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Chapter 12: Emerging trends and future directions in ai-driven smart medical device technologies

12.1. Introduction

Artificial Intelligence (AI), specifically Machine Learning and Deep Learning, are becoming more and more common in healthcare, providing prediction algorithms that can fill decision support needs everywhere in a patient's life cycle. Researchers have utilized AI and Machine Learning to help speed up the diagnosis of diseases, like COVID-19, Alzheimer's, or others. Healthcare AI-powered smart medical devices, present in the patient's home and in hospitals, get faster and more accurate diagnoses, increasing both the quality of care and the life expectancy of patients. Devices for diabetes and cardiac patients have been available on the market for years. Solutions monitoring food intake, alcohol consumption, nutrition, or mood and facilitators for healing like virtual reality have appeared and progressed in the latest years. More recently, advances in Neuro-Symbolic AI have made possible the utilization of intelligent digital assistants that can teach patients and provide tailored recommendations. Telemedicine has appeared on the rise with COVID-19 and is merging with Artificial Intelligence in the objective of decreasing healthcare expenses, increasing the lifecycle of patients, and reducing the number of readmissions in hospitals (Cirani & Picone, 2015; Chowdhury & Rahman, 2020; Guberović et al., 2021).

The adoption of AI healthcare systems often faces resistance from both healthcare workers and patients. The supporting role of expert systems as the base for decisions made by healthcare professionals is often amended which makes some doctors distrust any prediction made by these systems. Finally, the empathy human doctors can provide is often irreplaceable and can influence both patients' adherence and trust. The COVID-19 pandemic has favored and brought momentum to the further development of smart medical devices and AI-based health and medical systems. We illustrate the rapidly expanding AI field with some of the most exciting recent research and industry development directions and emerging trends. More specifically, we present some applications based on breakthroughs in building capabilities, including Natural Language Processing, Video and Image Analysis, Biomedical Device Control, and Digital Assistants (Ray & Saha, 2022; Luo et al., 2023).

