The Science of Medical Devices Engineering for Healthcare

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Abstract

Bioengineering has matured as a full-fledged field of research, and now bioengineers are designing medical devices, techniques, and therapeutic approaches to combat disorders and to treat and prevent diseases for better healthcare. Among medical technologies, medical devices have assumed importance in disease prevention, health promotion, diagnosis, treatment, and rehabilitation. In general, a medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease or conditions. Recently, there has been an increasing initiative to encourage researchers to develop medical devices that could be used for the rapid detection of diseases often prevalent in developing and underdeveloped countries. This text presents an overview of medical devices and discusses briefly the engineering principles involved in the development of point-of-care diagnostics.

Chapter - 1

Introduction to Medical Devices

According to science, medical devices are instruments, equipment, appliances, materials or other items, whether used alone or in combination, including software necessary for proper application intended by the manufacturer for persons for the purpose of diagnosis, prevention, monitoring, prediction, forecasting, treatment, alleviation of diseases and injuries, investigation, modification of the anatomical structure or physiological processes, etc. [1]. The device plays a crucial part in medication because it can assist in patient care more hospital care. Consider a device bottle that could be utilized to load medicine into a syringe: if the bottle has been designed improperly, the medicine could become trapping in it or there could be leakage about the bottle because of face designs or materials. The main aim of the necessary patient would be greater cause harm. The smartphone applications used to manage blood pressure might be easier for user and hence apps brings down the blood pressure levels of high blood pressure patient. If the app does not perform well, the patient might suffer from stroke [2].

This book was written by engineers wishing to explain the role that medical device development should play and how engineering innovation will ensure that it improves the quality of life, helps to avoid or manage illness, and promises simpler diagnostics and treatments. Today's patient requires a device solution that is of superior quality and achieves a full recovery in the shortest time. Furthermore, any new therapy must be delivered at an acceptable life-cycle cost and be value for money. This book covers each of these issues in detail, giving background information, practical advice, and case histories.

In this book, most chapters have two authors (each an expert in the chapter discipline) and take you through the different stages of medical device development, explaining the design process, the quality assurance needed, the testing required, the responsibilities of the people involved, the regulations that must be followed, and the standards that must be applied. Alongside the text sit clinical and hospital engineering points, questions, and answers. The subjects are diverse, from plastics to silicones, and clinicians to operations

managers: the team that develops medical devices and meets customers' changing needs is equally wide, usually interdisciplinary, and always so. If your degree in medical device engineering or life sciences in the medical device industry did not already prompt you to adopt these roles, you will strive to if you want to join a successful company. You will also want a copy of this book on your bookshelf.

Medical devices are used to diagnose, monitor, and treat medical conditions. They affect patient care, patient outcomes, and cost-effectiveness. The term medical device covers a wide range of devices from tongue depressors to x-ray machines. Some medical devices are invasive, such as heart valves and stents, while others simply involve patient contact, such as prosthetic limbs. Medical device regulation dates back to the Medical Devices Amendment of 1976, which improved safety and effectiveness requirements. The need for these requirements has become increasingly clear, as demonstrated by recent significant recalls of devices that were cleared by the process. The regulation process has seen dramatic changes in the four decades since the 1976 Amendment. The latest changes establish new procedures for reclassification of medical devices. The initiates a three-tiered classification for devices, which is intended to expedite the approval process for devices demonstrating substantial clinical improvement. Computational modeling to help evaluate the safety and effectiveness of medical devices is introduced at the Office of Science and Engineering Laboratories. Three components of advancing regulatory science are described: computational modeling of devices, use of real-world data for model validation, and development of knowledge-base tools to advance modeling methods. Many details about tools and methods are presented, with a particular focus on cardiac devices such as leads, devices, and ablation catheters. Several graphical visuals aid in conveying key concepts. The perspective concludes with a discussion of future directions and challenges in this space. Medical devices are not benign tools that can be unleashed on the market at will, and concerns have been raised about how to generate data for new devices under the scenario. Any therapeutic effect, whether based on device design or patient or disease variable, can be modeled. Since these effects are typically not separate but are highly inter-twined, the expected result is that a device that is effective in one circumstance might not be so in another. For example, a cancer drug that is effective in patients with large tumors might not be if there is no appreciable difference in tumor size. Technology that requires real data must also be supplied to create numerical instances for the model parameters. Such tools raise the barrier of entry for the creation of new devices.

In the broad sense, medical device is an instrument, apparatus, implement, or device, biological material or other article; whether used alone or in combination, intended by the manufacturer to be used for diagnosis, monitoring, treatment, relief or prevention of disease or monitoring, alleviation of, or compensation for an injury or handicap; to investigation, replacement or modification of the anatomy or of a physiological process; which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. Therefore, by its functionalities this definition encompasses a wide range of devices, systems, and technologies, utilizing the appropriate means for a wide range of purposes. Devices can be classified based on their particular functionality as: Devices for diagnostics and guidance – devices that are used to diagnose disease or other conditions; devices used for a wide range of monitoring, either on short or longer time periods; imaging systems, including X-ray, Computed Tomography, Ultrasound, Magnetic Resonance Imaging, Optical Coherence Tomography based imaging; devices for positioning, navigation and stabilization during surgical operations, like robots, as well as imaging-based guidance devices; blood pressure, temperature, respiration rate, glucose level, Oxygen saturation level monitoring devices etc. Devices for treatment – include surgical instruments; therapeutic devices for percutaneous, non-percutaneous or other type of ablative treatment, for example RF ablation therapy devices; brachytherapy devices; physical therapeutic devices, for example external or internal ultrasound; diabetes; other therapeutic devices implanted in human body (e.g. stents, meshes etc.); prosthetic and orthotic devices; In-vitro devices e.g. dialysis fluid changing devices for stomach, blood, for automated monitoring of chemistry parameters based on the blood samples, separate blood draining and return lines for patients on dialysis therapy, devices for effective sealing of blood vessels based on inflated cuffs stopping the blood flow (e.g. Blood pressure measuring device in a form of sphygmomanometer), devices for hemostasis of the blood (e.g. hemostatic clips), devices using blood as medicine. Also devices that are not blood containers or similar, but fabricated in contact with body for more than 30 days are, in principle, excluded from this list. Urological catheters and similar devices were invented and already in use as early as XVIII century. Head, both diagnostic and therapeutic, is important part of the medicine, and thus, the work on the devices containing, or otherwise interacting with the head, is always ongoing. In line with the above, it has been proposed that the brain computer interfaces used for controlling other devices, can be classified as a medical devices. All these facts, for demonstration purposes, highlight the basic meaning of

medical device and their interconnection with the certain aspects of medicine. The meaning and importance of medical devices in modern medicine, and general technological terms, are described in greater detail. In meantime, let note that some kind of robotic devices used for neurosurgery on the brain is only used in neurosurgery anesthesia. It was developed and implemented in 2018. Other useful robots in neurosurgery, in the form of assisting during the surgery and adapting to the movements and vibrations, such as ROSA robot, have been on the medical technology market since 2017. Overall, medical devices have been widely used in the treatment; monitoring diagnostics etc.; of a wide range of acute, chronic and aging diseases [1]. Tens of thousands of different devices are covering every aspect of the human body, each classified in many different subclasses. Thus, a variety of some urgent and important examples of medical devices as different types for new wide knowledge finds are included in the document, this list only emphasizes that fact in a limited number of devices. Acoustic, ECG and PET functional brain imaging devices; Diagnostic devices for cancer screening, for kidneys, liver; bionic, robotic eye implants; Light-based intracranial devices after traumatic injury in car accident; Prostheses for knee and hip replacement, bionic arms and leg; Vaccine administrations, vaccine manufacture equipment; Stents, AICD and drug-eluting stents; Breast implant saline filling devices; Ranolazine DDS, Varenicline gums; Intravascular and other types of construction embolization; Psoriasis disease treatment devices; Extensions of inflammation sounds ETC.

Medical devices may differ in their aims and configurations. These types involve equipment, items, accessories, resource components, and application of software reagents or alternative incubation. They may be utilized either on their own, in groups or in conjunction with other items – like the machine, software, and equipment. The procedure may be physical, mechanical, philological, chemical, electrical, IT, merging operations, or biological. Equipment to calculate patient important signs (respiratory rate, blood pressure level, and heat beat), X-ray devices, associated logical program, bands, tensors, acoustic, dental and additional medical equipment, non-contact support equipment to spread body energy products into tissues and to discover its electrical status device, diagnostic procedure that internally go into the body or are surface evaluated, analyze system of the electric or motor ability of a human body, check body odors, etc. with their main function is or estimation of a medical situation to choose a treating way. Equipment to monitor or maintain life-different aimed equipment that monitors or maintain life or essential functions of the body, even if the devices does not fit within the definition of medical devices [3, 4, 5].

1.1 Definition and Classification of Medical Devices

Medical devices are defined within the healthcare sector as a wide variety of instruments, apparatus, implants, software, and reagents intended by the manufacturer for use on human beings for therapeutic and diagnostic purposes. Many definitions of medical devices take into account the intended use. Such equipment is used, either alone or in combination, for diagnosing, measuring, treating, monitoring, alleviating, compensating for an injury or handicap, controlling conception, or disinfection. Risks and benefits related to the application of a medical device need to be taken into account. Due to these aspects, different categories of medical devices have been classified. The most common classification system divides them into four major classes: class I, IIa, IIb, and III. These classes reflect the vulnerability levels of the patients: the higher the class, the higher the respect of them [6]. Furthermore, it is aimed at providing general guidelines to assist manufacturers, notified bodies, and competent authorities in the interpretation and application of medical device definition. Several medical devices are considered to meet the definition of active medical devices. This requirement applies specifically to medical devices that incorporate electronic programmable systems and software that drive medical devices, like a ventilator or the quantitative analysis of medical images. The classification of the medical devices is established to regulate the market access. It can't be arbitrary and cannot be changed, except as provided by the EU regulations. Regulatory criteria need to be clearly stated and fixed, to ensure legal certainty for all parties involved in the medical devices field. Therefore, as foreseen by the EU medical device framework legislation, classification of the medical devices needs to ensure the safety of the patient and the user, be designed and manufactured in such a way that, in normal conditions of use, they do not compromise the clinical condition and the safety of the patient and the user and their performances do not differ from the performances declared by the manufacturer. On the contrary, class I devices should be designed and manufactured so that, when used in accordance with the intended purpose, they are safe and comply with legal requirements, bearing in mind that class I devices can integrate also by themselves a proprietary medicinal product, including chemical sterilization. As a matter of fact, different rules and standards do apply to the various classes of the devices. The aim of these legal obligations is to go from conceptualization of an idea for a device on the market (manufacturing process) up to the final disposition: withdrawal of the device from the market and its proper disposal. This defines the complete life cycle framework for the medical devices, including post-market surveillance and clinical follow-up of the devices, in addition to vigilance.

Chapter - 2

Biomedical Engineering Principles

In modern healthcare, medical devices are used as integral components of patient care across a broad spectrum of clinical specialties and disease states. This includes drugs and biomedical instrumentation, imaging modalities and implantable technologies, minimally invasive and robotic procedures. The development of such devices requires a thorough understanding of the foundational principles of biomedical engineering, which rest at the intersection of engineering and biological sciences. Scientists apply principles of mathematics and physics, chemistry and biology, material science and computing in a thorough understanding of living organism operation in order to design solutions for its health preservation under specter of various diseases and conditions [7]. However, it falls to engineers to further translate these principles into products that find use in patient care. In simple terms, the professional discipline of these engineers is in the design and validation of medical devices.

