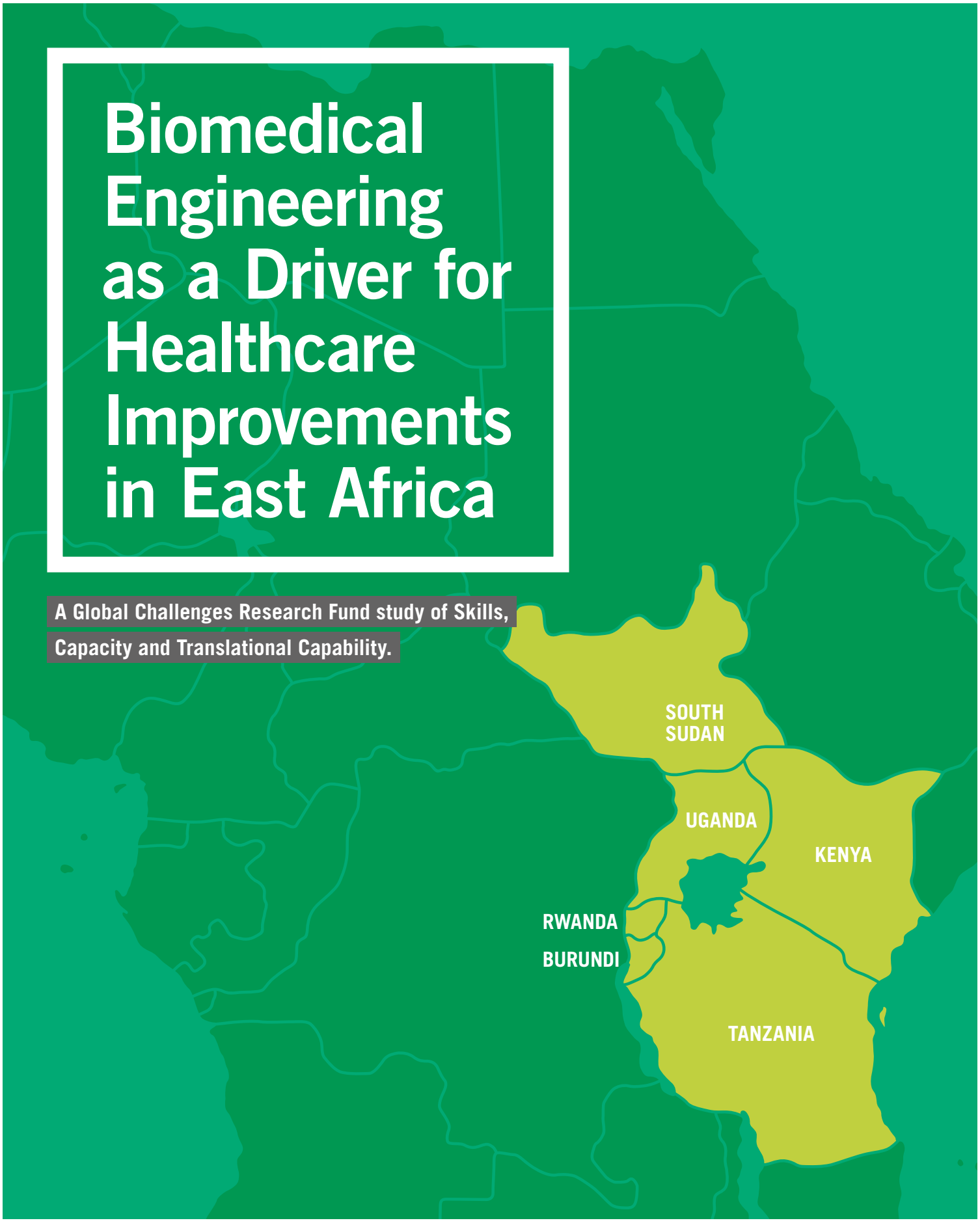
# Biomedical Engineering as a Driver for Healthcare Improvements in East Africa

A Global Challenges Research Fund study of Skills, Capacity and Translational Capability.




Medical Technologies Innovation and Knowledge Centre

GCRF Global Challenges Research Fund

Royal Academy of Engineering

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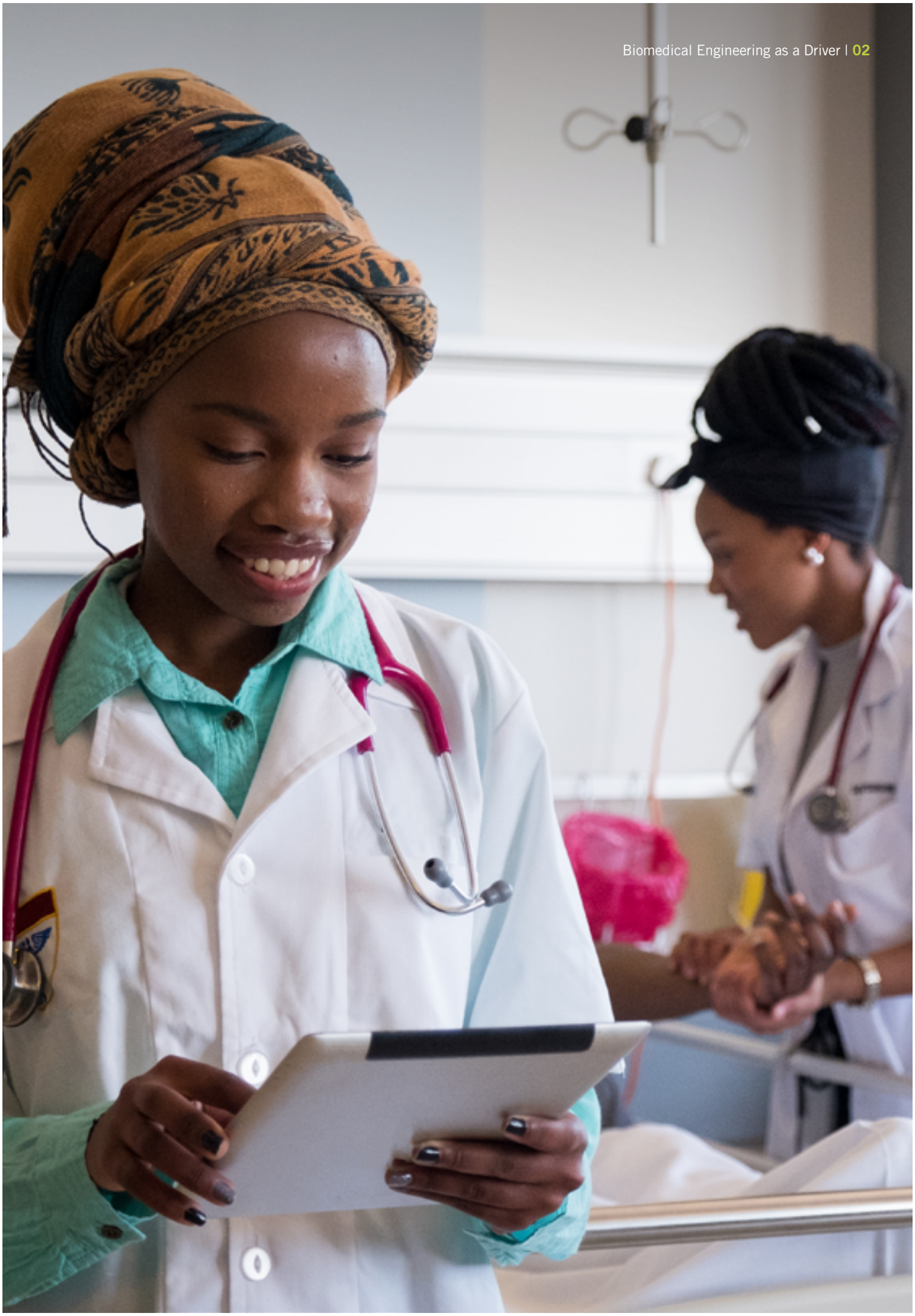

# Foreword

**This report is an output of a Global Challenges Research Fund-supported project to examine the capacity and translational capability of biomedical engineering (BME) in East Africa. These countries each face particular challenges in providing healthcare to their populations. We wanted to understand the extent to which the BME specialisation could contribute to meeting these challenges. Given the right conditions and support, can BME drive improvements in this provision?**

We have sought to review status, strengths and weaknesses – for BME itself and of the ecosystem in which it is applied. We have provided case studies to shed light on these and on barriers encountered. Through field work, remote data gathering and workshops our Leeds-Makerere team have consulted widely to ensure that this report reflects the views of the community involved in translating and delivering medical technology (as an output of biomedical engineering).

It is therefore our hope that the findings, conclusions and recommendations presented here will aid policy- and decision-makers in devising strategies and creating conditions that allow the current and potential benefits of BME for East Africa to be fully realised. These are more likely than ever to be crucial as Africa responds to the effects and consequences of Covid-19 and economic shocks arising from climate change, global inflation and the instability connected to Russia's invasion of Ukraine.

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# Executive Summary

**Biomedical engineering (BME) is the application of engineering principles to medical, clinical, and biological settings to design and create equipment, devices, computer systems, and software used in healthcare. As such, it occupies a pivotal role in the provision of appropriate equipment, the delivery of diagnoses and treatments, and the management of the health of the populations to which it is applied.**

**Its overall output, medical technology (MedTech), is a global sector growing in both economic value and strategic importance.[1] Consequently, BME should be well placed to be a driver for healthcare improvements, economic growth, and job creation.[2]**

It is in this context that we undertook the audit of skills, capacity, and translational capability in East Africa described in this report. Simply put, can support for "health technologies, especially medical devices... empower health workers to provide lifesaving healthcare services"[3] in this region?

East Africa has an opportunity to take advantage of BME as a relatively new field that is already served by training institutions located in the nations of this region. Health systems are mostly sufficiently developed to accommodate a greater role for biomedical engineers, although there are structural and professional barriers which we draw attention to in this report. The East African Community (EAC) has challenges serving a very young and growing population, providing basic healthcare to all, and dealing with the growing burden of non-communicable diseases. To this has now been added the severe challenge of Covid-19. Africa is dependent on imported medical equipment and devices[4], much of which is neither adequately managed nor designed with the levels of redundancy needed for these settings; consequently, these devices and equipment are not well adapted for the environment in which they are deployed.[5] As noted in this report, the translation of new MedTech products, designed appropriately for the East African setting, faces barriers of uncertain regulatory pathways, funding constraints, and limited opportunities for local companies to penetrate this market. Although there is a steadily increasing middle class driving demand for healthcare services, incomes in the overall population are low. Internet connectivity is inconsistent across the region despite a growing demand for mobile healthcare applications.

Our team, based largely in Uganda, gathered data from across East Africa using questionnaires, telephone and one-to-one interviews, roundtable meetings, and workshops involving stakeholders. With these, we explored the hypothesis underpinning this audit. Workshops were used to present preliminary findings. Consensus statements were generated at a workshop held in Kampala in November 2019 attended by stakeholders from Burundi, Kenya, Rwanda, Tanzania, and Uganda. This report thus captures the views of this community.

We found that Biomedical Engineering as a Driver for Improvements in Healthcare in East Africa is an aspiration that can be realised if barriers and gaps in skills, resources, translational competence (with new, structured translational pathways), and regulations are addressed and other organisational issues (such as procurement and role/status of biomedical engineers) are tackled. Furthermore, national priorities for BME need to be established and a trans-EAC group set up to coordinate training, professional development, and establishment of good practice with an aim to build capacity and capability in BME. A nascent MedTech industry addressing the healthcare needs of populations within the EAC and other low- and middle-income countries (LMICs) should be encouraged and supported.

**This report concludes with a set of recommendations designed to address the barriers listed above. These are to:**

- **Prioritise BME to address skills gaps.**
- **Streamline medical device regulations.**
- **Establish systems for better professional organisation, training and accreditation of BME throughout East Africa.**
- **Invest strategically in industry and ecosystem so that East Africa is recognised as MedTech innovation hub.**
- **Improve medical equipment procurement and lifecycle management.**

We urge that these recommendations are reviewed and implemented to facilitate the development of BME as a profession and the building of the required levels of capacity and capability. Regulations need to be well defined to allow for the efficient and safe translation of technology and the establishment of a vibrant MedTech industry that can effectively address the healthcare needs of East African populations.

# An Audit of Skills, Capacity, and Translational Capability supported by the UK Global Challenges Research Fund

## Introduction

**A recent (2019) World Bank regional outlook report for Africa[1] is a sombre read. Growth forecasts were cut to 2.6% from the previous 2.8%. Strong GDP growth during 2018 decreased slightly in 2019 for East Africa – although Rwanda remains one of the strongest growing economies in the world. Despite a modest GDP growth, the number of people living in poverty across Africa as a whole continues to increase – estimated at 416.5 million in 2015 (compared to 278 million in 1998)[1].**

**The outlook that Africa may be home to 90% of the global poor by 2030 is not an encouraging one. Coupled to this is the observation by WHO in 2006 that "sub-Saharan Africa, with 11% of the world's population, 24% of the global disease burden and only 3% of the world's health care workers, faces the greatest challenge"[2].**

**Of course the emergence of Covid-19 in 2020 has further exacerbated this situation. Additional economic shocks have followed.**

In this report, Biomedical Engineering as a Driver for Healthcare Improvements in East Africa, supported by the Global Challenges Research Fund (GCRF), we review, amongst other things, the national strategic plans of the six countries of the East African Community (EAC). Taken together, these stress the importance of STEM (science, technology, engineering and mathematics), innovation, upskilling of the workforce, and structural adjustments in the economy to improve competitiveness. An emphasis on enhanced healthcare provision, often through investment in infrastructure and training of healthcare professionals, is a common theme of these plans. We consider this alongside the demands on healthcare systems and the resources made available as summarised in the following sections of this Report. As the World Bank report notes, "New technologies will play a key role in connecting people to jobs and markets, building their skills, and making health and education services more accessible and higher quality."[3]

The title of our report – "Biomedical Engineering as a Driver for Healthcare Improvements in East Africa" – is actually a proposition for which we have now conducted preliminary testing. Critically, we wanted to know:

- **Will continued – and possibly increased – investment in biomedical engineering (BME) across the nations of East Africa result in improvements in healthcare?**
- **What might facilitate this further and what works against it?**

In the West, in addition to being applied in a number of different fields[4], BME provides the knowledge, skills, practices, and capabilities to drive the MedTech industry which, in turn, is a key provider of economic (as well as health and societal) benefits.[5,6,7]

The conclusions of the Science and Innovation Audit (SIA) of the UK's Leeds City Region[8] also support this, as do the conclusions of a major study of the East African region by the Social Entrepreneurship Accelerator at Duke (SEAD) at Duke University.[9]

Supporting and developing capability and capacity in BME in East Africa works towards the UN Sustainable Development Goals (SDGs) to "[b]uild resilient infrastructure, promote sustainable industrialisation and foster innovation" (SDG 9) and to "[e]nsure healthy lives and promote wellbeing for all at all ages" (SDG 3).[10] As noted in WHO's overarching and comprehensive review[11, 12], biomedical engineers (as practitioners acting "where biology meets medicine meets engineering") should be considered as important members of the health workforce supporting the goal of universal health coverage.

Consequently, this report considers the status of BME and its potential to be a strong contributor to these goals and an agent for improving healthcare provision in East Africa.

# Overview: Biomedical Engineering in East Africa

**BME is the application of engineering principles to medical, clinical, and biological settings to design and create equipment, medical devices[13], computer systems, and software used in healthcare. The term first emerged after World War II as engineering began to be applied to medicine and biology.[14]**

The field itself began to emerge in Africa with the establishment of the Department of Systems and Biomedical Engineering at Cairo University in 1976[15] and initiatives in Nigeria around the same time[16]. However, those few African universities that did subsequently introduce BME courses tended to teach curricula transferred from Western universities that emphasised the conditions, technologies, and equipment infrastructure prevalent in those settings.[17] A bottom-up, pragmatic approach emerged alongside university-based training with the BME training at certificate level that began to be offered in Kenya in 1978 (see Biomedical Engineering Training Institutions in East Africa, below).

BME is still viewed as a new discipline. This opinion was frequently encountered during interviews conducted for this project. Training at certificate, diploma, and degree levels was introduced in the context of numerous challenges faced by the health sector, including limited access to medical equipment support services and a dearth of critical medical devices. The lack of biomedical engineers and technicians in East Africa eventually led to much medical equipment in health facilities being out of service and even unserviceable due to the specialist nature of much of this equipment and its sourcing from Western countries, which made call-out of an engineer for repair or service both impractical and unaffordable. East African countries comprehended that improving healthcare delivery involved strengthening training institutions, hospitals, regulatory bodies, government policies, and medical equipment manufacturers and suppliers.[18,19,20] It is on this note that a strategy of training biomedical engineers and technicians was developed to improve the state and usability of medical equipment in health facilities.

Training in BME was first introduced at certificate level in Kenya in 1978 in collaboration with the Austrian government.[21] Programmes were introduced at diploma level in Uganda in 2007 by the Ernest Cook Ultrasound Research and Education Institute (ECUREI), in Rwanda in 2010 by the Integrated Polytechnic Regional Center (IPRC), and in Tanzania in 2011 by Dar es Salaam Institute of Technology (DIT). In 2011, Makerere University in Uganda became the first East African university to offer a degree training programme in BME. Figures for 2019 indicate that Uganda had 186 diploma and 282 bachelor's students enrolled in BME training.

The national strategic plans of East African countries indicate a willingness to embrace technology and invest in innovation and training to close the healthcare gap so that patients benefit fully from available medical equipment (see[22], for example). In addition to centralised planning, there is evidence of BME capability being improved through the establishment of private–public partnerships[23] and collaborations with organisations from both within and outside the region. These organisations include charities, voluntary bodies, government bodies, community organisations, social enterprises, diagnostics and device companies, cooperatives, and private research institutes.[24]

The African Biomedical Engineering Mobility (ABEM) project[25], through the Africa Biomedical Engineering Consortium (ABEC), has collaborated with universities in East Africa (Mbarara University of Science and Technology [MUST] and Kenyatta University[26]) to train postgraduate students in needs-based health technology research, development skills, and specialisations not offered at their home institutions. Correspondingly, Makerere University established partnerships with Duke University, USA, to set up a master's scholarship programme for a total of six BME graduates to train at Duke over the period 2017–2020[27], with the aim of building and equipping the Biomedical Engineering Faculty at Makerere.

Centres of Excellence have been established in all East African countries to, amongst various other aims, further increase the numbers and competences of trained personnel and close the gap in healthcare delivery. These centres serve not only to advance the biomedical engineering field but also address issues affecting the quality of healthcare in East Africa. Rwanda has assumed a role as East Africa's hub for technology and is home to the regional Centre of Excellence in eHealth and Biomedical Engineering (CEBE; see Case Study 3, p. 48). Uganda is the Centre of Excellence in treating cancer, while Kenya is charged with a focus on urology, Tanzania focuses on cardiac disease treatment improvements, and Burundi handles nutritional issues.[28] In addition to the presence of Western-based multinational companies (e.g., Abbott[29] and Roche[30]), local medical companies have been established to supply medical equipment in East Africa. For example, Crown Healthcare (see The MedTech Industry in East Africa, p. 29) has grown to be a leading solutions provider of medical equipment within the East African Region, with offices in Kenya, Tanzania, Uganda, and Rwanda.

With the training of biomedical engineers now well established, the emergence of medical equipment companies and the strong track record of partnerships and collaborations with Western universities have created a rationale and environment for the current project's systematic review of the capacity and capability of BME as a specialist field in East Africa. This review invites a consideration of how best to use this field as a resource to drive improvements in healthcare delivery in East Africa and to generate economic benefits consistent with SDGs 8 and 9[10].

# Biomedical engineering training institutions in East Africa

**BME training levels – certificate, diploma, bachelor's, master's, or PhD – are classified according to the degree of complexity of the training programme. Graduates at certificate level may be known as artisans, and those at diploma level biomedical technicians; graduates at bachelor's level are termed biomedical engineers. Master's and PhD programmes enable biomedical engineers to specialise in a specific area – usually in research or as a university teaching faculty member.**

As stated in the previous section, BME training in East Africa started at certificate level in Kenya in 1978. At the time, the Ministry of Health in Kenya observed that 70% of the medical equipment in their hospitals was non-functional due to lack of skilled personnel for repair and maintenance.[31] They thus initiated the first training for biomedical artisans at Kenya Medical Training College (KMTC). The next BME curriculum offerings emerged over two decades later, with diploma-level programmes training biomedical technicians offered by Uganda (2007), Rwanda (2010), and Tanzania (2011) – see below - and the first degree programme for biomedical engineers in East Africa by Makerere University (2011).

As of 2019, there were 29 institutions training biomedical engineers and technicians in East Africa. These institutions are distributed rather unevenly – the majority are located in Kenya (17) and the remaining institutions in Uganda (7), Tanzania (3), and Rwanda (2). BME technicians undertake diploma-level programmes that typically run for 2 years, whereas bachelor's programmes are typically 4-year degree courses. Figure 1 shows pilot study data for graduate outputs and faculty members at BME training institutions in Uganda. The aim is to extend this initial study to other East African countries in a subsequent phase of this project.

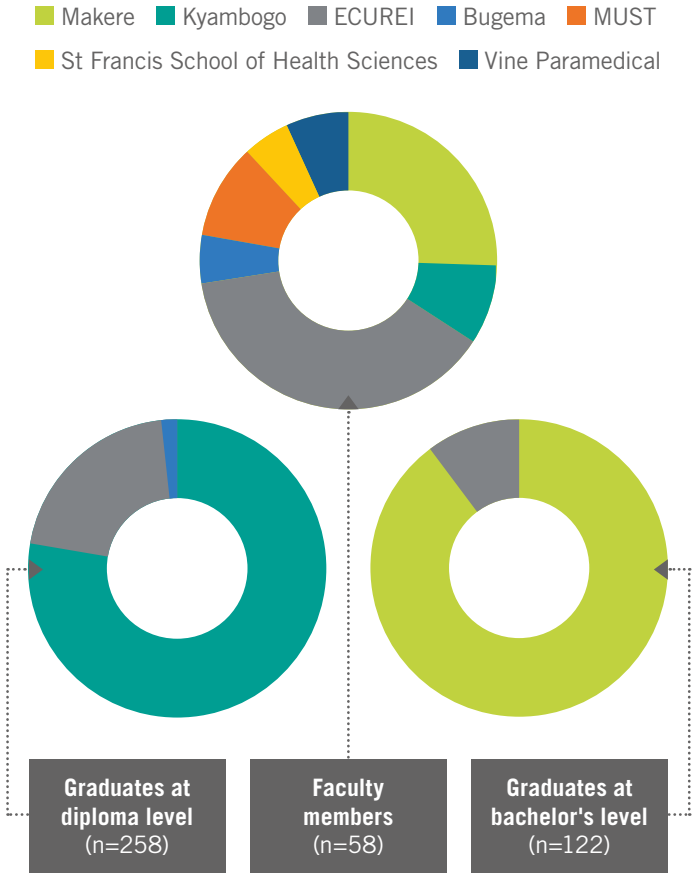



Figure 1: Graduate outputs and faculty members of BME training institutions in Uganda (2019 figures)

## BME training in Uganda

**We have previously reviewed the background and context for BME in Uganda[32]. BME training started at diploma level at ECUREI in 2007.**

Subsequent to this, the Ministry of Health, in collaboration with the Uganda National Association of Medical and Hospital Engineers (UNAMHE), supported Kyambogo University to start training biomedical technicians at diploma level, with the first intake for this programme in 2010. As stated previously, Makerere University's bachelor's programme, run jointly by the College of Engineering, Design, Art, and Technology (CEDAT) and the College of Health Sciences, had its first intake of BME students in the same year. Currently, there are six institutions training BME students at diploma level and four universities training to bachelor's level – namely, Makerere University, Kyambogo University, MUST, and ECUREI. There were 186 and 282 diploma and bachelor's students enrolled (but yet to graduate) respectively as of July 2019.

