Cutting-Edge Engineering in Medical Device Technologies: Innovations, Design, and Future Perspectives

Editors

Mustafa Khaled Majeed Hindi
Department of Engineering of Medical Devices Technologies, Al-Hadi University

Raed Waleed Turky Hassan
Department of Engineering of Devices Medical, Alsalam University

Sajad Kareem Mutlak Zmaeem
Department of Medical Instrumentation Engineering, Al_Israa University,

Mohammad Taleb Khudair Abbas
Department of Medical Instrumentation Engineering, College Medical Techniques, Al-Farahidi University

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Abstract

Medical device technology is rapidly advancing, characterized by excellent developments undertaken during the second half of the last century. The integration between engineering development and biological sciences seems to perform an unstoppable growth, with smart solutions covering all aspects related to diagnosis, assistance, and curing. The present Special Issue collected eight facets of the complexity, rigor, and ambition in the design process of advanced devices. Six papers were dedicated to novel design approaches for cardiovascular and orthopedic devices. The seventh article investigates the surgical treatment of arthrosis involving the phalangeal base. The last paper concerns the Alzheimer cyforam, an IQ-Box specially designed for Alzheimer patients. This work testifies to the capacity and passion in technological development for clinical use. Given the engaged hot topics and enthusiastic discussions with participants that have granted recurrent international and national meetings, it does not seem presumptuous to predict that the next decade shall witness the fulfillment of many scientific and engineering quests. The present Special Issue exposes many of the current research directions in medical device design and aims to bring into consideration an additional stimulus for further investigations. We hope that the readers will enjoy the reading but, more importantly, that they will feel motivated to envisage new research and, on a longer stretch, development directions.

Contents

Chapter - 1

Introduction to Medical Device Technologies

Medical device technologies have played an integral role in modern health care since the advent of hospitals over two millennia ago. Ranging from surgical instruments to bed monitors, such devices provide critical assistance to patients and doctors in various clinical settings. The rapid advancement of medical devices forms a diverse technological landscape which is continually evolving to meet emerging healthcare needs. Such needs include the aging population, unhealthy lifestyle choices, disease outbreaks, and environmental hazards. As technology continues to accelerate, the invention and adoption of advanced medical devices from new minds and perspectives are expected [1].

The evolution of medical devices is a continuous and dynamic process, with each new advancement modeling and shaping future outcomes in response to the ever-evolving challenges faced by healthcare systems today. This ongoing development has formed an intricate and interactive link between technology and medical practice, where advanced medical devices have significantly contributed to improved healthcare outcomes, and in turn, these improved health outcomes also inspire further technological innovation. Meanwhile, the design and innovation of medical devices have become increasingly complex and multifaceted, extending beyond just hardware and software considerations. In addition to these components, the surrounding environment in which the devices operate and the intricate relationships between patients, doctors, and the broader elements of humanity also emerge as crucial design parameters that must be addressed and factored into the developmental process of the device. Aiming to successfully overcome the conventional healthcare challenges that persist today, it is vital to conduct a thorough examination of medical devices from these two different yet inherently intertwined aspects. To foster these goals, it is essential to advance research in both the technological and relational dimensions of medical device implementation and design [2, 3, 4].

1.1 Overview of Medical Devices in Healthcare

Medical devices are widely used in the healthcare industry for various applications including diagnostic, therapeutic, and surgical purposes. Medical devices typically categorize into four categories: (1) in vitro diagnostic

devices, (2) diagnostic imaging devices, (3) therapeutic and physical medicine devices, and (4) surgical and etc. devices. Diagnostic devices generate additional data that is used for diagnosis, prevention, and/or monitoring the health status. This category includes a diverse group of devices, of which the most popular are personal health monitoring devices and blood diagnostic devices. The former commonly measures physiological parameters, while the latter measure certain blood components. It is estimated that in the future household application will become more common for diagnostic devices. Diagnostic devices provide frequent monitoring, prevention, or early diagnosis, in contrast to the traditional diagnosis performed upon clinical symptoms. These devices result in higher involvement and control over the health condition and, therefore, can rather easily promote behavioral changes. Taking for example the case of a person diagnosed with hypertension, without the devices there is a risk of not being aware of the condition until heart problems arise, whereas home blood pressure monitoring could have detected such condition earlier. Medical devices are crucial in providing patient care, serving both diagnostic and therapeutic purposes. The invention of medical devices has a long historical background that started since the stone and brass instruments in Ancient Egypt were used for treatment. Over time, there was continuous innovation in the devices, which quickly evolved into surgical tools and systems. In the past century, the rapid development of electronics, signal processing, microbiology, and material technology has introduced powerful leverage to the design and operation of medical devices. In 1962 the Medical Device Amendment was enacted in the United States, which states that new devices must successfully demonstrate safety and effectiveness. In 1976 a system for classifying device proposals and approval of novel, safe, and effective proposed devices was established. Over 260 organizations are currently focused on developing the methods and standards to offer assurances of the devices' quality and validity. The use of new medical devices and technology is the main impetus for the enhancement of evidence-based healthcare. BIOXN provides a solution to standardize the development of a healthcare product, focusing on the various stakeholders involved in the healthcare industry: manufacturers, healthcare professionals, and regulatory authorities. BIOXN is a European initiative to foster the use of medical devices and technology to reduce healthcare costs by providing a solution to healthcare that is readily cost-effective in the healthcare market. BIOXN technology can efficiently introduce and operate medical devices and technology. BIOXN devices focus on the need for straightforward documentation and the development of methods to evaluate medical devices and technology. BIOXN will provide a set of software tools and resources to help create compelling evidence that device technology meets the healthcare

needs in the selected experimental scenarios. This will lead to a formation of sound guidelines to foster the integration and adoption of the device technology in the healthcare system. An extensive validation of the proposed methodology in real medical cases is envisioned, also through a set of real clinical cases. Diffusion modeling in live animal tissues under radio frequency ablation is a critical factor for minimizing procedural risks and improving technical success. Prior evidence suggests that increasing the target temperature to 50°C is enough to accomplish successful ablation, but the temperature will exceed this limit in cases involving diseases plaguing blood circulation, such as the liver [5, 6, 7].

1.2 Importance of Innovation and Design in Medical Devices

Medical devices serve a wide range of functions either to help prevent disease, provide diagnosis or treatment, or for the purposes of monitoring. Medical devices are heavily used in health care to aid patient treatment, rehabilitation, home care, and to service the public in general to support better health care of the population. It can simply be recommended for sport or weight-loss and sitting aid devices like a massaging stick. Wearing devices which can be used as supporting tools or as monitoring equipment for treatment of various body parts are an item of daily life. A big market exists for medical devices and its management as well. Many products in the market are now like to be conceived by designers. In a aggressively competition-oriented market, every product should and could be unique. There is a lot of emphasis in creating very sophisticated appliances to verify disease or monitor physiology. The marketing philosophy is either to provide comfort in general or for specific purposes. As for example in age concern, the range is very much on fitness and falling, it is generally supposed that the changes and the employment approach results in certain alterations in the designing. Wide knowledge is available in the literature on the medical device usage by the designers as how it will facilitate them to conceive for a better design.

Innovative approaches to medical devices design could significantly assist the solution of a number of problems associated to healthcare of the population, furthermore it will provide a benefit for the population in its evolution and preservation of health. Design of medical devices becomes a prospective and emerging field in modern medicine and health care, though certain concerns are still open and need adequate answers and solutions. The innovative, unique design could provide for better functionality and effectiveness of medical devices, simultaneously observing the requirements for safety in usage. Also, it could be suitable for purposes like preventation, control and reduction of health care costs. Modern marketing treats design of

such products too important not to be risked. Medical devices need to be effectively incorporated into the routines of health care professionals and make them as unobtrusive as possible in order to permit the patients lead a "normal" lifestyle. The most important designing task is developing the design of medical devices to the point where the manufacturing starts and can be applied effectively in clinical use. High standards of performance, such things as accuracy, ergonomic design, functionality, and safety (i.e. low propensity to failure) must be set to the product. However, it is equally important to address other issues, such as ease of use, aesthetics, and related aspects of organizational and contextual fit, if they product is to become a commercial success. The design of products can have a major impact on patient safety, but the interaction of task with the development of a product is often neglected until an advanced stage of development [8]. In the medical device industry, successful navigation of regulatory requirements is essential to bring a product to market [9], and concerns about "design control" can mean a fear of compromising creativity. Even when it comes to innovations that are not visible to an end user – that might happen "behind the scenes" during the initial phases, definition and development of algorithm for image analysis to be used in a diagnostic medical device – design still has a key role in constructing an effective specification which takes into account a wide range of technical and medical factors [10, 11, 12].

Chapter - 2

Fundamentals of Engineering in Medical Devices

Cutting-edge developments in engineering have the potential to revolutionize the field of Medical Device Technologies. However, to innovate successfully, a strong grounding in the fundamental principles of engineering – the "nuts and bolts" – is first required. This includes the ongoing innovation and improvement of the devices themselves, as well as those that are used to manufacture, maintain, and evaluate the quality of the devices. Several engineering homes must also synchronize the development of medical devices with the integration of an array of separate technical solutions. Vibrant economic and societal principles must also be considered, to maximize benefits from the resulting medical products. By taking this integrated view, innovators will be better able to drive new products forward. At present, the vast array of technologies must be synthesized to create cohesive and reliable medical products. Engineers play a crucial role in this process, working to match the diverse game of the different technologies to achieve functional and reliable operation [13]. Furthermore, technologies and products must be integrated cohesively so that their separate functions interact in a logical manner. As an entire industry dedicated to adhering to standards and practices within the engineering landscape, it is too important not to foreground dominant paradigms of innovation when introducing new possibilities. When innovations are engineered in a device from the beginning, or as early as possible in the process, a medical device can be safely regulated, manufactured to defined standards, and effectively serve its intended purpose. Virtually every hospital or remote healthcare facility in the world is now reliant upon medical sensors and instrumentation, underlining their critical role in the modern treatment paradigm. These sensors are used to obtain valuable data about a patient's physical condition, which is then interpreted by clinicians to make more informed decisions about potential treatment pathways. This integration of patient data into the diagnosis and treatment of illness is a multifaceted aspect of modern healthcare that is intended to be further democratized, in part through the output of these innovations. For that same reason, the engineering of medical devices must retain a strong emphasis on global and societal need. Specifically, with the knowledgeable integration

of economic principles such as market research or user feedback, the result may be directed to democratize healthcare in more low-resource areas. Furthermore, by very careful and lean engineering, additional functions can be added to a device, beyond that which it was originally conceived to produce [14, 15, 16].

2.1 Materials and Manufacturing Processes

The selection of most suitable materials and the employment of high-level manufacturing processes are crucial issues in medical device development. Biocompatible, biodegradable, synthetic and specific composite types; their properties and their applications may be used by designers. Material properties have significant impact on performance, safety and patient comfort. For device development, the relationship between biomechanical performance and material properties is essential. Selected materials should meet biomechanical and biological demands to ensure efficient performance [17]. The mechanical, ablative, and thermal capacities of materials have a direct influence on the biomechanical performance, durability and lifetime of the device. Materials with low damping loss factors and superior dielectric properties could minimize conducted noise and heat generation, leading to an increased energy efficiency and safety. Advanced materials may provide lightweight, durable and miniaturized designs, thus improving the CT system. Parameters such as powder type, porosity and bulk density of the materials may affect their thermal behaviour during loading. High thermal conductivity and moderate specific heat capacity results in a more efficient ablation. Also, the harmful fumes containing carbon black particles occurring during ablation processes are avoided with such materials that provide an environment-friendly operation. Ceramics containing ZrO2 and Si have aesthetic qualities with high-temperature properties and tribological wear resistance. Such device components give the patient comfort and confidence for treatment.

There are many advanced manufacturing processes such as additive manufacturing or 3D printing; injection and compression molding with advanced tooling design and surface coating; high-pressure processing; and computer numerical control (CNC) machining with micro or nano-scale coolants and grinding wheels. Injection and compression molding with advanced tooling design, coating and technologies represent a significant advance both eco-friendly and cost-wise in manufacturing of medical devices [18]. As a result of the coating with a suitable thickness, being polished, and produced by high-quality process, the advanced tools can be used for many cycles with providing molded products without forming, fitment and burrs. It is crucial to utilize the micro or nano-scale coolant that requires minimum

lubrication in high-speed machining in order to manufacture more complex and high-quality parts in the designed and qualified shape. The synthetic cutting fluids, which are water-based nanoparticle emulsions, may provide efficient cooling and lubrication with a reduction of both energy consumption and cycle time. In machining of medical device components developed by using injection or compression molding; the choice of different coolants, such as synthetic or biocompatible using synthetic lubricants or vegetable oils is essential. The CNC machining of prototype parts requiring more rigid fixturing and higher cutting forces will be manufactured using composite or bulk nano-structured materials. After the test of final prototype, the found machining process, fixturing setup and machine parameters will be applied to mass production. For the development of medical devices, the process of prototype parts will involve machining various size, design, and biomedical component materials. The machining process will also inform iterations to design and functionality of the initial device concept, based on the test, biomedical and usability feedback [19, 20, 21].

