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Critical elements in the design, development and use of medical devices. A systemic perspective of orthopedic devices landscape in low- and middle-income countries

Trust Saidi [a,b,*], Tania S. Douglas [c,1]

[a] University of Oslo, Centre for Technology, Innovation and Culture, P.O Box 1108, Blindern, 0317 OSLO, Norway
[b] Centre for Connected Care (C3), Oslo University Hospital, P.O. Box 4956, Nydalen N-0424, Oslo, Norway
[c] University of Cape Town, Division of Biomedical Engineering, Private Bag X3, Observatory 7935, CAPE TOWN, South Africa

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ABSTRACT

Objectives: The paper reviews the critical elements in the design and development of medical devices in general and orthopedic devices in particular as well as illustrates by means of examples the initiatives that have been put in place to incorporate contextual factors in low resource settings.
Methods: Data was collected by means of a targeted literature review from different databases using key terms. The search was done using combinations of key terms namely 'medical devices', 'low- and middle-income countries', 'high income countries, drivers of innovation', 'technology transfer' and 'local production'.
Results: The study yielded five critical elements which are indispensable in the development of medical devices. It emerged that the context of use, by virtue of encompassing the stakeholders, geographical space and medical devices provides a vantage point for addressing the complexities in the development of medical devices in low resource countries. The paper argues that approaching the critical elements from a contextual standpoint provides a systematic perspective for developing medical devices that are customised to the prevailing environments in low- to middle- income countries.
Conclusion: With the growing markets for medical devices, the review highlights the importance of forging strategic alliances between high income and low- to middle- income countries in developing appropriate medical devices for the users. The paper contributes to the policy discourse targeting both local and foreign manufacturers of medical devices as well as stakeholders from the public sector, industry and not for profit organisations on the importance of contextual awareness in the development of technologies.
Public interest abstract: The paper reviews the factors that influence the development of medical devices in general and orthopedic devices in particular. Focusing on low- and middle- income countries which tend to rely on medical devices and donations, the study advocates for the need to address context-oriented challenges that interfere with usability and compatibility, such as lack of electricity to operate the technologies and spare parts for maintenance. To minimize these problems, it is imperative to consider the prevailing conditions of developing countries in their broad context in order to customize the medical devices and enhance their usability. This study illustrates by means of examples the initiatives that can be adopted to facilitate collaboration between developing and developed countries for their mutual benefit. The study is useful to policy makers, local and international producers of medical devices and other stakeholders as it illuminates the importance of context in the production of medical devices.

Trust Saidi studied for a Bachelor of Science degree in Geography from Zimbabwe Open University, Bachelor of Science Honours degree from University of Zimbabwe, master's degree in Public Policy and Human Development from Maastricht University and doctoral degree in Science and Technology Studies from Maastricht University.Tania Douglas earned a bachelor's degree in Electrical and Electronic engineering at University of Cape Town. She completed her master's degree at Vanderbilt University, Tennessee in Biomedical Engineering. She studied for her doctoral degree in Bioengineering Engineering at the University of Strathclyde in Scotland. She graduated with a master's degree in Business Administration from University of Cape Town.The data, models, or methodology used in the research are not proprietary.

* Corresponding author.
E-mail address: trust.saidi@tik.uio.no (T. Saidi).
[1] Deceased: Formerly at Division of Biomedical Engineering, University of Cape Town.

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Introduction

The burden of musculoskeletal conditions such as traumatic injuries, congenital anomalies, chronic back pain and arthritis is growing and it is one of the major causes of disability in low- and middle- income countries [1–3]. These conditions are increasing due to high number of traffic related crashes in low- and middle- income countries as a result of a sharp rise in vehicles [4,5] and an aging population that is bringing a new tide of musculoskeletal challenges associated with old age [6,7]. Injuries in particular attribute to more than five million deaths each year, which is more than the number of people who succumb to HIV/AIDS, tuberculosis and malaria combined [8]. From these figures, it is estimated that more than 90% of injury-related deaths occur in low- and middle-income countries [9]. Timely and adequate care of trauma patients through the availability of appropriate orthopedic devices is of utmost importance as it has been proven that faster response time and adequate care can dramatically improve the condition in critically injured patients [10]. However, there are barriers to orthopedic surgery in resource-poor settings due to the lack of appropriate devices for managing musculoskeletal diseases [11].

