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INNOVATING FOR BETTER HEALTH

BUILDING BIOMEDICAL DEVICES INNOVATION CAPACITY IN AFRICA

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Note

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The term “innovation” is used to refer to the application of knowledge in product, process, design, market and organizational improvements that are new, not necessarily to the world but to the region, country, centre, firm and/or individual. Unless otherwise stated, it may not include “policy innovations” or entrepreneurship in general.

The terms “number”, “proportion” and “percentage” refer only to the total number of centres or entities that completed the survey and not to the country. Therefore, a statement such as “10 per cent of the researchers have PhDs” refers, not to the national average of researchers, but to the centres taken part in the survey.

The term “biomedical engineering” as used in this publication refers to the deployment of engineering, biology, medicine and their related fields (e.g. physics, computer sciences and information technology) to advance knowledge and innovation to improve health outcomes. This includes the teaching and learning of the related disciplines, as well as the research, development, manufacture and sale of biomedical engineering products.

Acknowledgements

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This report was prepared by a team led by Kasirim Nwuke, Chief of the New Technologies and Innovation Section, Special Initiatives Division, ECA. Fatima Denton, Director of the Special Initiatives Division, provided overall direction and guidance. It was conceptualized by Kasirim Nwuke and is based on a consultancy coordinated by Victor Konde, Scientific Affairs Officer, New Technologies and Innovation Section. The team consisted of Mr. Konde (Chapters 1, 2, and 5), June Kazira Madete, Senior Lecturer, Kenyatta University (Chapter 3), and Elizabeth Molyneux, Paediatrician and Researcher, Queen Elizabeth Central Hospital, Blantyre (Chapter 4).

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CHAPTER 1
Introduction

All countries have health facilities, namely, hospitals, clinics and health centres, to provide health care to their citizens. Each facility has health-care professionals who use modern medical devices, technologies and innovations to address the health-care needs of citizens. The degree to which desired health outcomes are improved therefore depends on the degree to which medical devices and innovations are employed productively in a health-care system. It can explain the gap in health outcomes among countries and the rate at which they can make progress towards achieving the targets of the health-related Sustainable Development Goals.

Health outcomes and indicators in Africa are known to be poor, although with significant variations in countries. Health systems are also weak, poorly financed and inadequately equipped with the medical devices needed to provide care in the twenty-first century. The present report, which builds on the outcomes of the Economic Commission for Africa's (ECA) multi-year biomedical engineering project, entitled "Engineering expertise to improve health outcomes in Africa", makes the case that that innovation is key to achieving improved health in Africa and for achieving the health-related Sustainable Development Goals in Africa.

Modern health facilities play a critical role in empowering health professionals to diagnose diseases early, provide prompt, effective and safe treatments and in expanding access to health services. Medical devices have become indispensable tools, from the simple thermometer to sophisticated imaging devices that are enabling health professionals to see deeper into the inner workings of the human body. Innovations have been key in bringing to market robust, easier-to-use and cheaper tools that have moved the early detection of HIV/AIDS from high specialized hospitals to small clinics (points of care), which, in turn, has made voluntary testing possible for millions of people, even in remote areas. Innovation, namely biomedical innovation, will be critical for bridging the gap in health outcomes if it improves access to quality health care.

Evidence suggests that many health facilities in Africa have limited access to basic medical devices needed to enhance the provision of health services. Part of the explanation lies in limited funding for hospitals. Another reason is the near absence of medical devices manufacturing capacity on the continent. Consequently, most health facilities on the continent depend on imported or donated medical devices or both. Most of these devices are designed for market in developed countries with limited consideration for Africa's unique operating environment, such as unstable electric power supply, dust, heat and humidity and low technical skills. In addition, improper use, poor maintenance, lack of spare parts and the high cost of importing technical experts to service the devices when they break down result in a significant proportion of these machines being inoperable for extended periods of time, costing several lives. In other cases, medical devices imported at great expense or donated remained uninstalled due to limited in-country biomedical engineering skills.

This situation is not tenable in the long term. For it to change, African countries must innovate in health. They must build the human capital necessary to source and develop the appropriate medical devices that suit their environment and

needs. They must also build the competence necessary to install and maintain such devices to ensure that they remain operational most of the time and to design and produce medical devices domestically. Given the rapid changes in technology, Africa will need to build as quickly as possible the technical and professional biomedical engineering expertise to meet not only its teaching, research, technological needs, but also its industrial aspirations in order to achieve her health goals.

This is possible if the appropriate support mechanisms that encourage actors, namely, universities, health facilities and manufacturing firms, to work across disciplinary boundaries, encourage students and researchers to be innovative and promote close government-industry-university collaborations. An important element of this equation is the provision of spaces in which young people with innovative ideas can experiment, produce and test their designs. Evidence suggests that this can play a catalytic role in bringing innovation to market very rapidly. While biomedical engineering requires a good understanding of engineering and medical-related sciences, success in bring inventions to market depends on entrepreneurial skills and experience and business development skills.

This study is based on a combination of field work in selected countries and on desk research. The countries in the study were not selected at random; rather, they were selected because of the participation of their universities in the ECA biomedical engineering programme. South Africa was selected because it is the leading country on the continent in the manufacture of biomedical devices. The study shows that, notwithstanding enormous odds, in terms of limited technological and industrial experience, countries have been able to bring locally developed innovative medical devices to market. This provides useful lessons for other African countries considering the creation of an indigenous biomedical manufacturing sector.

Market size is often a determining variable in the decision to manufacture. The hospital and health-care market in Africa has recently expanded as incomes have risen. This study confirms that Africa has a fast-growing market for medical devices. The authors underscore that, while national markets are expanding, many remain relatively small and a regional approach to market is key to the development of an African medical devices industry. This presents another opportunity for promoting intraregional research collaboration and intraregional trade. The study further sets out various ways in which countries can encourage universities and institutions to instil and enhance entrepreneurial and innovative culture among young people and researchers to help to build an innovative and dynamic biomedical devices industry.

CHAPTER 2
Overview of Africa's health challenges and progress

Key highlights

This chapter examines Africa's fast-evolving health-care landscape against a backdrop of rapid advances in technology. The recent Ebola outbreak (2014-2016) in the Mano River region of West Africa underscored the fragility and weakness of Africa's health system and the role that advances in technology, especially information and communications technologies (ICT) can play in improving health outcomes. The Sustainable Development Goals and the African Union's Agenda 2063 contain specific targets that need to be achieved by 2030 and 2063, respectively. The Goals seek to "leave no one behind". Poor health is often a causative factor in leaving people behind. It therefore follows that improving health outcomes for all is central to achieving the Goals and realizing the aspirations of Agenda 2063.

This introductory chapter discusses progress made in Africa on health. It identifies successes and challenges. It reviews aggregate health expenditure and the increasing role that health technologies, especially medical devices, plays in the provision of quality health services. Some of the major highlights of the chapter include the following:

Sharp rise in life expectancy: Africa has made significant progress in improving the quality of health of its people during the past two decades. While most of the countries on the continent may not have met all the health-related Millennium Development Goals, life expectancy at birth has risen rapidly since 2000, especially among countries that are disproportionately affected by communicable diseases such as HIV/AIDS, malaria and tuberculosis. However, the region still trails the rest of the world with respect to life expectancy at birth.

Rapid fall in deaths caused by communicable disease: Deaths caused by communicable diseases declined between 2000 and 2012 by 42.4 per cent per cent, while deaths caused by non-communicable diseases dropped by a mere 5.9 per cent during per cent the same period. As a result, the proportion of deaths caused by non-communicable diseases in total deaths increased from 13 per cent per cent in 2000 to 19 per cent per cent in 2012. By 2012, non-communicable diseases caused almost as many deaths associated with HIV/AIDS and from malaria combined in 2012.

Rapid increase in health-care expenditure: Health expenditure has, on average, risen in real terms in countries not mired in conflict. This is due to a number of factors, including the peer pressure arising from meeting the health-related Millennium Development Goals, debt relief and increased revenue from the commodity boom. Consequently, per capita health expenditure in a number of countries has grown rapidly. For example, in Equatorial Guinea, it grew from $64 per capita in 2000 to $663 per capita in 2014. Other countries that registered a rapid rise in health expenditure per capita included Angola (961 per cent), the Sudan (763 per cent), the Republic of the Congo (643 per cent), Nigeria (583 per cent) and Algeria (490 per cent). Another 18 African countries saw their health expenditure per capita rise by between 200 per cent and 480 per cent during the same period.

Emerging technological opportunities: New technologies offer Africa great opportunities to design and produce medical devices that meet

its needs, not only in urban areas, but also in rural communities, and to participate, in the medium to long term, in the export of health-care services. Such advances in medical devices could help countries to position themselves as health-care hubs to generate a new source of national income. This will call for an even greater investment in medical devices and technologies.

2.1 Health-care aspirations of Africa and the world

Africa continues to make significant and steady progress in improving the quality of life of its people. All available evidence suggests that the prevalence of several diseases has been stemmed. The increased availability of treatment has reduced the burden of HIV/AIDS and education and information have reduced the rate of new HIV/AIDS infections. The burden of tuberculosis and malaria is also falling (or holding steady) in a majority of countries. This success was achieved, in part, through increased awareness, improved access to medical facilities and a rise in health-care personnel. Notwithstanding this progress, some African countries failed, as of the end of 2015, to meet most of the health-care targets set out in the Millennium Development Goals (African Union et al., 2015).

The Sustainable Development Goals, adopted in 2015 by world leaders, seek the sustainable transformation of the world by 2030 in 17 specific areas (United Nations, 2015). The objective of Sustainable Development Goal 3 is to "ensure healthy lives and promote well-being for all at all ages" by 2030. Some of the targets set to measure the achievement of this Goal include reducing the global maternal mortality ratio to less than 70 per 100,000 live births; reducing neonatal mortality in all countries to about or less than 12 per 1,000 live births; ending the epidemics of HIV/AIDS, tuberculosis, malaria, neglected tropical diseases and other communicable diseases; and strengthening the capacity of all countries for early warning, risk reduction and the management of national and global health risks.

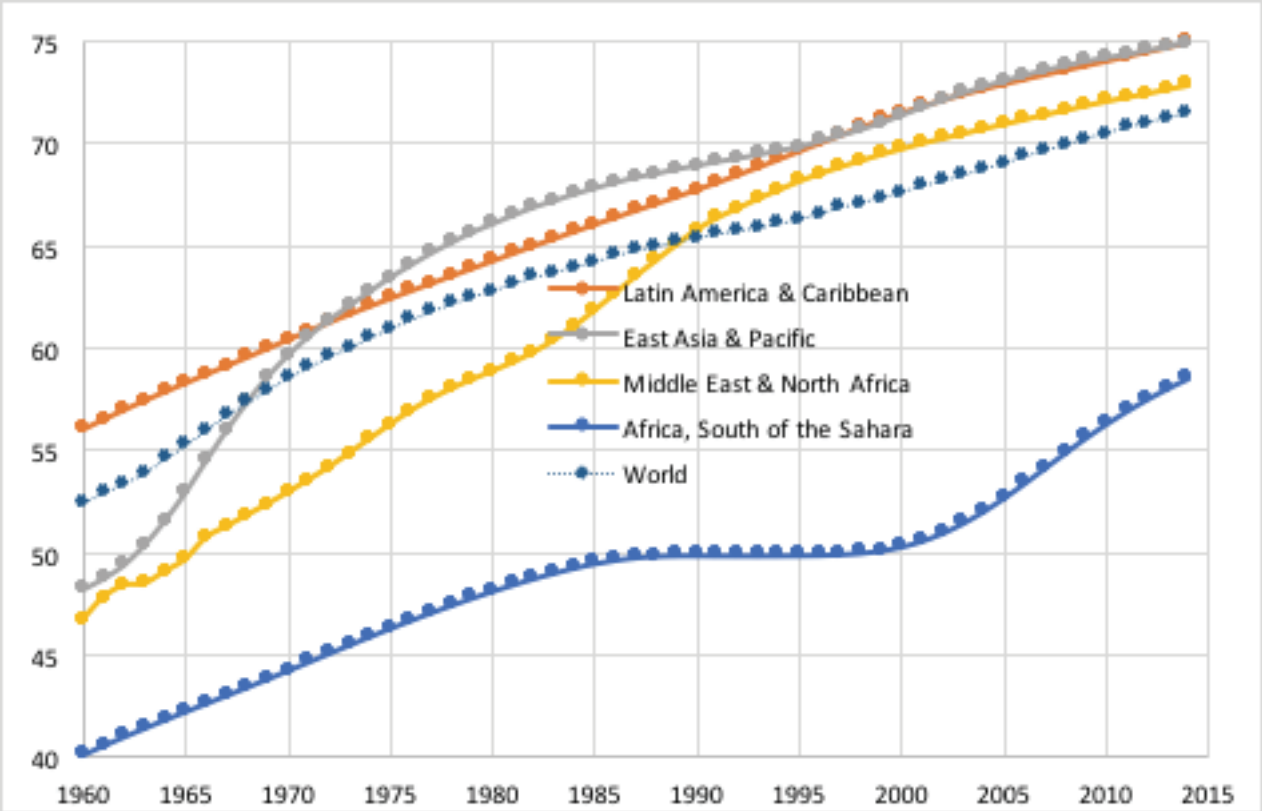
At the continental level, Africa has set even higher goals in its recently adopted 50-year plan: Agenda 2063: the Africa We Want. According to Agenda 2063, Africa aspires that, by 2063Every citizen will have full access to affordable and quality health care services, universal access to sexual and reproductive health and rights information, and these services will be available to all women, including young women, adolescents, women with disability, those living with AIDS and all vulnerable groups……Integrated and comprehensive health services and infrastructure will be in place, where services are available, accessible, affordable, acceptable and of quality. The African population of 2063 will be healthy, well nourished, and enjoying a life expectancy of above 75 years (African Union, 2015).

Historical evidence suggests that Africa has never been short on aspirations and goals. The continent's history of limited success in achieving its goals implies that exceptional commitment and strong dedicated efforts are required to achieve the targets that have been set out not only in Agenda 2063, but also in the 2030 Agenda for Sustainable Development. Significant increases in investment in health-care infrastructure, the training of adequate health-care professionals and the integration of science, technology and innovation as cornerstones of the health-care sector will be required.

2.2 Improvements in health and changing health-care challenges

African countries have made steady improvements in a number of health indicators, which have led to a significant improvement in the health status of their citizens. Nevertheless, they have yet to catch up with the rest of the world in terms of life expectancy. For example, the world has seen the average life expectancy rise from 52 years of in 1960 to 71 in 2014. All other major regions, except sub-Saharan Africa, have attained a life expectancy of between 72 and 75 years of age. In this regard, sub-Saharan Africa has one of the lowest life expectancies at birth (58.6 years of age) and added only 18 years to its life expectancy between 1960 and 2014 (see figure 2.1). Most of the growth in life expectancy occurred between 1960 and 1985 (adding 9.5 years) and between 2000 and 2014 (adding 8.5 years).

Figure 2.1: Changes in life expectancy at birth by main regions



Source: World Health Organization Global Health Observatory.

At the national level, all African countries reported a rise in life expectancy in the past decade and a half. Countries where life expectancy at birth increased between 2000 and 2015 include Eritrea (19.4 years added), Zambia (18 years), Botswana (17.9), Rwanda (17.8), Malawi (15.2) and Zimbabwe (14.7). In another eight African countries, life expectancy increased by 10 or more years over that time. The recent improvements have, in part, resulted from the improved control and management of diseases and illnesses, especially those related to HIV/AIDS, malaria and tuberculosis, and the increased availability of health services (i.e., surveillance, diagnosis and treatment).

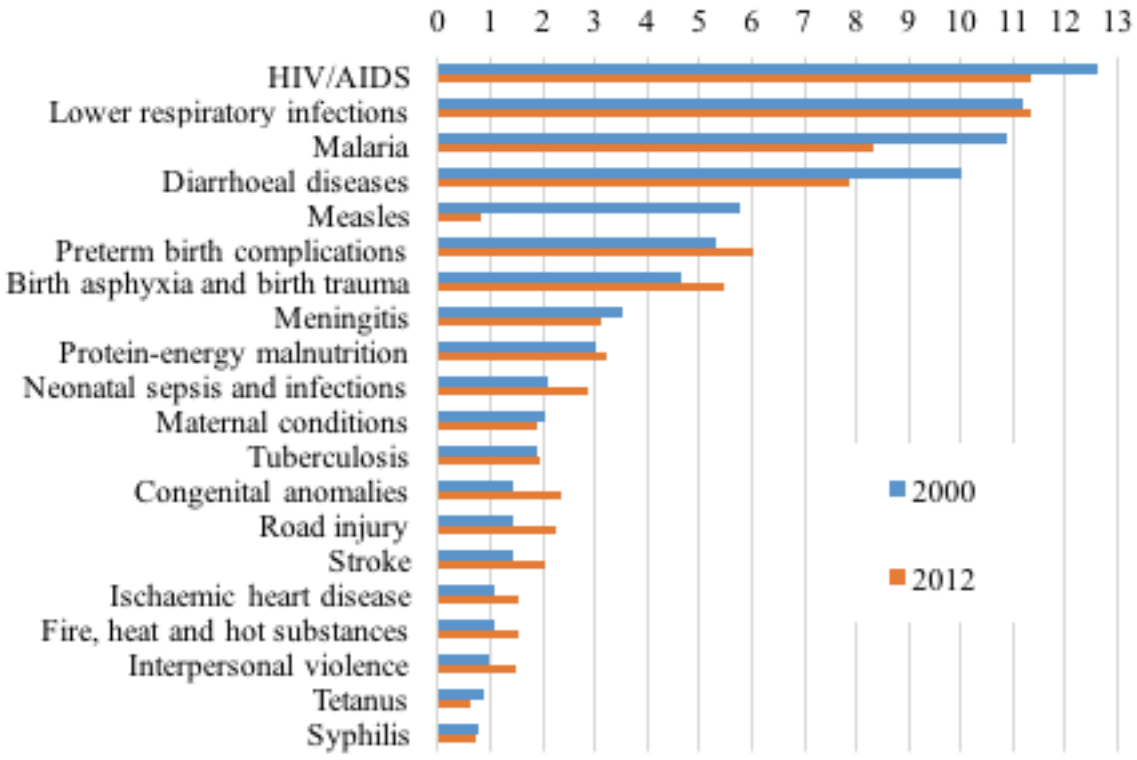
This is reflected in the changes of causes of death. For example, the major causes of death as measured by the number of years of life lost per 100,000 inhabitants declined by 35.6 per cent between 2000 and 2012, indicating that Africa's inhabitants are living longer, as already observed. This is reflected in the major strides that African Governments have made in reducing mortality rates (see table 2.1). As can be deduced from figure 2.2, communicable diseases registered a higher decline (42.4 per cent) between 2000 and 2012 than non-communicable diseases (falling only by 5.9 per cent).

Table 2.1: Changes in major causes of death (Years of life lost per 100,000 inhabitants)

Major groups	2000	2012	Change (per cent)
All causes	98,039.3	63,153.4	-35.6
Communicable and other group I diseases	77,476.7	44,627.8	-42.4
Infectious and parasitic diseases	48,972.0	24,418.6	-50.1
Non-communicable diseases	12,794.5	12,045.3	-5.9
Neonatal conditions	12,199.6	9,354.8	-23.3
Parasitic and vector diseases	11,746.0	5,724.3	-51.3
Respiratory infections	10,995.8	7,321.7	-33.4
Lower respiratory infections	10,971.2	7,302.8	-33.4
Diarrhoeal diseases	9,799.8	4,967.4	-49.3
Cardiovascular diseases	3,483.7	3,159.6	-9.3
Nutritional deficiencies	3,297.2	2,354.6	-28.6
Protein-energy malnutrition	2,930.8	2,021.5	-31.0

Source: World Health Organization Global Health Observatory.

Figure 2.2: Contribution of most frequent causes of death to total years of life lost
(Percentage of total years of life lost per 100,000 inhabitants)



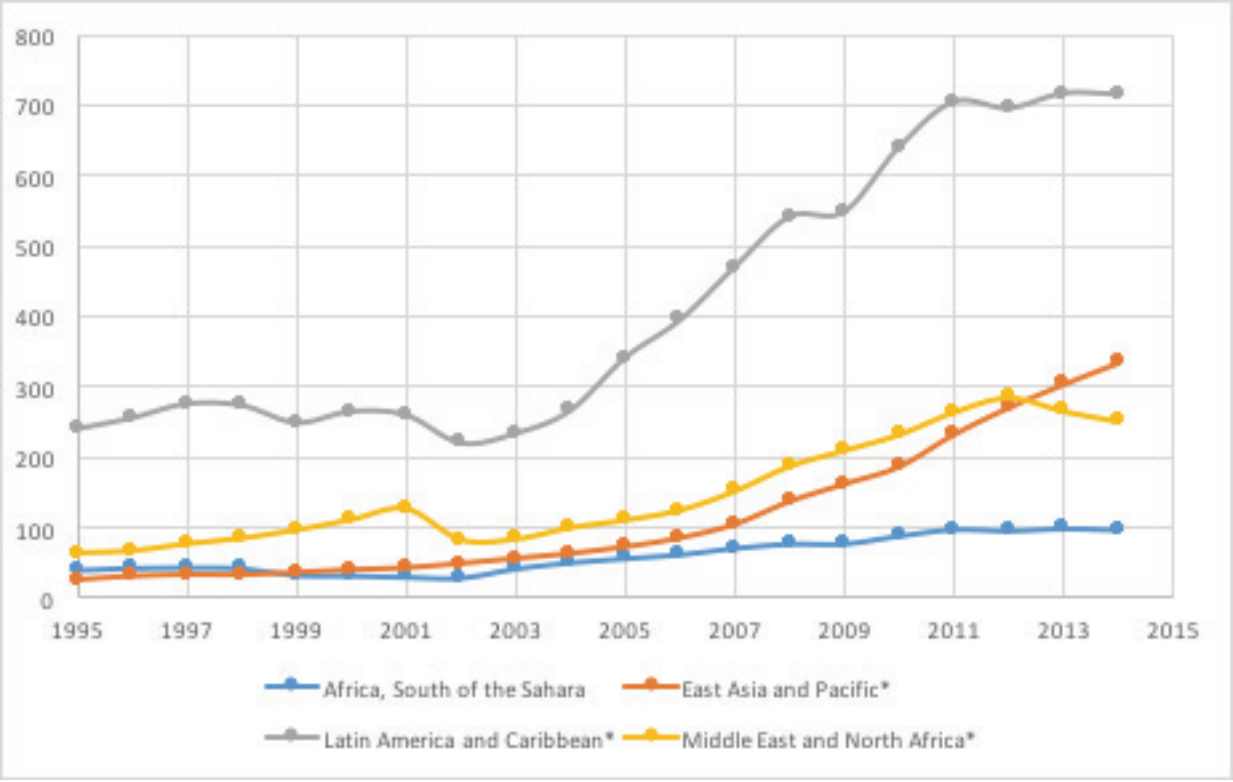
Source: World Health Organization Global Health Observatory and Economic Commission for Africa analysis..

It is clear that Africa has made steady gains in reducing communicable diseases but it has not achieved a comparable reduction in non-communicable diseases such as cardiovascular diseases, cancer, chronic respiratory diseases and diabetes. This group of diseases is associated with various risk factors and diagnosis, treatment and management requirements from that of communicable diseases such as malaria and HIV/AIDS (Mensah, 2016). African countries may need to redouble their efforts to strengthen their health systems in order to make similar gains in the control of non-communicable diseases. Such gains are likely to have a positive impact on the economic performance of a country. For example, Swift (2011) observed that an increase in life expectancy resulted in an increase in total gross domestic product (GDP) and in GDP per capita in the long term Accordingly, countries that aspire to grow may wish to invest in improved health services to ensure their populations have long, productive and healthy lives, in line with the aspiration in Agenda 2063 of Africa "enjoying a life expectancy of above 75 years".

2.3 Africa registered a rise in expenditure on health

The above-mentioned changes and improvements in life expectancy and years of life lost have, in part, been driven by increased expenditure on health by African Governments, which had decreased precipitously during the structural adjustment period of 1980-1995. By 2002, the continent had reversed the decline in expenditure on health per capita. Since then, expenditure on health per capita by sub-Saharan African countries increased from $29.6 in 2002 to $97.0 in 2014, or a growth of 227 per cent (see figure 2.3). Among the developing regions of the world, only the Asia and the Pacific region registered a faster rate (744 per cent) than Africa during the same period. Nevertheless, Africa's expenditure on health in absolute value remains much lower than that of all other major developing regions of the world (see figure 2.3).

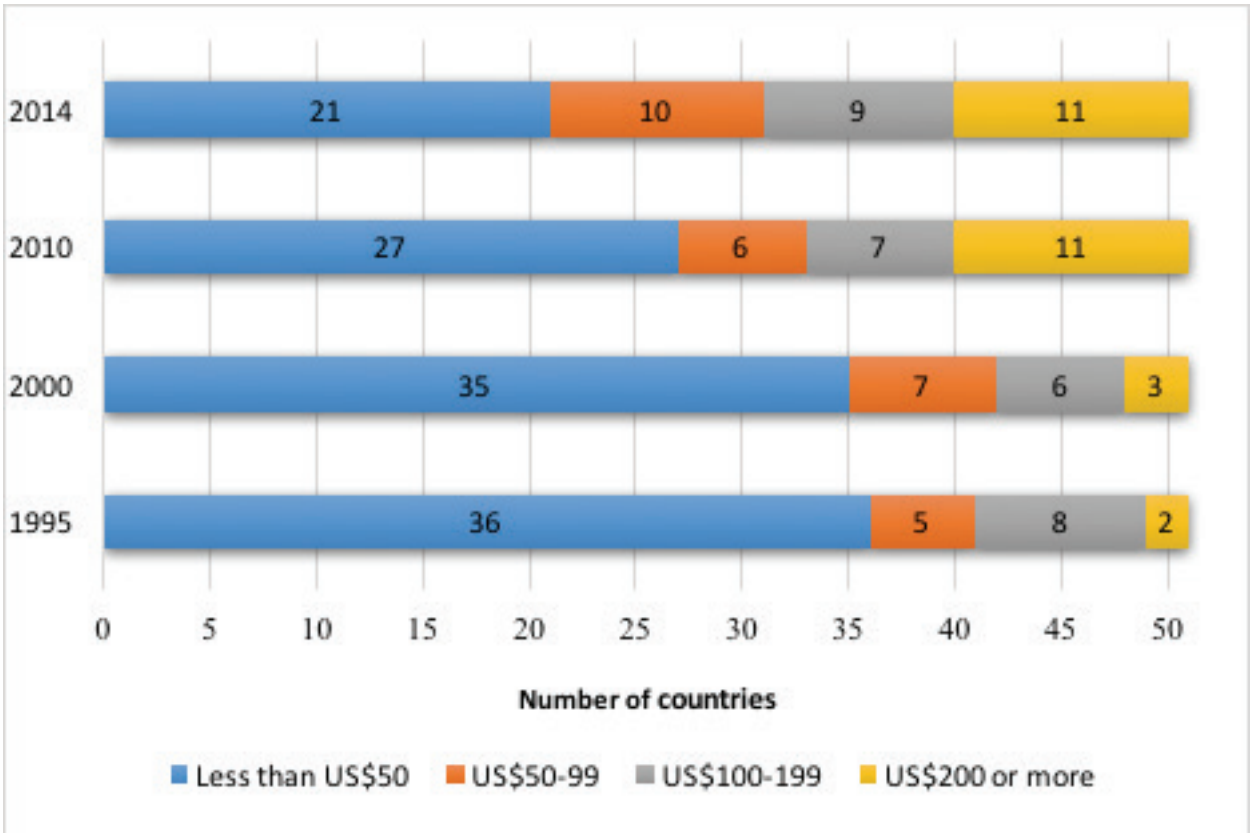
Figure 2.3: Expenditure on health per capita (United States dollars)



Source: World Bank 2016 world development indicators.

[a] Developing countries only.