2.2 Sensors and Instrumentation

Monitoring various physiological parameters is a critical component of medical devices employed for diagnostics, health monitoring, and therapeutic applications. The time and accurate data collection enable the diagnosis of disease and bodily function analysis over time. Recently, the introduction of innovative technologies and sensors has expanded the range of monitored vital signs, leading to better diagnostics and life quality improvement. Medical technologies achieve wireless connectivity through the use of sensors and smartphones. Advanced sensors embedded into clothing or wearable gloves have been integrated into health-monitoring systems. Smart-skin patches composed of fully functionalized printed circuit boards have been developed to measure bio-signals (heart rate, temperature, and tapping), analyze data, and send reports to a physician. The accurate calibration of sensors and device performance is also a key design consideration. It generally requires a well-prepared and costly testing environment. The intended application case may not be fully considered in the lab for the heart rate sensor of a wearable device. In this case, the manufacturer always provides instructions on achieving the accurate use of the device. A proprietary method of skin impedance measurement yields heart rate data. Inertial sensors are used to measure motion acceleration. The data is processed with the algorithm, exported to a personal computer, and then shared, with the algorithm.

Sensors work in combination with software algorithms that process the input raw data and output it in a form suitable for viewing and expert analysis.

Through this processing, signals can be extracted that should help the doctor determine if further diagnostic steps are needed. Monitoring physiological signals outside the clinic ensures that data can be analyzed continuously over time and therefore with a greater probability of information gain. In addition to traditional diagnostic tools used primarily in clinics, an effort is also being made to miniaturize devices and integrate them into clothing or other wearable accessories. Using miniaturization, the individual functions of the analyzed measurement devices are reduced. Medical devices can be divided into broad classes: active and passive. As the name implies, passive devices operate with their own generated signals, while active devices require external excitation. Whatever the type, care should be taken to ensure the proper calibration and accuracy of the instrument, especially if the device is to be used either to simply warn of impending health problems or to provide data for making a diagnosis. A warning system can only be considered reliable if it successfully raises alarms when health indicators exceed or underestimate some standard level of safety. Everything takes a different direction with diagnostic devices. Look at the huge leap made by companies to create diagnostic machine learning algorithms and create hardware that can be used with a smartphone. Such devices, on the other hand, process the raw data detected by the sensors and provide the clinician with information that can help with a quick diagnosis. This information is very often a derivative parameter that is not directly measured by the sensor and cannot be seen when looking at the initial obtained data. In doing so, the measurement data is transformed into an interpretative conjugation understandable to a person expert in this matter. With the development of multi-sensor platforms adapted to the specific needs of the population, an ecosystem is created that can immerse the clinician in a cloud of data. The redactor and weight processing algorithm of the obtained data should transform it into an expert-vision shape (features extracted for expert practitioner review), which will point to possible therapeutic interventions. Monitor very basic vital signs and other relevant health parameters. It is in the practical pairing of sensors and implemented algorithms in the form of a device that the real clinical potential is revealed. This range of products made it possible to depart fundamentally from the diagnostic arsenal with a scope limited for the most part to a group of people specially prepared to use this technology. The triumphant symbiosis of sensors, instruments, and analysis algorithms gradually enters everyday life and makes it possible to think about effectively controlling personal well-being without needing to leave the comfort of your own home. The atmosphere of the pandemic only intensified research in this area, and the presented technologies finally began to flourish, subject to exponential

development. In the era of explosive development of telemedicine and remote devices, much is said about telemonitoring and it is still difficult not to draw attention to the possibilities they offer. In practice, these are often miniaturized variants of traditional instruments used to collect uniparametric data (for example, a blood pressure monitor). Most of the time they are designed for one-off measurements, which is why they are not a perfect substitute for monitoring stations. On the other hand, they have a crucial impact on a continuous basis on the care for the patient at home. The therapeutic effect of medicines taken should be monitored over a certain period, which is possible when conducting measurements in the nilling and evening hours. In the living conditions of a clinic, the dose adjustment of a given drug may not bring the desired effect, which entails long-lasting stays in hospital conditions, costly for the health system. Monitoring a set of vital signs does not capture complex life situations, which in the case of more advanced ailments has a significant impact on the interpretation of the state of health. This problem is largely eliminated thanks to the continuous monitoring of the patient at home, which allows the provision of personalized, more precise care with a noticeable improvement in clinical outcomes across a large population [22, 23, 24].

Chapter - 3

Innovations in Medical Device Technologies

In a journey providing the most comprehensive overview of medical device technologies and applications, ranging from design and developments to contexts and perspectives, this special issue has thus far discussed a broad spectrum of the latest advances in medical device technologies. This final article reviews groundbreaking innovations transforming healthcare. The increasing convergence of technology and medicine is lucidly unveiled, emphasizing breakthrough innovations improving the diagnosis, treatment and patient management. Such aspects include new imaging technologies enhancing diagnostic accuracy. Technological advancements in both hardware and software are also changing established practice and creating new procedures ranging from upcoming minimally invasive surgeries to improved rehabilitation technologies. Robotics and intelligent systems play a growing role in this. Miniaturization of sensors and electronic components, often crucial in "advanced" devices, might also reduce new solutions' invasiveness and increase "humanization", leading to more comfortable, "wearable" or "ambient assisted" technologies. Complex intelligent systems, often entailing problems in their validation and certification phases, are essential for devices in direct interaction with the human brain. Some other innovations concern the new materials and sensors suitable for biocompatibility, the upcoming micro and nanotechnologies, homologation standards ensuring a safety trade-off, or the extended use of IEEE11073 standard capable of improving the interoperability of different devices and systems [25]. Appropriate power supply technologies and energy saving human exposure issues should not be neglected. Devices capable of analyzing emotions, using biosensors and intelligent software and intended for the recognition of pathological states associated with emotional impairment, such as autism spectrum disorders are currently in the research phase. This kind of innovative technology is equally being transferred to the sports and entertainment industry with the creation of personal devices dedicated to evaluating the emotional involvement of an audience during the vision of artistic performances. However, there is also a need to answer a plurality of critical questions: is social acceptance in ethical and moral issues granted? Are there unexplored detrimental effects from empowering means and devices? Some concerns about the possibilities of

technologies might take also the perspective of leading industrial sectors manufacturing devices of wide critical use and scale of deployment. Being subjected to powerful and potentially harmful equipment is a straightforward example, but privacy and data security might also be addressed if seen as high-level criticalities of each system and consequent network of interaction. In fact, one of the crucial dynamics is presumed to be the layered composition of platforms enabling different levels of interactions with the device or system itself [26, 27, 28].

3.1 Advancements in Imaging Technologies

The diagnosis and treatment of various diseases had been expedited with the help of medical imaging. Different medical imaging modalities were established having their unique importance and some limitations. With the development of technology, various medical imaging modalities have evolved in parallel. By overcoming the limitations of one modality, another modality can compensate the solution in various disciplines such as visualization of primary structures, internal organs, body fluid, inflammatory process, cancer detection, atherosclerosis and damaged tissue detection, osteoporosis detection, bone mineral quantification, monitoring of patients heart disease and detection of heart attack, etc. Different medical imaging modalities, including X-ray, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Nuclear Imaging (Single Photon Emission Computed Tomography and Positron Emission Tomography), Ultrasound, Electrical Impedance Tomography (EIT), and Emerging Technologies for in vivo imaging are widely used in today's healthcare [29].

Medical imaging has revolutionized healthcare and has fundamentally changed the way many diseases are currently managed. Imaging refers to visual representation of an object with or without the use of coherent light. Unassisted physicians could only see the condition in their patient by direct observation, or through external symptoms such as swelling, or other out-turns to the skin. In this way medical imaging cannot identify fluid accumulation, tumors, virally infected cells and detailed internal anatomy. The art of medical imaging to assist diagnosis started to evolve with Wilhelm Conrad Roentgen's discovery of the X-rays in 1895. Although X-rays were discovered by accident, this new form of radiation excited the imagination of a number of scientists, researchers and physicians. This resulted in the rapid publication of a large number of scientific papers about the properties, practical use and safety measures related to X - rays. Initially X-ray images were acquired by placing the object under study between an X-ray tube and a photographic film. After the exposure to X-rays, the image was taken out from the dark and auto-

processed. The essential development of radiography was beheld by the medical imaging community [30, 31, 32]. Advancements in imaging technologies have had profound impacts on diverse fields ranging from biomedical research and healthcare to security and environmental monitoring. Research in this area has both flourished in recent years and become more comprehensive with new developments reflecting rapidly increasing societal needs. Any new imaging technology must, in the first instance, be understood in relation to long-standing basic principles. Conversely, a technology as pervasive and diverse as imaging cannot be adequately understood simply by focusing on principles alone. A comprehensive understanding thus requires at least one foot in the basic principles of imaging and another in the latest technologies, and applications that continue to augment society's use of imaging services. This set of essay encompasses an introductory discussion of the basic principles, fundamentals, emerging technologies and a sampling of important applications. Part 2: Imaging the Fundamentals, the reader is referred to an introduction to the underlying physics of imaging and specific details related to one modality - X-ray transmission imaging. Vertical and horizontal derivations of the essay are often provided, as with parts on the Doppler effect, lensing and focusing, image quality and MTF, and medical ultrasound. As such, the essay can be tailored to varied audiences. However, most readers are likely to benefit from an understanding of both parts. A comprehensive reference list is also provided in this essay. At the same time, there is a widely recognized tendency for new technologies to be shaped, often profoundly, by the pre-existing societal context into which they are introduced [1]. This can be observed, for instance, in the use of imaging as both a technology of medical diagnosis and in the maintenance of social order and national security. From a different perspective, technological systems are frequently adopted to fulfill a narrow perceived need, only to have unanticipated changes in that system's social function dictate subsequent unconventional development. An example of this aspect of technology-society interaction, namely automated image analysis, is also provided. Broadly speaking, new advances in imaging have led to improvements in either the diagnostic accuracy of information that may be obtained, or the efficiency of the operational systems on which new image technology is based. In each of the following sections, these two aspects will be explored with respect to way in a range of imaging technologies and sociotechnical systems. In doing so, however, a number of common issues are identified that are likely to shape the evolving landscape of imaging practice.

Introduction

Medical imaging is crucial in the diagnosis, detection, and examination

of numerous diseases. It involves non-invasive techniques to generate visual representations of internal organs, tissues, and the functioning of various body systems. Medical diagnoses, surgical preparation, and follow-up treatment rely heavily on these images, which detect, diagnose, treat, and monitor various diseases. Medical imaging is widely used to examine bones, organs, blood vessels, and other internal structures. The medical imaging community benefits greatly from various advances in medical image formation hardware, software, and screening technologies. However, it is necessary to understand the standard principles underlying prevalent imaging modality applications before delving into innovations in imaging techniques [2]. This offers a comprehensive comparison and understanding of the performance of different imaging modalities. With an understanding of the resolution, imaging speed, and safety of the apparatus and the systems methodologies adopted in clinical practice, a rigorous and coherent discussion can then be made regarding the detection and developments of imaginative imaging technologies that further expand the research effort.

Establishing a detailed understanding of common and significant medical imaging technologies coincides with ongoing research into algorithms used to image the agent in each modality. A brief review of each imaging modality is provided below and its plausible usage in detection is examined. This is done with an emphasis on a system overview and how images are obtained. Illustrations will be presented where helpful. Following the review a more comprehensive comparison between imaging technologies is laid out, looking at the pros and cons of each. Subsequent discussion and analysis rely on this knowledge and establish overlap to establish a common framework between the discussion of existing techniques and the discussion of emerging techniques moving forward.

Optical imaging, which uses visible light to create images, is the most common form of imaging and the most foundational in the scientific application. This technique of imaging has inspired the advancement of other imaging techniques in other radiation generating and detecting instrumentations, including ultrasounds, x-rays and γ-ray-based systems, as well as particle imaging, such as scattering and entrainment emissions [3]. An image, in a strictly physical sense, is an arrangement of light, in the electromagnetic spectrum, that carries information of a scene or object of interest, or label in general. Since its invention over one hundred years ago, researchers have been exploring different ways to improve image formation and subsequent image processing and analysis. Generally image formation modality or a technique involves an illumination or generation of light that interacts, reflect, refract, scatter, or absorb in an object and then collection of

that light information, both physically and digitally. The most common methods involve cameras as light detectors with various pattern of illumination--multiplying its application.

As a general modality, the primary principle of imaging involves a light source, although other methods have been explored since the invention of x-ray computed tomography and nuclear magnetic resonance imaging, each with its own principle of magnetic and sound fields generation [4]. In the simplest examination, light probes the universe, interacts with an object, travels to the eyes, and forms an image in the brain. In a more advanced application, light interacts with compound most commonly at wavelengths with an energy gap corresponding to a possible electronic transition, exciting an electron to an upper band, or inciting an over-discharge of longitudinal acoustic plasmon oscillations, in a lattice structure. There are a number of optical imaging techniques with its own modality. Fluorescence can be natural, or exogenous, and only emit after the absorption at higher wavelength light of its bandgap after decay time resides, usually nanoseconds to microseconds, and is a volumes limited technique. Recently, it has gained huge advances in its application in life science, with high-sensitivity presentation and drug delivery. Another technique is confocal microscopy, that uses point illumination and spatially filters the image; hence, exclude distant out-of-focus structures, producing better resolution and contrast.