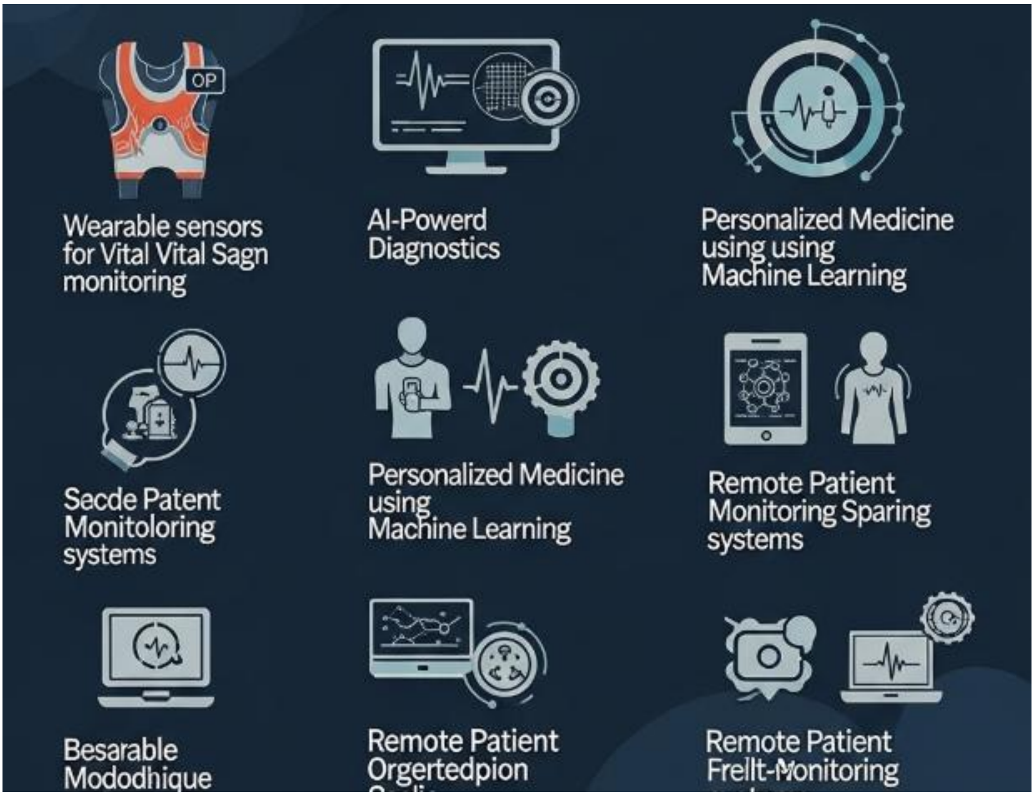

Fig 12.1: AI-Driven Smart Medical Device Technologies

12.2. Overview of Smart Medical Devices

Smart medical devices that deliver accurate diagnostics, reduce error rates, and increase quality of care are fundamental to the development of the next generation ecosystem of smart medical devices. Smart medical devices can track specific health conditions and risk factors using user-friendly interfaces enabling patients and connected caregivers to receive alerts on disease progression which facilitates task delegation that achieves greater efficiency. The integration of different smart medical devices gives rise to a smart medical device ecosystem that offers three critical features: data connectivity, mobility, and reliability, which help realize the main goals of a structured healthy environment.

A smart medical device comprises multiple hardware and software components including transmitter module, receiver module, central control and/or processing unit, power source module, smart technologies for data acquisition, and communication technologies. The transmitter module is either on-board or external. Upon the completion of the data acquisition process, the processing unit transmits the processed data to either a local receiver module or a remote server. Then, the transmitted data, which typically include biometric signals and potential alarm systems, are used by the healthcare professionals or patients/caregivers to make an appropriate medical decision. The reliability of a smart medical device depends significantly on the performance of its components, which can be energy efficiency, size, and data quality. Smart medical devices are mobile; the transducer and communication technologies enable the measurement and transmission of various signals without being attached to an external server.

12.3. Artificial Intelligence in Healthcare

Advances in computing and data processing capabilities have enabled the advent of machine learning methods and deep learning algorithms, particularly in the form of convolutional neural networks which are able to achieve impressive performance levels when learning from large amounts of labeled data. Such progress has led to the perception of, and a push for adoption of increasingly widespread use of artificial intelligence in areas where deep learning methods have become state of the art, such as visual and audio signal processing, reinforcement learning in games and robotics, natural language processing and image synthesis, and generative modeling, among others. With the promise of improved performance and lower cost over the apparent current levels, artificial intelligence is seen as a means to make healthcare more equitable and accessible, along desired axes of outcomes and affordability.

Among its many potential applications, commercial use of artificial intelligence has been focused on the areas of medical imaging and diagnostic support, including general-purpose models for biomedical image analysis and specific-purpose models for specialty uses. Other areas of interest are medical decision-making, including therapeutic or preventive uses and predictive modeling to ascertain the likelihood of clinical course of action outcomes. Many artificial intelligence-driven healthcare technologies originated from uses outside of direct patient care to provide drug and vaccine discovery, clinical trial matching, hospital operations planning, provider-payer operations improvement, research study recruitment, and technology-enabled remote patient monitoring, among others. The apparent value of artificial intelligence based technologies has attracted attention and funds from all sectors – healthcare providers, healthcare payers, health technology companies, and venture capital. The excitement is driven by the underlying promise of increased efficiencies in several areas in healthcare, keeping patient safety top of mind.

12.4. Current Trends in AI-Driven Medical Devices

Artificial Intelligence (AI) has had profound effects on many aspects of modern life and medical technology is no exception. AI has penetrated several domains such as medical imaging, diagnostic tools, hospital workflow, robotic surgical instruments, and mobile health devices. In this essay we will be exploring some of the recent research in AI driven smart medical devices. Moreover, the second half of this essay discusses possible areas of enhanced research and development, which may further improve medical devices and patient health outcomes. While a lot of the areas discussed in the latter part are still considered to be futuristic, the areas under the first part are finding their way to the products people use today, thus enhancing the capabilities and the reliability of medical diagnosis, treatment, and surgery.

Most of recent discussion concerning AI driven medical devices centers on augmenting the ability of human health care providers. Given the varied range of devices labeled as "medical devices", the variety of applications, and proposed uses of AI, it should come as no surprise that most of the prominent companies developing AI driven smart products continue to cater to those areas. Wearable health monitors have proliferated for both consumer and clinical applications. While these include consumer devices which are generally used for fitness tracking and have limited reliance on automated AI driven algorithms, those proposed or developed actually integrate AI powered analysis of the acquired data, for instance chemical biomarkers, for assisting and aiding health clinicians in providing clinical intervention or alerts.