Figure 2.4: Shifts in total health expenditure per capita for 51 African countries

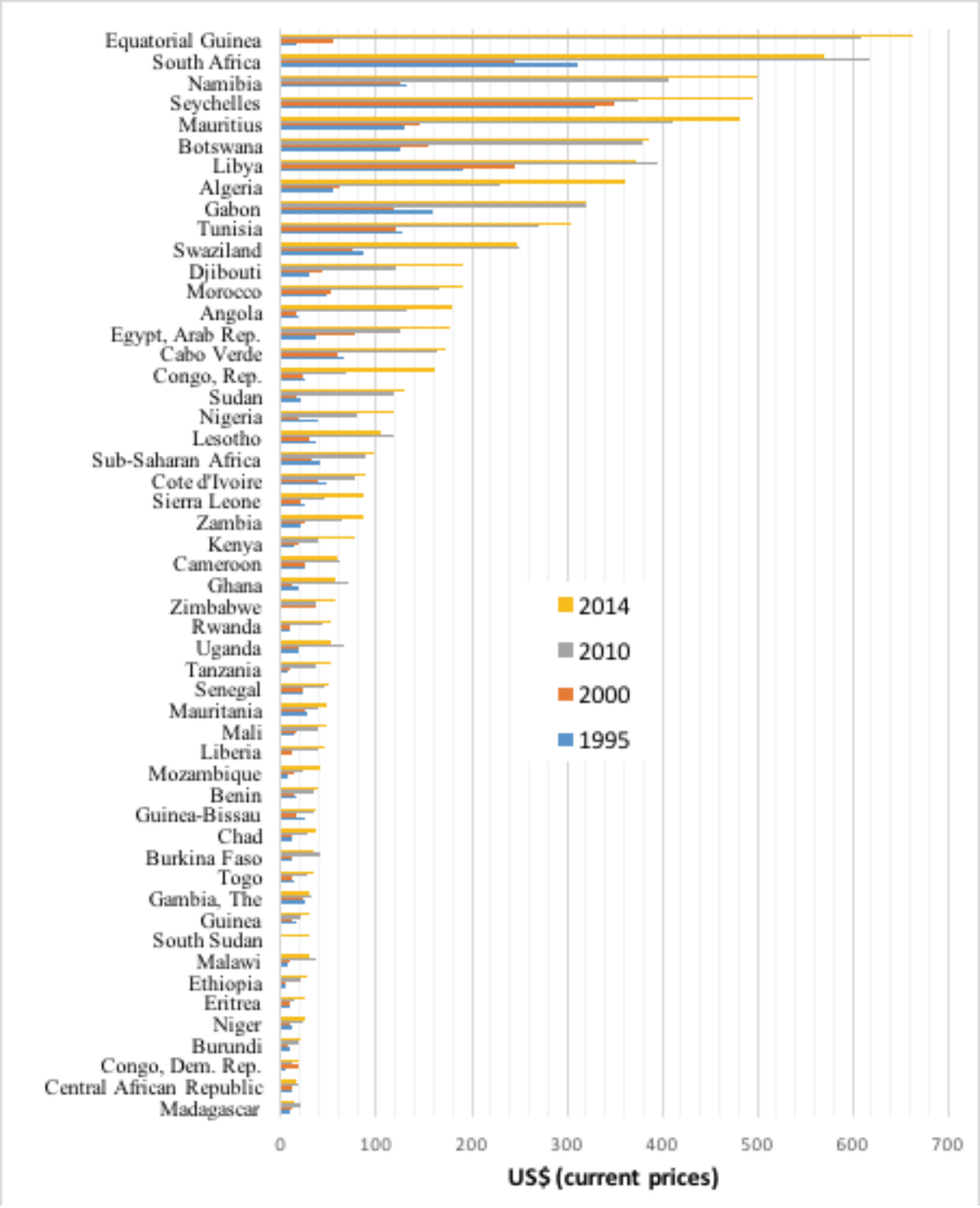


Source: Economic Commission for Africa analysis based on World Bank world development indicators.

At the national level, the picture varies widely. As shown in figure 2.4, total health expenditure per person in a number of African countries has grown rapidly, especially among counties that experienced a rapid expansion of their GDP. Between 2000 and 2014, the GDP of Africa expanded 3.8 times, from some $636 billion to $2.46 trillion at constant 2005 United States dollars. Countries such as Equatorial Guinea saw their GDP increase by 14.6 times between 2000 and 2014. As a result, the total health expenditure per person of Equatorial Guinea also grew from $64 in 2000 to $663 in 2014 (a ten-fold increase). Equatorial Guinea now spends more on health per capita than any other country on the continent for which data are available. Other countries that registered a rapid rise in expenditure on health per capita between 2000 and 2014 include Algeria (490 per cent), Angola (961 per cent), Nigeria (583 per cent), the Republic of the Congo (643 per cent) and the Sudan (763 per cent). Moreover, 18 African countries saw their health expenditure per capita rise by between 200 per cent and 480 per cent during the same period. In short, 23 African countries recorded a faster growth rate in expenditure than the region's average.

However, in absolute terms, only two African countries, Equatorial Guinea and South Africa, spent more than $500 per capita on health. They are followed by Mauritius, Namibia and Seychelles, which spent close to $500 per capita on health (figure 2.5). An additional six countries spent between $200 and $400 per capita on health care. Other than those countries, 31 African countries spent less than $100 per capita on health in 2014. Given that the world average of expenditure on health per person per year in 2014 was $1,058, the majority of African countries would need to make a substantial increase in expenditure on health in order to catch up.

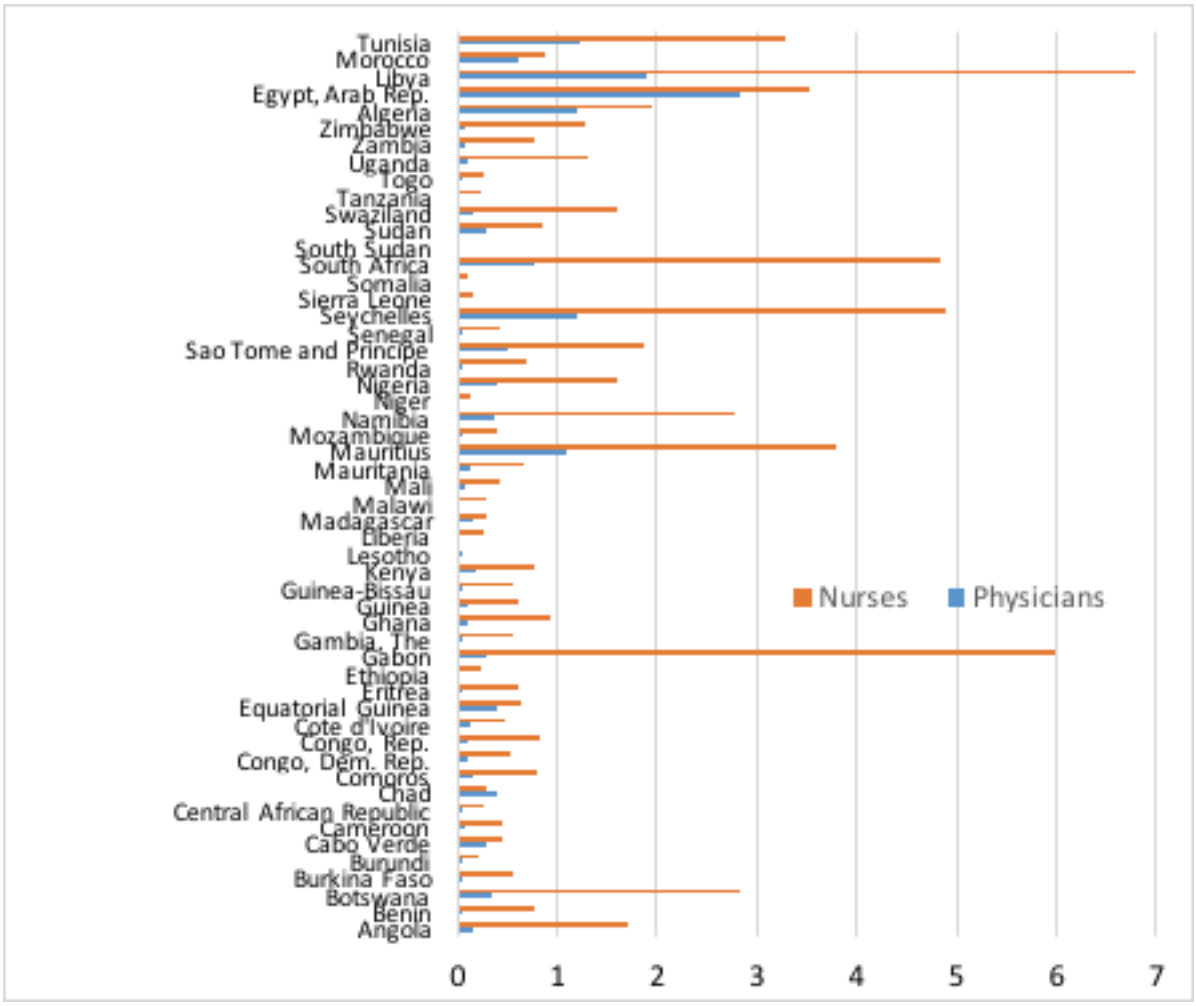
Figure 2.5: Total health expenditure per capita (Current United States dollars)



Source: World Bank world development indicators.

Increased investment in health is a major factor contributing to the steady gains in life expectancy at birth in Africa. While communicable diseases remain a major challenge, increases in life expectancy and changing lifestyles are likely to lead to a rise in non-communicable diseases. The growth in expenditure on health is likely to lead to increased investment in health-care technologies. Africa needs to invest adequately in facilities, such as child and maternal hospitals, cardiac clinics, trauma centres and cancer treatment and research facilities, in order to manage and reduce deaths and disabilities caused by non-communicable diseases, while

Figure 2.6: Number of physicians and nurses per 1,000 inhabitants in 2010



Source: World Bank world development indicators.

simultaneously making additional gains, or at least maintaining the gains already made in the control of communicable diseases. The need to grow new health-care centres in urban and rural areas and to develop specialized medical facilities is accompanied by a demand for investment in health-care technologies and medical devices in particular.

2.4 Health workers and health outcomes in Africa

Although data on health workers are not up to date, very few African countries have the recommended 2.28 health workers per 1,000 inhabitants. Based on the most recent data (2010), only 11 African countries have more than 2.28 nurses and physicians per 1,000 inhabitants (figure 2.6). However, there are expectations that this number is going to increase owing to the rapid expansion of medical schools and colleges. Between 1980 and 2010, the number of medical training institutions in sub-Saharan Africa alone had grown from 51 (Monekosso, 2014) to 156 (Mullan et al., 2011). As of 2016, there were at least 219 such schools, according to the World Directory of Medical Schools database.1

Although personnel availability or numbers matter, countries with similar levels of health workers per head of population attain different health outcomes. Among the key factors are differences in diseases, illness and other medical conditions; population distribution; resource availability; technological applications; and quality of infrastructure (e.g. electricity and transportation). A country such as Namibia,

1 https://search.wdoms.org/

Table 2.2: Evolution of HIV/AIDS diagnostic testing

Year	1985	1987	1991	1997	2015
Generation	First	Second	Third	Fourth	Fifth
Antigen Source	Virus-infected cell lysate	Lysate and recombinant	Recombinant and synthetic peptides	Recombinant and synthetic peptides	Recombinant and synthetic peptides
Specificity	95-98 per cent	>99 per cent	>99.5 per cent	99.5 per cent	99.5 per cent
Sensitivity	99 per cent	>99.5 per cent	>99.5 per cent	>99.8 per cent	100 per cent
Negative Window	8-10 weeks	4-6 weeks	2-3 weeks	2 weeks	2 weeks

Source: Alexander (2016).

with a large surface area but a small population, is estimated to need 4.3 health workers per 1,000 inhabitants, while the Republic of the Congo needs only 0.7 health workers per 1,000 inhabitants to attain the same percentage of births attended by trained health professionals (World Bank, 2013).

The use of technologies could expedite the processing of patients, while also reducing the distance between health workers and patients and extending the reach of health workers. For example, a mercury thermometer takes up to six minutes to measure body temperature, while tympanic and electronic thermometers take only up to 30 seconds. Combined with the miniaturization of many items of medical equipment (e.g., ultra sound and X-ray machines), the productivity of health workers can be significantly improved.

2.5 Advances in medical devices for improved health

Health and health care have remained a technology-intensive and innovation-driven field. Until the nineteenth century, health professionals relied more on experience, knowledge and instinct to manage and treat their patients. Since then, the traditional doctor's bag no longer accommodates the multitudes of technologies that have changed the detection, management and treatment of diseases and illnesses.

Innovation in medical devices has been at the forefront of improving health globally. This can be clearly seen in the area of HIV/AIDS. From the early 1980s to the 1990s, HIV/AIDS testing and counselling was the preserve of well-resourced laboratories of established hospitals and clinics. Significant developments in life sciences and medical engineering have resulted in the design, fabrication and deployment of HIV/AIDS diagnostic kits that can be used in rural health clinics and voluntary testing and counselling centres. The HIV/AIDS kits reduce the need for expensive infrastructure (e.g., cold storage) and formally trained personnel. They also enable the use of a smaller sample (e.g., blood from a finger prick or a mouth swab) and can be performed in a single step (Constantine and Zink, 2005). As shown in table 2.2, a steady reduction in the time between exposure to HIV/AIDS and the detection of a positive test for HIV/AIDS infections has also been reduced from up to 10 weeks to within 2 weeks. In 2012, the first home-based HIV/AIDS diagnostic kit was approved by the United States Food and Drug Administration, making it possible to perform home and community-based testing and counselling. Technological innovations have made the testing of HIV/AIDS easier, simpler, faster and earlier.

Advances in information technology, material science, biotechnology and nanotechnology have enabled the development of new medical devices that are smarter, easier, faster and more accessible to a wider range and number of professionals. They also empower individuals

to monitor and evaluate their own vital health status. For example, digital X-ray machines have eliminated the use of chemicals traditionally used to develop X-ray films and have enabled computerized analysis and image-sharing. Similarly, digital health bands enable their wearers to monitor their heart and breathing rates, blood pressures and exercise patterns.

The world is also moving closer to achieving personalized medicine. Some of the areas in which technological advances bring about new medical devices for personalized medicine include whole genome sequencing, 3-D printing of personalized devices, laboratory-developed tests, drug-diagnostic co-development (United States Food and Drug Administration, 2013) and information technology for point of care.

New technological platforms are making whole genome sequencing affordable, which, in turn, enables doctors to design personalized treatment based on patient and disease (e.g., cancer) genetic makeup. Similarly, doctors can now print personalized device implants to suit the anatomy of individual patients, while hospitals can design their own laboratory tests. Information technology promises to bring the doctor, the laboratory and the hospital bed closer to the patient. Self-care is likely to become a central component of health service delivery as the digital revolution makes patient-doctor interaction easier and more accessible and informative than ever before. Lastly, new technologies are changing and will continue to change the concept of the co-development of the drug and the diagnostic test for disease (Jørgensen, 2014).

Notwithstanding these technological developments, many clinics in Africa lack even the most basic medical devices and technologies or a basic laboratory for routine urine, blood and faecal analysis. Without such tools, health professionals continue to rely on their intuition, instinct and experience to provide support. It is here in which advances in technology may have to be deployed, especially for clinics located in rural areas. With more than 60 per cent of Africa's population living in rural areas, significant attention is needed to provide at least basic tools that can help to improve health-care delivery in such locations.

In recent years, the Internet and mobile networks have been considered powerful tools in closing the rural-urban divide in the provision of health-care services. The 125 countries covered in reports on eHealth strategies in a World Health Organization (WHO) publication (2015) include a total of 31 countries in Africa. However, eHealth platforms are still more widely employed in urban health centres than in rural health centres, owing to differences in the availability and the quality of information technology infrastructure and skills. New technologies such as drones are also hoping to improve the efficiency of the delivery of medical supplies and samples, enabling rural areas to benefit from facilities in urban areas (British Broadcasting Corporation, 2016)

However, many facilities in African countries remain hampered by limited access to modern technologies and specialists. This is often forcing people who can afford private health care and those that can access public health-care resources to travel abroad. An estimated 100,000 residents of East Africa seek medical care in India annually, costing the East African Economic Community some $1 billion annually (East African, 2015) in payments for medical services to India alone. Similarly, the number of individuals traveling to South Africa to seek medical services increased from 327,000 to more than 500,000 between 2006 and 2009, more than 80 per cent of whom were from other African countries (Crush and Maswikwa, 2012). While more affluent individuals are free to seek the best medical services abroad, a majority of Africans are relatively poor and have to rely on local facilities. Most Governments are unable to meet the medical fees charged by advanced facilities abroad.

Building and improving the capacity of hospitals at home is necessary for extending health services to the majority of the people. For example, the commissioning of a modern cancer diseases hospital in Zambia (International Atomic Energy Agency, 2007) (Slone et al., 2014), at a

cost of $10 million, saw the number of cancer patients treated in the country rise from 37 to 1,825 between 2006 and 2012, some 6,000 cancer patients in seven years. By comparison, between 1995 and 2004, Zambia could afford to send abroad for treatment only some 350 of its estimated 5,000 cancer patients on the government waiting list, owing to the high cost of treatment, which is estimated at approximately $10,000 per patient (AllAfrica, 20121).There is a good indication that the Government and the country in general are saving lives and money and are building technical capacity.2The Government has since decided to invest an extra $25 million in expanding the cancer diseases hospital, while also establishing centres for cancer screening and treatment in its research and provincial hospitals and in building human capacity.

This case highlights the key role that investment in health facilities and infrastructure could play in saving lives and money. It also highlights the high demand for advanced services, both for the provision of health and research services, for a critical mass of qualified human capital to offer support to researchers and physicians.

2.6 Conclusion

In order to meet most of the goals that Africa has set for itself through Agenda 2063, African countries will need to continuously invest in improved health-care services. Doing so will have to include investment in skills to use and operate medical devices safely; to design, develop and manufacture medical devices; and to support infrastructure and systems that are capable of delivering improved health-care services at an affordable price. Innovation holds the key in the design, development and implementation of such systems in order for Africa's health-care services to exploit and realize the benefit from existing and emerging technologies.

Innovation in this case will not always refer to products and processes that are only new to the world, but also to the continent, country and, in some cases, to the health-care facility. Each product and process could be context-specific and driven by various needs, opportunities and challenges. Similarly, innovation may in this case does not always represent only a technological superiority, but also new organizational-level and system-level arrangements that may be more efficient and productive (e.g., workflow improvements and the integration of processes, resulting in significant gains).

In this regard, Africa could use the budding manufacturing sector to build a medical devices industry and improve health-care outcomes. Alternatively, it could promote the biomedical device industry as a tool for achieving health-care targets and manufacturing goals. Africa's unique challenges, such as excessive heat, moisture and a dusty environment, an erratic power supply and limited technical and financial resources, may drive innovation in the form of radical redesign (e.g., eliminating fans in equipment) or of adapting existing devices to meet its specific needs (e.g, making cheaper versions).

2 Such technical capacity includes linear accelerator, cobalt 60, orthovoltage, high-dose-rate brachytherapy unit, a treatment planning system, simulator, fabrication of treatment aids (mould room and workshops), laboratory services, mammography, ultrasound, computed tomography scan and magnetic resonance imaging.

CHAPTER 3
Africa in the global medical devices market

Key highlights

This chapter focuses on the global and continental markets for medical devices by using available data on trade to determine Africa's participation in the global medical device market. It concludes with an examination, in which implications are drawn, of the budding South African medical device industry. In the absence of firm data on revenue, domestic sales are used to estimate industry size. The following provides a summary of the key messages in this chapter:

A small but growing market for medical devices: Estimates suggested that the African market for medical devices could be worth at least $3.8 billion by 2014. Imports for such devices grew at a compound annual growth rate of 10.5 per cent between 2002, and 2014 while exports recorded a compound annual growth rate of 14.3 per cent during the same period. Countries such as Equatorial Guinea, Ethiopia, Malawi, Rwanda and Zambia saw their imports of medical devices increase by more than 900 per cent during the same period.

Algeria, Angola, Egypt and South Africa were the top four import markets for medical devices in Africa. The top African countries exporting medical devices were Egypt, Mauritius, South Africa and Tunisia, but only Mauritius and Seychelles were net exporters of the products. Regional markets are important, in particular for South African and Kenyan medical device exporters.

The changing producers of medical devices: At the global level, the United States of America is home to more than 7,000 medical device firms, followed by Germany, Japan, Switzerland, France, Netherlands, Denmark, the United Kingdom of Great Britain and Northern Ireland and Sweden. In recent years, countries such as Brazil, China, India, Mexico and the Republic of Korea have been emerging as key producers of medical devices.

Spotlight on South Africa's medical devices industry: South Africa is the largest exporter of medical devices in Africa and home to at least 160 companies operating in the medical device market. Of these firms, 26 are local manufacturers, 68 are distributors and 30 are multinational firms, while the rest offer a variety of support services (e.g., logistics). The industry's top products include syringes, needles and catheters, as well as electrodiagnostic devices, imaging parts and accessories and dental and irradiation devices. In total, these products account for some three quarters of the industry's output.

3.1 What is a medical device?

There are several definitions of medical devices. For example, the United States Food and Drug Administration defines a medical device as the following:

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the

cure, mitigation, treatment, or prevention of disease, in man or other animals, or

- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

The European Union directive on medical devices (European Council, 1993) defines a medical device as the following:

Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Referring to the above definitions, one could expect medical devices to vary widely from simple spatula and tongue depressors to complex full body scanners, dialysis machines and pacemakers. Accordingly, medical devices are also categorized on the basis of their level of perceived risk (European Council, 1993) as follows:

Class I covers devices considered to be low risk (may include devices such as corrective glasses and frames, eye occasion plasters, permanent magnets for removal of ocular debris)

Class IIa and IIb cover devices considered to be medium risk (may include devices such as contact lenses, contact lens care solutions, intraocular lenses, surgical lasers, Scleral and corneal implants, instrumentation and sutures)

Class III covers devices considered to be high risk (may include implants containing medicinal substances or manufactured utilizing tissues of animal origin) (British Standards Institution, 2017)

The majority of medical devices in Classes II and III are manufactured predominantly by large and/or specialized firms, such as Phillips and General Electric. Most of the smaller firms produce primarily Class I medical devices because these devices carry lower risks, are generally less technology-intensive and are subject to fewer regulations. Therefore, entry barriers are likely to be lower in the manufacturing of Class I medical devices to attract and allow the participation of smaller firms in the market.

3.2 Global market for medical devices

Globally, the medical devices market was thought to be worth between $320 billion (International Trade Administration, 2016a) and $360 billion in 2014 (Kalorama Information, 2016). It was growing at an annual average rate of 6 per cent (**Cunningham et al., 2015**) and is expected to reach at least $636 billion by 2022. The United States remains the largest market for medical devices, accounting for 39 per cent of the world's share. It is followed by Japan, occupying 11.3 per cent of the market, and Germany, with 7.6 per cent. Other top markets for medical devices include Australia, Brazil, Chile, Canada, China, France, Italy, Mexico, the Republic of Korea, South Africa, Spain, Turkey and the United Kingdom.

The fastest growth has been recorded in the developing world. China's medical devices industry is now the third largest, behind those of the United States and Germany. The Chinese

market grew at an annual average rate of 20 per cent between 2009 and 2014. The emergence of China as a global manufacturing hub has driven the growth of the export market. Notwithstanding the presence of thousands of local manufacturers in China, a majority (more than 90 per cent) produce low-technology products (e.g., syringes), while most of the technologically sophisticated products are imported from abroad (Elsinga, 2014). The majority of high-tech equipment is imported into the country. The import of mid-end to high end products have decreased in recent years, but this has largely been owing to foreign companies moving their production plants to China (Ibid.).

The European Union is another major player in the medical devices market, accounting for more than a quarter of global market share. It is estimated that the European Union market for medical devices will grow at approximately 3 per cent annually, lower than the global average of 6 per cent. Within the European Union, Germany is the top market for medical devices, followed by France, Italy, the United Kingdom and Spain.

Africa's share of the world market for medical devices was estimated to be $3.2 billion in 2010, and remains the world's fastest-growing market for medical devices, with a compound annual growth rate of 7.5 per cent during the period 2006-2010, according to BMI Research (2012). Recent estimates suggested that the economic slowdown, especially among sub-Saharan African countries, would result in negative growth and a decline from $1.4 billion in 2015 to $1.2 billion in 2016.

Based on existing research, South Africa is Africa's largest market for medical devices, with 90 per cent of its $1.2 billion market value in 2014 being met by imports. This put the local supply of medical devices in the market at approximately $120 million. The other major markets in Africa include Egypt ($432 million), Nigeria ($155 million (2014)), Kenya ($106 million (2014)) and Ghana ($58 million (2014)). Other than South Africa, most of the other African markets depend almost exclusively on imported medical devices (BMI Research, 2012).

In terms of growth, the Kenyan market was expected to grow 9.2 per cent in 2015, driven in part by public sector spending through an initiative to equip hospitals with modern medical equipment. On the other hand, the Nigerian market was expected to decline owing to the fall in revenues resulting from the drop in petroleum prices on the global market. The Ghanaian market was expected to reach approximately $60 million in 2015. In general, most African markets have been growing rapidly, but remain small, compared with those of developed economies.

3.3 Assessing Africa's performance in the trade in medical devices

In order to provide some indication of Africa's performance over the past couple of years, trade data, in particular import data, for medical devices was used. This is justified, given that most African countries depend significantly on imports. Because data on medical devices are neither complete nor available for all countries and types of devices, the data used in this section should be treated as indicative rather than comprehensive. An assessment is also made of Africa's performance in terms of exports on the part of a few selected economies whose export of medical devices appeared to be relatively large, compared with those of other African countries.

In terms of methodology, there are two major trade databases: the United Nations Commodity Trade Statistics Database and the Handbook of Statistics of the United Nations Conference on Trade and Development (UNCTAD). Both of them provide import and export data for medical devices. In the United Nations Commodity Trade Statistics Database, medical devices fall under the harmonized system code 9018 (instruments and appliances used in medical, surgical, dental or veterinary sciences), which could be, and has been, used as a proxy. This classification of a limited type of related products, however, captures approximately one third of South Africa's imports. Its import of medical devices was expected to be approximately $1 billion for 2013, as already noted, whereas the United Nations Commodity Trade Statistics Database recorded its imports to have a value of only approximately $380 million for the same year (i.e., accounting for 38 per cent of the estimates). Accordingly, it is wise to caution against the interpretation of

data recorded in the United Nations Commodity Trade Statistics Database and consider them a rather distant proxy.

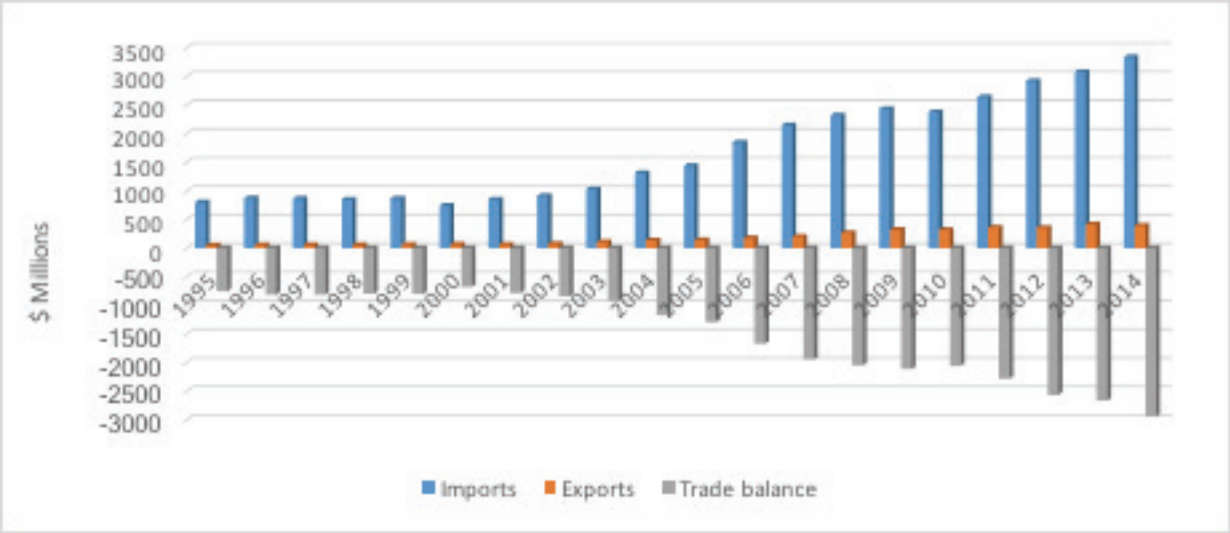
The use of data in the UNCTAD Handbook of Statistics database is therefore used for the purpose of analysis. Data from the ***Standard International Trade Classification*** codes 774 (electrodiagnostic apparatus for medical sciences, etc.) and 872 (instruments and appliances, not elsewhere specified., for medical, etc.) have been combined. Products covered by these two classifications are relatively more inclusive in relation to the definitions of medical devices discussed in the previous section. Code 774 comprises electrocardiograph apparatuses; other electrodiagnostic apparatuses; ultraviolet or infrared ray apparatuses; apparatuses based on the use of X-rays; apparatuses based on the use of alpha, beta or gamma rays; X-ray tubes; and other items (including parts and accessories). Code 872 comprises nine subcategories that can be summarized as follows: dental instruments and appliances; dental drill engines; syringes, needles, catheters and the like; ophthalmic instruments; mechanotherapy and massage appliances; therapeutic respiration apparatuses and masks; and other apparatuses and appliances related to such use (see United Nations, 2006).