## BME training in Burundi

The University of Burundi has a Faculty of Agronomy and Bioengineering, but there is no current information available on BME training there.

## BME training in South Sudan

There is no current information available on BME training in South Sudan.

## BME training in Kenya

**As noted above, the development of BME training in Kenya began when the Kenyan Ministry of Health raised concerns about the condition and lack of proper maintenance of hospital equipment and in 1978, an artisan training programme – the Certificate in Medical Engineering – was initiated at Loitokitok sub-district hospital.**

This course was later revised and introduced into three Hospital Maintenance Training Schools (HMTSs) under the auspices of the KMTC at Kilifi, Meru, and Eldoret in the 1980s. In 1986, the first Diploma in Medical Engineering was established at Mombasa Polytechnic (now Technical University of Mombasa), and in 2000, an in-service diploma course was initiated at KMTC Nairobi to upgrade certificate holders to diploma level. Egerton University started a Bachelor's Degree in Industrial Technology with a medical engineering option in 2003. In 2006, a higher diploma course was established at KMTC Nairobi to upgrade the skills of diploma holders with this course subsequently extended to other campuses of KMTC. The first bachelor's programme in BME was established at Kenyatta University in 2013. As of July 2019, there were 16 institutions in Kenya training BME at diploma level and one university (Kenyatta University) training BME at bachelor's level. Moi University in Eldoret is aiming to introduce BME training in 2021 or 2022.

## BME training in Tanzania

**BME training in Tanzania started at diploma level at DIT in 2011.**

Arusha Technical College (ATC) started a diploma programme in 2013 and later a bachelor's programme (Bachelor's Degree in Electrical and Biomedical Engineering) in 2016.[33] As of July 2019, ATC had graduated 140 students at diploma level and had 163 students enrolled in this programme. Mbeya University of Science and Technology is also currently training BME at diploma level.

## BME training in Rwanda

**Rwanda started BME training at the IPRC in 2010. In 2018, the Rwanda Polytechnic awarded the first Advanced Diplomas in BME to graduates from its eight IPRCs.[34]**

Rwanda is home to the regional Centre of Excellence in Biomedical Engineering and eHealth (CEBE), funded by the African Development Bank[35] to provide the administrative leadership, intellectual capacity, and resource infrastructure required to accelerate the delivery of cost-effective, technology-supported healthcare services in Rwanda and the East African region. CEBE is planning to start training BME at master's level (MSc in Biomedical Engineering) at some point post-2020.[36]

## Partnerships

As noted in the preceding section (Overview: Biomedical engineering in East Africa), many of the training institutions in East Africa have partnerships with other institutions in high-income countries aimed towards strengthening BME capacity in East African countries – although mutual benefits should result[37]. We conducted a case study in Uganda and found that the top four training institutions each had 3 to 12 active partnerships with institutions in the global North. These partnerships support low-resource institutions by strengthening their capacity for training, donating training equipment and infrastructure, and providing support for research activities.

## Curricula for BME training – similarities and contrasts

**Three countries were considered for curriculum comparison – namely, Uganda, Kenya, and Tanzania. This comparison is detailed in Table 1 below.**

| Country | Comment on curricula | Similarities and contrasts |
|---|---|---|
| Uganda | • Institutions training BME at bachelor's level generally focus on critical thinking, electrical skills, computer skills, and designing projects with real-world relevance to solve healthcare challenges. The programmes run for 4 years.<br>• Institutions training BME at diploma level tend to focus on electronics and applied engineering skills. | • Bachelor's programme is 4 years in Uganda and 5 years in Kenya.<br>• All institutions training BME at bachelor's level focus on electrical, computer, and design skills.<br>• All institutions offering BME at diploma level focus on applied engineering skills such as repair and maintenance of medical equipment (clinical engineering).<br>• Most diploma programmes have a duration of 2 years. |
| Kenya | • The bachelor's programme at Kenyatta University Is a 5 year course that focuses on transforming acquired theoretical knowledge into the development of biomedical equipment and tools through design, product development and manufacturing.<br>• Institutions training BME at diploma level in Kenya tend to focus on clinical engineering skills. | |
| Tanzania | • The bachelor's programme at ATC focuses on electrical, computer and design skills<br>• Institutions training BME at diploma level in Tanzania tend to focus on clinical engineering skills. | |

Table 1: Comparison of BME curricula in Uganda, Kenya, and Tanzania

## Challenges faced by training institutions

According to data collected in Uganda, Kenya, and Tanzania for this report, major limitations to advancing BME in training institutions include insufficient numbers of teaching staff, limited infrastructure, and limited funding/lack of suppliers to set up laboratories and purchase equipment. The challenges noted by the programme heads at the training institutions in Uganda are shown in Figure 2, plotted according to their estimation of the intensity of each problem.

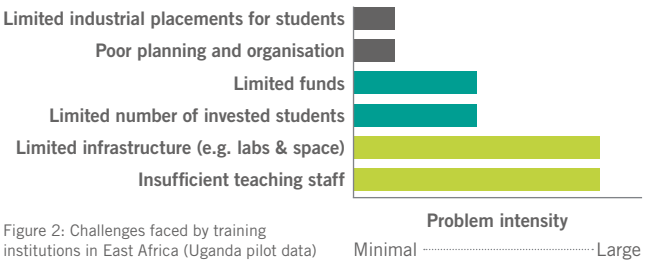



Figure 2: Challenges faced by training institutions in East Africa (Uganda pilot data)

## Career paths

A case study conducted in Uganda as part of this research project showed that, with the exception of national referral hospitals, regional referral hospitals, and a few district and private hospitals, most healthcare facilities do not employ biomedical technicians or engineers. Based on data collected and assumptions made, the majority of BME graduates (50%) are employed in government hospitals, 35% work for private medical technology companies, while the remaining BME work sectors can be divided into academia (10%) and business/others (5%). Few BME graduates have the opportunity to take innovation and entrepreneurship courses during their training[38] which might otherwise influence their career ambitions. It is proposed that a more comprehensive survey of career paths to cover all East African countries should be conducted in a subsequent phase of this project.

# Burundi Profile

## Introduction

**Burundi is the second most densely populated country in Africa, and 74.7% of the total population live below the poverty line.[1] The UN High Commissioner for Refugees (UNHCR) reports that there are more than 335,000 people from Burundi living as refugees and asylum seekers.[2]**

**The economy of Burundi relies heavily on agriculture, which employs about 80% of the total population. Despite the scale of this sector, around 50% of the population is chronically food insecure.[3]**

**Spoken languages are French (official) and Kirundi.**

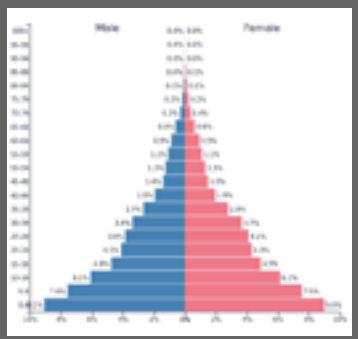
## Strategic plan priorities for healthcare

- **Vision Burundi 2025**[16] states that its health policy is designed to improve the supply of health services, including ensuring universal access and a focus on the principal problems which adversely affect public health.
- **The National Development Plan**[17] is built on 11 pillars, including improving knowledge based on technology and expertise; diversifying and promoting a competitive and healthy economy; creating an enabling environment for industrialisation; and developing human capital.
- **The World Food Programme's Country Strategic Plan (2018–2020)**[18] addresses the challenges and gaps hindering the elimination of hunger. Priorities include ensuring children, adolescent girls, and pregnant and lactating women and girls have improved nutrition status all year round.

*The boundaries and names shown and the designations used on the map below and others throughout this report do not imply official endorsement or acceptance by the United Nations.*


Map Sources: UNGIS, IGN.

*Map created in July 2019*



Source: PopulationPyramids.net

*Burundi – 2020*

## Population and demographics

| | |
|---|---|
| Population: | **11.89m** (2019)[4] |
| Annual growth rate: | **3.21%** (2019)[5] |
| Urban population: | **13.37%** (2019)[6] |
| Population density: | **414 people/km²** (2020)[7] |
| Median age: | **17.60 years** (2015)[8] |
| Birth rate: | **41.3/1,000 population** (2017)[9] |
| Population aged 0-14: | **46%** (2018)[10] |

## World Health Organisation (WHO) data and other key indicators

| | |
|---|---|
| Maternal mortality ratio: | **712 deaths/100,000 live births** (2015)[11] |
| Health expenditures: | **7.5% of GDP** (2014)[12] |
| Hospital bed density per 1,000 population: | **0.8 beds** (2014)[13] |
| Reported number of biomedical engineers: | **≥1** (2017)[14] |
| Biomedical engineers per 10,000 population: | **<0.05** (2017)[15] |

## GDP and healthcare[19]

| | |
|---|---|
| Gross national income per capita (PPP international): | **$820** (2013) |
| Life expectancy at birth (years, m/f): | **58/62** (2016) |
| Probability of dying under 5: | **61 per 1,000 live births** (2017) |
| Probability of dying between 15 and 60 (years, m/f): | **320/260 per 1,000 population** (2016) |
| Total expenditure on health per capita: | **$58** (2014) |

## Research and development (R&D, all 2018)[20]

| | |
|---|---|
| R&D expenditure (% of GDP): | **0.2%** |
| Scientific and technical journal articles per annum: | **21** |
| Researchers in R&D per million people: | **23** |
| Technicians in R&D per million people: | **7** |

# South Sudan Profile

## Introduction

South Sudan officially gained independence from the Republic of Sudan on 9 July 2011, although there have been intermittent conflicts since that time which have undermined the development gains achieved following independence and worsened the humanitarian situation. Around 7 million people (more than half the population) were considered by the UN to be severely food insecure between May and September 2018.[1]

South Sudan is the most oil-dependent country in the world, with oil accounting for 80% of its GDP. GDP per capita dropped to $243 in 2020 (from $1,310 in 2014)[2]. Beyond the oil sector, the economy is based on low productive agriculture and pastoralism.[3] The major languages spoken are English, Arabic (both official), Juba Arabic and Dinka.[4,5]

## Strategic plan priorities for healthcare

The South Sudan Development Plan (2011–2016) includes the following priorities:

- **Economic development:** facilitate diversified private-sector-led economic growth and sustainable development which improves livelihoods and reduces poverty.
- **Social and human development:** promote the well-being and dignity of all the people of South Sudan by progressively accelerating universal access to basic social services, in particular health and education.[15]

A new National Development Strategy, released in November 2018, includes the prioritisation of access to basic services, such as health and transport.[16]


Map Sources: UNCS, SIM, Natural Earth.
*Map created in January 2012*


Source: PopulationPyramids.net
*South Sudan – 2019*

## Population and demographics

| | |
|---|---|
| Population: | **11.19m** (2019)[6] |
| Annual growth rate: | **0.79%** (2019)[7] |
| Urban population: | **19.90%** (2019)[8] |
| Population density: | **18 people/km²** (2019)[9] |
| Median age: | **18.60 years** (2015)[10] |
| Birth rate: | **35.5/1,000 population** (2017)[11] |
| Population aged 0-14: | **42%** (2018)[12] |

## World Health Organisation (WHO) data and other key indicators

| | |
|---|---|
| Maternal mortality ratio: | **789 deaths/100,000 live births** (2015)[13] |
| Health expenditures: | **2.7% of GDP** (2014)[14] |
| Hospital bed density per 1,000 population: | * |
| Reported number of biomedical engineers: | * |
| Biomedical engineers per 10,000 population: | * |

## GDP and healthcare[17]

| | |
|---|---|
| Gross national income per capita (PPP international): | **$1,686** (2016) |
| Life expectancy at birth (years, m/f): | **58/60** (2016) |
| Probability of dying under 5: | **99 per 1,000 live births** (2017) |
| Probability of dying between 15 and 60 (years, m/f): | **335/308 per 1,000 population** (2016) |
| Total expenditure on health per capita: | **$73** (2014) |

## Research and development (R&D, all 2018)

No data was available to compare South Sudan with other East African countries for Research and Development; nor were institutions teaching biomedical engineering identified in South Sudan.

* No data available

# Rwanda Profile

## Introduction

Rwanda is a relatively small, landlocked country located south of the equator and east of Lake Kivu, one of the African Great Lakes. It is bordered by Uganda in the north, Tanzania in the east, Burundi in the south, and Democratic Republic of Congo in the west.[1] Inter-ethnic conflict characterised the period following independence in 1962, leading to the genocide of 1994 in which at least 800,000 people died. In the past 25 years, economic recovery has been significant; and infant mortality was halved between 2000 and 2015 – cited by UNICEF as 'one of the most significant achievements in human history'.[2] Post-genocide in 1995 GDP per person was $125; it is now around $800.[3] There is near-universal primary school enrolment. Languages spoken are Kinyarwanda (official language of Rwanda), English, French, and Swahili.


Map Sources: ESRI, Gov't. of USA, NISR, UNCS.
*Map created in Dec 2011*

Source: PopulationPyramids.net *Rwanda – 2019*

Tourism, minerals, coffee, and tea are Rwanda's main sources of foreign exchange. Rwanda is being positioned as a regional leader in information and communication technologies with projected middle-income status by 2020.[4] However, this target date now now appears to have been revised substantially.[5]

## Rwanda Vision 2020[18]

- Accelerate Rwanda to middle-income status and achieve better quality of life for all Rwandans through sustained average GDP growth of 11.5% and accelerated reduction of poverty to less than 30% of the population.
- Develop a citizen-centric health sector targeted to improve healthcare for the poorest population.
- The Centre of Excellence in Biomedical Engineering (CEBE) was proposed by the NCST (National Council for Science and Technology) to be one of the influencers to build a vibrant and competitive national healthcare service industry.
- Targets for 2020 were to reduce infant mortality rate from 107 to 50 per 1000, reduce maternal mortality from 1070 to 200 per 100,000, and increase life expectancy from 49 to 55 years. These are close to being, or have been, achieved.

*Photo credit: Centre for Disease Control (CDC ref. 22355)*

## Rwanda Health Sector Strategic Plan 4 (2018–2024)[19]

- By 2024, quality, affordable, and efficacious medicines and medical products will be available to all Rwandans.
- By 2024, a qualified, competent, and motivated workforce will deliver quality health services.
- To collaborate with academic institutions to train highly qualified staff (biomedical engineers) for medical equipment maintenance.
- Strengthen diagnostics and medical technology capacities.
- HSSP4 lays a foundation for Vision 2050 ("The Rwanda We Want"), which will transform Rwanda into a high-income country.

## Institutions teaching biomedical engineering in Rwanda

| Institution (n=2) | BME curriculum |
|---|---|
| Integrated Polytechnic Regional Center (IPRC) | Advanced Diploma in Biomedical Engineering |
| University of Rwanda: Centre of Excellence in Biomedical Engineering and eHealth (CEBE) | Biomedical engineering professional skills development training modules. MSc in Biomedical Engineering to be launched in 2020. |

Additional details can be found in the Biomedical Engineering Training Institutions in East Africa section, p. 7 (see also[22]).

## Population and demographics

| | |
|---|---|
| Population: | **12.95m** (2019)[6] |
| Annual growth rate: | **2.58%**[7] |
| Urban population: | **17.31%**(2019)[8] |
| Population density: | **492 people/km²**[9] |
| Median age: | **19.40 years** (2015)[10] |
| Birth rate: | **27.9/1,000 population** (2020 estimate)[11] |
| Population aged 0-14: | **40%** (2019)[12] |

## World Health Organisation (WHO) data and other key indicators

| | |
|---|---|
| Maternal mortality ratio: | **248 deaths/100,000 live births** (2017)[13] |
| Health expenditures: | **7.5% of GDP** (2014)[14] |
| Hospital bed density per 1,000 population: | **1.6 beds** (2007)[15] |
| Reported number of biomedical engineers: | **15** (2017)[16] |
| Biomedical engineers per 10,000 population: | **0.0043** (2015)[17] |

## GDP and healthcare[20]

| | |
|---|---|
| Gross national income per capita (PPP international): | **$1,430** (2013) |
| Life expectancy at birth (years, m/f): | **66/70** (2016) |
| Probability of dying under 5: | **35 per 1,000 live births** (2018) |
| Probability of dying between 15 and 60 (years, m/f): | **224/172 per 1,000 population** (2016) |
| Total expenditure on health per capita: | **$125** (2014) |

## Research and development (R&D, all 2018)[21]

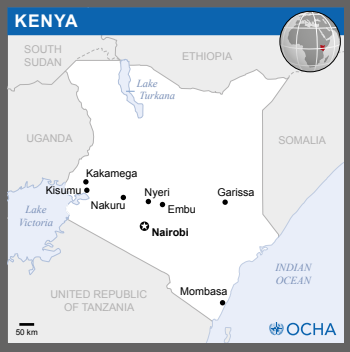
| | |
|---|---|
| R&D expenditure (% of GDP): | **0.7%** (2016) |
| Scientific and technical journal articles per annum: | **170** (2018) |
| Researchers in R&D per million people: | **13.9** (2016) |
| Technicians in R&D per million people: | **5.7** (2016) |

# Kenya Profile

## Introduction

**The Republic of Kenya has the largest and most diversified economy in East Africa. Kenya also has a young, ambitious, and well-educated workforce able to contribute to the development of the country and which has helped Kenya become a leader in mobile money and information and communication technology. As "the gateway to East Africa", Kenya also plays a vital role as a transportation hub for much of sub-Saharan Africa.**

**English is the official language and Kiswahili, spoken by 97% of the population, remains the national language. The adult literacy rate (i.e., people aged 15 years and above) was 81.5% in 2018[1], which compares to a rate of 61.5% reported in a benchmark survey in 2006[2].**




Map Sources: ESRI, UNCS, GAUL.
*Map created in Sep 2013*

Source: PopulationPyramids.net *Kenya – 2019*

*Photo credit: Centre for Disease Control (CDC ref. 22502)*

## Strategic plan priorities for healthcare (Kenya Vision 2030)[15]

- By 2030, transform Kenya into a newly industrialised, middle-income country providing high quality of life for all its citizens in a clean and secure environment.
- Improve access to healthcare through the Universal Healthcare Scheme and the National Healthcare Insurance Plan. Priorities include:
  - Eliminate communicable diseases.
  - Halt and reverse the burden of non-communicable diseases.
  - Preventable and primary healthcare and the development of reproductive, maternal, neonatal, child, and adolescent health (initial focus).
  - Emergency, environmental, and rural health services.
- Improve access to quality universal education.
- Develop infrastructure, industrialise the country, and develop the manufacturing sector.
- Improve healthcare delivery services through development of health infrastructure, healthcare financing, ensuring quality of health commodities, and provision of medical equipment.

## Institutions teaching biomedical engineering in Kenya

| Institution (n=17) | BME curriculum |
|---|---|
| Kenyatta University | Bachelor's degree |
| Technical University of Mombasa | Diploma-level programme; Bachelor's degree |
| Mount Kenya University | Diploma-level programme |
| Kenya Institute of Applied Sciences | Diploma-level programme |
| Kenya Medical Training College | Diploma-level programme |
| St Mary's School of Clinical Medicine | Diploma-level programme |
| Annex Medical Training Centre | Diploma-level programme |
| Pine Breeze Hospital Medical Training Hospital | Diploma-level programme |
| Tropical Medicine Community Health | Diploma-level programme |
| Clive School of Nursing | Diploma-level programme |
| Menengai Medical Training college | Diploma-level programme |
| Kenya College of Biomedical Sciences Technology | Diploma-level programme |
| Nakuru Institute of Medical Sciences and Management | Diploma-level programme |
| Gussi Institute of Technology | Diploma-level programme |
| Rift Valley Institute of Science and Technology | Diploma-level programme |
| Kabete Polytechnic Training College | Diploma-level programme |
| Thika School of Medical and Health Sciences | Diploma-level programme |

Additional details can be found in the Biomedical Engineering Training Institutions in East Africa section, p. 7 (and see also[18] which mentions the University of Eldoret's involvement with ABEC[19] and the training in Medical Engineering provided by Kenya Medical Training College).

### Population and demographics

| | |
|---|---|
| Population: | **53.77m** (2020 estimate)[3] |
| Annual growth rate: | **2.30%**[4] |
| Urban population: | **27.51%**[5] |
| Population density: | **93 people/km²**[6] |
| Median age: | **20.00 years** (2020 estimate)[7] |
| Birth rate: | **27.2/1,000 population** (2020 estimate)[8] |
| Population aged 0-14: | **39%** (2019)[9] |

### World Health Organisation (WHO) data and other key indicators

| | |
|---|---|
| Maternal mortality ratio: | **510 deaths/100,000 live births** (2015)[10] |
| Health expenditures: | **5.7% of GDP** (2014)[11] |
| Hospital bed density per 1,000 population: | **1.4 beds** (2010)[12] |
| Reported number of biomedical engineers: | **50** (2017)[13] |
| Biomedical engineers per 10,000 population: | **0.0043** (2015)[14] |

### GDP and healthcare[16]

| | |
|---|---|
| Gross national income per capita (PPP international): | **$2,250** (2013) |
| Life expectancy at birth (years, m/f): | **64/69** (2016) |
| Probability of dying under 5: | **41 per 1,000 live births** (2018) |
| Probability of dying between 15 and 60 (years, m/f): | **256/184 per 1,000 population** (2016) |
| Total expenditure on health per capita: | **$169** (2014) |

### Research and development (R&D, all 2018)[17]

| | |
|---|---|
| R&D expenditure (% of GDP): | **0.786%** (2010) |
| Scientific and technical journal articles per annum: | **1,247** (2018) |
| Researchers in R&D per million people: | **230.7** (2010) |
| Technicians in R&D per million people: | **654.2** (2010) |

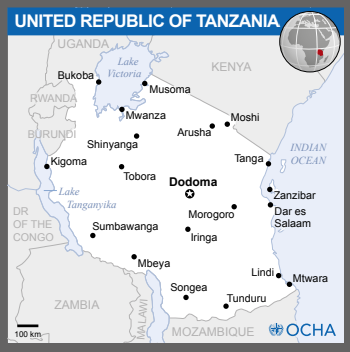
# Tanzania Profile

## Introduction

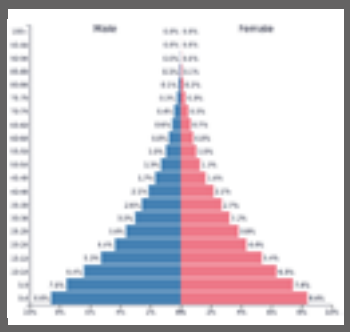
Tanzania is a union comprised of the former republics of Tanganyika and Zanzibar and shares borders with eight countries. The main languages spoken are English and Swahili.