12.4.1. Wearable Health Monitors

Wearable medical devices are experiencing rapid development and advancement, and currently available products include wrist-based heart rate monitors, accelerometry-based activity monitors, and myriad other variants monitoring various aspects of health. Unlike the rest of the chapters in this book, which focus on more established medical devices, this chapter focuses more on newborn devices that are being approved and marketed, focusing the discussion on sensors that have been verified to be wearable. The design assumptions for wearable health monitors differ markedly from those for traditional medical devices. The larger errors of wearable devices are more tolerated for longer-term use because of the noninvasive, lower-cost, and non-traditional uses of wearable devices.

Unlike traditional medical devices, which are used under the supervision of healthcare professionals, or for a small number of patients at high risk, wearable health monitors are increasingly being marketed for mass, unsupervised, and long-term uses. Sensors that have been medically certified, targeting these use scenarios, are only just starting to emerge. Continuous ECG monitoring using patches has been recently approved, opening endless possibilities for long-term, longitudinal ECG analysis of patients in different physiological and pathological states. Researchers are also exploring the use of electric taste sensors for long-term, noninvasive blood glucose monitoring. With technology that powers risky and demanding tasks, such as exploration of the Moon, cuffless blood pressure monitors that consist of only wearables are fast becoming a possibility. Technology that enables the detection of health data from the wearer's skin is also being explored. Such developments open up new use cases for invisible aesthetics. These captivating and tantalizing developments will supplement existing wearables, such as motion sensors, heart-rate monitors, electrocardiography sensors, hearables, smart eyeglasses, and ambient sensing systems.

Fig 12.2: Wearable Health Monitors

12.4.2. Remote Patient Monitoring Systems

Increasing mortality and morbidity due to contagious diseases, increases in old-age population suffering from chronic diseases, and rising patient transfer-related costs to the hospital have led to the creation of Remote Patient Monitoring Systems. These systems are a network of digital transmission systems that provide continuous health monitoring of patients by transferring clinical data from their homes to a clinical repository. AI has the potential to act as a bridge in these systems to enable continuous health technology. Continuous clinical data would help physicians make accurate diagnoses, create risk assessments, and develop subsequent intervention and management strategies. Direct evaluation of clinical data gives predictions better than those that rely solely on medical history. The purpose of these systems is to gather, analyze, and share patient data electronically without requiring patient involvement at home. The aim of remote patient monitoring is to send an alert to the physician or a physician assistant if monitoring points deviate from the established normal range. These systems collect physiological and clinical data through various sensors in collaboration with mechanistic algorithms to detect the body's physiological responses. Various body homeostasis functions, including respiration rate, heart rate, blood oxygen saturation, body temperature, blood pressure, and blood glucose levels, are assessed.

Off-the-shelf wearable health monitors, despite their potential to evaluate and assist with the maintenance of health, are not considered reliable diagnostic devices. Monitoring systems that are medically certified are already being applied for respiratory, cardiovascular, and glycemic functions. These medically-certified Patient Monitors use optical sensors, electrocardiograms, and biosensors to evaluate the aforementioned functions. Due to the numerous limitations of wearable Patient Monitors, systems have been established that take advantage of non-physiological and passive signals for remote patient monitoring. Patient Monitors embedded in smart home environments are used to study non-physiological parameters such as speech, motion, activity, posture, and fall, along with physiological parameters, to help patients maintain a healthy lifestyle.

12.4.3. AI-Powered Diagnostic Tools

Automated diagnosis of medical images and pathology samples can help reduce the heavy workloads of highly trained and often overworked medical professionals such as radiologists and pathologists. AI tools can rapidly scan huge quantities of data and highlight outlier cases that require further inspection. Advanced deep-learning-based algorithms are being successfully employed for image classification segmentation of medical imaging scans for various injuries and disorders including brain tumors on MRIs, diabetic retinopathy in retinal fundus images, tuberculosis on chest X-rays, skin cancer on dermatoscope images, and covid-19 virus on CT scans and X-rays. These tools can also be utilized for slides of pathology samples for identifying tumor cells, grading tumors, detecting cancer metastases in lymph nodes, and for many other purposes. AI tools are also useful for analyzing other forms of medical data, such as genomic, clinical, and histopathologic data, in order to assist centers in making the right diagnosis for complex multiclass disorders.