The total of the two classifications provides a better approximation of trade in medical devices. In the case of South Africa, imports in 2013 were valued at $809.8 million (capturing 81 per cent of the $1 billion value of imports estimated by market research) and, in the cases of Ghana and Kenya, returning approximately 100 per cent of their value, and, in the case of Egypt, even slightly more. On the basis of a comparison of the value recorded in the UNCTAD Handbook of Statistics with that of United Nations Commodity Trade Statistics Database, the Handbook presents a better proxy by absolute value of trade in medical devices than the United Nations Commodity Trade Statistics Database. From this point on in the report, data from the UNCTAD Handbook of Statistics for analysis and interpretation will be used.

As shown in figure 3.1, the African market for biomedical devices could have been worth at least $3.8 billion by 2014. This seems reasonable, given that the estimated market for medical devices in 2010 was $3.2 billion. In terms of growth, imports grew at a CAGR of about 10.5 per cent between 2002 and 2014, while exports recorded a compound annual growth rate of

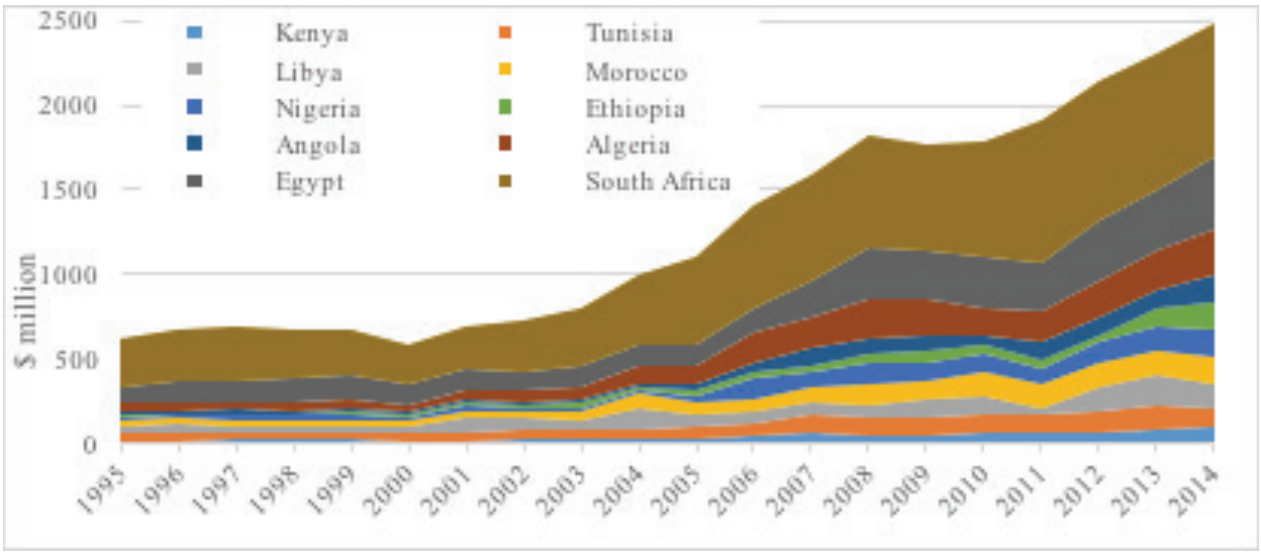
Figure 3.1

Africa's import and export of medical devices (Standard International Trade Classification 774 and 872)
(Millions of United States dollars)



Source: Economic Commission for Africa analysis based on the United Nations Conference on Trade and Development Handbook of Statistics.

Figure 3.2: Import of medical devices by the top 10 markets



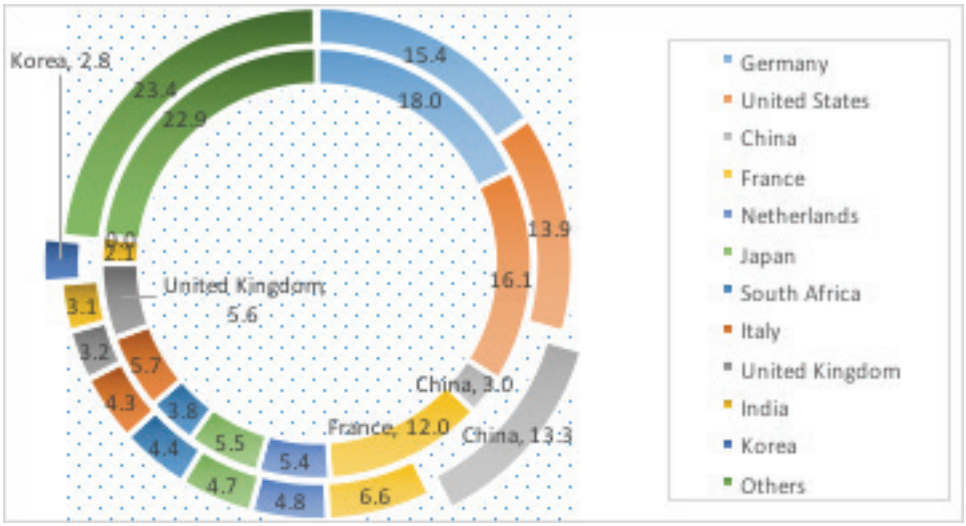
Source: United Nations Conference on Trade and Development Handbook of Statistics.

14.3 per cent during the same period. Although exports grew faster than imports, the value of exports was still far lower than that of imports, with the gap widening from $820 million to $2.94 billion between 2002 and 2014.

As in other sectors, the market grew rapidly, by approximately 350 per cent, between 2000 and 2014. Countries such as Equatorial Guinea, Ethiopia, Malawi, Rwanda and Zambia saw their import of medical devices rise by more than 900 per cent during that period. The top 10 African markets accounted for approximately $2.5 billion, or 67 per cent of total imports of medical devices on the continent. Algeria, Angola, Egypt and South Africa were the top four import markets in Africa.

The import market for Africa's medical devices changed during the last decade (see figure 3.2). In 2003 most of Africa's medical devices were imported from Germany, the United States, France, the Netherlands and Japan. Those countries accounted for more than half of the total import value of medical devices to Africa as a whole in 2003. By 2013, China had become the third major exporter of medical devices to Africa (accounting for 13.3 per cent of total imports), just behind Germany and the United States. At the same time South Africa (accounting for 4.4 per cent of total imports) had become the seventh major source of medical devices for the continent. Other countries whose share of Africa's imports increased during that time include India (3.1 per cent, up from 2.1 per cent) and the Republic of Korea (2.8 per cent, up from 0 per cent in 2003).

Figure 3.3: Changing import markets for medical devices[a]
(Percentage of totals)



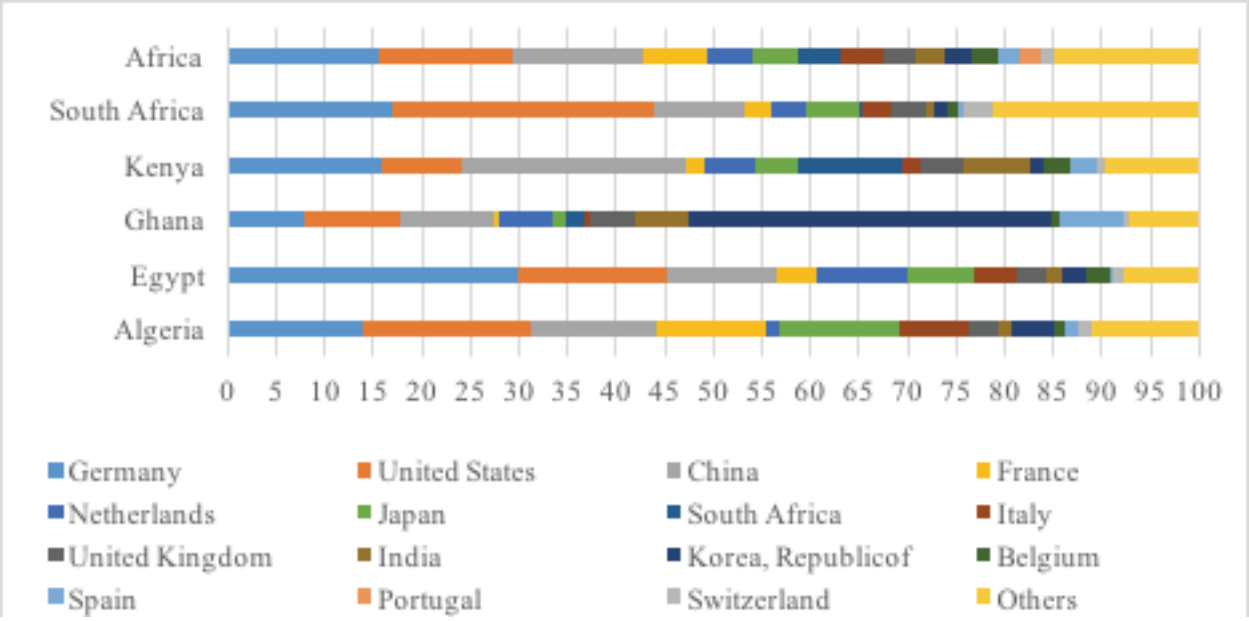
Source: Economic Commission for Africa analysis based on the United Nations Conference on Trade and Development Handbook of Statistics.

[a] Inner ring refers to 2003 and the outer ring to 2013.

The rise of China as the destination for foreign direct investment in manufacturing and the rise of domestic manufacturers of medical devices may account for most of the shift in medical device imports to Africa (Elsinga, 2014). In this regard, traditional exporters of medical devices to Africa saw their shares fall sharply. For example, the share of Africa's medical device imports from France and the United Kingdom dropped by approximately half between 2003 and 2013, while that of Germany, the United States shrank by up to 15 per cent.

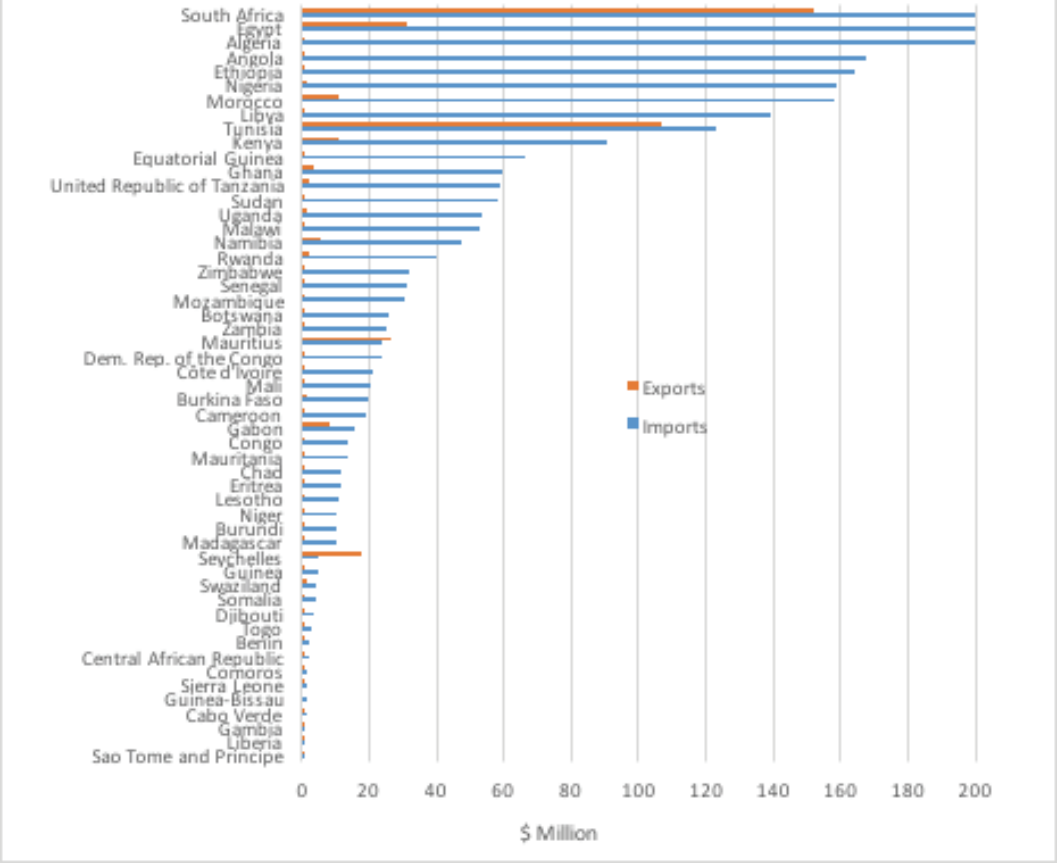
The regional picture does not always reflect national differences or preferences for the sources of imports (see figure 3.4). At the national level, Ghana imported 37 per cent of its medical devices from the Republic of Korea, while Egypt imported 30 per cent of its medical devices from Germany, with South Africa importing nearly 27 per cent of its medical devices from the United States. Similarly, Kenya's main import markets for medical devices were China (23 per cent), the United States (16 per cent) and South Africa (11 per cent).

Figure 3.4: Top 15 main import markets for medical devices of selected countries
(Per cent)



Source: Economic Commission for Africa analysis based on the United Nations Conference on Trade and Development Handbook of Statistics.

Figure 3.5: Comparison of import and export of medical devices
(Current United States dollars)



Source: United Nations Conference on Trade and Development Handbook of Statistics.

In terms of exports, the major African countries exporting medical devices are South Africa and Tunisia, which exported $152.1 million and $106 million worth of devices, respectively, in 2014. Other notable exporters on the continent include Egypt and Mauritius, whose exports amounted to more than $20 million each. Only Mauritius and Seychelles are net exporters of medical devices (see figure 3.5). Although data are not available, a number of top American firms such as GE Healthcare, 3M, Abbott Laboratories, Alcon, Medtronic and Newport Medical Instruments are represented in Mauritius. It is possible that they may be assembling and/or re-exporting from Mauritius. Although Tunisia is a net importer of medical devices, the gap between its imports and exports is very small (approximately 15 per cent of its export value). Irrespective of how the context is examined, Africa's export of medical devices is too small for a continent most of whose research and development is said to be focused on health-related sciences (Economic Commission for Africa, 2013; NEPAD Planning and Coordinating Agency, 2014).

It is important to gain some insight into the destinations for Africa's exports and, to some extent, into the types or categories of medical devices exported. For this purpose, exports from Egypt, Mauritius, South Africa and Tunisia (the four major African exporters) and Kenya (one of the country cases) are examined. Wide differences in export markets were observed (see table 3.1). Most exports from Egypt, Mauritius and Tunisia go to countries outside Africa. It is possible that countries whose exports go largely to advanced countries host the manufacturing, assembling or distribution affiliates of multinational enterprises or have developed a specialized manufacturing capability in the area.

Table 3.1: The major export destinations of medical devices of five African countries
(Per cent)

Egypt ($30.9 million)		Kenya ($10.8 million)		Mauritius ($26.3 million)		South Africa ($152.0 million)		Tunisia ($106.9 million)	
	Country		Country		Country		Country		Country
17.7	Germany	24.6	Somalia	63.3	France	29.6	Namibia	56.2	France
16.4	Islamic Republic of Iran	23.4	Uganda	18.2	India	11.0	Botswana	24.7	Italy
14.1	United Kingdom	9.4	United Republic of Tanzania	3.8	United States	6.4	Zimbabwe	3.5	Poland
10.3	Saudi Arabia	7.3	Rwanda	1.8	Germany	5.2	Swaziland	3.0	Belgium
4.9	Brazil	7.2	Zimbabwe	1.7	Israel	4.8	Zambia	2.0	Algeria
4.2	Turkey	4.4	Democratic Republic Of the Congo	1.6	Islamic Republic of Iran	4.6	Mozambique	1.7	Libya
3.3	Yemen	3.5	Zambia	1.6	Madagascar	3.5	Lesotho	1.5	Ireland
2.8	Greece	1.8	Malawi	1.4	United Kingdom	2.4	United States	1.4	Germany
2.5	Tunisia	1.7	Sudan	1.3	Spain	2.2	Kenya	1.0	Spain
2.2	Morocco	1.7	United Kingdom	0.9	Hungary	2.1	Mauritius	1.0	Morocco
21.7	Others	15.0	Others	4.4	Others	28.1	Others	4.1	Others

Source: Economic Commission for Africa analysis based on the United Nations Conference on Trade and Development Handbook of Statistics.

Kenya and South Africa largely export medical devices to other African countries. More than 72 per cent of South Africa's exports of such devices were to Africa and the countries of the Southern African Development Community, accounting for 8 of the country's 10 major export destinations for medical devices. A similar picture is also observed in terms of exports by Kenya, for which countries in Central, Eastern and Southern Africa account for 9 of its top 10 export destinations. It is likely that these countries either have emerging medical device producers or host assembling and distribution firms.

Of the two classifications of medical devices used by the UNCTAD Handbook of Statistics (774 and 872), only South Africa has fair distribution. Among South African exports, devices that fall under Standard International Trade Classification 774 accounted for 35 per cent, while those classified as Standard International Trade Classification 872 accounted for 65 per cent. For the other countries considered here, the export of medical devices that fall into the 774 category constituted only 1.4 per cent for Mauritius, 3 per cent for Egypt, 6 per cent for Tunisia and 13 per cent for Kenya in 2014.

This is not exactly surprising, given that Standard International Trade Classification 774medical devices are more sophisticated and knowledge-intensive. Africa's ability to compete in terms of both safety and technological know-how is lower than that of advanced economies. However, Standard International Trade Classification 872 medical devices can be easily manufactured, given the availability of the right machinery and basic engineering skills. It appears unreasonable to believe that Africa cannot make the most basic medical devices, such as needles, syringes, masks, furniture for dental and surgical treatment or some instruments for assisted breathing, as the case of Malawi demonstrates (see chapter 4). In a report by Deloitte (2015), it was explicitly recommended that the medical furniture sector serve as an attractive area for local manufacturing in South Africa, considering both its growth rate and the manufacturing capability that is needed.

3.4 Factors likely to fuel the growth of the medical device industry in Africa

The growth of the medical device market in Africa is being driven by a combination of various factors, some of which may be temporary, while others are likely to persist in the short to medium term. Among other things, influential factors include increased public sector spending, increased and/or changing disease burdens, the rapid growth of the middle class, the growth of and competition among private sector health-care providers and the rapid diffusion and evolution of technologies. A number of these factors are likely to persist in the medium to long term.

3.4.1 Rise of African economies

Africa's economic fortunes have changed significantly since 2000. The question of whether Africa could claim the twenty-first century, posed by the World Bank in 1999, has been roundly and broadly answered in ways that many national and international analysts did not expect. A total of 25 of 54 African countries registered an annual economic growth rate of more than 5 per cent in 2013. Africa moved from having only one economy (South Africa) with a GDP valued at more than $100 billion in 2000 to having six countries, namely, Algeria, Angola, Egypt, Nigeria, Morocco and South Africa, that reached a GDP value of more than $100 billion in 2013. Another five countries, namely, Ethiopia, Kenya, Libya, the Sudan and the United Republic of Tanzania, saw their GDP surpass the $50 billion mark. Three African countries, namely, Egypt, Nigeria and South Africa, are now among the top 30 largest economies in the world, while the GDP of Africa as a whole has surged from approximately $600 billion in 2000 to $2.4 trillion in 2014 (United Nations Conference on Trade and Development, 2015).

Notwithstanding the recent collapse of international prices for major commodities, Africa's economic growth is still robust and driven by three main trends: a youthful population and growing labour force in a world that is rapidly aging; rapid urbanization, which fuels productivity growth and consumption; and rapidly accelerating technological change

Table 3.2: Health-care spending per capita of selected African countries
(United States dollars)

Per capita United States dollars	Countries
500-1,000	Equatorial Guinea, Seychelles, South Africa
100 - 499	Algeria, Angola, Botswana, Cabo Verde, Djibouti, Egypt, Gabon, Lesotho, Libya, Mauritius, Morocco, Namibia, Nigeria, Republic of the Congo, the Sudan, Tunisia
50 - 99	Cameroon, Côte d'Ivoire, Ghana, Mali, Rwanda, Sierra Leone, Togo, Uganda, Zambia,
10-49	Benin, Burkina Faso, Burundi, Central African Republic, Chad, Democratic Republic of the Congo, Eritrea, Ethiopia, the Gambia, Guinea, Guinea-Bissau, , Kenya, Liberia, Madagascar, Malawi, Mauritania, Mozambique, Niger, Senegal, South Sudan, United Republic of Tanzania

Source: World Bank world development indicators .

that is unlocking growth potential and helping to leapfrog the limitations and costs of physical infrastructure (McKinsey Global Institute, 2016).

Foreign investors have taken note of such positive fundamentals. Inward foreign direct investment in Africa reached $73 billion in 2014, up from $14 billion in 2004. Africa is today home to 700 large and increasingly pan-African companies, with revenue of more than $500 million each. These companies have a combined total revenue of approximately $1.4 trillion, with many continuing to grow rapidly. Large companies in utilities, transportation and health care attained doubledigit revenue growth in local currency terms between 2008 and 2014 (United Nations Conference on Trade and Development, 2015).

3.4.2 Increased health-care spending

During the past two decades, African countries saw a rapid growth in health-care services driven in part by increased revenue by Governments, investment from the private sector and contributions from development partners or donors. For example,, sub-Saharan Africa's health-care expenditure per capita increased from some $38 per capita in 1995 to $60 per capita in 2005 and $101 per capita in 2013. During that time (1995 to 2013), the population of sub-Saharan Africa increased from 584 million to 948 million, which translates into an increase of 4.3 times in dollar terms (from $22.3 billion to $95.7 billion). This presents an expanding market with great opportunities for health-care infrastructural development, of which medical devices are a key component.

Notwithstanding the above regional level observation, health-care spending per capita among African countries grew at various rates and remains much lower than the average for sub-Saharan Africa. The fastest growth rates in health-care spending per capita between 1995 and 2013 were recorded in Equatorial Guinea (more than 4,000 per cent) and Angola (1,200 per cent), followed by the United Republic of Tanzania (670 per cent), Rwanda (620 per cent) and Ethiopia (500 per cent). Others that registered a growth rate of between 300 per cent and 500 per cent include Algeria, Burkina Faso, Djibouti, Ghana, Mozambique, the Republic of the Congo, the Sudan and Zambia.

As shown in table 3.2, only three African countries spent more than $500 per capita on health care. Another 15 spent between $100 and $500 per capita, while 30 countries spent less than $50 per capita on health care. All the top import markets (e.g., Angola) except Ethiopia are among those that spent more than $100 per capita on health care. Increased health-care spending has thus been considered to be one of the major drivers of growth in the medical device market, given that it can be translated into increased demand.

According to the African Development Bank (2011), the middle class as a percentage of the population of Africa rose slightly, from 26 per cent in 1980 to 27 per cent in 1990, growing rapidly to 34 per cent in 2010. Approximately 60

per cent of this middle class spends only $2 to $4 per day, while 40 per cent spend between $4 and $20. The size of Africa's middle class is small, compared with that of Asia (approximately 50 per cent of the total population) and Latin America (approximately 77 per cent). Nevertheless, an increase in the middle class population drives demand for improved health-care services, among other things (see table 3.3).

Table 3.3: General description of the African middle class

What they, in general, are not:
They do not derive income from farming and rural economic activities
What they, in general, are:
They live in urban centres in permanent dwellings equipped with modern amenities
Have higher levels of tertiary education and hold salaried jobs
Are small business owners, young and in the acquisitive phase of life
Have fewer children than previous generations and certainly than those in the rural areas
They tend to opt for private education and health services and send their children to overseas universities
May receive remittances from relatives living in the diaspora
Have widespread ownership of major household durable goods, such as refrigerators, telephones, flat screen televisions and automobiles
They have more recreational time, harness technology, are politically assertive and are culturally self-confident

Source: Deloitte (2013).

3.4.3 Increased policy focus on healthcare

The devastating impact of diseases such as HIV/AIDS, malaria and tuberculosis on the quality of life and their social and economic impacts have also demanded a stronger policy focus on improving health care in the past two decades. The Millennium Development Goals highlighted both the need and the urgency for the world to turn its attention to providing policy guidance, actions and measures to improve health care. Of the eight Goals, three focused on health improvement in child and maternal mortality, as well as in HIV/AIDS, malaria, tuberculosis and other diseases. Significant efforts have been devoted to universal access to health services through the expansion of and growth in health-care facilities and services, as well as through an improvement in national health systems and increased funding (World Health Organization, 2016). All these have driven innovation in and demand for medical devices that have made voluntary testing for HIV/AIDS possible, even in rural areas.

Although Africa has registered steady progress in meeting health-related goals, the continent faces a twin challenge of reducing the current high disease burden caused by communicable and infectious diseases (e.g. malaria, tuberculosis and HIV/AIDS) and an increasing disease burden due to non-communicable diseases such as cancer and diabetes, as already discussed in chapter 1. Both the public and private sectors, as well as domestic and foreign players, have introduced new ways of increasing access to and improving the quality of health-care services. Non-communicable diseases tend to increase demand for some of the most sophisticated medical devices. For example, the demand for skills and medical devices and technologies needed to run an effective cardiac or cancer hospital are relatively higher than those for treating malaria. For Africa, the demand for diagnostic devices will remain high, especially in the face of emerging health-care threats, such as Ebola, bird flu and Zika virus, and the need to contain existing challenges posed by infectious and non-infectious diseases.

3.4.4 Increasing life expectancy and population growth

Africa's demand for medical devices is likely to rise in order to meet the needs of a growing and increasingly educated population that is health-conscious and has a longer life span. While the African population is likely to remain fairly young for at least the coming five decades, increasing life expectancy will also lead to an increase in the proportion of the population 60 years of age and above. Combined with a rise in income, the demand for improved health care will rise and, in turn, increase demand for medical devices.

3.4.5 Evolution of new technology as a driver of change

The rapid evolution of new technologies is presenting new opportunities for the development of affordable and robust devices. These include portable medical devices for home and personal use; less invasive and non-chemical systems that require less expertise to operate; and new wearable systems for managing, storing, processing and sharing medical information. Such devices are empowering individuals to know their health status and undertake preliminary research on optimal, new and emerging treatments and their related efficacies. In combination with increasingly sophisticated wearable devices, such as digital watches or arm bands that track key health factors, health-care managers and providers are likely to face increased pressure to keep up and invest in new systems that enable them to meet both the demands of informed clients and their own need to be economical. This may result in increased demand for both medical devices and skills to manage increasingly integrated systems combining computation, storage, sharing, visualization and real-time observations, among other things.

3.4.6 Rapid urbanization and population concentration

The rapid rise of African cities presents many unique opportunities for industrial development, especially in the service sector. The best hospitals, especially private for-profit hospitals in African countries, are currently concentrated in or close to urban areas. It is, therefore, expected that the increase in the number and size of African cities and urban areas will drive demand for health-care services to meet the needs of their increasing number of prosperous inhabitants.

Given that urban areas are centres of all key resources, including talent, industries and political power, there is also an expectation that a medical device industry capable of servicing, managing and manufacturing some of the basic medical devices will emerge in these areas. Accordingly, urban clients' needs for improved health care and medical devices will be higher and continue to grow.

3.4.7 Expansion of health insurance coverage

There is also an expansion of health insurance in Africa that is driven by the rise of the middle class, who can afford to pay insurance premiums, and the growth of a dynamic private health-care service offering a mix of public and private insurance schemes, as well as the rise of Africa's private and public sectors capable of insuring workers and the expansion of the insurance industry itself. According to Ernst and Young (2016), all the markets surveyed were expected to see the insurance industry grow by between 6 per cent and 11 per cent in 2015. In general, an estimated 0.3 per cent of Africans have private health insurance, which is much lower than the developing world's average of 17 per cent (KPMG, 2015). In other words, the penetration rate of health insurance in Africa remains low, which therefore presents substantial opportunities for development and expansion. Annual insurance premium payments per capita for a selected number of countries ranged from $925 for South Africa, $39 for Kenya and $18 for Zambia to $10 for Nigeria, $6 for the United Republic of Tanzania and $5 for both Malawi and Uganda in 2014 (Ernst and Young, 2016).