X-rays are a form of electromagnetic radiation, similar to visible light and radio waves. When X-rays encounter materials, they can penetrate those that are not too dense or too thick. Part of the X-rays are absorbed by the material, while some may be scattered, and the rest may go straight through. Since different materials (and human tissue) have different densities, these differing behaviors often lead to good contrast, making some materials easy to see when looking through other materials. A powerful application of this is 'X-ray imaging', where people can make a picture of the inside of something (like a backpack or a leg) by examining the X-rays that pass through.

X-ray imaging is extensively used in fields such as medicine (for diagnostic radiography, detection of fractures or tumors, etc.), threat detection (e.g., at the airport), industrial inspection, and many other applications. Importantly, it is non-invasive (though dangerous in high doses), and portable versions are available (like in a dentist's office) [2]. Traditional X-ray imaging is typically done using a radiographic film, though the transition to digital radiography is happening in many hospitals due to its many advantages. The quality and duration of scanned X-ray images are improved, plus the efficiency is better, with the ability to easily backup and share the images.

However, this comes with a trade-off, as processing can obscure subtle details of an image. The widespread use of X-ray imaging raises concerns about general radiation exposure, though, when following safe practices, the risk is minimal. Early and protective shielding is widely used. On the other hand, portable X-ray machines now being used routinely help ensure patients receive proper care quickly. Although X-ray has been mostly replaced by the more fashionable and powerful MRI and CT, due to the ubiquity and ease of use, X-ray remains a major player in diagnostic radiology. It is still the most common tool used clinically and is difficult to replace by others in many cases.

Since being clinically used in the 1950s, ultrasound imaging has become a main stream diagnostic observation procedure in the field of medicine, from obstetrics to neurology. Ultrasound imaging employs high frequency sound waves to produce images of soft tissues so it is often used in observation procedures where X-ray is less useful. The principles of ultrasound imaging are based on the reflection and echo ranging of acoustic waves; a transmitted sound wave will be reflected by object with a different echogenicity. The echo returns to the probe which transforms the signal into an image. Echogenicity is influenced by the density or acoustic impedance of the structure. Knowledge of the principles may explain the reason behind the artifacts observed in the procedure, and is basis for the understanding of color flow Doppler or Elastography. Internationally, in 2012 alone, the market of diagnostic ultrasound system is valued 5,983 million U.S. dollars, this means that ultrasound is an ever advancing field where more research and progress can be made. Compared to other diagnostic imaging technologies, such as computerized tomography (CT), ultrasound is a non-invasive, ionizing radiation-free diagnostic tool that has been widely accepted for initial studies of pregnant woman. In addition, the application of imaging techniques has progressively expanded since the early 1980s, running from obstetric to cardiac, in recent years to vascular and abdominal imaging. In obstetric imaging, ultrasound is used for detection of fetus heartbeat and gestational age. In more advanced countries, an ultrasound examination is usually accompanied by a serologic triple screen test to detect Down syndrome. In countries of the Asia-Pacific region, there is a lack of the system of the serologic triple screen test. In cardiology, the technology of Doppler ultrasound examines blood flow in the heart and makes the ejection fraction a more accessible indicator of cardiac function than the traditional cardiac catheterization. Efforts have also been made for left ventricular image analysis to examine wall motion, and tissue harmonic imaging or contrast agent injection to get a clearer endocardial boundary. Combined with CT data, there are reports on better CTA analysis. The above applications provide clear

evidence that ultrasound technology continues to progress and does for such obvious reasons, ultrasound still plays a crucial role in healthcare today. However, there are several limitations when utilizing ultrasound. It is dependent on the operator and accessible windows in the body. Also, the intrinsic pattern of the echogenicity from a musculoskeletal structure renders the ultrasound beam difficult to penetrate when evaluating bones. The advantages of its short wavelength means the ultrasound beam will be easily corrupted in certain conditions. There have been technological progress and innovation since this new imaging technique surfaced. The advent of 3D imaging is an example, demonstrating that the advancement in ultrasound technology has not been overlooked and has instead attained abundant benefits for research and clinical practices.

Over the past few decades, a remarkable development of imaging technologies has led to an increasing availability of a wide range of imaging modalities. Alongside such classical tools as radiography and ultrasonography, this range now encompasses among others computerized tomography, single photon emission computed tomography and positron emission computed tomography. All these imaging modalities have found their way into common clinical practice, as they provide valuable information about different aspects of morbid processes. The development of parallel imaging, the increasing availability of hybrid imaging scanners, as well as other specialized imaging techniques, such as magnetic resonance spectroscopy, electrical impedance tomography and near-infrared spectroscopy, have further highlighted this role. However, on the grounds of its unique capabilities, magnetic resonance imaging (MRI) stands out among the valuably complementary imaging approaches available in current medical practice [5].

The basic principle of MRI is simple: the body is placed inside a strong static magnetic field that aligns nuclear spins. Radiofrequency pulses excite protons out of equilibrium. When the radiofrequency excitation is turned off, the protons relax back to their equilibrium state, emitting a radiofrequency signal that can be observed. Although the physical basis of MRI is electron magnetic resonance, the original discovery has nothing to do with hospital imaging devices. The prototype for MRI is nuclear magnetic resonance. Although the concepts sound magical, they operate on the principles of physics and chemistry. Nevertheless, the application of magnetic resonance in imaging human bodies required a long list of innovators and crises, among which Sir Peter Mansfield learned the most from “journeys through adversity.” The complexity of the NMR principles, the unprecedented

technological requirements to operate at the levels of clinical physics, and the constant threat of strong opposing forces complicated the development of MRI from NMR, and at times success seemed improbable. Without the device the authors managed to bring from the laboratory to the clinic, all the knowledge and techniques in the world would have been useless. Then, the demands of the device partially played to the Britain-based group's underdog status, spinning a yarn of achievements that time after the event seemed poignant [6].

MRI proffers the best soft tissue contrast of all the medical imaging modalities ever used in radiology and stays ineluctable in neurological, musculoskeletal and oncological imaging. In the beginning, MRI scanners were almost entirely magnetic. However, when the costs of magnet construction fell, the cheaper systems flooded the market, and despite dubious diagnostic outcomes, economic imperatives demanded their use. There are restrictions on MRI applications concerning safety reasons. There are contraindications for implant bearers. If a patient is mistakenly selected for an MRI examination, the consequences can range from minor inconveniences to severe injuries. Given that performing routine MR procedures in small rooms is challenging, given the large magnet size. Suitable venues for installing scanners are limited owing to spatial and investment constraints, so patients in remote areas are often unable to access MRI technology. Advances in technology have contributed to the greater ubiquity of MRI scanners. fMRI gauges brain activity by observing blood oxygen levels. DTI measures the directionality of water diffusion in fibrous tissues. A safe technique that is capable of visualizing soft tissues with unsurpassed resolution. MRI stays a pivotal part of modern imaging practices. MRI imaging is not like other imaging techniques. On the contrary, generating data in this mode is without visible radiation. What is harkened to is the implementation of very powerful magnet systems. This technology can be said to be "rather more complicated." Viz. it is magnetic, and it is an odd thing indeed.

MRI plays a pivotal role in the panorama of medical imaging by producing high-quality images with excellent soft-tissue contrast. A variety of challenges and constraints circle around quantitative MRI, precluding automatic creation of numerous valuable tissue property maps that can be used for diagnostic and treatment purposes. One of the standard challenges for quantitative imaging techniques is the long duration of an MRI scan. Meeting the need for high-resolution images in combination with the desire to acquire extensive tissue property maps, it is necessary to sample a correspondingly large number of k-space points. As a result, long scan times may be induced, and due to the unpredictability of breath-hold durations and motion or

pulsation/physiological artifacts, obtaining dense k-space coverage may not occur during the acquisition of a specific line of k-space. To counter this issue in MRI, techniques of data acquisition are designed in which k-space is subsampled during the scan, forming the basis for time-resolved imaging. Tackling this problem, under sampled k-space data acquisitions acquiring the central part of k-space are designed, grapplingly hand in hand with a pseudorandom pattern. Simultaneously, the design of efficient reconstruction techniques is crucial in order to reliably reconstruct high-quality images from the under sampling k-space data. Due to the non-ideality of missing k-space data, the reconstruction of MR images from under sampled datasets leads to various artifacts. To handle this, compressed sensing and conjunctional K-t under sampling, have been developed as ways to reduce MRI scan times and to alleviate under sampling artifacts. Innovations in reconstruction techniques are pivotal for cutting-edge MRI technology and the solemn broader usefulness of patient-specific quantitative imaging can be enhanced by supplementary developments in this regard. MRI technology is continuing to develop apace. There are numerous novelties, such as DTI and fMRI, that were not present twenty years ago. There are undoubtedly further exciting prospects to come. Everything MRI obtains is unseen, but other imaging systems do not have that power. To deity who bestows magnetic resonance visibilium non datur.

Keeping pace with digital technology, software to help diagnosis has developed significantly. With the aid of modern computers, image processing software interprets MR images in a way that the human eye cannot perceive alone. High-speed MRI scanners are becoming more widespread and more affordable, although the price of the examination per machine still remains higher than for other imaging techniques. Aside from breathtaking MR images, a considerable amount of useless diagnostic information is often generated. These days diagnostic centers themselves proffer interpretation by radiologists for a fee. Unfortunately in a modern urban environment, unforeseen limitations hinder the practicality of day-to-day work. The facts must be faced: there are never enough MRI scanners. Not only are rural areas unconsidered, even well-equipped district hospitals are often stretch. Finally, insurers are not generally disposed to honoring MRI prices burdened by the weight of amortization outlays and costly maintenance costs. So, as thrilling an employment as it may be that unfolds the wonder of the human interior, there seems to be a deficit between what modern MRI technology offers and its more general utility in society.

Computed Tomography (CT) was discovered in the 1970s. It has since

become an essential diagnostic tool in healthcare [7]. CT scans employ rotating X-ray source and detectors to produce a cross-sectional view of the body. Precise control of the X-ray source, detector rotation, and bed movement are needed to obtain a 3D volume of the scanned field. With its high imaging speed and detailed view, CT has revolutionized diagnostic capabilities. It is crucial in situations like trauma, where speed and a general overview of the injury are required. CT is also used to investigate more complex medical conditions. It can detect small, hard-to-find masses, and is useful for cancer staging. It can produce high-resolution, 3D images of blood vessels. These are only a few applications of CT in healthcare. Over the years, CT technology has advanced significantly. One of the key developments is multi-slice CT, where there are multiple source-detector pairs allowing the acquisition of multiple slices with each rotation of the source and detectors. This has greatly increased the speed and resolution of CT imaging. However, better resolution comes at the expense of higher radiation dose. Efforts have been made to minimize radiation exposure, as radiation risks cause increased screening before examination and could lead to less use of CT as a diagnostic tool [8]. There are on-going developments of low-dose CT devices, and the use of AI and machine learning-driven radiology could assist the interpretation of CT images, facilitate radiology workflow and provide added value. Nevertheless, cost and access are still the reasons why CT is not a widely used diagnostic tool in some countries.

In the last decades, significant advances in imaging technologies have taken place. The latest innovations in this domain arise from a broad range of research fields: from the holographic representation of objects to the imaging of materials and of biological samples at a multispectral level, to the high-resolution imaging of tissues through the combination of optical and ultrasound techniques. These imaging modalities are presented, explaining the new perspectives they open up, possibly reshaping the professional scenarios of the innovative and stimulating field of modern imaging [2]. Holographic imaging, allowing a 3D representation of the object, is playing a revitalized role in the representation and imaging of objects in multiple scientific research contexts, as well as in industrial applications.

In the hologram reconstruction, the original wavefronts reflected by the object illuminate a 2D recording of the interference pattern to produce a 3D image of the object. The possibility of recording holograms as a single image has opened up to further and broader applications. Holograms are employed in a broad range of applications, from Laser Doppler Techniques for velocity measurement of fluids and vector reports for PIV-based analysis of the flux as

a flexible replacement of laser light sheet for Laser-Induced Fluorescence applied to natural convection in a rectangular cavity. A different approach is provided by the reconstruction and visualization of Computer-Generated Holograms for modeling and diagnostics of complex aeronautical test models [9]. The fundamentals of the method and the first experimental results are shown, demonstrating the breaking of the diffraction limit in the image of EUV reflective samples. Special focus is given on the aspects of the implementation in a laboratory environment, including phase and amplitude noise, mask templates, and reference metrology, which have intrinsically been seen as the bottleneck of practical implementation of this emerging technology.

Three-dimensional images that can be viewed from any angle have recently become widely familiar due to the spread of video holograms and 3D printers. A hologram filmed at a dance concert, for example, can make viewers feel as if they are actually there. Likewise, digital holography is said to be a "game changer" in the field of visual measurement, and its applications have been rapidly expanding beyond the conventional use in observation and image processing to diagnosis and remote sensing. This technology allows the recording and reproduction of information related to the light waves reflected and scattered by an object, forming three-dimensional (3D) images that show the depth of the object and can be observed and analyzed numerically. Currently, both hardware and software have been developed for holography [10]. This work aims to introduce digital holography, describe how holographic images are recorded and visualized, and discuss some of the applications and new possibilities of this technology.

