicians density (physicians per 1000 inhabitants)	0.09	0.16	3.95
Houses with centralised electricity supply	22%	43%	100%
Quality of electricity	3.43/7	2.06/7	5.91/7
Mobile phone subscriptions (per 100 people)	57.27	82.38	137

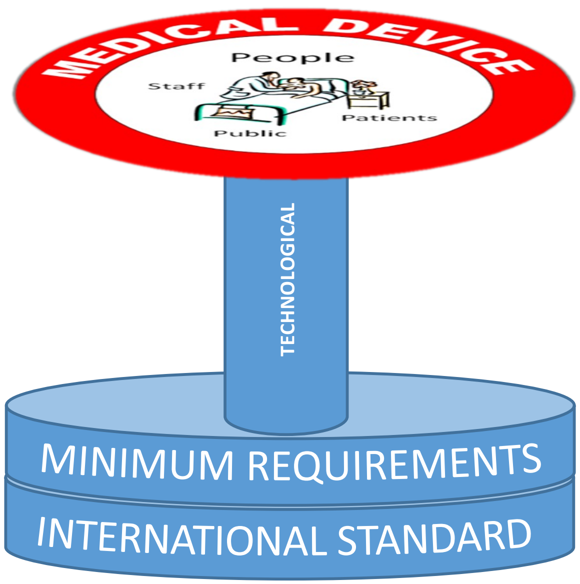
[a]Human immunodeficiency virus

Are the current standards and regulations universal?



Are the current standards and regulations universal?

Are the current standards and regulations universal?



Medical devices

Organizational
- # of specialised clinicians
- # of personnel
- clearly show/manage expiry dates
- …

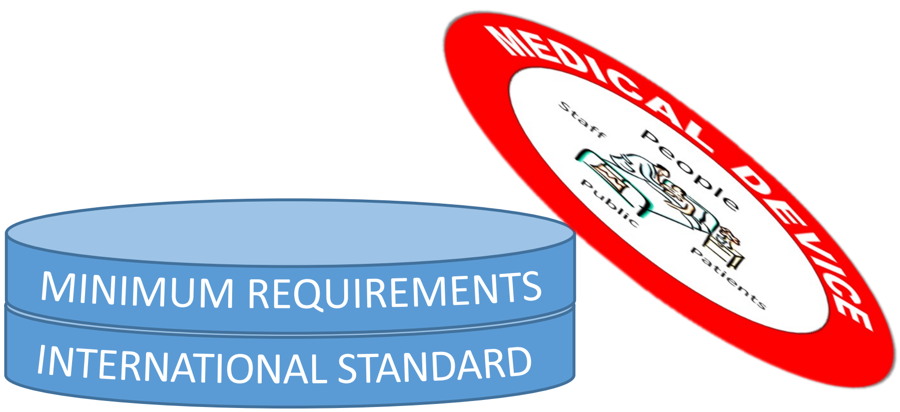
Structural
- Wards layout
- Min floor space
- # of beds…
- Separate toilets
- …

Technological
- Min technological equipment
- Min emergency equipment
- …

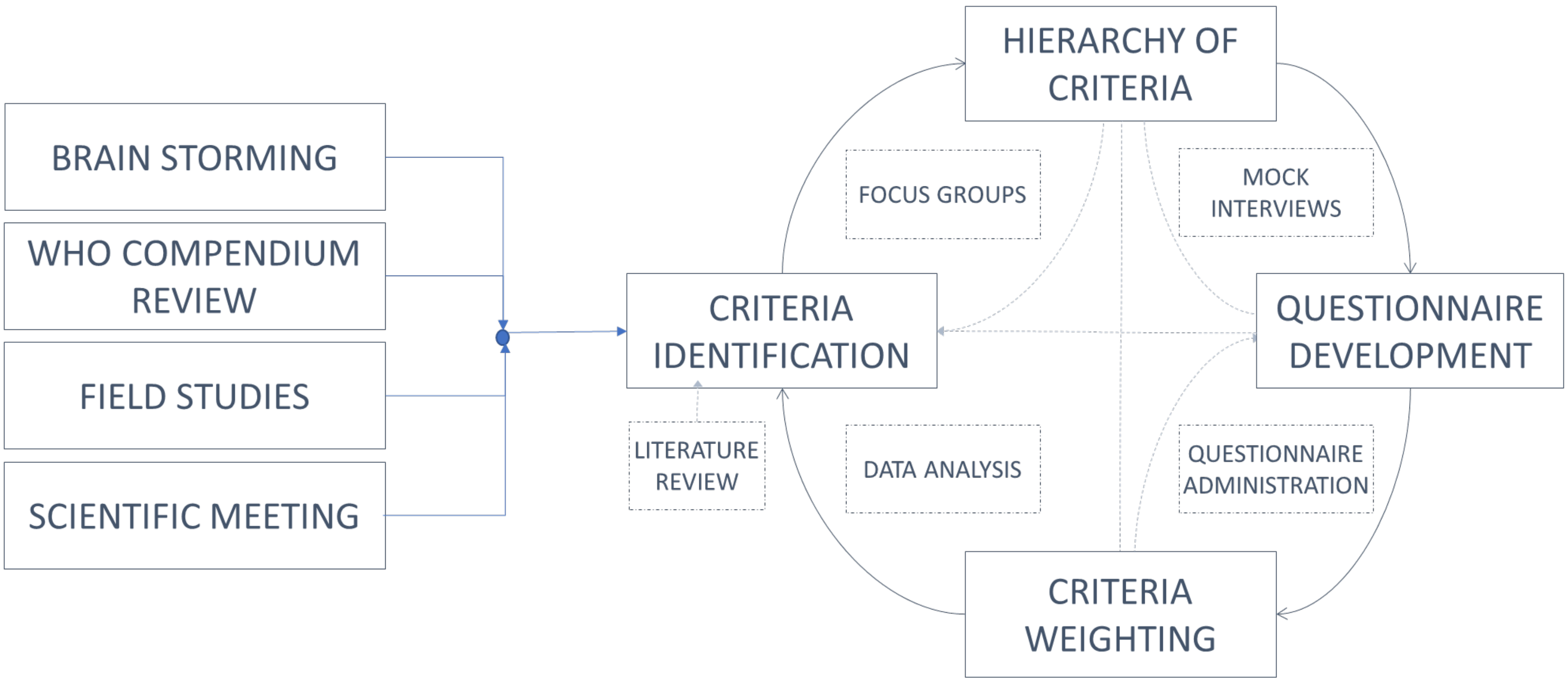
Minimum Requirements

International Standards

Are the current standards and regulations universal?

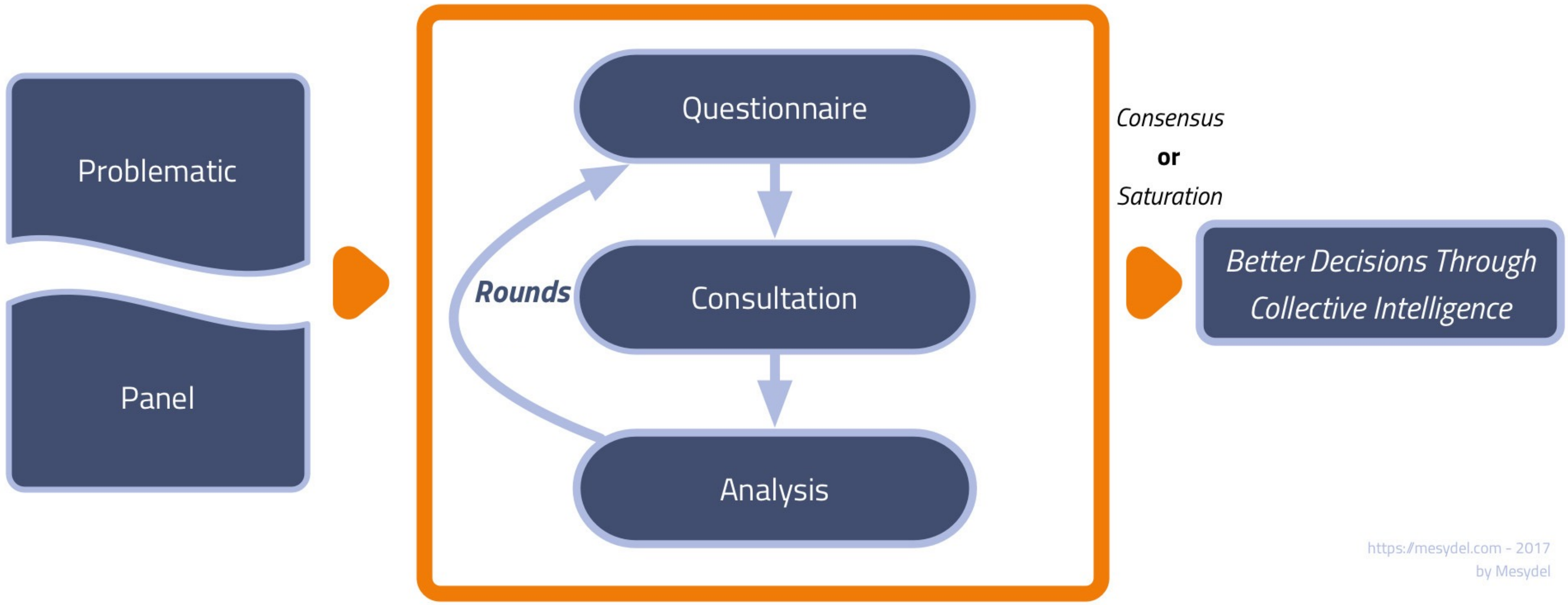


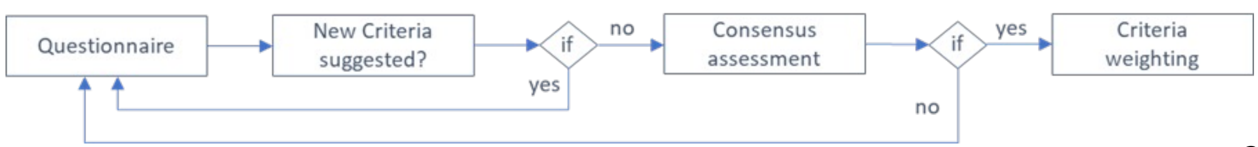
A framework for designing MDs resilient to LRSs



Piaggio D, Castaldo R, Cinelli M, Cinelli S, Maccaro A, Pecchia L. A framework for designing medical devices resilient to low-resource settings. Globalization and Health. 2021 Dec;17(1):1-3.