Insurance plays an important role in driving the growth of an innovative medical device industry because it provides security for health-care providers for payment in return for the better, sophisticated and complex services made possible by medical devices. In turn, competition among health-care providers drives investment in world-class facilities, better medical devices and trained health-care professionals. In simple terms, hospitals and other health-care facilities wishing to distinguish themselves as top-notch centres of excellence in the provision of health service are likely to need higher-quality medical devices in order to attract and retain clients who are seeking better services. As health insurance uptake speeds up and competition grows, the demand for medical devices is also likely to expand.

3.5 Africa in the global production of medical devices

As part of the core effort to improve the continent's health-care infrastructure, investment in developing and expanding the medical device industry is crucial to meet Africa's unique health-care needs, while promoting innovation, creating good jobs and diversifying its exports. While imports will remain the bedrock of acquiring advanced medical devices, Africa should focus on building and advancing its continental manufacturing base for some of the commonly used medical devices, while also designing medical devices for its unique needs and environment (e.g., unstable power supply, dust and heat).

This will entail investment in education, research, development and the design and production of medical devices. The United States currently has the highest number of producers of medical devices: it is home to more than 7,000 medical device firms, located primarily in California, Massachusetts, New York and Minnesota (Daniel, 2014). These states are also among the major investors in research and development. For example, in 2011, California and Massachusetts spent 4.8 per cent and 5.7 per cent of their GDP, respectively, on research and development (States Science and Technology Institute, 2014). A majority, or approximately 80 per cent, of the firms have fewer than 50 employees (International Trade Administration, 2016), while the entire industry in the United States is thought to employ some 400,000 workers directly and more than 2 million indirectly.

Table 3.4: Selected global medical devices firms

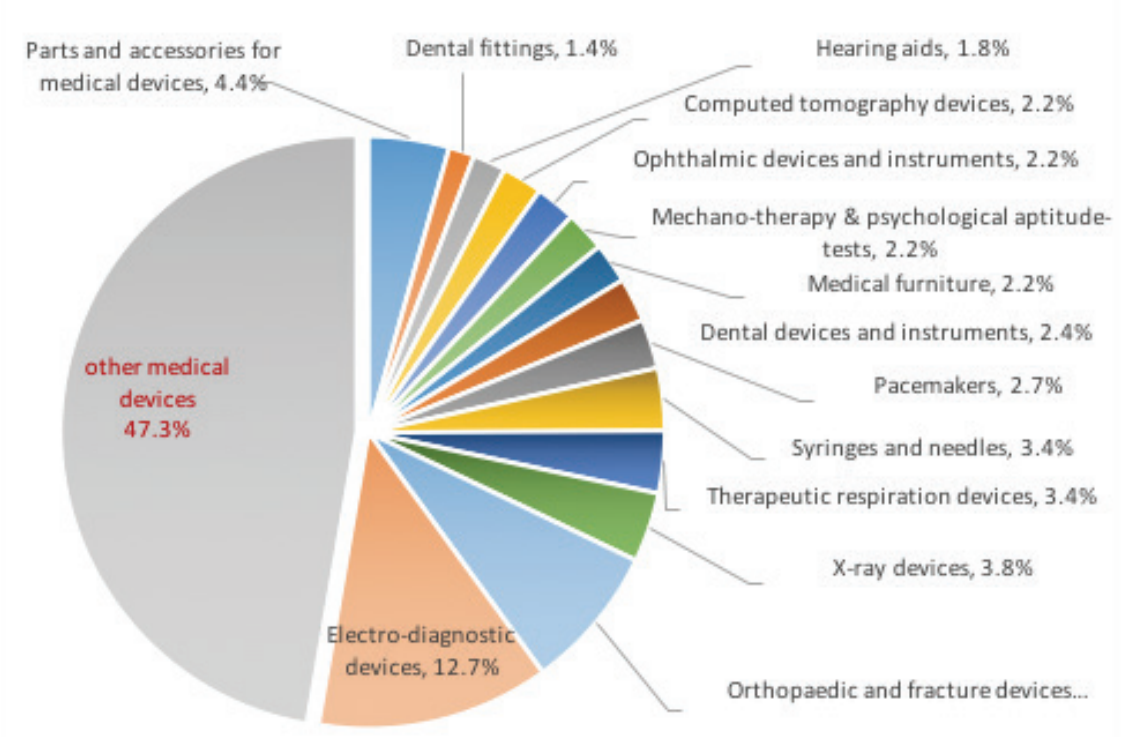
Firm (market value in billions)	R&D expenditure	Presence in Africa
Johnson & Johnson ($27.5)	$1.7 billion (2014)	Egypt, South Africa
GE Healthcare ($18.3)	$0.9 billion (2014)	Ghana, Kenya, South Africa
Medtronic ($17.0)	$1.6)	South Africa
Baxter International ($16.7)	$364 million	Egypt, Tunisia (through Gambro acquisition)
Siemens Healthcare ($15.8)	$1.4 billion	South Africa
Philips Healthcare ($11.2)	$1.1 billion	Ghana, Egypt, Kenya, Nigeria, South Africa
Abbott Labs ($10.1)	$0.95 billion	South Africa
Varian Medical ($3.0)	$200 million	Egypt, South Africa

Source: Authors' research based on official firm websites and market information.

The top producers of medical devices are predominantly major technology-intensive and strong research and development-performing multinational enterprises. As shown in table 3.4, the top firms by market value are, in general, from Europe and North America. As shown in the annex, the top 40 large medical device producers had a combined revenue of $220.1 billion. The majority of these top firms are from the United States, Germany, Japan, Switzerland, France, the Netherlands, Denmark, the United Kingdom and Sweden.

In terms of product groups (see figure 3.6), diagnostic devices account for 13 per cent of all medical devices, followed by orthopaedic and fracture devices (8 per cent) and X-rays (4 per cent). Fast growth in demand for electrodiagnostic devices is expected to continue in emerging markets such as China and in developing countries in Africa, Asia and Latin America. Countries such as China and India are expected to become major consumers and exporters of medical devices.

Figure 3.6:Market share of medical devices by main classes
(Percentage of sales)



Source: Cunningham et al. (2015).

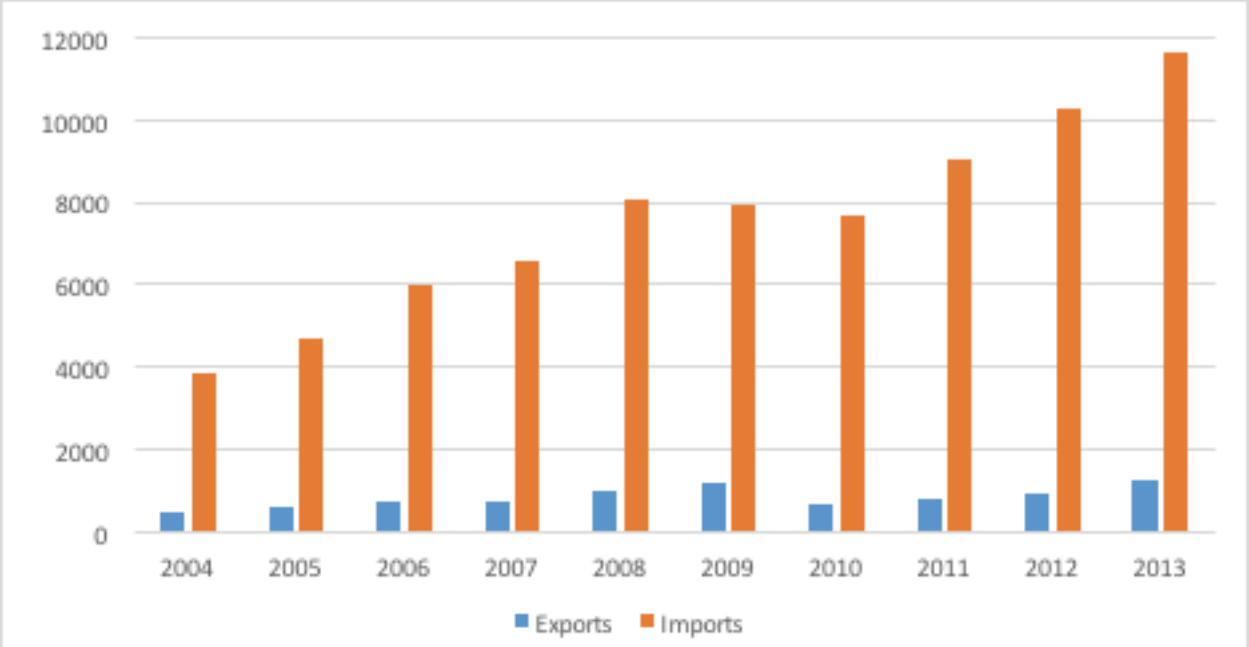
In terms of research and development, estimates suggest that expenditure on it grew at an annual rate of approximately 6 per cent between 2008 and 2014, to reach $14.3 billion in 2014 (Ernst and Young, 2015). Research tools are one of the areas that saw growth in research and development expenditure. Expenditure on research tools increased by 40 per cent between 2008 and 2013. Growth was also recorded in other sectors, such as the therapeutic devices subsector. Research and development is needed to drive innovation in the medical devices industry. It was observed that new pre-market approvals of medical devices by the United States Food and Drug Administration alone increased from 21 to 28 between 2013 and 2015 (Ibid.).

3.5.1 A budding medical devices industry in Africa: focus on South Africa

The extent to which Africa is participating in the growing market for medical devices is small, as discussed, but is not well researched. Research to date suggests that South Africa is the largest African exporter of medical devices and is home to dozens of medical device manufacturers. Given this, the development and current status of South Africa's medical device industry is worth a closer examination.

According to the South African Medical Device Industry Association, there are at least 160 companies operating in the medical device, medical equipment and in vitro diagnostics sector. Of these, 124 are ordinary members composed of 26 local manufacturers, 68 distributors and 30 multinational firms. The rest are support firms (e.g., DHL), research institutions (e.g., the Council for Scientific and Industrial Research) and associations (e.g., the Medical Devices Manufacturers Association) that play different and equally important roles in building a dynamic and innovative medical device industry.

Figure 3.7: South Africa's medical device industry
(Millions of South African rand)



Source: 2014 Trade Map. Available from www.trademap.org.

As noted earlier, the South African medical device market generated some 12.1 billion rand in revenue in 2013 and was ranked among the world's 30-largest markets for medical devices. The major driver of market growth was the development and upgrading of hospitals through public-private partnerships. However, domestic producers are thought to have accounted for only 10 per cent of sales volumes.

The top medical device products from South Africa included syringes, needles and catheters; electrodiagnostic devices and imaging parts and accessories; and dental and irradiation devices. Some estimate that these four groups of medical devices account for approximately three quarters of the industry's output. It is expected that, by 2020, consumables (e.g., syringes and needles) will account for approximately1.6 billion rand, while electrodiagnostic devices and imaging parts and accessories products may be valued at 692 million and 610 million rand, respectively.

While the future of the South African medical device industry is bright, a number of opportunities and challenges have been identified. What follows are highlights of some of the key opportunities and challenges that the industry faces.

A. Incentives and investments in medical devices

Although there are no specific incentives for medical device manufacturers at present, a host of manufacturing-related and innovation-related incentives can be accessed by manufacturers of medical devices. These include incentives that are offered through the Manufacturing Investment Programme, the Innovation Fund and the Foreign Investment Grant and the Support Programme for Industrial Innovation, among others. Specifically, the incentives offer grants qualifying assets (e.g., machinery and equipment) for each new investment up to 30 per cent of their cost, grants of up to 10 million rand, repayment grants conditional on successful commercialization and interest rate-related risk minimization and support for qualifying firms and investments based on royalties and intellectual properties.

Notwithstanding the existence of these incentives, foreign direct investment in the medical device industry remains low. Between 2003 and 2014, estimates suggest that there were six new investment projects in the South African medical device industry, with a total value of 177.72 million rand, or $17.7 million. While

that may seem sizeable, it accounts for only approximately 0.1 per cent of total foreign direct investment flows into South Africa.

The home countries of the investing firms included the United States (Emergo and Medtronic), China (Mindray Medical International), the United Kingdom (Verna Group), Japan (Nipro) and Singapore (ESCO Africa). In addition to Emergo (involved in business services) and Medtronics (education and training), most of the investing firms were involved in sales, marketing and support. Taken together, foreign direct investment in the medical device industry is small and mostly not involved in the manufacturing of devices.

B. Emerging biomedical industry

The South African medical device industry is geographically concentrated around Cape Town and the Western Cape areas, where the local authorities view it as one of their major investment opportunities (WESGRO, 2014). Cape Town and the Western Cape area received a larger share of recorded investment than other areas. For example, Emergo is estimated to have invested approximately67million rand in the region (Ibid.). Of the 17 medical device firms assessed by BMI Research in South Africa, eight were in the Cape Town–Western Cape areas. Some of the top firms include CapeRay Medical (Pty) Ltd., SensiDiacostic Medical Devices, DISA Vascular (Pty) Ltd., Sinapi Biomedical, Specific Medical Solutions and Ti-Tamed.

Recognizing some of these challenges, authorities in the Western Cape area, in collaboration with the private sector, are in advanced stages of developing the Cape health technology park in Cape Town. The $50 million that it seeks would generate approximately 5,000 new jobs and contribute up to $400 million to the local economy (CapeRay, 2015). According to local authorities, the park will bring together research and development firms, universities, academic hospitals, venture capitalists, government and the private sector to drive innovation, in the hope of creating business ventures and establishing a globally competitive health innovation region.

The Cape health technology park has been designed to provide a number of hard and soft services for some innovative medical device firms wishing to work in the technology park. Hard services proposed will include office space, specialized laboratories, technology platforms and generics facilities, amongt other support infrastructures, while soft services may include technology transfers, facilitation, professional services and shared services (WESGRO, 2015). The park is aimed at hosting closely related health technologies, including medical devices, natural products and biological and small molecules, which would promote the cross-pollination of ideas and skills among several technologies that may share similar technology platforms. It is hoped that more than half the tenants will be from the medical devices sector.

Table 3.1: Opportunities and challenges faced by the biomedical industry in South Africa

Strength, weakness, opportunity and threat analysis of South Africa's medical devices industry	
Strengths	**Weaknesses**
Relatively wealthy economy	Poor infrastructure, in particular in rural areas, limited efficiency of health-care delivery and shortage of medical personnel
Better health-care systems	
Presence of good universities	Private sector out of reach of the poorer population
Strong and sizeable private sector	Purchasing procedures are complex
Opportunities	**Threats**
Growth of public-private partnership	Inadequate public funding for the development of public health system
Imports account for some 95 per cent of the market	
Emergence of the affluent and the middle class	The depreciating rand is making imports less affordable

Source: WESGRO (2014).

C. A solid biomedical engineering research foundation

The technology park in Western Cape is being built to capitalize on the existence of a vibrant private sector, top universities and world-class research hospitals and clinics. For example, the University of Cape Town and Stellenbosch University are among the top universities in Africa, having established themselves as world-class universities, with strengths in medical sciences and engineering. The University of Cape Town is also one of the few African universities to boast a Nobel laureate in science, while Stellenbosch University contributed to the design of South Africa's satellite in space. Both universities are internationally recognized for their distinguished contributions in the field of scientific research. The region is home to 12 medical devices manufacturers, biotechnology firms and engineering companies.

Box 3.1: Examples of firms inspired by university research

1. Strait Access Technology Holdings

Strait Access Technology Holdings is a medical devices manufacturer that hopes to bring affordable and durable heart valve implants to the estimated 15 million people that are affected by rheumatic heart disease annually around the world. The majority of the afflicted people live in poorer countries, with limited or no access to surgical services. In this regard, it produces prosthetic heart valves and valve repair devices and delivery vehicles, eliminating the need for sophisticated heart-lung machines and for highly skilled surgeons. Instead, this minimally invasive technique allows surgeons to introduce and insert the valve in the blood vessel. With two United States patents granted for its delivery devices, Strait Access Technology Holdings has several patents pending for its inventions. It relies on university research by faculty members and partners and is supported by the University of Cape Town. It has received 11 million rand from the Technology Innovation Agency of the Government of South Africa and an investment commitment of 51 million rand from Bidvest, a Johannesburg Stock Exchange-listed investment company.

2. Diacoustic Medical Devices (Pty) Ltd.

Diacoustic Medical Devices (Pty) Ltd is a software-based Stellenbosch University research output that enables medical professionals to listen to heart sounds. Diacoustic incorporates the stethoscope to create a computer-aided auscultation device called SensiCardiac, which is cost-effective, more advanced and more accurate in determining whether a child has a pathological or an innocent heart murmur. The software can be used in combination with an electronic stethoscope and an electrocardiogram device to digitally capture the patient's heart sounds, while analysing and providing a full summary of the findings in a user-friendly format. Since then, an ISO standard has been registered (see **https://sensicardiac.com/** for details).

3. CapeRay

CapeRay is built on intellectual property developed at the University of Cape Town and with the De Beers Group for the early detection of cancer in women with thick breasts. About 40 per cent of women globally have thick breasts, and X-rays tend to miss small tumours buried in thick tissue. CapeRay has developed a novel medical device that combines X-ray and ultrasound imaging into a single device. By doing so, the device co-registers the images from the two imaging technologies, significantly improving diagnostic accuracy for cancer in dense breasts. The design and combination has several other advantages, such as the use of lower dosage X-rays than traditional single systems, and a two-thirds reduction in the duration of the procedure and less compression on the breast, allowing for improved imaging. To date, clinical trial data have shown the effectiveness of the product, a patent has been registered in the United States, a CE mark has been obtained for the camera and several ISO marks have been received.

Source: Official websites.

3.6 Concluding remarks

This chapter has shown that the medical devices market is growing rapidly at the global and continental levels. Given the incompleteness of current data, the national demand for medical devices is likely to be considerably higher than the current levels of recorded imports and exports. Changes in the import market for medical devices create opportunities for Africa to seek strategic alliances with suppliers in other emerging markets, such as China, to establish local assembly and manufacturing facilities in their countries.

Governments could play a positive role by brokering and supporting joint ventures in the medical device industry. One possible way to achieve this would be by including medical device manufacturers and producers as distinct investment opportunities, especially in the development of joint special economic zones. As a priority area, together with pharmaceutical and information technology, Africa can quickly build its continental production base for the maintenance, assembly, design and manufacturing of medical devices.

At the product level, significant opportunities exist in the supply of medical furniture and other medical supplies that involve lower risks and that are less technology-intensive. Building on the budding manufacturing sector, Africa could, in collaboration with development partners, invest in facilities to produce less knowledge-intensive everyday items such as bandages, needles and syringes and respirators. It needs, at a bare minimum, a level playing field that assists domestic producers and foreign suppliers to compete and collaborate, while also allowing the creation of and access to a market for those producers to compete in the supply of basic services and devices, such as beds.

Regional markets within Africa will remain key to promoting the growth of the domestic device industries of individual African countries, such as South Africa. Since the medical devices sector is a knowledge-intensive and research and development-intensive sector, equal priority should be given to an additional policy focus on improving the supply of a skilled labour force, providing tax incentives for investment in research and development and manufacturing facilities and promoting export markets and funding.

CHAPTER 4
Growing Africa's budding medical device industry: the case of Kenya

This chapter provides a picture of Kenya's medical device industry, with a special focus on measures, policies and regulations likely to stimulate the industry's growth. It is aimed at providing an overview of practices and policies that are currently in place in Kenya with regard to medical devices. The chapter provides a review of those relevant policies. It follows with an examination of the procurement practices of the Ministry of Health and the Kenyatta National Hospital. The chapter concludes with the main challenges faced in this sector and offers potential ways of addressing them.

Summary of findings

A fast growing insurance market: The insurance industry in Kenya grew at a compound annual growth rate of 20.3 per cent between 2009 and 2013, while the health insurance industry attained even higher growth during the same period. Research suggested that the growth of the health insurance component was likely to remain robust in 2016.

Total health expenditure per capita remains low: Total health-care expenditure of Kenya was estimated to have increased from $2.16 billion in 2010 to $2.74 billion in 2013. This translates into per capita total health-care expenditure of $67, an amount far lower than the sub-Saharan Africa average of $97 or the world average of $1,060.

An emerging health-care hub: Kenya's large private health-care providers, who are supported by the Government, are positioning themselves to attract a share of the world's health tourists. Given its position as East Africa's top tourist destination, Kenya is already emerging as a health tourism hub. However, the limited investment in health infrastructure that is important to boosting the confidence of patients from developed countries making up a large share of Kenya's tourists and the limited availability of qualified personnel to correctly use, repair and maintain medical devices are still major challenges to exploiting this position.

Rapid growth of the medical devices market: The import of medical devices grew 4.5 times between 2003 and 2014, while exports grew four-fold during the same period. However, exports are approximately 10 per cent of the value of imports. Although domestic production remains small, the number of small medical device manufacturers around Nairobi and Kisumu has begun to increase.

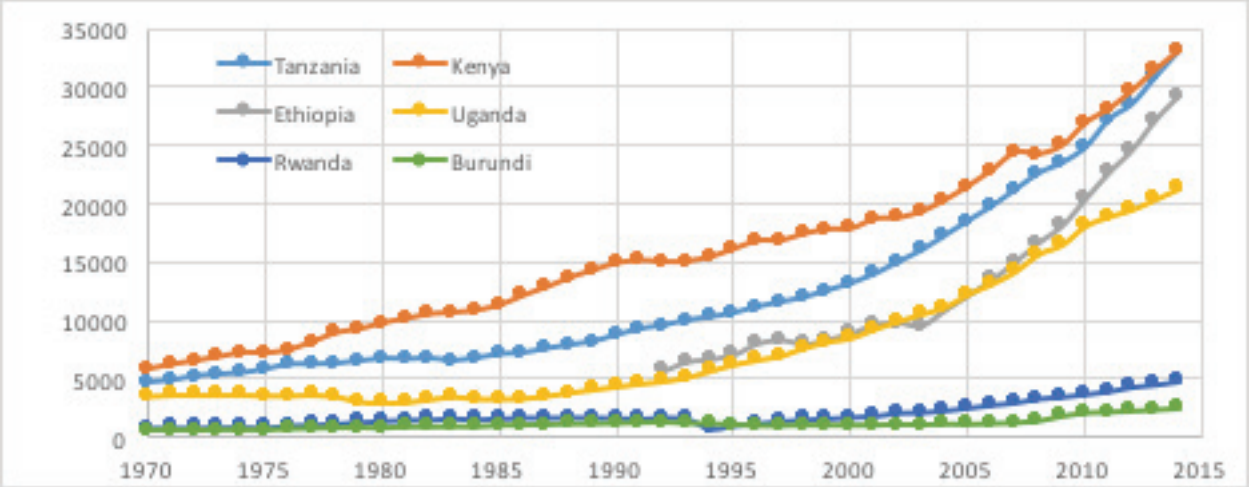
Key challenges faced by local manufacturers: Some of the top challenges faced by emerging manufacturers include limited capacity to meet tender volumes, unclear regulations for medical devices, lack of government initiatives to support local producers and intense competition from established, well-resourced firms.

4.1 Setting the scene

4.1.1 Economic performance

Kenya's economic performance has been mixed during the past decade. On the one hand, it has maintained a robust but much slower growth rate than Ethiopia and the United Republic of Tanzania. At a constant 2005 United States dollars, Kenya retained its leadership as the largest economy among the three in East Africa until 2014, when

Figure 4.1: Changes in size of economies in East Africa
(Millions of constant 2005 United States dollars)



Source: United Nations Conference on Trade and Development Handbook of Statistics.

the economy of the United Republic of Tanzania was estimated to be equal to, or slightly larger than, that of Kenya. However, at current market prices, the Kenyan economy is $10 billion larger than that of the United Republic of Tanzania, and is the ninth largest economy in Africa. However, the Kenyan economy is expected to grow at 5.9 per cent in 2016 and 6.1 per cent in 2017 (World Bank, 2017) against Africa's growth rates of 4.1 per cent in 2016 and 4.7 per cent in 2017 (International Monetary Fund, 2016). Growth will be driven by increased investment in infrastructure, manufacturing and services.

Kenya registered a significant increase in foreign direct investment in 2014. It rose from $259 million in 2012 and $505 million in 2013 to $989 million in 2014 (United Nations Conference on Trade and Development, 2015). By comparison, the United Republic of Tanzania remained the main recipient of foreign direct investment in the region, with an inflow of $2.1 billion, followed by Ethiopia and Uganda, with approximately $1 billion each in 2014. Burundi and Rwanda remain the lowest recipients of foreign direct investment in the East African region, at approximately $32 million and $258 million, respectively. As is the case with other countries, the growth of foreign direct investment in Kenya was linked to increased investment in the mining sector, especially oil and gas, and in infrastructure, especially transport.

4.1.2 Financing health care in Kenya

Kenya is also a major financial and innovation hub of East Africa. Kenya is rated highly in terms of ease of accessing credit in the world. This is due in part to the existence of a well-established stock market, a large pool of domestic and foreign banks and savings and credit associations/ cooperatives, and a large insurance industry. For example, the Nairobi Stock Exchange was founded in 1954, with its share value estimated at some $28 billion in 2014. It was the second stock market in Africa (after Johannesburg) to go public through a $21 million initial public offering, issued in 2014.

The insurance sector is particularly important for the growth of a medical devices industry, especially among independent and privately owned health-care firms. Kenya's insurance industry grew at a compound annual growth rate of 20.3 per cent between 2009 and 2013, while the personal accident and health-care component grew at a rate of 28.8 per cent during the same period. However, the health-care insurance grew even faster, at 41.2 per cent between 2010 and 2013. A total of 38 of the 48 insurance firms offer personal accident and health insurance. The value of the insurance sector in Kenya is accordingly now estimated at approximately $1 billion, with personal accident and health insurance accounting for some $558 million.

Table 4.1: Kenya health and economic indicators

Year	2000	2006	2010	2014
Population, total (millions)	31	36	40	45
Annual population growth (per cent)	2.49	2.62	2.66	2.64
Gross national income per capita, Atlas method (current US$)	420	600	1,000	1,290
Life expectancy at birth, total (years)	50.8	54.6	58.7	61.6
Under-five mortality rate (per 1 000)	107.9	80.7	62.1	51.3
Prevalence of HIV/AIDS, total (percentage of population between 15 and 49 years of age)	9.9	6.4	5.6	5.3
Net official development assistance and aid received (billions of current US$)	0.5	0.9	1.6	2.7

Source: World Bank world development indicators.

However, expenditure on health care in Kenya remains low. Total healthcare expenditure is estimated to have increased from $2.16 billion in 2010 to $2.74 billion in 2013 (Government of Kenya, 2015). This represents $67 per capita, compared with the sub-Saharan Africa average of $97 or the world average of $1,060. Indeed, Kenya is one of the countries that has failed to meet the Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases of 2001, in which countries were called upon to allocate at least 15 per cent of their national budget to the health sector. At 6.1 per cent of total public expenditure, Kenya has a long way to go to meet the objectives contained in the Declaration (African Union Commission, 2013).

Increased expenditure has a major impact on the capacity of hospitals and other health facilities in Kenya, where the private sector is relatively large. For example, of current Kenyan health-care expenditure ($2.55 billion in 2013), the share used by Government hospitals stood at 25 per cent, while the share used by private hospitals was 13 per cent. Most important, the share of current health-care expenditure spent on private hospitals increased from 12 per cent in 2010 to 13 per cent in 2013, while that spent on public hospitals declined from 35 per cent to 25 per cent during that period. The share used by private clinics increased from 2 per cent to 5 per cent during the same period (Government of Kenya, 2015).

The above figures indicate a fast-growing private health-care component in the country, which is likely to fuel further growth in the sector. Private sector health-care facilities were traditionally the preserve of the rich, with few options for the middle class. Kenya currently has a host of quality private health-care facilities that cater to the emerging middle class. To meet the need of these price-sensitive but value-conscious customers, a host of low-cost hospital business models that keep the costs of medical tests and specialists' consultations low have emerged (Economist, 2013). The increased spending on and availability of health insurance and the existence of a large pool of private hospitals and clinics together constitute a unique market for those seeking to provide both devices and their services (e.g., installation, maintenance, repairs and upgrades).

4.1.3 Kenya as an emerging health-care hub

As noted earlier, one of the key drivers of the medical devices market is the state and quality of health-care services. Kenya's 45 million inhabitants had a life expectancy at birth of 61.6 years in 2014, up from 50.8 years in 2000, and its under-five mortality rate was 5.1 per cent in 2014, down from 10.2 per cent in 2000. Similarly, Kenya's HIV/AIDS prevalence nearly halved in just four years, between 2000 and 2014, while the population growth rate remained at 2.6 per cent. Kenya has a relatively large population that will continue to demand improved health services.