The principle behind holography was first patented in 1947 by the British physicist Dennis Gabor, who would be awarded the Nobel Prize for this discovery in 1971. Gabor had the idea to use the interference between the light reflected on an object and a coherent reference beam to record the intensity distribution at the object in a photographic film. The so-called hologram could then be illuminated with this same reference light and the 3D image reconstructed by the diffraction of light. This difference between a holographic recording and traditional photography is that the formers registers not only the intensity of light, but also its complex amplitude. Unlike photographs, the holographic image is a recording of all the data from the field of an object, and thus contains the depth information that allows the visual systems to perceive depth. A hologram of a scene gives a vivid impression of seeing the object which generates the light [11]. Because of the requirement of mirror-like reflection, holography was at first limited to transparent or

remotely illuminated objects, and since the available imaging technique until the 1960s were large, costly, and with long setup times and even longer exposure time, the full potential of holography took some time to be developed and realized. From that time, the experimental advancements had been quite impressive, shifting from laborious work to prove the principle to the current state-of-the-art stand-off systems. Major story lessons, and associated technical development can be reviewed for the care of acknowledge to this research avenue.

Recent years have seen an increasing number of new imaging technologies that advance beyond traditional modalities. The combination of light absorption and ultrasound technology gives birth to the novel imaging technology named photoacoustic imaging (PAI), which provides high-resolution images of tissue. Photoacoustic imaging is based on the photoacoustic effect, the physical process by which light absorption results in the generation of sound waves. In one typical regime, short laser pulses are used to induce the rapid thermoelastic expansion of an optical absorber. The expansion generates a small pressure perturbation that then propagates as an acoustic wave for subsequent detection (photoacoustic wave). The photoacoustic signal generated by the tissue generally scales with the local light absorption with good or strong linearity and can be employed to produce high-contrast images [12]. This makes photoacoustic imaging a valuable tool for both pre-clinical and clinical research, potentially revolutionary for therapeutic and diagnostic purposes.

A compelling feature of photoacoustic imaging is that images with outstanding contrast can be constructed from an endogenously present target chromophore without using the injection of extrinsic contrast agents. Photoacoustic signals are generated when biological tissues absorb nanosecond laser light to transiently heat and thermally expand, which generates ultrasonic waves [13]. The ability to generate high-contrast images of endogenous light-absorbing tissue components has propelled the development of photoacoustic imaging as a powerful research tool. The combination of the practical advantages of imaging methods based solely on ultrasound detection, with the good image contrast of pure photoacoustic imaging in an instrument capable of real-time output, excites a number of noteworthy new applications. Endogenous target contrast based on chromophores displayed a more rapid circulatory uptake rate than surrounding tissues, permitting temporal separation between this absorbing blood pool and longer timescale uptake related to the leaky vasculature in tumour tissues. An imaging probe based upon this mechanism was developed and validated in vivo on murine flank tumour models.

Multispectral imaging captures image data across a subset of the electromagnetic spectrum, often consisting of adjacent or discrete channels that can be in a wide-range or narrow-band wavelength. By utilizing multispectral imaging, detailed information regarding the spectral properties of the imaged objects and scenes can be captured, providing a more comprehensive view compared to common digital imaging capturing data at only three distinct channels (red, blue, and green). Conducting imaging using multispectral wavelengths has gained for a wide range of applications, expanding across different disciplines such as material identification, ecology and environmental monitoring, agricultural crop assessment, and medicine diagnostics. Capturing objects and scenes' detailed spectral properties as well as their spatial aspects has been an essential factor in achieving better analytical results [14]. Multi- or hyperspectral images can also be combined with additional sensor data to further enhance the descriptive aspects.

Broadening the wavelengths can reveal the hidden features of the objects and scenes, enhancing unique aspects that could not be visualized using a common digital RGB image. Advances in sensor technologies and data processing have allowed to efficiently obtain and analyze multi-and hyperspectral data. The wide use of sensor-based devices in recent years has promoted the development of numerous sensors that can capture image and spectral information simultaneously. This progress has led to the development of both professional-grade sensor devices suitable for laboratory experiments as well as portable sensor-based devices equipped with advanced data processing and calculation functions. Despite the rapid development, it remains a challenging task to process and interpret multi- or hyperspectral images effectively. As multispectral cameras capture a vastly more comprehensive spectral range, the need for a substantial amount of data is generated, which requires extensive storage and may increase the complexity of analysis. Moreover, incorporating the captured spectral information with spatial aspects results in a substantial increase in data volume and complexity. Nevertheless, the detailed spectral and spatial information captured in multi- and hyperspectral images allows to explore or analyze various objects and phenomena in greater detail, and moreover, in an advanced way. Emerging multi- and hyperspectral imaging technologies have a promising future and are expected to develop proficiently in various advanced research and industrial applications.

Imaging technology is the creation of visual representations of objects, and photography is one of the earliest forms developed by mankind. With the implementation of many new imaging technologies, such as the introduction

of photoconductors and computer image processing, imaging technology has experienced rapid development, and imaging technology is now commonly associated with image processing technology. The concept of imaging technology as visual representations allows for the capture of information on physical objects, and the information captured can then be applied to the analysis of the object, aiding greatly in research. Some notable categories of imaging technology are: general imaging devices such as cameras, general imaging considerations, the development of visual feelings through devices such as spirit writing paper and electric eyes, and a business arena involving imaging technology including scanners, facsimiles, and personal computers. MRI, X-ray, and Computed Tomography are examples of medical imaging technology that will be discussed individually.

In 1972, Computed Tomography was introduced, utilizing the attenuation characteristics of X-ray beams through the human body. By rotating an X-ray source and detectors around the patient's head and examining the degree of attenuation for each rotation, an imaging technology called CT was developed. In 1990, by applying gradient magnetic fields to nuclear magnetic resonance, a technology was developed that could generate images of the internal structure of the human body. All of these medical imaging technologies have strong relationships with mathematics, as data must be manipulated using mathematical techniques to develop images. In turn, images are also used in mathematics when the circuit conditions for X-ray technology or equipment for examining temperature distributions are to be developed. Mathematically, photographs are understood via the analysis of autocorrelation or cross-correlation done on the brightness distribution of light values.

Medical imaging is an application of imaging technologies in medicine and health care, where images of the body are captured and analyzed to diagnose or monitor medical conditions. It is most well-known for producing visible-light images of anatomical structures like bones and organs, but medical imaging devices are capable of capturing images across the electromagnetic spectrum at a wide range of scales and modalities. Medical imaging plays a crucial role in the modern healthcare system by enabling health professionals to accurately diagnose and monitor medical conditions. The integration of medical imaging into clinical workflows has a significant impact on patient care, aiding health professionals in making informed decisions and leading to better treatment outcomes. Medical imaging has made significant advancements over the years, with improvements in imaging precision and resolution, leading to better-defined, clearer images and more accurate diagnosis. Many modern imaging devices are capable of imaging at the cellular or molecular level. However, imaging technologies are not without

limitations, safety concerns, and ethical considerations. For example, magnetic resonance imaging (MRI) is considered generally safe, but the powerful magnetic fields can interact with metal implants inside the body, which can lead to injury or heat up and higher resolution microscopic imaging can require potentially toxic contrast agents. Since the cost and access to medical imaging are a concern, advocacy groups call for equitable access to imaging technologies. Emerging imaging devices and techniques may address some of these concerns. Imaging technologies are becoming more portable, affordable, and easier to use. Simple, cheap, and less sophisticated versions are increasingly used for mass public health screenings. At the same time, the development of new imaging technologies with higher throughput and improved resolution is crucial for advancing diagnostics and therapeutic monitoring, especially in pre-clinical and clinical research [2] The pressure to further develop these techniques comes from the rising demand for drug development and personalized medicine. For example, molecular imaging techniques are essential in understanding the mechanisms of action, biodistribution, and pharmacokinetics of new drugs, leading to the creation of theranostic agents. Together with radiation and genetic methods, they promote the development of advanced therapies, such as radiopharmaceuticals with theranostic capabilities, in the treatment of cancer and neurological disorders. The aging population and the rapid increase in the number of patients are another factor driving the need for early and accurate disease diagnosis and for new medications. The understanding of disease progression helps in identifying surrogate markers used in image-guided, minimally invasive procedures, and robotic surgery. Techniques like photoacoustics, superspectral, or hyperspectral imaging are emerging for non- or minimally invasive imaging analysis of tissues, cells, biomarkers, and pharmaceuticals, for research and clinical use. Plenoptic and Fourier imaging or advanced light-sheet microscopy with compressed sensing reconstruction and single-molecule imaging are expanding imaging of biological specimens. However, the interpretation of condensed data from these techniques poses many challenges, from simplified anatomical, OAR, and brain models for radiotherapy planning to tools for automated ICH, cerebral aneurysms, and tumours detection or segmentation. Innovative techniques combining hybridities or simple integration of several modalities are necessary. Medical imaging is one of the largest and most sophisticated industries within healthcare, contributing rapidly to scientific research, bioinformatics, and therapy development. Imaging itself is a complex phenomenon with a multitude of variables affecting structures, fixation, field-dependent effects, artefacts, and implicitly the image of special knowledge. Moreover, in the case of living subjects, time-dependent cellular and molecular processes,

hemodynamic parameters, oncological diagnostics, surrounding impedance changes, and pharmacokinetics in tissue and vessels may interfere with the structure. On the other hand, recording a large amount of multimodal data allows the identification of typical patterns, which can be explored by AID to assist in diagnosis, treatment planning, or post-surgery follow-up. As evidence of the data available in this domain, it is reported that the ERR 2018 challenge with clinical and demographic data sets, in image processing, image content, radiogenomics, and the definition of stratification therapies for head-and-neck, lung cancer, and brain metastasis, has attracted participation of 1433 researchers working since BCE Analyzing computer vision-based multimodalities from a variety of imaging techniques. Major role subsets have been developed: carers, end-users and researchers. Caregivers, such as CNs, paramedics, or surgeons, require advanced knowledge of radiology and the application of therapeutic domains, accompanied by the ability to evaluate and interpret intricated text reports comprehensively. On the other hand, clinical users (e.g., radiologists, clinicians, therapeutic planners) need tools for decision support, CADx, 3D reconstruction, segmentation of tumours and organs at risks, tamponade positioning, or dose verification in order to adapt to side effects. Non-patient related research tries to understand the end-to-end process of deep learning-based imaging pipelines converge, double-checking, or cavity loss reduction. Helps in improving data acquisition, reconstruction, and quantitative analyses, by integrating patient health data to build computational models, considering genetic, morphological, and sub-pixel features. It is also interesting that trending papers and imaging tools in the VSG field are clusters. Overall, it is evident that the range of topics is broad and dominates automatic analysis or synthesis towards helping the experts. On the other hand, training generative networks with multi-objective learning can disturb the balance and integrity of the model output if unforeseen biases, limitations, or artifacts occur, forcing outputs to out-of-distribution configurations. This is especially significant when the images are used as input into a more general system. Specific results can be accepted less than the overall model architecture: detection/recognition of cancer. For example, contrastive learning with mask augmentation is reported on histology with PET, enabling the extraction of features by segmenting lymphocytes with an additional study of unsupervised learning in malaria detection. Despite generalization difficulties, the MES solutions have the potential to significantly improve the quality of post-imaging treatments or relax restrictions on data acquisition, while some of the presented results are pioneering and partially exceed state-of-the-art achievements.

Imaging technologies have been widely used in various fields such as medical imaging, biotechnology, and computer vision. In recent years, they

have expanded into industry, construction, and personal applications. With the development of technologies and the reduction in cost, industrial imaging has become more common in sectors of manufacturing, construction, quality control, etc. Industrial imaging not only provides image data as a visible reference but is also crucial for data processing and automation reasons. With essential algorithms, the related applications can improve safety, efficiency, decision-making, etc. [15]. X-ray imaging is another technique that can reveal the inner structure of products, which is essential in Non-destructive Testing (NDT) in the manufacturing process. Images taken in infrared have good result presentation capabilities, which is used by experts in the construction sector. There is a need for real-time solutions for image data collection, which may prevent incidents by monitoring the affected sites. On the other hand, real-time data provide more information with high resolution to improve future analysis results.

Nowadays, automation is a trend in industrial imaging applications. For example, an Inspection and Location System (ILS) was developed, which shows an automatic analysis of optical images. Industrial cameras have been developed to be integrated into equipment and systems. To achieve a smarter operation, cameras with intelligent vision systems are additionally installed. Another trend is system integration to combine different types of image data. Additionally, images can be collected in multimodal ways. However, there are high costs and difficulties in developing analysis algorithms, and effective information cooling and data processing are required.

Astronomical imaging involves capturing light beams passively radiated or reflected by celestial bodies and phenomena. Advanced imaging technologies acquired by large ground-based observatories and space telescopes make it feasible to achieve higher sensitivities and resolutions for better astronomical observations. There are many techniques for astronomical observations, including optical, millimeter, submillimeter, ultraviolet, X-ray, radio, and gamma-ray imaging [16]. Optical imaging is the most common technique, capturing visible light that is passively radiated by stars and an array of known celestial phenomena. Other types of observations are complementary to optical imaging; for example, radio imaging is useful for revealing phenomena such as active galactic nuclei and pulsars that are invisible in the optical.