Engineers involved in medical device development then are the figure that bridges the gap between medicine and technology. As the basis of medical device development is human healthcare it is vital to understand human organism operation and structure, the functional state of the body and of its discrete components. For similar reasons, it is useful to comprehend the principles of medical kit operation, particularly those principles that are universal and not bound to a particular technology or a specific piece of hardware. The operation of medical devices is based on a set of principles each grounded on one or more natural phenomenon. The precision of the devices in diagnosis or treatment relies on the coherence between the devices principles and their inherent phenomena and the biological processes phenomena which the device aims to articulate with. Therefore, comprehensive understanding of the principles of devices operation is required for the professional of medicine that deals with devices, the development scientist who designs them, and the uninitiated (most of which are the patients whom the devices are designed for). Supplying such profound knowledge will be one of the objectives of the manuscript, which in turn will encompass a set of lectures that were given in consecutive semesters of

lecturing on Assisting Devices. The background as refers to the aforementioned principles spans from the most basic mathematical and physical knowledge to the highest league of engineering that formulates design considerations or can research complicated physiological systems. These subjects, in turn, cover a wide range of sciences. Nonetheless, some issues are ubiquitous in nature relate to a variety of biomedical disciplines and are therefore seem to be suitable as foundation for the manuscript [8, 9, 4].

2.1 Biomaterials and Biocompatibility

Medical devices are tools that provide a number of healthcare options. The development of prostheses, diagnostics tools, life-sustaining equipment, and inserts all owe themselves to innovation in medical device creation. This progress, of course, longs to a large degree to advancements in technology. The application of engineering to a medical context has led to a rise in both the quality and quantity of available devices. However, the importance of the concord between a patient's physiology and the materials used in a device should not be understated.

In biomedicine, devices are generally categorized as absorbable, nonabsorbable, or combined types. Natural, synthetic and polymer metals compounds are what make up the structure of these devices. The structure of a device must be taken into account. A stent's crimped structure, for example, allows it to move through a catheter with the same general structure before deployment. The material used in a device must be appropriate so as to prevent health complications post implantation; a poorly designed metal biomaterial can lead to a histotoxic or cytotoxic response. If long-lasting devices are needed then alloy metals or polymers must be used for the prevention of biodegradation [10].

Biomaterials scientists have a role in the selection of appropriate materials. There is a vast array of different types of biomaterials which can be used. For example, artificial skin grafts can be constructed from biodegradable silk materials. Despite the many options, there must be understanding of which to use. This is because once deployed, the body may reject a foreign device. A classification for the Body's Rejection Response (BRR) to medical devices in general. Materials or the pollutants they generate may accelerate these responses; polyurethanes, for instance, directly cause high inflammation. Despite potential of device innovation, efficacy, the understanding must be continuously sound. Principles of biomaterials are fundamental to performance. At the very least, biocompatibility should always be tested. The more a device's performance is enhanced by its materials; understanding

should become more deeper. Therefore, the relevant topic discusses recent advances in relevant materials research and how the benefits can be expanded. When medical devices are designed for clinical roles, the role of biomaterials inherently enters biomedical design [11, 12, 13].

Chapter - 3

Design and Development Process

Design and Development of medical devices is a structured process of understanding user needs, and then turning these into comprehensive Design Requirements that are subsequently used to guide the creation of a safe, effective and fit-for-purpose device. A systematic approach is often utilized to achieve this, but how this is done can differ greatly between manufacturers. It might not be apparent to the clinical end-user, but many of the medical devices they encounter have been through a fairly typical design process. This iterative cycle of design, prototype and testing results in both the functionality of the device and the user interaction with it being refined over time. There is significant interplay between user-centric design and the core technology of the device, (e.g., how a user is going to adjust a setting on the device will also significantly affect how that setting is being measured) [14]. The process can often be initiated by an identified user need, or even perhaps by a new technology, but is then followed by a cycle of careful specification and testing to iteratively refine the device. Design is therefore a process that can greatly benefit from a good level of user interaction, be they clinicians, patients or other users.

Design is only one part of this system however. It's also about how designs are tested and refined through use, and how through life there are tools to monitor device performance and redesign if necessary. The role of Engineers and the design process in the development cycle is often overlooked, but (as in many other fields) Engineers have an appreciation for design criteria that is of a scope beyond that of the designer, in the same way that designers appreciate capabilities of design that the Engineer does not. Device quality is also assured throughout this process through a mix of stringent 'Design Controls' combined with comprehensive risk assessments, which both ensure a 'poking and prodding' approach to design. Devices that are developed are designed to be reliable and safe, and then they are tested well beyond their operational limits. However, safety can not only come from a safe design, but it's also about being able to predict and adapt designs to a range of use conditions that are not anticipated during development. This is why device manufacturers insist on being involved in case studies of products

after they are released; with no insight into these use conditions it is impossible to design to them.

3.1 User Needs and Requirements

The development of medical devices is a complex, multifactorial process that must account for a range of technical and clinical concerns. In view of this, much effort is required early in the development trajectory to ensure that upon completion a device successfully meets the predefined and relevant user needs [15]. Firstly, research is required to establish what these needs are, and their relative priorities; then, clear and actionable design requirements must be developed based on these insights. Pharmaceutical companies, research institutes, and governmental bodies increasingly recognise the importance of implementing a user-inclusive approach to ensure that devices are effective within their intended application. Accordingly, both the FDA and the EMA have introduced new guidelines which encourage developers to actively engage with end-users throughout the device development process [16]. It is suggested therefore, that user needs analysis is an integral and iterative part of the medical device development process. The most productive manner in which to meet user needs is to begin by identifying the desired features and acceptability of a proposed device through direct user consultation. This information can then be used to initiate and refine the development of a device, incorporating the views of both healthcare staff and patients at each stage. As the development progresses, further feedback can be sought through the implementation of a range of methodology, such as usability tests, focus groups, clinical simulation, and direct observations. These feedback loops will continue throughout the R & D process, continually shaping and refining the intended design, culminating in the production of user-friendly, widely accepted devices that meet the stringent clinical demands currently in place. Two and a half million children underwent medical or dental treatment under general anaesthesia in England between April 2012 and March 2016. Six out of ten have one or more teeth removed, and it is the most common reason for hospital admissions of children aged five to nine. Almost a quarter (24.7%) of five-year-olds have tooth decay in England, and this is of particular concern in urban areas such as Greater Manchester, where child tooth decay is higher than the national average [17, 18, 19].

Chapter - 4

Regulatory and Quality Assurance

From neonatal ventilators to MRI machines, medical devices have made an unquantifiable impact on healthcare, decreasing mortality rates, improving patient quality of life, and providing more efficient patient care. Practitioners and academics aiming to enter the rapidly growing medical device industry are required to understand the science of medical devices as well as the design and manufacturing processes. However, the regulatory landscape that governs this multi-billion-dollar global industry is rarely discussed within academia or the broader engineering community. These regulations are vitally important for ensuring safety, efficacy and enabling industry growth. This article aims to explore and demystify the medical device industry's regulatory framework in an accessible way for those looking to enter the field.

Medical device regulations and standards differ significantly around the world. In the U.S., the Food and Drug Administration (FDA) has long been in charge of regulating medical devices. The FDA groups medical devices into one of three categories based on potential risk to the patient. Devices classified as low risk, such as elastic bandages, are placed in class I and typically require only general controls to achieve regulatory compliance. Medium risk devices comprising the vast majority of medical devices, such as surgical gowns and portable defibrillators, are classified as class II, and may require special controls in addition to general controls to ensure safety and effectiveness. Finally, high risk devices or life-supporting machinery such as ventilators, pacemakers, and replacement heart valves are placed in the highest risk category-class III-and generally must have pre-market approval (PMA) to ensure safety and efficacy [20]. The class to which a device belongs has a pivotal effect on timelines, costs, and validation requirements of the device development process. Over in Europe, medical device regulation is significantly more fragmented. The CE marking process first exists at a national level involving 34 different competent authorities, before the involvement of CE marking by accredited third-party certification bodies notified by the bound state [21]. These diverse regulations and standards present engineering businesses with a complex and globally daunting environment.

4.1 FDA Regulations and CE Marking

Every medical device must meet a certain set of regulatory requirements before it can be brought to the market and sold. Understanding the regulatory pathway is essential for companies preparing to bring new medical devices to the market. In the United States, regulation is conducted by the Food and Drug Administration (FDA), which sets requirements for safety and effectiveness. In Europe, the relevant authority is the European Commission, which indicates conformity with the CE marking of medical devices.

Medical devices are classified as I, II, or III in Europe, or as I, II, or III in the United States, depending on their potential risk to patients (this classification generally aligns well between the two systems) [21]. In general, the classification considers duration of contact with the body, potential invasiveness, contact with the blood or cardiovascular system, and other factors related to potential biohazard or disturbance to normal body functions.

Together with the rules and regulations of the nation the medical device will be sold in, the classification helps determine the pathway that must be taken for the medical device. While some aspects vary between the United States and Europe, the standards for acceptable safety and effectiveness are generally very high. However, the process for a medical device to conform to those standards differs between the two regulatory regimes. Understanding both similarities and differences may help the developer save precious time when moving into new markets [22, 23].

Chapter - 5

Emerging Technologies in Medical Devices

Emerging technologies are shaping the future of medical devices. These cutting-edge innovations will revolutionize healthcare in diagnostics, treatment, and monitoring. The trends driving the medical device industry are miniaturization, connectivity, and personalization – allowing, for example, ports for smart phone Android applications that can check blood oxygen levels, pulse rate, and other vital signs. Emerging technologies can be categorized by type - materials, sensors, actuation, systems and communications - and each is illustrated. While regulation often stifles innovation, a new breed of medical devices that are not disease or condition-specific and target general wellness, are not FDA-regulated. Research and development in medical devices covers a wide range of applications. Some examples are given in telemedicine, minimally invasive surgery, and robotic surgery [24]. Products and technologies that may not yet have been invented will come into being as a result of a 3-year interdisciplinary research project to "Decipher the Brain". To establish a model of how the brain processes auditory location, mathematically based algorithms will be developed, and a micro-devices company will design micro-scale biological and electronic components for integration into a neuro-electronic interface implant with the brain. The clinical partner will be responsible for housing the implant in the skull and interfacing it with the brain. The project will demonstrate the benefits of long-term collaboration between clinicians, technologists, and engineers. Post MARK Technologies is a small innovative company. One of the applications of its unique technology platform is a low-cost fingerprint reader that can be integrated into a range of mobile phones, smart cards, and thumb print mice. This immediately provides an opportunity to make mobile-based health care improvements and to develop real-time health-monitoring devices that can wirelessly interface with home PCs. These technologies can meet multiple global health care needs [25, 26, 27].

5.1 Artificial Intelligence and Machine Learning

Artificial intelligence (AI) and machine learning (ML) have found a home in the design and operation of medical devices, creating a powerful tool for

healthcare improvement. ML particularly can equip devices to analyze enormous data troves with speed and precision far beyond human capacity. In turn, devices can act on that data in real-time, delivering diagnostics or treatment plans which were once only possible with lab-intensive techniques. Through combining the enduring concept of 'self-optimizing, self-monitoring' (SOSM) machines with modern ML tools, medical devices can adapt to changing parameters for improved performance [28]. Medical devices can take data from vast and varied sources, both direct-through patient interaction, and indirect-such as humidity and pollution levels, to create a detailed physiological profile. These devices can monitor vast sets of data in real time for both the patient in question and the wider population, developing predictive, personalized care. For a single patient, such a device may notice early markers of depression from, for example, a change in sleep patterns, recommending an increase in their outdoor time while maintaining gentle exposure to daylight and making an inventory of mental health resources. For clinicians, devices can have time to suggest diagnoses or screening regimes, and flag cases which need urgent care [29]. Currently, the highest profile applications for ML in healthcare are predictive analytics for in-hospital monitoring of patients and decision support systems or doctors. On both accounts the potential benefits are enormous, improving clinical outcomes while reducing treatment times and costs. There are, however, significant challenges to be overcome. At present, the 'black box' aspect of many ML algorithms is an issue where the interpretation of outcomes, particularly within the clinical context, is necessary. In the wide-ranging, underfunded and otherwise neglected field of automation safety, there will need to be particular attention to the balance between commercial confidentiality and transparency of these 'internal' workings. There is a potential for bias in the utilisation of ML algorithms which will require ethical oversight and ongoing dialogue between clinicians, regulators, and device designers or operators. AI-driven medical devices are not yet widespread, but with a rapidly evolving technological landscape and the ongoing inroads of AI into all aspects of modern life, it is not a question of 'if' but 'when' they will become a feature of the healthcare system. Regulators will need to anticipate and adapt to accommodate these devices in a manner that prioritizes safety and efficacy rather than retrenching into defensive positions [22, 30, 31].