Nevertheless, Kenya is looking beyond its borders and is positioning itself to serve as the favoured destination for foreign patients and for medical tourism. The latter refers to individuals

Figure 4.2: Comparison of the total number of medical facilities in four Kenyan counties

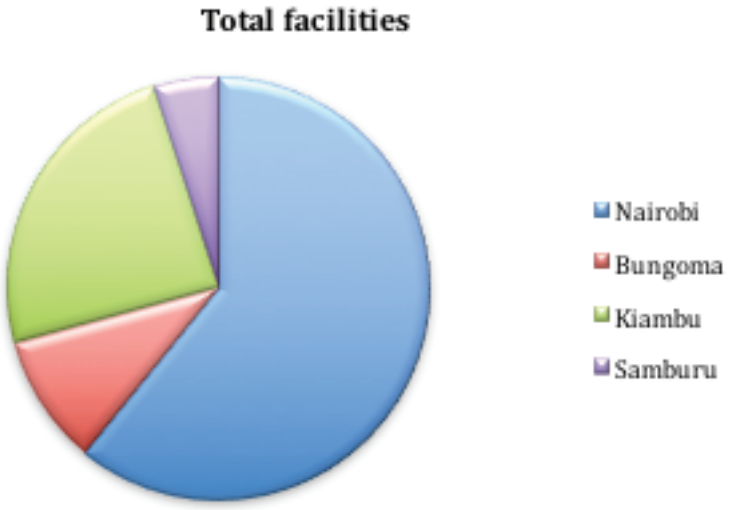
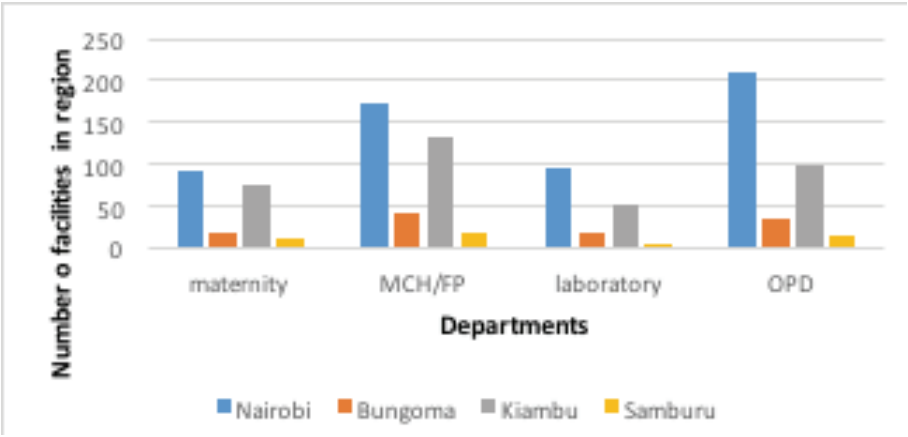


Figure 4.3: Number of hospital facilities in four Kenyan counties



who may fly into the country for leisure, while at the same time scheduling special health-care treatment. India, Jordan, South Africa and Thailand and Jordan are well-established medical tourist destinations that compete on the cost and the quality of both medical and packaged tours. In this regard, tourism and health-care agencies are working together with the Government to place Kenya on the international map for medical tourism.

Such positioning is not far-fetched, given that Kenya is already a well-established tourism destination with adequate infrastructure. Its medical services, however, will need to be upgraded to a level that offers confidence to patients from advanced countries, who account for a large proportion of its tourist arrivals. To achieve the goal of making Kenya a top destination for medical treatment, the Government has embarked on attracting investors willing to set up and run quality medical facilities by offering a host of incentives, such as access to land (AllAfrica, 2015).

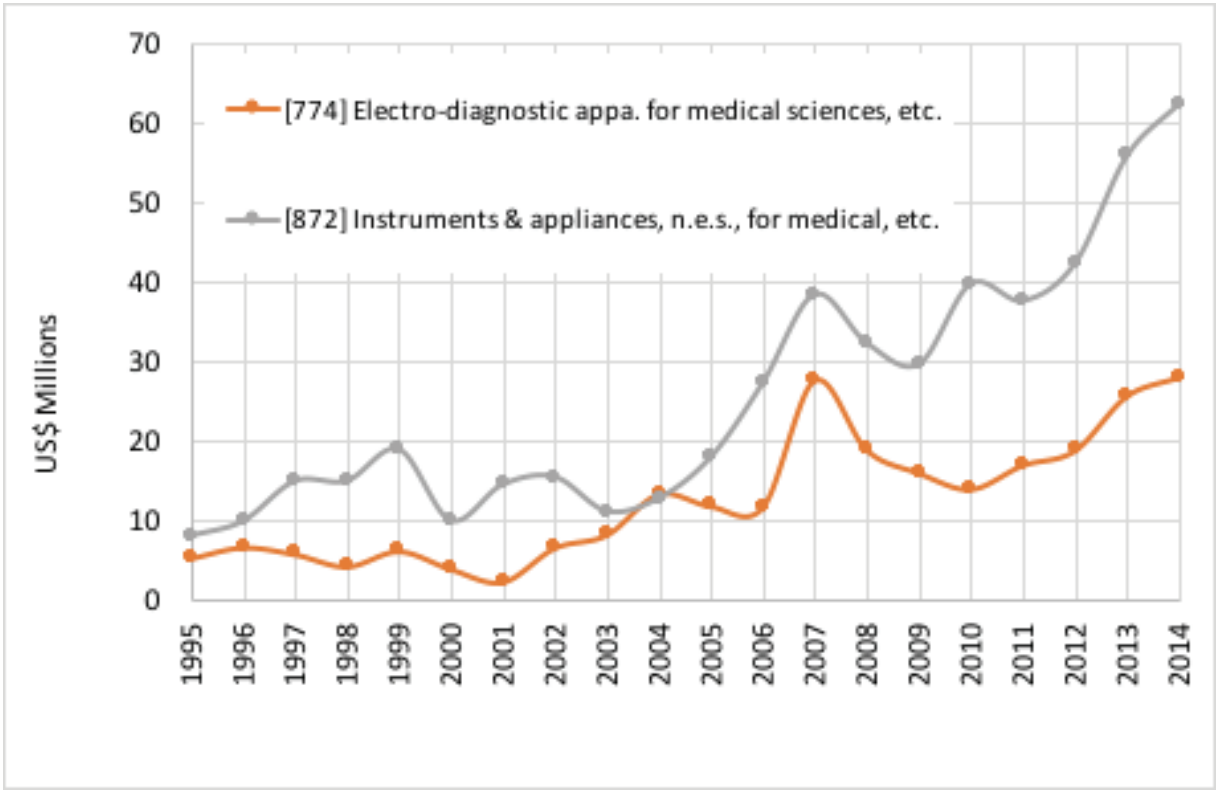
Most of the medical facilities are currently located in Nairobi. While this concentration may help to establish Nairobi as a major health-care hub (see figure 4.2), it will certainly pose challenges in terms of achieving universal access to quality health-care services for the majority of the population that does not reside in Nairobi. It is possible that a number of places, such as Eldoret, Kisumu and Mombasa, could also be developed into medical hubs that could serve patients from neighbouring countries.

4.2 Domestic market for medical devices

Kenya's market for medical devices is relatively small, but is growing fast. Estimates suggest that the market is going to grow at approximately 10 per cent annually between 2014 and 2019. If data on imports are used, then the market is growing at a much higher speed. Between 1995 and 2003, Kenyan imports of medical devices remained flat, at an average of approximately $20 million annually. Since then, its imports of medical devices climbed steadily, to approximately $90 million in 2014. About two thirds of its medical devices imports are instruments and appliances (Standard International Trade Classification 872]), while electrodiagnostic apparatuses (Standard International Trade Classification 774] account for the remaining one third of imports. The fastest-growing segment appears to be instruments and medical appliances (see figure 4.4).

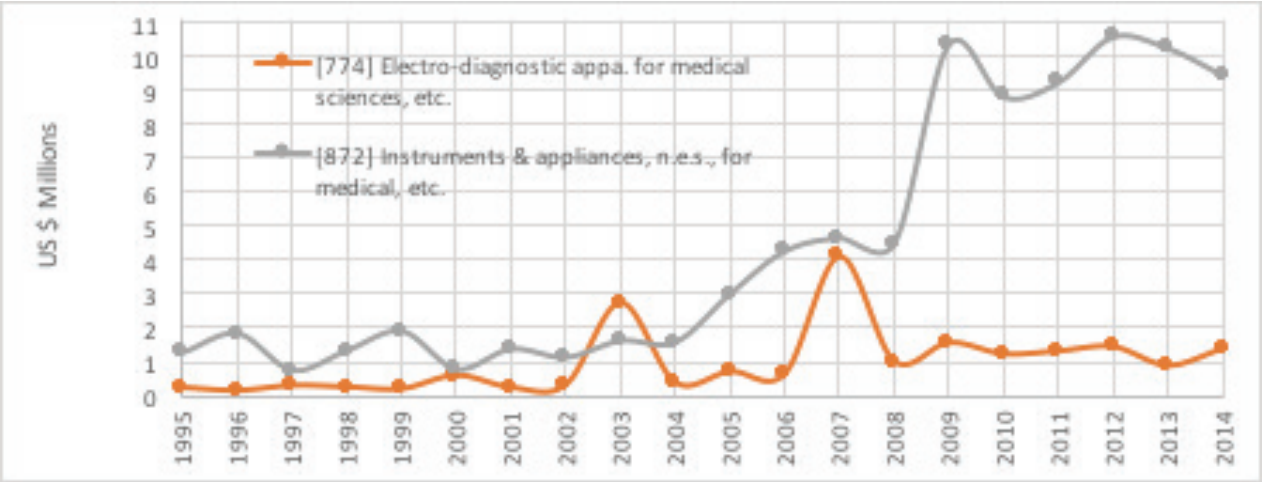
Kenya's export figures suggest that its domestic medical devices manufacturing industry is small but growing (see figure 4.5). Until 2005, domestic exports of medical devices remained relatively negligible, at approximately $1.5 million annually. Thereafter, exports of medical devices grew rapidly, to reach $11 million annually in 2011, and have stayed relatively unchanged since then. While the amount is small by global standards, it constitutes approximately 10 per cent of Kenyan imports of medical devices. By comparison, the proportion of Kenya's import to export value is similar to that of South Africa.

Figure 4.4: Kenyan imports of medical devices
(Millions of United States dollars)



Source: United Nations Conference on Trade and Development Handbook of Statistics.

Figure 4.5: Kenyan exports of medical devices



Source: United Nations Conference on Trade and Development Handbook of Statistics.

4.2.1 Local production of medical devices

While imports will remain key to improving and meeting future health infrastructure needs in Kenya, domestic medical devices services and manufacturing firms will be needed to customize, repair and maintain imported medical devices, as well as design and produce medical devices that may be better suited to local conditions. New and emerging technologies could play a key role in stimulating such an industry.

Kenya's health-care facilities showed that "broken machines litter the labour ward at Kenyatta hospital in Nairobi" and "nurses struggle to open oxygen valves with their fingernails because the buttons and valves are all broken on the baby incubator", according to a report from the British Broadcasting Corporation (2015). The reporter commented that "this lack of basic equipment could explain why Kenya is struggling to reduce maternal mortality rates". Baby incubators are very important in reducing deaths among babies born prematurely. Given that the basic designs of infant incubators are often simple, it is expected that their production and maintenance should not be too difficult, even for local manufacturers. Existing local manufacturers, however, continue to face a number of challenges to master the technologies for producing some of the basic equipment, as highlighted in box 4.1.

Box 4.1: The case of a User Experience Technologies

The case of a Kenyan company called User Experience Technologies serves to highlight some of the emerging domestic firms and the challenges that they face when entering and competing in the local market.

User Experience Technologies, an emerging Kenyan firm, is one example of a small-scale manufacturer. Like other domestic devices manufacturers around Nairobi, its manufactures well-established and noninvasive medical devices such as incubators and physiotherapy equipment. It supplies and delivers medical equipment and consumables that are largely imported by it or that are produced locally. It also develops and manufactures crutches and physiotherapy equipment.

This local manufacturing has the benefit of reducing costs and providing equipment tailored to suit the Kenyan market. Nevertheless, the lack of trust among potential clients in Kenya for locally manufactured equipment is a major challenge for User Experience Technologies to develop and upgrade its business. Many of its potential clients would prefer imported products even when they cost more than those produced locally.

Like all other players, User Experience Technologies participates in the market and has been granted tenders by the Government. Most of the tenders that User Experience Technologies was fulfilling at the time of the interview were with the Government. However, its participation in large tenders is limited by its small production capacity and technological requirements.

To overcome challenges, such as lack of trust on the part of its Kenyan clients, User Experience Technologies has adopted a unique business strategy enabling it to sell locally manufactured equipment to its clients. It supplies its clients with both imported and locally manufactured devices to prove that the local devices function as well as the imported and more expensive ones. The research and development branch of the company says that this strategy has enabled it to sell and prove that local products that they manufacture are as good as, or better than, imported ones. It has increasingly established a local clientele, with a number of institutes opting for their domestically manufactured products over imported ones.

The challenges faced by User Experience Technologies are not unique, but are common among other local manufacturers of medical devices. In order to help to address these challenges and support the growth of local players, government procurement of locally manufactured products will be fundamental to fostering the growth of the sector. Financial support to help achieve large-scale production may be needed if local manufacturers are to compete favourably in national and international markets. One possible way is to encourage joint tenders between manufacturers of large medical devices and smaller domestic firms to help to build confidence and trust among users regarding the quality of domestic products.

4.2.2 Current human capital needs

The availability of qualified personnel underlines the quality of services and medical innovations. This includes professional and technical staff who know how to use medical devices properly, maintain and repair existing medical devices and design and upgrade new and emerging ones. There is, in general, a need to ensure that medical devices are used safely and properly. Most important the findings of any medical device must not be wrongly interpreted by users who may not be well informed.

This is one area in which Kenya is still lagging, in particular the challenge relating to the availability of qualified personnel to install, service and upgrade or customize medical devices at the hospital level.

Research has noted that Kenya lacks the manpower to support quality cancer research, prevention, early detection, treatment, and end-of-life care interventions for the entire population. Furthermore, oncology specialization is rare (Topazian et al., 2016). The breakdown of the only radiotherapy equipment at Kenyatta National Hospital in March 2015 revealed that the hospital had only four radiation oncologists, six medical oncologists, four paediatric oncologists, five radiation therapy technologists, three oncology nurses and two medical physicists (Daily Nation, 2015b). That seems to be a rather small number of medical professionals for referrals to the only public hospital serving thousands of cancer patients in the entire nation. At the time of the breakdown of the radiotherapy equipment in March 2015, the waiting list for repairs extended to 2017.

In 2015, Kenya had only 420 biomedical engineers, of whom 140 were medical engineering technologists with only diploma qualifications, while 270 had certificate qualifications (Daily Nation, 2015a) and 10 had other qualifications. The groups were neither qualified nor registered as engineers. None of the institutions offering the programme were even recognized as training centres for engineers. Under Kenyan law, such graduates cannot serve as engineers.

Kenya has a rapidly developing economy, a growing population whose incomes and life expectancy are increasing, a dynamic financial market with a fast-growing health insurance subsector and a small but growing medical device manufacturing sector. All the key ingredients appear to be in place, except for its personnel base. Investment in medical devices must be accompanied by investment in human resources and support facilities in order to maintain, calibrate, use and upgrade or develop improved medical facilities.

4.3 Policy and regulatory environment for medical devices

The health policy and/or strategy of countries often includes medical devices, but focuses largely on their availability and use in the provision of quality health services. Accordingly, national health policies may highlight areas of national interest, incentives offered to manufacturers and suppliers and challenges and opportunities. Such policies may also indicate areas of future and procurement. This is important information for firms that produce and supply medical devices. Countries also have specific regulations and directives that may offer greater clarity about the definitions, standards and safety of medical devices, as well as about the qualifications for biomedical professionals.

4.3.1 General health policy in Kenya

The Ministry of Health is mandated to develop and implement policy on various aspects of health-care provision. The policy provides for improved health care in line with Kenya's development agenda and its Vision 2030. The health policy for the period 2012-2030 contains strategies that focus on health-care infrastructure are aimed at adopting evidence-based health infrastructure and developing maintenance master plans and guidelines for donations and procurement.

The Health Sector Services Fund recognizes that health products and technologies are a vital component of health care. As a critical area for health investment, the strategic outcome envisaged is universal access to essential health products and technologies. In other words, these should be available, affordable, safe, efficacious and of good quality and appropriately used, thus contributing to optimal health care. The sector will adopt a comprehensive approach to investment in all aspects of health products and technologies so as to maintain a reliable supply of these inputs (availability), as well as the requisite management systems for ensuring that they are affordable, effective, of good quality and appropriately utilized (Government of Kenya, 2013).

Policy guidelines are important for the development of a medical devices industry. For example, Kenya has been developing a national list of essential medical devices. Such a list could be used by emerging and small-scale manufacturers to determine areas of the health-care infrastructure or system that they would like to target, in the same way as pharmaceutical firms use the essential drugs list. In such cases, local firms and the Government could focus on devices of significant interest to their needs and working environment. It could also help smaller firms to decide whether to enter fields in which global competition and international pressure on domestic agencies are likely to be intense. For example, medical devices used to diagnose diseases/illnesses of significant global interest, such as HIV/AIDS, may be unpredictable in terms of prices, global requirements, competition and changes in guidelines. It may accordingly be more difficult for smaller firms to enter and compete in such markets.

Another key policy element of interest to the medical devices industry are the health technology assessment guidelines (World Health Organization, 2011). Health technology assessment is a framework that provides the means

by which decisions to purchase medical devices take into consideration multiple dimensions such as economy, effectiveness and usefulness (Kriza et al., 2014). Unlike drugs and vaccines, medical devices present a variety of challenges that include rapid changes in technology, effectiveness, which may depend on user knowledge and experience, and pricing, which may be more dynamic than drugs. Manufacturers and suppliers of medical devices can package maintenance and upgrades in the selling price of medical devices. By doing so, established and large firms can undercut emerging and small medical device suppliers. Alternatively, government agencies and privately owned hospitals can carefully balance their needs to ensure that they get the most out of their investment and build domestic capacity to reduce costs in the near future through strategic alliances and human resource development. Kenya has institutionalized health technology assessment guidelines adopted in 2014 (see chapter 4 for details).

In addition to the health policy, it is reiterated in Vision 2030 that, to build a cohesive society, the main goal should be to improve the quality of life of all Kenyans and Kenyan residents, something that calls for improvements in the health and education sectors as a key to development. Vision 2030 prioritises both the industrial medical devices industry and improvements in the quality of all hospitals. With new devices being invented at a fast rate in a rapidly evolving market, quick adaptation in the Kenyan health industry will save many lives, while also improving the country's rate of development.

4.3.2 Regulations for medical devices

In Kenya, it is not clear who is in charge when it comes to the regulation of medical devices. The following are the authorities that have been, or currently are, responsible for the implementation and enforcement of some aspects of regulations for medical devices:

a. **Association of Medical Engineers in Kenya**: it petitioned to change itself from an association into a board in order to be covered by an Act of Government, something that has yet to be approved. Housed in the Ministry of Health, it seeks to encourage capacity-building and to inform government regulations. However, it does not make policies or enforce policy, but promotes the interests of biomedical engineering professionals;

b. **Pharmacy and Poisons Board**: it is mandated to regulate the medical devices industry on the basis of a 2002 Act of Parliament. It is responsible for registering medical devices that enter the market. It does not have its own guidelines, but adopts those of the following: the Global Harmonization Task Force for Medical Devices, the European Union Directives on Medical Devices, the In Vitro Diagnostic and Active Implantable Medical Device Directives and the United States of America Food and Drug Administration and the Australian Therapeutics Goods Act;

c. **Ministry of Health**: Under the new health bill, it provides one central location for medical device regulations. This bill is still pending, with all regulatory bodies having been put on hold;

d. **Health Care Act**: It is still in the stakeholders' review stages but, if enacted, will allow for a unified health system that should coordinate the interrelationship between the national Government and county government health systems. Moreover, the bill is to provide for the regulation of health-care services and health-care service providers, as well as for health products and health technologies and for related purposes, in addition to establishing a single regulatory body to regulate health products and health technologies. This regulatory body will oversee the licensing of health products and health technologies and the licensing of manufacturers and distributors of health products. It will also regulate contractors for medical devices and physical security for products, including radioactive and biological materials. Article 31(1) of the proposed bill looks at the procurement of health products and technologies. It states that this shall be undertaken in line with both the Public Procurement and Disposal Act and the health bill.

However, it is expected that the structure will be more streamlined in the coming few years. It is hoped that the Government will finally assign a clear mandate to one authority to oversee and control medical devices, thus enabling a clear line of accountabilities.

4.3.3 Procurement practices in Kenya

Kenyan procurement practices for medical devices are governed by an Act of Parliament overseen by the public procurement oversight authority. The process is initiated by users, who stipulate their requirements and develop specifications. The tendering is normally open and is advertised both locally and internationally. Quotations are received and tenders are evaluated on the basis of the quotations. The award can be based on either the technical specifications or the financial attributes of the tender. The winner is determined on the basis of the request for tender. The flaw in the process arises here, because the technical specifications of the tender rarely include the longterm cost of the device. Moreover, procurement committees rarely consist of professionals in the field in question, who are adequately equipped to know what is needed and how much it will cost. There is therefore a need to advise and improve on procurement practices to ensure that the most adequate and essential devices are submitted to the procurement committees and are eventually used in the hospitals.

In 2015, the Government, through the Ministry of Health, planned to procure medical devices through international competitive bidding worth 38 billion Kenyan shillings over the coming 7 to 10 years under a managed equipment service project. Equipment to be procured included theatre equipment, surgical instruments and sterilization equipment, laboratory equipment, kidney dialysis equipment, ICU equipment, ultrasound and imaging equipment, digital X-ray machines and 20 magnetic resonance imaging machines, for a total of 3 billion Kenyan shillings. The bids were awarded to well-known and reputable companies: General Electric from the United States, Philips from the Netherlands and Mindray Biomedical from China. The major sources of funds for medical equipment are the Government and the World Bank. The managed equipment service providers will be required to provide training to the users of the equipment, including medical engineers, health workers and ICT experts. This is a bold move, ensuring that the maintenance, servicing and life-cycle care of the equipment are well managed over a period of time.

As an example of these procurement practices, procurement practices at Kenyatta National Hospital, together with Nairobi Hospital and Aga Khan, one of the largest private hospitals in Kenya, are reported on and examined on the basis of interviews with their senior staff.

Most of the procurement budget at Kenyatta National Hospital is spent on recurrent costs, including maintenance, to ensure that the hospital runs smoothly. This leaves very little allocated in the budget for the continuous development of the department of biomedical engineering in terms of facilities for the improvement and upgrading of medical equipment, training for staff development and the provision of medical devices. In fact, the maximum amount allocated in the budget for research and development is only 11 per cent.

4.4 Establishing a solid foundation for the medical devices industry

4.4.1 Building human capital base in bio-medical engineering

The population of biomedical engineering staff in Kenya is insufficient. The Ministry of Health document on the service availability report and readiness assessment showed that there were only 420 biomedical engineering staff in hospitals. This is less than 1 per cent of all medical personnel in the whole country. This is a staggeringly low 0.1 per 10,000 people in the population. The Government is mandated by law to train engineers to maintain medical equipment and to procure services for the medical public sector. Steps have been taken in this regard, but more needs to be done. The focus should be not on the quantity of biomedical engineers but on their quality and on a clearly defined need for such posts. Their ratio should be in proportion to the medical equipment in any given hospital. This will ensure that competent and efficient medical services are placed where the need is greatest.

A. Training of users and engineers at the hospital level

As new technologies and medical devices are procured and enter hospitals, the training of technicians, engineers and users (doctors and nurses) becomes even more important in ensuring that the devices are used and maintained properly. For example, training practices at Kenyatta National Hospital shed useful light on the practice in public hospitals.

When a new machine is procured, biomedical engineers are given initial training only after it has been installed by the supplier. This may include travel for up to one week to the country in which the supplier is conducting its training. Such training, however, is not adequate to meet the maintenance of the equipment through its entire life cycle in the hospital. For example, when a radiotherapy machine is procured, training is provided following its installation, but training on how it can be maintained and eventually decommissioned is often not included. As a result, most radiotherapy equipment is installed, maintained and serviced through external service contracts, which is expensive in the long run.

Steps are, however, being taken to require the multinational firms that are supplying equipment in leasing schemes to train engineers. Under the current arrangement, companies undertaking the operation of the equipment in 47 counties are required to provide more in-depth training of local partners and even to partner with local training institutions to ensure sustainability. For example, Mindray Company in China is training 120 technicians and biomedical engineers in China, while General Electric flew some 100 technicians and engineers to the United States. It is hoped that, by expanding the number of individuals who are trained, medical devices are likely to remain in service or use for longer than is currently the case. Given that training is very specific and depends on the availability of various items of medical equipment, the Ministry of Health appears to have included training as a key component in its tender notices for the procurement of medical equipment.

Moreover, the Ministry of Health organizes training for all county engineers when the need arises. The training targets the calibration of equipment for newly ordered devices through the medical equipment services offered by suppliers. Training engineers in simple techniques used for simple yet vital devices, such as surgical tools and orthopaedic screws, will reduce the current maintenance budget and focus more on developing hospitals' medical engineering departments.

B. Biomedical engineering training at colleges and universities

While the above efforts appear to be substantial, formal biomedical engineering training is needed to ensure that Kenya has an adequate and constant supply of technicians, engineers and researchers with the skills necessary to meet its national goals. Hospitals such as the Kenyatta National Hospital, which houses some 3,000 medical devices including 2 computerized tomography scanners, 1 magnetic resonance imaging scanner, 1 catheterization laboratory, 2 laboratories for radiotherapy and 24 dialysis machines, and which is constantly buying new equipment, cannot afford to send its small teams of technicians and engineers for training. The presence of biomedical innovation and specialized biomedical engineers can help to ensure that imported equipment can be managed by suitably qualified and experienced staff, thus quickly narrowing the need for in-house training.

Only two universities are currently offering undergraduate biomedical engineering and medical technology. Kenyatta University launched its biomedical engineering undergraduate programme in 2014. Demand for training for biomedical engineers at undergraduate level has been high, especially from diploma holders working at various hospitals and institutions. Kenyatta University has accordingly been exploring the possibility of offering the programme at its city centre campus in order to make it accessible to workers. The same thing has happened at Egerton University, which, in 2003, launched a bachelor's degree programme in industrial technology, with an option for biomedical engineering. However, a fully fledged biomedical engineering programme was not developed.

At the diploma level, a host of universities and colleges offer biomedical engineering training. Of these, Mombasa Polytechnic (now the Technical

University of Mombasa), with support from the German Technical Cooperation Agency, launched a diploma course in medical engineering in 1986. The Technical University of Mombasa is now seeking to introduce a bachelor's degree in biomedical engineering. Others offering diploma programmes include the five Kenyan medical training colleges and Mt. Kenya University, Eldoret Polytechnic, the Rift Valley Technical Training Institute, the Kenya Institute of Applied Sciences–Eldoret, the Mautuma Youth Polytechnic, and the Gusii Institute of Technology.

The experience of South Africa, however, suggests that most biomedical engineering experts (more than 70 per cent) are employed in the private sector. While training personnel for the installation and maintenance of biomedical devices is important, training should also account for the needs of the emerging medical devices industry. Most of the engineers being trained are likely to serve as supervisors and heads of department in hospitals and ministries or as innovators, researchers and entrepreneurs. The latter group of actors includes those who are likely to keep public and private institutions informed about new and emerging technologies.

4.4.2 Ensuring the quality of biomedical engineering training

There is no institute that provides the certification and accreditation necessary for the biomedical engineering discipline. In 2013, a bill was tabled in parliament that sought to regulate the training, practice and licensing of biomedical engineering personnel. The lack of clear regulation of the profession has presented many challenges for the training and career progression of biomedical engineers. At the training level, Kenya's Engineers Registration Board did not recognize biomedical engineering as an engineering discipline until recently. This was a significant hindrance for universities, given that their graduates could not be registered and, hence, could not practise as certified biomedical engineers.