The country has recorded economic growth over the last decade of 6–7% a year. Policies and actions reduced the country's poverty rate from 34.4% to 26.8% between 2007 and 2016, although the absolute number of people living below the poverty line has remained at about 13 million due to high population growth.[1]

The Tanzanian economy is weighted towards agriculture (29%), with manufacturing contributing 6%.[2,3] The Export Zone Processing Agency was established in 2008 to promote manufacturing exports and structural transformation and has helped attract around $1 billion in foreign direct investment. Tanzania's manufacturing sector is now one of the fastest growing in Africa.[4]




Map Sources: ESRI, UNCS.
*Map created in Sep 2013*



Source: PopulationPyramids.net *Tanzania – 2019*

*Photo credit: Centre for Disease Control (CDC ref. 22512)*

## Strategic plan priorities for healthcare[17]

- Main objective: Reach all households with essential health and social welfare services.

Sub-Objectives:

- Improve quality of primary health care services.
- Improve equitable access to services.
- Achieve active community partnership through intensified interactions with the population.
- Ensure the health and social welfare sector achieves a higher rate of return on investment by applying modern management methods and engaging in innovative partnerships.
- Address the social determinants of health.

## Institutions teaching biomedical engineering in Tanzania

| Institution (n=3) | BME curriculum |
|---|---|
| Arusha Technical College (ATC) | Diploma-level and bachelor's programmes |
| Dar es Salaam Institute of Technology | Diploma-level programme |
| Mbeya University of Science and Technology (MUST) | Diploma-level programme |

Additional details can be found in the Biomedical Engineering Training Institutions in East Africa section, p. 7 (see also[20]).

### Population and demographics

| | |
|---|---|
| Population: | **60.91m** (2019)[5] |
| Annual growth rate: | **2.98%**[6] |
| Urban population: | **35.5%** (2019)[7] |
| Population density: | **61 people/km²** (2019)[8] |
| Median age: | **17.3 years** (2015)[9] |
| Birth rate: | **42.9/1,000 population** (2017)[10] |
| Population aged 0-14: | **44%** (2018)[11] |

### World Health Organisation (WHO) data and other key indicators

| | |
|---|---|
| Maternal mortality ratio: | **398 deaths/100,000 live births** (2015)[12] |
| Health expenditures: | **5.6% of GDP** (2014)[13] |
| Hospital bed density per 1,000 population: | **0.7 beds** (2010)[14] |
| Reported number of biomedical engineers: | **20** (2017)[15] |
| Biomedical engineers per 10,000 population: | **0.0007** (2015)[16] |

### GDP and healthcare[18]

| | |
|---|---|
| Gross national income per capita (PPP international): | **$1,750** (2013) |
| Life expectancy at birth (years, m/f): | **62/66** (2016) |
| Probability of dying under 5: | **54 per 1,000 live births** (2017) |
| Probability of dying between 15 and 60 (years, m/f): | **299/222 per 1,000 population** (2016) |
| Total expenditure on health per capita: | **$137** (2014) |

### Research and development (R&D, all 2018)[19]

| | |
|---|---|
| R&D expenditure (% of GDP): | **0.5292%** (2013) |
| Scientific and technical journal articles per annum: | **603** (2018) |
| Researchers in R&D per million people: | **19.2** (2013) |
| Technicians in R&D per million people: | **6.2** (2013) |

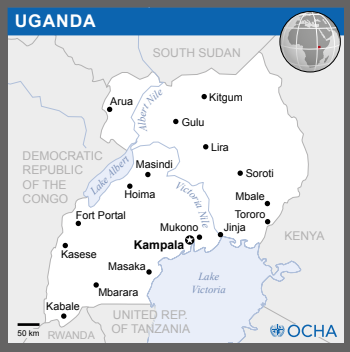
# Uganda Profile

## Introduction

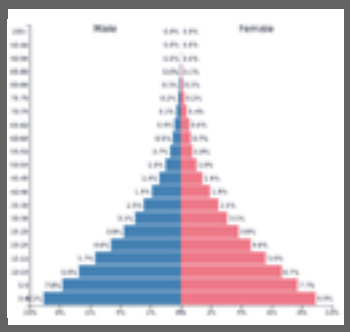
Uganda is the world's second most populous landlocked country after Ethiopia.[1] It has substantial natural resources, including fertile soils, regular rainfall, and sizeable mineral deposits of copper and cobalt.[2] The country has largely untapped reserves of both crude oil and natural gas.

Uganda's economy consists of agriculture (24.2%), industry (25.5%), and services (50.3%). It has experienced recent economic growth of around 6 - 7% per annum.[3]

Uganda's main languages are English, Luganda, and Swahili (Kiswahili).[4] Education is considered a right, and although 90% of children attend primary school, that figure drops below 25% in secondary school due to facility shortages.[5]




Map Sources: ESRI, UNCS.
*Map created in Sep 2013*



Source: PopulationPyramids.net *Uganda – 2019*

## Strategic plan priorities for healthcare

- Use STEI (science, technology, engineering, and innovation) to meet healthcare needs, develop industries, and overcome economic challenges.[18]
- Enhance academia–industry–government cooperation to stimulate innovation and entrepreneurship.[19]
- Special programmes to develop relevant skills in emerging industries (e.g., biosciences, nanotechnology, and engineering).[20]
- Scale up public health interventions to address the high burden of preventable diseases.[21]
- Improve reproductive, maternal, neonatal, child, and adolescent health services to reduce avoidable deaths of mothers and children and improve their health status.[22]

*Photo credit: Centre for Disease Control (CDC ref. 19319)*

*Ms Noel Aryanyijuka, Report Project Coordinator*

## Institutions teaching biomedical engineering in Uganda

| Institution (n=7) | BME curriculum |
|---|---|
| Makerere University | Bachelor's programme |
| Mbarara University of Science and Technology (MUST) | Bachelor's programme |
| Kyambogo University | Diploma-level and bachelor's programmes |
| Ernest Cook Ultrasound Research & Education Institute (ECUREI) | Diploma-level and bachelor's programmes |
| St Francis School of Health Sciences | Diploma-level programme |
| Bugema University | Diploma-level programme |
| Vine Paramedical | Diploma-level programme |

Additional details can be found in the Biomedical Engineering Training Institutions in East Africa section, p. 7 (see also[25]).

### Population and demographics

| | |
|---|---|
| Population: | **44.27m** (2019)[6] |
| Annual growth rate: | **3.46%** (2020)[7] |
| Urban population: | **24.95%** (2020)[8] |
| Population density: | **189 people/km²** (2020)[9] |
| Median age: | **15.8 years** (2015)[10] |
| Birth rate: | **42.3/1,000 population** (2020 estimate)[11] |
| Population aged 0-14: | **47%** (2018)[12] |

### World Health Organisation (WHO) data and other key indicators

| | |
|---|---|
| Maternal mortality ratio: | **343 deaths/100,000 live births** (2015 estimate)[13] |
| Health expenditures: | **7.2% of GDP** (2014)[14] |
| Hospital bed density per 1,000 population: | **0.5 beds** (2010)[15] |
| Reported number of biomedical engineers: | **49** (2017)[16] |
| Biomedical engineers per 10,000 population: | **0.0125** (2015)[17] |

### GDP and healthcare[23]

| | |
|---|---|
| Gross national income per capita (PPP international): | **$1,370** (2013) |
| Life expectancy at birth (years, m/f): | **60/65** (2016) |
| Probability of dying under 5: | **49 per 1,000 live births** (2017) |
| Probability of dying between 15 and 60 (years, m/f): | **333/243 per 1,000 population** (2016) |
| Total expenditure on health per capita: | **$133** (2014) |

### Research and development (R&D, all 2018)[24]

| | |
|---|---|
| R&D expenditure (% of GDP): | **0.17%** (2014) |
| Scientific and technical journal articles per annum: | **673** (2018) |
| Researchers in R&D per million people: | **27.8** (2014) |
| Technicians in R&D per million people: | **10.8** (2014) |

# Burundi's Healthcare System

**Burundi's civil war (1993–2000) resulted in the degradation of physical infrastructure, social stability, and human capital. Healthcare infrastructure was destroyed, and many healthcare professionals were killed or forced to flee.[1]**

**This disruption was compounded by the spread of HIV during the conflict.[2] The lack of health system infrastructure and adequate human resources to meet significant health challenges continues to the present time.[3]**

**Progress in rebuilding and improving healthcare has been made since 2005, but reforms have fallen behind those of neighbouring Rwanda, which faced a similar need to rebuild following the genocide of 1994. Inadequate coordination in implementing health policy between the Ministry of Health in Burundi and NGOs operating in the country may partly explain this slower progress.[4] Universal health coverage continues to be a challenging aim.[5]**

Overseas aid is a significant contributor to the healthcare system, with 17% of the total aid being spent on health in 2011.[6] See the Burundi country profile section (p. 9) for full details and context of the status, focus, and resources applied to health.

## Priorities

**Vision Burundi 2025 (produced in 2011) outlines a health policy designed to improve the supply of health services, including ensuring universal access and a focus on the principal issues affecting public health (malaria, HIV/AIDS, diabetes, and maternal and neonatal services). The policy "will reinforce the institutional, human, infrastructural and equipment capacities in order to allow for effective accessibility to quality health-care – both front-line care and benchmark care in hospitals".[7]**

## Health centres and facilities

Burundi operates a system of health centres, district hospitals, and national hospitals. USAID and other international donors contribute programmes for prevention and treatment of HIV/AIDS and malaria. These are community-based and involve peer educators.[8]

## Disease burden

**Communicable, maternal, neonatal, and nutritional causes of illness dominate and were reported to be responsible for 76% of all years of life lost in 2010.[9]**

Rates of HIV infection and tuberculosis increased while nutritional causes of illness declined from 2000 to 2010. Nevertheless, 58% of all children were chronically malnourished, with around half suffering severe malnutrition in 2010.[10]

*Centre for Disease Control (CDC ref. 22494)*

# South Sudan's Healthcare System

**Efforts to improve public health continue to be hindered by tensions remaining within the country despite the peace agreement of 2015.**

**Health resources are extremely stretched, with reportedly less than 200 doctors to serve the entire population of over 11m[1].**

**Non-government organisations (NGOs) assist in the training of nurses, midwives, and other healthcare professionals[2,3] as well as assisting in the provision of health services[4].**

See the South Sudan country profile section (p. 10) for full details and context of the status, focus, and resources applied to health.

## Priorities

**The National Development Strategy (November 2018) includes the prioritisation of access to basic services such as health and transport. Universal access to healthcare is included in the South Sudan Development Plan (2011–2016).[5] Standard Treatment Guidelines (STGs) covering all tiers of the South Sudan Health System were agreed in 2019.[6] STGs are statements that guide healthcare workers in providing appropriate treatments for common health problems and reflect the consensus based on the latest WHO recommendations.**


*Centre for Disease Control (CDC ref. 19432)*

## Health centres and facilities

**As of 2013, South Sudan operated a four-tier health services system, but official referrals were not made, leaving the patient to make the decision whether to seek specialised treatment.[7] Conflicts and civil disruption since that time have resulted in a lack of investment in infrastructure and the means to deliver healthcare[8,9,10] and only 25% of the population has regular access to health facilities.[11]**

According to the International Organization for Migration[12], there were 15 county hospitals, 88 primary health care centres (PHCCs), and 348 primary health care units (PHCUs) in South Sudan in 2012. The most advanced treatments are provided by county hospitals located at county administrative headquarters. PHCUs offer "basic, preventative, promotive and curative services"[13], and patients may be referred to county hospitals for secondary care by PHCCs.

An agreement is in place with the Chinese firm Civil Engineering Construction Corporation to build 26 hospitals in South Sudan. The agreement includes the upgrading of the main referral hospital, the Juba Teaching Hospital.[14]

## Disease burden

**Malaria is a major cause of death in South Sudan. One NGO (MSF) alone treated nearly 270,000 people in 2018.[15] Significant pockets of kala-azar (visceral leishmaniasis) exist in the Upper Nile region. HIV and TB are common.**

There are recurrent outbreaks of measles, meningitis, rubella, and yellow fever due largely to the reduced immunisation rate in children under one year of age (20% in 2019; 60% before the civil war in 2013).[16] Potential for disease is extremely high, with large numbers of displaced people, high levels of malnutrition, and limited access to health care. South Sudan has among the world's highest infant mortality and maternal mortality rates (60 deaths per 1,000 live births and 2,000 deaths per 100,000 live births, respectively).[17] South Sudan's relative performance towards attaining health-related SDGs and against other health-related indicators as of 2016 is reported in [18] which indicates the additional disease burden contributed by violence and conflict.

# Kenya's Healthcare System

**The right to access the highest attainable standard of health is included in the Kenyan Constitution of 2010 and is reflected in the priorities of the national development plan (Vision 2030), which lists a comprehensive range of actions to develop and strengthen the health sector.[1]**

**The current health policy (2012–2030) translates this further and emphases the societal and economic benefits to be realised.[2]**

See the Kenya country profile section (p. 13) for full details and context of the status, focus, and resources applied to health.

## Structure

**The healthcare system in Kenya is structured in a hierarchical manner (see Figure 1) with four tiers consisting of: community health workers engaging in community-based activities, such as health promotion and disease prevention (Tier 1); primary healthcare facilities, such as dispensaries and health centres (Tier 2); county referral hospitals (Tier 3); and national referral hospitals (Tier 4).[3]**

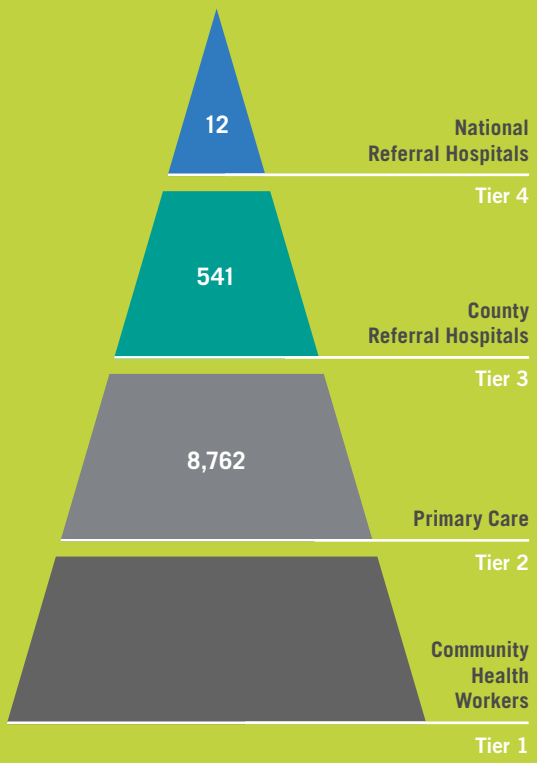



Figure 1: Healthcare service levels in Kenya[4,5,6]. Numbers for Tier 2 – 4 refer to healthcare facilities reported by Kenya Ministry of Health in 2016; World Vision reported supporting 4,275 community health workers in 2015 but the number nationally is not known.

## Staffing

**Kenya has made progress in improving healthcare workforce staffing levels and training provision. The Kenyan National Bureau of Statistics (KNBS) Economic Survey of 2020 indicated a significant rise in both the number of registered healthcare personnel and those in training between 2015 and 2019 (36% and 23% increases, respectively).[7]**

However, the Kenya Health Workforce Report (2017)[8] considered these numbers to be inadequate for the demand and far below those recommended in the WHO's *Workforce 2030*[9] if SDGs are to be met. The *Workforce 2030* target is 44.5 physicians, nurses, and midwives per 10,000 population. The latest available report by the World Bank indicated that Kenya had 13.23 per 10,000 in 2018.[10,11] See Kenya Profile (p. 13) for other relevant data.

**Biomedical Engineering staffing:** A 2015 report[12] states that, according to the Kenya Ministry of Health, 420 biomedical engineers were employed in public hospitals at that time. Only 10 were qualified to bachelor's level, with 140 and 270 diploma and certificate holders, respectively, constituting the bulk of this category. The report concludes that Kenya was falling well short of the overall national target of 5,000 qualified BME personnel. It is not known to what extent this shortfall has been addressed in the period 2015–2020, although, with the number of institutions now known to offer training in BME (see Kenya Profile, p. 13), improvements should have resulted.

A breakdown of all professional healthcare workers is shown in Figure 2.

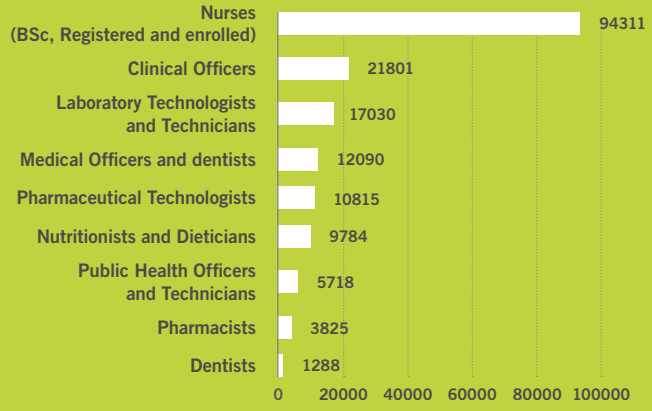



Figure 2: Kenya registered health personnel by cadre (2019)[13]

## Healthcare financing

**Kenya's healthcare is funded from three main sources: government expenditure (i.e., tax-financed and allocated from the national budget and National Hospital Insurance Fund [NHIF]), household (out-of-pocket) payments, and external donors (although this contribution has declined from 32% to 22% since 2010)[14]. Strategic directions for healthcare investment and financing are contained in the Kenya Health Policy 2014–2030[15] and also discussed in detail by Kibui *et al.*[16] (see [17] and [18] for analysis within the context of the priority area of Universal Health Coverage).**

It is noted, however that priorities cannot all be met with a share of the national budget below the 15% of GDP target recommended by the Abuja declaration of 2001. In 2020/2021 the healthcare budget allocation was 111.7 billion KES (€916 million, $1 billion) out of a total budget of 2.75 trillion KES (4.1%)[19], although the sources noted above are also significant contributors to the financing of healthcare.

Kenya established the NHIF in 1966 to cover those in formal employment.[20] Currently, around 20% of Kenyans are insured – 88% of these through NHIF, with the remainder by private medical health insurance (including micro health insurance and mobile health wallet schemes) and community-based health insurance schemes.[21] Informal sector workers can join the NHIF voluntarily.[22]

## Disease burden and causes of death

**Kenyans are now living longer than they did 10 years ago. Life expectancy in 2018 was 64.4 and 68.9 years for males and females, respectively – an increase of over 13% from 2008 in both cases.[23]**

Although the incidence of communicable diseases is decreasing, HIV/AIDS, lower respiratory infections, diarrhoeal diseases, neonatal disorders, and TB remain the top causes of death.[24] Non-communicable diseases such as ischaemic heart disease, stroke, diabetes, and cirrhosis are an increasing burden on Kenya's healthcare system.[25] Kenya has had success in lowering the burden imposed by malaria (premature deaths reduced by over 50% between 2007 and 2017).[26,27] Significant risk factors are malnutrition, unsafe sex, water pollution, poor sanitation and hygiene, and air pollution.[28,29]

# Rwanda's Healthcare System

**During the 25 years following the genocide in Rwanda, the Rwandan Government has taken great strides to rejuvenate their healthcare system towards a more inclusive and target-based service provision sector.**

**The mission of the Rwanda Ministry of Health (MoH) is "To provide and continually improve affordable, promotive, preventive, curative and rehabilitative healthcare services of the highest quality, thereby contributing to the reduction of poverty and enhancing the general wellbeing of the Rwandan population"[1].**

See the Rwanda profile section (p. 11) for full details and context of the status, focus, and resources applied to health.

## Priorities

**Driven by the National Strategy for Transformation (NTS1, 2017–2024[2]) and Health Sector Strategic Plan (HSSP 4[3]), the MoH goals include:**

### Improving health across the whole of life

- **Decrease maternal and neonatal mortality.**
- **Increase antenatal and postnatal care access and uptake.**
- **Focus on early childhood development.**

### Creating a strong and resilient health system

- **Develop and strengthen human resources for health.**
- **Develop and maintain infrastructure and equipment.**
- **Improve efficiency in health service delivery through use of health technology (including tele-medicine and e-health).**
- **Provide specialised services.**

## Staffing

### Healthcare workforce

**Rwanda has a shortage of medical professionals, with only 1.09 physicians, nurses, and midwives per 1,000 residents in 2019.[10]** Although this represents an improvement compared to previous years, with a health-service-provider density of only 0.84 per 1,000 in 2013, this number is still much lower than the WHO's recommendation (2.3 providers per 1,000).[11] There is a network of 55,415 CHWs who provide primary care in the 14,937 villages and make referrals.[12]

### Biomedical engineering staffing

Rwanda does not yet have any tertiary training institutions that offer a degree in biomedical engineering, but it is expected that within the next 2 to 3 years, training at bachelor's and master's levels will be offered at the Centre of Excellence in Biomedical Engineering and e-Health (see CEBE, p. 48).

