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Engineering Open-Source Medical Devices

A Reliable Approach for Safe, Sustainable and Accessible Healthcare

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Preface

This handbook, ***Engineering Open-Source Medical Devices: A Reliable Approach for Safe, Sustainable and Accessible Healthcare***, is the result of an absorbing journey and has been prepared thanks to the contribution of a great team of inspiring engineering professionals.

The journey started with editors' and co-authors' passion for biomedical engineering and medical devices, with the conception and implementation of several project-based learning courses focused on medical technology, principally at the University of Pisa and at Universidad Politécnica de Madrid. Many of the ideas and concepts presented in this handbook were nurtured by a unique set of innovative summer schools organized by the African Biomedical Engineering Consortium (ABEC) and supported by the United Nations Economic Commission for Africa (UNECA), in which the concept of "open-source medical devices" (OSMDs) was coined. Subsequently, the "UBORA: Euro-African Open Biomedical Engineering e-Platform for Innovation through Education" project, funded by the European Commission's Horizon 2020 Programme (grant agreement n° 731053, 2017–2019), enabled the creation of a unique collaborative e-infrastructure for open-source medical technologies (the UBORA platform: https://platform.ubora-biomedical.org/). The platform has helped set the foundations for the systematic co-design engineering of OSMDs, underpinned by rigorous attention to the safety and efficacy of medical technologies.

Beyond those who have directly contributed to the different chapters of the handbook, there is an impressive community of researchers, educators and students (the UBORA Community), who are now transforming the biomedical industry in different countries with a focus on healthcare equity. In the last 5 years, more than 1500 students and colleagues from around 40 countries have taken part in UBORA-UNECA actions linked to the promotion of OSMDs as transformative technologies, and these experiences have been the fruitful soil for growing this text.

For us, as editors of the handbook, it has been a privilege to distil the key good practices and challenges involved in the engineering of OSMDs in this book, which we hope becomes a comprehensive reference for colleagues in the field.

We would like to thank the editorial staff at Springer for their support with the handbook. Finally, we express our deepest gratitude to our families, friends and colleagues for their understanding, patience and endless support.

Pisa, Italy — Arti Ahluwalia, Carmelo De Maria

Madrid, Spain — Andrés Díaz Lantada

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Chapter 1
Open-Source Medical Devices: Concept, Trends, and Challenges Toward Equitable Healthcare Technology

Carmelo De Maria, Andrés Díaz Lantada, Licia Di Pietro, Alice Ravizza, and Arti Ahluwalia

1.1 Introduction: The Social Product Development and the Modern Medical Technologies

Medical technology has transformed the practice of medicine and patient care, with a wide set of relevant breakthroughs achieved during the last decades high-precision medical imaging for improved diagnoses (European Society of Radiology, 2015), robotic-guided surgery and minimally invasive procedures for enhanced recovery after surgery (Ghezzi & Corleta, 2016), the progressive use of smartphones for diagnosing and monitoring patients (Freeman et al., 2020; Jamshidnezhad et al., 2019), and even 3D printing with biomaterials and biofabrication, as most innovative potential alternatives to conventional prostheses or organ transplants (Lanza et al., 2014; Atala & Joo, 2015; Moroni et al, 2018).

However, in many cases, medical technology is developed in secrecy, and patients' or medical professionals' needs are considered as a minor part of the decision-making process, which is currently under the pressure of marketing and immediate payback, instead of being driven by needs and by the knowledge and long-sighted view of technology developers (Fasterholdt et al., 2018).

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While the economic growth of medical technology developers and manufacturers is fundamental for reaching more and more patients in a sustainable way, decisions taken on the basis of short-term incomes tend to limit the creativity of medical device designers, hindering also the personalization of medical technology, and to leave rare pathologies and low-resource settings unattended, to cite just some drawbacks of the current state-of-the-art in the biomedical industry (De Maria et al., 2018).

In contrast with the biomedical industry, many product fields are now involving stakeholders and future users since the beginning of the product development process, embracing the new paradigm of "open innovation" (Ng & Jee, 2014; Gao and Bernard, 2017). In this new paradigm, the online sharing of information (concepts, blueprints, or other project documentation), with colleagues or even with developers outside the core team, is reinventing the product development process. In this sort of "social product development," thematic communities co-develop and share innovative solutions working on online platforms, such as Thingiverse or GrabCAD.