There is also a challenge for the in-country career progression of biomedical engineers, given that the current scheme of service was last updated 20 years ago. Accordingly, the entry level of biomedical engineers and their career progression in the public sector is not well established. Regulation of this sector is long overdue. Regardless of this, biomedical engineers are an essential workforce and much needed in the running of modern hospitals. There has, however, been a recent change in the recruitment of technical personnel that has not enhanced transparency in this regard. Until 2011, recruitment was done by the Ministry of Health but is now being conducted at the county level. County government data and the responsible county personnel are, however, difficult to find. Given that there is uncertainty about whether such data are being collected and recorded, it is difficult to give a full account of the number and activities of trained biomedical engineering personnel countrywide.

4.4.3 Addressing the main policy challenges

Currently, there is no one confirmed and specific policy or legislation on biomedical equipment that is applied to suppliers in Kenya. Anybody may accordingly apply for the advertised tender, applying either their own policy or any of the many used in the past. One consequence of such oversight is that major long-term costs, such as the after-sales management of equipment, service, labour, extended warranty and comprehensive services, is normally overlooked, given that they are not stipulated in the regulations and requirements. The outcome tends to be that the cheapest devices end up entering hospitals, regardless of their quality. This leads to increasing downtime for equipment, with more resources being spent on the replacement of parts and maintenance than on sustainable use.

Important information, such as the running cost and the total life cycle of equipment, is not included in the total quoted cost because medical device procurement is grouped with non-medical devices, with the same procurement committee and policy being applied to both medical and non-medical devices. Because most procurement committees look primarily at the cost of purchasing equipment, and not at its the running cost, the total value of the equipment is not known. Public health institutions accordingly end up needing more money to run the equipment than they had budgeted for. This accounts for the significant problem of unrepaired and unused equipment in hospitals.

To reduce this problem, the Government took a new initiative to transform the way in which procurement is done across the country to improve access to quality health care. As mentioned above, medical equipment services were introduced for state-of-the-art equipment is leased from highly reputable companies to level four and level five hospitals. The supplement published by the Ministry of Health shows that 94 hospitals will be fully equipped with theatre equipment, sterilizing equipment and complete surgical sets for all operations and laboratory equipment, with a further 11 hospitals equipped with intensive care unit facilities. This is a new practice that requires successful bidders to prove that they will be able to install, maintain and upgrade equipment, while providing training to technicians for a period of seven years. This new governmental approach ensures that proper health care is distributed evenly in all 47 counties, rather than being concentrated in Nairobi, as indicated in the 2013 Ministry of Health survey (Government of Kenya, 2014).

4.5 Conclusion

A rapidly growing economy should help Kenya to build a modest but growing medical device industry that can help to improve the quality of health care and meet rising demand for it. Indeed, Kenya has the basic ingredients to achieve this objective. In particular, the country already has a host of large public and private hospitals and clinics that are seeking to become regional and international health-care providers. A number of them attract patients from outside Kenya who are seeking specialized treatment.

To sustain and further establish a competitive position in the market, these hospitals will have to continuously improve and upgrade the quality of their services. The availability and quality of medical devices will be one of the key distinguishing factors for such hospitals to drive demand for their services.

Kenya's health insurance industry is well established, with most health-care providers accepting both domestic and international health insurers. Demand for improved and private health care is likely to increase, given that those who pay the insurance premiums (patients) will seek improved health care. With increased access to health information online and a younger population, most patients now arrive at health-care facilities armed with detailed knowledge of the conditions and treatments that are available globally. This will no doubt put pressure on health providers, requiring them to ensure that their medical devices are well serviced and up to date.

While reliance on the import of sophisticated and advanced medical devices will remain, the local production of hospital furniture, incubators and other simpler devices, as well as the local installation, maintenance and servicing of imported devices, should be encouraged. This could avoid some of the recent challenges in which machines imported at great expense remained unused, waiting for equally expensive repair and servicing by external experts.

Among other things, government procurement and support for personnel development are two important yet achievable ways to help to address some of the challenges to developing local producers and qualified personnel. Small and emerging firms that fail to attract tenders from large private hospitals could benefit from governmental procurement to grow their market and build confidence among potential clients. In terms of human capital, a number of Kenyan universities are establishing biomedical engineering teaching programmes. The support of the Government in addressing regulatory issues of importance to the profession will undoubtedly help. Because demand is high and a number of universities and colleges have recently launched biomedical engineering diploma and degree programmes, there is an urgent need to align regulatory practice regarding the registration of these programmes and their graduates. It is important for engineering regulatory bodies to be encouraged to recognize biomedical engineering as a field and for the Government to include biomedical engineers in public sector establishment structures. The public sector will remain an employer of biomedical engineers in the short to medium term.

CHAPTER 5
Innovation in medical devices for Africa: lessons from Malawi

This chapter provides cases of multidisciplinary research teams in Malawi and their partners in the United States to show how a collaborative relationship was pioneered to develop medical devices customized for the unique needs of and environment in Malawi. It also provides a detailed description of the development of two such medical devices with potential national and regional markets.

Summary of findings

Two technological innovations were developed to address important clinical needs: The **bubble continuous positive airway pressure (**bCPAP) and the Baby Lights products developed in Malawi cost less than one fifth of the imported commercial versions. The product design takes into consideration the environment (e.g. dust, space and limited oxygen supply) and the needs of users (fewer tubes, switches and parts to clean).

Lack of a manufacturing sector: The design, layout and blueprints of one of the two products were developed in Malawi. However, the bCPAP is still being manufactured in the United States because basic electronic components are not available in the local market, while the Baby Lights are still being produced by researchers at the University of Malawi using imported components. An industrial partner who understands the market and the regulatory needs of the continent is needed to achieve mass production in Malawi and to reduce the price of the products to meet local needs.

Innovation takes time: The concept for the project was identified and introduced in engineering student design projects in 2006. Initial designs were refined to incorporate feedback from clinical users, with the first prototype that could be used safely and ethically in a clinical trial being made available in 2010. A commercially viable product went to market in 2014. European Union accreditation was obtained in 2015, enabling the product to potentially enter the world market.

Long-term collaboration of interdisciplinary teams: Interdisciplinary teams of researchers, students, medical and engineering professions, civil society and industrialists worked together, contributing differently yet collectively to bring the technology to market. The various teams played equally key roles in securing funds, coaching students, identifying industrial partners and promoting and undertaking clinical trials, among other things.

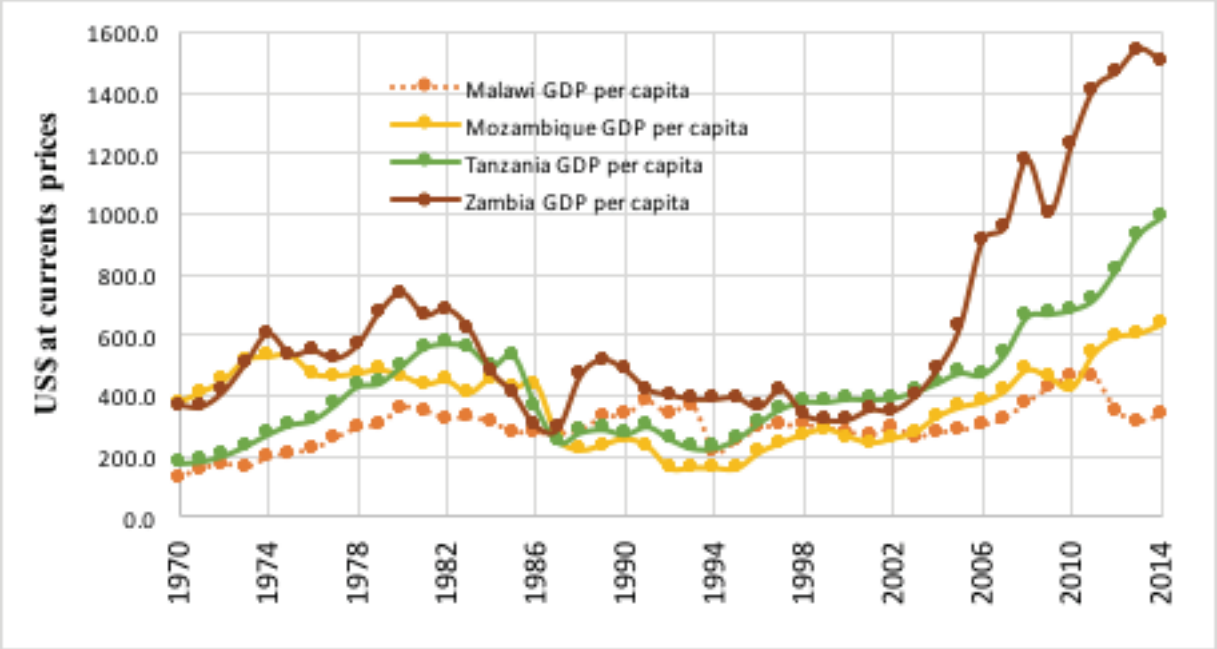
5.1 An overview of Malawi

5.1.1 The geography and economy of Malawi

Malawi is a landlocked country located in southern central Africa surrounded by three countries: the United Republic of Tanzania in the north, Zambia in the west and Mozambique in the south and south west. Geographically, Malawi's total surface area is 118,484 square km, of which 24,404 square km of water surface covers Lake Malawi. With a population of 16 million, Malawi has one of the highest population densities in the Southern Africa Development Community (SADC), estimated at 139 persons per km^2.

Malawi is predominantly a rural and agricultural country: 84 per cent of the labour force lives in rural areas, with 93 per cent of export earnings and 35 per cent of the GDP coming from agriculture.

Figure 5.1: Trends in GDP per capita of Malawi and its three neighbours
(United States dollars at current prices)



Source: United Nations Conference on Trade and Development Handbook of Statistics.

More than 80 per cent of the population lives in rural areas, with only 15.3 per cent thought to live in urban areas. This is a large rural population, compared with its neighbours. For example, the proportion of the population living in rural areas in Mozambique is 68 per cent, in the United Republic of Tanzania 69 per cent, and Zambia 60 per cent.

The past two decades have seen many African countries register very high growth rates, while their economies have expanded rapidly. Malawi's economy grew by 78 per cent between 2000 and 2014, while its GDP per capita increased by a mere 20 per cent during that period (see figure 5.1). This growth is much lower than that of its neighbours, all of which saw their GDPs expand by approximately 250 per cent or more. In a way, Malawi appears to have missed most of the opportunities that earned Africa the label of a "rising continent". Its economic development is, however, hindered in part by droughts that affect agricultural production and by government-donor disputes that affect flows of aid.

Official development assistance (ODA) to Malawi varied significantly, ranging from a low of approximately 15 per cent of gross national income in 2011 ($797 million) to a high of 30 per cent in 2013 ($1.13 billion). While such changes are not unique to Malawi, they are a specific challenge, given that ODA comprises a substantial proportion of its budget (up to 30 per cent in some years). With most ODA going to social sectors such as health, agriculture and education, rearranging budgets to meet the various competing needs of a country becomes difficult.

5.1.2 Health expenditure

According to the 2013 national health accounts, total health-care expenditure increased by 20 per cent, from $520.1 million in 2010 to $624.8 million in 2012. While the increase looks substantial in numbers, the amount, which translates to $37.8 per capita annually on health, is significantly below the WHO benchmark of $54 per capita annually. It was also lower than the $44.4 per capita annually needed to deliver the Malawi essential health-care package free of charge in 2011.

Malawi's health-care spending is more donor-dependent than in most other African countries such as Kenya, as discussed in the previous chapter. Donor contributions, in the 2013 national health accounts accounted for an average of 65.4 per cent of total health-care expenditure during the period 2011-2013. The national health accounts noted that Malawi's health system is highly

Table 5.1: Total annual health spending per capita of members of the Southern African Development Community
(United States dollars)

Years	2000	2005	2010	2014
Angola	16.9	64.7	131.8	179.4
Botswana	154.8	299.6	378.8	385.3
Lesotho	28.7	44.7	118.3	105.1
Madagascar	12.5	13.9	20.1	13.7
Mozambique	14.5	21.4	22.4	42.0
Mauritius	146.3	229.8	411.6	482.5
Malawi	9.5	17.7	34.1	24.4
Namibia	125.9	262.2	405.6	499.0
Sub-Saharan Africa (all income levels)	32.6	56.9	88.5	97.0
Swaziland	75.3	159.0	250.4	247.9
United Republic of Tanzania	10.1	21.6	36.1	51.7
South Africa	245.1	414.1	618.4	570.2
Democratic Republic of the Congo	18.2	6.7	12.6	11.6
Zambia	24.4	52.3	64.2	85.9
Zimbabwe	37.5	28.5	36.4	57.7

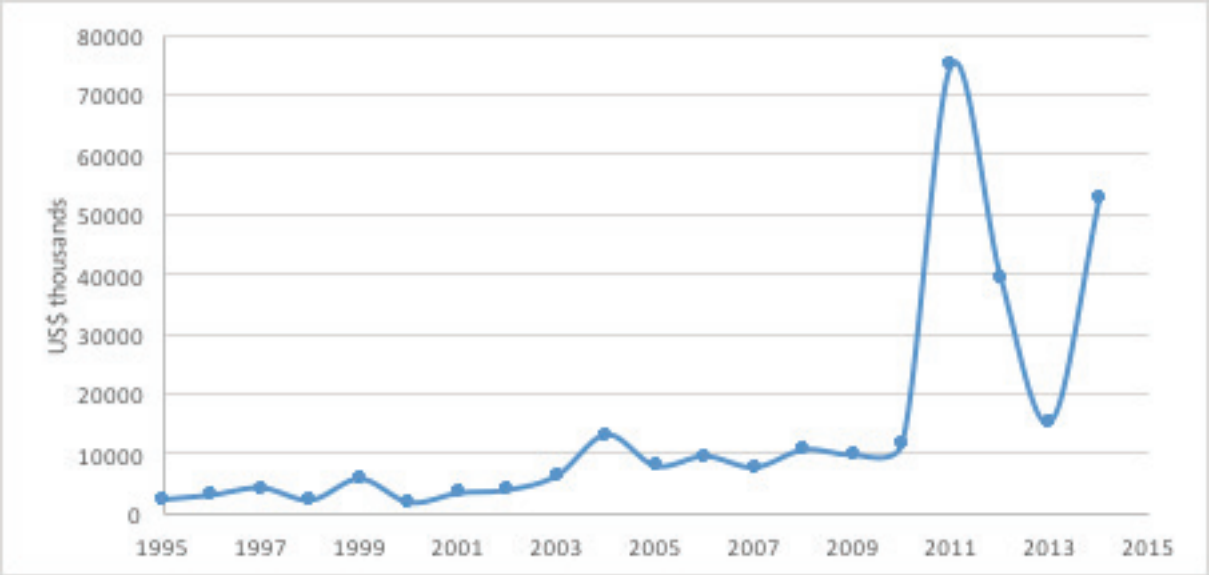
Source: World Bank world development indicators.

unsustainable in the event of a sudden withdrawal of or unpredicted shift in donor funding.

As shown in table 5.1, Malawi's health spending per capita is much lower than that of most other SADC members of , with the exception of the Democratic Republic of the Congo and Madagascar. In addition to being heavily donordependent, what appears to also stand out in the case of Malawi's total expenditure on health is the minimal involvement of the private sector. Out-of-pocket contributions accounted for 11 per cent of total health-care expenditure, while health insurance and corporations contributed 3.6 per cent and 0.8 per cent, respectively. While Malawi has a large number of privately owned health-care facilities, the majority are located in rural areas and belong to non-governmental organizations (NGOs) (e.g., the church), over half of which do not charge for their services. For example, the Christian Health Association of Malawi accounts for some 40 per cent of health services in Malawi. It has a service agreement with the Ministry of Health to deliver subsidized services to end users (SHOPS Project, 2016).

Given this context, Malawi's medical device market remains small and has varied widely in the past few years owing to the fluctuation of donor support and its relatively slower economic growth (see figure 5.2). It is estimated that Malawi's market for medical devices was, on average, $38.7 million during the period 2010-2014. Unlike Kenya, Malawi does not have an emerging domestic manufacturing base for medical devices. More than 56 per cent of private health facilities identified shortages of medical equipment and supplies as a barrier to growth (United States Agency for International Development, 2013). In the face of limited financial resources, innovation can help to offer solutions to some of the critical challenges.

Figure 5.2: Import of medical devices in Malawi
(Thousands of United States dollars)



Source: United Nations Conference on Trade and Development Handbook of Statistics.

5.1.3 Malawi's research community

Notwithstanding the above limitations, Malawi has a small but sound research base. According to research and development surveys, Malawi has 3,809 research and development personnel, of whom 1,843 are researchers (NEPAD Planning and Coordination Agency, 2014). Its personnel level is comparable to that of Zimbabwe and Mozambique, while its number of researchers is lower than that of Zimbabwe, but higher than that of Mozambique. Its population of personnel is predominantly male (80 per cent), compared with that of Mozambique (66 per cent) and Zimbabwe (73 per cent). Overall, the population of personnel is comparable to that of African countries with larger economies and to those with a well-established scientific base, such as Zimbabwe.

In terms of qualifications, Malawi had a higher number of researchers with a first degree (68 per cent) than Zimbabwe (59 per cent) and Mozambique (48 per cent). On the other hand, it had fewer researchers with doctoral and master's degrees. Although Malawi is an agricultural country, most of its researchers are in the engineering and technology fields (20 per cent), followed by medical and health sciences (19 per cent) and social sciences (18 per cent). By comparison, Kenya, another agricultural country, has 40 per cent of its researchers in the field of agriculture, followed by medicine and health science (26 per cent).

In terms of the financing of research and development, Malawi remains one of the few countries in the continent that invests more than 1 per cent of GDP in research and development (NEPAD Planning and Coordination Agency, 2010; 2014). The other country with a similar level of investment is Tunisia. Measured as gross expenditure on research and development, it is estimated that Malawi spent about $135.5 million purchasing power parity in 2010, the most recent year for which data are available. That amount, although it appears to be small, is substantial for the size of Malawi's economy. In terms of sectors of performance where the funds were spent on research and development, higher education accounted for $113.1 million, the government sector for $21.2 million and the not-for-profit sector for $2.2 million (NEPAD Planning and Coordination Agency, 2014).

5.2 Innovating for Africa

For countries that have limited budgets to fund the import of critical medical devices, while also facing huge variations in donor support (including donations of medical devices), innovation can help to fill the gap. Two cases are presented

below to show how the University of Malawi and the Queen Elizabeth Central Hospital in Blantyre and their partners at Rice University in the United States developed a unique strategy for identifying key health challenges and designing solutions that have been successfully brought to market. A number of key steps, components and research and development processes are described.

5.2.1 Development of bubble continuous positive airway pressure

A. The background

Respiratory distress is a common complication of neonatal pneumonia, sepsis and prematurity, causing more than half the deaths resulting in this age group. Premature infants lack a substance called surfactant, which means that their lungs tend to collapse between each breath, while babies are exhausted by the work of breathing. Infants with chest infections and other illnesses are exhausted by the effort of breathing. A bCPAP does not breathe for a child but assists children in breathing for themselves.

The bCPAP provides a regulated blend of air and oxygen to a baby through prongs placed in the nose. The pressure in the bCPAP system is controlled by immersing the end of the tubing in a bottle of water, with the depth of the tube in the water controlling the pressure. This constant gentle pressure improves functional residual lung capacity and eases the work of breathing. It has been shown to reduce morbidity and mortality and can easily be used by trained nurses.

Commercial CPAP machines are available and used widely in well-resourced centres. However, they are expensive (a minimum of $6,000 each) and rely on piped oxygen to function. In many parts of the world, the cost is prohibitive and piped oxygen is unavailable. CPAP has consequently not been widely used in Africa. Nevertheless, there was clearly a need for a simple, robust, efficient, inexpensive and user-friendly CPAP machine to use when piped oxygen is unavailable and health workers are overworked and few in number.

B. Conception and design of bubble continuous positive airway pressure

In 2006, a team of biomedical engineers from Rice University visited the Queen Elizabeth Central Hospital identified the need for a bCPAP. Discussions were held between the engineers from Rice University and doctors and nurses in Malawi. The engineers took the problem back to their students in the United States to try to develop solutions. According to Rice University (2010), a team of bioengineering students invented a low-cost bubble bCPAP device. The technology, which costs approximately 15 times less than conventional bCPAP machines, was created as part of the Rice 360° initiative, part of the university's Institute for Global Health, which offers a hands-on engineering education programme and offers innovative undergraduate programs that engage students in designing and implementing new technologies to solve real global health challenges.

The development and production of the bCPAP went through the various stages, summarized in tables 5.2 and 5.3, which show the funding source, the amount of funds available and the development stages that it went through. In brief, the first bCPAP designed by the students was rather basic and housed in a transparent plastic box (see figure 5.3). Although that initial design demonstrated the basic concept in action, the prototype was not sufficiently robust for use in public institutions. Subsequent designs became ever more sophisticated, with the significant involvement of users (nurses and doctors), researchers and industrial teams in the design process.

Table 5.2: bCPAP version 1 development

Year	Source	Funding (United States dollars)	Development
2010	Venture well grant	11 000	Market analysis of the need for bCPAP in Africa; develop a business plan for bCPAP; and collect user feedback and work with a private industrial design firm to incorporate this feedback, including better knobs, on/off switch, clearer indicators for tube attachments, and a more durable case for the device
2010-2012	Seed grant from the United States Agency for International Development	250 000	Clinical testing of the device in Queen Elizabeth Central Hospital with newborn children. Neonatal study is undertaken with excellent results: survival of premature babies with respiratory distress syndrome is 65 per cent with bCPAP and 24 per cent on nasal prong oxygen. Work with industrial design firm to develop device for commercial manufacturing and international regulatory approval
2010	African Network for Drugs and Diagnostic Innovation	100 000	Clinical testing of the device in Queen Elizabeth Central Hospital in infants weighing less than 10 kg

Source: Based on interviews with the research team in Malawi.

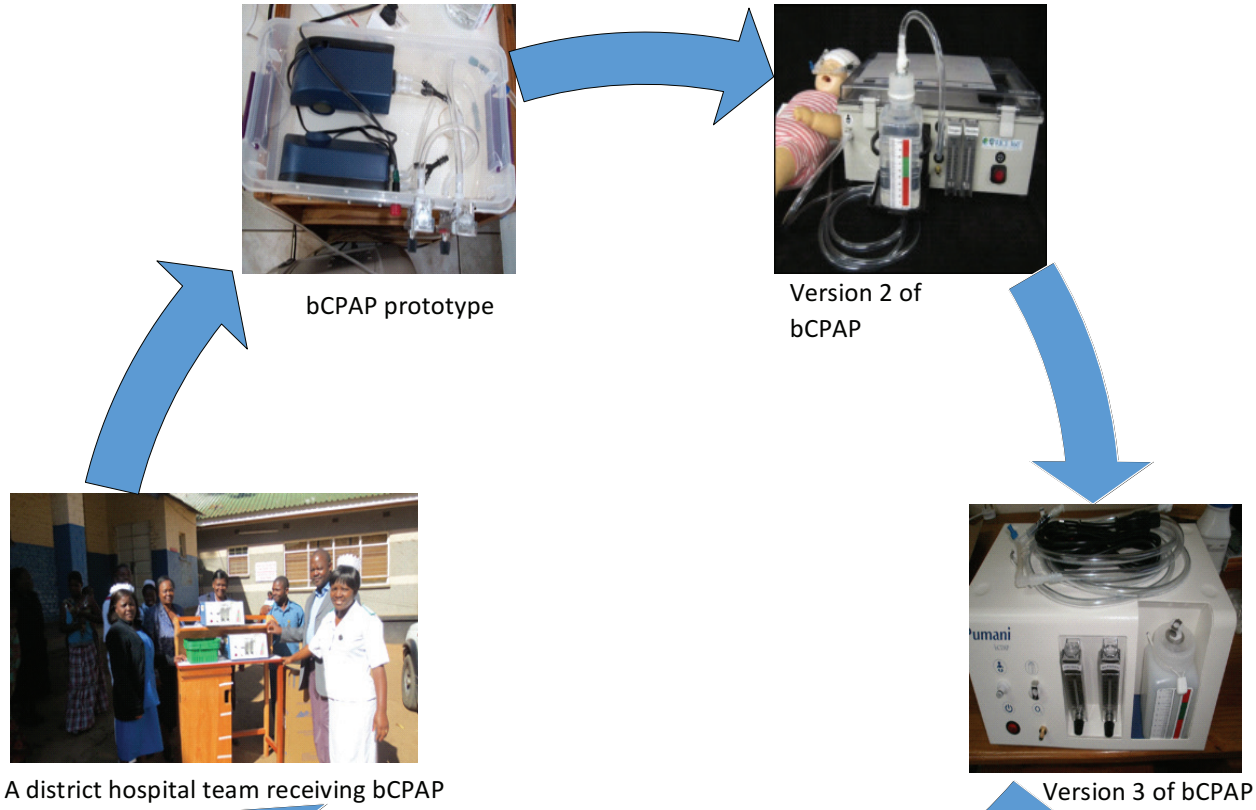
The case of the development and production of the bCPAP shows that the development of medical devices is possible in Africa, provided that a number of factors are in place. Among other things, these include the need for multidisciplinary approaches to addressing challenges. It would not have been possible for either engineering or health professionals working in isolation to have made such progress. Most of the initial design, research and development stages were made by students with access to key resources, such as laboratories for rapid prototyping and performance testing. Students interacted with their peers and researchers who were involved in other projects, enabling them to learn new techniques and to gain insights into how to address these challenges.

Table 5.3: Further development stages of bCPAP

Queen Elizabeth Central Hospital nurses name the bCPAP Pumani, which means Breathe in Chichewa
Stakeholder meetings with the Ministry of Health, the United Nations Children's Fund, Save the Children and WHO to demonstrate bCPAP and to discuss its possible roll-out to district hospitals
A $2 million grant applied for and approved by Saving Lives at Birth to roll out the use of bCPAP to 28 government district hospitals
Approval received from Malawi National Ethics Committee to roll out bCPAP to all government district hospitals
Partner with Ministry of Health to roll out in phases to 28 district hospitals
Roll-out includes collecting baseline data, identifying local coordinators, training, mentoring and providing the bCPAP machine and a suction machine, an oxygen concentrator, an oxygen saturation monitor and a respiratory rate counter, all in a custom-made cabinet made by a local carpenter
The manufacture of bCPAPis outsourced to a small company in the United States
2014: Patent application includes inventors from Rice University, the University of Malawi and the industrial partner.
Patent licensed to 3rd Stone Design (a private design company). Design continues to be fine-tuned
Proposal and budget submitted to a charity (at its request) to roll out to non-governmental hospitals
2013: GlaxoSmithKline and Save the Children Healthcare Innovation Award ($400,000) received to take bCPAP to South Africa, the United Republic of Tanzania and Zambia
2015: European Community accreditation received in April. Worldwide interest in Pumani

Source: Interviews with research team in Malawi.

Figure 5.3: Illustration of the bCPAP journey



C. Need for industrial partners

While the initial design, research and development were performed by students and researchers, the final products that hospitals globally wished to receive were designed by industry. The first working prototype was housed in a transparent plastic box and delivered the same flow and pressure as commercial bCPAP devices. The production of a device, however, that is userfriendly and that could be certified by industry and government regulators requires skills that are normally not present in research laboratories. In the case of the Pumani bCPAP, 3rd Stone Design, a professional design company in the United States, designed the final product.

The bCPAP machine was validated in the laboratory and compared with a commercial CPAP machine used in the Texas Children's Hospital. It delivered the same flow and pressure as the commercial device. The final products addressed some of the concerns of developing country users, such as improved knobs, an on/off switch, clearer indicators for tube attachments and a strong housing. These improved features required the input of industrial partners.

D. Key success factors

Long-term partnership: Between 2006 and 2014, the Queen Elizabeth Central Hospital hosted students from Rice University each year. During that period, the research teams at the University of Malawi, the Hospital and Rice University worked closely together to encourage students to design low-cost, user-friendly and robust medical devices for low-income countries. At the same time, researchers in Malawi and in the United States visited each other, collaborating in clinical trials and the co-development of projects. This helped to cement the relationship between the teams, building trust and confidence, which resulted in a longterm partnership beyond the length of any single project.

Education for innovation: The presence of a university student population is not of itself a major factor; rather, it is the existence of a hands-on education programme encouraging students to innovate that contributes to success. Among other things, Rice University's Oshman Engineering design kitchen, a fabrication laboratory, is a key component of the hands-on beyond traditional borders engineering education programme. This programme sends students to work and test prototypes designed at the overseas university. In 2014, it raised $375,000 in donations to expand Queen Elizabeth Central Hospital's neonatal facilities and to establish an innovation hub in which student-developed technologies can be proven and showcased. It is this education system that encourages innovation and enables students and researchers at Rice University to work closely with partners in Malawi.