The rise in an aging population and increase in traffic accidents in low- and middle-income countries is putting a demand for orthopedic devices. For example, the demand for orthopedic surgeries is projected to increase tremendously in India and China due to the high increase in the geriatric population pool, increasing per-capita income, rising disease awareness and improved health infrastructure [12]. With India, Thailand and South Africa having a cost efficient and advanced healthcare system driven by the increasing adoption of new technologies in relation to other low- and middle- income countries, medical tourism is boosting the growth of the market for medical devices [13]. South Africa is emerging as one of the largest markets for medical devices in Africa by virtue of having a large population and being Africa's most industrialised economy [14]. The size and composition of the medical device market in South Africa by device category is shown in Table 1.

In 2018, the South African market for medical devices was estimated to be worth $1.278 billion of which orthopedics and prosthetics constituted about 12% of the total market.

Several low- and middle- income countries have agencies that deliver medical care for the senior citizens through the support of the social security system with Argentina having 4.5 million old people protected under the National Health Insurance Programme for the Elderly [15]. The Philippines and Vietnam have expanded financial protection of their citizens through encouraging voluntary enrollment in social health insurance agency, while Thailand use funds from general taxation [16]. In Africa, Rwanda has achieved high voluntary insurance coverage [17], while Ghana has made remarkable progress in expanding health care coverage through a national health insurance scheme program which is compulsory for the formal sector [18]. The reimbursement for coverage costs for orthopedic devices and other medical devices through insurance schemes has facilitated their adoption in low- and middle- income countries as it allows hospitals and doctors to seek more advanced devices that are unaffordable to many under normal conditions [12].

Designing and developing medical devices specifically for low- and middle- income countries is considered to be fundamental to the widespread adoption of technologies that are not only affordable, but also culturally appropriate [19]. However, the process is not linear, but complicated as there are challenges from the manufacture and distribution of the medical devices until they reach the market. Although low- and middle- income countries present emerging markets for medical devices, the manufacturers are located and attuned to users in lucrative high-income markets [20]. Instead of manufacturing medical devices on their own for local consumptions, many low- and middle- income countries rely on imports which are not only expensive, but also risky with high propensity of technology failure [21]. For example, in 2018, medical devices with a total value ZAR15.2 billion were imported in South Africa, while those that were exported constituted ZAR2.67 billion [14]. These figures show that there is a viable market for medical devices, but the challenge is on the imbalance of trade due to limited local manufacturing activities.

Despite the growing awareness and focus on promoting access to medical devices, there still exists formidable barriers in low- and middle-income countries, particularly with heath technologies that originate from developed countries [22]. An analysis of the patents reveals that 70% of the applications filed worldwide originated from high-income economies, whereas low- and middle-income economies contributed less than 4% [23]. There are many factors that militate against the development and use of medical devices in low- and middle- income countries [24]. They are multifaceted ranging from those directly linked to the medical devices such as regulatory components and product characteristics [25,26] to those beyond the technology itself such as infrastructure and operating environment [27].

There are obstacles that hinder the successful design and diffusion of medical devices from high income to low- and middle- income countries [28]. This invokes the need for the producers of medical devices to tailor their designs to suit the local needs and conditions of the users [29–31]. To develop medical devices that are customised to the underlying needs of users and their operating environment in low- and middle-income countries, it is imperative to get an understanding of the factors that drive innovation in those distinct settings. It is against this background that this study is two-fold in that it is aimed at i] establishing the critical elements in the design and development of medical devices in general and orthopedic devices in particular and ii] illustrating by means of examples the initiatives that have been put in place to incorporate the contextual factors as a way of providing a systematic perspective of the critical elements in the development of medical devices in low resource settings.

Table 1
The medical device market for medical devices in South Africa for the year 2018 (14).

