Chapter 8

Frugal Biodesign: An approach for Developing Appropriate Medical Devices in Low-resource Settings

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Introduction

Medical devices are indispensable in the prevention, diagnosis and treatment of illness and disease, as well as in rehabilitation. The World Health Organization has emphasised that the achievement of health-related development goals is dependent to a large extent on the accessibility of appropriate, good quality, safe and affordable medical devices that are compatible with the settings in which they are used (WHO, 2017). In order to ensure access to appropriate medical devices, it is important to understand the specific needs of the country, region, community, or facility. An understanding of the context is important to avoid unnecessary wastage of resources, particularly from inappropriate investments in medical devices that fail to meet high-priority needs, do not suit existing infrastructures, and do not function effectively and efficiently (WHO, 2010a).

This chapter describes a course on medical device design, which is aimed at improving access to suitable medical devices in South Africa, a country with multiple health changes that require innovative approaches. It starts by giving an overview of medical device challenges in developing countries and of the medical device sector in South Africa, and proceeds to explain the structure of the medical device design course offered to postgraduate students in Biomedical Engineering at the University of Cape Town.

Medical device challenges faced by developing countries

In low- and middle-income countries, medical devices are often a low priority or even absent from the agenda; developing countries lack policies, budgets, infrastructure (basic services, human resources, logistics), as well as rules and regulations pertaining to medical devices (WHO, 2010a). These constraints result in many developing countries relying on medical device donations. In some countries, nearly 80% of health-care equipment is donated or funded by international donors or foreign governments (WHO, 2000; Finch et al., 2014; Borrás, 2017). Although donations of medical devices can be of great value to health facilities with limited resources and are generally made with good intentions, the outcomes are not always positive (Sodhi et al., 2014). For example, donations can be problematic when they are provided without taking into consideration the particular needs of the end-users. There is a risk that poor communication between donors and recipients of medical devices may result in the former not being aware of the local realities of the latter (WHO, 2011). This may result in the donation of inappropriate medical devices which are technically unsuitable, or incompatible with existing equipment. The WHO (2010b) points out that a large number of medical devices that are

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https://openbooks.uct.ac.za/bmeafrica

acquired by developing countries from developed countries remain idle, or are sub-optimally or inappropriately used. Jones (2013) cites an example of incubators for premature babies which were donated in a developing country, but did not function because they required a higher electrical voltage than is standard. However, health facilities with limited resources are reluctant to decline or complain about donations as they feel obliged to accept them (Kaur, Hall & Attawell, 2001).

Many developing countries have renowned and productive scientists who are capable of contributing to the medical device industry. However, due to lack of funding, such scientists may end up working on research projects whose objectives are determined by funders in developed economies (Lorentzen & Mohamed, 2010). This poses the danger of developing inappropriate technologies that have very little utility for developing countries, resulting in low take-up by industry. The developing countries become a source of 'brains-for-hire' as scientists go into consultancies where they sell their skills to the highest foreign bidder rather than joining university departments (Lorentzen & Mohamed, 2010). Although globalisation opens opportunities for developed and developing countries to interact, it also poses threats in that global knowledge networks rarely accommodate small players who are left with the option of either being absorbed or left out (Krishna, Waast & Gaillard, 1998).

The conventional approaches to innovation in medical devices are difficult to implement in low-resource settings. Hobday (2005) argues that the various generations of firm-level innovation models used in developed countries such as the United States of America and Japan do not appropriately cater for latecomers from developing countries. The models tend to concentrate on large firms that pursue highly structured research and development, which is geared towards market products at the expense of smaller firms that more informally pursue innovation. The major shortfall of these models is that they prescribe practices which are considered appropriate for other countries (Tödtling & Trippl, 2005). This is subject to debate as Hobday (2005) argues that one of the essential features of innovation is rule-breaking rather than identifying and pursuing rules or patterns. Langergaard and Hansen (2013) point out that the appropriateness of a model for innovation depends, to a large extent, on the context. Considering the differences in resource endowment between countries in the developed and developing world, it is not possible to approach the development of medical devices with a 'one size fits all' model. Instead, it is important to understand the particular circumstances of each country and respond with customised approaches.