## Health centres in Rwanda

The health sector in Rwanda is pyramidal (see Figure 1), with a referral system that has 8 National Referral Hospitals at the apex, followed by 4 Provincial Hospitals, 36 District Hospitals, and a number of specialised and non-specialised clinics and dispensaries. At the base, the country is served by over 55,000 community healthcare workers (CHWs).[4,5]

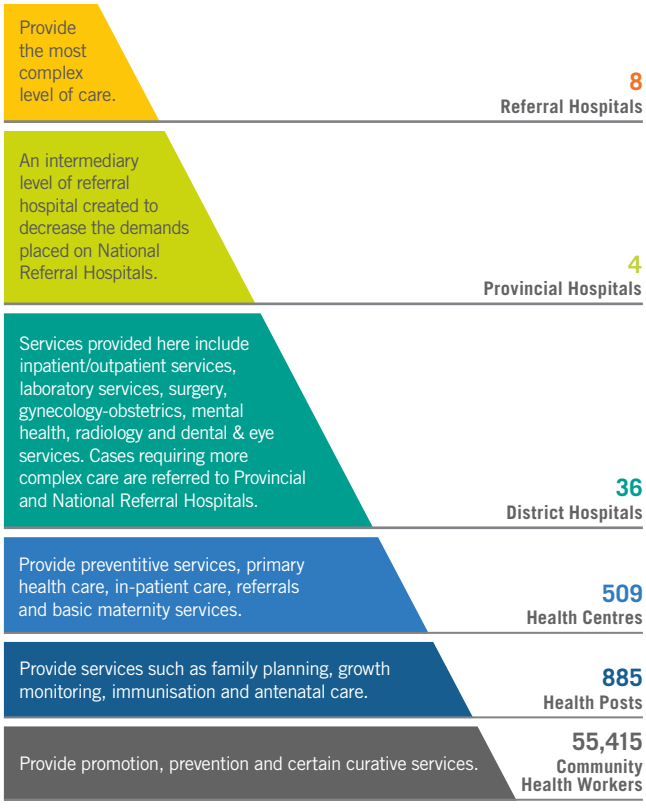



Figure 1: Healthcare service levels in Rwanda (2019)[6,7]

## Universal healthcare coverage in Rwanda

**Rwanda has significantly advanced towards universal health coverage with the efficient community-based health insurance programme (CBHI) – Mutuelle de Santé (Mutual Health) – and the Rwanda Social Security Board formal sector employees' medical scheme, which, together, cover more than 90% of the Rwandan population.[8]** Healthcare funding is decentralised to the district level, and healthcare centres are given autonomy to plan activities specific to their needs.[9]

*Centre for Disease Control (CDC ref. 22510)*

## Healthcare financing

Since 2012, about 45% of the healthcare system has been funded by insurance premium payments, with the rest coming from domestic and external funding (including international donors).[13,14,15] There has been a modest decline in the former, and the MoH's share of the national budget was 8% in 2019/2020.[16,17]

### Healthcare Insurance in Rwanda

**Health insurance became mandatory for the Rwandan population in 2008; in 2019 over 90% of the population was covered.**[18] Under the Mutuelle de Santé scheme (see above), residents of a particular area pay premiums into a local health fund and are entitled to draw from it when in need of medical care. Premiums are paid according to a sliding scale, with the poorest members of society entitled to use the service for free, while the wealthiest pay the highest premiums and are charged co-payments for treatment.

## Disease burden and causes of death

**Life expectancy has improved markedly in Rwanda since the 1994 genocide (from 32 to 64 years in 2016[19]).** However, many preventable deaths still occur, and these are being addressed by improvements in immunisation, sanitation, environmental standards, and appropriate medical care (including the current focus on preventive healthcare). Among the common causes of mortality in Rwanda are pre-term birth complications, neonatal sepsis, respiratory diseases, diarrhoeal diseases, and HIV/AIDS.[20,21]

# Tanzania's Healthcare System

## Priorities

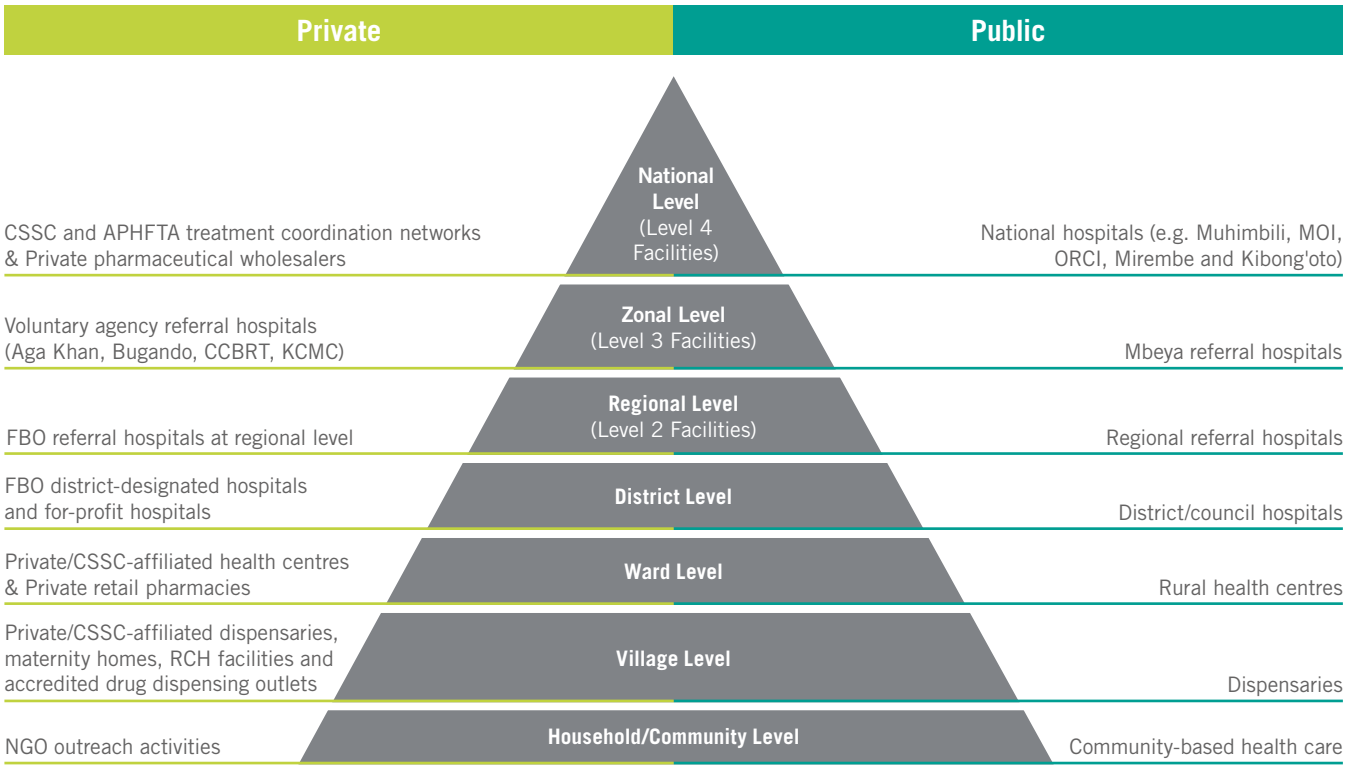
**The United Republic of Tanzania's fourth Health Sector Strategic Plan (2015–2020) provides for a new health financing strategy aimed at achieving universal health coverage.[1] The Tanzania Development Vision 2025 aims for a healthy society with improved social well-being that will contribute effectively to individual and national development.[2,3] However, the health system faces significant challenges – including high rates of HIV/AIDS and limited human resources.[4]**

Key health system targets include an under-five mortality rate of less than 45 deaths per 1000 live births; maternal mortality below 250 deaths per 100,000 live births; reducing the prevalence of HIV to 3%; and raising life expectancy to from 61.8 (in 2015)[5] to 66 years (see Tanzania country profile section (p. 15) for detailed data). The World Bank notes, however, that "government efforts to expand access to social services like education, health, and water have been undermined by their declining quality as the population rises faster than the supply of the services".[6]

## Structure

Figure 1 displays the structure of Tanzania's healthcare system, which is underpinned by a major emphasis on primary care. Hospitals with increasing levels of responsibility for more complex health and disease conditions (i.e., from minor surgery through to intensive care) are fed from this base. Facilities up to Level 2 are managed regionally, whilst tertiary (zonal) and national referral hospitals (i.e., Levels 3 and 4) are controlled by the Ministry of Health.[7]

Non-governmental organisations, including faith-based agencies, are major contributors to the health system. According to the latest available data from the Health Facility Registry (2020), there were 369 hospitals, 469 clinics, 926 health centres, and 7,163 dispensaries in Tanzania.[8]




Notes: APHFTA = Association of Private Health Facilities in Tanzania, CCBRT = Comprehensive Community Based Rehabilitation in Tanzania, CSSC = Christian Social Services Comission, FBO = faith-based organisation, KCMC = Kilimanjaro Christian Medical Centre, MOI = Muhimbili Orthopaedic Institute, ORCI = Ocean Road Cancer Institute, RCH = reproductive and child health.

Figure 1: Tanzanian health system referral pyramid[9]

## Staffing

As of 2015, the numbers of clinicians and nurses was below the national average distribution in 13 of Tanzania's 31 regions (see Tanzania profile, p. 15), and 554 dispensaries were reported to lack skilled health professionals.[10]

**Biomedical engineering (BME) staffing:** In 2017, in an interview with Tanzania Daily News, Mr. William Ole Nasha – Deputy Minister of Education, Science, Technology, and Vocational Training – highlighted an acute shortage of biomedical engineers, with over 7,000 additional staff needed to manage procured medical equipment in government hospitals.[11] We sought clarification for this report via an interview with Mr. Valentino Mvanga, Head of Health Care Technical Service, Ministry of Health and Social Welfare. He commented that, as of July 2019, the country had only 10 biomedical engineers trained to bachelor's-degree level (target: 144) and only 175 diploma holders contributing to this overall target of 7,000. Some hospitals, especially the lower-level facilities, have no BME technicians (see also [12]).

## Healthcare financing and insurance

The National Health Insurance Fund (NHIF), established by an Act of Parliament in 1999, became operational in 2001. The scheme was designed to cover public employees but has more recently been revised to allow contributions from private members. Other insurance providers include the Social Health Insurance Benefit (SHIB), Community Health Fund (CHF), and Tiba Kwa Kadi (TIKA).[13] Overall, 32% of the population are reported to have health insurance cover.[14]

## Disease burden and causes of death

Tanzania is grappling with healthcare challenges also present in many other developing countries, including communicable diseases; maternal, newborn, and childhood health and illnesses; as well as the recent rise in non-communicable diseases.[15,16] Tanzania is among the 22 TB High Burden Countries, with an incidence of 253 per 100,000 population.[17] This rate has, however, declined from around 470 per 100,000 in 2008.[18]

According to the Centres for Disease Control and Prevention and the Global Burden of Disease project, the main causes of death in Tanzania are maternal and neonatal disorders (11.5% of all deaths), lower respiratory infections (9.8%), HIV/AIDS (8.3%), and cancer (8.1%).[19,20]

*Centre for Disease Control (CDC ref. 22775)*

# Uganda's Healthcare System

## Priorities

**Uganda's core healthcare objective is universal healthcare for all Ugandans.[1,2] See the Uganda profile section (p.17) for full details and context of the status, focus, and resources applied to health.**

## Structure

**Uganda's healthcare system is segmented into three main categories: Public healthcare facilities (dominant), Private not for Profit (PNFP) and Private for Profit (PFP).**

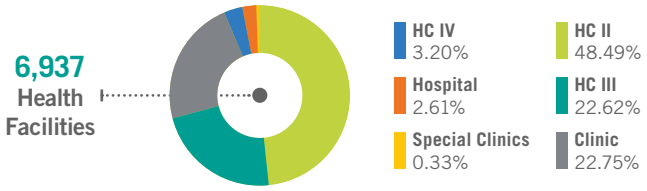



Figure 1: Healthcare facility levels (2018)[3]

According to the Master List released by the Ministry of Health (MoH) in 2018, there are 6,937 healthcare facilities and specialised clinics from 128 districts in Uganda (see Figure 1). Of these, 45% (3,133) are government owned (i.e., Public), 15% (1,002) are PNFP, while the remaining 40% (2,795) are PFP[4] (see Table 1 for regional distribution). Uganda thus operates a mixed health system: PNFP organisations operate across the range of facilities (40% of hospitals [e.g., Mengo Hospital, Kampala[5]] and 22% of lower-level provision[6]), while the PFP-operated facilities include high-level hospitals with ICUs (e.g., Case Hospital, Kampala) as well as much of the provision in rural areas[7].

## Healthcare facility levels

### Health Centre (HC) II

An HC II facility, typically led by an enrolled nurse working with a midwife, two nursing assistants, and a health assistant, serves a few thousand people and is able to treat common diseases like malaria.[8] Every parish (made up of a number of villages) should have a centre, according to MoH guidelines.

HC IIs are supported by an informal structure of Village Health Teams (VHTs). These are community volunteers who conduct surveillance for outbreaks of disease and dispense health information to their communities.[9] It is intended that every community has three volunteers reporting to HC IIs.[10]

### Health Centre (HC) III

According to the MoH, these units should have 18 staff members, led by a senior clinical officer who runs a general outpatient clinic, and a maternity ward with a laboratory. However, some have fallen short of these requirements.[11]

### Health Centre (HC) IV

An HC IV is a mini-hospital with about 35 beds that serves as a county hospital (i.e., for a population of about 100,000). In addition to the services provided at HC III level, it should have separate wards for men, women, and children and should be able to admit patients. It should have a senior medical officer and another doctor offering theatre and emergency services as well as blood transfusion.[12]

### District/General Hospital

The Ugandan health policy requires each district to have a hospital, capable of providing all services offered at a Health Centre IV, plus specialised clinics – such as those for mental health, eye and dentistry with at least one consultant physician.[13]

### Referral Hospitals

Referral hospitals are at the top of the healthcare system. These facilities serve a population of 1 million and offer more specialised services than General Hospitals; the level of specialisation increases at regional- and national-level referral hospitals. These serve populations of 2 million and 10 million, respectively. The highest level of medical skills can be found at these hospitals, although staff often work part-time at private clinics to supplement their government salaries.[14]

The Uganda Cancer Institute serves as the East African regional Centre of Excellence in Oncology and provides a precedent for co-operation in specialist health care provision across the region.

| Region | Central | Eastern | Nothern | Western |
|---|---|---|---|---|
| **Facilities (total)** | 3,133 | 1,333 | 1,061 | 1,410 |
| **Facility type** | | | | |
| **Government** | 667 | 838 | 733 | 896 |
| **PFP** | 2,129 | 243 | 176 | 247 |
| **PNFP** | 337 | 253 | 152 | 267 |

Table 1: Health facilities by type and region

### Where do Ugandans go for healthcare?

The liberalisation of the economy in 1987 provided the environment for a private healthcare sector in Uganda. The private sector now provides healthcare services to half of the population and contributes around 55% of all healthcare facilities in the country.[15] The majority of consumers seek care in both the private and public sectors.[16] However, because of the lack of an efficient referral system, the majority of the population simply visit the hospitals nearest to them. For example, Mulago National Referral Hospital serves the whole of the Kampala metropolitan area, with 829,817 outpatient visits, 761,573 inpatient admissions, 61,568 emergencies, and 39,081 deliveries recorded in 2014/2015.[17] In addition, 1,738,652 lab tests were conducted, 33,949 X-rays and 27,142 ultrasound scans taken, and 13,397 major surgeries performed.[18] This level of workload, along with other challenges experienced by healthcare workers, is recognised to adversely affect the quality of service and the motivation and retention of these workers.[19,20]

## Biomedical engineering staffing

**Through the surveys conducted for this project, we found that, with the exception of the national referral hospitals and regional referrals hospitals, only a few district hospitals or lower-level facilities had in-house biomedical engineers or technicians and, where this was the case, these were often employed by implementing partners and foreign-funded projects.**

Mulago National Referral Hospital had two biomedical engineers and three biomedical technicians out of the 1,800 facility staff. On average, every regional referral hospital had at least one biomedical engineer and/or one biomedical technician.

Those health facilities without biomedical engineers or technicians are served by regional workshops located in every region and managed by the Health Infrastructural Division. The largest (Central Workshop) is located at Wabigalo in Kampala.[21] In total, there are nine regional workshops in the country.[22] Each workshop, with the exception of the Central Workshop, is manned by a workshop manager at the level of biomedical engineer and at least three biomedical technicians. The Central Workshop is headed by the senior Biomedical Engineer of the MoH in Uganda.

## Healthcare financing

**With the exception of the 2017/2018 financial year, when the budgetary allocation to healthcare decreased to 6%, the Uganda government has worked towards its commitment to increase the healthcare budget each year.**

The health sector accounted for 8.9% of the national budget in 2019/2020, and expenditure is forecast to increase in each of the next 4 years.[23] This allocation (UGX 2.3bn, or $610m), is still far below the 15% minimum of national budgets agreed in the Abuja Declaration by the heads of state of African Union countries.[24] This budget is intended to fund all public healthcare facilities and to subsidise the PNFP facilities that make up around 15% of the system as well as other ambitious targets.[25]

## Healthcare insurance in Uganda

The introduction of national healthcare insurance in Uganda is expected to be imminent[26], and private insurance schemes are also used by some Ugandans (purchased either by themselves or by their employers).

The country has taken many years to enact the National Health Insurance Scheme into law. Proposals were first developed in 1999 and, at the time of writing, details are still being considered, and a functional national health insurance plan and policy are yet to be implemented.[27]

## Disease burden

**Communicable diseases account for much of Uganda's overall burden of disease. Malaria; HIV/AIDS; TB; and respiratory, diarrhoeal, and vaccine-preventable diseases are the leading causes of illness and death and are responsible for over 50% of morbidity and mortality.[28]**

In addition, the incidence of non-communicable diseases, including heart disease, diabetes and cancer as well as mental health disorders, is increasing. Maternal and perinatal conditions substantially contribute to disease burden but maternal and perinatal deaths are decreasing. Neglected Tropical Diseases (NTDs) remain a challenge in rural poor communities in particular. Underlying socio-economic, gender, and geographical conditions and disparities influence the health status profile across the country.[29]

# The MedTech Industry in East Africa

## The Market

**There is a growing medical device market in Africa. This was valued at $4.9 billion in 2017 and is forecast to reach $7 billion by 2023 (1.3% of the global market).[1] This constitutes a compound annual growth rate (CAGR) of circa 6.3% between 2017 and 2023.[2]**

This growth is projected to be driven by the distinctively young customer base for Africa – as shown by the population pyramid charts included in the country profiles (see pp. 9–18) – and applies to the continent as a whole, with an estimated 62% of the population being under 25 years old[3] (with 42% of the sub-Saharan population being 0 – 14). In contrast, the European workforce is expected to shrink from 63% in 2010 to 51% in 2050[4] as these populations age and so provides an opportunity to develop an African MedTech industry to serve this particular demographic profile. Furthermore, there is a rising African middle class with increased buying power – most evident in South Africa, Nigeria, Algeria, Egypt, and Morocco.[5] Three East African nations form part of the "Frontier Fifteen" consumer markets, which, together, represent almost 30% of the continent's consumer class.[6]

Running counter to these opportunities are significant barriers. Principal amongst these is the low per capita income (see country profiles, pp. 9–18) and the poor connectivity and infrastructure in many parts of Africa. In contrast to other global regions, the decline in extreme poverty in sub-Saharan Africa (SSA), as measured by the World Bank[7], has been gradual between 1990 and 2015 (from about 60% to 40% of the population). This has translated principally into a steady increase in the population living on between $3.20 and $5.50 per day (the latter being the national poverty line used by the World Bank for upper-middle income countries [UMICs][8]). At present, the middle class generally account for a negligible proportion of the population; hence, the increase in purchasing power may not be a significant market driver in East Africa for many years. Based on 2015 data, 85% of Africans live on less than $5.50 per day.[9]

**Other important African MedTech market characteristics are:**

- **Price sensitivity. Opportunities exist for devices with lower costs and appropriate features for the combination of resources and disease burden encountered in sub-Saharan Africa (see [10] and [11]) to develop this segment.[12]**
- **Investment in physician education and training as a growth driver.[13]**
- **First mover advantage is significant. It is difficult to dislodge the market leader, given the low profit margins associated with low-cost devices and the limited customer base in sub-Saharan Africa. Relatively high switching costs and a low competitor pool present barriers to entry.[14]**
- **Other market barriers such as the high cost of imported medical devices, the intricacies and inconsistencies of the various regulatory frameworks (see Medical Device Regulatory Processes in East Africa, p. 41), and the current low penetration of medical devices in Africa need to be considered. Many African economies are dependent on exports of primary commodities, which can cause export revenues to be unstable.[15,16]**

## Key international players in the market

- **Mindray Medical International Ltd** (China) are suppliers of patient monitoring and life support systems, medical imaging systems, and in vitro diagnostics.
- **Philips** (Netherlands) has a major focus on Africa. "Africa is an important growth market for Philips. We have a comprehensive understanding of the complexities of the African market as well as the key challenges facing Africa today. We are well positioned to increase our presence on the continent by developing local talent and organizations, increasing our footprint and introducing innovative products and solutions which are relevant for the local needs" – Frans van Houten, CEO of Philips.[17]
- **Siemens** (Germany). While signing a memorandum of understanding with Uganda and Sudan to support their healthcare, industry, and transportation at the World Economic Forum on Africa in 2017, Siemens CEO Joe Kaiser said: "Africa's economies are gaining ground and can develop their full potential with the right partner ... Our goal is to double our order intake in Africa to more than 3 billion euros by the year 2020."[18]
- **GE Healthcare** (US). In 2011, GE renewed its focus on meeting Africa's infrastructure and technology needs and established its regional headquarters in Nairobi, Kenya. This opened doors to the East African market. In 2017, GE employed more than 2,600 people in Africa and generated revenues of over $3.7 billion. GE has a major presence in Kenya, where it has installed over 100 diagnostic (CT scan, MRI, ultrasound, and X-ray) imaging units and audited all 18 of its referral hospitals.[19]
- **Johnson & Johnson** (US). Through its Global Public Health Organisation, J&J conducts operations in Africa with a focus on infectious diseases such as HIV, tuberculosis – and now Covid-19 - and works with national governments to find solutions to infectious diseases and neglected tropical diseases.[20] It also runs the Africa Innovation Challenge 2.0, which presents an opportunity to African entrepreneurs to share solutions to health-related challenges.[21]

Africa Health is a trade show that was due to be held for the 10th time in 2020[22] (although it did take place online in 2021). It is the largest healthcare event in SSA. In 2019, medical equipment and medical devices from 30 countries (including from the companies highlighted above) were exhibited.[23] Amongst the over 600 companies represented, only 39 (6.5%) were from SSA (38 from South Africa and one from Botswana), suggesting that, with the exception of these Southern African companies, SSA MedTech companies are not mature or robust enough to make a contribution at this level.