Delphi survey





Analysis

Consensus based on interquartile range (Q1-Q3):

- a “Sufficient” range ($2 \geq \Delta \geq 1$), “Fair” range ($1 \geq \Delta > 0$) or a “Full consensus” range ($\Delta = 0$).

Reliability (measures how the criteria are relevantly measuring the same overarching concept), based on polychoric matrices and ordinal alpha

- Values over 0.7 being “Acceptable”

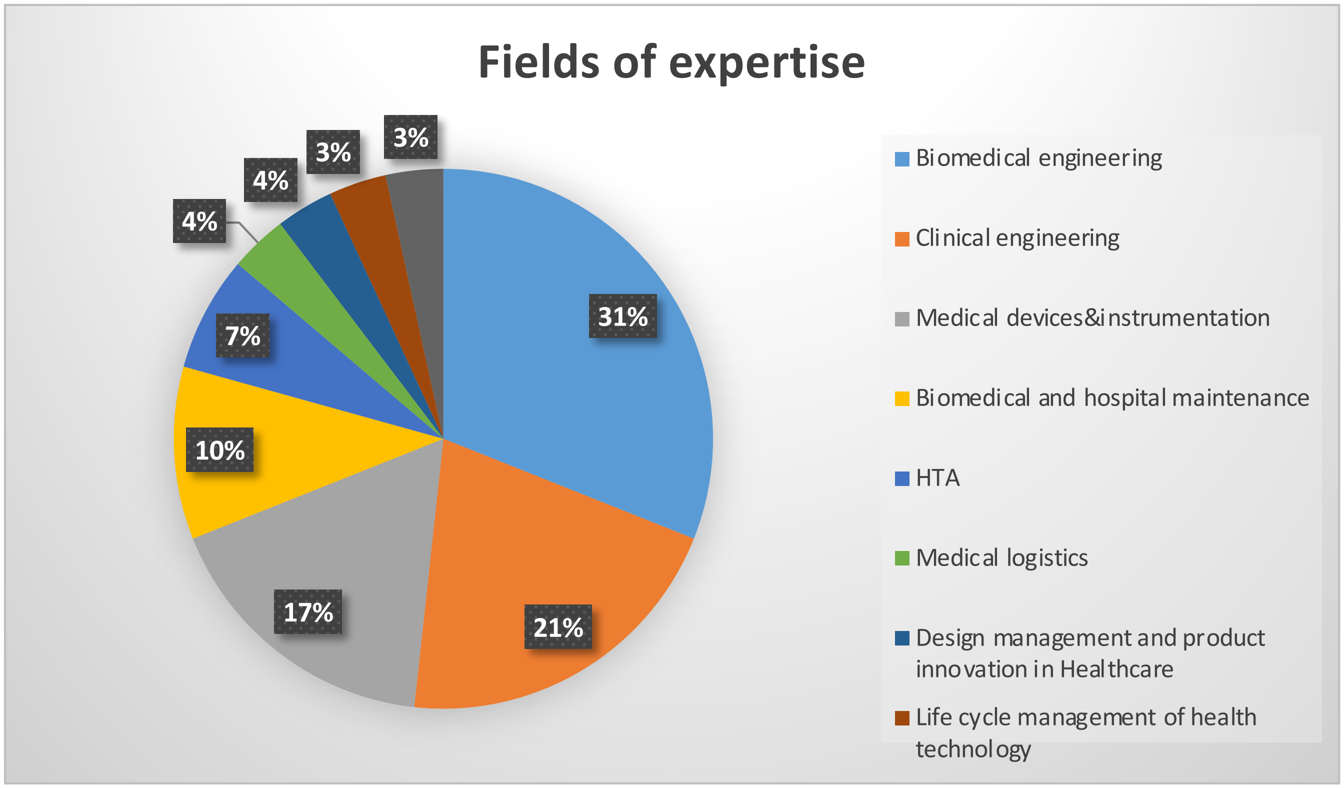
Correlation based on Goodman and Kruskal Gamma:

- Values > $|0.5|$ and p-val < 0.05 suggest a strong significant correlation

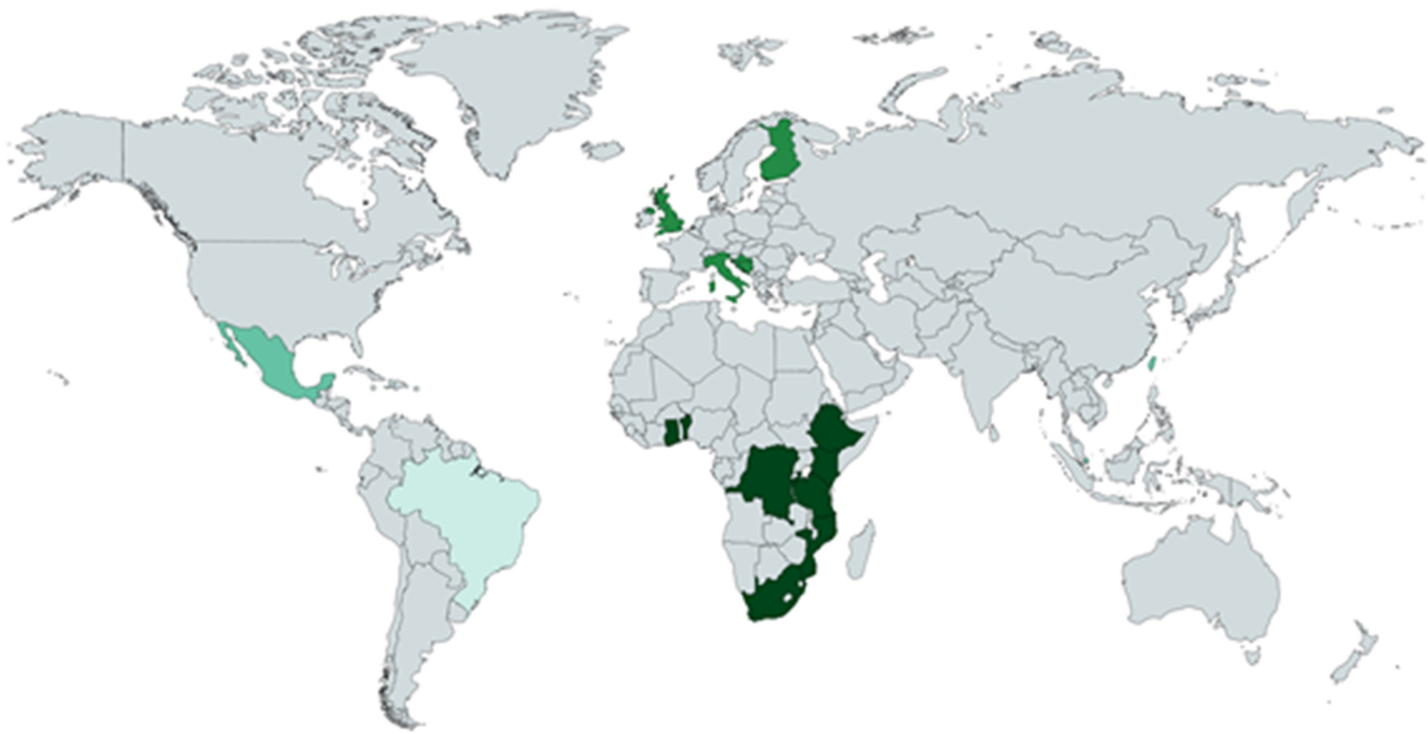
Ranking based on:

$$RI = \sum_{i=1}^{5} \frac{w_i f_i}{N}$$

Panel characteristics



Panel characteristics



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In your opinion, what are the most relevant criteria to be taken into account when designing medical devices for LRSs?

MDs resilient to LRSs

- Initial cost
- Maintenance cost
- Running costs

COST:
3 criteria

- Lifetime
- Lifetime of spare parts/components

AREA VII LIFETIME:
2 criteria

- Installation requirements
- Maintenance frequency
- Maintenance complexity
- Compatible consumables/ spare parts
- Need for consumables
- Need for spare parts

HTM:
6 criteria

- Portability, compactness, robustness
- Number of components/ spare parts
- Reusability

DESIGN:
3 criteria

MATERIALS:
2 criteria

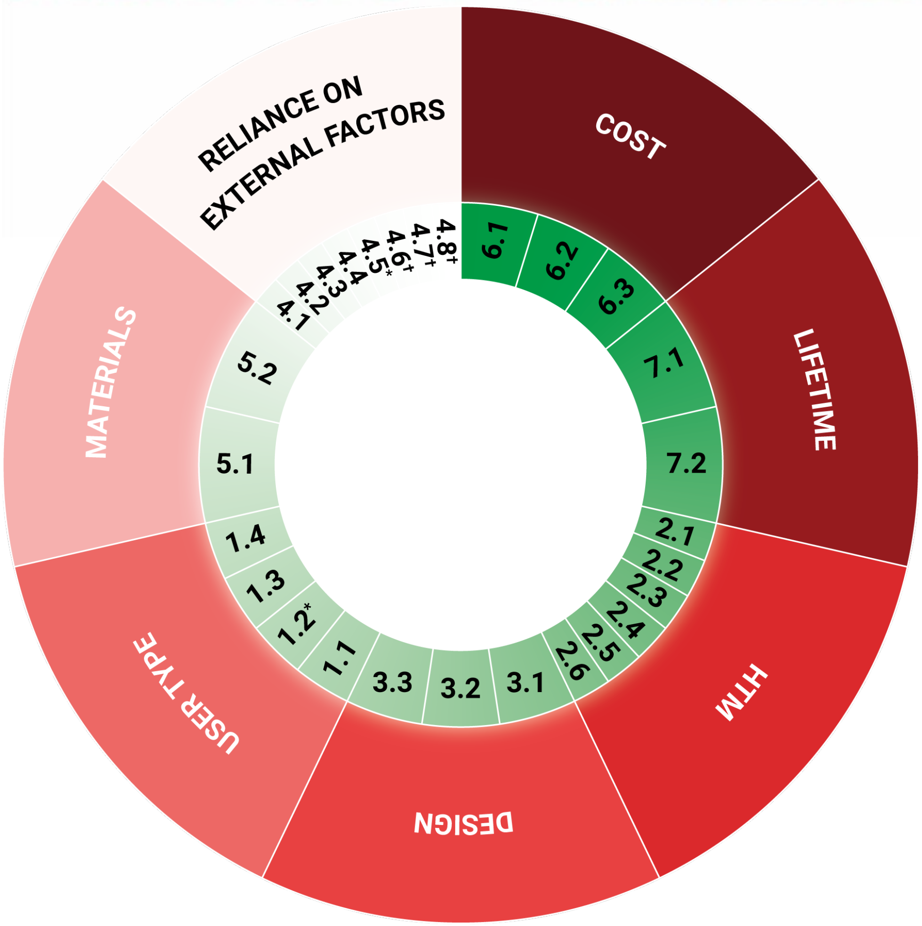
- End users' background
- Training needs
- User's understanding of technical and clinical impact