The medical device industry in South Africa

The South African medical device industry is growing and holds huge potential for contributing towards health care. According to SAMED (2014), the industry was estimated at USD1.2 bn in 2013 and ranked among the top 30 largest in the world; it was expected to grow by a compound annual growth rate of 7.7% between 2013 and 2018. Despite the positive outlook on the growth of the medical device industry in South Africa, the dominance of imports, which cater for about 90–95% of the market by value, is conspicuous (Abbott, Correa & Drahos, 2013). As a result, the market is inundated with imported medical devices which may not be

appropriate and affordable. The imports undermine the development of medical devices by local manufacturers, most of whom cannot compete with multinational companies. The medical device market in South Africa targets clients mainly from the private sector, which constitutes 70% of the market and where most of the revenue is consequently derived (KPMG, 2014). This reflects a dichotomous health system which is characterised by a well-developed private sector and an overburdened public sector, leaving room for the development of medical devices that are appropriate for public sector needs.

Frugal Biodesign in a medical device course

Frugal Biodesign is a unique approach to medical device design that is suited specifically to developing countries. It is aimed at stimulating postgraduate students studying Biomedical Engineering to devise inexpensive and, more importantly, innovative solutions to medical problems. It takes cognisance of the limitations that South Africa and other developing countries experience in terms of human, financial and physical resources.

The medical devices that the students work on during this course are informed by clinicians. The course adopts a cyclical and dynamic approach that involves the constant exchange of information between multiple stakeholders in the medical device sector as shown in Figure 1. The stages are discussed below.

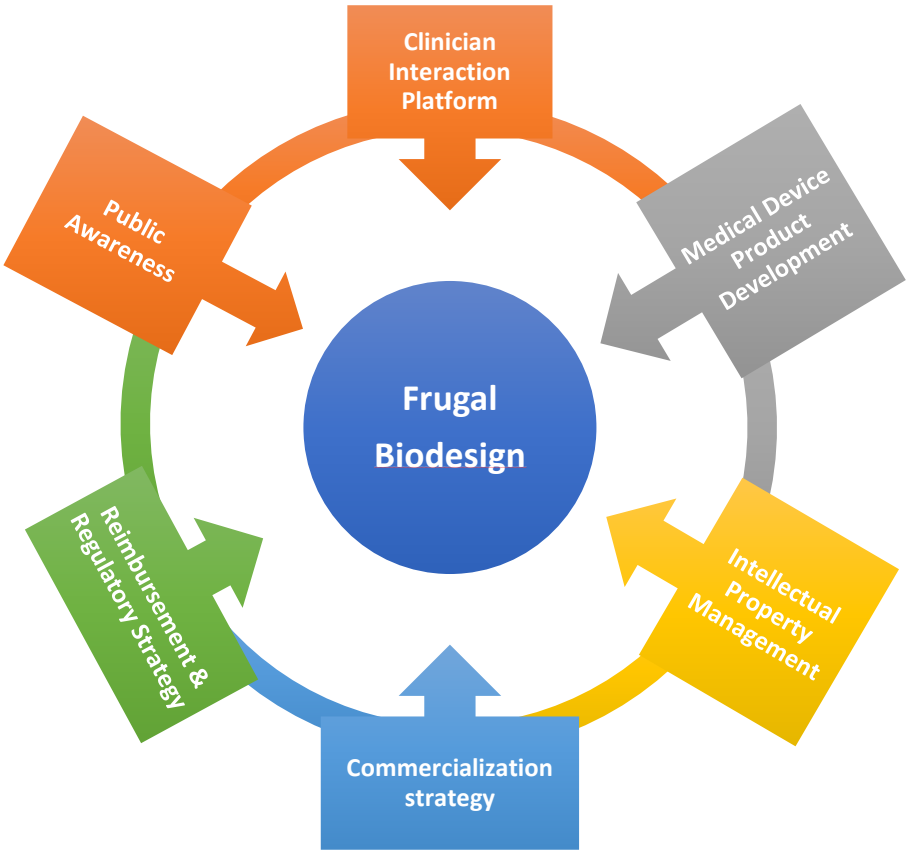

Figure 1: The stages of the Frugal Biodesign approach

Course structure

The two-semester, 10-month course on medical device design applies the principles of Frugal Biodesign and engineering design methodologies to fast-track the process of ideation. Ideation starts with identifying a need and continues until proof of concept is achieved.