These collaborative and open-source design strategies have been widely explored in software development, bringing benefits in terms of accessibility, sustainability, lower costs, improved performance, and even safety (Lessig et al., 2005). Nowadays, the capillary diffusion of entry-level 3D printers, available in co-working spaces and FabLabs born with the "makers" movement (Gershenfeld, 2005), as well as the lower access cost to the "printing factories" have given the tools to physically build the projects, downloadable from online repositories.

However, healthcare industry is still reluctant to taking advantage of the enormous potentials of open-source and collaborative approach toward a social development of medical devices, although it has the potential to increase the access to medical technologies (De Maria et al., 2020). In the medical industry, in fact, it is crucial to ensure the safety and efficacy requirements of medical technology, enforced by laws such as the European Medical Device Regulation 2017/775 and 2017/746. Indeed, despite several examples of healthcare technologies have appeared on the web (Niezen et al., 2016), only some of them have been designed to be compliant with medical device (MD) legislation (Arcarisi et al., 2019; Ferretti et al., 2017).

In our perspective, to prove truly transformative, open-source medical devices and their boundaries should be adequately defined, the expected outcomes of open-source medical technologies should be analyzed and the characteristics of pioneering success cases should be understood, so as to follow their path. In addition, collaborative research and development online environments, capable of enabling collaboration, helping to match medical needs and technological offers and devoted to guiding medical technology developers in their endeavors, should be arranged. The UBORA e-infrastructure developed by our team and described also in this introductory chapter constitutes a relevant breakthrough in this direction.

The following sections of this chapter deal with all aforementioned issues.

1.2 The Concept of Open-Source Medical Device (OSMD): Definition and Rationale

1.2.1 Reaching a Consensus Definition for OSMDs

Collaboration and information sharing are becoming fundamental in the biomedical field for developing technologies aimed at solving global health concerns. During the First International Conference on Collaborative Biomedical Engineering for Open-Source Medical Technologies (Pisa, September 2018), and in accordance with the principles of "The Kahawa Declaration" (Ahluwalia et al., 2018), an international focus group on open-source medical devices was established for working toward equitable access to healthcare technologies, by means of open-source approaches to the design of medical devices, and for helping to harmonize and articulate best practices in such emergent field.

The first tasks assigned to the mentioned working group, involving all UBORA partners and key stakeholders from the medical industry with experience in open innovation, as well as policymakers, educators, and healthcare professionals, included (a) the gathering of successful examples of open-source medical devices and open-source initiative in BME to understand the state-of-the-art and its current limitations and (b) the elaboration of a consensus operative definition for the concept of open-source medical device.

Relevant concepts were used for the elaboration of such definition, which tries to take into consideration several aspects present in the more common definitions of open-source software (Open-Source Initiative; Debian Project) and open-source hardware (Open-Source Hardware Association). However, in a way, the definition explained further on combines and expands both, in order to account for very specific and relevant issues present in medical technology development, for the fact that modern medical devices involve hardware and software, and for adequately incorporating recent trends in data management in collaborative projects (Wilkinson et al., 2016).

To start with, let's consider the concept of medical device:

1.2.1.1 Medical Device

According to the EU Regulation 2017/745 of the EU Parliament and of the Council on April 5, 2017, on medical devices, "medical device" means:

> Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: a) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, b) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, c) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, d) providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its

> principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Consequently, medical devices range from contact lenses to Band-Aids, from pacemakers to implantable heart valves, and from surgical instruments to large medical imaging equipment, and the definition of open-source medical devices proposed in current document is direct consequence of adapting the open-source concept, and its implications on the software and hardware industries, to the previously cited definition of medical devices from the MDR 2017/745 of the EU. For operative purposes, working this EU definition covers also most medical devices worldwide, as defined by other regulatory bodies, such as the US Food and Drug Administration or the Chinese Food and Drug Administration, to cite just a couple of relevant examples.

1.2.1.2 Open-Source Software

The most commonly used definition of open-source software (currently the open-source definition v.1.9: https://opensource.org/docs/definition.php) derives from the Debian Free Software Guidelines created by Bruce Perens and the Debian developers. In short, open-source software is software with accessible source code, hence allowing peer-review and rapid evolution, complying also with criteria such as free distribution, distribution in source and compiled code, allowance of modifications and derived works, lack of discrimination against specific persons or groups, lack of discrimination against fields of use, lack of restriction to other software, lack of product specificity, and technological neutrality. Examples of open-source software licenses include “GPL,” “BSD,” and “Artistic,” among others.

1.2.1.3 Open-Source Hardware

The Open-Source Hardware Association (OSHWA) defines open-source hardware in its Statement of Principles 1.0 and Definition 1.0 as: “hardware whose design is made publicly available so that anyone can study, modify, distribute, make, and sell the design or hardware based on that design.” The hardware’s source, the design from which it is made, is available in the preferred format for making modifications to it.