AI diagnostic tools can also play a vital role in the accurate detection of rare diseases and disorders in children. Children tend to display different symptoms in rare diseases and, often difficult to be recognized by care professionals, can go undiagnosed for years. This delay can worsen the severity of the case and lead to more difficult or even impossible treatments in the future. AI-based tools can help child caregivers in making accurate rare disease diagnoses promptly. A unique set of challenges, such as limited data availability, are offered by healthcare datasets, which can be addressed with various AI techniques and fed into different types of diagnostic models. AI-based diagnostic tools that employ various types of AI algorithms are used by a large number of stakeholders, including parents, diagnostic centers, pediatricians, and teaching hospitals.

12.4.4. Robotic Surgery Systems

Recent trends have seen a concerted effort to automate and enhance the scope of traditionally manual soft tissue surgical procedures with the advent of robotic surgical systems. The need to shorten hospital stay, offer minimal invasiveness, superior precision, and reduced postoperative pain and complications has led to the rapid evolution of autonomous and semi-autonomous robotic surgical devices. The innovative strategies for soft tissue robotic surgery include flexible, soft, and continuum manipulators, mobile robots, tethered robotic systems, vascular access, multimodal imaging, and integrated multimodal therapeutic systems. In particular, with significant breakthroughs in AI technologies such as machine learning, deep learning, and reinforcement learning, robots are being trained to recognize surgical environments, learn skillful manipulation, improve precision, and assist or supplement surgeons in their surgeries. Advanced surgical robotics methods with AI innovations including source separation algorithms, deep learning and reinforcement learning, unsupervised learning, multi-agent systems, large language models, and generative AI have accelerated surgical robotic advances. AI-enabled robots can provide valuable support for some basic incremental procedures, allowing the surgeon to interact with the robot, improving precision in difficult phases of a task, and providing haptic feedback when necessary. State-of-the-art mobile robotic surgical platforms driven by AI intelligence with integrated multimodal imaging guidance are evolving to provide not only surgical treatment but also diagnosis, preoperative planning, and photonics chip laser ablation through robotic endoscope for a wide range of diseases including cancers, vascular, respiratory, cardiac and orthopedic conditions, to name a few.

12.5. Regulatory Challenges

The deployment of smart medical devices that utilize AI-based technologies is increasingly seen as part of a transformative shift in healthcare delivery. The potential of AI-based smart devices to change the practice of clinical medicine, however, exacerbates existing tensions between the fast pace of technology development and the slow pace of regulatory oversight. In particular, regulatory authorities are faced with the challenge of safeguarding the interests of patients and the public while allowing for new and innovative technologies to come to market without a thick regulatory layer that could discourage research and development investment.

Of particular concern are algorithmic-deployed smart medical devices for which post-market performance improvements will involve continuous learning and system modifications without the need for resubmission. Traditional regulatory paradigms do not contemplate situations where smart devices will undergo updates through machine learning algorithms driven by real-world patient data. The concern is that a one-off submission will not guarantee safety and reliability – that the devices will negatively affect a small number of patients in ways that would not be revealed through randomized clinical trials before approval but which could occur after full market release.

Guidance addressing these concerns suggests a new risk-based approach for software modifications. Devices in which AI plays a more substantive role regarding the evaluation of patient data are placed higher up the risk scale. Prior to approval, manufacturers are expected to evaluate the safety and effectiveness of these devices, and to propose a methodology to evaluate and validate the performance of the algorithms over time, including analysis of harms due to patient population shift, selection bias, or other internal validation weaknesses different from the original product launch.

12.5.1. FDA Guidelines for AI in Medical Devices

A lot of regulatory uncertainty surrounds the approval of AI algorithms in medical devices. AI changes continuously as it sees more data and learns over time generating a dilemma for regulatory bodies regarding how to regulate such systems. For most of the AI algorithms in use today, the classification falls within the low-risk Class II lane. Class I are general controls, Class II represent moderate risk and Class III represent high risk.