In the first semester, the students are expected to work on 3 major themes, namely, 1. Needs identification and screening; 2. Concept generation and screening; and 3. Strategy development. These themes involve screening for an unmet clinical need, and identifying appropriate solutions. Various concepts are generated to solve the unmet clinical need and these design concepts are screened on the basis of manufacturability, patentability and clinical usability. For the clinical need and the concept design, a thorough intellectual property search is performed. The deliverables for the first semester of the course include: 1. A detailed needs analysis report; 2. A design report on concept generation and screening; 3. A design report on strategy for conceptual design realization; and 4. A completed University of Cape Town invention disclosure form for intellectual property review by the UCT's Technology Transfer Office (TTO).

In the second semester, the design approach moves to practical hands-on device development. The conceptual design developed in the first semester of the course is refined before it can be recommended for prototyping. The training includes selecting the consumables for the device, procurement, and dealing with external vendors. On successful laboratory bench testing of the device, suitable ethics approval is sought and the device is evaluated in a clinical setting. By the end of the semester, the student has been trained on converting a conceptual design into a tangible solution. The deliverables for the second semester include: 1. A design report on prototyping; 2. A bench test report; 3. An ethics application; 4. A clinical evaluation report; and 5. A working prototype of the proposed solution. The course ends with the demonstration of the working prototype in a suitable environment.

Clinician interaction platform

The clinician interaction platform is fundamental to the course. It is important in understanding the problem that needs a solution. The engagement of clinicians at an early stage serves to ensure their buy-in and create a working relationship for a long-term commitment to the project. The clinicians are carefully chosen based on their expertise in a particular field. They provide useful input in the identification of the problem, based on their clinical experience. Jones (2013) argues that it is the final users of medical equipment such as doctors and patients who are best positioned to innovate by first identifying the need for a novel device or for the improvement of an existing technology. At the University of Cape Town, there is no undergraduate programme in Biomedical Engineering. Instead, the students for the postgraduate programme are drawn from various non-medical backgrounds such as electrical and mechanical engineering as well as computer science. This means that those students possess the technical skills to design technologies but are not well informed on medical

problems that need solutions. This is the gap that in which the clinician interaction platform fills, by providing the clinical context.

Medical device product development

Once the problems have been identified by the clinicians, the next step is to assemble a group of experts. This group, referred to as a 'think tank', is made up of specialists from different backgrounds such as medicine, intellectual property rights, and industry, who, because of the nature of their work, are difficult to bring together. Cognisant of the time constraints of the think tank members, meetings take place quarterly and usually last for about 2–3 hours. To make the most of the meetings, four problems are presented at one sitting. The logic behind the think tank is to scrutinise the problems from different angles, assess needs, and generate ideas and conceptual solutions. The conceptual solutions are not real solutions per se, but suggest basic functionality to address the identified problems. This is done well in advance of the students starting the course and is an important phase of screening with the aim of designing minimum viable products. The outcomes from the think tank provide the entry points for the projects that the students will work on the during the course. The students continue to interact with the clinicians throughout the course.

Each student is assigned a problem and a proposed solution which he or she is expected to work on for the 10 months of the course. During this period, the students interact with clinicians as they work towards solutions. They also attend lectures which provide engineering design support. The students engage in concept generation and screening and develop a strategy on how to design a medical device that addresses the identified challenges. Multiple solutions are generated and screened using constraints such as cost, time and manufacturing resources. Quality is an important parameter; as the students work within a small budget, an effort is made to ensure that the quality of the solution is not compromised by limited funds. Students are expected produce a tangible prototype that solves the challenge. Course assessment involves testing the prototype for functionality and usability.