High-resolution astronomical imaging has allowed for the detection of many new galaxies in deep surveys and the monitoring of transient celestial events such as supernovae, gamma-ray bursts, and tidal disruption events. Technological advancements that have improved astronomical imaging

capabilities include the construction of large-diameter telescopes with adaptive optics systems, the development of large-format focal planes and wide-field instruments, and the emergence of new statistical and computational data analysis methods. However, high-resolution imaging is still challenging due to various deleterious effects, primarily atmospheric interference and light pollution. In order to overcome these issues, significant efforts have been made through international cooperation to build large telescopes at high-altitude sites and to organize international projects on developing a new generation of ground-based large telescopes. High-resolution imaging datasets also play an important role in enhancing theories and models of astrophysics and subsequently in developing an understanding of the universe.

Security and surveillance imaging applications have been the major driver for the development of advanced, and increasingly complex, imaging technologies. Security-related applications of imaging typically require extensive monitoring of an environment, using cameras or other sensors to continuously record activities and detect threats [17]. An overview of the advances in imaging technologies that are employed or have the potential to be applied to security and surveillance imaging applications. This includes coverage of the significant trends in these imaging technologies, and an analysis of the technical challenges and future research directions arising from these trends.

Security and surveillance imaging encompasses a broad range of image capture, representation, processing, and analysis tasks, intended to improve the security of individuals and property, and the prevention of criminal activity. Applications of imaging in such scenarios include, but are not limited to, automated threat detection, intelligent video surveillance, facial recognition, crowd behaviour analysis, and aerial imaging. The past decade has seen rapid and disruptive advances in these imaging technologies and this is likely to continue in the future, with implications for security and surveillance imaging applications. There have been significant advances in stealth surveillance cameras & thermal imaging cameras, including millimetre wave and terahertz cameras, which can ‘see’ through various common materials like walls, and detect concealed objects (including weapons) on the human body [18]. Thermal imaging cameras can detect and record heat signatures of moving objects that would be otherwise invisible to the human eye. These technologies can be applied in a variety of security contexts.

Most current security cameras are (CCTV) cameras with stationary lenses, capturing 2D (visible) images. A trend within camera imaging for

security and surveillance applications is the increasing deployment of intelligent camera systems. These systems will have on-board computing capabilities for real-time image analysis, and there will be a reduction in the retrieval of video files for post hoc analysis. Real-time image processing is important for security and surveillance applications. However, it is difficult to perform real-time processing, because video files have a much higher signal-to-noise ratio than still images, and the sheer volume of data involved is typically too large to be processed in real-time on a standard desktop computer. Moreover, intelligent processing of the video requires complex algorithms, such as for object detection or behaviour analysis, and computationally intensive mathematical operations. Generally, the less compressed the video file, the slower it is to be analysed. The simplest solution to the data weight problem is to compress the video files. A key question facing all those involved in the large-scale collection of surveillance images is how long images should be kept, how they should be stored and how they should be analysed. Data protection legislation allows promotion of such technology but only within a narrow context. A further set of issues concern the ethics of using such technologies. The desire by authorities to maintain peace and security following terrorist attacks is seen to inhibit open debate on legitimacy privacy and civil virtue. Another urgent line of research is the development of adaptive imaging technologies based on machine learning and Artificial intelligence (AI) to cope with the enormous volume of data generated by security cameras, on board police vehicles, drones and Satellites. Machine learning and image analysis could be used to automatically detect aggressive movements or the presence of objects that could potentially be used as weapons. Cities are increasingly using imaging in the form of cameras to guide different civil applications, such as monitoring traffic movements, guiding the spacing of public transport routes, and facilitating communication with emergency vehicles. There is a growing interest in the use of imaging technologies for real-time urban planning and public safety initiatives. For instance, imaging systems are often deployed in city centres or other areas of high human density. Their role in aiding communication, emergency response and situational awareness in case of natural and man-made disasters, or during public protests, is envisioned as a safety and preventive measure to safeguard the communities.

Innovations in imaging are continuously pushing the boundaries of what is technologically possible, leading to spectacular breakthroughs in various scientific, industrial, medical, and other domains. There is a profound importance to deeply understand both the fundamental principles and the innovations of such a rapidly changing field. The study has an equally strong

focus on the progression of these technologies from foundational developments to very recent breakthroughs, such as the combination of multiphoton and terahertz imaging techniques. Some of the most significant applications of these technologies in a multitude of sectors, from cardiovascular surgery and biomolecular imaging to satellite-based remote sensing and 3D printing of structures are explored. The limitations that exist (resolution and cost, well as accessibility to recent monuments for emerging techniques) and still need to be overcome for the full utilization of these technologies are pointed out [19]. It is hoped that scientists and engineers in various fields will be able to orient and guide the development and the application of even more advanced imaging technologies through interdisciplinary innovation and collaboration.

3.2 Robotics and Artificial Intelligence in Medical Devices

In recent years, engineering in medical device technologies has undergone rapid development. This subsection reviews some cutting-edge engineering topics that underpin that progress, seeking to inform readers on innovations and plausible future development in this field. The subsection begins with the latest trend on the impact of modern robotics and artificial intelligence (AI) in medical devices, and it is associated with both encouragement and alertness for engineering research in this area. The second part scrutinizes the current design trends in medical device developments. The last part then measures the future research perspectives in this specific field of engineering research.

Robotics has integrated with artificial intelligence (AI) nowadays, revolutionizing how people work in various fields. Some robotic systems have been designed to work co-operatively beside people, accompanying with AI-driven algorithms to execute complex tasks as well. In the medical field, robots have made their way into surgery, such as da Vinci surgical systems mainly for telesurgery. Other surgical robotic systems, like the Versius robot, have been designed for eventosurgery, which needs collaboration with the operating surgeon [33]. The advantages of these robotic systems include steadiness during surgical procedures, hence improving precision, more miniatory movements which are impossible to perform by hand, less invasive surgical techniques against traditional open surgeries, and in some cases shorter recovery times and smaller post-procedure scars. This high precision approach is so attractive it became the focus of surgery at the expense of some in mind disadvantages. Nonetheless, surgical robots may be developed to restore such abilities, such as the NeuBtracker device applying neurofeedback to restore motor skills and focusing on aiding in complex surgeries.

Chapter - 4

Design Principles in Medical Devices

Healthcare technologies have emerged as a new paradigm for the protection of individual and public health, due to a growing demand for precise, efficient, and patient-specific procedures and treatments. The maturation of cutting-edge tools in the domain of signal, image, and language processing lay at the base of innovative applications and tools design for healthcare, with particular attention to use-cases with potential biomedical impact. Here bio-signal acquisition from properly designed devices provides a machine with important information about health and diseases, supplying the background for several exploitation scenarios, such as personal healthcare, clinical applications, and medical training. From a technical point of view, the investigation of innovative techniques for feature extraction and selection from selected physiological signals has been pursued together with research on new frameworks for the development of applications and the design of user interfaces. Hence, a non-intrusive solution for heart rate monitoring is presented, based on image metadata analysis, providing a 0.31% error in heart rate estimation compared to a reference method. Another innovative approach towards smart home solutions for healthcare is the joint use of both light and on-body sensors. Here, a novel unsupervised optimization technique for multi-sensor fusion together with robust window-based statistical analyses has been carried out, giving a precision rate higher than 70% even for hard patterns recognition. The work reports on user-centred interaction design process leading to the development of a healthcare media-centric workstation for diagnostic and therapeutic purposes.

The design of medical devices is governed by 3 main criteria: safety and performance, which derive from technical standards, the state of the art and the international regulations; ease of use and the satisfaction of the “use” requirements both refer to the interaction between the medical devices and the end-users. A user-centered design methodology for the establishment of the interaction between medical devices and their end users is proposed. User-centered design is a concept derived from the broader human factors and ergonomics domain and considers the characteristics of the end user as a fundamental criterion to address during the design of products. From a process

perspective, the project develops a user-centered design workflow specifically designed for the medical device development industry. Two case studies are presented in the cardiovascular domain: a class III implantable cardiac pacemaker and an extra-corporal shock wave lithotripter. The projects involved several partners including research institutes, end users and industrial companies providing a variety of competences and interests for the establishment of an interdisciplinary process. As a methodological contribution it is shown that the proposed approach ensured the successful development of innovative medical devices that are better tailored to the needs and characteristics of the final users, maintaining efficient and unproblematic use [34, 35, 36].

4.1 Human Factors Engineering

When considering requirements during the design of medical devices it is essential to examine in detail the needs of the intended users. This involves an understanding of the tasks which the user will carry out with the device, as well as an awareness of the environment within which the device is to be used. Analysis of the device-user interface is central to such considerations, along with an understanding of the users own capabilities, limitations and expectations. Usability issues must become a primary consideration for regulatory bodies to ensure that safety is optimized. All medical devices must keep this at the forefront of the design process, along with efficiency, effectiveness, and ease of use.

Since 1996, when the U.S. Food & Drug Administration recommended that user trials should be conducted for medical equipment, engineers have been considering the implications of this on the design and testing of medical devices. When undertaken in the initial stages of design modifications can be made before final safety testing takes place. These may be simple ergonomic changes, but it is often the case that new tasks and training issues are highlighted which require a complete redesign. Human Factors as a tool is well established in many industry sectors and methods have begun to be transferred to the assessment of medical equipment. Traditionally the medical profession has been resistant to the involvement of engineering human factors; however, outlined is a simple approach for the inclusion of such expertise. Though productivity in the workplace can be improved by training or through careful organization of tasks, the focus on productivity can lead to a neglect of safety. Stress, a common effect of increasing work rate, can lead to error and decline in performance [37]. The development of an understanding of the factors which affect performance in the workplace and subsequently the manipulation of these factors in system design can be achieved by the practise of human factors [6, 38, 39].

4.2 Usability and User Experience Design

Introduction Section 4 consists of several subsections that give a detailed account of different components of engineering design that contribute to the creation of new devices, illuminating some salient issues considering the broader medical device context. Subsection 4.1 focuses on initial phases of medical device development. 4.2 discusses usability and user experience design relevant to medical devices. Finally, 4.3 briefly considers technical documentation essential for translating a product concept into a marketable and functional device.

This subsection provides an overview of usability and user experience design principles from a broad perspective of engineering design innovation, before delving into the specifics of medical devices. It also outlines current trends and potential innovations in fields of usability and user experience design. Engineering design is not just about the way a device looks but also considerations of how it operates and the benefits it brings to the user. It is important that devices are usable. However, it is equally important to consider how a user experience impacts a wider emotional response, how satisfying they find a device to use, and how the perceptions of a particular brand or product line can be manifested in the look and feel of a device. A core tenet of user-centred design is the SDLC, ensuring that a product development systematically considers the needs and feedback of users at every stage of the system development process. A crucial stage of this cycle is usability testing, observational or experimental assessment methods where participants give direct feedback on how effective, efficient, and satisfactory they found a device or software platform to use [40]. Ultimately, the most successful designs will go unnoticed; that is, the machinery, devices, or software we interact with every day are for the most part intuitive, quick, and efficient [9].

Devices that are difficult to use, slow, or cumbersome to operate, stand out for all the wrong reasons. Instead, we appreciate an elegant horizon on the morning commute, we marvel at the ornate aesthetics of a watch face, or we treasure how the clean lines and curved edges of a mobile phone fit snugly in our pocket. In a healthcare setting, where the primary focus of a healthcare professional (HCP) should be the welfare and treatment of the patient, it is essential that medical devices clearly improve and expedite care delivery. At the same time, it is equally crucial that medical devices do not act as a source of frustration or an unnecessary distraction for HCPs. Furthermore, with medical devices becoming increasingly prevalent in a domestic setting, whether for self-administration or an in-home diagnosis, it is necessary that patients find the operation of these devices intuitive, efficient, and reassuring

(HCPs), with the most significant exposure to medical devices out of all healthcare professions. Understanding usability principles may prove particularly advantageous in the design of new medical products [41, 42, 43].

Chapter - 5

Regulatory Framework and Standards in Medical Device Industry

The increasing penetration of cutting-edge and nanotechnologies in the manufacture of medical devices is reflected in the rapid development of corresponding regulations and safety standards governing the materials, functionality, and clinical application of such medical devices as an intrinsic part of global harmonization efforts to facilitate international trade and technology transfer. To market innovative medical technologies and products, and at the same time to provide that clinicians and patients benefit from safe and efficient products, companies and developers need to understand the regulatory issues and safety standards relevant to their technology class and application. During the past decade, there has been a rapid evolution and expansion of biomaterials and medical device technologies built on the convergence of bio- and nanotechnology, in addition to the ongoing development of minimally invasive transluminal therapeutic procedures and novel biocompatible device concepts. Success in the development of novel medical device technologies, in turn, demands adaptation of the regulatory environment and the specific safety requirements of the products involved. Such requirements are not only specifically tailored to individual technology fields, but further depend upon successful integration of medical device technologies into the extensive and complex knowledge base of modern clinical medicine, encompassing concepts in biophysics, biochemistry, biomedical engineering, and the interdisciplinary development of medical, non-medical, healthcare, insurance, and security regulations. Similarly, the rapid development of advanced research tools and advanced therapeutic medical devices needs to be developed with envisioned regulatory approval routes in mind, and design strategies for regulatory conformity need to be considered early in the development of novel tools and technological paradigms. [44, 45, 46]. Medical devices play a critical role in modern healthcare throughout diagnosis or treatment processes. Rapid expansions in technologies give rise to the production of various medical devices that progressively become more complex. Such devices serve to characterize, reduce, treat or compensate for particular diseases or conditions, and the application of these medical devices involves especially sensitive human

systems. In the meantime, these medical devices could also lead to significant hazards in the case of variations or malfunctions comprising either physical injury or biological consequences.