# East African MedTech companies

A valuable review and analysis of medical devices in East Africa was performed by Mr Costica Uwitonze of the Rwanda Association of Medical Engineering (RAME). He concludes:

**"The medical technology segment has tremendous potential. This potential should be recognised by the developing countries including East African countries and there have been many initiatives to promote the sector [such as] setting up incubation centres and R&D departments [and] reducing tax from 16–18% to 5% or less for medical devices components. The sector will grow at more than 5–10 % by 2015–2025."[24]**

### Medtech Companies – Uganda

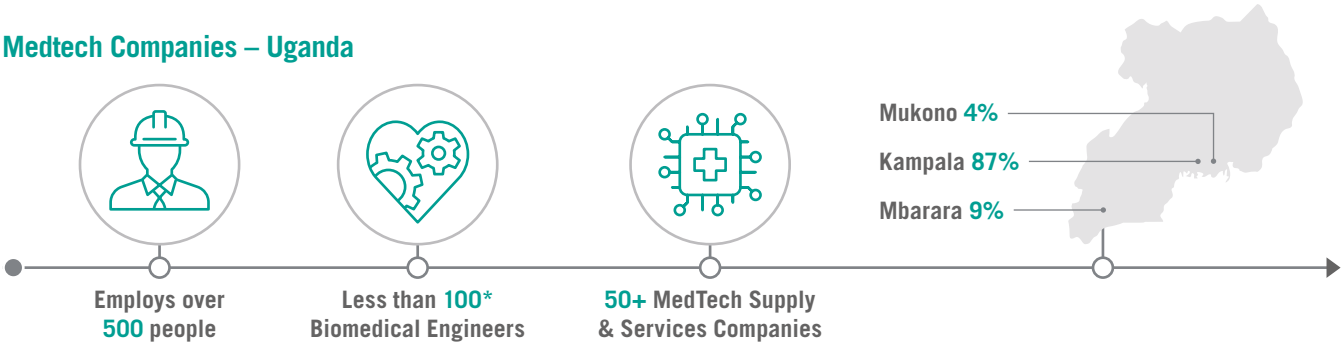



Figure 1. MedTech industry in Uganda. Most companies identified were medical equipment supply and service companies and the distribution of their location is also shown.
* Note number of Biomedical Engineers employed includes engineers and technicians.

## Uganda

Although there are several emerging MedTech start-up companies (see Case Study 6, p. 53), there is no established medical device manufacturing industry in Uganda. Almost all medical equipment is imported from developed markets through local distributorships, franchises, or donations.

This study identified over 50 private companies that deal in medical equipment in Uganda, employing more than 500 people (Figure 1). Companies from the northern, western, eastern, and central regions of Uganda were investigated. Purposive sampling was used, and the selection of companies was based on those that supply the largest number of health facilities within these regions. Joint Medical Stores (JMS) is the largest distributor of medical equipment within the country and operates in all regions; most other companies have a presence only in the central region since Uganda's highest GDP per capita is concentrated there.[25] The majority of companies deal in equipment servicing, maintenance, and sales engineering.

### Joint Medical Stores (JMS)

JMS[26] serves at least 3,000 medical facilities in Uganda. It is a non-profit organisation established in 1979 as a joint venture between Uganda Catholic Medical Bureau (UCMB) and Uganda Protestant Medical Bureau (UPMB). JMS started dealing in medical equipment in 1981 and has since grown to have a BME department with over 10 staff members – some of whom are BME graduates. JMS also provides internship opportunities for BME students and trains up to 10 students per period of placement. JMS has extended its operations into East Africa and has now delivered consignments to customers in Democratic Republic of Congo, South Sudan, Somalia, Kenya, Tanzania, Burundi, and Central African Republic.

### Microhaem Scientifics and Medical Supplies Ltd

Founded in 2012, Microhaem[27] is a private company dedicated to improving patient care and health service delivery through supply of high-quality medical equipment and pharmaceutical products, with a focus on laboratory equipment. Microhaem serves Uganda and Rwanda as a distributor for medical equipment companies such as Abbott, Welch Allyn and Alvo Medical, with a product range covering haematology, CD4 counting, microscopy, viral load testing, and clinical chemistry. The company currently employs four biomedical engineers.

> **"Local production of medical devices will be a good thing to boost, as it will reduce the overall cost of equipment and so generally reduce costs per test/ examination, leading to cheaper healthcare.**
>
> **Mr. Andrew Eugine Nyorigo,** Biomedical Engineer and Quality Assurance Manager at Microhaem Scientifics and Medical Supplies Ltd.

### Other companies

We found around 50 other companies listed as suppliers and/or distributors of medical equipment or medical supplies in Uganda.[28,29] These will not be highlighted further in this report. Data gathered supporting estimates for Uganda is shown in Figure 1. Based on field work conducted for this project, a similar profile is expected for Kenya but insufficient information is currently available for Tanzania and Rwanda. Time and resources did not allow the same analysis to be conducted for Kenya, Tanzania and Rwanda.

# The MedTech Industry in East Africa

## Kenya

### Crown Healthcare Ltd

Crown Healthcare was established in 1998 with a view to improving standards and expectations of the hospital equipment and supplies sector in Africa. From its initial offices in Kenya, Crown has expanded into the entire East African region, with offices in Kenya, Tanzania, Uganda, and Rwanda. It also has offices in Nigeria and is focused on expanding into the broader West African market. Crown deals in the entire spectrum of medical equipment and consumables, including theatre equipment, laboratory equipment and consumables, hospital furniture, ICU equipment, infection control equipment and consumables, and medical gases.[30] Crown Healthcare employs more than 250 staff, including approximately 40 biomedical engineers and technicians.

### Achelis Group of Companies

Achelis (headquarters Bremen, Germany) focuses on African markets, with its core markets being in Kenya, Uganda, and Tanzania.[31] Achelis deals in a broad range of industrial and technical equipment used for, amongst other things, energy and power generation as well as construction. Its Healthcare and Scientific Division focuses on diagnostic, surgical, and laboratory equipment and supplies. Technologies covered include X-ray units, electrosurgical units, microscopes, mortuary units, training simulators, modular operating theatres, mobile field hospitals, and ambulances.

### Meditec Systems Ltd

Meditec Systems was established in 1993 and has since become the major partner for Siemens in the East African region.[32] Founded and operating originally in Kenya, the company has grown into other East African markets, including Uganda, Rwanda, Tanzania, and Zambia. The company provides laboratory installations and equipment, including complex MRI systems. They have been instrumental in setting up key facilities in Kenya, including Cancer Care Kenya (in partnership with Siemens – see [13]), the Moi Teaching and Referral Hospital CT Scanner suite, and the Kenyatta National Hospital Catheterisation Laboratory. Meditec Systems also offer equipment maintenance and service contracts.

### Chem-Labs Ltd

Chem-Labs Ltd was founded in 1995 and distributes laboratory and medical diagnostic equipment. Its main focus is the provision, installation, user training, repair, and maintenance of laboratory diagnostic equipment.[33]

### Rivatex East Africa Ltd

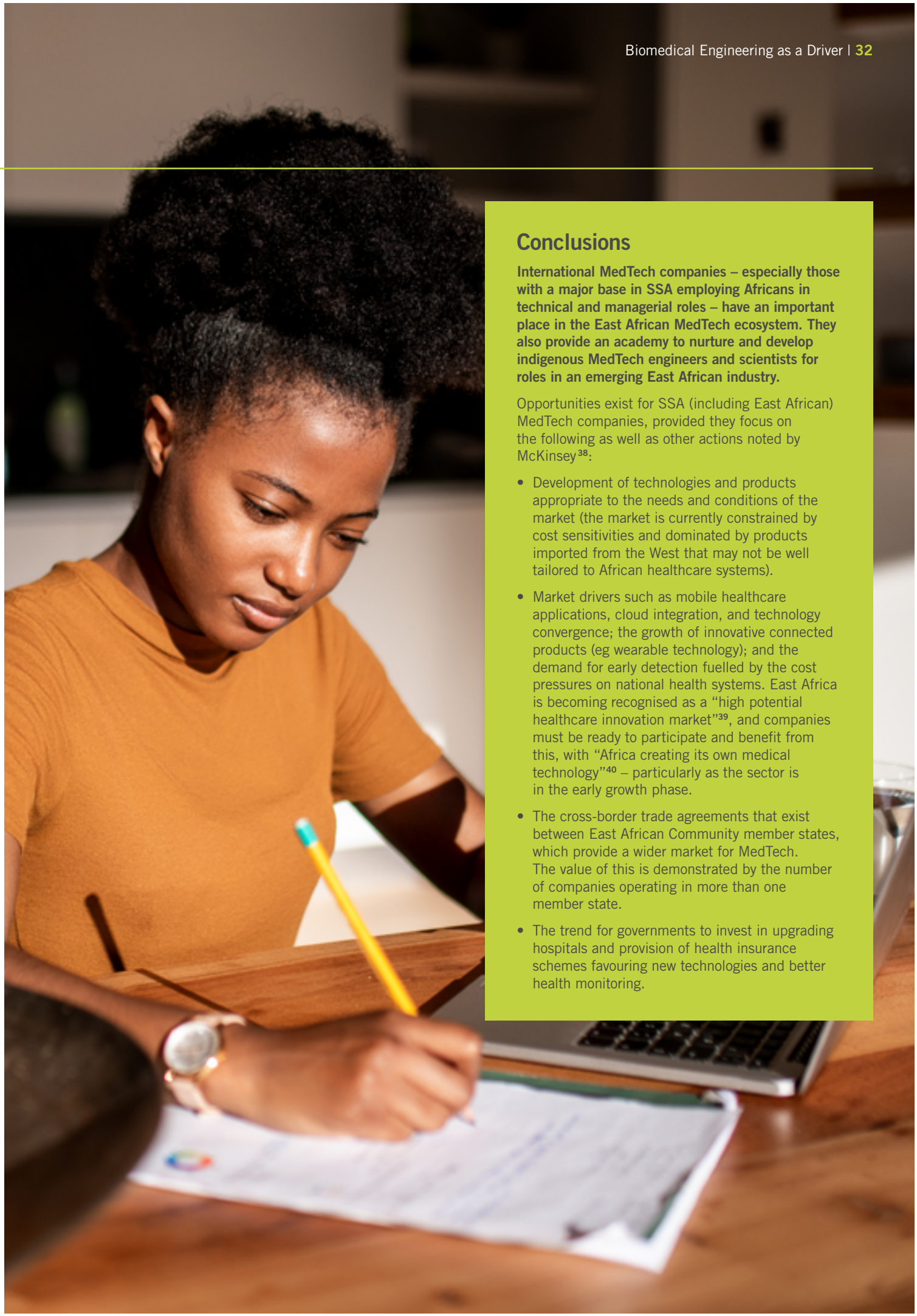
Rivatex is a textile company now owned and managed by Moi University, Kenya. Its principal activity is the conversion of cotton lint into finished products, but it also acts as a training, consultancy, research, and product development facility in textiles. With state-of-the-art apparel and garment-making equipment recently installed, Rivatex has the potential to be a major producer of medical textiles for the East African region.[34]

### Other companies

A simple internet search returned around 50 other companies listed as suppliers and/or distributors of medical equipment and medical supplies in Kenya.[35] Space does not allow all of these to be included in this report.

## Tanzania and Rwanda

Most of the major companies supplying Kenya and Uganda supply Tanzania and Rwanda as well. Key amongst these are Crown Healthcare, Meditec Systems, Achelis Group, and Microhaem Scientifics and Medical Supplies. In addition to these, many other companies were found listed as suppliers and distributors of MedTech in Tanzania and Rwanda.[36,37]



## Conclusions

**International MedTech companies – especially those with a major base in SSA employing Africans in technical and managerial roles – have an important place in the East African MedTech ecosystem. They also provide an academy to nurture and develop indigenous MedTech engineers and scientists for roles in an emerging East African industry.**

Opportunities exist for SSA (including East African) MedTech companies, provided they focus on the following as well as other actions noted by McKinsey[38]:

- Development of technologies and products appropriate to the needs and conditions of the market (the market is currently constrained by cost sensitivities and dominated by products imported from the West that may not be well tailored to African healthcare systems).
- Market drivers such as mobile healthcare applications, cloud integration, and technology convergence; the growth of innovative connected products (eg wearable technology); and the demand for early detection fuelled by the cost pressures on national health systems. East Africa is becoming recognised as a "high potential healthcare innovation market"[39], and companies must be ready to participate and benefit from this, with "Africa creating its own medical technology"[40] – particularly as the sector is in the early growth phase.
- The cross-border trade agreements that exist between East African Community member states, which provide a wider market for MedTech. The value of this is demonstrated by the number of companies operating in more than one member state.
- The trend for governments to invest in upgrading hospitals and provision of health insurance schemes favouring new technologies and better health monitoring.

# Funders and Investors

**It is acknowledged that health systems in SSA require substantial investment to meet agreed standards such as the SDGs – a study estimated this to be an additional $21 - $36 per capita (2015 values[1]).**

**This estimate has, of course, required radical revision in the light of the Covid-19 emergency – which does in itself present opportunities for reform and introduction of new technology and health workforce upskilling[2].**

Some much needed funding and finance for MedTech innovation, product development, and translation can be sourced from a range of (mostly international) providers – the third sector, national governments, incubators, and private investors (see Translation and Innovation Hubs, p. 49, for these last two). Some of the significant funders for MedTech in East Africa are described below.

## Third sector organisations

### The Royal Academy of Engineering (RAEng), UK

Through its Africa Prize for Engineering Innovations, the RAEng supports engineering innovations aimed at improving quality of life and economic development, encouraging African innovators from all disciplines to apply their skills in developing scalable solutions to local challenges.[3] Notable winners and finalists of the prize in the region are the Matibabu device from Uganda, a non-invasive, point-of-care malaria detection device[4] and PapsAI (from MUST, Uganda), a digital health system for cervical cancer screening, diagnosis and patient record management[5]. Innovators responsible for both were participants in this report.

### Grand Challenges Canada (GCC)[6]

Using funds primarily from the Canadian government, GCC supports innovations between LMICs and Canada, and boasts a portfolio of more than 1,300 projects in 106 countries. Their mission is to catalyse innovations that save and improve the lives of vulnerable people. GCC has supported 65 medical device projects in East Africa[7], including the low-cost Electronically Controlled Gravity-Feed (ECGF) Infusion Set[8] (see Case Study 2, p. 46) and the maternal post-partum haemorrhage belt (a first-aid device for controlling post-partum haemorrhage until the necessary intervention can be received)[9]. Other technology innovations supported by GCC are in diagnostics and telehealth (e.g., the Mobikit project in Kenya)[10]. Investors are attracted to projects that have been endorsed and nurtured by GCC, as evidenced by the estimated $2.03 leveraged from investors and partners for every $1 of GCC funding[11].

### Consortium for Affordable Medical Technologies (CAMTech)

"A global network of academic, clinical, corporate and implementation partners working to accelerate high-quality, affordable medical technology development for low and middle-income countries"[12] based at Massachusetts General Hospital, USA. Its partner, CAMTech Uganda is able to fund innovative, impactful, and scalable technologies through innovation awards made every year through its Hackathon programme[13] and now has a portfolio of 13 projects (see Translation Challenges Appendix, p. 38 for examples).

### United States Agency for International Development (USAID)[14]

USAID is the largest health aid donor in Uganda, with a focus on HIV/AIDS, TB, malaria prevention and treatment, maternal and child health, and health systems strengthening. MedTech innovations are funded mainly through their Development Innovation Ventures programme, which provides funds to test early-stage ideas up to proof of concept, scale-up, and evidence generation stages.[15] In East Africa, MedTech innovations are also nurtured through the USAID-funded Resilient Africa Network[16] (RAN; see Translation and Innovation Hubs (Case Study 4), p. 49). RAN is a partnership of 20 African universities in 16 countries (including Uganda, Rwanda, Tanzania, and Kenya) and US partners, led by Makerere University. Shishi International, a Ugandan company that assembles and manufactures oxygen splitters[17] (p.54), has received funding and mentorship from RAN.

### Other third sector funders include:

- The **Bill & Melinda Gates Foundation (US)**, which is a partner in the International Finance Corporation scheme (discussed below) and also works with governments and NGOs in Africa.[18] Focus countries include Kenya and Tanzania.
- The **Wellcome Trust (UK)**, which funds researchers all over the world for early-stage projects to address health challenges[19] and the **Andrew and Virginia Rudd Family Foundation (US)**, which supports the annual Big Ideas contest[20].

## Governmental funding agencies

### African Development Bank (ADB)[21,22]

Through its mandate to contribute to sustainable economic development and social progress of its African members individually and jointly, the ADB offers loans at affordable interest rates to foster development of education and healthcare. The ADB provided a $98 million loan towards the development of the four East African regional Centres of Excellence in biomedical sciences and engineering, one of which (CEBE) is the subject of a case study in this report (see Case Study 3, p. 48). These, in turn, build on an earlier initiative to establish pan-African Centres of Excellence in health innovation.[23]

### European Union (EU)

Two notable schemes aimed at building capacity in BME in East Africa have been funded under the EU Horizon 2020 programme:

- **The Intra-Africa Academic Mobility Scheme**[24], which funds the African Biomedical Engineering Mobility project (ABEM – itself overseen by ABEC (Africa Biomedical Engineering Consortium)). ABEM aims to build capacity in Africa for needs-based health technology research and development.[25] ABEM activities include postgraduate training in skills and specialisations not available from participants' home institutions, support for BME programmes at partner institutions, and a review of BME curricula taught in Africa with a view to harmonisation. East African partners are Kenyatta University, Kenya, MUST, Uganda, and Uganda Industrial Research Institute, Uganda.
- **The UBORA project**, the aim of which is to create an open-source e-infrastructure – the Euro-Africa Open Biomedical Engineering e-platform for Innovation through Education. This brings together academics, researchers, innovators, industry, and policy makers to co-create medical devices complying with international standards. The platform guides an innovator through the entire innovation process. UBORA notes that education and innovation in BME are both "flywheels for European and African economies"[26].

### The International Finance Corporation (IFC)

A member of the World Bank Group, IFC launched its Health in Africa fund in 2009 to make long-term equity investments in private sector companies delivering healthcare services. These include clinics, hospitals, diagnostic centres, labs, as well as insurance companies, distribution and logistics organisations, pharmaceutical and medical-related manufacturing companies, and medical education providers.[27] According to the report[28] launching the fund, the private sector "is only part of the solution and must work with the public sector to develop viable, sustainable, and equitable healthcare systems"[29]. The IFC's priority countries for investment include Kenya, Tanzania, and Uganda. The effectiveness of this public-private partnerships (PPP) model is, however, uncertain.[30]

### The Medical Research Council (MRC), UK

The MRC supports research across the entire medical sciences spectrum in both the UK and LMICs. It has now broadened its funding beyond HIV/AIDS to include other infectious diseases and non-communicable diseases in Uganda. The growth of BME at Makerere University has led to an MRC seed-funding grant to establish a centre of excellence for innovation and translation of maternal health devices in sub-Saharan Africa[31].

### Japan International Cooperation Agency (JICA)[32]

JICA runs training programmes in the use and maintenance of medical equipment in many developing countries, and their experience in this field has benefited the health ministries of Uganda and Kenya, in particular, for many years. A number of technicians and users have been trained on safe handling and management of medical technologies and equipment.[33] JICA training programmes are also aimed at improving managerial capacity at health facilities. Japanese health technologies are made available to improve health outcomes via loan, grant aid, and PPP arrangements.[34] Capacity building is supported through the Partnership for Health System Strengthening in Africa (PHSSA), initiated in 2011 to provide training on governance, leadership, and management in healthcare across Africa. 321 people from 38 countries were trained from 2011 to 2017. These participants have, in turn, trained approximately 3,000 people in their home countries.[35] Further examples of JICA-led initiatives are the Pan-African University Institute for Basic Sciences, Technology and Innovation (PAUSTI), hosted by the Jomo Kenyatta University of Agriculture and Technology[36], and open innovation challenge events in Rwanda, Kenya, and Uganda[37].

### East African National Government programmes

Such as UNCST, Uganda[38] which offers grants in all areas of science, technology and innovation to build capacity and to translate into solutions, and COSTECH, Tanzania, which works with the UKAid-funded Human Development Innovation Fund (HDIF)[39]. HDIF has supported a number of MedTech innovations[40].

# Skills Gaps

**If biomedical engineering is to fulfil its potential to be a driver for healthcare improvements in East Africa, the following skills gaps need to be addressed.**

**These have been identified during the course of this review of capacity and capability. Possible means of reducing and closing these gaps are also listed below.**

## Career-ready BME graduates

**Graduates from BME training institutions are not well prepared for the world of work. Institutions should undertake curriculum reviews with advisers drawn from the hospital sector, industry and professional associations.** Training institutions should develop short courses that equip graduate engineers with skills necessary to improve performance in the field. This would be most effective if undertaken and delivered by consortia of institutions in each country. Better provision of facilities for hands-on training is needed and sharing by these consortia should make this feasible.

A system of placements of BME students into hospitals, companies, and government departments should be developed by a working group drawn from all stakeholders (including professional associations) and be endorsed and supported by these stakeholders. Routes to chartership via completion of a combination of short courses and placements/experience in order to close these gaps should be defined.

## Research

**Postgraduate opportunities within the East African nations are scarce.** Priority should be given to creating a number of posts in each country that would work on projects of agreed strategic importance, taking advice from industry sectors. Opportunities for the creation of CASE-type[1] studentships should be evaluated. Postgraduate programmes should include training courses in research best practice.

## Regulatory and translational awareness

**Biomedical engineers need to be aware of the new product development (or translation) process for medical technology products.** This includes the regulatory processes that products have to pass through and the stages or technology readiness levels that need to be completed for a product to move from idea to market launch. Greater use of online distance learning (ODL) courses/MOOCs such as MedTech: Trends and Product Design[2] can contribute to improving this and should be implemented.

## International experience

**The LMIC nations of the EAC will, for now, require partnerships with Western universities and other organisations to allow the development of the BME field.** This may be as secondments into EAC training institutions of European or North American academics, exchange programmes, postgraduate training and research appointments, courses in the operation and maintenance of specialist equipment, or travel bursaries to allow attendance at conferences or courses.

## Entrepreneurship

**A thriving MedTech sector will need biomedical engineers with entrepreneurial skills that can identify customer needs, identify opportunities that address these needs, and secure the means to realise and achieve value for both customer and company (newly-formed start-up or existing company).**[3] Investment is needed to establish innovation and entrepreneurship courses in East African training institutions – particularly if this can be linked to innovation in healthcare and medical technology.[4] Such initiatives are needed to help address the low ranking of East African nations in the Global Entrepreneurship Index[5].