Category	US$ Millions
Consumables	241.00
Diagnostic imaging	199.30
Orthopedics and prosthetics	153.70
Patient aids	156.00
Dental products	41.30
Other medical devices	487.40
Total	1 278.40

Methodology

The paper is based on a targeted review of literature that were searched from PubMed, Web of Science and Scopus databases. The search was done using combinations of key terms such as 'medical devices', 'low- and middle-income countries', 'high income countries, drivers of innovation', 'technology transfer' and 'local production'. Concurrently, gray literature was searched using internet searches and via the World Health organisation website to find guidelines on the development of medical devices. The search was limited to the literature that describes the process of medical device development in both low and middle income and high-income countries with the aim of building a narrative on the influence of the critical factors. Only guidelines, research articles and websites in English were examined. Upon gathering the relevant literature, a synthesis analysis was done by grouping thematically the critical elements driving innovation into general principles for medical device development.

Critical elements in the design and development of medical devices

The potential users of new medical devices play an important role during the design and development process in identifying the clinical needs for a new medical device and making adjustments to existing

devices [32].In this regard, the users exert a lot of influence, not as passive consumers of medical devices, but innovators and builders of the original prototype. Von Hippel underscores the role of users in the design and development of medical devices by arguing that several key innovations are driven by users and not the ultimate manufacturers [33]. The integration of the end users is a critical factor in identifying and understanding their needs through the opening of opportunities for comprehensive and timely input [34]. Incorporating user requirements during medical device development reduces the likelihood of product recalls and modifications.

The observable features of the product itself, such as its architecture and functionality have an influence on the design and development of medical devices [35]. According to Medina, et al., the product characteristics are an important factor for consideration as they are related to the specific uses of the devices, which define the clinical problem to be solved and the context of use [36]. Medical devices are known to comprise not only the device itself, but also product system elements which render it important to factor the entire system, that is the parts in isolation and as a whole [37]. The product system elements include accessories such as training kits, surgical tools, software, batteries and chargers which should be compatible with the medical devices.

The development of medical devices is governed to a great extent by regulatory regimes, which manifest in different forms, such as standards and pharmaceutical laws, which are oriented towards promoting safety [32]. The regulations exert a lot of influence in the use of medical devices in that they safeguard the technologies from risks that can threaten the product development process, in terms of price, timing and quality [38]. Central to the legislative aspect is the key issue of consistency in the classification of devices in terms of risks as well as the transparency of the approval process [21]. The regulations for medical devices are multi-faceted as they include registration, pre-marketing notification, record keeping and labeling [26]. They vary from continent to continent and even between countries and they can be difficult to synchronize [39].

Intellectual property protection is a crucial element in the commercialization of medical devices. Considering that the profitability of medical devices depends on leveraging patents in the manufacturing and distribution, intellectual property law can be a formidable barrier to innovation, especially in low- and middle- income countries [40]. Intellectual property rights serve as a powerful tool for protecting investments, since they grant exclusive rights for a certain period of time [41,42]. However, the geographical distribution of patents for medical devices are skewed towards the developed countries. Although inventors of medical devices from low- and middle- income countries could be interested in pursuing patent protection of their technologies, exorbitant costs such as expenses for filing and fees for legal counsel and maintenance of the patent are formidable barriers [43].

The environment in which medical devices are used has an influence on their design and development [44]. The environment does not only affect the design and development of medical devices, but also the commercialization process and availability to consumers [45]. It encompasses the broader setting in which the medical devices are used such as cultural environment and organisational structures [24]. There is need for compatibility between the design of the medical device and the environment in which the technology is used [44]. It has been demonstrated that the development of medical devices is not limited to the relationship between the users and technologies, but also the physical environment and organisational context [46].

In considering the critical elements that influence the design and development of medical devices, specific questions can be asked to guide the process. Table 2 provides examples of questions that can be posed to generate insights on the development and use of medical devices.

The questions in Table 2 are not an exhaustive checklist but serve as pointers to the key areas that should be considered in the development of medical devices. The five critical elements that have been reviewed do not stand on their own but interact with each other. This renders it important to approach the critical elements from a systemic perspective.