Ideally, open-source hardware uses readily available components and materials, standard processes, open infrastructure, unrestricted content, and open-source design tools to maximize the ability of individuals to make and use hardware. Open-source hardware gives people the freedom to control their technology while sharing knowledge and encouraging commerce through the open exchange of designs.”

The definition is based on the previously mentioned open-source definition for open-source software.

However, as hardware differs from software by requiring the use of physical resources for the creation of physical goods, it is important to highlight that these Principles and Definition of OSHW also state that "persons or companies producing items ("products") under an OSHW license have an obligation to make it clear that such products are not manufactured, sold, warranted, or otherwise sanctioned by the original designer and also not to make use of any trademarks owned by the original designer."

1.2.1.4 Open-Source Medical Device

Working on the basis of previous concepts and definitions and considering the current state-of-the-art in the field of collaborative biomedical engineering, as well as ongoing international initiatives pursuing equitable access to healthcare technology, the UBORA consortium, in connection with the international focus group on OSMDs, proposed an operative definition for open-source medical devices as follows:

> An open-source medical device is a medical device whose design and product development information are made publicly available so that anyone can study, modify, distribute, make, and sell the medical devices, and their related software or hardware, based on the initial available design and information. The design of the open-source medical device should be shared in a format conceived for enabling validation, verification and modification. Open-source medical devices rely on widely available materials and components, benefit from being designed according to international safety standards and processes aimed at guaranteeing patients' safety, take advantage of modularity, even being designed as inter-changeable and inter-operable kits, and rely on open e-infrastructures for information dissemination and promotion of collaboration. FAIR (findable, accessible, interoperable, reusable) data principles are proposed for open-source medical devices. Persons or companies producing and commercializing open-source medical devices are obliged to attribute to the original designers and to make clear that such medical devices are not manufactured, sold, warranted, or otherwise sanctioned by the original designer.

The definition has been officially submitted to the World Health Organization ICD-11 to be used as new concept for the biomedical industry and has been also presented in the new Handbook of Clinical Engineering (De Maria et al., 2020), in connection with the innovative paradigm of open-source biomedical engineering and with co-creation environments.

In the opinion of the authors, the definition constitutes a relevant step in the harmonization of open initiatives, technologies, and resources that are emerging in connection with biomedical engineering and with the future of biomedical industry. The process for the elaboration of the definition has been supported by interesting debates that have also influenced decisions taken by the consortium responsible for arranging the UBORA community regarding the final guidelines for open licensing of designs through UBORA, the use of FAIR data principles, UBORA's alignment with the "free as in freedom" concept, and the dissemination and communication strategies for UBORA devices, which have benefited from a clearer explanation of UBORA's mission and of the meaning and potential impacts of OSMDs.

1.2.2 Rationale: The Reasons Behind Open-Source Medical Devices

Medical technologies are at the foundation of an efficient healthcare system. Despite "Good Health and Well-Being" as one of the Sustainable Development Goals (SDG), identified by the United Nations (United Nation 2015), the high costs of medical devices (MDs) can create a barrier for reaching this target. This cost derives from the long life-cycle of MDs (specification and planning, design, prototyping, manufacturing, certification, labeling and packaging, provision, installation, operation, maintenance, repair and disposal), in which each step is strictly regulated and controlled, to guarantee their efficacy and the safety of patients, healthcare providers, and bystanders. *Even removing the charge on a single step could not make the difference*.

For example, the World Health Organization (WHO) estimates that in low-income countries, more than 80% of medical equipment is donated, but only 10–30% of these become operational, given the high operational costs, the lack of personnel and the frequent failures due to harsh environment, extreme climate conditions, humidity, dust, power instability, and lack of maintenance (WHO, 2010a, b; Malkin, 2007a, b). These conditions, not foreseen in the design phase, cause more frequent failures and determine a higher request for spare parts, which are expensive and difficult to find, making maintenance and repairing as problematic as the acquisition itself (Douglas, 2011).

Compared to traditional medical device engineering methods, the social product development process based on the open-source and collaborative approach can be a possible alternative, both technically and economically viable. Open-source means making the design, documentation, source-code, blueprints, debated ideas, and results available for the general public. Having the software, electronic, and hardware design accessible under an open-source license and in the most suitable file format to study, modify, improve, and contribute to the design potentially leads to very rapid and more reliable innovation. In addition, the application of the open-source approach to medical device design has proven to offer a unique combination of advantages, such as increased safety, security, and reliability and reduced costs (De Maria et al., 2018).