The intended purposes also vary widely, such as the monitoring of a given patient's medical condition, the enhancement of performances of impaired physiological condition, the development, and control of supporting conditions for specific therapy, or the substitution of particular organic functions. To use such devices for the benefits of public health, their qualities, safety, and efficacy for patients and users have to be ensured. Hence, the essence of a regulatory framework that identifies these devices and demands to provide concordant proofs that they fulfill determined requirements in terms of quality, safeness, and efficiency [1]. A more and more vital role of medical devices in present-day healthcare and the inherent dangers and difficulties associated with such kinds of products advise a requisite review of the rules and standards in force in widespread bases. Increased risk for public health or user safety and transposition to medical devices of the pharmaceutical sector information are playing into well as reasons for this work. Along with the manufacturing and design rules define in the regulations and standards, regulators have to determine regarding these devices the needed tests and trials to assure a proper clinical evaluation and post-market vigilance [2]. Such procedures suffer to be on the level of complexity and care associated with the devices' level of risk; the fast-growing sophistication of these devices results in the rules and standards to being subjected to periodic re-examination. For the manufacturers of medical devices, compliance of these standards and rules conditions assessment and market access; breaching such requirements could fall legal consequences. Comparisons of significant regulatory frameworks effect in Europe, the United States, and China were performed for cardiovascular devices and related aspects of rhythm disorder therapy.

A medical device is defined by the Food, Drug, and Cosmetic Act as any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including a component part, or accessory which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or is intended to affect the structure or any function of the body and which does not achieve any of its primary intended purposes through chemical action and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes [3]. Medical devices can range from simple, low-risk devices such as tongue depressors, bedpans, and disposable gloves to complex, high-risk devices such as pacemakers, automated external defibrillators, and prosthetic heart valves.

In the most basic terms, medical devices are classified based on their intended medical purpose and the duration of use. In accordance with the European Union and the Food and Drug Administration in the United States, medical devices are classified as follows:

1. Class I devices are deemed to be low to moderate-risk devices that are typically simpler in design and function. Examples commonly include dental floss, bandages, stethoscopes, and heating pads. 2. Class II devices are considered to be moderate to high-risk devices that are typically more complex in design and function. While this class includes many types of devices such as wheelchairs, infusion pumps, and infusion catheters, it can also include test kits, syringes with needles, and vital signs monitors. Many devices within this class falls under the generic category; also known as the automatic class III de novo process. 3. Class III devices are considered high-risk devices that are typically more invasive and complex in design. Examples include implantable pacemakers, prosthetic devices, and defibrillators.

With the large range of potential devices currently active in the market as well as new devices entering the market, it is important for manufacturers and regulatory bodies to accurately classify devices for review. An appropriate classification will allow for manufacturers to meet the necessary regulatory pathway and approval processes. For regulatory bodies, classification of devices will help to ensure safety and effectiveness to the patient. Understanding and knowing the classification of the device will help to ensure that unnecessary burdens are not placed on those who are subject to a device regulation. In turn, the establishment of fair classification and transparent criteria will protect public health in understanding what classification a device has and why.

Innovations in the medical technology are very dynamic field, focused primarily on improving the patient´s life quality, and promoting health in both prevention and cure aspect. By using the medical devices, certain physical functionalities might be improved, or completely substituted by another enhanced one. The effectiveness and safety, usually with some non-technical requirements, i.e. usability, reliability, human and environment protection, are among others evaluated and assured by the regulatory framework in form of law-related technical standards. Other standards providing reasons and precise description for essence of "therapeutic devices", and the mechanisms supporting it, help to understand the background for regulation evolution. Importance of the effectively available market access and fair competition on the B2C field is shortly discussed, and a set of remarks on the discussed lists of standards is added. A paramount example, providing how to design

standard in order to protect patients, most of which are not doctors and usually do not work in hospitals, is included. This patient protection volume, on which further text upon this subject is going to be mostly based, stipulates how to create the consumer-safety policy in supporting "therapeutic devices", and what kinds of products it exactly covers. Additionally to the certain prescriptions for these products, a way on how to control these products is described (including requirements on information supplied with the product, documentation, and measurements of physical and functional properties). Next to the consumer safety, the disincentive of using group or species in favour to another is briefly discussed. But since the "devices" must be defined in the regulations as the characteristics of product matter and biology is strictly described, most of what is said applies equally to this exclusion too. The sovereignty agreements for the medical devices market is outlined and provided. Using the standardized methods defined within quality management systems and good market practices provides an explicit indication on the level of development capability in order to fulfill legal obligations and customer requirements, and can as well be internal guidance for the design process. Furthermore it helps to implement the mindset culture in the environment of the research and production units. In-depth discussion: Compliance with regulatory requirements is not only a statutory obligation, but also builds a strong relationship of trust not only among consumer and healthcare providers. This is valid even more in conditions where the inherently unsafe and harmful products can be easily developed and distributed presenting as the medical products.

Quality and safety are vital considerations in the manufacture of medical devices. At present, there are many international standards that provide an effective guide for designing and maintaining a medical device quality management system, including ISO 13485. With the recent global opening of markets, it is worth noting that enterprises that comply with international standards have a great advantage in the market competition. There are many standards for medical devices; the criticality of applying the latest edition or version cannot be ignored. As an example, IEC 60601-1 edition 3.1 is a document about safety requirements for medical electrical systems. If the manufacturer's product is intended to meet the safety performance specified in the applications technology, it should follow this standard. Otherwise, in the surveillance and test of optimum after a period of use, the medical device may be applied with a claim in terms of safety. As many international standards can be referred to medical device manufacture, safety, effect, management, commit to quality management, and development of general activities. The ability to effectively cooperate with other departments,

including research, purchasing, and quality control, is needed. The means for the activity of the standard in your region are also proposed.

A rigorous system of standards is indispensable to ensure that specific devices perform correctly and safely. But the means to meet the procedures according to these standards are often lacking and difficult to understand. Every year, there are many standards revised and released, resulting in a substantial run-up cost for manufacturers, which is difficult for a manufacturer outside the developed counties to bear. This is why several international standards need to change attention, and the safety performance is taken as an example. For the limited evaluation of the medical device, the innovative task is deeply understood and then the medical device console is controlled. In conjunction with the study of international standards, the manufacturers are with an opportunity to prosecute consistent development of goods, manage or manage safety or lawful demands, and promote a general understanding of the development of the medical device itself. To other economies, Arizona is almost the common process disease this capacity. France voted with several standards, having the effect of the prescribed level approach the safety performance; those are. In terms of the European Union, devices with performance specifications that approach the general public intended to meet the essential requirements [4].

ISO 13485 has been published as a facilitation of the harmonization of national and international quality management system standards specific to the medical devices industry. Given the broad diversity of health technologies, this standard is often regarded as a set of complementary standards and not as a substitution to ISO 9001. Medical device manufacturers are obligated to comply with ISO 13485 in order to provide evidence that they are able to consistently meet customer and applicable regulatory requirements. It aims at enhancing customer satisfaction by the effective application of the system, including processes for continual improvement and the assurance of conformity to customer and applicable regulatory requirements [5].

Regulatory requirements have been rapidly tightening in the medical device industry, thus adopting effective quality management strategies becomes critical for sustainable success. There’s a need for manufacturers to assess and implement measures that assure the effectiveness of their quality management system, making sure that such system keeps pace with the fluctuations in risks and requirements. This should be demonstrated through comprehensive evaluations, improvement goals, and subsequent structuring preventative actions when risks exceed the accepted levels. The manufacturer must ensure the evaluation is conducted and maintained through specific data.

It recognizes that policies, procedures, and activities performed by the organization can only be regulated, followed, and improved when properly documented. Document has been defined as the written procedural ethical, or quality system controls containing the perimeters and limitations within, all activities are set. In ISO 13485's context, these boundaries should define activities related to the quality system. It is crucial for the information contained within to be transparent, adhere to reality, and be easily auditable. Such materials must also be precisely worded and approved by the management. It is also the responsibility of the organization to maintain records, both as evidence of conformity and to enable traceability.

IEC 60601-1 has become an instrumental standard for establishing safety requirements for medical electrical equipment as well as systems. Compliance with normative requirements of IEC 60601-1 3rd edition series and general performance standards IEC 60601-1-2 is necessary for certification of medical devices. There are essential risks concerning electrical safety for patients or medical staff with regard to utilizing electricity for medical devices or electrical medical equipment. To establish safety, such negative impacts are to avoid using basic technology and the integration of safety regarding power sources and grounding continuity. IEC 60601-1 is about "Medical electrical equipment – Part 1: General requirements for basic safety and essential performance". IEC 60601-1 3rd edition was issued in 2005, 30 years after the 2nd edition was issued in 1977. It came into effect in 2012 for the 3rd edition series. Furthermore, IEC 60601-1 4th edition was established in 2012 and came into effect in 2020. Two overviews and a comparison have been published on the 2nd, 3rd, and 4th editions and a report edition too. The object of IEC 60601 2nd edition is to establish a set of basic safety objectives that will provide protection to termed patients and operators under the condition regarding the medical electrical equipment or system employed in its proper manner. The classification of inputs to biotechnology is outlined for new users designing or utilizing medical devices. It is intended that this categorization be consistent with IEC 60601-1 and appropriate for specialized practical stages, as technical information is utilized. A general overview of standard/work is provided, with a description of the testing and validation process to indicate compliance with these safety standards. Understanding IEC 60601 "Medical electrical equipment" is essential for manufacturers designing medical electronic equipment that is safe and reliable. There are also insurance and liability considerations in the medical market. Inspection of legal cases indicates that compliance with IEC 60611 is in focus for safety issues by the appraisal of alleged experiences [1]. Describes that CHAdehyde microspheres mostly regarding the safety requirements for attendant exposure,

then contrast how the IEC and wireless network modeling view such exposures. Evidence adapts that the network constitutes the exposure computer model strengthening personal safety and medical literature. In this, the network modeling propagation model is subtended and the needed constraints and the model validation are detailed.

Before new medical devices can be legally marketed in the U.S., manufacturers must comply with U.S. Food and Drug Administration (FDA) regulations. Medical device manufacturers must ensure the devices they manufacture have gone through the necessary post-market surveillance and quality control checks. A significant part of this is ensuring the devices have appropriate labeling and technical testing to ensure they are safe and effective [3]. FDA regulates this aspect of the manufacturing process and is responsible for making sure medical devices that go on the market in the U.S. are safe and effective. The FDA has developed regulations for overseeing medical devices that are outlined in the Food, Drug, and Cosmetic Act of 1976 (FD&C Act). Medical devices manufactured or distributed in the U.S. still must meet U.S. standards, regardless of whether they need to comply with international standards.

Medical devices are classified in one of three groups based on risk potential to patients: Class I, Class II, or Class III. Some products also receive classification according to combination/product devices. Class I products are simple in design and intended use; these products have a low or moderate risk to patients. Class II are more complex and have a moderate or high risk to patients. Class III products are subject to the highest level of regulation due to the significant risk they pose to patients. The regulatory class of the product plays a significant role in determining which FDA regulatory pathway to market is most applicable. There are many requirements of manufacturers prior and post-market release including compliance, reporting, quality systems, and labeling regulations. It is important for companies to consistently monitor the regulatory standards to ensure they are compliant, as these standards can change.

The 510(k) is a premarket submission made to FDA to demonstrate that the subject device is substantially equivalent (as SE and more specifically SE with Indications For Use) to a device that was legally marketed for the same intended use prior to May 28, 1976; it allows the commercialization of a device in the U.S. market [3]. When manufacturers identify that their device does not comply with the predicate device classification or with that of low risk devices, they will use the De Novo pathway.

The De Novo process uses a special form of submission for devices that

do not meet the substantial equivalency after the 510(k) review but do not warrant the categorization of Class III either. Due to the problems of the 510(k) pathway, the FDA has also taken action to further up-classify and regulate devices in Class III; the processes of filing the 510(k) application and submitting the de novo classification request have been closely followed together; there has been extra precaution regarding new devices and has also led to an improbable impacts on innovation and the entry of new devices into the market.

Medical device manufacturers aiming to introduce a new product on the US market have to obtain marketing approval from the Food and Drug Administration (FDA). The FDA uses a rigorous regulatory process to clear or approve medical devices, which is designed to assure that patients and healthcare workers have access to efficient, safe, and high-quality devices. Medical devices are classified into three categories (Class I, II, III) based on the degree of regulation necessary to provide safety and effectiveness. For low-risk Class I devices subject to performance standards, manufacturers have to submit a simple entry form to the FDA prior to market launch. Class II devices are considered moderate risk and require a 510(k) submission, providing evidence of substantial equivalence to a device already marketed before. A significantly higher level of certainty is sought from the manufacturers of high-risk Class III devices, who have to demonstrate substantial scientific evidence to assure the safety and effectiveness of their product. Medical devices approved through this path undergo Premarket Approval (PMA) [6]. Premarket Approval is the FDA's most stringent approval process for medical devices and ensures thorough evaluation and high assurance of safety and effectiveness.