Chapter - 6

Ethical and Social Implications

In a workshop climate, every single deliberation that is held is not just a mere discussion; it is a trajectory and a vital resource for future endeavors. Enrichments and enhancements should be considered the customary and expected reaction to the subjects that have been resolved within these discussions. When we delve into the historical progression of this residential foundation that was established back in 1985, the coordinators involved in this initiative reasoned that the task was fundamentally about the contemplation of the civilized and material atmosphere that most notably supports and backs healthy victories of scientific endeavors in the realm of diagnostics. This specific focus on engineering tailored for healthcare is undeniably more pertinent today than ever before. The creation and use of medical devices is a complex interaction that is inextricably entwined with the ethical, societal, and legal implications that arise from medical practices. This particular station of thought examines several ethical choices that professionals in the field must navigate, and it forces forth a comprehensive schema that highlights the value field alongside other important considerations, diverging from the perspective of mere commanders who may overlook these critical aspects. In a workshop atmosphere, each deliberation serves as a powerful means to explore varied dimensions of any issue at hand. Furthermore, if the contained subjects reveal particular insights and provide given tickets for certain engaging topics, the remainder of this post will endeavor to thoroughly explore infections, along with related topics within the sphere of economic practices that intersect with healthcare and diagnostics [32, 33, 34].

6.1 Privacy and Data Security

Patient data is being managed and tracked by medical devices more and more frequently as the boundaries between consumer health devices, medical devices, and patient model validation tools are blurred. To improve user health or fitness, wearables, implants, and other monitoring devices collect physiological data created, transmitted, and processed. Diagnostic and therapeutic devices also take data from patients, but it aims to satisfy clinical, biomedical, and treatment research aspects. Microcontrollers and memory of

data become omnipresent in medical devices. Patients expect their data to be kept secure, through security breaches and unauthorized data entry, keeping discrete by third parties. If data safety does not improve faster than patient data tracking and processing by medical devices, relational data handling may be adversely affected. Many computational medical devices are wireless inputs or configurable over wireless interfaces, expediting direct security vulnerabilities [35].

The ethical, legal, and practical dangers of patient data tracking and protection by computational medical means are addressed. Safe data protection by strategies concerning security risks, defensive style, and information sharing awareness is recommended. However, these suggestions are not itself a comprehensive framework and are recommended as a part of a broader strategy by patient data tracking and protection. This section discusses privacy and data safety related to the medical device handling of patient data. Unauthorized access, data brakes, and data confidentiality violations are typically dangerous information observation machine. When visited, it is challenging to retrieve and may contribute to a lack of trust in societal skills. Users may face discrimination in care and eco settings, may be confidently discouraged, and avoid care walking away from devices that may otherwise have been beneficial [36]. The data storage, broadcast, or other transactions of patient-developed medical records or clinical trial data used to generate patient displays are also taken into account with the patient data. Safeguard sensitive information in medical device operation, manufacture, transport, and other consumer-produced needs. In order to protect health-related information gathered or handled by entities within the US, the Health Insurance Portability and Accountability Act (HIPAA) introduced many rules and compliance activities. EMC and electronic safety are topics of significant importance in formal science and medical testing demands. However, encryption [37, 38, 39].

Chapter - 7

Case Studies and Examples

Research, development and innovation in medical devices will be transformed by the Internet of Things and the availability of huge new sets of health and personal data. These technical changes will both enable new products and structures and lead to social and behavioural changes. Legal frameworks are being developed which seek to make use of the potential for users, whether patients or healthcare professionals, to take greater control and responsibility for medical decisions and treatment. Given the cost-effective adoption and use of new support equipment has long been a significant issue for new healthcare technology, particularly in the developing world, the implications these rapid developments will be explored through key examples and studies.

An overview of what makes a successful medical device will provide the background to a wide range of case studies and real life examples from academic and industry partners. These show how novel engineering combined with an understanding of the needs of the users can result in breakthrough products that are changing healthcare worldwide. They also outline the steps in the process from inspiration and needs identification through prototype production, evaluation and on to successful market introduction, while also including the more numerous failures and important lessons learned. The importance of joint working with both healthcare professionals and end-users, calls for which will become more widespread with the new era of patient control of treatment, will be highlighted throughout [40, 41, 8].

7.1 Successful Medical Device Innovations

Medical devices have transformed healthcare delivery around the world, opening new frontiers for patient monitoring, surgeries, and diagnostics every day [16]. But where do they come from? How are these life-saving instruments born? Since the days modern engineering design began, some done by happy accident or tinkering, but much born of blood, sweat and tears (and equations) of very clever men and women. This work neither celebrates all their sufferings, nor demands understanding of the endless intricacies and hair-pulling induced by finite element studies of saccular aneurysms. Medical devices have historically played a crucial role in healthcare practice, as

essential tools for diagnosing, monitoring, and treating patients. They have evolved together with medical sciences and other healthcare practices, as biomedical engineering innovations were adopted more widely in the clinic. Key inventions and discoveries that have been assimilated in the healthcare system have taken place in different moments of history, since medical knowledge was imprecise and rudimentary, especially in ancient times until the Renaissance onwards. Noteworthy examples of devices and products not considered medicine at the moment of their invention are lenses in the XIII th Century, the printing press in 1455, or a practical steam engine in 1712. The stethoscope was invented in 1816 and it is considered a landmark in healthcare practices even if the concept of "germs" was not widespread at its time, and therefore its use was contested [2].

With the Renaissance and due mainly to the subsequent developments in the understanding of electricity, chemistry and optics, the creation of devices intended for medical purposes became more frequent. The French Revolution also had a remarkable influence on medical practices by generating an approach to medical knowledge based on observation, measurements and treatment, with consolidated results in modern Western medicine. For that reason, X-ray has not been included in this historical list, despite it was discovered accidentally in 1895 because its use on medicine did not take place until some years later, when its effects and limitations were better understood.

Biomedical engineering (BME, also recognized as bioengineering) is a multidisciplinary area that specializes in the development of tools, systems, and technologies for the delivery, monitoring, and enhancement of health care. Biomedical engineers work together with health professionals and scientists to apply engineering principles to medical and biological problems, integrating a wide range of activities from the conceptual design to modeling and simulation to the development and management of health systems and regulation. Hence, the biomedical engineering field sums up modeling, simulation and design of devices, systems and medical procedures.

Core to BME is the study of anatomy and physiology, so devices and systems can be designed to be able to interact properly with the human body. Biomedical engineering is often said to be an interdisciplinary field because of the overlap and integration of its various coupled specialties. BME merges medical and biological sciences with the fields of engineering, in an overall effort for improvement of health care. The interdisciplinary nature of biomedical engineering is particularly relevant because it aids to create and maintain medical devices and regular health care systems stable, safe, secure, and tolerant to environmental and outside interferences which perhaps

wouldn't be that likely present in the event of a separate treatment between health sciences, or engineering [3]. Because of this significant role as a bridge between medicine and engineering, it is essential for students in Biomedical Engineering to learn closely about health and medical sciences, as well as basic know-how in biology and biotechnology.

Understanding the function and design of medical devices that interact with the body requires knowledge of basic anatomy and physiology. Thus, provided is an overview of both concepts prior to exploring the areas that will guide engineers in designing such devices [3]. As these concepts are already familiar to many healthcare professionals, only a brief primer will initially be provided before delving into issues that are particularly important in the context of device design and placement.

A variety of the structures described were first systematically named by Vesalius in 1543 and are still commonly known by their Latin terms. For the sake of comprehendibility, anatomical terms are translated where necessary, although Latin names are retained. Similarly, English terms are used for basic physiological concepts. The anatomical structures and physiological processes of eight body systems which are particularly important for designing medical devices and considering device placement are addressed, including the cardiovascular, digestive, endocrine, musculoskeletal, nervous, reproductive, respiratory, and urinary systems. An overview of the anatomy and physiology of these systems is provided, addressing those issues which are most pertinent when considering device placement and functionality [4]. One of the challenges in designing medical devices is that they are used in such complex biological systems. It is essential that a medical device is designed within the stipulated framework where it will operate. Therefore, discussing both normal and pathological aspects of the aforementioned body systems, and the implications of device design in both scenarios, can elucidate this relationship across many of the most common medical conditions and treatment modalities. It is clear that body systems are interconnected, and that directs how devices can impact more on them. As such, it may be 'further fields,' which are also basic to the understanding necessary for safe and efficacious devices, are explored.

The basics of anatomy and physiology are rapidly adopting a great significance in engineering. The future of medical devices relies on engineers who are able to design systems that interact with the body in controlled and comparatively predictable ways. In order for medical devices to safely and effectively treat or support failing body tissues, it is essential to understand the context surrounding them. That encompasses understanding the body tissues where the medical device is situated, the interconnections between multiple

tissues and biological systems, the efficient and accurate means by which devices can influence tissue property, the harmful effects devices have on surrounding tissues, the balance between beneficial and harmful treatment, and the means by which these and related knowledge are advanced.

Medical device development is the carefully considered design and manufacture of devices for the prevention or detection of illnesses, or the maintenance and surgical intervention of physiological conditions. The design, development, and manufacture of devices for healthcare demands a comprehensive understanding of math, sciences, thermal capabilities, materials, control and information theory, and the manufacture, processing, and fabricating of both engineered and biologically derived materials. As such, medical devices have been designed to bypass the limitations of healthcare interventions due to limitations in cost and ability, as they provide the potential to monitor physiological conditions remotely, delivering drugs or therapeutic agents with controlled release. Despite this potential, the development of medical devices for healthcare is a multidisciplinary challenge, having to overcome the complex biological landscape and strict regulatory pathways.

An essential component of medical device innovation is the choice of the material. Since the first iteration of devices, there has been an exhaustive search for materials with the best performance in certain applications, such as hardness and toughness of metals, visibility, and flexibility of polymers. Considering the application in healthcare, a different criterion is pursued, that is, the biocompatibility of device material with the biological systems. The material is considered for healthcare applications based on its processing, mechanical, and material properties, as well as how the device is intended for function and with respect to the method of manufacture. For healthcare applications, material biocompatibility with biological systems is the considered criterion above all others. From this point, engineer material experts have designed and engineered many different classes of materials with unique properties and applications; in biological systems, these are referred to as biomaterials. The careful and strategic choice of biomaterial is necessary for its intended function, as depending on its class, it can integrate with host tissues forming stable covalent bridges (metals, ceramics), produce a controlled immune response (polymers, composites), or modulate cellular responses, accelerating or decelerating. In healthcare, biomedical engineers have developed non-resorbable scaffold stents and orthopedic implants that promote tissue growth, and integration as well as resorbable alternatives allowing for natural tissue regeneration. Despite its success in the manufacture

of these medical devices, mastering the properties of biomaterials is complex, as they are subject to both material degradation and bioactivity, processes that are not well understood mechanistically and that depend greatly on the material in question with the biological system in question. As a result, while unassuming visual inspection indicates the simplicity of medical devices, understanding their safety and efficacy in clinical use involves a deep, comprehensive knowledge of material science and beyond, presents a significant barrier to entry for new devices and will be the focus of future biomedical research [5]. Nonetheless, there remains substantial opportunity for technological innovation; the understanding of emerging biomaterial properties can be exploited in medical device development. Amplification of this effect offers the potential for novel healthcare solutions in a myriad of settings beyond what is currently possible.