Translation and innovation hubs (p. 49) also have an important role in developing innovation and entrepreneurial skills to the point of investment-readiness and in connecting companies with investors.

# Translation Challenges

**Translation in the context of healthcare is the process of "moving knowledge and technology from 'bench to bedside"[1] and is complex and challenging[2]. Some resources will always be scarce, barriers will be encountered, and not all risks will be amenable to mitigation and reduction to ideal levels.**

**For this section, we sought to get the situational perspective of a small pilot sample of researchers and innovators from East Africa.**

A combination of one-on-one interviews, phone interviews, and online questionnaires was used to gather information from academic researchers, innovators, and innovation hubs in Uganda and Kenya. Some of the MedTech projects and products with which interviewees were involved are listed in the Translation Challenges Appendix (p. 38). The following challenges and barriers were frequently cited.

i. **Lack of resources (finances, infrastructure, and materials)**. All Ugandan researchers interviewed secured funding through grants from international sources (US, Canada, European Union, UK, Netherlands, Sweden, WHO). These included competitive grants and award competitions and covered some infrastructure and equipment. The nature, duration, and management of this type of funding presents challenges in itself.

ii. **Regulatory processes.** These are difficult to navigate for researchers and individuals involved in local development of medical technologies. The translation of research to products that can be applied clinically is lengthy and requires many resources. In Uganda, the researchers questioned indicated that, in their experience, the process was not clearly defined, leading to uncertainties about the pathway for evaluation of medical devices and in vitro diagnostics for clinical application within the country. Regulation of pharmaceutical products was felt to be better defined compared to that of other health products.[3]

> **"Getting local approvals has been a great challenge because there are no clear-set rules and regulations in place to approve medical devices in Uganda. However, after in-depth discussions with stakeholders, steps to acquire approval have been drafted and we are currently pursuing them.**
>
> **Phyllis Kyomuhendo**, co-founder of M-SCAN, Uganda

iii. **Inadequate protection of intellectual property rights (IPR)**. It has been found that "economies with good IP protection are 45% more likely to attract venture capital and private equity funding"[4] than those without a robust protection system. Enforcement of IPR is a challenge across East Africa[5], and the EAC lacks a common approach to IPR protection[6,7]; a regional framework has, however, been proposed[8,9] and is in the process of being implemented[10]. In Uganda, information obtained from the Uganda Registration Services Bureau (URSB) indicated that a total of between 20 and 25 patent applications for registration of health-related products and processes have been filed in the five years up to and including 2019. There were more than 600 copyright registrations – including computer programmes – during this period.

Further challenges were suggested by BME training institutions in East Africa (see Introduction, p. 5), and other needs were identified through engagement with incubation hubs (see Translation and Innovation Hubs, p. 49). We asked both what investments they would like to see in the next five years to enable the MedTech sector to realise its science and innovation potential. Responses included: having more investment (seed grants) to allow projects to gain proof of concept and so qualify for bigger grants; more government and private sector investment; more support and training in research best practice, management of processes, and skills development; capacity building of innovators to make them more investment-ready; greater financial support; and, lastly, international exposure.

> **"We envision running innovation competitions enabling access to medical healthcare. We also have a plan to set up a healthcare solutions lab for innovation competitions enabling access to medical healthcare.**
>
> **Brian Ndyaguma,** The Innovation Village Incubation Hub, Uganda

# Translation Challenges

## Output from Uganda workshop

**Additional information on translational challenges was collected during a multidisciplinary workshop held in August 2019 in Kampala for participants drawn from across the MedTech sector in Uganda.**

**Comments and responses are summarised in Table 1. Many of the responses relating to funding, infrastructure and regulation captured here mirror and reinforce those noted in the sections above.**

| Funding | Regulation |
|---|---|
| • More incubation space is needed, especially for BME.<br>• There is little awareness of locally made medical devices and the MedTech industry.<br>• There is a challenge in accessing funding to increase start-up formation rates.<br>• Funding for young innovators will motivate them to stay in R&D and not seek to engage in an already existing business.<br>• The mechanism of funding is a challenge; however, it improves somewhat through the right collaborations. | • There is no body in Uganda clearly responsible for ascertaining the quality of innovations and their compliance with standards.<br>• Regulation pathways must be made clear and regulatory documents made more accessible so that developers know what is required of them.<br>• It is difficult to initiate the involvement of relevant personnel at regulatory authorities, and they do not give sufficient information when engaged.<br>• The policy guidelines and standards for effective and efficient BME practice in healthcare are inadequate. |

Table 1: Summary of input from workshop participants, Kampala, August 2019

## Conclusions

BME innovators in East Africa face significant challenges in bringing new MedTech products to the market. Funding and regulation emerged as the main concerns. Preparation and training of graduates to undertake research and innovation are also critical; however, BME training institutions do not have the resources to fulfil these needs. Translation and innovation hubs play an important role in MedTech product development but greater access is needed. Collaboration and international exchange at student and staff levels will help prepare institutions and graduates to make greater contributions to healthcare improvements, and institutions should develop clear strategies to address the challenges of MedTech translation.

> **“Mechanisms for funding and scaling medical device development are still a challenge.**
>
> **Philippa Makobore**,
> Head of Instrumentation Division, UIRI Uganda

# Translation Challenges Appendix

**As stated in the main article, information on challenges was gathered from researchers involved in medical technology research in academia. One-to-one interviews were carried out, and a set of questions was used to collect information on the challenges faced in translational research.**

MedTech projects being conducted are listed below (Table 1). Information on projects supported and the levels of investment that may still be needed to support MedTech innovations was captured from nine innovation hubs in Uganda, using online and in-person questionnaires (Table 2).

| Research Projects | Project Funders | Name of Researcher (Principal Investigator) Interviewed |
|---|---|---|
| Development of an ultra-low-field MRI system for infant hydrocephalus. | US National Institutes of Health (NIH), Netherlands Organization for Scientific Research (NWO) Award. | Johnes Obungoloch[1], Mbarara University of Science and Technology (MUST) |
| The Maternal Post-Partum Haemorrhage (PPH) Belt.<br>Novel low-cost diagnostic tools and their impact in Africa.<br>Strengthening Ugandan BME HIV/TB human resource research capacity.<br>BME as a driver for improvements in healthcare. | Grand Challenges Canada (GCC).<br>Engineering and Physical Sciences Research Council, UK.<br>US National Institutes of Health (NIH).<br>Global Challenges Research Fund (GCRF), UK. | Robert Ssekitoleko[2], Makerere University |
| Development of a paper strip for rapid detection of Ebola and Marburg viral haemorrhagic fevers at point of care in Ugandan villages. | Grand Challenges Canada (GCC); European and Developing Countries Clinical Trials Partnership (EDCTP). | Misaki Wayengera[3], Makerere University |
| TB gene discovery and development of TB diagnostics (e.g., GeneXpert machine). | World Health Organisation (WHO); Special Programme for Research and Training in Tropical Diseases (TDR); Swedish International Development Cooperation Agency, Department for Research Cooperation (SIDA-SAREC); US National Institutes of Health (NIH); European and Developing Countries Clinical Trials Partnership (EDCTP); the European Union for TB; and US National Institutes of Health (NIH) | Moses Joloba[4], Makerere University |

Table 1: Projects led by academic researchers
See Case Study 7: Academic Researchers (p. 55) for further background and Case Study 1: Duke-Makerere BME Partnership (p. 45) for further information on the PPH belt.

| Innovation hub | MedTech innovation supported | Description of MedTech innovation | On market |
|---|---|---|---|
| Resilient Africa Network (RAN), Eastern Africa | Wekebere[5] | Simple wearable foetal monitor, designed with healthcare workers in Uganda for expectant mothers in resource-constrained facilities. | Yes |
| | Matibabu[6] | Point-of-care malaria diagnosis using red light and magnetism. | No |
| | MamaOpe[7,8] | A biomedical kit for early diagnosis of pneumonia and monitoring of treatment among children under the age of 5 years. | No |
| | e-Musawo[9] | Mobile telemedicine kit: Doctors can consult each other quickly and remotely. | No |
| | Human-Powered Jet Nebuliser[10] | A low-cost, bicycle pump-operated nebuliser to treat acute asthma attacks in low-resource settings. | No |
| Outbox Uganda | iDrain[11] | A chest drainage system that allows for drainage of pleural effusions from the lungs. | No |
| | Stre@mline[12] | E-health platform that enables clinicians in resource-poor settings to deliver healthcare efficiently by providing key patient safety prompts across the entire patient journey. | Yes |
| | Feyti[13] | Provides a platform for consumers to verify medication before consumption. | Yes |
| | M-SCAN[14] | Affordable mobile ultrasound devices for use in low- and middle-income countries. | No |
| Consortium for Affordable Medical Technologies (CAMTech) | AIR[15] | The Augmented Infant Resuscitator (AIR) is a low-cost add-on to existing emergency ventilation equipment. | No |
| | SaniDrop[16] | Affordable, locally-made hand sanitiser that kills 99.9% of germs. | Yes |
| | PRISMS[17] | Protecting Infants Remotely by SMS (PRISMS) is a mobile phone application that enables health workers to effectively manage at-risk or sick newborns. | Yes |
| | A-Lite Vein Locator[18] | A low-cost, non-invasive blood vessel illuminator that assists clinicians in finding a suitable vein in child patients during peripheral intravenous cannulation. | No |
| iLabs Makerere | MamaOpe[19] | A biomedical kit for early diagnosis of pneumonia and monitoring of treatment among children under the age of 5 years. | No |
| Social Innovation Academy (SINA) | Uganics[20] | An organic, mildly scented mosquito repellent. | Yes |

Table 2: MedTech projects and products supported and incubated by innovation hubs. Note: Innovation Village, Makerere Innovation and Incubation Centre, and Uganda Paradigm Communications (operator of VentureLabs East Africa) also supplied information, but no specific current MedTech innovations were identified by these respondents.

# Professional Associations in East Africa

*Eng. Sam Wanda, Former Assistant Commissioner, Healthcare Infrastructure Division, Ministry of Health, Uganda and President, UNAMHE.*

## Uganda

### Uganda Institute of Professional Engineers (UIPE)

**The UIPE is an umbrella body for all engineers in Uganda[1] and has around 4,000 registered members. It was established in 1972 with the aim of promoting general advancement of the science and practice of engineering and its applications and to facilitate the exchange of ideas amongst its members. The UIPE is organised into divisions covering all engineering disciplines including biomedical engineering.[2] The institute has different classes of membership from Fellows to student members.**

Currently, the UIPE is the only body that certifies engineers in Uganda. As of July 2019, despite its large membership base, "no professional biomedical engineers [were] registered under the body" according to Prof. Peter O. Lating, the chairperson of the Joint Assessment Committee (JAC) of the UIPE. This is because the registration requires graduate professionals to have a minimum of 4 years working experience. At this point (2019), the first BME graduate cohort, which graduated from Makerere University in 2016, had only had 3 years' field experience.

Within the UIPE Graduate and Student memberships, there were still no BME students or graduates registered at the time of writing. Although the UIPE is well known to engineering students at the College of Engineering, Design, Art, and Technology (CEDAT), Makerere University, it was found not to be well connected with BME students at the College of Health Sciences. "UIPE has also been hard to reach out to", said Mr Solomon Oshabaheebwa, one of the BME teaching staff at Makerere University.

### Uganda National Association for Medical and Hospital Engineering (UNAMHE)

**The UNAMHE was formed in 1993 to promote the development of science and safe medical and hospital engineering practices amongst the different engineering fields that work in hospitals.[3]**

As of October 2019, the UNAMHE had about 80 registered engineers, although there were reported to be only a "few" biomedical engineers among them. Despite its organisation of the important Uganda National Biomedical Engineering Conference (UNBEC) in 2017 and 2019, there appear to be administrative and organisational issues preventing the complete integration of most biomedical engineers into the UNAMHE. "There is no clear way we shall support Biomedical Engineering in Uganda if they do not join and enrol into the association", said Sam Byamukama, the Secretary General of the UNAMHE. There is an obvious need for improved dialogue between all stakeholders (see also Consensus, Conclusions, and Recommendations, p. 59).

## Rwanda

### Rwanda Association of Medical Engineering (RAME)

**The RAME was established in August 2014 with the "objective of encouraging the development of professionalism, dissemination of all related activities, and integration and utilisation of knowledge in biomedical engineering including manufacturing, supply, utilisation and maintenance of medical devices", according to Eugène Lucky Shema, Treasurer of the RAME.**

Currently, the RAME has 70 registered members – 20 biomedical engineers and 50 biomedical technicians. The RAME mainly provides updates on the latest technology in BME and represents its members in the field by liaising with the government regarding challenges faced - not least among these being the limited funds available to support the organisation.

## Kenya

### Association of Medical Engineering of Kenya (AMEK)

**Plans for the formation of AMEK were initiated in 1991 at an international meeting convened by donor agencies working to assist in the delivery of healthcare services in Kenya[4] and the organisation was registered in 1998.**

As of July 2019, AMEK had 1,200 registered biomedical engineers, providing a platform for effective exchange of skills and information in Kenya. It also offers continued professional education and research opportunities and works to build a culture of equipment maintenance necessary for the effective functioning of healthcare services in Kenya and other developing countries.

One of the challenges faced is attracting a wider membership, as AMEK does not certify professionals – something which the association itself has indicated may make some people reluctant to register as members.

## Other East African associations

The Association of Medical Engineers and Technicians Tanzania (AMETT) and the Association Burundaise d'Ingénierie Biomédicale et Hospitalière (ABIB) are listed as organisations that participated in the 6th East African Healthcare Engineering Regional Conference (EARC).[5]

## Joint activities of BME associations

### EARC

The EARC is a bi-annual conference organised in rounds by five East African countries (currently excluding the new member South Sudan). The associations profiled above all had a role in promoting the EARC 2018 (organised in Uganda by the UNAMHE) as a "call to action" event through which policymakers and other stakeholders in the healthcare sector could be influenced to drive change and improvements in healthcare in these countries and, potentially, more widely.[6]

The joint East African conference started in 2006 and has been instrumental in the networking of biomedical engineers in the region. Consequently, relationships between engineers have grown across boundaries, resulting in acquisition of skills and mutual support through sharing ideas on how to improve healthcare provision and the operation of equipment in medical facilities.


*6th East African Healthcare Engineering Regional Conference and Exhibition (EARC 2018).* *Photo Credit: UNBEC, EARC 2018*

# Medical Device Regulatory Processes

## Regulatory pathways for new medical devices

**The term "medical device", as utilised in this report, refers to any instrument or machine intended for diagnosis, prevention, monitoring, treatment or alleviation of a disease or injury (see Overview: Biomedical Engineering in East Africa, p. 6, for a full definition).**

The development of new medical devices is important for improving healthcare, and regulation of locally developed devices is important to ensure safety and quality. A stepwise regulatory system for medical devices that accommodates advances in clinical practices, public health needs, and evolving technologies is recommended by WHO.[1] Basic regulatory controls are categorised into three development stages: pre-market, placing on market, and post-market.

### Pre-market, Market, and Post-market regulation

Efforts to harmonise regulation of medicines and medical devices in the EAC were reviewed in 2016[2]. While regulatory activities are conducted in all the countries of the EAC, a further study found that, with the exception of Tanzania, pre-market regulation in other member states was mostly absent.[3] Burundi, Kenya, and Tanzania require international manufacturers to have a local agent that has legal accreditation before the product can be registered for distribution. In Uganda, pre-approval is also required before devices are imported, and the Uganda National Bureau of Standards (UNBS) gives guidelines for this process. Post-market surveillance was reported in all EAC member states, with Tanzania having the Private Health Laboratories Board, which has a mechanism for tracking substandard medical devices and, through TMDA (see below), recalling them[4].

*Photo credit: IMF Photo, James Oatway/Flickr cc*

### Regulatory pathways for locally developed medical devices – Case studies in Uganda

The regulatory pathway guiding local development and manufacture of medical devices was found to be unclear, and this became evident at the stage of clinical validation. For example, different pathways were reported in two cases studied in Uganda. Figure 1 shows the pathways followed by two medical device projects – the Electronically Controlled Gravity Feed (ECGF) Infusion Set (see Case Study 2, p. 46) and the maternal post-partum haemorrhage (PPH) belt (see Case Study 1, p. 45). Note that, in contrast to the pathway for the PPH belt, the UNBS was not involved in the approval pathway for the ECGF Infusion Set. This body usually tests devices or components that are approved for market and, furthermore, is reported not to have the capacity to test equipment of the type represented by the ECGF device. Conversely, the National Drug Authority (NDA) was not involved in the clinical trial approval pathway for the PPH belt.

With MedTech development being a new field in Uganda, most regulators were unsure how to manage the device regulation process. This was compounded by the necessary caution applied to ensure patient safety through the process. This observation was made by one of the teams consulted for these case studies, which was sent back and forth between regulators who would only commit to a final decision after approval from another regulatory body.

It is difficult to map out the regulatory pathway following clinical validation (i.e., leading to the product being placed on the market), as no locally manufactured medical device has to date made it past this stage. However, discussions with UNBS pointed towards the NDA as the appropriate regulator as medical devices are included in its remit (see below). Regulatory bodies that could play a role in the medical device regulatory pathway and their roles are outlined below.

A solution being pursued by the ECGF team is to seek European CE mark accreditation to compensate for the lack of harmonised standards within the EAC. It is then anticipated that the NDA will be responsible for review of CE mark data, and the UNBS would verify the quality and safety of the device and affix a quality mark necessary for sale of the device. It is anticipated that, should testing and clinical data support this, NDA approval would be sought to place the PPH device on the market.

Although these case studies are drawn from Uganda, there is evidence that a lack of clarity in medical device regulatory pathways is a challenge for the successful translation of innovative medical technology across East Africa (see Case Study 4: Translation and Innovation Hubs, p.49; Translation Challenges, p. 36; Workshop Outputs – SWOT, p. 57; and Consensus, Conclusions, and Recommendations, p. 59).

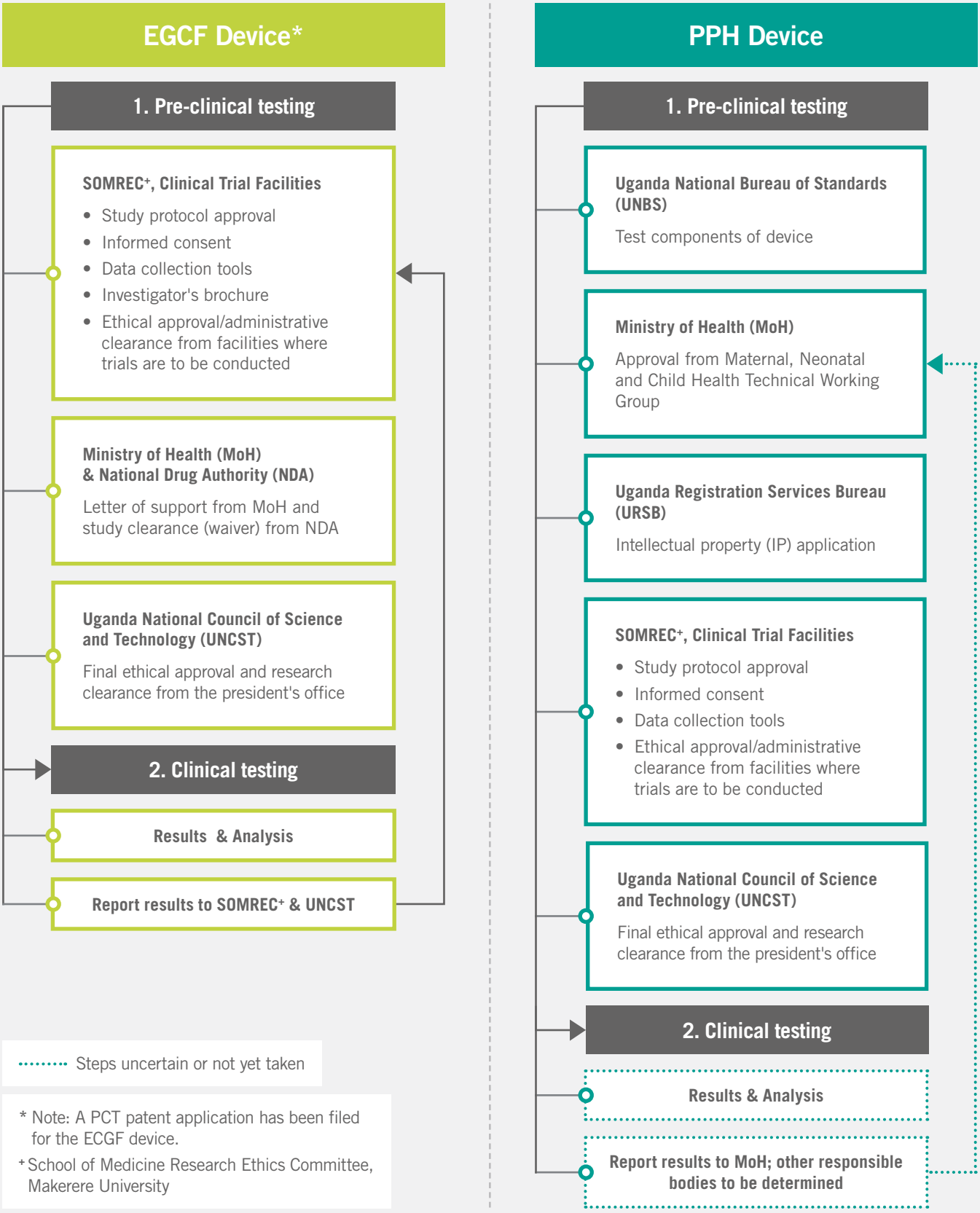



Figure 1: Clinical trial regulatory approval pathway taken by two medical device innovations in Uganda (ECGF & PPH devices).

# Medical Device Regulatory Processes

*Mrs Philippa Ngaju Makobore, Report Co-Investigator.*

## Medical device regulatory bodies in Uganda

### National Drug Authority (NDA)

The NDA was established in 1993 and enshrined in Ugandan law in 2000. Its mandate is to ensure the availability of essential, effective, and affordable drugs and health care products so as to provide safe and satisfactory healthcare to the entire population.[5] The NDA's Director of Product Safety, Helen Byomire Ndagije, explained that Section 40 of the National Drug Policy and Authority Act mandates the NDA to oversee drug-related clinical trials. These trials must be evaluated and cleared by the NDA, the Research and Ethics Committees (RECs), and the Uganda National Council for Science and Technology (UNCST).[6] The NDA also carries out verification of imported devices used in medical care as a regulatory quality assurance measure. The NDA's role in regulating locally developed medical devices does not seem to be clearly defined, however.