USER TYPE:
3 criteria

- Robustness
- Durability

- On power sources
- On water distribution
- On medical location air
- Need for sample preparation
- Resilience to dusty environments
- Resilience to high temperature environments
- Resilience to high-humidity environments

RELIANCE ON EXTERNAL FACTORS:
7 criteria



6.1 Maintenance costs

6.2 Running costs

6.3 Initial cost

7.1 Lifetime of MD parts/components

7.2 MD lifetime

2.1 Need for consumables

2.2 Need for spare parts

2.3 Installation requirements

2.4 Maintenance complexity

2.5 Maintenance frequency

2.6 Compatible consumables/spare parts

3.1 Portability, compactness, robustness

3.2 Limiting the number of components/spare parts

3.3 Reusability

1.1 End users' background

1.2 Easiness of use

1.3 Training needs

1.4 User's understanding of the technical and clinical impact

5.1 Durability of the material

5.2 Robustness of the material

4.1 Reliance on power sources

4.2 Reliance on water distribution

4.3 Reliance on medical location air

4.4 Need for sample preparation

4.5 Understanding/stating the dependence of the MD from the medical location characteristics

4.6 Resilience to dusty environments†

4.7 Resilience to high-temperature environments†

4.8 Resilience to high-humidity environments†

Piaggio D, Castaldo R, Cinelli M, Cinelli S, Maccaro A, Pecchia L. A framework for designing medical devices resilient to low-resource settings. Globalization and Health. 2021 Dec;17(1):1-3.

FRUGAL ENGINEERING in a nutshell

- Frugal is defined as “simple and plain and costing little” – Oxford Languages.
- Frugal comes from the Latin word *Frux*, *Frugis*, which means “fruit” to denote those who live by their own agricultural produce.
- Frugal engineering allows “achieving more with fewer resources” (Carlos Ghosn) aka a sustainable approach to engineering

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3 Pillars of frugal engineering

- **Cost reduction** – reducing purchase/ownership cost + minimise the use of materials and resources.
- **Core funtionality** – reducing complexity and efficiently respond to essential needs
- **Optimised performance** – improve performance in terms of durability, accuracy, etc. + take into account specific requirements of contexts of use (e.g., car horns in India).

Two examples

Jaipur foot – prosthetic leg made with rubber from irrigation piping

Thermoplan Lung ventilator – based on 80% coffee machine components (mass production of 800 per week at ¼ cost of an original ventilator

A reel of examples

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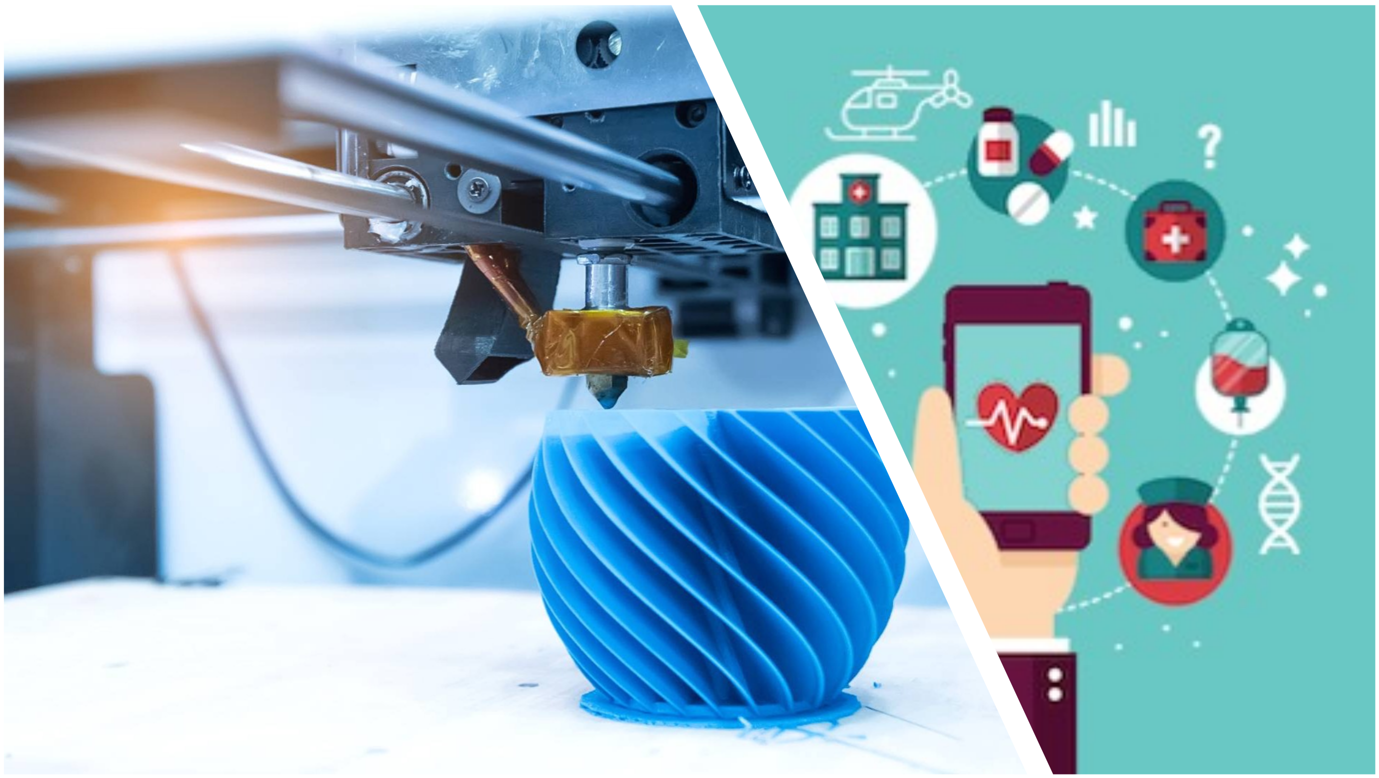
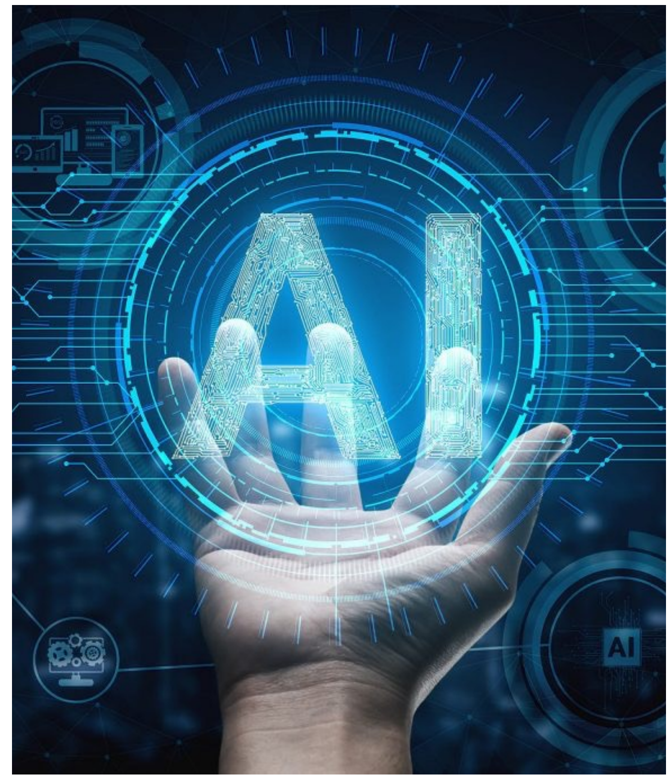
3D printing, mHealth, and AI





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A smartphone-based pupillometer

Aims and objectives

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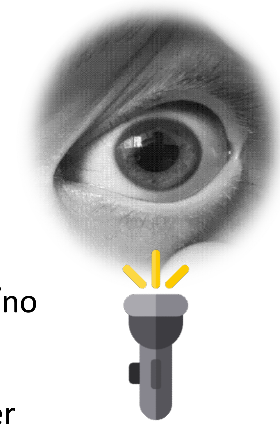
One of the 17 Goals is:

- «...ensuring Good Health & Wellbeing (3)»
- In particular, <u>Goal 3 target number 6 aims to:</u> «halve the # of global deaths & injuries from road traffic accidents by 2020»

Timely diagnosis of brain trauma is essential to avoid vehicular accident severe injuries and the related death and can be done through testing the photopupillary reflex, i.e., the reaction of the pupil to a flash of light.



The Goals of this projects were:

1. Design a digital pupilometer using only an android smartphone and little/no accessories for empowering lay-users in detecting brain-trauma
2. Validate the algorithms with manual annotated video frames and the performance of our system against a commercial infrared (IR) pupilometer
3. Test the device in LMICs

Loading . . .

Piaggio D, Namm G, Melillo P, Simonelli F, Iadanza E, Pecchia L. Pupillometry via smartphone for low-resource settings. Biocybernetics and Biomedical Engineering. 2021 Jun 8.

State of the Art

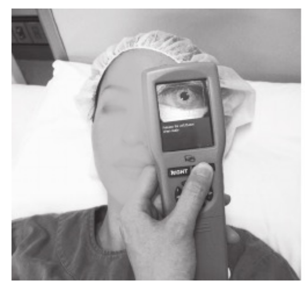
Up to $5

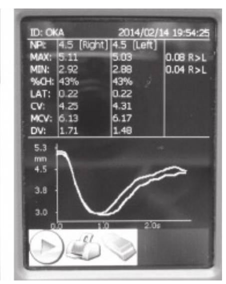
Penlight

Up to $8000

Pupillometer

Requires specialised doctors





Requires specialised doctors
It’s expensive

Piaggio D, Namm G, Melillo P, Simonelli F, Iadanza E, Pecchia L. Pupillometry via smartphone for low-resource settings. Biocybernetics and Biomedical Engineering. 2021 Jun 8.