Instead, this work focuses on systems-level medical devices, iterations of well-established principles driven by burgeoning technological capability, and disciplined design methodologies. Furthermore, devices later transformed through interdisciplinary collaboration between engineering, clinicians, and that most endangered of species: patients. Leading this journey is the humble pulse-oximeter, which routinely clips onto a patient's finger and siphons information from the randomness of haemoglobin into valuable feedback for doctors. In the 1980s, however, the engineers and clinicians behind this device had significant hurdles to overcome: duration, inaccurate readings, and motion artefacts precluded widespread adoption. Behind each beep in the cardiocatheter lab were endless hours learning, challenging, thinking, creating But engineering exists to solve problems, and solve them they did, with market domination in the process. And tens of millions of people lived happily ever after.

These success stories paint a very small vignette of medical device innovation, but they illuminate broader trends of the industry, moving arythmias to bedside, minimally invasive surgery from low-reliability tools to industry flagships, and uncovering previously invisible physiological information, all the while subject to rigorous regulatory standards. And the story continues on, automatically resuscitating arythmia patients, colonoscompod in the comfort of one's home, artificially-intelligent pathologist assistants. Like the hearts they monitor, medical devices will evolve and adapt ad infinitum, always striving to outsmart the ceaseless advance of Horn's scythe.

Chapter - 8

Future Trends in Medical Device Technology

This year, Medicine was affected like never before by the global pandemic, but it also fostered the chance for an intensive boost in technology development. Medical devices and technologies are the pivot of these changes, and the eventual future might bring the broad spectrum of purpose-driven, intelligent devices and technologies to be used personalized and pervasive in all settings, not only healthcare. A view of "Future Trends in Medical Device Technology" was discussed by four leaders of the most dynamic and prosperous Science, Industry and Markets fields. The discussion addressed how Technology is offering transformative solutions for Medicine, the need for a patient-centered design in Medical Devices, thoughts on Service and Support for sustainable and safe healthcare technology, and how to manage Regulatory Frameworks to overcome Technology. Current trends in medical device technology underscore a rapidly changing and exciting field. The integration of technology in health care has steadily increased and a number of new, innovative device technologies are now being developed that will transform medical device technology. The period 2003-2013 will see a focus on the application of nanotechnology. Consideration is also given to possible approaches to verifying the biocompatibility of devices as defined in ISO 10993 that use nanotechnology as a component of their construction, or for devices where a biological effect may be expected e.g. nano-positioning devices used in medicine.

It is well understood that within a couple of years devices that can present novel forms of delivering drugs: novel materials (including such materials as stronger, lighter materials for cast and splint technologies), more widespread use of fractal geometry (which has been proven to be important in predicting more uniform wear on tires), design innovations (improved aesthetics and ergonomics), new materials (enhanced performance, reduced weight) and manufacturing innovations (where first tial components are reduced from price points as high as $200 per device down to the $20-40 price point, material is retained where needed, reduced where not) have had a beneficial impact. At the same time, the maintenance imperative on other medical equipment is one of keeping it running until the technology has truly changed,

as with linear accelerators, cobalt units, and to a lesser extent, digital thermography devices. In general, the medical field typically lags a step behind the general consumer population [1].

Enrichment in science and engineering has always been in favor of better healthcare solutions. Over time, major innovations such as vaccines, antibiotics, and imaging modules made significant transformations, and new pathways to their utility have been prescribed. With the growing rate of people diagnosed with chronic diseases, numbers have pushed up on the development of healthcare tools for real-time health data monitoring. As a result, innovative methodologies were endorsed, and especially portable health monitoring devices were under the spotlight. The development of portable health monitoring devices and their technique use was a critical discovery for healthcare specialists. Portable health monitoring devices were first introduced by the Swiss Templar Knights in 1099. These portable devices were broadly used to monitor vital signs such as body temperature, heart rate, and blood pressure, which had been written down on the palimpsests [2]. It was easily observed if the patient was healthy or not by examining the written records. Recognizing that technology can make everything better, the healthcare industry has begun to invest remarkably in portable devices in the 20th century. Before that, healthcare professionals gathered data manually, and most evaluations were observations gained from patients. Therefore, medical data and diagnosis were not as reliable as they are now, and the healthcare industry failed from this point of view. The invention of portable devices set up a foundation for better health data collection and health record preservation.

There have been many reasons why the invention of new portable health devices has been gaining ground in the modern era and there are also many reasons for the use of the medical device. One other reason portable health devices are so important is because some devices can be attached to an outpatient on their arm, chin, or head and then join the individual at home. Each time you eat and produce vital signs, these devices demonstrate physical information to the individual. As a result, the patient can change their lifestyle and avoid overeating in a steady position, maintain oxygen levels in the blood, or incorrect times for nutrition intake. This has a direct impact on the avoidance of hospitalization. Another important attribute of portable healthcare devices is that they can supervise patients with chronic diseases. Patient behavior can be monitored within their activities by monitoring nearby devices [1].

Fast technological advancement is spurring innovations in medical devices to treat patients in a more effective, efficient, and comfortable manner. Emerging medical device technologies have been well integrated into the internet of things (IoT), artificial intelligence (AI), robotic systems, smart sensors, and much more. This essay aims to recognize those emerging trends for medical devices and foresees their future applications in the healthcare paradigm. This also proposes the evaluation methodology to study the effectiveness of those emerging medical device technologies, ideas, and the possible risks they may bring.

The aim of this study is to recognize the emerging trends in medical device technologies that will impact in the near future. It expects this research to identify the potential growth of medical devices and their transformations which will inevitably result in significant productivity gains across the healthcare services, diminishing the intensity of clinical activities and permitting healthcare facilities to treat more individuals. For instance, new classes of medical devices could execute unambiguous tasks, far exceeding human accuracy, consistently managing and maintaining an astronomical amount of detailed patient information as current systems are quite limited. In addition, emerging medical devices ensure the promise of more efficient and value-based healthcare service delivery. This research aims to examine prevailing and emerging medical device technologies in order to enhance the effectiveness of healthcare while affording a better and safer patient user experience, ultimately assisting in optimized physician involvement. To complete these comprehensive evaluations, monitoring effectiveness, and in-depth functional usability testing assessment methodologies are proliferated. The importance of modern medical devices, including potential usage growth within the developed, transformed healthcare paradigm, proposed methodologies to study related effectiveness, user experience, safety, as well as other potential ethical, regulatory, and socioeconomic factors are all analyzed thoroughly [1].

Many categories of medical devices have evolved into complex, computer-based systems that can increase the efficiency and effectiveness of medical treatment and patient care. However, the overall system safety and effectiveness can be limited by the capabilities of individual devices to interoperate with other medical devices and with healthcare information systems. To date, application of modern engineering solutions, especially those that are information and communicative technology (ICT) intensive, to these problems have been limited or ineffective. NIST has responsibility in enhancing the competitiveness of U.S. industry by understanding priorities

and supporting the development of measurements, measurement technologies, standards, and advanced manufacturing technologies. NIST may have interest in learning more about actions that can be taken in support of improved safety and effectiveness of medical devices as systems of systems, while understanding imperatives in the U.S. regulatory environment. In April, Professor were hosted at NIST's Gaithersburg campus to discuss such topics with a team of NIST engineers. To expand on this face-to-face dialog, the key insights that were revealed, as well as the exploratory and concrete tasks for NIST that were discussed, will be summarized to help guide planning on both sides.

In the contemporary healthcare sector, divergent advances in medical technologies have witnessed newfound acceptance and widespread use concerning medical devices. Medical devices are any apparatus, appliance, software, material, or article that are utilized in humans for prevention, diagnosis, treatment, monitoring, alleviation, or compensation of diseases. It's also used to examine, replace, alter the anatomical structure or physiological processes in the organism. Existing technologies encompass a broad category of wide-ranging tools, equipment, and instruments which include diagnostic devices, therapeutic equipment, monitoring tools and adaptive devices [3]. Therapeutic equipment represents one of the largest and most developed sectors among the family of medical devices and have a wide range of devices including modern non-invasive technologies such as laser therapy or electric therapy. Diagnostic medical devices also represent a major category of medical tools that has heralded several innovations in recent years. There are currently a vast multitude of tests, screenings, and examinations that can be conducted much quicker and with greater accuracy than previously possible. The emergence and uptake of digital technology within medical devices have altered the provision of health care as well as doctor's interactions with patients. The health data can be transferred quickly from medical device to doctor and scripted to the digital alerts, and patients can book a doctor's appointments without the need to visit a center. It's also revolutionized the patient approach with many free online medical applications that can diagnose, examine, and track the patient's treatment process.

Medical devices have become indispensable tools for any clinician that are used in the examination and recovery of the patient's health. During the treatment process, a wide array of medical devices is commonly used. Picture of a medical setting often involves a fixed medical device that is used in daily routine, for instance, diagnostic imaging equipment, or regular infusions with the specialized infusion pump. In hospitals, monitoring devices are created for

supervision of parameters such as electrical activity of the brain, ECG reading, and exhaled breath temperature. There are many examples of medical devices that are integrated with information technology. For instance, continuous glucose monitoring, insulin delivery, and analysis software tools are frequently used by diabetic patients. Recently, mobile health devices have gained popularity for commands from heart rate monitors, blood pressure meters, and pulse oximeters. Furthermore, pacemakers are a great example of a device that not only constantly monitors one's heart activity but also systematically responds to abnormal conditions by sending electrical stimuli. Furthermore, implantable drug delivery systems are programmed for the system release of drugs within the human body. Practically, all services provided outside of the intensive care unit can benefit from the use of medical equipment. As a result, medical devices are integral in influencing clinical outcomes and simplifying the clinical workflow.

Development and investment can be high for medical devices, including time input to design and create a new device. This is further compounded by the necessity of extensive clinical trials and other requirements to meet regulatory standards for each device on top of production costs. The accumulated and potential costs below, associated with obstacles to account, are a large reason that new medical device technology can be a rare treat. These costs ultimately affect the final product cost with the accumulation of costs along the way. The process starts with the time and investment required to design and produce a new device. That is just the beginning; unfortunately, it only gets more expensive from there. From designing the device there will need to be extensive clinical trials conducted in order to get the new device approved for mass production and use. After trials there is then more time and money spent to get the device approved for production. The next issue is the actual production cost since the device will likely be a unique production, the cost per device will be high since medical devices cannot be mass-produced in the space of a short time [4]. If a manufacturer wants to reduce cost then this increases the time duration the consumer must wait. These costs rise even higher if intellectual property protections are desired, as patents are expensive to file themselves on top of the legal costs associated with protecting and (hopefully) enforcing them. A more indirect cost that can be high impacts is the time and brainpower required to meet the previous standards. Given the variety of distinct devices that fall under this designation, the knowledge necessary to satisfy the regulatory bodies can be extensive, and hiring and retaining such knowledgeable employees is very expensive. Oftentimes, previous standards may not even exist yet for a niche or newly developed device, and so such internal knowledge is even more critical and harder to

retain or even develop. This crochet-cant tangle of costs and obstacles, most devices may require years of development before they are ever seen by a patient's bedside, and many, many devices will never make it quite this far. In fact, of 16 medical devices designed for children made up around half the estimated number of devices, only 3 even made it to clinical trials, and of those, only one was approved. All of this is unfortunate and know that there is room for skepticism in a field that is, both fortunately, and new inventions, and unfortunately, snake-oily, snake-oil salesman. There are also many cases wherein newer tech could potentially be damaging, hindering patient care, usually through a combination of the current devices being outdated and the newer tech being poorly implemented or understood. It is a fact that many medical devices are outdated and can be both damaging and inefficient when it comes to patient care and overall efficacy. Some of this is avoidable, but in other cases, there exists a more general tension between the desire for consistency and reliability in practices known and proven to work and the desire - and indeed necessity - to adapt in response to a rapidly changing world. No one aspect of either of these is sufficient by itself. In healthcare, this manifests as a combination of outdated and/or unnecessarily complicated medical devices in areas where they could be damaging or rendered effectively useless by diseases spreading, rapidly airplane early and updating practices, procedures, and protocols, and changing and innovating along with more widespread technological and biological shifts. While it is true that vigilant adapt and change can, and have, led to plenty of damage, even in fields dedicated to it, like business, and public policy, avoidance of change often leads to even more catastrophic results. Concerns come with removing barriers to data exchange, sharing datasets can lead to global health improvements, data gathered by implanted or bodily biological devices, IDS is able to smoothly collect and exchange data improve patient care and health outcomes, privacy and ethical considerations around the impacts of sharing patient data, since patient data is gathered without patient consent, created an ethical concern that this data sharing would be an inappropriate sharing of concordant data.