Intellectual property management

The medical devices developed during the course are assessed for novelty and commercial viability, for which knowledge of intellectual property (IP) management and of the requirements for taking a medical device from the laboratory to the market, is important. To provide the students with such knowledge, they attend a workshop run by experts who take them through a journey covering the nature of IP, the different forms of IP, and invention disclosure.

The students learn how to distinguish between inventions that can be patented and those which cannot. They are taught how to search a patent database which is provided by the university. They are also taught how to disclose inventions formally. Particular emphasis is placed on the following questions, towards filtering potential medical devices for patenting:

- What distinguishes your invention from existing technology, i.e. what are the improvements? Students are expected to provide a brief overview of existing, similar technology(ies).
- In what way is your invention 'inventive' or not obvious to people with your technical skills? Students are expected to describe any surprising effects or outcomes that could not have been predicted based on current understanding or theory.
- What possible extensions, variations or modifications are there for the device? This enables ongoing and future work to be accommodated in any patent specification.

Commercialisation strategy

The students are taken through different commercialisation strategies linked to intellectual property rights. The commercialisation strategies are a series of financing options that can be pursued in moving the technology/product from concept to market. The aim is not to prescribe a particular commercialisation strategy, but for the students to choose one that suits them. The strategies include start-ups, spin-off companies, licensing, and forming strategic partnerships.[1]

Reimbursement and regulation

The students are exposed to the reimbursement and regulatory requirements for different territories[2]. It is important for the students to know how medical devices are regulated so that they become aware of the steps to take if they wish to put their product on the market. The students learn about the procedures for certification with the South African Bureau of Standards and other regulatory bodies. They are exposed to the classification of medical devices based on their level of risk.

Another area that is given attention is reimbursement for medical devices, which deals with the logistics of who pays for the product; for example, reimbursement may be through insurance. With reference to South Africa, the students learn about the National Pharmaceutical Product Index code, which is a unique identifier for a given surgical or consumable product enabling electronic transfer of information throughout the healthcare delivery chain. The code is used as the standard for electronic information exchange for procedure and consultation claims.

Public awareness

The students learn the importance of raising awareness of products that are ready to be taken to the market, and at the same time they to learn to promote Biomedical Engineering as an area of scientific activity. They are exposed to different ways of showcasing their products, focusing on what the technology can do in comparison with existing devices. Raising public awareness

[1] Commercialisation strategy options and implementation may differ in different countries. For more information, refer to the chapter "Intellectual Property Protection and Commercialisation" elsewhere in this book.
[2] For further information on medical device regulation, refer to the chapter "The regulation of medical devices in Africa" elsewhere in this book.

takes various forms; these include radio and television shows, journal articles, exhibitions and public lectures. Examples of product communication to the public include:

- A video on a hand exoskeleton for stroke rehabilitation: https://www.youtube.com/watch?v=tiIOqoaP3jc
- An article on an open-access ptosis crutch design: http://www.rci.uct.ac.za/rcips/innovation_achievements/products/PtosisCrutch
- A lecture to inspire high school learners: http://tlabs.ac.za/?ai1ec_event=learners-lecture-dr-sudesh-sivarasu

Conclusion

The course on medical devices design prepares Biomedical Engineering students to develop medical devices that are appropriate to needs, at low cost. It takes into consideration the constraints which hinder technological development in low-income settings such as lack of funding, skilled personnel and infrastructure. By leveraging the skills of a pool of students drawn from different engineering backgrounds and the insights from clinical partners to develop medical devices, an interdisciplinary approach is applied to the problems being addressed. The course is intended to impart skills that will enable graduates to use technology to address public health challenges faced by developing countries, and ultimately to contribute to the growth of the local medical device industry.

References

Abbott, F.M., Correa, C.M. & Drahos, P. 2013. *Emerging markets and the world patent order*. [Cheltenham, United Kingdom]: Edward Elgar Publishing.