We conducted a SWOT (**S**trengths, **W**eaknesses, **O**pportunities and **T**hreats) analysis, which informed the definition of a framework for the contextualized & user-driven design of medical devices for LMICs

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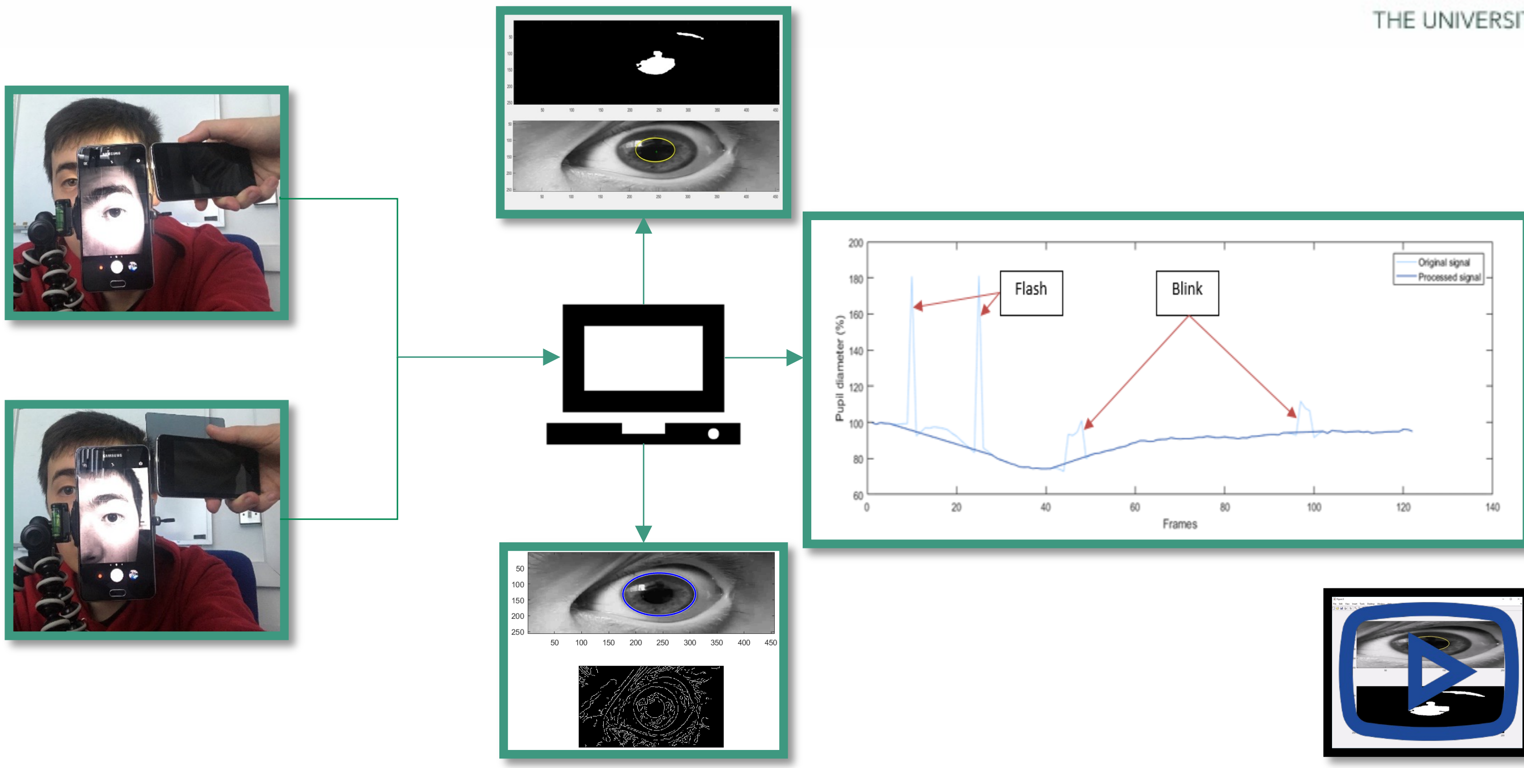
Strengths	**Weaknesses**
• Diffusion of smartphones • Easy-learners • Centralised leadership • Resilient workers • Peaceful and growing country	• Limited-resource country • Lack of specialised personnel • Poor supply chain • Poor infrastructures • Gender biases • Uneven distribution of resources
Opportunities	**Threats**
• Good coverage of wireless telecom • Flexible workers • Little/No-inertia to changes	• Shortcuts become chronic solutions • Empowered operators will never be medical doctors

- ICT-based medical device
- Low cost (free) design/deployment
- Use of familiar technologies (i.e. Apps)
- Target (potential) lay-users
- Decision support of healthcare professionals required to empower lay users
- Need to be battery based
- Easy deployment
- No maintenance
- No accessories (variable distance)
- Visible light (no IR embodied in the mobile phone)

Algorithm specs.

- Ratio Pupil/Iris
- Fitting with Gamma distribution

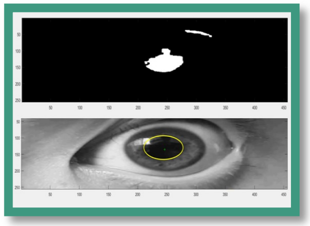
Signal Processing



Piaggio D, Namm G, Melillo P, Simonelli F, Iadanza E, Pecchia L. Pupillometry via smartphone for low-resource settings. Biocybernetics and Biomedical Engineering. 2021 Jun 8.

Materials

Matlab

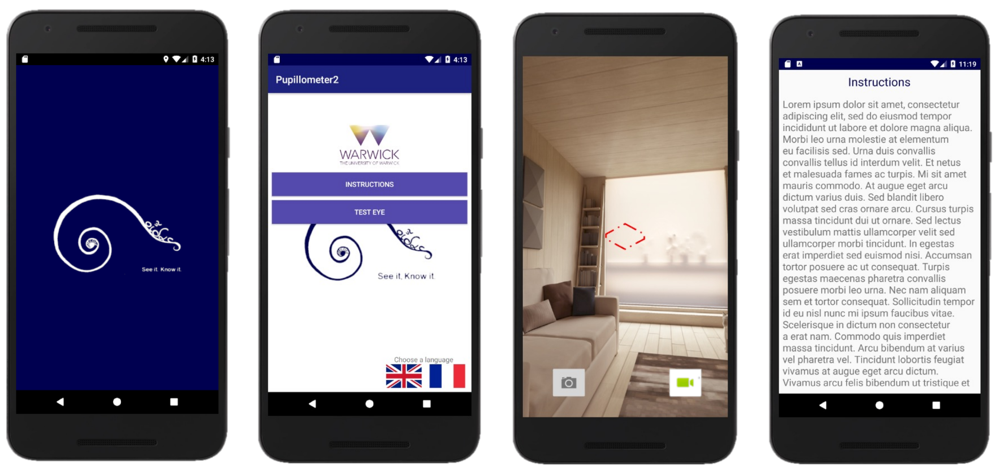


Hand Sketching

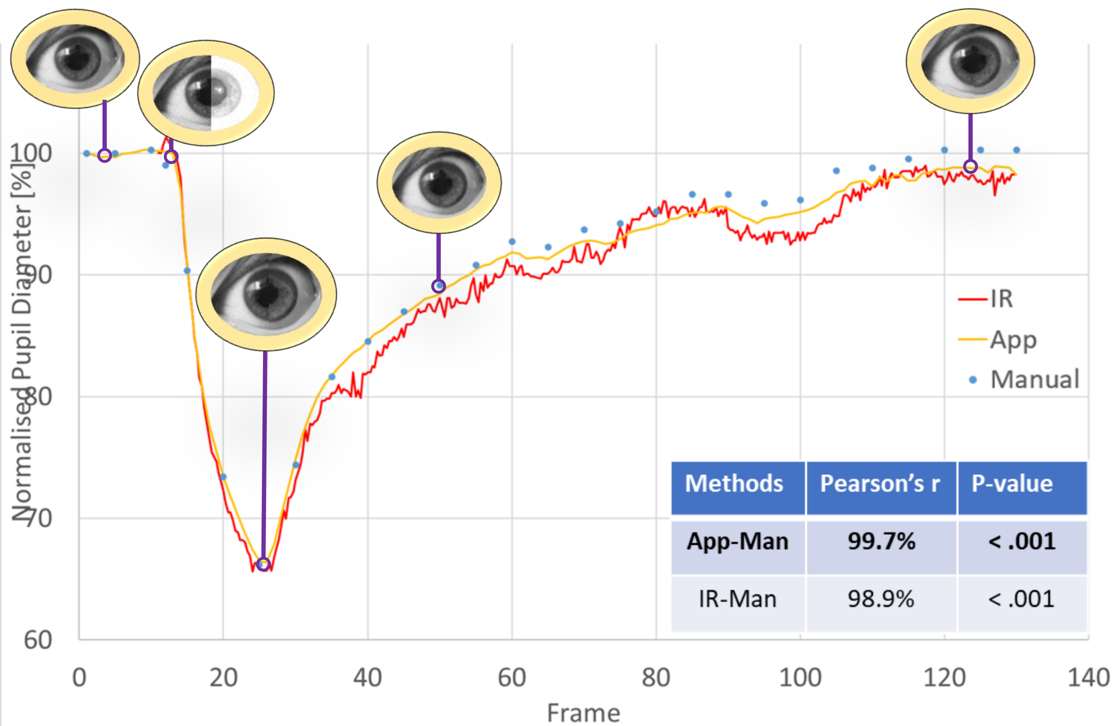
GIMP

Android Studio

Android Lollipop



Validation against a commercial IR pupilometer



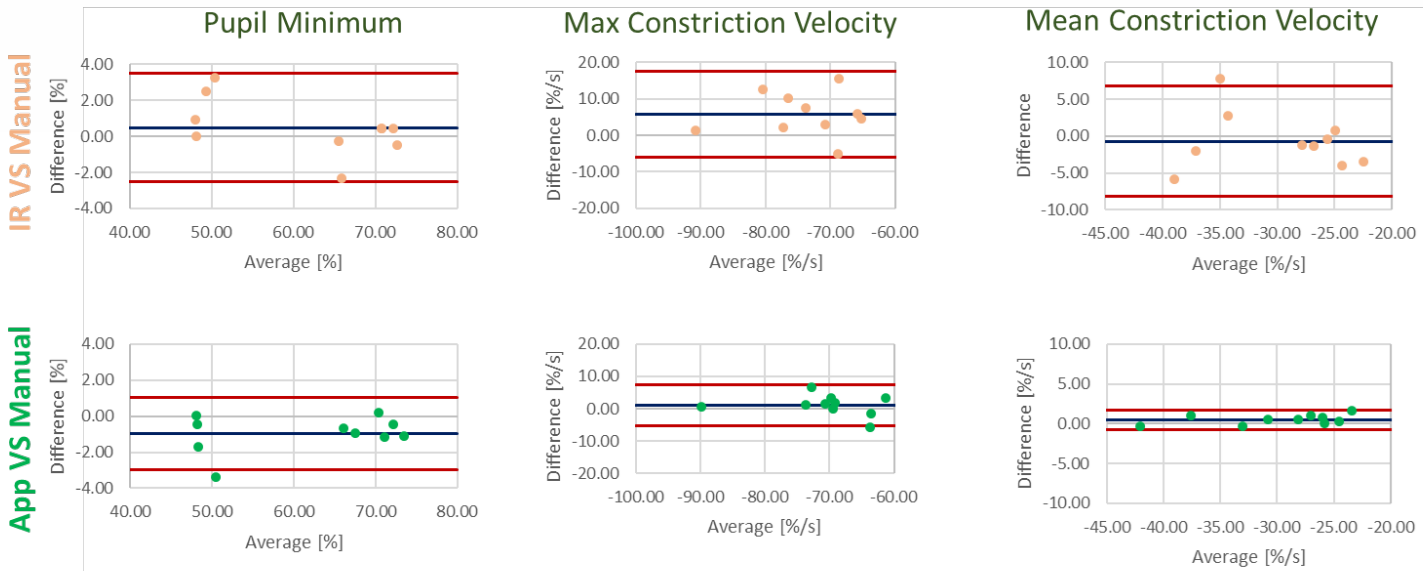
Methods	Pearson's r	P-value
App-Man	**99.7%**	**< .001**
IR-Man	98.9%	< .001