Innovations that change the way healthcare is approached, delivered, and experienced are about to reshape the medical field. From enhancing early diagnosis rates to completely automated treatment or precision patient care solutions, current trends can improve healthcare and medical services delivery drastically. Several key advancements, that are under development and set the stage for future improvements, are showcased. Artificial intelligence transforming medical practices are examined, with the advent of artificial intelligence the medical field is reshaped to become more predictive,

preventive, personalized, and participatory. From aiding in early diagnosis to facilitating completely automated treatment, the question shifts from if AI will become a key part of the medical field to how efficiently that will be done. Machine learning becomes frontline for most decision-making solutions, further expanding its stroke in various industries.

The rise of the Internet of Things in the medical field is explored, the Internet of Things is playing a major role in reshaping modern healthcare industries. Wearable biosensors and smart medical implants enable real-time medical monitoring and patient perspective transparency. Embedded medical devices became so sophisticated, and they able to communicate with each other and medical staff ensuring automatic observation and prevention. 3D printed medical instruments and cyber-physical drug delivery systems bring the industry to a whole new and customized era. As telemedicine and telecare become more and more prevalent, it ultimately increases the patient's mobility and the overall comfortability of treatment. Even though IoT has numerous advantages assisting medical practices, several challenges including data privacy, hacking threat, and data management issues need to be dealt with. The convergence of AI, IoT, and machine learning in medical practices and personalized care solutions are discussed, AI and IoT will popularize in the healthcare industry as a representative of the cutting-edge technology. The synergistic combination of these technologies will actively monitoring health conditions and create a comprehensive analytical report, further promotes the realization of a new era patient engagement. Both the government and commercial corporates will focus on developing intelligent applications yet compatible with the medical practices. Meanwhile, the medical practitioners could be overwhelmed as the patient profiles are availableness around time and place. Therefore, similar to the EMR system, a structured interface compatible with AI machine learning applications should be developed and implemented. To fully exert the importance and value of AI technological innovations, the data interchange and uniform format standards between medical devices should be considered and applied. In addition to strict regulations regarding data safety and confidentiality, the interaction between the IoT devices and medical machines should be more robust and secure. Last but by no means least, the researchers and investors need to develop effective preventative measures to cope with the AI-enabled medical malpractices.

From wearables and other digital health tools to bed-side remote care stations to smart cars for medical supplies delivery, medical technology and healthcare have been evolving and responding to technological innovation. Pacing that innovation are a number of transformative forces, considering

practicality, challenges, opportunities, and the future of healthcare. One transformative force is artificial intelligence and the flavours of machine learning, deep learning, and predictive analytics. AI algorithms can predict better than clinicians' median accuracy. A stream of studies have explored how AI could analyze patient history in the context of electronic medical records, blood tests, and questionnaire data, leading to interpretation and diagnostic suggestion. Large multi-center studies have demonstrated the potential of AI technologies in identifying features in routine tests that escape non-AI practitioners. Work covering raw, 1D, non-image, high-frequency time series has shown feasibility to imitate tens of clinical and laboratory information, and produce prediction tasks. Similarly, cutting-edge studies have shown the use of convolutional neural networks to fall in line with the performance of certified dermatologists in the identification of melanoma and related skin conditions. The potential impact of these technologies on patient care, especially in the direction of service optimization and personalization as well as symptom interpretation, has brought on a brisk interest from the technology push to the healthcare pull side. It is obvious that a complex and multidimensional future is envisioned wherein the use of such technologies will encompass a broader engagement with the characteristics of disease, the health of a patient, the input from clinical examination and tests, potential treatments, and treatment response. The recent crisis has further accelerated efforts towards the development and deployment of AI and machine learning for various healthcare applications, not least in diagnostic imagings. The ongoing explosion of work has led to widespread concerns about data availability, data quality, statistical methodology and ethics, transparency, replicability of findings, the role and expectations from regulatory agencies, integration into hospitals and clinical practice, the uptake, turnaround and operationalization into clinical workflow, the development and protection of intellectual properties, as well as the future landscape of medico-legal, practical stakes. Here, a closer look is taken in an attempt to both broaden the focus and present a mapping of the current trends within this transformative force. For those using or developing AI technology and the wider healthcare industry, the suits act as a primer on how to prepare and perhaps optimize the environment for potential engagement.

The Internet of Things (IoT) is a term used to describe consistently interconnected objects that can range from regular home appliances to digitised tools and clothing. Additional capacities have been expanding with IoT as industries go through technological development. Possessing information about almost all devices enables organisations to enhance them and adapt them to the environment. The concept of IoT is based on

connectivity formed by sensors embedded. These sensors accumulate information about their conditions, including their geography, usage, etc. The information is then analysed and thresholds are compared. If there is a distinction between the recorded and expected data, the device instructs its actuators to alter its operating conditions. In the healthcare sector, linkages can be made between smart phones, tablets and gadgets which record biometric data about the body and wearable devices that manage the drugs into the body [5].

There are more than 500,000 medical devices available in Europe alone and numerous more around the globe, which are expanding annually. Before they were allowed on the market, each device must meet very stringent technological requirements. IoT can be another healthcare resource to achieve more effective patient monitoring and clinical administration, hiring devices that are directly applicable to the patient and have the ability to interconnect with each other, dealing a complete and seamless data exchange. For several years, many healthcare professionals have been in agreement with the principle that anchoring data references are essential for determining clinical treatment choices. Wearable devices integrated into the theory could provide real-time insights into the health of the patient, demonstrating the reason for healing events and the patient's reaction to the medicine. The link between wearable devices and the comprehension of clinician plaints could better inform superior treatment choices. Because of the work of interconnected equipment and patient interactions both in the clinical setting and remotely through device-device exchanges, the goal of taking the parameters will be much easier to achieve.

Medical devices are sophisticated healthcare products that play a critical role in patient prophylaxis, diagnosis, monitoring, and therapy approaching. As populations age and the global requirement for healthcare expands, the popularity of medical devices shall broaden. Increasingly advanced and creative systems are likely to be executed to fulfill the rising needs in healthcare. This piece gives an insider's glimpse at the innovative advancements in medical devices. It examines new technologies featuring two different dimensions:

1) Innovations that might be incorporated into medical devices.
2) Innovations in the context of devices, equivalent to the computational scrutiny of medical devices.

Matching advances in other industries, for instance, the improvement of nanotechnology, are expected to have a remarkable influence on the

development of medical devices, namely for gadgets that have an in vivo application. Broadly defined, nanotechnology refers to efforts targeting the control and fabrication of nanoscale variables in the bulk matter [6]. Nanomaterials have particular characteristics that distinguish them from macroscale substances.

The combination of these characteristics and the diminutive size can mean nanomaterials are particularly appropriate to an extensive scope of therapeutic and pharmacologic systems. Nanotechnology holds an immense inherent in significantly advancing the characteristics and capabilities of medical apparatuses comprising their formulation and planning, as well as their form and engineering variables. Nano-materials can be developed that have purposes on a nanometer scale, including: nano-sensors that could be miniaturised to form a bio-sensor for miniaturisation to the extent of a nanometre in size [7]. Such small sizing can mean that the sensory can be in vivo and of precise position; and nanostructures that could be engineered to be medicines beyond those potential with macroscopic agents. Nanostructures can be established that can conjure particular particles; for instance, drug particles, to formulate an aggregate mind aimed at a tissue or cell objective. This aggregate could then conjure an array of responses; for instance, apparatuses to treat a disease state, tools to inspect to check the disease has been successfully treated, or tools to treat additional effects of this action, for instance a language embodying a course of speech. On account of the versatile and diverse nature of atoms, very intensive therapy of most infectious diseases and conditions is possible with such nano-machines.

The rise of bioprinting technologies in healthcare could revolutionize the way we treat patients. The ability to print living cells, from human skin to organs, opens up a world of possibilities for healthcare and medical devices. In the same vein, 3D printing technologies can offer advantages in medical device development heretofore unattainable through conventional manufacturing methods. This burgeoning technology allows the creation of patient-tailored prosthetics, implants, and medication, all designed to work optimally at the individual level of care. Bioprinting and 3D printing technologies are helping reduce patient time on the table and in recovery, with cost savings to manufacturers and healthcare providers as a significant caveat. At the innovational forefront of surgery, successive industry integrations with both bioprinters and 3D printers are already showing positive effects on surgery. One large frontier for bioprinting in healthcare is, of course, the ability to print living cells. While the above can be used for decisive treatment, the printing of lab-grown organs is where both the excitement over bioprinting

and much of the moral qualms lay. As the narrows to the actual production of organs, many unforeseen questions and potential pitfalls have been raised. The issue of organ availability, already a pressing need worldwide with over 112,000 individuals in the US alone waiting for an organ, assumes a whole new perspective when a waiting list can be drawn upon for comparatively quick printing [8]. The regulation of such a complex and new technology, ensuring both safety and efficacy in produced devices, is a daunting prospect. Finally, it is the less sensational stories of how bioprinting is used in medical devices, services, and pharmaceutical products which are already transforming healthcare. From revolutionizing hearing aid production to bespoke scoliosis treatment with 3D printed spinal implants, the applications of bioprinting technologies are already incredibly varied.

Wearable medical devices, including smartwatches and fitness trackers, are gradually becoming more popular. They can capture physiological data or real-world behavior under free-living conditions. This promises various applications in the area of healthcare, such as quantified self-movement monitoring, fitness tracking, wellness lifestyle assessment, and chronic and post-operative disease management. Wearable devices can also form a chain in applications that not only characterize an individual's phenotypic traits and behavior, but also analyze the context or consequence of that behavior. If a wearable is to be used as a medical device, and no longer as a simple tool for fitness and wellness, it must go through a process of validation of the accuracy and reliability of the metrics it generates. It is also important to ensure that the data collected from the wearable devices are analyzed using robust and established signal processing and machine learning techniques.

Smart textiles have emerged as a trend in the sports and sports fashion industry, but their application for biomedical tools, such as detecting vital signs during sleep, is expanding. It is possible that wearable diagnostics will find a place in the everyday life of society. So-called connected medical devices, sleeves or garments with sensors for ECG registration or basic devices for reading the most popular analytes, such as glucose concentration, could increase the effectiveness of preventive invasive diagnostic tests. This combination of clothing convenience in using diagnostic technologies with the possibility of obtaining result verification from existing the most accurate disease detection platforms will increase the well-being and health of the people of the world.

One of the most fascinating advancements in healthcare in recent years has been the rapid evolution of implantable technologies. These now range widely from relatively longstanding devices such as pacemakers and cochlear

implants through to drug delivery systems, those with more recent expansion into prosthetics and a broader 'wearables' market. All represent an excellent use of the unique capabilities of technology to improve patient health [9]. It is an excellent illustration of the capabilities of many developed materials and manufacturing strategies to provide useful devices, despite the very unfriendly environment of the human body. The use and selection of biocompatible materials are increasingly a critical part of the challenges faced in designing and providing such devices. Equally, the provision of effective and safe post-implantation connectivity and data handling is an important consideration for those charged with managing patients with such devices.