Systematic perspective in the development of medical devices

The high failure rates of imported medical technologies such as orthopedic devices in low- and middle-income countries is a significant health challenge, which invoke the need for in-depth understanding of the context of use. A holistic view of the medical device ecosystem is required to contribute towards the effective development and use of the technologies [45]. It demands among other things approaching the elements that influence the development of medical devices, not in isolation, but in an integrated fashion using the systematic perspective [44,48]. This is important considering that the design and development of innovative medical devices extend beyond the functionality of the products [35]. One potential entry point for approaching the different elements systematically is to focus on the broad context of the medical devices. This emanates from the fact that the context is an embodiment of the different elements as it consists of the regulatory, socioeconomic, technological, political-legal and physical environment [21].

In low- and middle- income countries, the challenges on the use of medical devices can be traced to the poor translation of the technologies from one context to another [49]. Most medical devices that are used in low- and middle- income countries are designed for the high income countries, which boast of adequate infrastructure that support the healthcare systems [50]. Apart from the differences in the orientation of medical devices towards the established target markets in developed countries, there are unique challenges experienced by low- and middle-income countries emanating from the context. Unlike low- and middle-income countries, most high income countries have hospitals that are well equipped with clean water and electricity, and there are skilled personnel for the proper upkeep of the medical devices [51].

There are many medical devices that have been imported or donated to low- and middle- income countries but failed to operate effectively [52–54]. The failure is attributed to contextual factors, for example facilities that do not meet the initial mandatory device requirements, such as running supply of distilled water or regular supply of oxygen or a reliable source of energy [55]. The sustainability in the use of the devices is jeopardised by the lack of access to parts or consumables that are needed for repair and maintenance, or trained personnel to operate the equipment for long-term use [56,57]. In some cases, the devices are sent with operating manuals in languages that are unfamiliar to recipients or without instructions altogether [55]. This invokes the needed for providing a sustainable supply of medical devices which are not only affordable but appropriate for the local conditions.

A paradigm shift towards context awareness

To address the challenges faced in the development of medical

Table 2
Critical elements and guiding questions [adapted from Knowles (47)].

Critical elements	Related questions
Technology	What is the purpose of the technology? What is the performance level needed? What features distinguishes the technology from others? What is the product life?
User	Who are the direct and indirect users? What knowledge, skills or impairments do they have? How do they interact with the technology?
Environment	Where will the product be used? Under what weather conditions will the device be used? Is the technology and accessories compatible with the physical environment?
Intellectual property	What patented technologies do competitors hold? What are the key patents to avoid in each market? Does the new medical device need patent protection?
Regulations	Which regulations and standards apply to the medical device? What is the pathway for regulatory approval? Is there need for clinical approvals?

devices, it is important to consider the context of the low- and middle-income countries. Aranda-Jan et al. argue that in order to adequately solve global health challenges faced by low- to middle- income countries, it is imperative that medical devices are designed to be sympathetic with the local conditions and context [58]. This demands balancing the largely supply-driven market in developed countries and meeting the actual needs of the healthcare population in low- and middle- income countries [50]. The supply-driven market is one of the driving forces behind inequitable access to medical equipment in developing countries, which is perpetuated by weak socioeconomic conditions and unstable political conditions [39,50]. The assumption of technology transfer as a linear process whereby medical devices from developed countries can be bundled, packaged and shipped is problematic.

To achieve success, the development of medical devices requires active involvement of local actors in aligning the technologies with contextual factors [24,59]. Over the recent years, there has been an expansion in the manufacture of diagnostic devices in a number of low- and middle- income countries [60]. There are initiatives to support local production and this has resulted in positive changes in the development of the medical device industry [23,61]. For example, local production of medical devices is being supported through the transfer of technology, both north-south and south-south [60]. Some low- and middle- income countries are promoting the development of medical devices directly through grants, subsidies, tax and duty exemptions for imported inputs meant to facilitate local production [22].

Interventions for facilitating the development of appropriate technologies

One of the ways in which the problem of access to appropriate medical devices can be resolved is through the development of technologies that are specifically designed for low- and middle- income countries [51]. The design and deployment of medical devices can benefit from a deep understanding of the context as an overarching factor. The influence of the context goes beyond the common appeal centered on the 'best interest of the user', to include the social identities of all stakeholders and the immediate environment in which they operate [62].