Borrás, C. 2017. *Defining the medical imaging requirements for a rural health center*. Singapore: Springer.

Finch, L.C., Kim, R.Y., Ttendo, S., Kiwanuka, J.K., Walker, I.A., Wilson, I.H., Weiser, T.G., Berry, W.R. et al. 2014. Evaluation of a large-scale donation of Lifebox pulse oximeters to non-physician anaesthetists in Uganda. *Anaesthesia.* 69(5):445–451. DOI: 10.1111/anae.12632.

Hobday, M. 2005. Firm-level innovation models: perspectives on research in developed and developing countries. *Technology Analysis & Strategic Management*. 17(2): 121–146. https://doi.org/10.1080/09537320500088666.

Jones, A. 2013. Medical equipment donated to developing nations usually ends up on the junk heap. *Scientific American*. Available: https://www.scientificamerican.com/article/medical-equipment-donated-developing-nations-junk-heap/ [2019, May 1].

Kaur, M., Hall, S. & Attawell, K. 2001. *Medical supplies and equipment for primary health care: a practical resource for procurement and management.* Coulsdon, United Kingdom: Echo International Health Services.

Krishna, V.V., Waast, R. & Gaillard, J. 1998. Globalisation and scientific communities in developing countries. In *World Science Report 1998*. Paris: UNESCO. 273–287. Available: https://unesdoc.unesco.org/ark:/48223/pf0000112616 [2019, May 2].

KPMG. 2014. *Industry overview and economic impact assessment for the South African medical technology industry*. [Cape Town: South Africa.]: KPMG.

Langergaard, L.L. & Hansen, A.V. 2013. Innovation – a one size fits allconcept? *Proceedings: XXIV ISPIM Conference*, Helsinki.

Lorentzen, J. & Mohamed, R. 2010. … to each according to his (or her) needs: Where are the poor in innovation studies? *Proceedings of the Innovation for Development: Frontiers of Research, Policy and Practice Symposium, 2010*. Johannesburg: University of the Witwatersrand. Available: http://repository.hsrc.ac.za/bitstream/handle/20.500.11910/4037/6578.pdf?sequence=1 [2019, May 2].

SAMED. 2014. *The South African medical device industry – facts*. Available: *http://www.samed.org.za/DynamicData/LibraryDownloads/224.pdf* [2019, May 2].

Sodhi, K., Talati, S., Gupta, A.K. & Arora, P. 2014. Equipment donation: a perspective from a teaching tertiary care hospital in North India. *Indian Journal of Scientific Research.* 8(1):112–114.

Tödtling, F. & Trippl, M. 2005. One size fits all?: towards a differentiated regional innovation policy approach. *Research Policy.* 34(8):1203–1219. DOI: 10.1016/j.respol.2005.01.018.

WHO. 2000. *Guidelines for health care equipment donations.* Geneva: World Health Organization. Available: https://www.who.int/medical_devices/publications/en/Donation_Guidelines.pdf [2019, May 20].

WHO. 2010a. *Landscape analysis of barriers to developing or adapting technologies for global health purposes.* Geneva: WHO. Available: http://apps.who.int/medicinedocs/documents/s17778en/s17778en.pdf [2019, May 2].

WHO. 2010b. *Barriers to innovation in the field of medical devices: Background paper 6*. Geneva: WHO. Available: http://www.who.int/iris/handle/10665/70457 [2019, May 2].

WHO. 2011. *Medical device donations: considerations for solicitation and provision*. Geneva: WHO. Available: http://apps.who.int/iris/bitstream/10665/44568/1/9789241501408_eng.pdf [2018, February 18].

WHO. 2017. *Human resources for medical devices – The role of biomedical engineers.* Geneva: WHO. Available: http://apps.who.int/iris/bitstream/handle/10665/255261/9789241565479-eng.pdf;jsessionid=8CE3A3FCA0515666B5DC01AAF1C0A258?sequence=1 [2019, May 2].