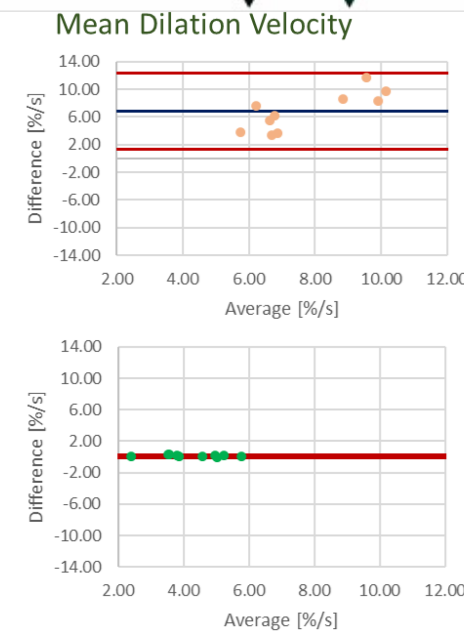
The App performed better than the commercial IR pupilometer:

- tracking better the pupil constriction compared to the manual frame-by-frame annotation, compared to the IR pupilometer (i.e., slightly better correlation)
- all the relevant features were computed with a lower error (see Table below)

	Pupil Minimum		Max Constriction Velocity per second		Mean Constriction Velocity per second		Mean Dilation Velocity per second	
	IR	**App**	IR	**App**	IR	**App**	IR	**App**
Absolute error	1.1%	**1%**	6.8%	**2.6%**	2.9%	**0.5%**	6.8%	**0.1%**
Root mean square error	1.6%	**1%**	8.0%	**3.3%**	3.7%	**0.7%**	7.4%	**0.1%**

Bland-Altman plots





Variable	Limits of Agreement (IR – Man)	Limits of Agreement (APP alg. – Man)
Pupil minimum	±3.03 %	±1.99 %
Max constriction velocity	±11.74 %/s	±6.33 %/s
Mean constriction velocity	±7.52 %/s	±1.23 %/s
Mean dilation velocity	±5.53 %/s	±0.20 %/s

The App developed performed better than the commercial IR pupillometer in all the relevant variables

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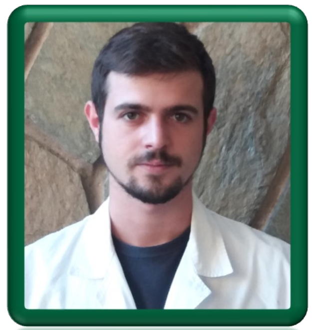
A frugal smart tool for screening for diabetic neuropathies

The team

D. Piaggio
BME

R. Castaldo BME

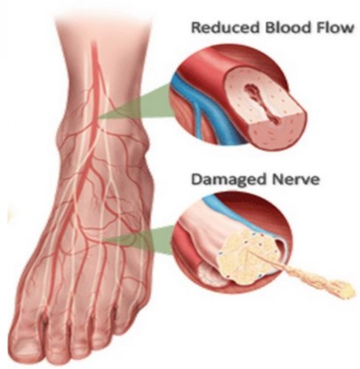


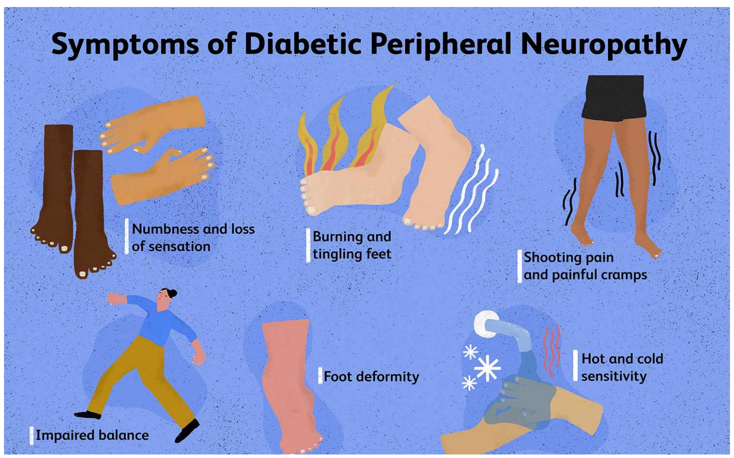
G. Garibizzo
Podologist

E. Iadanza BME

L. Pecchia
BME

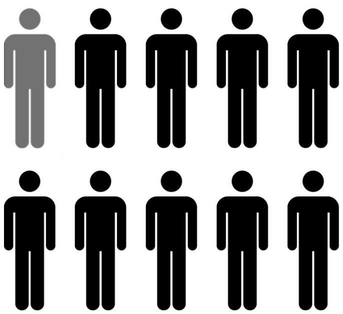
The context – Diabetic neuropathies



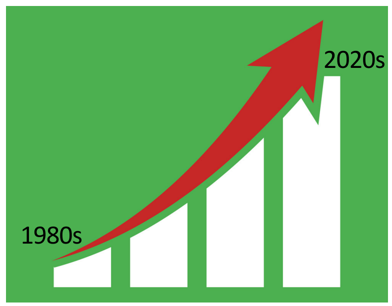


- **Diabetic neuropathies** are the top cause of neuropathy in the world and are **nerve damages** associated with **diabetes mellitus**
- Their **aetiology** is **multifactorial** - one of the main causes behind nerve damage is the direct effect of long-term hyperglycemia
- **Diabetic peripheral neuropathies** are the **most common** form
- **Symptoms** include burning/deep **pain**, hyperesthesia, **loss** of **touch**, vibration and pressure, etc.
- **Consequences** include **disability** and **mortality**

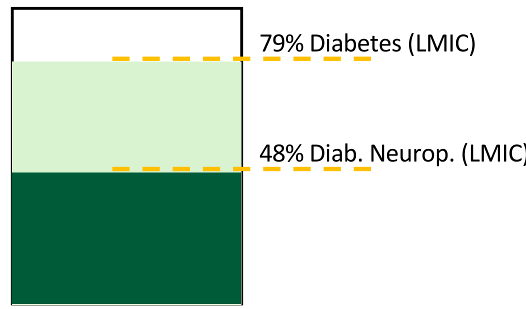
The context – Diabetes and Diabetic Neuropathies



463 million Adults affected by diabetes (2019)



Sharp increase in prevalence (x2) (still increasing)



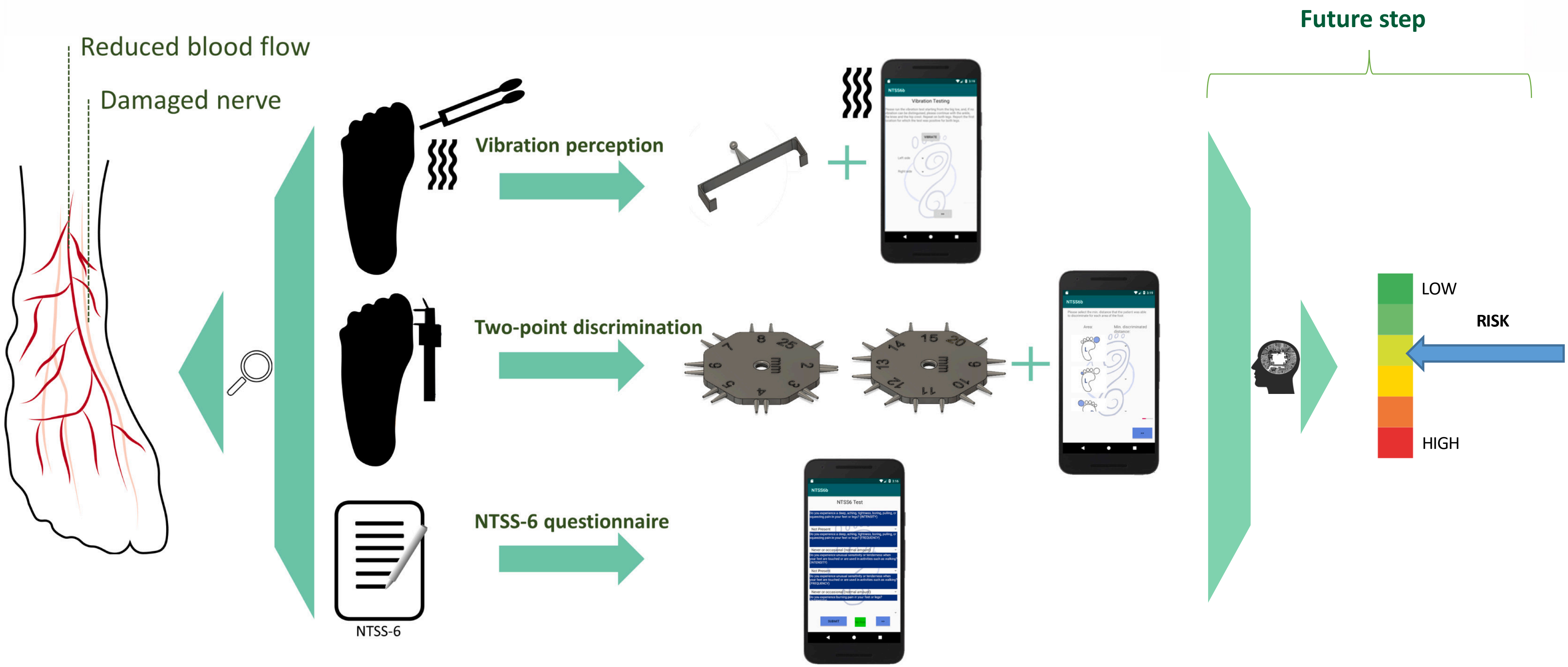
Cases from LMICs

Annual cost of diabetic peripheral neuropathies and its complications: **4.6 – 13.7 billion USD** (in US in 2001)

Aims

- In line with **UN SDG 3 – Good Health and Wellbeing - Target 3.4**. - Noncommunicable diseases: By 2030, reduce by one third premature mortality from noncommunicable diseases through prevention and treatment, and promote mental health and well-being.
- This project aims to design, develop and validate a smartphone-based screening tool for diabetic neuropathies.