Until a few years ago, the development of medical devices was essentially linked to companies and large research institutions, but recently several examples of OSMDs have appeared on the web, in connection with the advent of the maker movement, as reviewed in the following section.

1.3 Brief Overview of Pioneering Success Cases in the OSMD Field

Recent pioneering cases of success in the OSMD field already reaching the market can be cited, including open-source electronic kits for medical signals, such as the solutions by Bitalino (Alves et al., 2006) and ProtoCentral Electronics (Whitchurch, 2019), open-source ECG systems (Gamma Cardio Soft, 2019), and varied open-source software to support diagnostic processes, in medical fields ranging from neurology and cardiology to dermatology and preventive medicine, in some cases benefiting from advances in smartphones as support to medical diagnoses (MIT's Sana, 2020; Vlassi et al., 2017; Kassianos et al., 2015), to cite just a few. In connection with the maker movement, other inspiring pioneers have devoted themselves to explaining how to arrange DIY labs for prototyping (Pearce, 2014a) and detailed in an open-source way the development of varied solutions, such as varied laboratory equipment, adaptive aids for arthritis patients, or printable clubfoot bracer for children (Pearce, 2014b; Gallup et al., 2018; Savonen et al. 2019), while highlighting the potentials of distributed manufacturing to make medical devices reach those who need them most and analyzing the suitable business models for open hardware (Pearce 2017).

Other inspiring initiatives, trying to promote OSMDs and sharing of information for improved medical technology and healthcare, can also be mentioned due to their remarkable growth and international projection, such as the "Enabling the Future" project and the "Autofabricantes" community, focused on personalized prostheses designs for children; the "Patient Innovation" and "Patients Like Me" networks, focused on shared information for solving complex pathologies; and the "Open Prosthetics" initiative and the "Open Bionics" environment, both concentrated on low-cost personalized prostheses, among others (Enable, 2019; Oliveria et al., 2019; Open Prosthetics, 2019; Open Bionics, 2019), some of them with more than a decade of dedication to the field of OSMDs.

In a way, these initiatives evolve from analogous networks devoted to co-creation and to the promotion of collective intelligence in more conventional hardware and software development, which have already reshaped how common appliances for daily use are designed, manufactured, and continuously improved through cooperation. Among these well-established networks and environments, it is important to cite Thingiverse and GrabCAD for the sharing of computer-aided design files, GitHub, MyMiniFactory, and YouImaging for sharing complete design projects, the RepRap wiki for detailing how to build DIY 3D printers, or the FabLab and Shapeways networks for delocalized manufacturing of components.

Describing in detail all the current initiatives in the field of OSMDs and the whole collections of OSMDs already available and shared online is beyond the purpose of present study. However, we have summarized a selected collection of initiatives, open-source hardware and software, ongoing communities working in the OSMD arena, and remarkable cases of success of OSMDs, in many cases also collaboratively developed. These initiatives, networks, communities, and solutions are listed

in Tables 1.1, 1.2, and 1.3 to inform researchers, developers, patients, and healthcare professionals interested in these novel approaches to medical technology development. First, Table 1.1 presents more than 30 selected examples of open-source medical devices of recent development with their purpose, area of application, and link or reference for details. Then, Table 1.2 lists down open-source hardware and software resources with potential application for the development of OSMDs. Finally, Table 1.3 presents online communities of developers and online research infrastructures for the co-creation of OSMDs.

In accordance with all of the above, the OSMD field is already being explored worldwide, and several concepts and devices have been designed, manufactured, and tested. However, only some of them have been designed to be compliant with medical device legislation. Again we would like to highlight that it is crucial to ensure the safety and efficacy requirements of medical technology, and for this reason, the adoption of open resources must follow the standards and the current regulations (De Maria et al., 2015, 2018). To this end, a new e-infrastructure, UBORA ("excellence" in Swahili), which merges the open-source concepts with the safety and efficacy requirements enforced by the EU Regulation on medical devices (MDR) 2017/745, has recently been established (UBORA, 2020). The main features of UBORA and selected examples of OSMDs developed through it are presented in the following sections of this perspective.