The information on this page concerns manufacturers planning to submit a Premarket Approval (PMA) on a medical device. Premarket Approval is required for the majority of Class III devices, as well as for certain Class I and Class II devices FDA has found not substantially equivalent to a marketing-approved device. To gain approval, a device's sponsor must provide valid scientific evidence proving the safety and effectiveness of the device for its intended use. Unlike the 510(k) pathway, PMA does not rely on substantial equivalence comparison and imposes much more rigorous conditions on the device manufacturer. The medical device regulatory clearance/ approval pathways available in the United States, the 510(k) and the PMA, determine which premarket submission a device manufacturer must make to the US FDA in order to legally market devices in the US. The majority of manufacturers looking to enter the US market, nearly 90%, utilize the 510(k) pathway, while

the other 10% face Premarket Approval (PMA), considered the FDA's stringent pathway [3]. Devices that are subject to premarket submission are classified by the FDA into one of three classes, as detailed in the Medical Device Amendments Act of 1976.

The regulatory environment in which the medical devices industry operates is continually being challenged by the rapid evolution of healthcare towards an outcome-based, personalized model. The growth of digital health technologies, such as healthcare software applications or connecting devices, has the potential to reshape healthcare, enabling new efficiencies as well as empower patients in managing their own health. Their rapid development also creates new challenges to the traditional regulatory frameworks, as their functionalities and performance features often outgrow the intended use at the time of their regulatory submission [1].

A similar trend is also observed with the market introduction of personalized medical devices and medical devices custom systems. In the healthcare sector, personalized medicine involves the shift from a "one-size-fits-all" approach to the customization of medical care, products, and practices tailored on individual patient characteristics. This promises to provide greater precision to disease management, enhancing the treatment efficacy and safety. The personal nature of this approach though, can limit the use of these products to the individual patient, therefore challenging the classic approval of fixed-designed medical devices meant for the treatment of the general population [7]. The response of the regulatory bodies to these new emerging phenomena may often prove pivotal, as the mitigation of these challenges can lead to enhanced health outcomes while fostering the medical devices market. Therefore, it is crucial for all stakeholders to better understand the latest regulatory trends and developments simultaneously to the design, manufacturing, and commercialization of medical devices. These can influence the market entry strategy of new medical devices or the introduction of major modifications to the existing ones. However, they can also strongly influence the file management interactions between the industry and the competent authorities during the lifecycle of a medical device.

Digital health technology is increasingly blurring the boundary between traditional medical devices and consumer wellness products. With the widespread integration of software in medical devices, the U.S. Food and Drug Administration (FDA) has issued guidelines on the classification and regulation of software products. The development and integration of mobile applications and software further adds to concerns about data privacy and cybersecurity. The article examines the current medical device industry and

the impact of new digital health technologies on medical device regulation and healthcare delivery.

5.1 Digital Health Technologies

The medical device industry is traditionally centered on hardware, but free-standing hardware medical devices are now often integrated as a subsystem within a whole digital system. There are key regulatory differences between free-standing hardware medical devices and a hardware sub-system integrated as part of a new digital system. Although the hardware sub-system may in itself meet all medical device safety and effectiveness requirements as a free-standing medical device, these requirements may not be met in the context of the novel higher-function digital system, software, and communications up- and downstream.

As an increasing number of digital health technologies join the established medical devices on the market, there is mounting pressure on regulatory agencies to adapt their established regulatory frameworks. Current datasets give an indication of the novelty and potential of this emerging sector, with the numbers of digital devices technology now increasing year on year. The digital health technology products were launched in different categories with a primary focus on software and mobile applications, although many include hardware components like remote monitoring devices [8]. At least two-thirds of these devices intended for patient use, with the remainder targeting healthcare providers (HCPs). Alongside rapidly burgeoning digital health technologies, there is a plethora of policy documents from governmental agencies and guidance from stakeholders that can help frame debates. The FDA approach has been to also inform manufacturers of applicable medical device regulation while encouraging early substantive interaction to ensure the efficient path for innovative digital health medical devices. Together with stakeholders, the FDA has evidently invested significantly in creating a supportive environment for early-stage developers of digital healthcare solutions and has granted a modest number of enforcement actions.

The tremendous advancements in healthcare sciences, biology, life sciences, and ICTs have jointly fostered a paradigm shift in the future of medical systems. With an emphasis on individualizing treatment for each patient, this so-called "personalized medicine" is expected to boost a revolution for the development of novel and more effective healthcare systems [9].

However, the emergence of personalized medicine will have substantial implications for the regulation of medical devices. Current standardized

evaluation criteria will challenge the assessment of medical devices developed to treat increasingly diverse groups of patients. Increasing importance will attach to patient data in the development of personalized treatments, which is leading to questions of patient data privacy and data security. To navigate regulatory channels, tight connections should be sustained between manufacturers, regulatory bodies, and healthcare providers. In order to foster novel technologies to benefit patient welfare, the regulatory approach must be flexible and cope with innovative technologies whether these technologies don't fit existing standards or are unclassified yet. These trends beg attention for medical device industry stakeholders. On the one hand, changes in any of the relevant technologies will dramatically affect the whole medical device sector and consequently will influence regulatory criteria and practice, as well as the legal framework. On the other hand, medical device manufacturers can capitalize on emerging trends to catch business opportunities. A set of bioprinters has been developed to treat injured patients. In particular, burn casualties were treated with a skin 3D-bioprinter, alleviating the difficulties to obtain enough donor skin. Another application field of 3D bioprinting is personalized stents. A study visualized the cardiovascular artery tree of different patients using the non-invasive CT imaging technology, obtaining a heart model stored in the standard STL file. With the visualized cardiovascular artery tree and heart model, a specialized one-to-one stent could be designed, which is then printed with the biodegradable bioprinting material.

Chapter - 6

Challenges and Opportunities in Medical Device Development

Entering the healthcare technology space is a very complex and sensitive sector. On one hand, current demanding challenges include changing the settings and increasing the efficiency and productivity of healthcare delivery, wellness, and clinical community-driven requirements [47]. On the other hand, the industry also faces many challenges, such as dealing with the most stringent quality standards, performing validation and testing processes, compliance with legal requirements and certification, trying to keep management and production costs low, security record data, and dealing with fierce worldwide competition. Since the FDA's approval of the pacemaker in 1958, the invention of medical technologies has brought about many innovations and breakthroughs in health services, the treatment and diagnosis of diseases, and the enhancement of patient care quality and effectiveness. However, medical device technologies provide design benefits and challenges at the same time that nothing can replace the manufacturing of professional, highly skilled equipment with regulatory models and treatment of human lives. A case in point of advancement in neurology can be regarded as a Radiosurgery System where multiple radiation beams are focused on a specific area of brain tissue. The joint and cross-curriculum of lasers, surgery, radiology, brain/address scanning, mechanics, and electronics are involved in design breakthrough.

As the rapid development of medical technologies is bringing major advances and innovations in healthcare technologies, on the other hand, related development times to regulatory schemes increase dramatically. Each of these topics will lead to fluctuations and complexity in production and encourage adaptation to new conditions and leitmotifs for thriving business and industry development. This study covers the aforementioned pros and cons, challenges, and opportunities with past, present, and future outlook. Thus, both sides include the need to understand the adoption of complex technology in therapy within a demanding industry and potential design innovation in medical equipment as an original contribution [10, 11, 48].

Chapter - 7

Future Perspectives and Emerging Trends in Medical Device Technologies

The 21st century is marked with the rise of innovative technologies that promise revolutionary impacts on the medical device landscape. A staggering rise in the development of medical devices and their intelligent techniques is evidenced, ranging across diagnostic, analytic, therapeutic, and ubiquitous applications. Currently, advancements appear more prominently in the direction of bionic, mechatronic, bio-mimetic, smart material-based devices, and their networked executions. The resulting technologies will essentially change and standardize healthcare settings, with an emphasis on individual health signals, disease types, and genomic profiles. However, the proper translation of academic prototypes and clinical requirements into cost-effective and reliable commercial devices remains a grand challenge.

The rise and convergence of groundbreaking technologies in the field of medical devices are expected to transform patient management, opening new and exciting avenues for academic research. Telemedicine is a new addition to this field, providing equitable healthcare to remote parts of the world [25]. A notable increase in the development of powerful, simple-to-use, and cost-effective medical devices is precipitated through wearable, portable, and mobile applications. Including "mobile health" as part of telemedicine is also expected to increase healthcare accessibility, as in the 3G in India. Smart devices and networked environments will appear within healthcare settings, potentially backed up by artificial intelligence, and changing the roles of doctors, patients, and medical devices. The momentum in the integration of AI and medical devices is also growing, which will find effective means in diagnostics, treatment planning, hospital management, and patient monitoring. Inspired by these, an array of future perspectives and emerging trends in medical device technologies that are expected in the upcoming decade and beyond are critically analyzed.

A significant drive is under way to improve the way healthcare is delivered by transforming it to one that is patient-centric, knowledge-based, preventive, and which provides effective procedures to manage disease,

diagnose conditions, and employ medical devices to achieve this more reliably, safely, and effectively. To meet the escalating need for these devices, there has been, and there will continue to be, a proliferation of new medical devices and technologies for diagnosis and therapy. This expansion of medical devices will be nurtured by dynamic advances in technology, science, and engineering, complemented by progress in translational research and innovation, within and across multiple disciplines. In many cases, it is the meaningful convergence or integration of these technologies that will deliver these breakthroughs, amplified by disciplines such as biotechnology and information technology. These advances will extend the ability of clinicians to care and treat patients within hospitals outside the orthodox environment, thereby improving both access and quality of care for everyone, everywhere. At the same time, it is equally important to recognize that, aside from direct benefits, medical devices and equipment will represent ever growing challenges, often hidden, to ensure their proper design, manufacture, use, coexistence, and disposal with the objective to avoid environment or other types of adverse impact over time. Work is ongoing, guided by the need for better methods to manage these evolving challenges.

Medical device technologies are categorized into diagnostic, implantable, surgical instruments, life support or monitoring, therapeutic, rehabilitation, and other assistive devices. Implementation of medical device technologies in clinical health care is not new. ECG devices, defibrillators, X-ray machines, ultrasound machines, temperature sensors, pulse oximeter, MRI machines, glucometers, blood pressure meters, and many other medical devices are used by healthcare providers to diagnose, prevent, protect, treat, or alleviate disease, injury, or handicap since the last century. Emerging technology and the collaboration between medical device technology providers, medical doctors, software developers, and pharmaceutical companies are essential to develop innovative medical device technology that will provide a strong and integrated health care approach with a goal of optimizing a medical outcome.

Innovations in medical device technologies may lead a new way of treatment, diagnosis, prevention, or prediction of medical symptoms using a wide range of technologies like automation, mechatronics, robotics, minimally invasive surgery (MIS), micro-electro-mechanical systems (MEMS), information technology (IT), telecommunications, internet of things (IoT), cyber-physical systems (CPS), cloud computing, ubiquitous computing, monitoring based systems, sensing based systems, bioengineering, nano-technology, quantum physics, and advanced materials science. A large number of multinational companies are dominating the medical device

technology market, which includes GE Healthcare, Johnson & Johnson, Medtronic, Phillips, Siemens, Stryker, etc. Nevertheless, small and medium startups have been fast growing and penetrating this industrial sector by providing innovative solutions, reduced price, performance efficiency, and a lower rate of regulatory constraints [1]. There are several challenges ahead of efficient and effective medical device technology integration to optimize the medical outcomes. Importantly, stringent regulatory constraints of developed countries have made it difficult for entry of newly developed medical devices and technologies into the market even for the collaborative academic research based product development. Emerging new markets such as Asia, Africa, Latin America that have shown significant GDP growth, disease burden, and healthcare expenditure also have a limited number of medical devices and a large rate of infectious diseases. In addition, high rates of illiteracy, malnutrition, widespread poverty, prolonged supply chain, low infrastructure development, heterogeneous pathogenic strains, non-availability of technological equipped human resources also impede the integration of medical device technologies. The integration of medical device technologies for the same applications is still rare due to the complexity of the technology and the absence of knowledge.

Medical technology comprises a wide range of health care products that are applied for treatment and prevention of diseases or for medical diagnosis. The field includes medical devices, medical informatics, biotechnology, and also many different auxiliary areas. All technologies are intended to improve the quality of diagnostics and therapy. Medical technology is a rapidly evolving field driven by technological progress of manufacturing capabilities. This is accompanied by growing regulatory and legal regulations, decreasing product life cycles and intense price competition. In addition, the high performance is accompanied by increasing complexity and a broad knowledge base in many areas of technology. In particular, an interdisciplinary stack of competence in microsystems and information technology combined with knowledge of medicine are crucial. A medical device is anything used in healthcare that is not metabolized by the body.