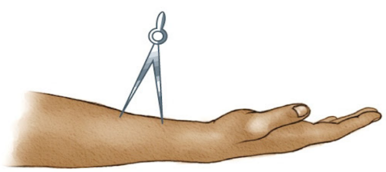
Literature review and expert-driven process selection



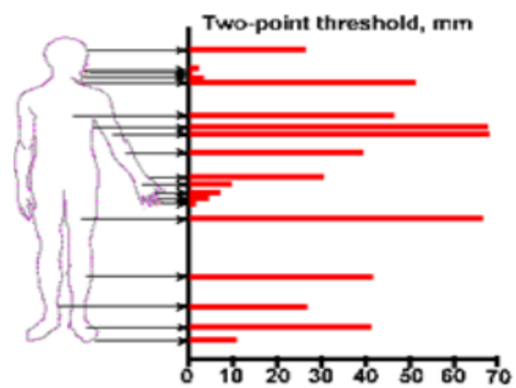
*Neuropathy total symptom score – 6 items

Further detail

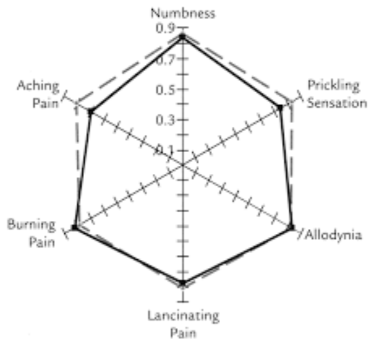
Vibration perception. 128 Hz tuning fork (but also much lower Hz), activate it and apply it to a bone on the tip of the great toe, the subject should be able to perceive the vibration (subsequent testing spots: lateral malleolus, lateral femoral condyle and hip crest).



Two-point discrimination. Two variable distance tips that pressed against areas of interest (e.g., Under the big toe), alternating one or two tips. The subject should be able to correctly individuate whether it's one or two tips touching their skin.

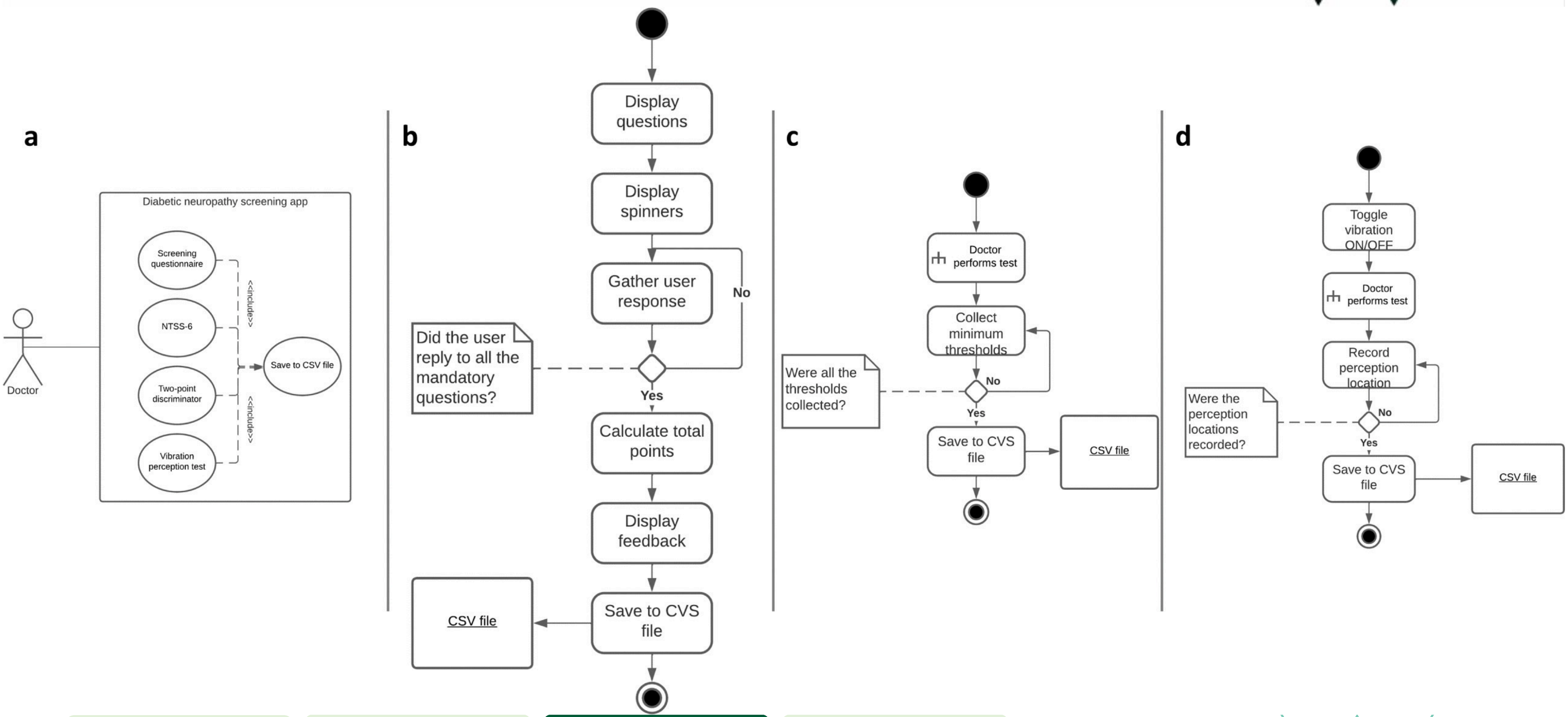


Further detail



NTSS6. Questionnaire asking about the frequency and intensity of 6 symptoms (e.g., numbness, aching pain, etc.).
Clinically significant symptoms are defined as an NTSS-6 total score >6 points.

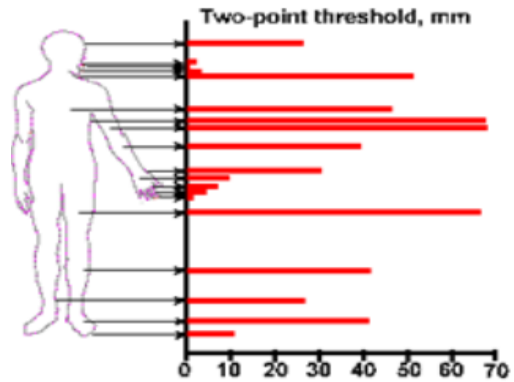
Further detail



Tests for finding normality thresholds

11 Subjects (average age of 32; 8 M) → 10 after removal of outliers

	2PD LH	2PD LLT	2PD RH	2PD LRT
Avg (mm)	8	8.5	7.5	7.7
St. Dev. (mm)	1.76	1.08	1.65	1.64

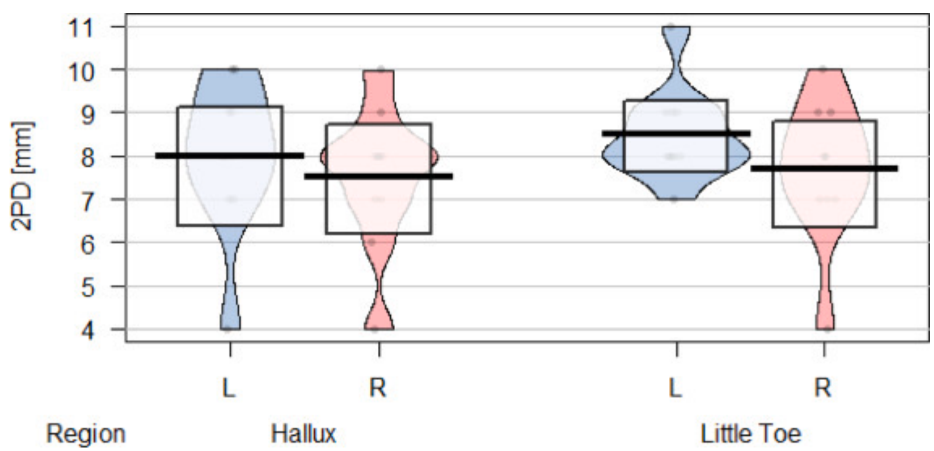


2PD stands for two-point discrimination;
LH stands for left hallux;
RH for right hallux;
LLT for left little toe;
RLT for right little toe.

Vibration was tested both with our tool and Vibratip.
Everyone could perceive Vibratip at the big toe, but only 6 could perceive our tool vibrating at the big toe (the rest at the knee)

Laterality affects the thresholds?

- The **Kolmogorov–Smirnov test could not reject the null hypothesis** that the data came from a normal distribution.
- **Paired t-test** was applied and **could not reject the null hypothesis** that the true mean difference between the paired samples is zero



Conclusions

- Designing **medical devices for low-resource settings requires** specific criteria (**frugal engineering**)
- **Our smart tool** for screening diabetic neuropathies follows this philosophy
- It proved to be **working quite well** on normosubjects
- **Limitations**: few subjects, vibration cannot be regulated in most smartphones
- **Next steps**: validate this tool in clinical practice

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A 3D-printed condom intrauterine balloon tamponade for low-resource settings

The Team / Workgroup

Prof Daton Medenou

Dr Roland C. Houessouvo

University Abomay-Calavi, Benin

Davide Piaggio (Research Assistant, PhD student)

Alessia Maccaro [Bioethicist] (Research Fellow)

Scott Hyland [mechanical eng] (MSc)

Katy Stokes [Biologist] (PhD student)

Prof Leandro Pecchia

Description

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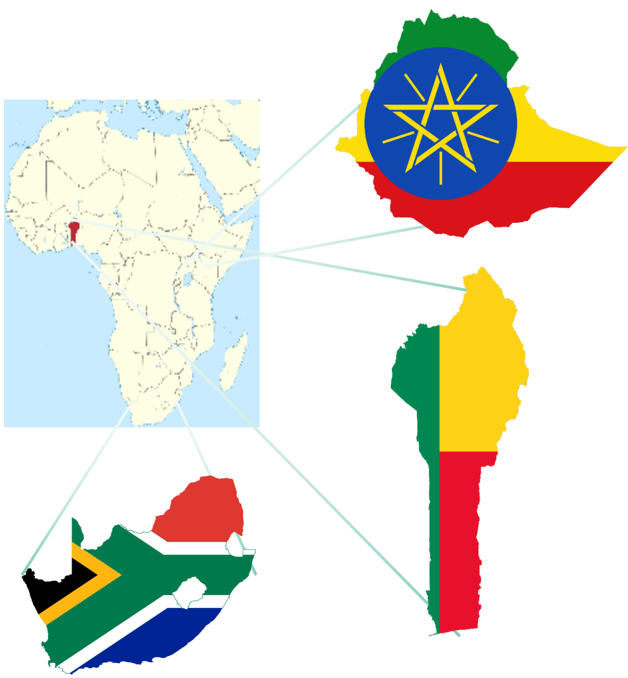
- 5 field studies in Sub-Saharan Africa in 18 months fed a SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis, which informed the definition of a framework for the contextualized & user-driven design of medical devices for LMICs
- This SWOT informed the contextual design of the 3D-printed intrauterine balloon tamponade, aiming to be a first-line treatment of postpartum haemorrhage (PPH) in low-resource settings (LRS).