1.4 The UBORA e-Infrastructure: Motivation and Purpose

Motivated by the fact that none of the aforementioned environments and collaborative design platforms provides designers with tools for a guided and systematic development process, in which open-source and collaborative design strategies play the central role, together with final safety promotion through harmonized standardization employment, our team decided to set up the UBORA platform. It is the first of a kind focused on the co-creation of medical devices compliant with EU Regulation on medical devices (MDR) 2017/745 and following internationally recognized standards. This platform or online e-infrastructure is, in consequence, developed for the promotion of collaboration through the whole development process of innovative open-source medical devices, whose complete development details, including specifications, design process, lists of components, computer-aided design files, and blueprints, among other relevant issues, are shared by means of an interactive and designer-oriented "wiki" structure, as explained in the following section. The collaborative design environment of UBORA provides quite unique features oriented to guiding developers through a systematic engineering design process, focused on patient safety and on achieving designs of medical devices compliant with international regulations, while fostering collaboration and joint decision-making for enhanced creativity, shared information, and peer-reviewed designs. A very singular aspect of this e-infrastructure is that it covers all types of medical devices (i.e., diagnostic tools, prosthetic devices, surgical tools, monitoring systems, therapeutic

Table 1.1 Selected examples of open-source medical devices (last access to reference website on August 2019)

Open-source medical devices (selected examples)	Technology	Medical area	Link/Reference
Software for management of medical records	Software	Management	https://www.open-emr.org/
Software for management in dentistry	Software	Management	http://www.opendental.com/
Software for psycho experiments	Software	Psychiatry	http://www.psychopy.org/
Eye tracking resources for communication	Software	Neurology	http://www.pygaze.org/
Eye tracking resources for diagnosis	Software	Neurology	http://www.pygaze.org/
Game for supporting diagnosis of malaria	Software	Preventive medicine	http://malariaspot.org/es/
Framework for app development	Software	Medical research - Preventive medicine	https://www.apple.com/researchkit/
Dermatological database to support diagnosis	Software	Dermatology	http://tkderm.sourceforge.net/index.html
Software for supporting dermatologic studies	Software	Dermatology	https://github.com/Sage-Bionetworks/MoleMapper
Software for personalized prosthesis design	Software	Orthopedics	https://github.com/mtu-most/most-3-d-customizer
Ultrasound stethoscope	Mobile-based technology	Internal medicine - emergency medicine	http://www.echopen.org/
Otoscope with disposable specula	Screening device	Otorhinolaryngology	https://github.com/GliaX
3D printed stethoscope	Screening device	Internal medicine - emergency medicine	https://github.com/GliaX
DIY pulse oximeter linked to Arduino	Monitoring device	Internal medicine - emergency medicine	https://github.com/GliaX
Multi-purpose platform for biosensing	Monitoring device	Internal medicine - emergency medicine	https://wearablesforgood.com/finalist-totem-open-health/
Multi-purpose platform for biosensing	Monitoring device	Internal medicine - emergency medicine	http://bitalino.com/en/
Multi-purpose monitoring platform	Monitoring device	Internal medicine - emergency medicine	http://www.libelium.com/
Brain computer interface	Monitoring device	Neurology	http://openbci.com/
Biosensing electrical brain activity (EEG)	Monitoring device	Neurology	http://openbci.com/
Biosensing muscle activity (EMG)	Monitoring device	Sports medicine - rehabilitation	http://openbci.com/
Biosensing heart rate (ECG)	Monitoring device	Cardiology	http://openbci.com/

(continued)

Table 1.1 (continued)

Open-source medical devices (selected examples)	Technology	Medical area	Link/Reference
Device for performing nano-immunoassay	In vitro diagnostic device	Diagnostic medicine	https://metafluidics.org/devices/
Wrist-powered hand prostheses	Prosthesis	Pediatrics - rehabilitation	http://enablingthefuture.org/
Elbow-powered hand prostheses	Prosthesis	Pediatrics - rehabilitation	http://enablingthefuture.org/
Finger prostheses	Prosthesis	Pediatrics - rehabilitation	http://enablingthefuture.org/
Ankle prostheses	Prosthesis	Rehabilitation - traumatology	https://niatech.org/technology/
Hand and forearm prostheses	Prosthesis	Rehabilitation - traumatology	https://openbionics.com/
Hand and forearm prostheses	Prosthesis	Pediatrics - rehabilitation	https://github.com/Autofabricantes/
MIDI percussion instrument	Supporting equipment	Pediatrics - rehabilitation	https://github.com/Autofabricantes/
IoT ECG-patch	Supporting equipment	Internal medicine - emergency medicine	https://github.com/Protocentral/protocentral_heartypatch
IoT patient monitor	Supporting equipment	Internal medicine - emergency medicine	https://github.com/Protocentral/protocentral-healthypi-v3
Defibrillator	Supporting equipment	Internal medicine - emergency medicine	Ferreti et al. Hardware X, 2017
Wearable device for breast self-examination	Self-monitoring device	Oncology	Arcarisi et al. Applied Sciences, 2019

devices) and bioengineering systems supporting medical practice (i.e., supporting lab equipment, mobile apps, and software).