A long-standing partnership between Rice University and the University of Malawi's engineering department was cemented with a grant from the Lemelson Foundation that has led to the creation of a fabrication laboratory in the polytechnic of the University of Malawi, next door to the Queen Elizabeth Central Hospital, and the establishment of a biomedical engineering curriculum.

Innovation takes time: The concept for the project was identified and included in the student programme in 2006. The first prototype that could be used in a clinical trial was eventually made available in 2010, with the commercially viable product going to market in 2014. European Community accreditation was obtained in 2015, enabling the product to potentially enter the world market. In short, it took nearly a decade to bring the product to market from the time when the challenge was identified. From this perspective, institutions that support students and researchers to find solutions to existing challenges need to provide sufficient space and time to ensure that their concepts and products can be refined.

Recognition and small marketing steps are critical: A number of the key steps highlighted small but major milestones that promoted the project. Promotion played a key role in winning awards that enabled the project to receive funding. The teams in Malawi and in the United States competed in a variety of competitions and told their stories in a compelling and effective manner, sharing the results extensively. As a result, institutions such the United Nations and the United States Agency for International

Development highlighted the project as one of the top innovations likely to have a major impact on the survival of babies.

Multiple team efforts: A single product is rarely the effort of one individual or team. In this case, teams in Malawi and the United States played interdependent roles to design, develop and bring the product to market. The team in Malawi identified the challenge, hosted the students, undertook the clinical trials and testing of the device and led some of the efforts to raise awareness and funds. The teams in the United States mobilized and supervised the students, found industrial partners that designed the final products and mobilized some of the financial resources. With every success, a number of interested partners joined to support the project. Each of the teams brought in various resources and expertise, as well as different views. For instance, the $400,000 prize that the technology won at the inaugural health-care innovation award programme sponsored by GlaxoSmithKline and Save the Children was led by Friends of Sick Children in Malawi, which wanted to replicate the success of Malawi's bCPAP programme in three neighbouring countries (Rice University, 2014).

5.3 Phototherapy to treat jaundice in newborns: case of Baby Lights in Malawi

A. The problem

Jaundice is the build-up of bilirubin in organs and skin that turns the skin yellow. It is common in newborn infants, especially those who are born premature. Some diseases cause jaundice or it may simply be that a baby's immature liver cannot metabolise bilirubin sufficiently to eliminate it from the body.

In the first week or so of life, high levels of bilirubin can cause permanent brain damage. It is important to prevent the bilirubin level rising too high and to bring the level down if it is already raised. Severe cases of neonatal jaundice are called hyperbilirubinaemia.

Phototherapy is widely used to prevent hyperbilirubinemia. Blue light of a certain wavelength and irradiance is required. Bilirubin absorbs the blue light and is broken down into water-soluble photo-isomers and other chemicals that are removed from the body as bile and through urine.

Phototherapy systems are available on the international market but are expensive. Spare parts are difficult to obtain locally and their maintenance is costly. Commercial phototherapy units use fluorescent lamps, quartz halogen lamps, gas discharge tubes and light-emitting diodes (LEDs) as light sources.

Of these light sources, LEDs consume the least power and are longest lasting. Blue light is concentrated on a wavelength band of 430-490 nm, with the most effective range being 460-490 nm. There are not enough phototherapy units in many developing countries. Many that are in hospitals are unusable, given that they lack bulbs or are broken.

B. Development process

This case highlights major steps in the design and development of a low-cost phototherapy system in Malawi called Baby Lights.

In 2009, biomedical engineering students from Rice University brought three first-generation prototype phototherapy units that they had designed and made in their student design kitchen. They had already tested them in the laboratory, finding that they provided the correct irradiance. In Guatemala, the phototherapy lights had been used in a clinical setting and were found to function well. The phototherapy equipment used blue LED lights.

The units were put to use on jaundiced babies in the neonatal ward of the teaching hospital. They functioned well but had minor issues that needed correction, for example, the fragile on/off push button switch and a glued wooden housing that fell apart when exposed to some heat.

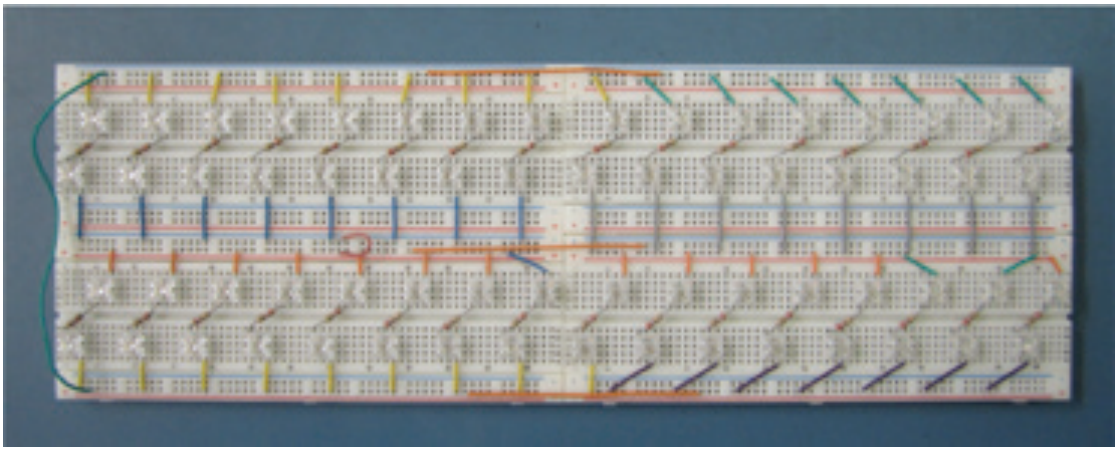
In 2010, students introduced prototype version 2 with a large, rocker-type on/off switch, but otherwise it was quite similar to the previous version.

In 2012, the African Network for Drugs and Diagnostic Innovation gave a grant to develop the phototherapy lights further and to try to have them made in Malawi.

Engineers in the electrical engineering department of the University of Malawi redesigned the unit to make it more robust when using an unstable electrical power supply. They also used components that can be bought on the continent (from South Africa).

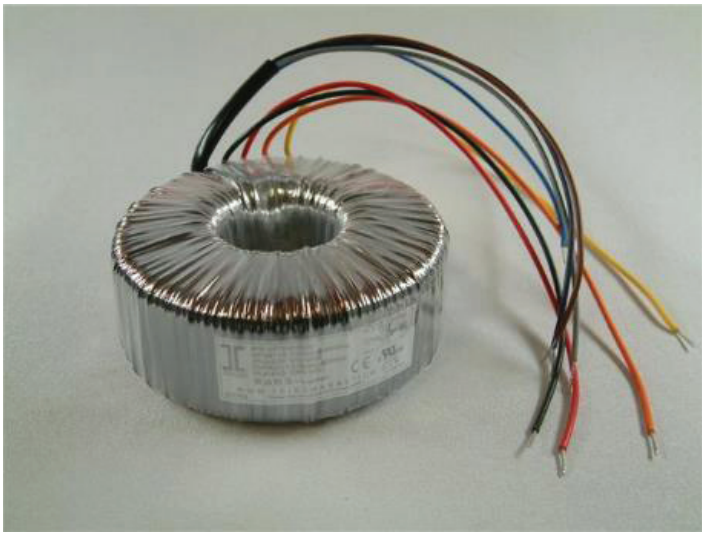
Each Baby Light has three parts: the power supply, the LED boards and the housing. Power requirements were for 144 LEDs to ensure sufficient and efficient power supply. After looking at various possibilities, a linear power supply was adopted.

Figure 5.4: Photograph of a breadboard showing LEDs and resistor connections



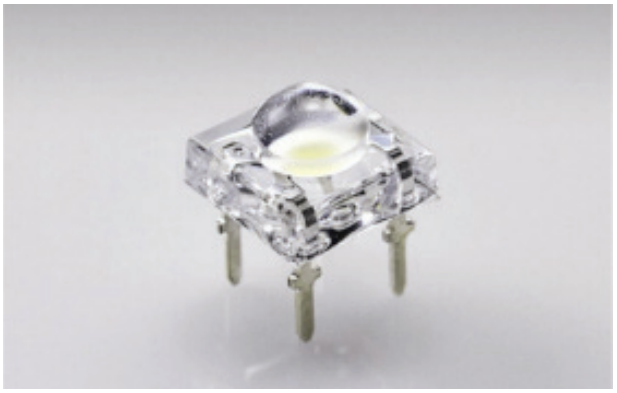
The power supply used a toroidal transformer and brightness control with pulse width modulation and a power transistor to deliver the required controlled current to the LEDs. The toroidal transformer (see figure 5.5) was used, given that it produces very little heat, eliminates most interference within the unit and is small.

Figure 5.5: Toroidal transformer



The brightness of the LEDs is varied using a potentiometer, which is connected directly to the pulse with modulation controller. The LEDs have a light intensity of 6 lumens and 5500 mcd each at a light wavelength and a viewing angle of 70 degrees. The wavelength falls under the medically applicable range for phototherapy of 430–490 nm.

Figure 5.6: 3 mm SuperBright LED blue LED



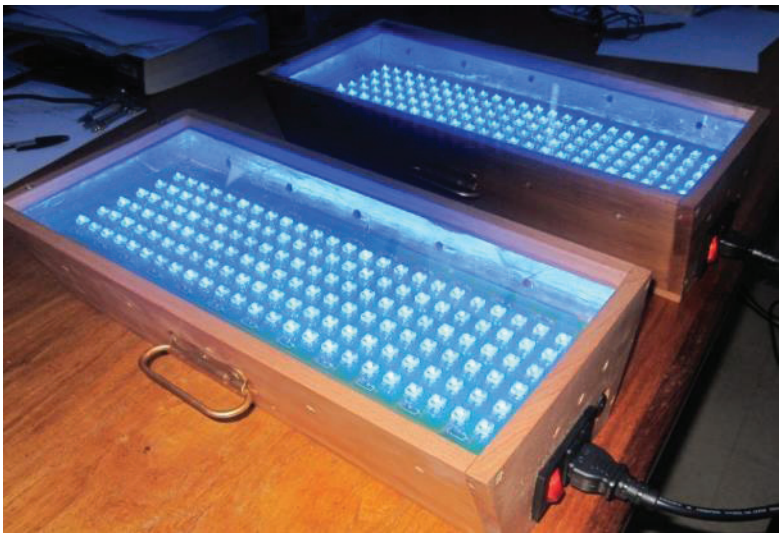
The Baby Lights housing was made from wood because it is easier to process. Holes in the wood panels allow air to circulate and reduce heat generated with the unit. The inside walls of the box were lined with reflective aluminium foil. Perspex covered the open side of the box.

Nevertheless, there were some complications:

a. (a) Prices for parts that were imported from South Africa doubled when transport costs and taxes were added;
b. (b) The assembly was slow because much of the machine work that could have been done automatically had to be done manually;
c. (c) The housing was made of wood because sheet metal of the right thickness was too costly
d. (d) Because the printer circuit boards used to carry circuits for the LED lights were too thick to be able to use bulbs that slotted into a socket, each bulb had to be soldered into place;
e. (e) The grant money was given in six monthly tranches, with the second tranche arriving six months late.

Notwithstanding those challenges, 20 Baby Lights had been made by 2014 and were tested and in use in the neonatal units of Queen Elizabeth Central Hospital and local district hospitals. The transformer, the power supply, the LED boards and all accessories were fixed into the box, as shown in figure 5.7.

Figure 5.7: Phototherapy box photographs at lowest level of irradiance



The Baby Lights are in use in several district hospitals and in the main teaching hospital in Malawi. The lights are placed on the Blantyre hot cot perspex cover but, when this is not possible, a stand was designed to hold the Baby Lights. (The Blantyre hot cot is a locally made reliable and robust incubator requiring minimal maintenance (see figure 5.8).)

Figure 5.8: Baby Lights on a stand

C. Lessons learnt and way forward

The two projects illustrated in this chapter can be considered successful in the following regard: the bCPAP machine was validated in the laboratory and against a commercial CPAP machine used in the Texas Children's Hospital, proving to be as reliable as the commercial device; and 20 Baby Lights were made, tested and were in use in the neonatal units of the Queen Elizabeth Central Hospital and the local district hospitals. The cases show that some great strides have been made in the right direction amid the challenges confronting Malawi's medical device manufacturing industry.

However, present challenges still impede the continuing development of the two devices. The challenges faced by the Baby Lights are similar to those faced by many medical devices on the continent at the moment, namely, the cost of importing parts and materials and a lack of local industrial-size collaborators with which to partner. The bCPAP is made in the United States, but production will probably be moved to India or China as orders increase. The Baby Lights are made to order but are almost entirely funded by project monies.

It is always difficult but necessary to find a balance between an entrepreneur trying to make a profit and the need for an affordable medical item. It is not always easy to find the right answer. With the help of the African Network for Drugs and Diagnostic Innovation and 3rd Stone Design, attempts are being made to find a commercial Baby Lights manufacturer in Africa. The success of Baby Lights will go a long way towards paving the way for prospective medical devices aspiring to be manufactured successfully on and for the continent.

CHAPTER 6
Building the foundation for an innovative medical device industry

How can African countries build an innovative medical device industry, taking into consideration their limited industrial base, scientific infrastructure and poor health-care system? This chapter attempts to highlight simple steps that African countries can undertake, individually and collectively, to develop an innovative and entrepreneurial medical devices culture. The focus is on how Africa can build the human resources necessary that are capable of bringing new and improved medical device services and technologies to market and of promoting innovations among young citizens. The case of an ECA-led initiative is used to highlight some of the ways in which key challenges could be overcome.[3]

Major observations

Interest in biomedical engineering is high: The number of universities wishing to run graduate and post-graduate biomedical engineering programmes is high, and the demand from students is even higher. Nevertheless, basic laboratories for training biomedical engineers and infrastructure that encourage research and innovation are either missing or emerging. Similarly, there are not enough suitably qualified lecturers to run fully fledged programmes.

Innovation awards and summer schools play a key role in promoting innovation: Interest in the innovators' school programmes plays a central role in spreading new knowledge, instilling entrepreneurial attitudes, encouraging creative thinking among young people and researchers and promoting collaboration among students across disciplines and gender.

Importance of the promotion of innovation by regional institutions: The case of the ECAinspired African biomedical engineering consortium has institutionalized a pilot project in a growing initiative that is attracting new members, promoting joint projects and funding and ensuring that academic and research excellence is maintained.

Ongoing challenge of translating research outputs into commercial products: Collaboration between government and partners is necessary to put in place the basic infrastructure for commercializing research output, for promoting joint ventures between domestic and foreign firms and for offering optimal incentives to encourage investment in the medical device industry.

6.1 Introduction

The main focus of this chapter is to highlight a number of basic and vital steps that countries with a limited scientific, technological and industrial base can take to develop a robust medical device sector. An innovative medical device industry is needed to provide key technical, business and professional services and value-added goods to the public and private health sectors. To achieve this goal, this chapter is premised on a number of assumptions. First, African countries aspire to provide the best health services possible to improve quality of life and to save the lives of

3 Participating universities come from Egypt (1; joined in December 2015), Ethiopia (2), Kenya (4), Malawi (1), Nigeria (2; joined in December 2015), South Africa, (1; serves largely as adviser or observer), Uganda (3), United Republic of Tanzania (2), and Zambia (1). Industrial research partners: Kenya (2), South Africa (2), Uganda (1), United Republic of Tanzania (1) and Zambia (1). International partners: Boston University (United States) and University of Pisa (Italy). Firms: Techno Mobile (Ethiopia); Enterprise Uganda; and Empretec Ethiopia and SIDO (United Republic of Tanzania).

millions of their inhabitants from preventable diseases. It is thus expected that Governments will provide incentives, support and investment to stakeholders in the medical devices industry.

Second, universities and research institutions in Africa would be encouraged to offer courses to build the human resources necessary and to undertake or encourage research in biomedical engineering. This will ensure that universities serve the function of providing the resources and commitment to build a sustainable mechanism for human capital development and for research and entrepreneurship promotion.

Third, Africa's youthful population will be attracted to careers in biomedical engineering research, innovation and business development. Demand for higher biomedical education will therefore continue to rise as the nascent medical devices industry and the rapid expansion of health facilities will offer attractive employment opportunities for biometrical engineering graduates.

It is perhaps important to emphasize that "medical device industry", as used here, encompasses a host of manufacturing and professional, scientific and technical service firms. The services that they provide include legal, accounting, architectural, engineering, installation, surveying, design, management, scientific, research and development and related services. Both manufacturing and service firms considered to be important for the development of a competitive and innovative medical devices industry. In this regard, the chapter focuses on personnel development, innovation and entrepreneurship promotion and support measures for industry development.

6.2 Building Africa's biomedical engineering human capital[4]

On cannot over emphasize the need for highly skilled personnel to address the ever-increasing requirement to identify, source, install, customize, service and upgrade advanced medical devices and other technologies. Africa currently depends not only on imports of medical devices, but also on technical, scientific and professional services to ensure that the few items of complex medical equipment are operational. For example, in 1988, Nyanza General Hospital in Kenya imported brachytherapy equipment for cancer treatments at a cost of approximately $500,000. The equipment was installed in 2002, but, by the end of that year, it was reported to have broken down. The hospital managed to raise the $16,400 pre-payment to have engineers sent in to inspect the equipment four years later, in 2006. The equipment was finally inspected in October 2008, six years after it broke down. The engineers found that the equipment was in good working order, but that it had not been properly operated (Daily Nation, 2009). As mentioned in chapter 3, both Kenya and Uganda have experienced similar delays in the repair of major cancer treatment facilities in the past few years. These incidents highlight the urgent need for skilled human resources to keep complex medical devices in good operating order.

6.2.1 Encouraging and supporting universities to develop biomedical engineering programmes

The need to produce skilled biomedical engineers is commonly recognized, but it varies, depending on the interest of the institutions involved. For example, most of the early efforts in Africa appear to have focussed on the training of technicians who could maintain medical devices in good working order. These ranged from short courses offered to qualified electricians and medical technicians at hospitals[5] and laboratories, ad hoc training for biomedical diploma programmes (e.g., in Uganda and Zambia) and established biomedical diploma training programmes (e.g., in Kenya). Technicians and technologists play a pivotal role in the maintenance and safe use of medical devices.

At present, the demand for a more comprehensive approach to skills training and the development of biomedical engineering human capital has encouraged and supported universities to develop and implement biomedical engineering

4 Based on Economic Commission for Africa (2014)

5 The Japan International Cooperation Agency has supported two-week training courses to personnel at biomedical centres in Malawi and equipped the personnel with calibration and testing kits in 2012.

undergraduate and graduate programmes. These programmes cover a wide range of engineering, medical, software programming and entrepreneurship courses, among other things. In general, these courses are specifically designed to develop a broad base of requisite skills in planning, procurement, designing, installing, commissioning, maintaining, decommissioning and safely disposing of biomedical devices.

Developing a new programme, however, takes significant time and effort. The curriculum needs to be designed and approved by various responsible university management committees and boards, and laboratories need to be built or refurbished to meet the requirements of new programmes. Unlike other areas of engineering, the implementation of biomedical engineering programmes requires closer collaboration, especially between engineering and health/medical faculties, as is implicit in the name bioengineering.

The development of new programmes is even more complicated by the requirement for engineering courses to be registered with regulatory bodies outside the university. Regulatory issues present major challenges to some universities. In some African countries, only four or so traditional engineering fields are registered by national regulatory bodies, while recent fields of study, such as biomedical and aeronautics engineering, are often not recognized. That means that graduates from such programmes can neither be registered as engineers nor use the term engineer. In rare cases, lecturers in engineering are also expected to hold a first degree in engineering. This is problematic in fields such as biomedical engineering because there may be a need for individuals with a background in areas such as physics and computer sciences who may also have pursued post-graduate courses in engineering-related subjects. Taken together, one can understand why a number of universities may be reluctant to develop and run biomedical engineering graduate programmes. Efforts to encourage and support universities in offering biomedical engineering programmes have to take into consideration a number of local interests, regulations and resources.

There are a number of steps that can be considered as critical to get a programme up and running efficiently. On the basis of a successful pilot ECA-led initiative, several steps, which were considered important, were undertaken. First, ECA staff visited and raised the awareness of key parties whose recognition and support are critical to developing and implementing the initiative. These key parties included government officials, hospital administrators, university leaders and heads of engineering and health/medical schools, as well as donors. It is important to ensure that common understanding and mutual recognition are attained at the highest level of government and university and that the teams to implement the programme at the university level are supported by their supervisors (Economic Commission for Africa, 2012).

Second, ECA, with the technical support of Boston University, hired a consultant to develop a generic biomedical engineering curriculum. The involvement of lecturers at universities with well-established biomedical engineering undergraduate and postgraduate programmes in the United States (e.g., Boston University and Duke University) and in Africa (e.g., the University of Cape Town and Stellenbosch University) ensures that concrete guidance and benchmarking are developed and provided for interested universities, which can then speed up the design and customization of biomedical engineering courses that meet their unique needs (e.g., industrial and social considerations) and can get approval from university administrations.

Third, ECA undertook a series of promotional campaigns in support of biomedical enginnering as both a core field of study and a health and economic challenge. These included presentations of the initiative at major meetings, such as the Conference of Vice-Chancellors and Deans of Science, Engineering and Technology, Science with Africa and the Committee on Development Information, Science and Technology. For example, Kyambogo University and Makarere University in Uganda joined the initiative after the presentation at the Conference of Vice-Chancellors and Deans of Science, Engineering and Technology and a follow-up visit to Uganda by ECA. Such promotional efforts have stimulated increased cooperation among universities and industrial partners and with Governments. One

such partnership in Uganda has enabled entire biomedical engineering classes at Makerere University to obtain access to the state-of-the-art facilities of the Uganda Industrial Research Institute.

Lastly, the early identification of champions, namely, individuals who go out of their way to promote and galvanize support for biomedical engineering, and interest enhances the prospect of success, even in the most challenging environment, for example Kenyatta University, whose schools of engineering and medicine were still being built at the beginning of the initiative. However, the university refused to be sidelined, notwithstanding its lack of facilities and personnel. Instead, it offered to meet the full costs of an ECA mission to visit the university. In order to maintain freedom of decision-making, ECA offered to visit Kenyatta University at its own expense, while the university covered all local costs. It became apparent that the Dean of the School of Engineering and the Director, Directorate of Intellectual Property Rights, had raised the awareness of the entire management on the need for the programme, given that Kenyatta University was building the first teaching and the only referral hospital that is wholly owned by a university in Kenya. Since then, Kenyatta University has acquired the basic infrastructure and staff needed to develop the programme and has progressed more rapidly than universities that had appeared to be better placed. Universities where individuals who originally championed the initiative either left (e.g., the University of Zambia) or retired (e.g., the University of Nairobi) have lagged in many respects.

By following these steps that helped lay down a solid foundation, the initiative has taken off in just a few years. It has resulted in estimated 915 students being enrolled in biomedical engineering programmes at universities in Ethiopia (1), Kenya (1), Malawi (1) and Uganda (2), and an additional 517 were enrolled at participating universities by the end of 2016. A total of 49 students had graduated in Uganda by 2015. Almost all the students who graduated in Uganda were employed by hospitals and by private businesses offering a variety of services to health-care facilities. Most biomedical engineering graduates are equally qualified to work in other industries, such as electrical engineering, electronics and software engineering.

6.2.2 Challenges in implementing biomedical engineering programmes at universities

African universities face many challenges affecting the effective delivery of biomedical engineering programmes. Other than challenges that are general to all training programmes, following are some unique challenges affecting biomedical engineering:

Limited numbers of lecturers with qualifications in biomedical engineering. As a new field of study at some universities, few lecturers have training in biomedical engineering and can effectively teach courses on the subject. In Uganda, two of the senior medical devices engineers at the Ministry of Health teach it at both Kyambogo University and Makerere University. Moreover, one of the biomedical engineers also serves as the resident biomedical engineer at the country's largest hospital (Mulago National Referral Hospital in Kampala). Kenyatta University had to specifically employ a lecturer to oversee the development of the biomedical engineering course because it could not find any existing member of staff with the qualification at that time. ECA also had to support an external consultant to adjust the generic curriculum to meet the needs of Kenya and Kenyatta University.

Given that the availability of qualified personnel at a university is a major criterion that engineering registration boards take into account in assessing and approving a course, some of the universities will have to rely on external partners and visiting professors to meet their minimum requirements. This is, however, a short-term measure. Universities need to have their own qualified personnel to sustain and support biomedical engineering programmes in the long run in order to ensure that students who have been trained are theoretically and professionally well grounded in the desired disciplines.

Lack of facilities: The basic laboratories for training biomedical engineering engineers are lacking, owing to limitations in funding. The integration of technologies into medical devices means that

teaching must include basic laboratories in the fields of emerging computation, information, material, imaging and biological technologies in order to provide students with up-to-date knowledge and skills in medical device development. For example, traditional X-ray machines are giving way to digital X-ray devices. While engineers will not be trained in how to repair devices, they will need to know the basic principles that enable new medical equipment and systems to work.

There is also a lack of infrastructure for undertaking research and innovation. This includes facilities for design and rapid prototyping, multidisciplinary platforms for addressing challenges (e.g., seminars), technology transfer offices and incubators. These facilities are fundamental to translating research into innovation that can be applied and deployed.

6.3 Innovation boot camps and awards in driving innovation and entrepreneurship

Awards and boot camps are perhaps one of the oldest tools for instilling change, altering attitudes and stimulating initiative and creativity in children and adults alike. They have been commonly used to change behaviour and to equip individuals with new skills. In recent years, awards have been used to help to stimulate research and innovation among various players (e.g., students, researchers, politicians, firms and communities) by encouraging competition and recognizing achievements (Smith et al., 2003). Awards are also intended to showcase great ideas and encourage creativity. It is for this reason that a multitude of innovation awards are offered in both developed and developing countries to celebrate creative ideas in almost all fields of research, business and society. For example, South Africa's top 100 technology in business award (Da Vinci tt100) is perhaps one of the most established awards that has been developed for almost 25 years. They celebrate leadership in technology discovery, application, business practices and innovation, among other things. Other awards include the Innovation Prize for Africa, co-developed by ECA, the African Innovation Foundation (Switzerland) and the Tony Elumelu Foundation (Nigeria), which seeks to develop 10,000 entrepreneurs who will create 1 million jobs and generate $10 billion in annual revenue. These initiatives offer various types of support, which may include financial awards (funds), training, mentorship and the promotion of entrepreneurs.

6.3.1 ECA's innovators' summer school

As part of the ECA-led "Engineering expertise to improve health outcomes in Africa" initiative, the innovators' school programme, commonly referred to as the innovators' summer school, is a one-week intensive activity that is aimed at igniting creativity, innovation and entrepreneurship in university students. The school is designed to:

a. Enhance the technical and engineering skills of students through exposure to new and emerging technologies and technology applications;

b. Build and stimulate the entrepreneurial competencies of students and researchers through training and hands-on business modelling and planning of lectures;

c. Encourage the emergence of multidisciplinary and multinational teams through strategic group building;

d. Instil the skills needed to promote and market innovative ideas and businesses.

Every student attending the summer school is selected on a competitive basis following a 6 to 9-month development phase that is held at the participating universities. A theme is announced between January and April each year. Students hold brainstorming sessions and talks to identify health challenges, create a multidisciplinary team and design engineering-based solutions. The solution is first vetted at the university level and submitted to an international panel composed of representatives of the participating universities, as well as of industrial and technology development institutions in Africa and in Europe. The projects are reviewed and feedback is provided to the student teams, which get another opportunity to review and modify their project designs and concepts before making a final submission by September. A final assessment is made, with

up to 24 projects shortlisted. The teams whose projects are selected can choose one member to attend and represent the project at the summer school.

This phase is specifically designed to help students to learn how to create winning teams that meet the project requirement for teams to be multidisciplinary and gender-diverse. It also encourages students to learn to mobilize and deploy various external sources of support, namely, fellow students, researchers, hospitals and business leaders, to consult on their designs and to seek new knowledge and information.

Students participating in the summer school are placed in groups of three or four and are assigned two mentors from among the lecturers, researchers and industrial partners. These mentors will guide the students in the development of their design concepts. Students are required to attend all training sessions offered during the week and to work on their projects in their own time. The 2015 summer school, for example, exposed students and researchers to advanced programming techniques for mobile phones in the design of mobile applications and in the analysis, storage, security and sharing of medical data between devices and health professionals. A team of professionals from Techno-Mobile (Ethiopia) and researchers from Italy and Germany were added to the trainers from within the network. A specific course on entrepreneurship was also provided at the 2015 summer school.