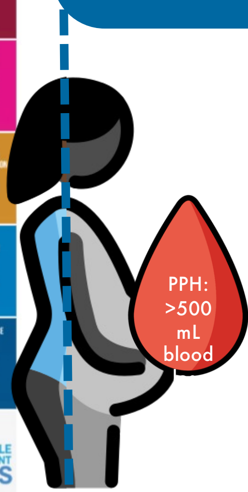


Strengths	Weaknesses
• Diffusion of condoms • Easy-learners • Centralised leadership • Resilient workers • Peaceful and growing country	• Limited-resource country • Lack of specialised personnel • Poor supply chain • Poor infrastructures • Gender biases • Uneven distribution of resources
Opportunities	**Threats**
• Flexible workers • Little/No-inertia to changes	• Shortcuts become chronic solutions • Empowered operators will never be medical doctors

- ❖ Leverage on **circular economy** (using 3D printers and protocyclers) and capacity building;
- ❖ Recycling old parts of the same device;
- ❖ Local manufacturing
- ❖ Use of **water bottles**;
- ❖ Use of **condoms;**
- ❖ **Affordable** (free) design/deployment
- ❖ **Target** (potential) lay-users
- ❖ Easy deployment
- ❖ No maintenance

Goals of the project and final users that will benefit

25% of maternal mortalities worldwide are due to PPH



Chance of death during childbirth and pregnancy in LRSs

Chance of death during childbirth and pregnancy in higher resource settings

One of the 17 Goals is:
«...ensuring Good Health & Wellbeing (3)»

In particular, Goal 3 target number 1 aims to:
«reduce the global maternal mortality ratio to less than 70 per 100,000 live births by 2030»

The Goals of this projects were:

1. **Design and prototype a 3D-printed condom-based intrauterine balloon tamponade,** based on circular economy principles, for empowering lay-users in treating PPH
2. **Preclinically validate device** measuring the water leak and the pressure drop over time in two conditions (i.e., open air and in a 3D-printed uterus model)
3. Run **clinical trials**

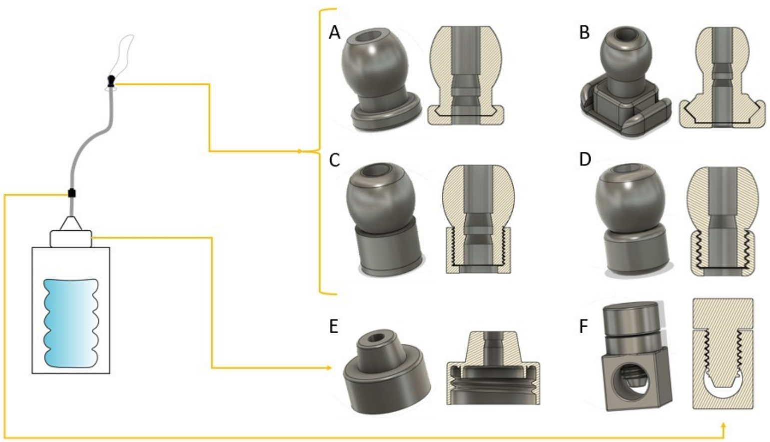
Loading ...

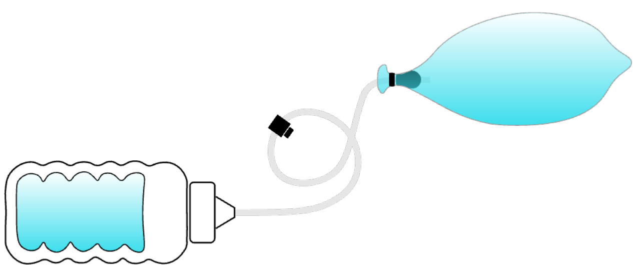
Final Users: given the scarcity of specialised doctors and of devices (and spare parts) for this health condition, there is a clear need for a simple but effective device to treat PPH

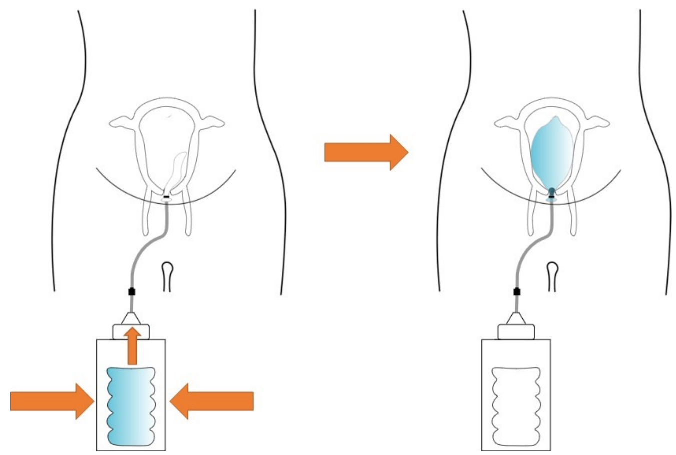
SUSTAINABLE DEVELOPMENT GOALS

Methods – Design and prototyping

- The device was designed using Autodesk Fusion 360, sliced on Cura, and printed on a Creality Ender 3 3D printer





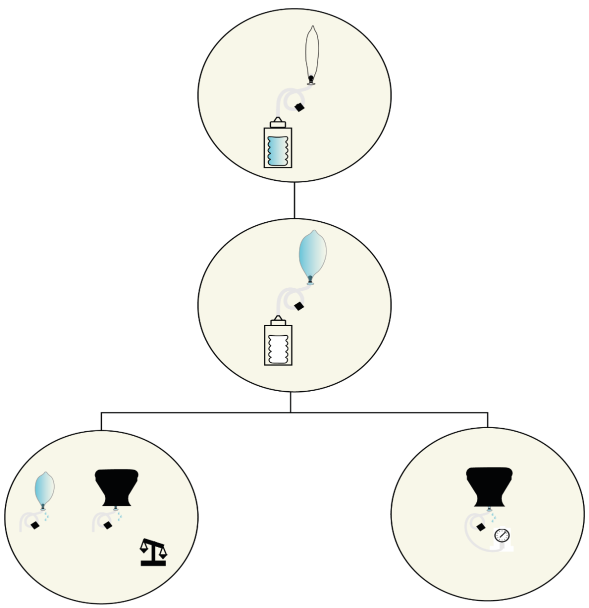


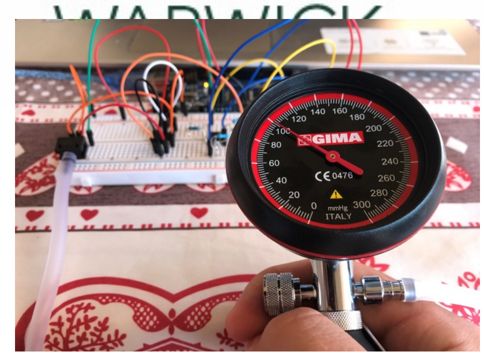
Material - PLA
Layer height - 0.16 mm
Infill - 15%
Nozzle temperature - 200°C
Bed temperature - 40°C

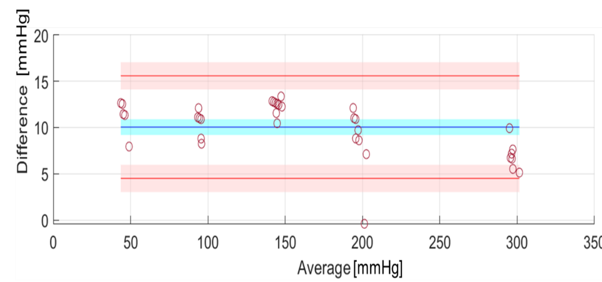
For threaded valves:
M11x0.75 (finer), M11x1.5 (coarser)

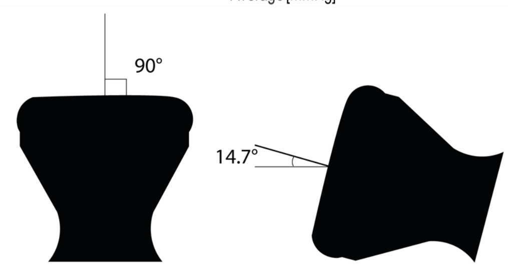
Methods – Validation and testing

The device was validated measuring the volume of leaked water and of lost pressure over time, in two conditions (i.e., open air and in a 3D-printed uterus model***). For measuring the loss of pressure an ad-hoc circuit was created on Arduino, using a pressure sensor (a manometer was used as a benchmark).









*** Uterus model adapted from: Mollazadeh-Moghaddam K, Dundek M, Bellare A, Borovac-Pinheiro A, Won A, Burke TF. Mechanical Properties of the Every Second Matters for Mothers-Uterine Balloon Tamponade (ESM-UBT) Device: In Vitro Tests. AJP reports. 2019 Oct;9(4):e376.