The increasing advanced (and complex) capabilities of implantables make them a part of future healthcare to watch. For patients, these devices can be truly life-changing, revolutionizing the ability to manage conditions long-term. Managing the significant risks of this powerful technology (including infection, device longevity, and patient acceptance) will be key to its future success. Regulatory consideration of such devices remains, rightly, in-depth. Regulatory frameworks will need to continue to adapt and develop in concert with these novel and transformative healthcare technologies. Developments such as the recent FDA guidance on artificial intelligence in healthcare show an appreciation of this need to allow these life-changing devices to become part of routine healthcare. These devices will only become more complex, and new questions of their design, safety and efficacy will have to be navigated. Among future improvements, exciting possibilities include advanced devices that offer near biofeedback systems, and self-regulating and responsive technologies that better integrate these devices as part of the broader systems. Early devices like this start to appear, such as an implant that dissolves blood clots before self-destructing, but the potential for advances in the area is incredible

Trends in Medical Device Technology are developing faster than ever before, and the ever-changing scenario continuously poses new challenges: biomedical engineering students are looking for a preparation able to cover this wide and diversified set of competences, which may also need to be periodically upgraded. In an attempt to better focus the educational effort, a group with a diverse geographical provenience and different professional experiences considered the future of Medical Device Technology in context of a two-dimension perspective, characterized by temporal axis involving a time frame in the range of 5-10 years. Strategic directions were then identified, together with the technological and scientific elements permitting to effectively follow them [42, 43, 44].

8.1 Personalized Medicine and Wearable Devices

As we look forward in medical devices in 2024, the market strategy may reflect trends that are happening today - or it may do a lick-finger-up-in-the-air guesswork estimate that could well be laughably naïve. Technology's quickening pace of advances means yesterday's science fiction can swiftly turn into today's science fact: 10 years ago, the notion that each schoolchild might one day carry a supercomputer in their pocket might have seemed pie-in-the-sky speculation, not the cutting edge of futuristic reality. Medical devices are an essential component for a variety of healthcare related tasks such as diagnostics, treatment, monitoring and research. They serve to meet some of the user needs in healthcare, which could be related to diagnosis, treatment or monitoring purposes. Generally device development follows systematic and scientific approach which involves understanding the need of the user followed by design and development work that meets the discovered need.

The development of a medical device could follow involvement in a research project to develop a device that supports data collection and publication of a research work. Alternatively a specific need for a medical device could be envisaged that supports surgical procedures or disease treatment at which point medical engineers would be involved to address the user requirements. At the initiation, the process of design and development of medical devices involves the definitions of user requirements for the device, initial concept generation, exploration of the concept feasibility and finally the device development and evaluation against the user requirement specification. A medical device development project can be initiated by different stake holders including clinicians, engineers and surgeons. There must be identified need/s that the new medical device will address. To better understand the users needs in medical device, different activities have to be undertaken. Generally it is necessary to identify the challenge faced by end users, obtain a knowledge of the existing product, research available scientific literature, and understand pathological clinical conditions.

The design and development of the new medical device can be seen as an iterative process. During the design process, a number of different designs will be generated and then evaluated against the user requirements. Based on the evaluation, additional concept may be analysed, or earlier designs modified. During prototyping and feasibility testing, the designs will be created in physical form and then evaluated. Note, it is almost certain that the initial prototype will not work as expected and this is not usually seen as a failure of the design process. This process of generating and evaluating alternative

designs will continue until a final satisfactory design is reached. A high frequency of iteration should be expected early in the design process, with fewer iterations towards the end of the project [4]. Design & development of medical devices requires involvement of engineer/s, clinician/s as well as legal and regulatory bodies. The interrelationship of these forces will define the success of the new product entry to the market. There are several roadblocks to the development of a medical device that is maybe technical, financial or regulatory. Example of technical problems includes the early need to gain an understanding of the anatomical systems and their function and the proposed treatment approach (or use of the medical device) as well as the existing devices or treatments applied to meet the user need. Regulatory constraints are a major shoe hazard for new activities, since the extensive package of trials, tests, and investigations that need to be completed might take years to finalize. Conversely, regulations play a crucial role and are the spine of reassurance for the medical device safety and effectiveness. Financial constrains are the primary motive for some researches since both prototype development and test evaluation are a rather expansive undertaking. A medical device project generally takes years for completion from the origin of the idea until the device is used to provide assistance in curing a condition. The development of medical devices follows the regulatory framework, including assessment of the device safety and effectiveness. User need is a very important aspect of the product design. The 'user centered design' principles should be considered for a truly meeting of the user needs with the proposed product. A framework to determine how easy and safe is to be used a medical device is discussed. Finally, issues about regulatory affairs are disclosed in regard to the local market, but also to the markets in countries abroad.

There is a critical phase in designing medical devices related to the needs assessment that the task force intends to highlight in this manuscript. As an early priority it is understood that the insights from the real users should inform the features and functionality of the subsequent medical device. In order to promote innovation and to maximize the likelihood of development efforts addressing significant clinical needs, attention should be paid to who is best qualified to articulate these clinical needs. Strategies to encourage a successful needs assessment and to subsequently manage user requirements are presented including recruitment advice, methods such as survey, interview or workshop, consideration of the benefits of video data, and the role of the facilitator in requirement meetings [6]. A series of industry-led case studies are offered as an illustration of the presented methods, and there is a brief discussion of the challenges that may be faced when attempting to carry out a needs assessment with the subsequent users.

A medical device is any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes. This definition should cover a wide range of products, from low- to high-risk, and in different technological sectors including robotics, decorative apparel, software or nanotechnologies. Since the goal is to develop a medical product that will be employed in diagnosis, prevention, monitoring or medical treatment of humans and animals, the directive on medical devices poses 5 principal principles such as safety & performance, medical devices must be designed and manufactured in such a means that, when used beneath the conditions and reasons intended, they will not compromise the scientific situation or security of patients, or the safety and health of users or, where relevant, different individuals.

"We realized we were engineers after all." This intriguing quote was drawn from a collaborative medical device development project involving engineers, designers, dentists, and a patient. They participated in an adventure for surgical kit design, engaging in ideation only with sketches and simulations. Through this process, the project team found that rough sketches often provide more creative conceptual device ideas rather than computer aided design. Sketches have been frequently used in collaboration with designers and users for medical device ideas, especially in early ideation phases. Initial ideas were easily distinguished by the different graphic features between sketches, extruding fundamental concept selection. The pivotal idea was depicted in a model with coherent views, quickening the embodiment of ideas through visualization. Making several sketches of the same device, however, is essential for thorough embodiment since various views reveal different issues. Models have usually been made to inspect ergonomics in the final phase. However, the embodiment required comprehensive models considering internal situations, so generic models would not be much help. A functional model with traces of estimation from sketches embodied the user's demands better. Simulations assisted in embodied models, spotting mechanical problems. For a Dental Laser, the user needed an indicator showing where the laser would be directed. Considering technical feasibility along with embodiment is necessary when establishing concept. After making the first model of concepts, a model with an improved shape was ideated based on the previous one. To realize the function of a surgical kit concept, the device needed to be moved to the appendix. However, a limitation was encountered since it would be hard to move the device to the appendix during surgery. Therefore, the concept was discarded, and another idea with the same

functions was imagined. After the embodiment of 2D sketches, the 3D configuration was addressed, leading to a concept rejection due to technical infeasibility. This sketch emphasized extravagance for a cosmetically polished appearance, not spatial consideration in a dental context when multiple devices are prepared.

The practical experiences of engineering for patient health have been gathering pace since the resurgence in wearable medical technology in the previous decade. With increasing demands in healthcare and an ageing population worldwide, the convergence of clinical unmet need and ingenious technology has driven engineering for healthcare to have one of the most successful and fastest growing areas of application among medical devices. The intention is to further discuss the engineering side of medical devices, from a perspective of a multidisciplinary team which includes engineers, clinicians and medical device regulators. The following are a variety of case studies that show a real-world application of medical devices. They underline a few notable innovations in medical devices and how they affected healthcare, and a detailed analysis on the performance and user feedback of these devices. These cases have been carefully selected to reflect a spectrum of device types and applications, and to be broadly representative in different medical fields. The challenges encountered in the deployment of these devices are openly discussed. These discussions will be useful for learning how to best approach engineering design and the adaptation of medical devices that can compete in a market that is complex and strictly regulated by authorities globally. It is anticipated these case studies will somehow stimulate and inform further developments, leading to the creation of a new generation of innovative devices that can become an integrated, functional part of healthcare both inside and outside the hospital.

Many successful medical device innovations have followed a route from an identified user need, through a process of design and development, to a point where technological advances have been made and clinical improvements achieved. A select few are presented here to demonstrate the impact that the engineering of medical devices can have [6]. Each of the case studies represents a difficult medical problem, a series of realistic and practical design attempts with genuine user feedback, and engineered solutions to these problems. The paradigm of the medical device innovation is often the goal of collaborative research aimed at combining a novel technical innovation with a push to translate it into the commercial sector.

In heart surgery, the technical challenges of minimally invasive procedures have been met by advances in robotics and bioengineering that

offer enhanced user safety. Diabetics benefit from the electronic control of insulin pumps and improved designs in lancet devices for blood glucose testing. The practice of inhalation therapy has been transformed by devices that increase drug delivery to the lung rather than the stomach. This progress has been made possible by innovations in drug formulation, the industry of device manufacture, and a detailed understanding of the biological response. Unarguably, much of this is outside the professional's expertise, but inhalers themselves remain relatively simple devices that offer an insight into successful design developments. Since these devices are for use by ordinary people and not trained medical personnel, questions of usability become paramount. Ultimately, and despite the different natures of the challenges, there emerges a common picture of effective collaboration between patients' needs and the doctors who treat them on the one hand, and innovative engineering design on the other. Being aware of this can offer valuable insights in any consideration of future medical device applications. Some successful innovations are scalable, allowing broad adaptation and translation to different clinical scenarios. There is a careful balance to be maintained here, between designing a medical device that is merely an extension of technology for technology's sake, and as a direct response to practical and clinical needs. A user needs to be identified first, but it is useful to push the boundaries of technological feasibility.

Looking at the shelves of any pharmacy, hospital, device manufacturer, or home appliance store, it's clear that medical devices constitute a vast industry. While the process to gain market entry may vary depending on the presence of a substantial equivalence claim or lack thereof, all established or new-to-market medical devices are regulated by the United States Food and Drug Administration (FDA). There's a complexity in the pipeline of patient care data to design and market medical devices. However, except for the study of health information technology's MAUDE records of adverse events, despite common inferences, the devices themselves are not studied in aggregate. The selection of hypodermic needle of same gauge and market value to study the process is scrutinized through the production of packages of data, sorted and analyzed to construct submissionable devices, thereby illustrating just a sliver of the immense body of work undertaken by manufacturers with the goal of engineering health in healthcare [7]. While a user-centered design strategy has considerable advantages, lack or misunderstanding of detailed clinical information can be a significant barrier to be able to contribute meaningfully during this process. This "industry validated" user-centered requirements elicitation process is comprised of: a graphical illustration of operating room layout and work processes; tasks

broken down, analyzed in terms of cognitive, physical loads and time constraints, with tools and equipment used explained; multidisciplinary teams visiting site, asking questions; a gatekeeper channeling all communication and site visits; consolidation of user feedback into a layout plan, high-fidelity prototype or storyboard of the solution proposed; iterative communication between industry and user representatives until a satisfactory agreement is reached and site approved; design development initiated.