There are notable interventions that have been made to ensure that people in low- and middle- economy countries have access to orthopedic devices for muscoskeletal conditions. This has been done mainly by addressing the contextual barriers in the design, development and use of medical devices. For example, a scalable and sustainable patient care model targeting low- and middle- income countries has been implemented by SIGN Fracture Care International to provide orthopedic care through a three pronged approach that involves imparting orthopedic techniques to in country local surgeons, supplying appropriately designed orthopedic devices and evaluating patient outcomes [63]. A successful output from this model is the SIGN Nail orthopedic device that has been developed for use in low resource settings to reduce delays in the timing of surgery [64]. It suits the conditions of poor countries as it can be placed without fluoroscopy or electricity. This is important in that many operating rooms in low- and middle- income countries experience frequent power surges which makes it difficult to use electric powered equipment.

In Tanzania, a novel and sustainable model has been developed to ensure that orthopedic surgery is not limited to only those who are wealthy, but also to the majority of the population through a financially viable, tiered payment system based on specific package designations [65]. The model is designed in such a way that the costs of those without the means to pay will be partly covered by those who are able to pay. It relies on collaboration between local and international stakeholders and it departs from the dependence on a donation system for orthopedic devices, which often by pass the manufacturers and avoids associated import taxes [66]. The new model is designed to provide culturally sensitive and affordable orthopedic care without disruption of the supply chain of the medical devices [67]. It is a public - private partnership which is driven by the need to enhance access to orthopedic surgery.

Strategic partnerships between high income countries and low- to middle- income countries have been forged with the aim of leveraging the resources and experiences that the developed countries have on orthopedic research and in-depth knowledge of locally relevant needs of developing countries [68]. This has proved to be crucial in addressing the unmet needs of advancing sustainable development and use of orthopedic devices in low- and middle- income countries. An example of such a partnership is the Ugandan Sustainable Trauma Orthopedic Programme, which brings stakeholders from Uganda and Canada together. The initiative has resulted in the development of several orthopedic devices that are oriented towards reducing the cost of providing orthopedic care without compromising quality [69]. Remarkably, the partnership has given rise to cost-effective innovations such as the drill cover system which facilitates non-sterile hardware drills to be used safely for surgical bone drilling. The device provides a proof-of-concept for a product that is capable of being commercialised, scaled and used in low-resource settings to improve access to safe surgery [70].

Conclusion

The study shows the importance of considering the contextual factors in the development of medical devices in low- and middle-income countries where the conditions are significantly different from high income countries. Context, by virtue of characterizing the situation of stakeholders, geographical space and medical devices themselves is critical to the development of medical devices in that it distinguishes different entities such as places (rooms, buildings etc.), people (individuals, groups), or objects (physical artefacts and accessories). The embodiment of environmental factors, equipment and tools, operating characteristics relating to user circumstances as well as organisational and social factors under the ambit of context invokes the need for collaboration between low- and middle-income countries with high-income countries as illustrated in the models presented in this paper. The collaboration is of mutual benefit in that the high-income countries have the infrastructure for the development of medical devices but lack knowledge about the context of use in low- and middle-income countries. Such partnerships are important in enhancing the creation of viable markets through the delivery of appropriate technologies. Thus, it can be concluded that collaboration between local and international manufacturers of medical devices can provide a point of entry for fusing the contextual factors and setting-dependent elements. Such collaboration, if properly nurtured can facilitate the development of the local medical device industry. The results from this review contributes to the policy discourse targeting stakeholders from the public sector, industry and not for profit organisations on the importance of contextual factors in the development and subsequent use of medical devices in low resource settings.

Author contribution

Please specify the contribution of each author to the paper, e.g. study design, data collections, data analysis, writing, others, who have contributed in other ways should be listed as contributors. Trust Saidi and Tania Douglas conceived and designed the review, collected data, analysed it and finally wrote the paper.

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Ethical approval

Not required.

Competing Interests

A conflicting interest exists when professional judgement concerning a primary interest (such as patient's welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It may arise for the authors when they have financial interest that may influence their interpretation of their results or those of others. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

Patient consent

Not required.

Declaration of Competing Interest

None.

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