Results

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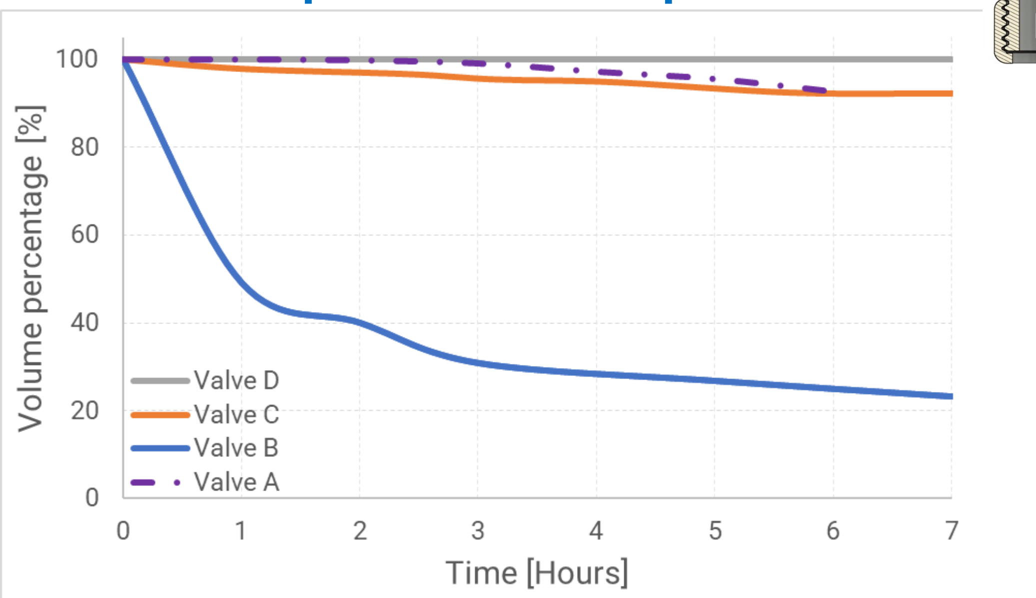
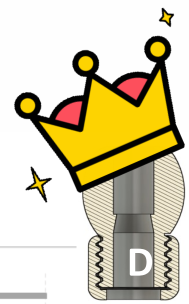
Valve performance comparison

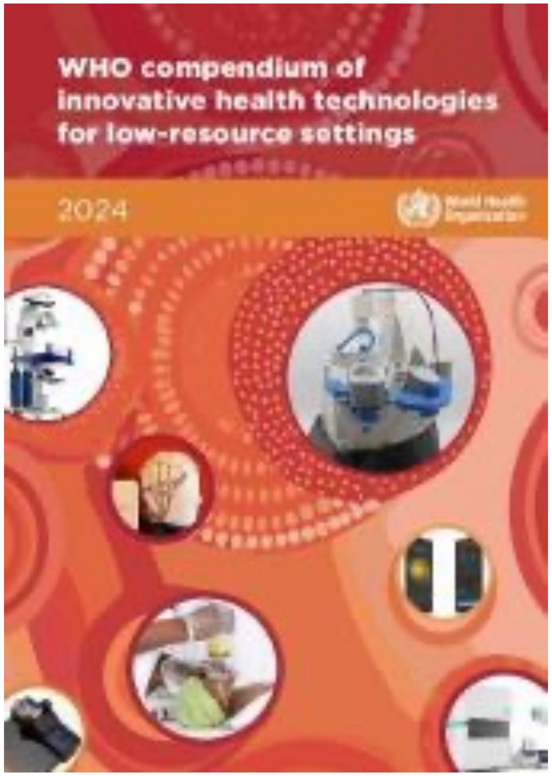




Variable	Open Air	In Uterus model***
Average Water Leak (mL/h)	0	2.47
Total Water leak (mL)*	0	14
Average Pressure loss (mmHg/h)	----	0.93
Total Pressure loss (mmHg)**	----	2.75

*over 5+ hours
** over 3 hours

Further considerations



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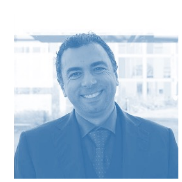
Pecchia L., Piaggio D., et al. "*Inadequacy of regulatory frameworks in time of crisis and LRSs: PPE and COVID-19*", Health and Technology, 2020

- Regulations require that PPE comply with tests and parameters set by international standers in order to be marketed/distributed
- Those standards are:
  - too generic;
  - mainly written be sellers with the aim at covering the wider possible market (e.g., getting the mask into any working place: hospital, foundry, sawmill…)
- For instance:
  - Visors have to pass the bullet test. While this is reasonable for sawmill, this is not for hospital
  - Masks have to pass heating test ad very high temperature (e.g., 75 degrees). Reasonable for a founder, not for hospitals
- We systematically analysed the needs and requirements for PPE in hospitals proposing a frugal set of essential tests that masks and visors should have been tested against, in order to be safe and effective.
- E.g., for Mask, only 3 tests are required (compared to the 20+ required by relevant standards):
  - Filtering
  - Breathability
  - Fitting

Pecchia L, Piaggio D, Maccaro A, Formisano C, Iadanza E. The inadequacy of regulatory frameworks in time of crisis and in low-resource settings: personal protective equipment and COVID-19. Health and technology. 2020 Nov;10(6):1375-83.



A. Maccaro, D. Piaggio, S. Pagliara, L. Pecchia, *"The role of ethics in science: a systematic literature review from the first wave of COVID-19"*, Health and Technology, 2021

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AIMS: To understand the impact and the perception of the pandemic during the first wave (January-June 2020) and the consequences one year later.

METHODS: PubMed was systematically searched up May 2020 to identify studies that took into consideration various ethical issues that have been arising from the Covid-19 outbreak.

RESULTS: 38 studies out of 233 met our inclusion criteria and were fully analysed. Accordingly, this review touches on themes such as fairness, equity, transparency of information, the duty of care, racial disparities, the marginalisation of the poor, and privacy and ethical concerns.

CONCLUSIONS: Reflecting one year after the outbreak of the pandemic, it is clear that the ethical issues linked to Covid-19 are many, particularly sensitive, and still need to be investigated further. Moreover, the need for the integration of ethics not only as a "humanitarian" enrichment to scientific studies, but as a moral compass in times of crises, is even clearer.

A. Maccaro, D. Piaggio, C. Dodaro, L. Pecchia, *Biomedical engineering and ethics: reflections on medical devices and PPE during the first wave of COVID-19*, BMC Medical Ethics, 2021

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AIMS: To investigate and analyse the relation among ethical issues emerged during Covid-19 pandemic and Biomedical Engineering

METHODS: bioethical analysis

RESULTS&CONCLUSIONS: Among the most recurrent ethical issues surfaced during the first months of COVID-19, there are: **allocation of resources, the responsibilities of science, and the inadequacy and non-universality of the norms and regulations on biomedical devices and personal protective equipment.**
These ethical issues, analyzed one year after the first wave of the pandemic, come together in the appeal for

- responsible thought
- responsible action
- responsible silence

This highlights the importance of interdisciplinarity and the definitive collapse of the Cartesian fragmentation of knowledge, calling for the creation of more fora, where this kind of discussions can be promoted.

A. Maccaro, D. Piaggio, M. Vignigbe, A. Stingl, L. Pecchia

“Covid-19 pandemic - Social and Healthcare dynamic impact in Benin”, at Health Promotion International

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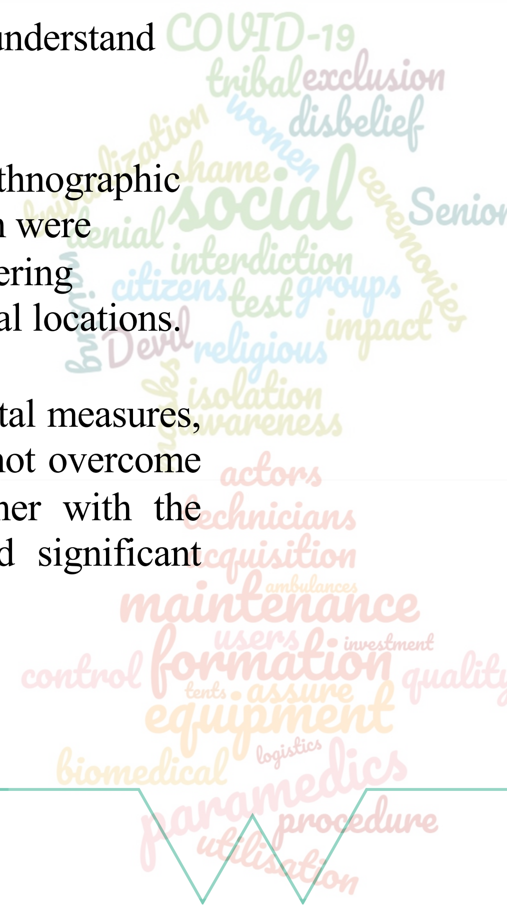
AIMS: To assess and analyse the perception and impact of the COVID-19 pandemic, as well as to understand the government and hospital preparedness in Benin, a sub-Saharan West African country.

METHODS: The research methodology was interdisciplinary and combined field studies that used ethnographic and social research methods with coding and data analysis, leading to theoretical dilemmas, which were analysed from the viewpoint of bioethical reflection. Furthermore, biomedical and clinical engineering approaches were used to assess the preparedness to COVID-19 of the governments and the medical locations.

RESULTS&CONCLUSIONS: Despite the preparedness to COVID-19 due to the promoted governmental measures, a peculiar management of the pandemic emerged. The latter, in fact, although noteworthy, did not overcome the typical technical challenges of medical locations in low-resource settings. This, together with the controversial transmission and reception of scientific information, and local beliefs caused significant economic and social consequences, exceeding the benefits related to the containment of the virus.



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APRIL

3 ... Assessment of Mould Remediation in a Healthcare Setting Following Extensive Flooding
With Manjula Meda, UK

10 ... Use of Artificial Intelligence for Healthcare-Associated Infection Surveillance
With Prof. Ruth Carrico, US

Afro-European Teleclass
22 ... Cost Analysis of a Hand Hygiene Improvement Strategy in Long-Term Care Facilities
With Dr. Anja Haenen, Netherlands

24 ... What's Lurking in Your Sinks? Past Problems, Present Challenges, and Future Technologies
With Dr. Mark Garvey, UK

Australasian Teleclass
30 ... The Impact of Sink Removal and Other Water-Free Interventions in Intensive Care Units on Water-Borne Healthcare-Associated Infections
With Jia Ming Low, Singapore

MAY

5 ... Special Lecture for World Hand Hygiene Day
With Prof. Didier Pittet (and friends), Switzerland

15 ... Non-Ventilator Hospital Acquired Pneumonia
With Prof. Michael Klompas, US

22 ... COVID-19 Preparedness – What Went Wrong? What Are the Next Steps? The Point of View of a Biomedical Engineer
With Prof. Davide Piaggio, UK

JUNE

2 ... IPAC Considerations in Global Emergencies
With Dr. Bois Marufov, Canada

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