Chapter 1

Introduction

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Healthcare in low-and middle-income countries (LMICs) lags behind that of the more industrialised and high-income world, primarily because of limited financial and human resources. The disease burden is different, especially for lower-income countries which have high mortality rates from tuberculosis (TB), human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), malaria, and other treatable infectious diseases. Infant and maternal mortality related to childbirth also remains unacceptably high. Appropriately designed technologies can be used in the prevention, diagnosis, monitoring and treatment of disease. In the context of LMICs, such innovations can additionally *save many lives.*

Health technology development in LMICs, including countries in Africa, falls far short of meeting the healthcare needs of these settings. The result is a heavy reliance on products and technologies imported from industrialised countries that are often not suited to, or sustainable for, LMICs.

When making decisions to invest in the research and development (R&D) of new products, most device manufacturers that are based in high-income countries often require prerequisite levels of projected annual sales, market growth and rates of return to prioritise project investments. Because of these investment criteria, very few medical devices are designed primarily for LMICs, which are not perceived to provide adequate profit potential. Additionally, because of the way devices and consumables are priced and paid for in developed countries, there is little motivation to develop technologies that are more effective, affordable and accessible, easier to use, and able to deliver superior scalability. Transplanting healthcare systems and technologies from high-income countries to resource-limited settings is slow and expensive, and in many instances, challenging if not impossible. Developing *new* healthcare delivery methods and devices tailored to LMIC environments and conditions is a faster, better and more cost-effective alternative.

Appropriate healthcare products for LMICs are best developed in these countries, where local knowledge and understanding of needs, context and available resources may be incorporated into designs and implementation plans. For local innovation of health technologies to become the norm, capabilities in health technology are required for needs assessment, market analysis, product design, prototyping and testing, manufacturing, distribution and management. In Africa, economic growth, increasing healthcare expenditure, the availability of digital technologies, and young populations provide opportunities for the development of robust health technology innovation systems.

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The objectives for enabling health technology development in LMICs include: 1) expanding the base of expertise through research training programmes with a problem-solving focus; 2) stimulating new knowledge, approaches and solutions by enabling innovation; and 3) integrating research communities within and across institutions to build critical mass.

The field of biomedical engineering is central to health technology innovation. Education in biomedical engineering is essential for the development of the skills required to transform healthcare in LMICs through the development and deployment of essential technologies. While biomedical engineering traditionally has operated at the interface of health systems and engineering sciences, it is clear that African approaches need substantial expansion, if they are to address the health technology needs of the continent. For successful implementation of health technology in Africa, biomedical engineers require an in-depth understanding of the social factors that impact on technology adoption, an appreciation of rapidly evolving health systems, as well as an understanding of critical factors such as ethics, regulation, intellectual property management, entrepreneurship and commercialisation.

This book is a response to the need for biomedical engineering capacity in Africa. It is grounded in the African context. It serves as a resource for academics and students in biomedical engineering, for those interested in entering the field in any capacity and for practitioners at every stage of product development. University leaders intent on establishing new biomedical engineering programmes or departments, may draw on the content for guidance on structuring their offerings. The book reaches beyond Africa, as it is relevant to other low-resource settings, and provides insights to guide global health initiatives focused on technology innovation.

Part 1 provides different perspectives on the imperative for biomedical engineering in Africa and describes the development of a set of academic programmes in the field. Part 2 describes a range of considerations and approaches to be applied in converting healthcare needs into products, and includes a methodology for the design of medical devices. Part 3 presents a set of case studies on the design of solutions to address African health-related needs. Part 4 introduces the ethical, legal and regulatory factors that should be considered in the development and implementation of health technologies. Finally, Part 5 places biomedical engineering and its products within the broader health system.

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