### Uganda National Council of Science and Technology (UNCST)

The UNCST is mandated to register and issue research permits. This is done to ease research coordination and oversight, ensure integrity and compliance with regulations, and protect the environment and humans as research participants.[7] The UNCST issues research permits following approval from the RECs and ensures that ethics are adhered to while conducting research. The Council also accredits the RECs for quality assurance. In addition to skills training offered through seminars and workshops, the UNCST offers intellectual property (IP) training to researchers.

### Other regulatory bodies in Uganda

The UNBS, established by an Act of Parliament under the Ministry of Tourism, Trade and Industry in 1989, has a mandate to develop and promote standardisation, quality assurance, laboratory testing, and metrology to enhance the competitiveness of local industry and locally manufactured products[8]; strengthen Uganda's economy; and promote quality, safety, and fair trade.[9] Limited experience with medical devices could impair the development of local MedTech.

The Uganda Registration Services Bureau (URSB) is a semi-autonomous body established by the URSB Act. The bureau is responsible for IP rights registration, including industrial designs, patents, trademarks and service marks, and copyright.[10]

## Medical device regulatory bodies in Tanzania

### Tanzania Medicines and Medical Devices Authority (TMDA)

The TMDA (renamed from Tanzania Food and Drugs Authority in 2019) is an executive agency under the Ministry of Health, Community Development, Gender, Elderly, and Children. It is responsible for regulating safety, quality, and effectiveness of medicines, medical devices, and diagnostics. The TMDA also ensures that all clinical trials for medicines and medical devices follow authorised standards.[11]

## Medical device regulatory bodies in Kenya

### Kenya Bureau of Standards (KEBS)

The KEBS is a statutory body mandated to provide standards, metrology and conformity assessment, quality inspection of imports based on Kenya Standards or approved specifications[12], and testing and calibration of precision instruments and scientific apparatus. Human health (medicines or medical devices) is not listed among the industry sectors for which KEBS is responsible.

### Pharmacy and Poisons Board (PPB)

Although the PPB mainly deals with the regulation of pharmaceutical products, they are also involved in medical device regulation, including those manufactured locally.[13] In 2012, the PPB adopted WHO recommendations by constituting a department under the Directorate of Registration and Evaluation to evaluate applications for marketing authorisations of medical devices, including in vitro diagnostic devices (IVDs). Regulations put into place by this body now apply to locally manufactured medical devices as well as those imported into the country[14].

## Medical device regulatory bodies in Rwanda

### Rwanda Standards Board (RSB)

The RSB is a public National Standards Body established by the Government of Rwanda to spearhead the development and declaration of standards in the country. The body also conducts research on standardisation.[15] The regulatory body, Rwanda Food and Drugs Authority, which was established in 2018 with responsibility for human medicinal products, has recently also introduced guidelines for the registration of medical devices to be marketed in Rwanda (Rwanda FDA, 2020[16]).

## Discussion and conclusion

The medical device regulatory bodies in East Africa are focused mainly on imports. Discussions about regulation of locally produced medical devices have only recently emerged – likely due to the rising number of local innovations in the health sector. Much development and refinement still needs to take place with regards to regulation of local innovations to move them through the design process, onto market, and post-market. It is expected that as these devices go through these phases, a pathway will be mapped out as has been attempted for clinical trials. However, coordination and dialogue between the various bodies involved across the region is essential. To this end, we welcome efforts for harmonisation of regulations across the EAC as an important step.

*Professor Eng. Simiyu Sitati, Dean, School of Engineering, Moi University, Kenya*

# Case Study 1:
# The Duke – Makerere BME Partnership

**The transcontinental partnership between Duke University (Durham, NC, USA) and the BME Programme at Makerere University (Kampala, Uganda) has supported capacity building of academics from Uganda and collaborative learning between Ugandan students and Duke students.**

This partnership was started in 2015 by Professor William (Monty) Reichert, who had spent 2014–2015 as a Fulbright Scholar at Makerere University.

The partnership – with the overall aim of the development of BME in Uganda – was supported by Duke through its BME Department, Provost's Office, Global Health Institute, Pratt School of Engineering, and Duke Africa Initiative.

## Building BME capacity

Between 2017 and 2020, the partnership sponsored six Ugandans through the Duke–Makerere BME Scholarship Programme to receive master's degrees from Duke University, and two of these students are currently pursuing their PhD research studies.

> **The main deficit for the Makerere University BME program is the extreme shortage of qualified instructors. Since the gateway degree for becoming an instructor is the Masters of Science (MS) degree, setting up a program to enable Makerere BME grads to come here and get an MS in BME seemed like a no-brainer.[1]**
>
> **Professor William (Monty) Reichert**, founder of the Duke–Makerere BME Programme

> **The program has been very beneficial - I have gained more knowledge and skills in tissue engineering and hope to transfer these skills back to my country.[2]**
>
> **Beryl Arinda,** Ugandan graduate of the Duke–Makerere BME Programme.

## DukeEngage

Case Study 5 (p. 51) discusses how instrumental the Duke–Makerere partnership has been for the Engineering World Health (EWH) programme in Uganda. EWH is a not-for-profit, third-sector organisation that focuses on improving health through biomedical engineering, especially in LMICs.[6] The Duke and Makerere University chapters collaborated to create opportunities for students from Duke to be placed in Ugandan hospitals, working together with Makerere BME students during their summer to carry out repair and maintenance of medical equipment. The DukeEngage scheme provided funding to those students selected from Duke University to participate.[7] The EWH programme has also employed four biomedical engineers from Uganda as on-the-ground coordinators (OTGCs) to plan and execute the programme.

## Collaborative learning

The partnership also supports collaborative learning through a joint design class for BME students at Makerere and Duke Universities using maker spaces at both sites. This has provided a unique opportunity to share knowledge from both universities and to allow students to co-create solutions addressing healthcare challenges faced in Uganda. The scheme also involves Duke students travelling to Uganda, where they interact with their Ugandan project partners. The development of prototypes for significant projects has resulted from this collaboration.

> **We very much appreciate the funding for the prototypes from Duke University as this helped us take our projects to another level.**
>
> **Brian Matovu**, former student in the Duke–Makerere BME Programme design class.

Some of the projects that have progressed to secure funding from other funding bodies (notably Grand Challenges Canada) include:

- A pre-eclampsia diagnostic kit for low-resource countries, which has amassed funding of more than $100,000 and is currently at the clinical trials phase.[3] It uses a lateral flow strip designed for early diagnosis and functions in a similar manner to a pregnancy test strip in which urine is applied to one end of the strip and is pulled across by capillary action to where antibodies specific to biomarkers indicative of pre-eclampsia are immobilised. Specific antibody binding leads to the formation of a test line allowing a positive or negative diagnosis. A control line indicates the proper functioning of the device.
- A maternal post-partum haemorrhage (PPH) belt that was awarded funding of CAD 100,000 to conduct clinical trials in Uganda.[4] This is a non-powered device designed to treat mothers with PPH in LMICs.[5]

*Students in the EWH programme repairing medical equipment in Ugandan hospitals.* *Photo Credit: Engineering World Health*

## Case Study 2:

# Uganda Industrial Research Institute (UIRI)

**The Uganda Industrial Research Institute (UIRI) is a centre of excellence in industrial research for the East African Community (EAC) and a member of the World Association of Industrial and Technological Research Organisations (WAITRO). It was awarded this status during a Heads of State Summit held in Kampala, Uganda in 2013. The institution is the Ugandan government's lead agency for industrialisation, established by an Act of Parliament in 2003.**

Reporting to the Ministry of Science, Technology, and Innovation (MoSTI), UIRI's remit is to support the entire national applied Science, Technology, and Innovation ecosystem and transform the industrial sector in Uganda by undertaking applied research and development of appropriate technology. It also offers a business incubation programme to nurture SMEs to create a strong, effective, and competitive industrial sector.

The Instrumentation Division is a department under the Technology Development Centre at UIRI that undertakes applied research and development in the area of embedded electronics for application primarily in healthcare. The department has secured both local and international funding for innovation.[1,2,3]

UIRI

# Electronically Controlled Gravity Feed (ECGF) Infusion Set

### Background

The ECGF project started in 2013 after the Instrumentation team visited the Children's Acute Care ward at Mulago National Referral Hospital. It was noted that fluid resuscitation was being carried out manually, which increased the probability of human error. In addition, the ward lacked appropriate infusion equipment, with most available equipment having been donated. The few infusion pump units were used only for children in critical condition in the high dependency unit. There was no assurance that the infusion sets in use were accurate, and this equipment was also difficult to use in terms of user features. The ECGF device aims to deliver accurate intravenous (IV) fluids and drugs by controlling the rate of fluid flow based on feedback from a drop sensor, in addition to providing requisite safety through alarms and an easy-to-operate user interface. The device was awarded the Innovation Prize for Africa by the Africa Innovation Foundation in 2017.[4]

### Implementation steps

With the challenges related to administering IV fluids documented, the initial concept of the ECGF device was developed: measurement of the drop rate in real time with a drop sensor and subsequent regulation of this rate with a tube constriction mechanism. After publishing the proof of concept[5], the project received initial funding from the Patient Safety Movement Foundation based in California. This allowed for the design of the casings, refinement of the control algorithms, and pre-clinical testing[6] to be completed as a precursor to clinical trials. The casings were designed with support from Design without Borders.[7,8]

The device has been clinically validated in adults and children; 12 adult patients from the Infectious Diseases ward at Mulago National Referral Hospital were placed on the ECGF device and had infusion therapy administered.[9,10] Results demonstrated that the ECGF was able to maintain an accuracy of ±7% between the actual and prescribed rate of fluid flow. A clinical trial in the paediatric population was then conducted to ascertain initial safety and non-inferiority when compared with the existing standard of care (manual regulation). A total of 168 children between the ages of 2 months and 8 years were enrolled and randomised to either the control or intervention arm. This study was completed in February 2019.

### Next steps

The next steps are to further improve the functionality and fabrication processes of the ECGF device such that it can be CE marked and approved for use in hospitals across East Africa. The Instrumentation Division has partnered with the Fraunhofer Institute for Manufacturing Engineering and Automation (Automation in Medicine and Biotechnology division) in Germany for this stage of development. US Food and Drug Administration (FDA) approval may be sought depending on demand.

Nurses being trained in installation and operation of the ECGF device, Kiruddu Hospital, Kampala, Uganda

*Photo credit: Philippa Ngaju Makobore*

# Case Study 3:

# CEBE: East Africa Regional Centre of Excellence in Biomedical Engineering and e-Health

**CEBE is the Regional Centre of Excellence in Biomedical Engineering (including Rehabilitation and Mobility Sciences) and e-Health, hosted by the University of Rwanda. It was established in 2015 as one of the East African Centres of Excellence approved and financed by the African Development Bank (AfDB) and is strongly supported by the government of Rwanda as it seeks to develop the country's science and technology capability.[1,2,3]**

**CEBE's regional responsibilities extend to the whole of the East African Community (EAC), with objectives to:**

- Train biomedical engineers and technicians, rehabilitation and mobility specialists, and e-health professionals for industry (public and private health sectors). The specific objective of the project is to provide a high-quality, competitive, and skilled workforce in the EAC.
- Apply engineering principles and technology to medical and biological problems in healthcare to facilitate timely and accurate diagnosis.
- Form industry–academia partnerships to address local Biomedical Engineering (BME) and e-health challenges through innovation.
- Form strategic university partnerships with international institutions in order to develop CEBE and promote education and research excellence at the University of Rwanda.

## Future Direction

CEBE is well placed to extend the use of telemedicine (where a patient is able to access healthcare services from a doctor or healthcare professional remotely via a smartphone) and provide research and training opportunities in the key medical equipment/device and digital health/e-health sectors in Rwanda and across East Africa.[4] In this way, the number of skilled healthcare professionals will be increased, facilitating regional social and economic development.

Plans are in place to introduce professional training in e-health and master's degree courses in BME, Health Informatics (e-health) and Rehabilitation and Mobility Sciences[5,6]. Partnerships have been established with EnMed (an Engineering and Medicine programme at Texas A&M University, Purdue University, and Colorado State University, USA[7]); University of Oslo, Norway; University of Stockholm, Sweden; Vrije Universiteit Brussels and Ghent University, Belgium; and Strathclyde University, University of Dundee, and University of Glasgow, UK.

> **"At CEBE we have identified different partners from recognized international universities and companies, with each one providing expertise in CEBE's areas of interest - mainly Biomedical Engineering, Rehabilitation and Mobility Sciences and e-Health (Digital Health). Each partner will play their role in terms of teaching, research and development. The diversity of partners will also increase the research diversity around the CEBE intervention areas**
>
> **Dr Célestin Twizere**, Director of CEBE

Plans are currently being formulated to re-locate an expanded Centre of Excellence to the new Kigali Innovation City – an Africa-focused innovation hub currently being developed in the Special Economic Zone on the outskirts of Kigali.[8]

## Next steps

Considerable investment has been devoted to establishing and resourcing CEBE and challenging and ambitious objectives have been set. It is vital that evidence is collected to support the effectiveness of this initiative (with measures such as graduates, devices or systems developed, publications, company partners coming from collaborations, improvements in health services) as CEBE would be expected to play a major role in the development of BME in East Africa. These should be evaluated in a follow-up phase of this project.

*Biomedical Engineering Masters students from CEBE visiting University Central Hospital of Kigali (CHUK).* *Credit: CEBE*

# Case Study 4:
# Translation and Innovation Hubs

**Translation and innovation hubs provide entrepreneurs and start-up companies with space to develop ideas into business opportunities and allow their co-location with other similar businesses.**

Hubs also provide access to in-house advice and support and are often located close to university campuses and research facilities in order to foster collaboration and the flow of innovative concepts. Hubs may act as incubators (for very early-stage concepts), accelerators (in which mentoring and seed funding is made available), and co-working and grow-on spaces (the latter for companies that need to add employees and build ideas to address the next stages of the translation process). The importance of innovation clusters has been noted.[1]

Translation and innovation hubs are attracting the attention of researchers and innovators in the East African region. Research conducted by AfriLabs and Briter Bridges in 2019 documented 643 "tech hubs" across Africa.[2] The number of tech hubs had increased from 442[3] in 2018 and were defined as incubators, accelerators, co-working spaces, technology parks, maker spaces, hacker spaces and other innovation centres with incubator, accelerator and co-working categories accounting for the majority. The report lists the numbers of hubs in East Africa as 93 (Kenya, 50, Uganda, 10, Tanzania, 23, and Rwanda, 10) while another report notes the recent launch of a hub in Burundi.[4] The growing number of hubs in Africa generally and in East Africa in particular can be seen as an indicator of the increasing innovation activity in the region. It also indicates the improving innovation ecosystem and connectivity of technology development organisations in Africa with partners and collaborators overseas as well as with healthcare providers in the region. Around 24 of the hubs surveyed by AfriLabs/Briter Bridges[5] across Africa were reported to specialise in health, with software/IT, agriculture, and education among the most frequent specialisations selected by survey respondents (with between 40–50 respondents selecting each of these categories).

Nine innovation hubs and other support organisations were sampled for our current study. These were Outbox Uganda, Resilient Africa Network (RAN) Eastern Africa, the Consortium for Affordable Medical Technologies (CAMTech), Paradigm (VentureLabs), Makerere Innovation and Incubation Centre, iLabs Makerere, Social Innovation Academy, Innovation Village, and Fund Africa Inc. These hubs and support organisations were mostly concentrated in Kampala, Uganda, with each providing support to an average of 2.5 start-ups that were involved in MedTech (with the exception of Fund Africa Inc., which did not have any start-ups in this field; see Translation Challenges Appendix, p. 38 for projects and product developments supported by these hubs). This corresponds to an estimated 5 – 15% of total start-ups supported (CAMTech excluded). The funding sourced by these hubs to support MedTech start-ups was mostly from international organisations and donor governments. Many of these offered workspaces, links to investors, mentorship, training, free internet, and free electricity, while some offered technical support such as IT support, CAD design, and prototyping.

We also discussed Villgro Kenya (now Villgro Africa) with its co-founder, Dr Robert Karanja. Villgro[6] is a business incubator and investor based in Nairobi that aims to facilitate innovative thinking to solve Africa's toughest health challenges. It has supported innovators in East Africa since 2015. Funding is sourced from PATH[7], Grand Challenges Africa[8], Amref Health Africa[9], FINCA Ventures[10], and many others (see also Funders and Investors, p. 33), and 16 healthcare start-ups across East Africa have been supported. These include Matibabu and Mama Ope (see Translation Challenges Appendix, p. 38).

Villgro Africa has provided over $1 million, but their model goes beyond funding to include mentorship, validation of business models, and access to established investment networks. Robert Karanja believes that medical devices used in Africa will be developed locally in around 5 years from now. However, for this to happen, further investment, academia–industry partnerships, and more straightforward regulatory pathways are all needed.

> **East African countries should polish and harmonize their regulatory frameworks and standards if local healthcare innovations are to move to the market.**
>
> **Dr Robert Karanja**, Co-Founder and CEO, Villgro Africa.

For the current project, we asked a healthcare investor, Steven Adjei (founding partner of the African healthcare incubator BlueCloud Health[11], and founder of the Afya Fund, which invests in MedTech and health services in Africa[12]) about the importance of translation and innovation hubs for Africa's health and MedTech innovation ecosystem. Mr Adjei stressed the importance of a comprehensive business plan and a highly competent management team in order for companies to be investment-ready (see also the "Five Determinants" for investment in the healthcare sector[13]). He told us:

> **As a health incubator, BlueCloud works to help businesses get beyond the post-innovation funding gap. This is where many companies get stuck for the need of funds to expand and get products to market. We are able to expose companies to investors who have not yet been involved in Africa.**
>
> **Steven Adjei**, Founding Partner, BlueCloud Health.

# Case Study 5:
# Engineering World Health

**Engineering World Health (EWH) is a third sector organisation with headquarters in Durham, NC, USA.[1] EWH activities in Uganda grew out of a partnership between Duke University in the US and Makerere University Biomedical Engineering programmes (see also Case Study 1, p. 45). This followed plans drawn by the Makerere Biomedical Engineering Head Dr Robert Ssekitoleko and Fulbright Visiting Professor Monty Reichert in response to the clear need for servicing and repairs of medical equipment in Uganda.**

**Large numbers of medical equipment items in health facilities were non-functional – mainly due to the lack of skilled personnel to maintain and repair them.**

EWH programmes were already running in a number of countries, including neighbouring Rwanda and Tanzania. These programmes afford engineering students from developed countries the opportunity to spend their summer break in LMICs fixing medical equipment. In June 2017, Makerere University hosted its first cohort of eight EWH fellows – in this case, engineering students from Duke University. This was followed by a 10-week training programme for a further 14 fellows from University of New South Wales, Australia, held in December 2017. This training developed into the Uganda January Institute, which ran in 2018 and 2019.[2]

## Tasks

EWH fellows are selected from different engineering disciplines with many coming through the DukeEngage program.[3] For the 8-week Summer Institute, they attend a custom-designed, in-country, intensive 4-week training on medical equipment theory, including practical sessions in electronics. They also take culture and language classes. The first 4 weeks are spent in Kampala, and during this time, the fellows spend at least 1 day per week visiting and working in hospitals around Kampala. In the second month, fellows are sent to hospitals across different parts of Uganda, where they spend time working with local staff to solve medical equipment challenges.[4] The main tasks include taking inventory, servicing and repairing equipment, training of users, and many other tasks as dictated by local needs.[5] The fellows, who are teamed up with local students upon arrival in the country, have the opportunity to explore places of interest and enjoy local delicacies.

While the programme is hosted by Makerere University Biomedical Engineering Unit (MakBME), planning and coordination is done jointly with the EWH Summer Institute Coordinator in the US. In most cases, teams work with an electrician, but there are also many cases where there are no technicians at that location. EWH also sends an on-the-ground coordinator (OTGC), who is usually an alumnus of the programme, to conduct the practical training and provide technical support to the fellows in the second month of the Summer Institute programme. The MakBME team is also available to provide technical support during this period.

## Benefits and Outputs

**The hosting hospitals have greatly benefited from the Summer Institute through:**

- having more functioning medical equipment;
- having inventories routinely updated – a task that had proved very challenging due to limited human resources. The updated inventory helps the hospitals know the condition of medical equipment and, in the long run, to plan accordingly.

**The programme also helps to:**

- tackle the most immediate challenge of unused broken equipment - since it started, the programme has assisted over 20 hospitals around Uganda with the fixing of over 300 items of equipment[6];
- improve the medical industry's perception of the capabilities of biomedical engineers/technicians who are graduating from the relatively new degree and diploma courses in Uganda.

Over 150 general hospitals (with an approximate capacity of 100 beds each) do not have in-house technicians. Beneath these in the overarching health facility structure, there are Health Centre IVs that have operating theatres but no technicians. This demonstrates the still large need for technical support, and it is anticipated that the programme will grow further.

Equipment repair – Uganda, February 2020.

Photo credit: Engineering World Health Fellows

Equipment repair – Uganda, February 2020.

Photo credit: Engineering World Health Fellows

# Case Study 6:
# Innovators and Spin-Outs

**The importance of entrepreneurs and innovators, and the spin-out companies founded, in establishing a vibrant MedTech sector serving the specific needs of the East African population with "contextually appropriate" products cannot be overstated.[1,2,3,4]**

(See The Medical Technology Industry in East Africa, p. 29 and also Funders and Investors, p. 33, and Translation Challenges Appendix, p. 38).

The experiences of two innovators – Ms Sheila Bagayana Mutetire, CEO ShiShi International Ltd., and Mr Stephen Tashobya, CEO of Wekebere Ltd. – have been documented for this report.

## Wekebere Ltd, Kampala, Uganda

**Wekebere[5], founded in 2017, has designed a wearable device to measure foetal heart rate and uterine contractions of a mother during the last stages of pregnancy (Figure 1).**

This device combines wearable technology with data analytics to reassure expectant mothers about the course of their pregnancy and provide health workers with better information in order to improve birth outcomes.

Wekebere has its origins in work undertaken at Makerere University, and the prototype device is currently at the clinical testing phase. The company has received support from industry and academia, including the Uganda Industrial Research Institute (UIRI), University of Liverpool, Resilient Africa Network (RAN), Uganda Communications Commission, Villgro Africa, and Royal Academy of Engineering (RAEng); funding of over $50,000 has been raised. This funding has enabled technology development, generation of technical documentation, regulatory support, business development, and progression along the medical device pathway. However, challenges anticipated in moving to the next development step include a lack of accredited standard laboratories for electrical and electromagnetic tests, lack of a unified process and the funding to conduct a clinical study, and shortages of skilled personnel and the specialist resources and tools needed.