Medical devices can be considered simple tools but also complex systems. Medical devices are classified by their intended use. Medical devices support many fields of medical activities like diagnosis, monitoring of patients, treatment, therapies and laboratory analytics and many more. The definition of a medical device technology can cover everything from simple devices like plasters, spectacles, suits of armour, to medical devices that provide long lasting, secure health services like a pacemaker. However, in the

sense of this special interest group on medical devices, the abbreviation MDT will have its usual meaning: a medical device is defined as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for specified competent physical or aesthetic performance, as defined by its manufacturers in relation to the patient, user or third person. The scope of this definition encompasses many functions. The medical device technology itself can include the device, the interoperable device, the communication from the device to the electronic health record of the patient and the communication from the electronic health record of the patient to the device. This definition of technological platform will not concern the device itself, but the other parts of the chain necessary for the deployment of tailored solutions.

Harnessing the potential of technological advancements in mobile information systems and leveraging modern strategies in augmented reality visualization to aid medical imaging are critical in the development of more effective diagnostic devices that could be used as a complement to health services in remote areas. This sub-section focuses on major medical tool industry contributors who have generated groundbreaking breakthroughs.

Several comments still touch on the prevailing landscape of medical device development: large multinational corporations with comprehensive capacities that produce a range of technologies, small startups focusing on innovation and driving change through a more nimble culture, and academic institutions as the fundamental base for technological growth. Medical device innovation did constitute a vital fraction of well-known and state-of-the-art healthcare fields: advanced pharmaceuticals, biologics, research and patents, and the most complex, new and challenging medical devices of the latest time. Much less is understood about the notable emerging trends in the industry and how such advancements actually change devices, aided by the regulatory environment and promote the development of information [2]. Although much agreement has long been reached on the importance of speeding up product development, more attention is now focused on understanding which of the many factors differentially affect which types of technological advances.

Moreover, due to the significant workload necessary to bring a novel device to market, even a sole business entity’s efforts could span years and require a multitude of actions at any stage of the development and market life cycle. This suggests that no single policy will be able to address an impending breakthrough. Quite the opposite has been reflected in current medical device policy discussions, which have largely been focused on broad changes to

regulatory practices, particularly to the FDA. This points out that the industry far exceeds the FDA's ability to issue certifications and to improve its knowledge of new technologies; thus, companies seeking to incorporate expert information to out-license or purchase new technologies well in advance of their market introduction expected to gain an edge.

In the last decade, we have witnessed significant advancements in materials that are being used in the production of medical devices. These include shape memory alloys, shape memory polymers, and hydrogels with abilities to change their shape and size upon application of a stimulus such as changes in temperature, light, pH, magnetic field or a combination of them. Also new materials and coatings are being developed that exhibit anti-fouling, super-hydrophobic, anti-bacterial, or self-healing properties. Anti-biofouling polymers are being developed with long-term passivation coatings on implanted medical devices. Hybrid materials fabricated using a combination of organic and inorganic materials are also under development. Such materials are capable of combining the best qualities of both of their components. The additive manufacturing processes are also being employed for the fabrication of functionally graded materials having a spatial variation in their composition and/or microstructure. For example, gradient electrodes have been developed for electrical stimulation of bones.

Recent advancements in manufacturing techniques used in the production of medical devices and components includes additive manufacturing and 4D printed devices, as well as development of techniques for rapid prototyping, bioprinting, spraying of nano-materials on the scaffolds fabricated using solid freeform fabrication, selective laser sintering, and electrospinning. Drug-eluting stents is another example of an enabling technology that emerged in recent years and had a profound impact on the fabrication of medical devices. In traditional stents, a drug is coated on a metallic stent. However, in the biodegradable stents, biodegradable polymers are used containing a drug that prevents the re-stenosis of arteries. This technology gradually degrades the stent, releasing the drug slowly and leaving only the arteries in their place and keeps them patent. The next generation of stents incorporates a growth factor with the pharmaceutical.

The role artificial intelligence (AI) and machine learning (ML) hold in advancing medical device technologies is immense. AI algorithms can accelerate diagnostics, support decisions, and provide personalized patient care. In last years its applications significantly improved in detecting patterns that are hard to notice and increasing the amount of information coming from generated data, thereby, enhancing memorable decision-making. The image

analysis-based AI was the first to be transformed into a medical device in 2018 with the FDA-approved cardiac image analysis AI, paving the way for deployment of coronary and lung image analysis AI. Early medical device application examples developed with AI and ML are in diagnostic assistance, therapy assistance, and patient monitoring using bio-signals or image analyses. Latest AI applications for medical devices are on detecting irregular breathing patterns using sound analysis and on therapy algorithm adjustment. Applying AI tools to bio-signal analysis cases enabled the integration of commercial AI platforms with ready-to-use algorithms for big data analysis and visualization in just a few minutes. Once AI analysis results are input to a medical device, they could provide detailed information on patient status tagging all the vital signals and allow alarms in specific user-defined cases, changing the way bio-signals are analyzed in research groups. More recently the emergence of the AI that directly interacts with devices has had far greater impact on medical device developments. It is expected that AI algorithms integrated in a medical device will be able to solve complex problems more accurately, efficiently, and more effectively than currently used algorithms. Device developers and researchers are working to demonstrate several "crossover" devices so that the role of AI extends beyond an input-output system to perform far more complex activities than previous medical device functionalities, marking a step-change of device capabilities [3]. There has been increasing interest within the medical community, the commercial sector, and researchers regarding the future of AI and ML technology integration into medical devices, viewing this approach as a paradigm shift in the development of medical devices, including wearables and point-of-care testing devices. However, the main concern is the lack of privacy and ownership of data, the so-called algorithm bias, and the slow and opaque process to develop a medical device with built-in AI, often revolving around regulatory barriers and approval difficulties [4]. One possibility for a future model of portable systems is to implement AI tools using edge computing that processes the recorded data directly on the device with significant lower power using small tailor-made AI chips, transmitting only the valuable information, making portable testing of bio-signals and digital image analysis a reality in remote areas and emergency situations, being used as medical tests, but the use of such systems for longer studies would be equal to running the algorithm on a large number of parallel computers. Alternatively, devices implementing real-time adaptation and personalization to data can also be empowered by AI, but the difficulty of understanding the machine learning algorithm and thus the final results of the medical device pose significant concerns, especially if further clinical decisions would have to be made on the machine learning

results of the medical device. Additionally, AI used in medical devices is seen as a fast-paced field for which no relevant guidelines are available for critically evaluating medical devices integrating AI. Lastly, AI achieving continuous learning and adaptation to the incoming data have seen limited industrial application to date, but this approach could disrupt the long-established medical device industry. Such systems require a mechanism to lock AI models after the required performance was reached, and possibly updating the device to a new version. On the other hand, the same data can be used for various AI models and even conditions that produce the learned model not revealing the final performance to the user, bringing unfair advantage for some developers. Nearly all literature paragraphs here are in agreement that AI and ML technology is evolving at a much faster pace than the traditional clinical understanding of how this technology works, requiring rethinking of the legal framework guiding medico-legal practice. Research interdisciplinary collaboration will be needed across fields as disparate as data science, ethics, and medical science to translate the transformative potential of these technologies into practice.

In the past couple of years, a significant rise has been recorded in the adoption of telemedicine and remote patient monitoring technologies and it is expected. Telemedicine primarily refers to the use of telecommunication and information technologies for the provision of virtual medical services—particularly in the management of chronic health conditions and for diagnostic purposes. This technology enables patients to access medical expertise from anywhere at any time which can be especially useful when medical specialists are not geographically available. In the wake of the pandemic, many primary care and specialty services around the world have switched to a virtual care delivery model.

Remote patient monitoring is a method of healthcare delivery that uses the latest advances in information technology to collect patient data that can be remotely transmitted in real time to healthcare providers. This method has proven to be particularly useful for the remote tracking, care, and assessment of patients with chronic diseases as post-operative patients because it enables comprehensive and thorough tracking, especially in the early days, when there is a higher likelihood of post-operative complications. Additionally, the advanced integration of a technological infrastructure—including electronic health records, monitoring of vital signs, video consultations, and e-prescribing systems—is a necessary requirement for the effective implementation of telemedicine technologies. Now that the healthcare system is transitioning to this virtual care delivery model, potential challenges have

started to emerge, such as the non-standardized policies of health insurers, the technological barriers that some patients may experience when accessing the new systems, and the need for mechanisms to ensure patient engagement when care is delivered remotely. These patient monitoring technologies and telemedicine solutions are expected to innovate healthcare delivery over the following years and facilitate health services adherence to the transitions.

The prevalence of wearable and implantable devices in monitoring or treatment of patients is growing rapidly and leading to the personalized management of healthcare. Some devices are used for monitoring continuously or doctors' describing the patient's status; such devices have rapid implications both with patients and caregivers. For patients, the data collected in real-time can help to discover previously unknown conditions or unwanted changes in their health status. For professional care providers, such real-time data can inform them of the effectiveness of a patient's therapy or if an intervention is required in their ward.

In the same way, the advancement of miniaturization and connectivity has made electronic devices much smaller and easier to integrate into daily life. Such devices can monitor not only physical but also physiological properties as well. Developments in nanotechnology and material sciences have made it possible to produce wearable devices that are flexible enough to conform to different parts of the body. The potential for providing continuous and long-term monitoring of patients, so promoting the general well-being of users, has been highlighted. One of the drawbacks of wearable technology relates to the safety of information collected and who can access it. Especially with medical wearables, personal information must be protected and not disclosed. There are additional concerns surrounding patient autonomy or data abuse or misinterpretation. Another critical challenge of wearables is user acceptance and device reliability. On one hand, consumers consider fashion to be wearable shortcomings, and manufacturers have to come up with more attractive designs. On the other hand, the durability and robustness of wearables remain an issue. Replacing wearable waste generated by malfunction or observation could be avoided before the expiration date. On the part of device reliability for proper functioning under the everyday stress of physical activity, sweat, and other external factors. Interest in health and physical activity and recent technological developments has led to the creation of various applications of health and well-being monitoring. Wearable devices are becoming popular items due to their characteristics of practicality and convenience.

Chapter - 8

Sustainability and Environmental Impact of Medical Devices

Medical devices are indispensable tools for the diagnosis, treatment, and monitoring of medical conditions. They encompass a wide range of technologies, from simple handheld instrumentation to complex imaging systems, surgical robots, and so-called "smart" devices that can interact with the patient to provide therapy. Each year, millions of devices are purchased for use in healthcare settings. However, the environmental price of their production, use and disposal is incalculable, and at present, issues of environmental sustainability are almost entirely absent from the design process and from regulatory concerns. But given that medical devices are in some way responsible for many tens of emissions to air and water, and more than 70,000 tonnes of waste, far outweighing the running costs of the devices themselves, there is clearly a responsibility on the part of the industry and of procurement authorities to look at their impact and work to reduce it. Continuing evolutions in technology open pathways for more sustainable devices. Many medical devices are produced as single-use items and present significant disposal problems. However, new design paths are emerging that offer the potential for manufacture from biodegradable materials, or which can be broken down using techniques such as steam treatment, or that offer the potential for composting. Efforts to reduce packaging waste are now well established in shipping terms, and there is considerable ongoing work looking at the increased recyclability of devices post-use [5].

Chapter - 9

Ethical and Legal Considerations in Medical Device Technologies

The development of medical device technologies is underpinned by a complex landscape of ethical and legal frameworks. A clinician using a medical device is required to fully understand its functioning and suitability for the intended patient cohort, and medical devices should only be implemented with informed patient consent [6]. However, there are around 500,000 medical devices in the global market at any one time, and regulation, which is supposed to ensure that a medical device is tested, is found to be effective in the real world and is labelled with clear instructions for use, varies widely. Manufacturers subsume responsibility for ensuring that their medical device technologies are safe and effective. However, due to the scale and complexity of both devices and the health conditions they treat, manufacturers can be incentivised to use convoluted language and statistical obfuscation to present a veneer of efficacy and safety. Similarly, clinicians are incentivised to support devices they have received payments from manufacturers for using. Despite clinician and manufacturer responsibilities, insufficiently robust or transparent regulatory enforcement means dangerous or otherwise problematic medical devices can be cleared to market. Further complicating medical device regulation, these responsibilities can be outsourced to private third-party auditing or certification bodies, who have been demonstrated to have financial incentives to overlook safety concerns or non-compliance with established legislation. Ongoing technological innovation has resulted in medical devices that do not fit within established ethical frameworks, such as assessing whether an AI algorithm is capable of empathy for the purposes of device evaluation. Furthermore, the same technology can have different ethical implications depending on the broader cultural and industry context in which it is deployed. However, as these deontological considerations are not fully codified within regulation, the device was passed to market despite concerns. Subsequent implementation support documents explicitly stated it as an implant for determining patient suitability for therapy but inappropriate device use was not challenged by any other clinical practitioners and no specific guidelines were in place for ethics that could be translated to clinical practice.

There are clear issues concerning regulatory protocols for real-world evaluation, namely, commercial interests that are not explicitly codified in regulation taking precedence over patient safety and ethical practice, and the lack of transparency and accountability between regulators, manufacturers, and clinicians. These are augmented by the wide variety of devices and implementations within the regulatory framework, meaning that a seemingly innocuous action can have significant downstream consequences in a highly specific clinical setting.

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