The UBORA platform has been also developed following the principles of "The Kahawa Declaration" (Ahluwalia et al., 2018), a call of attention for pursuing the democratization of medical technology signed in the closure of the First International Design School of the EU-funded UBORA project (Nairobi, December 2017). UBORA was officially launched to the public, before representatives from ABEM, ABEM, UNECA, and WHO, during the First International Conference on Collaborative Biomedical Engineering for Open-Source Medical Technologies and the successive UBORA Design School 2018, held in Pisa from September 1–7.

To date, the e-infrastructure, available at the address: https://platform.ubora-biomedical.org, has around 500 users and 300 projects, at different stage of development. In turn, UBORA aims to arrange a diverse and truly global community of

Table 1.2 Open-source hardware and software resources with potential applications for the development of OSMDs (last access to reference website on August 2019)

Name	Type of resource	Sector	Country of development	Year of release	Additional comments	Link/reference
FreeCAD	Open-source software	Multidisciplinary	Germany	2002	Open-source CAD software	https://freecadweb.org/
OsiriX	Open-source software	Medical	Switzerland	2003	Open-source software for DICOM files	http://www.osirix-viewer.com
Arduino	Open-source hardware	Multidisciplinary	Italy	2005	Open-source and low-cost electronic prototyping kits	https://www.arduino.cc/
Libelium (& MySignals)	Open-source hardware and software	Multidisciplinary and medical	Spain	2006	e-Health and medical IoT development tools	http://www.libelium.com/
Bitalino (PLUX)	Open-source hardware	Medical	Portugal	2007	Open-source and low-cost biomedical prototyping kits	http://bitalino.com/en/
OpenSCAD	Open-source software	Multidisciplinary	Austria	2010	Open-source CAD software	http://www.openscad.org/
Slic3r	Open-source software	Multidisciplinary	Italy	2011	Open-source software for generating G-code for manufacturing	http://slic3r.org/
MEDIKits	Open-source hardware	Medical	US	2011	Open-source low-cost biomedical prototyping kits	https://d-lab.mit.edu/projects/150/medikit
3D Slicer	Open-source software	Medical	International team	2012	Open-source software for managing medical images and personalizing biodevices	https://www.slicer.org/
Ultimaker Cura	Open-source software	Multidisciplinary	Netherlands	2013	Open-source software for generating G-code for manufacturing	https://ultimaker.com/en/products/ultimaker-cura-software
ProtoCentral	Open-source hardware	Multidisciplinary	India	2016	Open-source and low-cost prototyping kits with biomedical sensors	https://www.protocentral.com/

(continued)

Table 1.2 (continued)

Name	Type of resource	Sector	Country of development	Year of release	Additional comments	Link/reference
GitHub	Open-source collaborative version control software	Multidisciplinary	US	2005	Collaborative version control. GitHub and Bitbucket offer git services for free	https://git-scm.com/
Redmine	Open-source project management software	Multidisciplinary	International team	2016	Redmine is a free and open-source, web-based project management and issue tracking tool	https://www.redmine.org/
NIH 3D printing exchange	Repository for sharing files and blueprints	Medical	US	2014	A Public Resource for Bioscientific and Biomedical 3D Prints. Created by the US National Institutes of Health	https://3dprint.nih.gov/
Thingiverse	Repository for sharing files and blueprints	Multidisciplinary	Global community	2008	Open CAD library of all sorts of industrial components and devices	https://www.thingiverse.com/
GrabCAD	Repository for sharing files and blueprints	Multidisciplinary	Global community	2009	Open CAD library of all sorts of industrial components and devices	https://grabcad.com/
BodyParts3D	Repository for sharing files and blueprints	Medical	Japan	2009	Open CAD library of body structures generated from medical images	http://lifesciencedb.jp/bp3d/
Bioverse	Repository for sharing files and blueprints	Medical	Sweden and online community	2018	Open CAD library of biodevices for the biofabrication field	http://bioverse.co/

Table 1.3 Online communities of developers and online research infrastructures for the co-creation of OSMDs (last access to reference website on August 2019)