Now is a very exciting time for the medical devices industry, with emerging technologies increasingly blurring the lines between biology and engineering. Innovative solutions enable the design of advanced medical devices with the potential to revolutionize the healthcare industry. This presents a comprehensive overview of the most promising emerging technologies in the medical devices sector.

There is a growing interest in innovative solutions that leverage predictive analytics, artificial intelligence, and machine learning algorithms to improve diagnostics and facilitate a shift towards more personalized medicine. These cutting-edge solutions allow medical devices to assess longitudinal data over time and provide actionable, real-time recommendations to medical professionals. As fully embedded medical systems develop, it will pave the way for devices that can make better clinical decisions and provide superior patient outcomes. Of course, this realm introduces significant challenges around the robustness, interpretability, and security of these medical devices and the supporting data pipelines.

Another transformative advancement in the medical devices industry is 3D printing. 3D printing, known as additive printing, was invented in the 1980s and has gained traction due to declining costs of equipment and wide range of available material solutions. A uniquely exciting area of potential is the possible customization of medical devices to individual patients. The ability for 3D printing to enable devices of almost any shape and size has substantial implications for more complex healthcare devices, spanning drug delivery systems, diagnostic imaging adaptors, surgical guides, and flexible, biodegradable electronics. Moreover, this technology could greatly assist in drug development and medical research such as human tissue replicas for pharmaceutical testing. The revolutionary impact of 3D printing on the medical devices sector has not gone unnoticed and investments in commercial 3D printing technologies for healthcare applications are multiplying. Another appeal of 3D printing is associated with reductions in device manufacturing cost and lead times. Its additive nature enables rapid prototyping, low costs related to material waste, and capability to manufacture complicated structures

hard to achieve with traditional machining. Yet, its seamless integration into existing healthcare frameworks is held back by strict regulatory compliance, ethical considerations, cybersecurity concerns, and substantial disruptive changes needed in global supply chains.

Considering the pace of development, medical devices should not generally use the latest technologies, such as artificial intelligence (AI) or machine learning (ML). There are some exceptions, where AI application is the only choice. Nearly all new diagnostic medical devices that come to market based on ML are interoperable of it. Manufacturer impact assessments for all interoperable devices are expected from MDCG and important for manufacturers to deliver.

Manufacturers have demonstrated that even sensitive patient groups and cases are included in the check-up data. Manufacturer has vouched that the daily concerned physician has been in the training set and has sent as much adverse data as possible. It is difficult to find any acceptability measure for ML. There are no universally approved metrics. The extant ones have flaws. Any performance metric, such as sensitivity or AUC, must be accompanied by a baseline dataset and say how well the machine did. Major problems remain in 'explainability' and dealing with continuous learning systems. A robust and in-depth testing methodology for continuous learning system remains notably absent. Broad applications of AI in medical products, especially in diagnosis tools, are looked forward to. It may well be that AI technologies would temper societal disapprovals. Given the amount of work this will create a 1-year delay is asked. As these kinds of predictive analytics systems provide decision support for health systems employees, derogation training is not required, alongside the fact that this training could compromise algorithms.

Regarding the current and potential uses of AI and ML, medical imaging analysis is an early but still fast-growing application. This includes x-ray imaging devices relevant to infectious diseases but also diagnosis assistance systems using other complex images. These could range from ginger diode magnifying skin inspection tools to whole-slide scanners analyzing histologic preparations. Beyond diagnosis tools, there are important use-cases thriving. These include imaging tools simplifying complex imaging devices or applications and also more general predictive analytics AI systems. Examples of this more general use can be found in interventional or surgical set-ups where the AI system monitors a multitude of sensor inputs in real-time and issues alerts. There has been spectacular progress in the last years, notably in automating workflows, making them more "intelligent."

Medical devices are crucial thrive in a quickly evolving space that blends delicate medical services with innovative engineering. Their production has long been investigated, designed, and perfected to ease and maintain human living conditions. Medical devices describe a product used to treat a disease or injury. This commodity is used up to achieve this outcome if properly used according to the supplier's guidelines. This consists of various health activities including normal detection and observation, operative surgeries and contact with the patient's body, and body shape or its anatomy. There are several kinds of equipment that fall under the heading of Medical Devices. Analyzers for the diagnosis of diseases, pumps employed during brain operations and dental plate used to restore teeth are a few instances of such products. They are used both as therapeutic, safety or prevention equipment in various healthcare activities. These components are indispensable in bringing the operator body replacement or improvement. Medical Tools are frequently used in the health industry to raise the intervention or problem detection efficacy. Some of:-

- X-Ray Goggles and Plate Stuffers.
- Stethoscope and Sphygmomanometers.
- Course Monitors and GUIs.

The use and development of medical devices present a number of broader ethical and societal considerations when contextualized in healthcare. Today, devices have evolved in sophistication and outnumber clinicians in service delivery to patients worldwide. With the emergence of new devices in patient care, and the growth of new illness detection and treatment practices, the scrutiny of these issues is prudent. This section explores those tensions. Patient privacy and data protection are the crux as devices record growing lists of health data. However, new perceived threats to patients arise, e.g., individuals with unique surgeon implants or devices are easily identifiable. This begs questions concerning the transparency of the width, size, power source, and efficiency of these products. There is potential to enrich this information with malpractice history data, or post-implantation health patterns and use them for malfeasance. An ethics framework would mandate some safeguard concerns are potentially addressed [8]. A second aspect is the link of broader social and demographic disparities with the emergence of a divergence technology gap. In both these respects, it is to question how medical device design may be involved in social bads. The rise of 'faulty' health devices or 'smart' tools that are unusable without client payment to an additional commercial platform are signaled. By contrast, devices for wellness are fabricated to be less reliable in poorer neighborhoods. An adequate ethics counter-narrative would need to provide transparent access to BD in tools. This is to expose the preceding and

an open debate, preferably at devices' pre-design stage. Finally, there is an outline of broader epistemological concerns.

To manage a chronic issue or ameliorate an ailment, devices in unison with drug and behavioral interventions have frequently received caution. The same concerns may be projected onto the development of medical devices. An ethics framework is sought to manage the device design and deployment life cycle. The obligations of equipment manufacturers pertain essentially to ensuring the proper design, testing, and post-marketing safety surveillance of the product. There are additional ethical expectations over the accuracy of the promotional material, or direct engagement in a facilitating dialogue with regulators. Concerns about the clarity of patient information also cover the adverse effects, data regarding the patient risk group status, and the level of background anesthesia to be used. Ethically, manufacturers should endeavor to ensure that patients have a clear understanding of all the risks involved in choosing health devices. Generally, this is not achieved and, given the complexity of risk-benefit relationships in the device domain, not an easy task to achieve. On the clinical side, the design duty involves a balance of technological innovation and familiar modalities. Such a compromise sounds at odds with the demand of treatment perfection played by DTs who, in lucidity with the MD, ideate and make decisions on the nature of prosthesis, like brand and size. Nevertheless, there can be nothing faulty other than fair treatment. This is a common approach in the rundown selection of off-brand drugs which, to some extent, still allows a DT to follow safety guidelines. Wearables, in their variety, are instead chosen to gear an auxiliary, albeit complex, answer to the device issue. This diverse panorama makes the communication of comprehensible risks an intricate challenge. Shockwaves generated during nebula drinks are a case in which the connection between the devices' active principles and the involved health risk cannot be easily schematized or predicted. Besides, specific therapeutic or diagnostic applications, a broad reflection on the societal and ethical implications of BD and AI is more than necessary. Central funding for worldwide research, as well as an impartial dissemination of data, would be most appropriate. Device manufacturers, who place building devices on the market, have seen significant advancement of their manufactures by future development. With a delivery influx of BD and AI health technologies, the consumer protection schemes and industry support by national compliance have been amended in aid of responsible innovation in this rapidly evolving sphere.

Health information is a sensitive asset, worthy of protection from misuse-intentional and accidental-as well as disclosure to unauthorized users.

Disclosure events can stem from unexpected or unwanted uses. Any medical device's interface and accompanying communications are subjects of concern. Nonetheless, such interfaces are also vulnerable entry points with a high clinical engagement. Robust physical and software safeguards potentially can minimize risk. Manufacturers are well positioned to integrate and bolster defenses throughout their devices' life cycles. Moreover, manufacturers for some devices are subject to regulatory mandates to demonstrate reasonable attention to data security. One manufacturer pursuing proactive attention is Medtronic. Security efforts depend on global, cross- divisional undertakings, coupling critical analyses to testing and risk assessment methodologies, relevant to congenital heart disease issues [9]. The brief survey provided here is underscored by a strong general admonition: be cautious. Health care networks should be cautious in entrusting device security to the manufacturers and in assuming that manufacturers with extensive security experience in other product lines already have a handle on device security. Providers and patients should also be cautioned, as many mistakenly believe that "security sealed" devices firmly protect data and underappreciate the full extent of network and systemic vulnerabilities. On the other hand, the goal is not to drive unnecessary alarm but to engender a thoughtful, scientific, and engrossing dialog, one that encourages problem awareness and ongoing private engagements. At a symposium in 2010, Ioanins summarized device cybersecurity investigations rolling out of his lab. He said, "The closer we looked, the more we found". A similar trend is hoped for and needed in device cybersecurity research and will come to benefit those in the clinic. However, security researchers in their presentations to medical device manufacturers and patient groups would do well to initially ask, "What do you know about security research? How can we be of help?"

Approximately 0.9 billion people did not have access to basic healthcare, and 100 million individuals were pushed into extreme poverty due to healthcare expenses in 2015, despite the World Health Organization (WHO) pledging to 'leave no one behind' [10]. In addition to prohibitively high treatment costs, lack of access to healthcare often results in poor overall health outcomes. Rural families often have to travel long distances to the nearest hospital. The treatments aren't cheap. Good healthcare is a privilege - something provided by government-issued insurance and vendor benefits. Millions often die due to a lack of proper treatment. Relatives die due to insufficient medical care. It's a daily occurrence. The patients crowd on floors as they wait for their daily doses. Hospitals often don't have the required number of beds. The patients must share. More than 5 million people have been forced to become refugees or migrants in the health sector [11]. In

addition, people living in poverty usually need to wait for hours to avail of medical and healthcare services. Private healthcare is especially expensive while insurance bills aren't cheap either. This creates a great disparity in health and wellness. As a result, deaths can be observed. The aforementioned scenario underscores a wider issue on access to healthcare treatment.

Can emerging medical technologies bridge these gaps, whilst also being cognisant of the risk that new technologies can exacerbate such disparities? Emerging medical devices and technologies present a major opportunity to extend diagnostic and treatment services beyond hospital settings. But, does this come at the expense of vulnerable populations? Mobile health, for example, typically requires patients to have access to a smartphone or tablet. What if there was a set of inclusive design practices for the development of these new devices and their software to ensure that the devices can be used by a wide range of patients? Importantly, what if global healthcare policy, such as the work of WHO, were to promote design standards that ensure all new devices are accessible by those in need? This chapter will open up these themes by first looking at examples of where policy and design are supporting more accessible medical devices today. It will then map out the challenges in making treatment technologies accessible beyond secondary care settings. These are all issues that the design and implementation of new medical devices will need to think about. Beyond the devices themselves, healthcare policy will also need to consider practical guidelines for supporting the equitable provision of care, such as through the integration of treatment technologies into lower-resource health centres. The final part of the chapter will look at these issues: how, in the context of the expanding diversity of treatment devices that are, and will be, available, there can be a commitment to designing medical devices so they serve all patients equitably.