The main aim of this design approach in the boot camp is to improve the knowledge of students in new and emerging fields of technology. For example, the 2013 summer school introduced students to three-dimensional (3-D) printing technology and open-source programming. Students had to assemble the 3-D printer and use it to make components for a baby monitor using open-source software and components programmed during the school. For almost all the 30 students and most of the researchers, this was their first encounter with a 3-D printer costing no more than $4,000.

The summer school awards served to focus the interest of students on their projects. In general, three awards are presented to honour the most innovative concept, the concept with the greatest social impact and the concept with the greatest economic impact.

In 2014 and 2015, cash awards were introduced, with a focus on entrepreneurial issues. An award for the most feasible business concept and for the best business pitch for the project was offered in both 2014 and 2015. The main aim of both awards is to encourage students to look for alternative ways of finding solutions to health challenges, while taking into consideration the viability and applicability of the solutions, not only from a technological point of view, but also from a business point of view.

The design of the summer school takes into consideration the need to spread knowledge, instil entrepreneurial attitudes and encourage creative thinking among young people. In 2015, 42 projects by 108 students, with a focus on maternal health solutions and technologies to help to prevent the spread of viral diseases such as cholera and Ebola, were received from 13 universities in Africa, as well as two projects from Europe. Of these, 24 were represented at the summer school in 2015 in Addis Ababa by at least one student. In general, at least 400 students have participated in the design of innovative concepts and 41 have attended the summer school in the past four years.

In terms of impact, the summer school has become a cornerstone of the entire programme for sharing emerging technologies, encouraging universities to invest in them and promoting innovation and entrepreneurship among young people. It has been observed that the quality and thoughtfulness of the programmes have continued to rise. Most of the projects developed in the past two years have been better informed and technically more sound than those presented in earlier summer schools. A number of universities have since established their own Fablabs or have bought 3-D printers.

Box 6.1: Case of 2015 summer schools on the use of mobile technology to deliver health-care solutions

Introduction

Although smartphones and mobile technology are increasingly common in medical practice, there is no evidence of mobile phones being used for design or as support tools or accessories for biomedical engineers. To introduce the concept of mobile technology as a tool for better health and the generation of innovation, an ECA-funded innovators' summer school on the application of mobile phones in health-care product design and development was held in Addis Ababa from 11 to 15 January 2016.

The aim was to empower students with basic skills and know-how to kick-start innovation by integrating mobile applications into their own projects. They were therefore introduced to Java-based Android programming and courses on how to turn the smartphone into a life-saving medical device and to critically consider the business models for their mobile apps. Given the lack of time and the various levels of programming skills and basic knowledge on sensors, microelectromechanical systems and electronics, applications were restricted to simple mathematical algorithms.

Implementation

Once students had been prepared with the basic skills, a competition on the application of mobile phones to develop medical devices was held. The students were split into groups and selected one of their proposals to develop a relevant mobile application. Among the apps developed were:

- E-NAT: a mobile application for monitoring maternal and child health by healthcare professionals
- Fist-app: a multi-parametric model for the prediction of a predisposition to obstetric fistula
- MySkinAdviser: a mobile app for skin disease screening
- IMCI: the integrated management of childhood illnesses
- MOBIcare: an infectious disease tracking system

Results

The course was a success among the students, all of whom were proud to have developed their first app. The fact that groups were established at the very beginning of the course enhanced interactions and bonding. Student enthusiasm was demonstrated by their high rate of attendance at lessons and in the classroom after dinner. Proper instruction to make judicious use of sensors and processing capacity in portable technology may provide the necessary impetus for co-designed projects and shared innovation. Although much work still needs to be done, the training provided students with a sense of empowerment and with an appreciation of the fact that that the phone has multiple uses beyond social networking and catching Pokemons

6.3.2 Lessons learned from innovators' summer school

Several key lessons could be highlighted from the experience of the summer school. While the it has become popular and the projects submitted annually have been increasingly scientifically and technically sound, the limited availability of research and fabrication facilities at universities hindered students from developing prototypes.

The international nature of the summer school encourages teams to engage beyond their institutions and countries. This is built in to the requirement for team formation, which requires teams to be multidisciplinary, multinational and gender-diverse. For example, all four innovation awards were won by women-proposed concepts and major changes in project designs over a week often happened in teams with members from different backgrounds.

The involvement of industry and industrial research institutions has played a positive role, especially in demonstrating entrepreneurial and employment opportunities. In addition to providing practical skills, they show how small but critical improvements to existing systems and gaps in current designs and new applications can spur new businesses and major improvements in health service delivery.

6.4 Creating a sustainable regional innovation institution

A regional innovation institution that promotes excellence in biomedical engineering training, research and innovation could help to bridge differences in knowledge, technological and industrial development and safety standards. Such an institution could serve as a platform for the sharing of teaching and research materials and methods, and the exchange of staff and students within its membership. It will also help to develop guidelines for open-source standards and codes to enable users to adapt software to their own needs and to address both regulatory approval and safety issues.

6.4.1 African Biomedical Engineering Consortium

It is for the above reasons that ECA encouraged and supported the formation of the African Biomedical Engineering Consortium. It seeks to serve as a multidisciplinary focal point for articulating health-care challenges, promoting excellence in human capital development and research, encouraging entrepreneurship among students and researchers and mobilizing resources and stimulating partnerships among key stakeholders in the medical devices sector. Founded in August 2012, its membership has increased from 5 to 13 universities in Africa and from 2 to 6 partner universities in developed countries.

Since then, ECA has slowly handed over a number of its original efforts and activities to the Consortium. It is now responsible for, among other things, ensuring the quality of its members' academic programmes and in setting and selecting the theme of the annual summer school, reviewing student projects and selecting students participating in the school. This has led to increased collaboration among the universities, which now have to continuously communicate with each other rather than through ECA. For example, staff from the University of Pisa (Italy) recently offered a two-week intensive biomedical design class at Addis Ababa University in 2016, where the teams have been collectively developing research projects for funding. By 2016, two projects submitted for funding by Consortium members and their partners will be funded by the European Union from January 2017, while teams from Kenya and Ethiopia exchanged staff in 2015. Moreover, the 2017 and 2018 summer school will, for the first time. be funded by project funds from Consortium members. There is an expectation that it may, in the long term, ensure the sustainability and growth of the initiative in Africa.

6.4.2 Towards an open-source innovation institution in Africa

Building on the experience of the summer school and innovation competitions discussed above, the need for a common platform through which researchers and innovators can share information on their design and use of biomedical devices is seen as both timely and complementary. Such a platform will help students to further improve their design concepts after the summer school and will allow researchers from within the network to provide guidance on technical, legal, regulatory and safety issues that need to be considered. It could also offer guidance on new and emerging practices in biomedical engineering.

Open innovation platforms such as Innocentive harness global brain power to solve challenges faced by firms, NGOs and public institutions in developed countries, often at a price. There exist, however, several open innovation platforms that are free and that focus on a few issues such as the fabrication laboratory (Fablab) of Fab Foundation, of the Massachusetts Institute of Technology, the Open Prosthetic, Open Bionics and a host of othersm, including the Rise of Open-Source Prosthetics. The teams share their designs, and further refinements and improvements are shared by the group. They therefore encourage a do-it-yourself spirit of innovation to stimulate creativity among the group's members.

One of Consortium's projects that has successfully won funding from the European Union will support the development of an open-source innovation platform. This platform will bring together researchers in all the participating universities, with the Uganda Industrial Research Institute serving as one of the technical training hubs and the University of Pisa providing the technical operation for and backup of the

platform. It is expected to be the first platform that will have the function of vetting and guiding users on the rules, regulations and safety of their designs. Such a platform will make it possible for users to collaborate and request technical support across institutions and country borders. The other European Union funding mechanism, namely, the intra-Africa academic mobility scheme, which was awarded to the Consortium in 2017, facilitates the academic mobility of students and staff within Africa, which could add substantial value to biomedical engineering teaching and research on the continent.

6.5 Measures to promote innovation and industrial growth

It is expected that some of the research in African universities and industrial research institutions will lead to commercially viable products. Various case studies presented in this report also show how alternative solutions can be achieved with minimal financial investment. Finding ways in which such projects could be supported until they are realized commercially will be important. As in the case of Malawi, two such products are already saving lives and are retaining their commercial value thanks to the support that they have received. Nevertheless, they are still not in commercial production.

Some of the students and researchers in Uganda, for example, opted to form their own businesses to make simple medical devices (e.g., baby incubators). They have been appointed as technical partners of a major European medical supplier in the Democratic Republic of the Congo and in the United Republic of Tanzania. Several jobs could accordingly be created in the service sector where entry barriers, including capital requirements, may be low. A number of challenges do not relate to complex medical devices. Indeed, the team in Uganda identifies and focuses on a viable business opportunity for advising on the installation and servicing of basic and less complex medical devices. The development of local qualified service firms could help not only to maintain medical devices, but also to ensure that the right equipment is ordered.

In terms of manufacturing, a number of innovative products have been developed that could enter global markets. For example, the Uganda Industrial Research Institute has developed an electronically controlled gravity feed infusion add-on that significantly improves the efficacy of intravenous fluid and/or drug delivery, especially to children under 5 years of age (Patient Safety Movement Foundation, 2016). The design significantly reduces deaths in children due to the shock effects suffered by approximately 10 per cent of children admitted. It was awarded the first prize of $50,000 the United States by the Patient Safety Movement Foundation (2016). Until the domestic private sector emerges, however, moving such innovations from the laboratory to the hospital bedside or the hospital laboratory will require the dedicated support of Governments and key partners.

In the short term, government procurement contracts can be used to drive technological learning and to inspire domestic industrial growth. First, suppliers of complex medical devices (e.g., electron microscopes and magnetic resonance imaging) should be required to train as many interested technicians, researchers and students as possible in their installation, proper use and maintenance. Second, joint ventures and industrial alliances between international suppliers and domestic firms should be encouraged. Third, certain contracts should be reserved for domestic investment promotion or for domestic producers or service providers. Lastly, some contracts could be used to stimulate the development of novel medical devices and to support services to meet domestic challenges or requirements. All these avenues offer ways in which procurement could be deliberately deployed to promote national technological learning and innovation and to support local industrial development.

Governments can work with hospitals as users to establish innovation hubs and technology parks, focusing on health innovations and medical devices in particular. The proposed health technology park in Cape Town, South Africa, presents a good example for countries such as Kenya, which already has a high concentration of large public and private hospitals, to host medical device firms and to have a number of

Fablabs working on medical devices. In the short term, Fablabs at universities can accelerate innovation and attract private sector interest. This is demonstrated in the cases of Malawi and South Africa.

Prioritizing the medical devices industry as one of the investment promotion industries could help to attract foreign investors while also extending existing investment incentives to the health sector. A number of African countries offer a variety of incentives that could encourage the acquisition of the technologies, skills and materials needed to produce medical devices. For instance, Zambia already offers firms that invest more than $500,000 in a “Priority sector”, namely, a 0 per cent tax rate on dividends for five years from the year of the first declaration of dividends; a 0 per cent tax on profits for five years from the first year of operation for manufacturing projects in rural areas, multi-facility economic zones and industrial parks; and a 0 per cent import duty rate on capital goods and machinery, including specialized motor vehicles, for five years. Nevertheless, African Governments often neglect to include medical devices in their priority sectors (Zambia Development Agency, 2014). This is not unique to Zambia, given that South Africa also does not include medical devices among its priority sectors, notwithstanding their significant social, industrial and economic impact. Countries aspiring to develop their medical devices industry may wish to give medical devices and health technologies prominence among their priority sectors.

CHAPTER 7
Conclusion and recommendations

As African countries continue to grow and urbanize, the need for improved health-care services will rise rapidly, given that medical devices are indispensable for the provision of modern health care. Changes in technology, increased life expectancy, the rise of the middle class, the emergence of new health challenges and the need to control existing ones and the need to expand the manufacturing sector are driving both the import and the growth of domestic medical device sectors.

Africa could use the budding manufacturing sector to build a medical device industry. Although Africa's exports of manufactured goods, especially products requiring high technology, have not increased rapidly, in absolute terms such exports have grown and are largely consumed domestically and exported to neighbouring countries. Fortunately, medical devices fall in to the entire category of manufactured products, from those requiring few technological skills to those that are technology-intensive. Africa can enter the medical devices industry, depending on its scientific, technological and industrial level, either through the production of devices that have a low level of risk coupled with a high level of use (e.g., disposable needles and bandages) or through technologically advanced but less invasive products (e.g., information technology-enabled products).

Africa's unique working environment, characterized by excessive heat, moisture, dust, an erratic power supply and limited technical and financial resources calls for the redesign or adaptation of some devices to meet specific local needs. This will depend on a critical mass of qualified and experienced technicians, as well as on engineers, designers, and information technology and health professionals, who are capable of developing, manufacturing, installing and servicing medical devices locally. Human capital is also needed to advise public and private procurement agencies on the options, sources and requirements necessary for medical devices and for the design of medical facilities and regulations that support the growth of the industry.

To date, the medical device market has been growing rapidly. Given the limited availability of data, it is possible to imagine that the national demand for medical devices is perhaps far higher than the current levels of imports and exports. Given that many African countries have defined priority sectors for foreign direct investment, medical devices could be singled out as one of the top priority investment industries, given their linkages to health care and manufacturing.

The market potential for domestic device development and service provision is relatively large. With government support, significant opportunities exist in the supply of medical furniture and other medical supplies with lower risks. Building on its budding manufacturing sector, Africa could invest in facilities to produce everyday items such as bandages, needles and syringes, in collaboration with development partners. However, this requires significant support and commitment from Governments to create an environment conducive for the growth of the sector. Such an environment should, at a bare minimum, provide a favourable or, at least, a level playing field for domestic producers and foreign suppliers on which to compete and should even make available a market for domestic

producers to compete in the supply of services and basic devices, such as beds. A regional market will remain key to the growth of domestic devices industries. Other key factors may include the supply of a skilled labour force, tax incentives for investment in research and development and manufacturing facilities and the promotion of export markets and funding. As shown above, the medical device sector is a knowledge and research and development-intensive sector.

The lessons from Malawi suggest that the development of even simple medical devices takes several years. All support measures should accordingly be designed and implemented from a long-term perspective to facilitate corporate planning and to enable research teams and their partners to develop safe and acceptable products likely to have international appeal. As shown by the bCPAP in the Malawi case, a product initially developed for Africa has gained international appeal, with expressions of interest from around the world.

In order to encourage the design and development of medical devices for the continent, the areas discussed below may require special attention.

7.1 Building the human capital base

One of the main challenges facing the development of the health sector and the medical device industry in Africa is the limited availability of qualified and experienced human capital. The rapid growth in university education has not been automatically and proportionally translated into the development of specialized programmes in this field. The engineering field appears to have lagged for a number of reasons, including a low numbers of trainers and the higher costs of expanding science and engineering programmes, compared with the social sciences and humanities. The ECA-led initiative has demonstrated that interest among students and universities in biomedical engineering programme is high.

University-level biomedical engineering programmes are designed not always to train technical staff, but also to train supervisors and managers for hospitals and public institutions and researchers and innovators for industry. Technical staff are important, given that decisions on procurement are made in the boardrooms of hospitals and ministries. The leadership hierarchy of large hospitals often does not include technicians in management teams, a consequence of which technical errors in orders are often not identified. Supervisors and innovators help to ensure that Africa can participate in the rapidly growing and evolving industry by ensuring a supply of researchers and innovators. In any case, the technology used in some of the medical devices (e.g., software and sensors) does not differ radically from that used in other industries.

Interested African universities should be supported in overcoming a number of challenges that affect the effective delivery of biomedical engineering programmes. Such support may include the provision of scholarships and funding to enable universities to increase the number of lecturers with qualifications in biomedical engineering and to acquire basic laboratories for training biomedical engineers, as well as other facilities for design and rapid prototyping, technology transfer offices and incubators. These will enable universities to train biomedical engineers who are inspired to identify and realize innovation opportunities.

7.2 Building innovation infrastructure

To encourage innovation, engineering students and innovators need tools with which to experiment. Fablabs or design kitchens are names given to laboratory/workshops that are well equipped and stocked with the basic materials and tools to design and make prototypes. Students can work in groups to invent, design and test their own ideas. Students from engineering, health and other disciplines can join the groups, contributing to their ideas. Universities in Africa need such innovation support infrastructure to encourage and foster innovation. Industry can sponsor such laboratories or the ideas developed within them and can assist in staffing them. This would expose students to the needs and the ethos of industry and would enable the integration of future employers in industry with academia.

Box 7.1: Case of the Economic Commission for Africa-led 2013 summer school on open-source digital printing and design

Introduction

Resource-sharing for the design of medical instruments and devices is a powerful tool for emerging African biomedical engineers. To introduce the open-source concept to the African engineering community and thereby develop and nurture resource-sharing and technological self-competency, a one-week introductory course on open-source design and rapid prototyping specifically for biomedical engineering was held during the second innovators' summer school at Kenyatta University, Nairobi. The course was organized by the University of Pisa's Centre for Bioengineering and Robotics and Fablab Pisa. An experienced clinician from the University of Malawi helped to focus the application on a specific problem in paediatric health care.

Course implementation

From the first day, students were divided into working groups to facilitate interaction. The groups were given specific tasks relating to documentation and note-taking to gather material for a course e-booklet. Besides an introduction to the concepts of open-source resources starting with electronics, software and biomedical device manufacturing, close attention was paid to the safety and ergonomic dimension of the devices to meet the regulatory and performance standards for biomedical devices.

A 3-D printing system was set up from scratch, with participants being introduced to computer-aided design and the conversion of design to a stereolithography and G code for fabrication, as well as to electronic system design and programming. Sessions on medical instrumentation, safety and standards were also included to contextualize the learning process. Practical group activities were dedicated to the making of a neonatal monitoring device, starting from first principles using entirely open-source design and open-source electronics. Students played an active role in the identification of the problem and the selection of components, as well as in the design, assembling and testing of the device and in the discussion of regulatory issues relating to its development.

Results

Given that most students and staff were unaware of the existence of tools such as Arduino, FreeCad, Slicer and Media Wiki, let alone of the power and implications of open-source design and prototyping, the course was instrumental in bringing new knowledge to participants. The majority of students had only a general idea of generating objects using computer graphics, but little experience with computer design. Similarly, lecturers saw the power of the system as both a teaching tool and an electronic device development platform. Since then, a pan-African open-source platform has been launched.

Soft infrastructure for innovation may include online knowledge exchange and open innovation platforms. Such platforms enable creative individuals to post exciting challenge solutions and to share new technologies. These may include free design software packages that can be downloaded and used to create and develop innovations. To use these effectively, there must be affordable and reliable Internet access and information technology support units in institutions in Africa. This remains a significant challenge, given that the costs of Internet usage may be high, while the service may be slow and unreliable.

The increased development of innovation hubs and technology parks in Africa could help to reduce some of the challenges identified above. In addition to providing space, most innovation hubs and technology parks offer a range of services to help innovators, entrepreneurs and small firms to develop their products cost-effectively. They may also help to match their tenants with potential investors, funders, technology partners, suppliers and consumers. South Africa appears to have taken a lead in developing health technology parks, incubators and funding vehicles.

7.3 Collaboration between academia and industry

Both research and entrepreneurial collaboration need to be promoted and encouraged. Research teams in Africa are best placed to identify needs and to seek solutions, while research partners in developed and emerging economies may have

access to facilities and industrial skills that may accelerate the design and development of research products. In the short term, such collaboration could be beneficial if it addresses and is informed by Africa's needs. Most important, researchers in life sciences, engineering, business and related fields bring various perspectives to research projects that may improve both their relevance and their commercial dimensions. In the case of medical devices, the inclusion or participation of members with legal and industrial design and production experience could help to improve the projection and assessment of final costs, the protection of intellectual property rights and the early identification of technological challenges and business opportunities.

For innovation and development to flourish, industry and academia need to combine their expertise. To understand the applicability and utility of products, there must also be sound medical input. To test equipment or new therapies, clinical trials are required, not to mention clinicians to run them. By bridging differences and encouraging integration, the successful outputs of each group are multiplied. For example, biomedical engineering prototypes usually require clinical testing and medical input, which is traditionally provided by academics and healthcare professionals. Integration could help to anticipate this in the design of medical devices by entrepreneurs and innovators.

In particular, entrepreneurial collaboration between small medical device firms and larger and well-established firms could help smaller firms to acquire technology, access financial resources and markets, learn new management skills and build their reputations. Unlike small firms in developed countries that may be keen to invest in research and development, most small firms in Africa lack the financial and human capital and facilities to undertake research and development. However, smaller firms are agile, understand the local conditions and may have key contacts that make them valuable partners. It is thus possible that Governments could ensure, through procurement contracts with large firms, that domestic firms are included, given that they are likely to provide continuous after-sale services at a reasonable cost and beyond the contract period.

7.4 Increasing access to financing

National policies should encourage local and international institutions and industry to invest in innovation. This can be done with tax exemptions, financial donations, research and development expenditure and initiatives to encourage the employment of young graduates and entrepreneurs. Governments should encourage innovation by giving financial support to local institutions involved in innovation.

In this regard, seed grants can be offered by government agencies and major donors such as the Bill and Melinda Gates Foundation, the National Institutes of Health, the Department for International Development and the European Union. Seed grants are usually for a period of one year, in the region of $100,000 and facilitate the development of innovation, from bench to bedside. The innovation is usually still a prototype that needs fine-tuning and testing so that larger grants can be accessed in order to enable the device to be validated in clinical use. Increasing access to such grants enables innovators to generate the information needed in assessing the technical viability of the medical devices before larger resources can be committed.

In order to bring the device to commercial production, larger investments are needed to acquire the technologies, skills and intermediary inputs and accessories needed to manufacture the medical device. As the case of bCPAP in Malawi demonstrated, the funding levels needed to acquire such levels of expertise and production capacity are, for the most part, lacking. Governments may have to work with development partners to provide adequate funding to seed a local manufacturing industry for medical devices.

7.5 Improving the regulatory environment

The legal and regulatory environment plays a key role, as was shown in the cases of Kenya and Malawi. These may include a national health sciences research council and national research and ethics committees, as well as intellectual property agencies. Regulatory infrastructures and ethics committees are required to provide independent oversight and to ensure protection of human

research subjects or patients. Governments should ensure that biomedical research ethics and safety committees are adequately funded, at both the national and institutional levels. Regulatory bodies stimulate research and innovation by providing advice on emerging safety concerns, alternative methods, cost-effective approaches and overall scientific guidance. If properly managed, regulatory agencies could help to drive innovation and to ensure that concerns are addressed in advance.

Similarly, national and institutional intellectual property and technology transfer offices could help to protect and commercialize research outputs. As was shown in the case of bCPAP, the involvement of industry appeared to have driven the need to acquire intellectual property on the design. In this regard, African universities need to establish and strengthen their intellectual property and technology transfer offices. Such regulatory units help to acknowledge individuals' input, as well as that of universities, while also determining the sharing of the commercial and intellectual outcomes of innovations and professional partnerships. Although the extent to which national intellectual property laws in African countries serve to encourage innovation remains unclear, they should not be stumbling blocks owing to their high cost or cumbersome administrative processes.

7.6 Procurement, maintenance and innovation of medical devices

To promote the sustainable, economic and effective use of medical devices in the African health-care industry, attention must be paid to the total life cost of the equipment and the procedures established to ensure that they are stipulated in the specifications. Development and education will benefit from country-wide access to the guidelines and tools required for the regulation, assessment, selection, procurement, management, training and use of medical devices, as provided in WHO resolution WHA60.29 on health technologies.

The health-care system needs a central procurement committee to oversee the number of devices being procured, the training of technical personnel and the management of the rate and consistency of upgrades. The procurement committee should include experienced personnel, both knowledgeable in the relevant fields of medical equipment and involved from the writing of the tender notice through to regulating the location and quantity of the equipment in the country.

All these recommendations are in line with a request to WHO by the World Health Authority in its resolutions 61.21 and 62.16 to implement the global strategy and plan of action on public health, innovation and intellectual property, specifically:

a. Prioritizing research and development needs;

b. Promoting research and development;

c. Building and improving innovative capacity;

d. (d) Transferring technology;

e. (e) Applying and managing intellectual property to contribute to innovation and to promote public health.

Moreover, procurement remains one of the key tools for policymakers wishing to encourage the emergence and growth of a medical devices industry. Governments should consider reserving some contracts for domestic suppliers and manufacturers, while encouraging international firms that win large procurement contracts to work with domestic firms and research institutions. For example, universities could serve as training bases for technicians and users by exposing academics and researchers to emerging technologies and capacity-building in universities and research centres, as well as by strengthening national networks of engineers and health professionals.

For many small producers of medical devices, government contracts may initially be their only or main source of business. While there are no guarantees that these firms will invest the earnings in their businesses and will grow, successful firms could be encouraged to innovate through gradual increases in standards or technological requirements that may be slightly above their comfort zones. This could help to nudge firms into upgrading their systems, knowing that doing so improves their chances of being awarded contracts.

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Annex

Shifts in spending on health per capita

1995	2000	2010	2014
Less than $50			
Equatorial Guinea, Madagascar, Central African Republic, Democratic Republic of the Congo, Burundi, Niger, Eritrea, Ethiopia, Malawi, South Sudan, Guinea, the Gambia, Togo, Burkina Faso, Chad, Guinea-Bissau, Benin, Mozambique, Liberia, Mali, Mauritania, Senegal, United Republic of Tanzania, Uganda, Rwanda, Zimbabwe, Ghana, Cameroon, Kenya, Zambia, Sierra Leone, Côte d'Ivoire, Lesotho, Nigeria, Sudan, Republic of the Congo (36 countries)	Madagascar, Central African Republic, Democratic Republic of the Congo, Burundi, Niger, Eritrea, Ethiopia, Malawi, South Sudan, Guinea, the Gambia, Togo, Burkina Faso, Chad, Guinea-Bissau, Benin, Mozambique, Liberia, Mali, Mauritania, Senegal, United Republic of Tanzania, Uganda, Rwanda, Zimbabwe, Ghana, Cameroon, Kenya, Zambia, Sierra Leone, Côte d'Ivoire, Nigeria, Sudan, Republic of the Congo (35 countries)	Madagascar, Central African Republic, Democratic Republic of the Congo, Burundi, Niger, Eritrea, Ethiopia, Malawi, South Sudan, Guinea, the Gambia, Togo, Burkina Faso, Chad, Guinea-Bissau, Benin, Mozambique, Liberia, Mali, Mauritania, Senegal, United Republic of Tanzania, Rwanda, Zimbabwe, Kenya, Sierra Leone (27 countries)	Madagascar, Central African Republic, Democratic Republic of the Congo, Burundi, Niger, Eritrea, Ethiopia, Malawi, South Sudan, Guinea, the Gambia, Togo, Burkina Faso, Chad, Guinea-Bissau, Benin, Mozambique, Liberia, Mali, Mauritania, Senegal (21 countries)
$50-99			
Egypt, Angola, Morocco, Djibouti, Cabo Verde (5 countries)	Angola, Equatorial Guinea, Djibouti, Cabo Verde, Egypt, Morocco, Algeria (7 countries)	Ghana, Zambia, Cameroon, Uganda, Nigeria, Republic of the Congo (6 countries)	United Republic Of Tanzania, Uganda, Rwanda, Zimbabwe, Ghana, Cameroon, Kenya, Zambia, Sierra Leone, Côte d'Ivoire, (10 countries)
$100-199			
Tunisia, Gabon, Algeria, Libya, Botswana, Mauritius, Seychelles, Namibia (8 countries)	Tunisia, Gabon, Botswana, Mauritius, Seychelles, Namibia (6 countries)	Lesotho, the Sudan, Cabo Verde, Egypt, Angola, Morocco, Djibouti (7 countries)	Lesotho, Nigeria, the Sudan, Republic of the Congo, Cabo Verde, Egypt, Angola, Morocco, Djibouti (9 countries)
$200 or more			
South Africa, Seychelles (2 countries)	Seychelles, Libya, South Africa (3 countries)	Swaziland, Tunisia, Gabon, Algeria, Libya, Botswana, Mauritius, Seychelles, Namibia, South Africa, Equatorial Guinea (11 countries)	Swaziland, Tunisia, Gabon, Algeria, Libya, Botswana, Mauritius, Seychelles, Namibia, South Africa, Equatorial Guinea (11 countries)

Source: African Union et al. (2015).