Name	Type of resource	Country of development	Year of found.	Additional comments	Link
Patients Like Me	Community for sharing medical cases and information	US-UK and global focus	2011	Search and posting of solutions for medical issues with supporting forum	https://www.patientslikeme.com/
Patient Innovation	Community for sharing medical cases and information	Portugal-founded and global focus	2014	Search and posting of solutions for medical issues with supporting forum	https://patient-innovation.com/
Open-Source Imaging Initiative	Community for sharing medical cases and information	Germany-founded with global focus	2016	Community collaborating in the development of open-source solutions for medical imaging	http://www.opensourceimaging.org/news/
OpenMRS	Developers of open-source medical devices	US-founded and global focus	2004	Open-source medical record system platform, open-source solutions for improved communication, open-source solutions for big-data health	https://openmrs.org/
Praekelt	Developers of open-source medical devices	Africa-based	2006	Open-source ICT solutions for helping with medical practice and patients' management	https://www.praekelt.org/
Open Prosthetics	Developers of open-source medical devices	US-founded and global focus	2006	Search and posting of solutions linked to open-source prostheses	https://openprosthetics.org/
SymbioLab	Developers of open-source hardware and software	Slovenia	2017	Open-source hardware and projects for bioprinting	http://irnas.eu/symbiolab
Enabling the Future	Developers of open-source medical devices	Global community	2011	Global community; open-innovation based on needs and proposals; sharing of complete projects; files and blueprints; focused on hand prostheses	http://enablingthefuture.org/
Glia Free Medical Hardware	Developers of open-source medical devices	Gaza Strip	2012	Developers of free (or extremely affordable) medical hardware with complete projects on stethoscopes, otoscopes, pulse oximeters, among others	https://glia.org/

(continued)

Table 1.3 (continued)

Name	Type of resource	Country of development	Year of found.	Additional comments	Link
Open Bionics	Developers of open-source medical of devices	UK	2014	Developers of low-cost personalized prostheses with open-source collaborative approach	https://openbionics.com/
Soft Robotics Toolkit	Developers of open-source medical devices	US	2014	Open-source projects focused on soft robotics and its applications, many of them in the biomedical sector	https://softroboticstoolkit.com/
Nia Technologies	Developers of open-source medical devices	Canada	2015	Developers of open-source solutions for personalized scan and imaging-based design of medical prostheses	https://niatech.org/
Autofabricantes	Developers of open-source medical devices	Spain	2015	Focused on the collaborative design of personalized prostheses and biodevices; sharing of information	http://autofabricantes.medialab-prado.es/
Metafluidics	Developers of open-source medical devices	US	2017	Open-source community-driven microfluidic devices, many of them with diagnostic purpose, developed and shared in a collaborative way	https://metafluidics.org/
CamTech	Acceleration program for the affordable of medical devices	US	2014	A Communication Platform for Medtech Innovators (not open-source)	http://camtechmgh.org/
UBORA	Developers and e-infrastructures of open-source medical devices	Euro-African community and global focus	2017	Global community; open-innovation based on needs and proposals; sharing of complete medical device projects; sharing of teaching materials	https://platform.ubora-biomedical.org/

engineers, healthcare professionals, patients and patient associations, members of the "maker" movement, amateur designers, families of patients, and citizens in general, so as to help them unite efforts and share their ideas, skills, and resources, toward patient-driven biomedical and regulation-supported engineering research, while pursuing equitable access to healthcare technology.

Hence, the promotion of open innovation, placing patients and healthcare professionals in the center of medical technology development and matching technological offers and demands, constitutes a pivotal strength of the UBORA e-infrastructure (and related community). In the mid-term, UBORA will help to harmonize and systematize the way medical products are developed, as all projects developed within UBORA follow the same standardized structure, and promote the application of standards and the compliance with directives with worldwide recognition, even in low-resource settings and distant communities, where application of regulations and market overview campaigns should increase.

Main UBORA's features, some selected cases of study and forthcoming related projects and activities, covering from biomedical engineering education to detection of medical needs and design and deployment of effective, efficient, sustainable, and affordable medical technologies and devices, are described in the different chapters of the handbook. Such chapters discuss key challenges and expected trends linked to the innovative field of open-source medical devices, hoping that our views and efforts may inspire healthcare professionals and technology developers to join the UBORA community and support the equitable access to healthcare technology.