A pilot clinical study will determine the safety of the device, and will precede a clinical trial to determine the accuracy and efficacy. Accessing guidance in terms of resources required and a framework for planning, benchmarking, and conducting these trials presents a further challenge. After confirming efficacy and accuracy, clinical validation studies will be conducted in order to obtain the required certification to roll out the device to the market. Wekebere were due to complete this phase by the end of 2021.


*Figure 1: The Wekebere foetal heart rate device*
*Photo credit: Stephen Tashobya, CEO Wekebere Ltd*

*Figure 2: Stephen Tashobya, CEO Wekebere Ltd*
*Photo credit: Stephen Tashobya*

## ShiShi International Ltd, Kampala, Uganda

**Shishi International[6] has been in operation since 2017. Its main focus is on improving neonatal and maternal care through providing high-quality medical products and services. Thus far, the company has developed phototherapy eye shields for neonates and oxygen splitters (Figure 3).**

Their model is based on leveraging existing designs and improving them to suit specific needs for hospitals in low-resource settings through local assembly and manufacturing.

Makerere University mechanical workshop has been key in enabling the development of prototypes and the iteration of designs. RAN and Makerere University School of Public Health have been fundamental in enabling ShiShi to collect data on user needs in hospitals and different environments. RAN has also provided expert knowledge on business planning, facilitated introductions for ShiShi to pitch their work, as well as provided funding to acquire certification and scale up.

ShiShi has received funding worth $20,000 from the United States African Development Foundation (USADF)[7] and RAN[8]. This funding has supported development of the first oxygen splitters (OxyLife splitter) piloted on the Ugandan market and the creation of awareness around the device. Furthermore, this funding will support in-country registration with the Uganda Registration Services Bureau (URSB), Uganda National Bureau of Standards (UNBS), and National Drug Authority (NDA) to gain market approval.

ShiShi is currently scaling up production of eye shields and OxyLife oxygen splitters. They report their biggest challenge has been the unclear pathway for standardisation, accreditation and approval that allows locally manufactured and assembled medical devices to be used in Ugandan hospitals.

*Figure 3: The ShiShi 5-way OxyLife splitter – paediatric*
*Photo credit: Sheila Bagayana Mutetire, CEO ShiShi International Ltd*

*Figure 4: Sheila Bagayana Mutetire, CEO ShiShi International Ltd*
*Photo credit: Sheila Bagayana Mutetire*

## Conclusions

**These case studies illustrate the importance of quality, locally-based support and advice to assist start-up companies in navigating through the requirements for gaining clinical evidence and placing a device on the market. They also provide an indication of the cost of early-stage product development and launch onto a national market. A major challenge encountered by both companies is the lack of clarity on the regulatory pathways for clinical and market approval. A more in-depth discussion of these types of obstacles can be found in Translation Challenges (p. 36).**

# Case Study 7:
# Emerging Medical Technology

## Academic Researchers in East Africa

### Dr Robert Ssekitoleko

Dr Robert Ssekitoleko is a Senior Lecturer in Biomedical Engineering as well as acting Head of the BME Programme at Makerere University. Dr Ssekitoleko graduated with an MEng in BME from Queen Mary University of London and an EngD in Biomedical/ Medical Engineering from University of Strathclyde, UK. His overall research interest is in improving Global Health Technologies and his research covers clinical engineering, medical imaging, disease surveillance, mHealth, eHealth and telemedicine, infectious diseases, and assistive technology. He has worked on diagnostic ultrasound integrated into biopsy needles, which is at prototype development and testing stage.[4,5]

Dr Ssekitoleko has been awarded 10 grants from international funders and has also started 2 companies: Ng'aali Group[6], which offers mentorship to young professionals to build capacity in research and innovation, and Knowledge for Change[7], a third-sector organisation that aims at improving healthcare in low-income settings.

As challenges, Dr Ssekitoleko highlights the limiting effect of a lack of funding, lack of supporting policy, deficiencies in regulatory bodies, poor internet connectivity, lack of raw materials, and lack of protection for intellectual rights. However, he also highlights the importance of support gained from research funding, mentorship, peers, international collaborators, and his employer.

> **"My motivation to carry out research comes from observing the needs and opportunities and how this feeds into my desire to improve healthcare provision in Africa."**

### Professor Moses Joloba

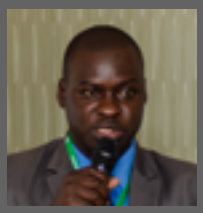
Professor Moses Joloba is the Dean of the School of Biomedical Sciences at Makerere University. He completed his MBChB at Makerere University and his MSc and PhD in molecular microbiology at Case Western Reserve University, USA. His research interests are in microbiology and molecular biology, with a focus on TB. Motivated by the need to solve challenges in healthcare in Uganda, Joloba established the Molecular Biology Laboratory at the College of Health Sciences, Makerere University, in 2003.

Prof. Joloba has been awarded over 88 grants from international funders, has contributed to more than 100 publications, and has supervised 25 PhD and over 100 master's students. He led work that resulted in the introduction of molecular detection of MTC (TB) infections using the GeneXpert® nucleic acid amplification system as a routine test in Ugandan public health labs in 2011.[1,2] GeneXpert® systems are now used in many hospitals in East Africa.

Prof. Joloba comments that bringing about change is difficult, and good support networks and collaboration are needed:

> **"Research is not for faint-hearted people because there are many disappointments. However, those who are ready to learn from the things which do not work will do better in research."**

### Dr Johnes Obungoloch



Dr Obungoloch is Dean, Faculty of Applied Sciences and Technology (FAST) at Mbarara University of Science and Technology (MUST), Uganda.
He obtained his Master's in Biomedical Engineering from Keele University, UK, and his PhD from Penn State University, USA. He is an emerging expert researcher with particular interest in medical imaging and the development of appropriate and sustainable MedTech for LMIC settings.

Dr Obungoloch worked on low-field MRI during his PhD research and subsequently led a programme at MUST to develop and implement a cost-effective MRI system for the diagnosis of conditions such as infant hydrocephalus.[3] This project was a collaboration between MUST, Penn State University, and Delft University of Technology, Netherlands, among others.

Dr Obungoloch recognises the importance of international collaborations, support networks, and mentorship opportunities in being able to achieve his aims – particularly the development of inexpensive MRI diagnostic imaging for low-income countries. He comments that funding and availability of raw materials are limiting factors.

## Dr Misaki Wayengera

Dr Wayengera is a researcher with the Department of Pathology at Makerere University's College of Health Sciences. Dr Wayengera holds an MBChB from Makerere University, a Postgraduate Certificate in Bioentrepreneurship from University Hospital Network, Toronto, and a PhD in pathogenomics from Makerere University.

"My Motivation to become a researcher is from within (internal) since childhood," states Dr Wayengera. The focus of his research is infectious diseases. He has successfully developed a rapid diagnostic test for the Ebola and Marburg viruses that has attracted the interest of WHO[8] and is now being readied for market; an HIV treatment; and a genetic test for cancer. He also chairs the Covid-19 Scientific Committee at the Ministry of Health, Uganda.[9]

Dr Wayengera's collaborations in Canada led to the founding of Restrizymes Biotherapeutics in Uganda[10], where he heads the research team.

> **"To me, support factors have been the bioentrepreneurship opportunity in Canada, Makerere University, and international collaborations.**

More background is found in an interview conducted in 2015[11]. He has been faced with the challenge of limited funding and emphasises that a better infrastructure framework is needed in order to improve the research capacity in Uganda.

Further information on projects conducted by Uganda-based researchers is contained in the Translation Challenges Appendix (p. 38).

## Dr June Madete

Dr Madete is a biomedical engineer, researcher, and senior lecturer at Kenyatta University, Kenya, with a special interest in biomechanics and motion (gait) analysis software and hardware. She received her Bachelor's and Master's degrees in Medical Engineering and a PhD specialising in biomechanics, motion capture, and imaging studies from Cardiff University, UK.

Dr Madete is passionate about empowering women in science[12] by being involved as a mentor in projects such as Lions of Science, the African Entrepreneurship Award[13], and STEM-Africa[14] – an initiative with the University of Michigan, USA. She is also a mentor at the Chandaria Business Innovation and Incubation Centre[15] at Kenyatta University.

Dr Madete is the Coordinator of the African Biomedical Engineering Consortium and, in this capacity, leads the UBORA (Open Biomedical Engineering e-Platform for Innovation through Education) and ABEM (African Biomedical Engineering Mobility) initiatives (see Funders and Investors, p. 34). Through these, it is her aim to develop and promote the BME profession within Kenya (and more widely within Africa) through capacity-building activities and knowledge and skills transfer among students, lecturers, and scientists across various sets of expertise.

> **"Being a new field, trying to start it [BME] in Kenya has been challenging, there is no known scheme of service for a recent graduate in Biomedical Engineering and the boards and the policies in place in the field are also not clear as to what a BME is.[16]**

## Conclusions

**All researchers in East Africa interviewed acknowledge international collaborations and international funding agencies as being main support factors; 70% of science and technology publications from East Africa – and probably a greater proportion for MedTech – involve international collaborations[17]. All researchers mention the need for peer networks and mentors in order to maintain motivation to overcome challenges such as insufficient infrastructure and lack of recognition.**

**These observations reflect factors identified in our analysis (See Translation Challenges and Professional Associations in East Africa p. 36 and 39 respectively).**

# Outputs of an Expert Workshop

## SWOT Analysis

**We held a workshop with invited experts from across East Africa on 7 November 2019.** The aim of this workshop was to outline the work conducted on the project and to seek input from experts on strengths, weaknesses, opportunities, and threats (to construct a SWOT analysis) for BME in East Africa and how the skills made available by this discipline would be most effective in realising healthcare improvements across the EAC. We also asked experts for their recommended actions needed in order for this objective to be met.

### Strengths

#### We asked:

*In what ways does BME in East Africa excel? What are the sources of excellence and best practice? Are there unique technologies or regionally/internationally recognised training programmes? What institutions, organisations or partnerships stand out? Are there examples of good cooperation with Government ministries?*

#### Responses:

- There is a vibrant human resource of young biomedical engineers with brilliant minds – an agile resource.
- BME is a new field and can be shaped/streamlined for maximum effectiveness.
- BME training programmes have a strong multidisciplinary curriculum at the interface of both medicine and engineering.
- There is a high demand and market for BME services.
- East Africa has a young population that can be attracted into education and training in BME.
- Governments are supportive – the number of institutions in Kenya and Uganda exemplify this.
- Communication channels, transport, and distribution within the region are all improving.
- BME is being included when hospital infrastructure is planned – the Kenyatta University Hospital is an example of this.

### Weaknesses

#### We asked:

*What stops BME from acting as a driver for healthcare improvements? What areas need to improve? What resources or facilities are missing? Is the current perception of BME holding back development of the discipline?*

#### Responses:

- Limited resources to run the current undergraduate programmes and to support professionals.
- A Lack of priority given to BME training in the region and funding allocated is limited.
- There are gaps in the curriculum – some content is missing.
- The lack of graduate programmes is a weakness.
- The lack of research opportunities within the region holds back development of BME.
- A lack of well-trained staff in BME.
- Specialised training in sophisticated machines (X-ray, etc.) is lacking with few opportunities to acquire such training.
- The inappropriate medical equipment installed for the healthcare environment of East Africa and limited ability to calibrate, repair, and service this equipment.
- A lack of knowledge and awareness about BME within the region's population.
- Unclear standards, regulations, and guidelines.
- Weak government policies and bribery in the procurement of equipment.
- The poorly defined distinction between roles of BMEs and BMETs.
- A lack of diversification opportunities for BMEs.
- The lack of incubators (see Translation and Incubation Hubs, p. 49) that cater for BME and MedTech innovations.
- The slow growth of internet and network connectivity in some regions.

The SWOT analysis provides a critical evaluation of the potential for BME to act as a provider of health, economic, and social benefits for the EAC but also of the restraints encountered in seeking to realise this potential. Many of these are also reflected and considered in the Analysis and Case Studies sections of this report.

However, not all factors and questions raised were addressable at this stage. The outputs recorded here have informed and fed into the final conclusions and recommendations of this report (see Consensus, Conclusions and Recommendations, p. 59).

## Opportunities

### We asked:

*What favourable external factors could stimulate the development and expansion of BME in areas of healthcare (including start-ups and industry, regulations, etc.)? How can we use the strengths identified to access these opportunities? What steps need to be taken to reach this point?*

### Responses:

- A young population that is eager to venture into the field of BME.
- The existence of BME training institutions with the opportunity to direct trainees.
- Partnerships – opportunities to establish collaborations with both international and local bodies and thereby access more funds through grants. The UBORA platform (see Funders and Investors, p. 34) is a good example of this.
- The commitment of governments to the SDGs (regionally and internationally).
- The existence of unique and diverse challenges.
- The digital revolution in financial technology (FinTech).

## Threats

### We asked:

*Are there factors that have the potential to harm or impede the development of BME and prevent it from being a driver for healthcare improvements? Are there (for instance) rising costs for materials, reduction of university budgets, increasing competition from the West?*

### Responses:

- There is no ready job market for graduate biomedical engineers.
- The number of graduates is high compared to the number absorbed into employment related to BME; career choices are not clear.
- Little support is available from governments with no established regulations to guide programmes or profession; brain drain is a consequence.
- Professionals in related disciplines, but with more experience, are doing the same work BME graduates are trained for.
- Disagreements exist among different regulatory bodies, especially for the regulation of locally made MedTech.
- Technology is changing rapidly but there is limited exposure and limited opportunity to gain the knowledge required to use it.
- Competition – low-cost and better equipment is being produced elsewhere in the world rather than in East Africa.
- Political instability.
- Covid-19 has disrupted healthcare, economic and educational systems. Recovery will be slow.

# Consensus, Conclusions and Recommendations

**In the course of the current project, we have consulted with researchers, educators, regulators, practising biomedical engineers, innovators, funders and clinicians to explore the premise that BME can be a driver for improvements in healthcare in East Africa.**

The Workshop Outputs SWOT Analysis (p. 57) provides a summary of some of the main points raised in support of this premise (Assets) along with the Limitations and Barriers experienced or anticipated for each by these experts. The SWOT Analysis, together with other findings documented in this report such as skills gaps (p. 35) and translation challenges (p. 37), allow us to bring forward the following consensus statements/conclusions (Table 1), and recommendations.

| Assets and Limitations | Barriers Encountered |
|---|---|
| BME is a new and attractive field but is not yet organised for maximum effectiveness in healthcare settings or as a technical resource for the MedTech industry. | • A lack of undergraduate and graduate training opportunities and limited industry opportunities for BME graduates.<br>• Funds allocated to BME training may be diverted.<br>• An uneven distribution of biomedical engineers across all health facilities.<br>• The MedTech industry is not well developed.<br>• Conflicts between those with specialised BME training and less qualified staff with BME responsibilities. |
| Good quality BME training is available in most East African countries, but curricula need to be reviewed to ensure consistency, the setting of appropriate targets and to address skills gaps. | • A lack of facilities and appropriate human resources or expertise in certain fields of BME. |
| Regulations, standards, and guidelines are unclear and are a cause of delay in the bench-to-bedside translation of technology. | • The translational pathway for locally developed devices is poorly defined and not well supported.<br>• Procurement decisions favour imported versus regionally made equipment. |
| Translation and innovation hubs are important sources of support and advice, and more hubs that specialise in MedTech are needed in order to realise the growth opportunities in this sector. | • Resources (funding, facilities, skilled people) required to grow the BME field are not available or given priority. |
| The professional status and registration of biomedical engineers requires improvement and should be reviewed by the responsible professional associations. | • Conflicts and lack of understanding of particular requirements of BME as an engineering discipline; there are some signs of improvement but this needs to be sustained. |
| Partnerships between East African training institutions and universities in Europe and the US are important for the development of BME capability in the EAC. | • Limited training, development, and industry opportunities for BME graduates in the EAC. |

Table 1: Consensus statements/conclusions on whether BME is (or can be) a driver for improvements in healthcare in East Africa.

Barriers identified by this process may be categorised as skills gaps, resource gaps, political and organisational issues, and translational gaps.

> **Competence is knowledge, skills, and attitude together. We learn from mistakes, we gain confidence as we work; hence, companies shouldn't be afraid to give students training opportunities.**
>
> **Joseph Ssali**, Head of Biomedical Engineering at ECUREI, Uganda

## Recommendations

**We make the following recommendations aimed at overcoming existing barriers and stimulating growth and opportunity:**

### 1. Recognise and Prioritise BME

In order to address skills gaps and improve return on investment: Establish national and regional priorities and targets for BME through engagement of all stakeholders, and ensure funding is committed.

**Responsible:** Ministries of Health and of Science/ Technology of all East African governments; international funders.

### 2. Harmonise Medical Device Regulations

In order to realise the efficient and safe translation of technology and the establishment of a vibrant MedTech industry that can effectively contribute to addressing the healthcare needs of East African populations: Streamline and harmonise regulation, certification, and support within the EAC.

**Responsible:** Ministries of Health, Science/Technology, and Industry/Innovation of all East African governments; EAC Secretariat/EAC Medicines Regulatory Harmonisation (MRH) initiative.

### 3. Invest in People Development/Human Resources

In order to build capacity and capability in BME and promote professional development: Form a trans-EAC body with a single head to establish agreed standards for accreditation, training, certification, and professional development; establish good practice; improve communication and coordination among training institutions to facilitate curriculum development; and stimulate the innovation ecosystem through investment in targeted skills training and entrepreneurship training. This body should also monitor the closing of identified skills gaps (see p. 35).

**Responsible:** EAC Secretariat working with Ministries of Health and of Education of all East African governments, relevant professional associations, academic institutions offering BME training, translation/innovation hubs, and ABEC (see Funders and Investors, p. 34).

### 4. Catalyse the MedTech Industry

In order to stimulate investment in the MedTech sector and develop innovative devices and equipment addressing healthcare needs of populations within the EAC and other LMICs: Strategically invest in an ecosystem for the creation, support, and scale-up of innovative MedTech companies so that East Africa is established and recognised as a MedTech hub able to attract investment from international companies; create incentives and infrastructure for appropriately designed, low-cost, "contextually specific" medical equipment to be produced locally.

**Responsible:** Ministries of Science/Technology and Industry/Innovation of all East African governments, working with Investment Authorities of all East African countries, translation/innovation hubs, and international funders.

### 5. Establish Policies for Efficient Medical Equipment Management

In order to realise the benefits from existing medical equipment and optimise the commissioning and supply processes for new equipment and devices to better manage healthcare needs: Improve national policies and processes for procurement of quality medical equipment and management of the entire equipment lifecycle; establish a forum involving companies (local and international companies with a base in EAC), hospitals, government, academic institutions, and existing initiatives such as ABEC.

**Responsible:** Ministries of Health of all East African governments.

## Implementation

The recommendations above address human resource, regulation, policy, equipment, and industry needs. All are important and should be adopted if a return on investment of the scale presented by BME and MedTech in East Africa is to be realised.

These proposals require review, organisation, and coordination at **national governmental levels** and also the establishment of a **new EAC-wide group** to oversee the development of BME as a profession and the building of the required levels of capacity and capability. We recommend that **Working Groups** be convened for each of the five recommendations, part of which will involve roundtable discussions between key stakeholders – including innovators, universities, government, and the private sector – once initial reviews have been conducted by the responsible government ministries.

The focus of these dialogues must be to identify realistic and tractable routes to achieving these five improvements and to propose short-, medium-, and long-term targets for each that the responsible ministries will adopt. There must be a mechanism for coordination and information sharing between the five Working Groups.

It is recommended that external reviewers conduct further audits 2 and 5 years following publication of this report to assess progress and help the groups steer future work. As mentioned in the Foreword, it is our hope that this report and recommendations will aid and inspire policy- and decision-makers in devising strategies and creating conditions that allow the current and potential benefits of BME for East Africa to be fully realised and thus bring critical social, economic and health benefits to this region.

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**The project was led by the Medical Technologies Innovation team at the University of Leeds (UoL), UK, with vital collaboration from College of Health Sciences, Makerere University, Uganda, and Uganda Industrial Research Institute (UIRI).**

The report attempts to capture the conditions affecting the provision and delivery of healthcare in the countries in the East Africa Community and the capacity and capability that exists within the field of biomedical engineering (BME). This, in turn, determines the extent to which BME is able to exert an influence towards healthcare improvement. We look at the translation of medical technology products from idea stage to the clinic and the market and consider barriers and impediments to progression. We capture some of the suggestions and analyses contributed at the dissemination workshops run during the course of this project and draw some recommendations from these various packages of information. We recognise that BME is just one component of a complex ecosystem which seeks to keep the populations of the countries of East Africa in good health.

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# References

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## Executive Summary (P. 4)


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## Introduction (P. 5-8)


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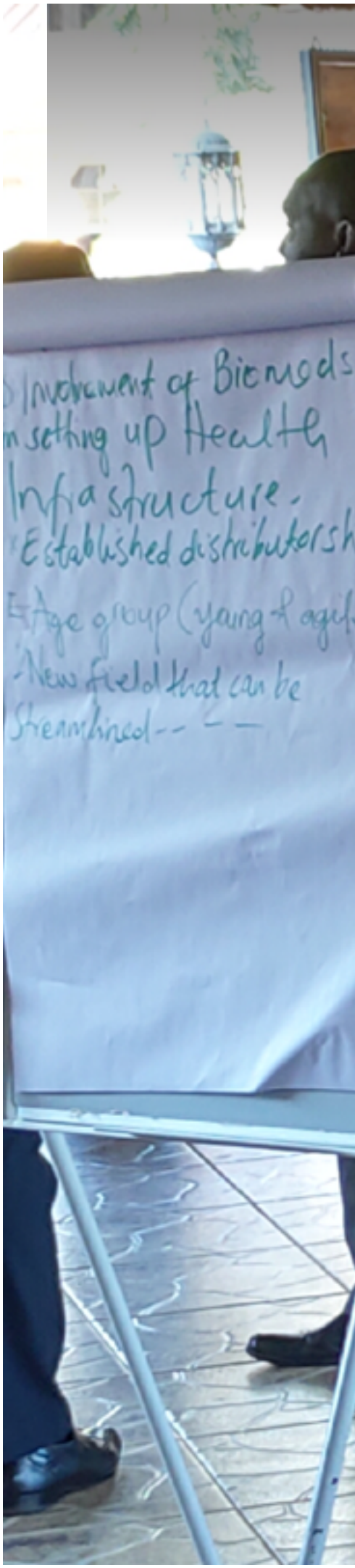
> **Biomedical engineering can save lives. Knowledge is combined to improve health – often through the design of medical devices for diagnosis, treatment and rehabilitation. African countries need to start producing and developing their own medical devices.**
>
> Professor Tania Douglas

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