In recent years, a significant advancement in scientific and technological research has led to the development of innovative healthcare solutions in the form of medical devices. Such devices, based on high-performance sensors, portable and/or wearable and considering data-fusion methodologies, can monitor a wide range of physiological parameters, not only covering the spectrum of prevalent cardiovascular diseases but also enabling their early-detection thus contributing to timely and effective treatment. Unlike other contemporary devices, healthcare solutions designed here are characterized by the enrollment of real-time automated algorithms able to detect pathophysiological events and to warn patients to prevent critical situations. Personalized medicine – deep data-collection and -analysis to tailor treatment to individual patients' unique profiles – is likely to be 'the new sexy' of the

healthcare industry in the 21st century, and how wearables will enable this revolution.

A swift overview of the emerging medical technology examples of recent years indicates why, even for the cynically sceptical, it doesn't take a crystal-ball gazer to foresee the transformative potential of personalised medicine and wearables in the healthcare sector by the end of the 2020s.

Chapter - 9

Robotics in Surgery and Healthcare

Medicine is continuing to evolve, experiencing ongoing transformations and breakthroughs, with the technology advancing significantly over the years. There are many new technologies and devices that are redrawing the boundaries of medicine and allows for its various technologies to fit seamlessly together. One of them is surgical procedures with robotics, which by their nature, are special. Its procedures are widely carried out on a daily basis, from cesarean sections to heart operations, with an ever-diversifying range of highly specialized operations performed at greater frequency than ever before [11]. Using the full range of robots, special technologies and supplementations frequently has far-reaching significance from the choice of procedures, regularity, timing and accuracy, down to the tools, auxiliaries and possible phases. This also broadens the aspects, optics, and viewpoints considerably. Robotics often allow for procedures by providing more precise and accurate movements than a human hand would be capable of. They make use of almost entirely minimally invasive surgery, in which some advantages have been already recognized. One of them, for example, is that patients recover faster after the procedure. Robotics not only provide better precision and visibility but in the future they will also have an impact in the context of changing standards which may impose the envisioned obligatory use of such devices or others like them.

Surgeons realize that there is more to robotics than simply becoming skilled in the operation of a robotic system. It is what lies behind the technology that will establish a good understanding on how and when this novel tool is best employed. There are a number of outstanding issues to consider, ranging from consequential strengths and weaknesses to a broader philosophy over where and to what extent robots should be used. Desires to take on roles that people are not able to perform may be constrained, but there is a need to clear up wide disagreements over capabilities and possibilities. Moreover, adoption of robots often encounters insurmountable barriers in the clinical setting, including expenditure, restricted access, and above all, lack of robust data on outcomes in clinical trials.

The COVID-19 national emergency declaration triggered a mass shift in how patients were able to access care, with a significant expansion of telemedicine and remote monitoring care. As of the declaration, physicians have been able to waive the requirement to have a prior relationship with patients to provide remote care; with staggering results. From the declaration through June 2020, more than 35.2 million beneficiaries were served through more than 34.5 million telehealth services in total. The vast majority of these services were rendered over common telecommunication tools. With these tools, healthcare providers can render any service they would provide in person: evaluation of history and current medical complaints, patient education and counseling, and even follow-up evaluation. Telemedicine enables patients to receive medical evaluation and treatment when a face-to-face appointment may not be the most timely or convenient option. It allows people to connect with a physician from the comfort of their home or favored location, alleviates the need to spend time driving and sitting in traffic and the associated fuel and opportunity costs, and benefits individuals with mobility constraints. While remote monitoring may refer to a few things, such as labs or vitals that were gathered elsewhere, in this case it is for patient monitoring equipment that is used at home and the data is shared with a healthcare provider. Expanding telehealth to allow for a broader array of suppliers and practitioners to provide telemedicine would allow all healthcare providers, regardless of specialty or location, to be better able to care for their patients by providing telehealth consultations when needed. There is the potential to both improve and neglect patient care and safety if a robust and resilient telemedicine plan is not well-established. Broadband policies are needed to guarantee equitable access to a doctor no matter what area someone lives in. In conjunction with faster internet speeds, devices need to be intuitively designed so that technology does not cause additional barriers or dissuade vulnerable populations from adopting it. Strengthening telehealth cybersecurity measures and developing plans for mitigating risks may ensure patient confidentiality and data availability. Uncertainty surrounds what the future of patient care will look like, but as telemedicine desegregates from telecommunication facilities, expect a rise in remote care startups and investment and the emergence of telehealth as a novel space of business. It has also been predicted that the public health emergency will expedite the journey to total virtual care with significant cumulative doctor and patient cost savings over the next two decades.

Chapter - 10

Regulatory Considerations and Ethical Implications

It's clear that the next generation of health technology is attempting to leave its stationary home in the clinic, and head home with patients. For example, the growth of wearable technologies, mobile applications, and remote health monitoring devices have created a surge of data that never existed before. However, the current regulatory landscape surrounding these products is a gray area at best. With the age of at-home genetic testing brought on by companies such as [4], a new flood of personal health data is cascading into a highly unregulated space. The Federal Drug Administration (FDA) approach to regulating mobile health applications (mHealth) is a "risk-based" framework, meaning that current regulation is focused on the technology rather than the data it collects analyzes and interprets, potentially leaving a massive loophole untouched. Standard FDA approval is on a case-by-case basis, but there are well over 100,000 health apps on the consumer market. Furthermore, the Health Insurance Portability and Accountability Act (HIPAA) has failed to maintain its relevance in an age where technology enables personal medical information to leave traditional closed systems. Thus, there is a significant barrier to ensuring the privacy and security of new patient-generated health data. Digital health technology is moving fast. The technology industry moves at breakneck speed, where FDA regulation has been described as "too little, too slow" at times, preventing regulations to keep pace with radical shifts in technology in the rapidly evolving digital medicine field. But with this speed comes a few black marks in the record – namely privacy issues. The release of the personal digital assistant raised ethical concerns surrounding the privacy of personal information collected from conversations with the device. While all voice activity is recorded, only the conversation when the wake word is spoken is stored. However, entire history logs can be accessed through the online portal, and accidentally waking has led to the device recording and potentially storing unwanted conversational data. While digital medicine is undeniably transformative, the risks and challenges should be ethically mitigated and understood so as to maximize its benefits to society.

Chapter - 11

Future Directions and Predictions

We are living in the age of digitalisation, always interconnected. Progress in our daily life is constantly more monitored and quantified through an increasing number of devices. In the following decade, it is expected that critically ill patients' vital parameters could be constantly monitored and directly sent to physicians by implantable biosensors, precluding life-threatening situations in public spaces. The Internet of Medical Things (IoMT) blends patient monitoring devices, wearables, implantable, and hospital devices with data management softwares and telecommunication providers. Artificial intelligence (AI), including collaborative robots (cobots) adapted to work in proximity to humans, will dramatically change healthcare delivery, further personalised. Besides, smart materials harnessing biotechnology benefits could be used for medication nanocapsules, as already trialled for some oncological patients, or tissue bioengineering. Nine technological trends in medical devices that could bend healthcare will be explored together with their main foreseen impacts over the next 10 years. Finally, the main hurdles that stakeholders will face will be assessed.

The 3D-printed prosthetics for amputees or to reconstruct dental defects have shown an emerging trend for fabricating custom long-lifeparts. Such technological cutting-edge devices could encourage a new era for recyclable medical devices. Input would be made on opened questions about the regulatory issues to comply with, and on how to ethically maximise the profit of these breakthroughs for patients, healthcare professionals, and manufacturing companies, making them at the same time socially sustainable and resilient. Tech-driven talent is perceived to be a long-term solution for making a breakthrough in regulation and harmonising growth in a fair trade within this market. It is recognised that this approach can be challenging for new startups localised in countries with low manpower resources and lower education availabilities, thus it is advised to build up strong connections with professionals of other relevant expertises. Policymakers would be exhorted to incentivise synergic research events between different skill domains. Multi-disciplinary challenge-oriented students' competitions could be a powerful stimulus for an exponential growth in health tech innovations over the

following two decades [12]. Adaptation and education within the healthcare force to face radical changes of patient care delivery should unbiasedly be a target too.

Chapter - 12

Conclusion

In conclusion, the acknowledgment that many tools of industrial engineering are traditionally used in the engineering of medical devices for the improvement of healthcare delivery plays a critical role in improving the effectiveness of employee benefit plans. The findings go further in elucidating the systemic problems inherent in today's healthcare by supporting the argument with evidence from the engineering literature. Quality improvement in the practice of engineering is key to making cost-effective benefit plans work well. In the current environment, the lack of transparency and accountability of medical product developers, those who purchase and use these products, and those who review and monitor the safety and efficacy of these devices reduces safety and efficacy and increases cost. Despite this lack of transparency, the various payers still must place trust in the payees to act and make decisions in the best interest of the payer and of the patient for whom the payer is responsible. In conclusion, it is the development of principles, technologies, and devices that can transform healthcare with the goal of solving unmet clinical needs. These goals are accomplished in partnership between engineering and medicine as science informs clinical practice and vice versa. Key to all advances is the focus on the patient, the individual that spins the path between the two disciplines. The many aspects of the development and use of medical devices include topics such as advances in imaging, sensors, devices, accessible and precision medicine, big data, artificial intelligence, and robotics. All can contribute towards faster patient recovery, shorter hospital stays, fewer complications, better patient experience, and lower total cost of healthcare.

Substantial benefits will be available when medical devices can support pre-detection or pre-emption of clinical issues so that treatment can be administered in real or near-real time, putting the replacement for the damaged item back firmly on thriving feet. The two greatest challenges today to advance medical device development are obtainable healthcare access and faster patient recovery, but how we get there remains the question. We will need years of planning and investment, thoughtful dialogue among ethical and policy makers, robust research, and objective evaluation of the various policy

approaches to ensure that medical device production runs smoothly and that all who need them can access them affordably in a timely manner. Medical device technology has been an area of rapid expansion for investments in health research and technology adoption. Only a few medical devices were widely used about two decades ago, mostly high-tech items on one end such as computed tomography scanners, linear accelerators and pacemakers, and low-tech items such as needles, syringes and wheel chairs on the other. The future trends in healthcare technology seem to be in that direction again- with a rush in both high-tech and low-tech items – and the segment in between growing at a slower pace.

Each level of technology has direct influence on the possible at the healthcare delivery system, and on the choice between sitting up the needed services, accordingly with the available technology, or using innovation to leapfrog stages. Treatments that can be accurately standardized and tied to clear biological variables, using simple technology, such as electrocardiographic monitoring, are well suited to relatively low-tech services. It has been observed that where one makes great investments in hi-tech diagnostic equipment in low or mid-level technology zones, the utility of this equipment is very limited, and that subsequent maintenance of degrading equipment can in fact destabilize a health care system

It is essential to recognize the tension and opportunities between high and low technology equipment and procedures on one hand, and the possible leapfrog opportunities that seem to exist in midrange technology world, with significant growth in a variety of technologies. Developments of processes, products and tools, and the use of processes, products and tools, has been a primary capacity feature of humans since prehistoric times. Without tools, the human species have no physical capabilities to extend the possibilities of the body, or to overcome the limitations of the body, specifically, the biological constraints of the human body. The knowledge surrounding products and tools needed to exist prior to their existence; but also tools and products cannot be created unless organized bodies of information and practices already existing.

To truly improve the practice of healthcare, address patients' needs, and provide the best combination of outcomes, device-makers must provide the best solutions in a manner that is transparent and accountable. The burgeoning cost of healthcare and the magnitude of quality problems-often with high human and financial costs-demand that we increase the knowledge and rigor of the improvement. Specific needs for improvement include:

1) More rigorous and transparent responsible use of medical devices.

2) Improved design for safe and effective use.
3) Development of additive, synergistic, and contributing technologies.
4) Improved decision aid systems and logistic systems for better information management.
5) Reliable risk stratification assessments.

The upcoming aging and increasingly ethnically diverse population will also require advances in personalized medicine and individualized healthcare. These improvements can be implemented to influence clinical outcomes, increase the efficiency and long-term effectiveness of medical care, and reduce the financial and human costs created by the looming healthcare crisis.

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