1.5 Perspective: Current Challenges and 5-Year View

Taking into consideration all mentioned issues and the understanding of OSMDs we have acquired during the last years, in parallel to the implementation of the UBORA e-infrastructure, to its validation through cases of study and to the arrangement of the international community, our personal 5-year outlook perspective regarding OSMDs can be summarized as follows:

- Open-source medical devices are bound to reshape the biomedical industry in the next decade by letting patients, patient associations, healthcare professionals, and technology developers play more relevant roles in the planning, specification, and conception of innovative healthcare technologies.
- Following the example of open-source approaches in other industries, open-source medical devices may well lead to safer and more affordable healthcare technologies, thanks to information sharing and peer-reviewed decisions along their development and through the regulatory compliance verification process.
- Personalization of medicine will be promoted by means of patient-specific developments, including a special focus on rare pathologies, as open-source medical devices can prove technically and economically viable, and still be affordable, regardless the size of production series, thanks to technological design and

manufacturing advances applied in their development that allow a shift from mass production to mass personalization.
- The needs of remote and rural populations will be more adequately addressed and answered, thanks to innovative supply chains that may delocalize the production of open-source medical devices, placing the fabrication facilities in the point of care. This will generate also a synergic economic growth in poorer regions and bring medical technologies to where they are more needed.
- However, several challenges need to be faced and solved in a collaborative way, for supporting the growth of the OSMDs sector. Relevant questions linked to regulation, privacy, safety, traceability, intellectual property, sustainability, and policymaking, among others, still require to be understood, and their reliability demonstrated to a larger scale, in this new paradigm of medical device development.
- We expect that worldwide connected collaborative design environments or communities and related medical device project repositories, from which the UBORA e-infrastructure and community constitute a remarkable example, will enlighten the path toward affordable, safe, regulation compliant, and accessible healthcare technologies for all.
- The question about the possible conversion of selected online collaborative and open-source communities into global notified bodies for certifying medical devices using harmonized standards and directives remains still open but constitutes and interesting thread to follow.
- To achieve all this, reinventing biomedical engineering education, so as to prepare the biomedical engineers of the future for working in international contexts and for developing biomedical projects applying collaborative and open-source methodologies is essential.

Open-source medical devices constitute an emerging trend with the potential for completely transforming the way medical devices are developed and the whole biomedical industry, as some of the examples presented in this study have helped to illustrate. However, several challenges still need to be overcome, in order to deploy the power of open-source and collaborative bioengineering design strategies, toward affordable and equitably accessible healthcare technologies. In this direction, initiatives such as the UBORA e-infrastructure and related international and multidisciplinary communities, as described in detail in this perspective, may turn out to be truly transformative resources for supporting the endeavors toward a well-founded future for biomedical engineering, which will be more open, collaborative, and equitable.

The success of the field relies on the adequate gathering and fulfillment of real medical needs and on the safety of the medical devices developed and delivered to healthcare professionals and patients. To this end, the UBORA e-infrastructure provides a framework to develop ISO compliant medical devices starting from clinical needs by sharing ideas, blueprints, and data. If properly implemented, UBORA medical devices are aligned with the MDR 2017/745 from the design point of view and ready for screening and examination for certification. In a nutshell,

its final aim is to promote well-being for all, increasing access to medical devices and moving toward health equity in accordance with the United Nations 2030 Agenda and the Sustainable Development Goals.

Considering all of the above, the answer to our driving question "Can we transform the medical industry toward healthcare equity through open-source medical devices?" is *yes, we can*: counting with the collaborative efforts of a new generation of medical device designers, understanding the benefits of the open-source paradigm, and adequately funneled to relevant medical needs and safe performance, with the support of online co-creation environments and communities, from which UBORA constitutes a one-of-a-kind example. The transformation is already happening.

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Chapter 2
Towards a Harmonized Methodology for the Development of Safe and Regulation Compliant Open-Source Medical Devices

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2.1 Modern Product Development and Systematic Design Methodologies

One century ago, with the foundation of the Bauhaus and related design schools in Germany, the UK, Russia and the USA, among other countries, systematic engineering design principles were established (Droste, 2019). Until the beginning of the twentieth century, design had been considered an art and not a technical activity or science. Product development had been hence confined to arts and crafts workshops and kept separated from engineering sciences. Working on the principles established just before the World War II, more modern ideas on systematic product development were empowered by relevant figures (Kesselring, 1951, 1954; Tschochner, 1954; Matousek, 1957 or Niemann, 1975), whose proposals continue providing ways for the resolution and management of concrete tasks in engineering and product design projects in general (Kaiser & König, 2006). Kesselring in the 1940s and 1950s proposed engineering design methods based on successive approximations, through which technical and economic criteria were optimized by using varied principles (minimal costs, minimal weight and volume, minimal losses, optimal function). In the 1950s, Tschochner highlighted four essential design variables: function,

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