The majority of AI systems fall under the Class II category requiring a submission. In a submission, the manufacturers must demonstrate that their algorithms are substantially equivalent to any one of a number of predicate devices that have already received approval.

Earlier this year, a new marketing submission pathway was introduced for devices designed with ML algorithms that cannot show substantial equivalence to a predicate because they are unique in ways that are new to the market. The feedback guidance is focused specifically on a narrow subset of ML algorithms used in software as a medical device and serves as a roadmap for manufacturers which helps clarify the Pre-Exam process. This new framework is designed to build confidence in ML algorithms used in medical devices. The framework builds on a cornerstone principle of device safety and effectiveness, which requires that device design be repeatedly validated before it can be released into the market. The main objective of these guidelines is to provide manufacturers with sufficient clarity on regulatory requirements to help foster innovation in AI-enabled software devices.

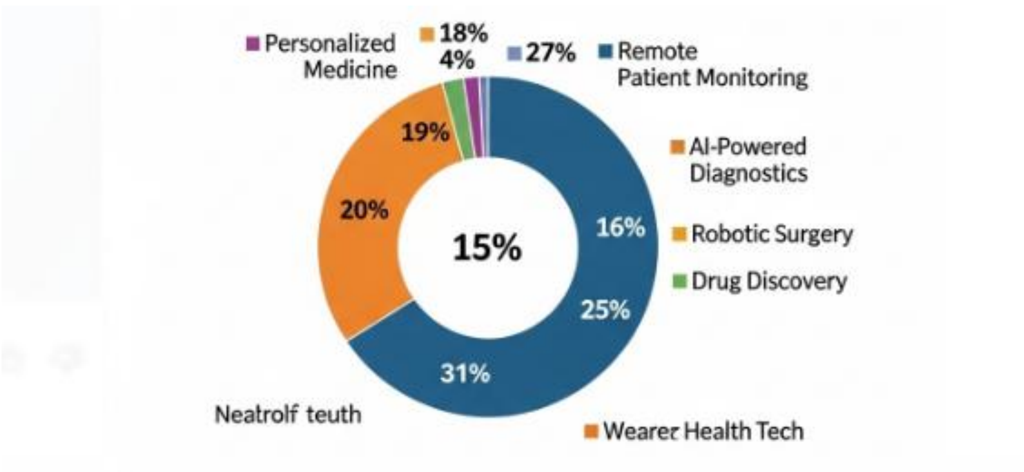

Fig 12.3: Emerging Trends and Future Directions in AI-Driven Smart Medical Device Technologies

12.5.2. International Regulations

Countries in the European Union established the CE marking process in 1985, which harmonized regulations in all member states. The medical device compliance framework became unified via the Medical Device Regulation and In-vitro Diagnostic Medical Device Regulation, which went into effect in May and December of 2022, respectively. All manufacturers must secure a conformity assessment declaring compliance with these regulations before selling in EU member states. The purpose of the Medical Device

Regulation and In-vitro Diagnostic Medical Device Regulation is to ensure that medical devices provide intended patient and user safety and health and do not pose unacceptable risks. They set forth extensive requirements regarding clinical evaluations, post-market surveillance, transparency, and using a notified body for risk classification, including some Class I devices. An organization brings together medical device regulatory authorities from around the world with the goal of harmonizing and streamlining regulatory requirements. This organization created a Software as a Medical Device group in 2013 which published their first report in 2014, detailing a risk-based framework for the regulation of Software as a Medical Device. The organization is continually revising and expanding on these reports since they recognize the importance of software in the medical device domain.

Regardless of the relatively rapid pace of global regulation formation, many global regulatory authorities are following similar paths in their goal to create an adequate yet efficient framework around AI-based medical devices, including the United States and European Union members. All authority roadmaps are beginning to converge, forming a clearer direction for the future in which innovative, risk-based processes are established, allowing for the ability to streamline approval processes to bring products to market safely and efficiently. With the rapid advancement of capabilities in AI technology usage across diverse domains, the medical sector has shown tremendous synergies using these tools, particularly around healthcare automation and diagnosis.

12.6. Ethical Considerations

As intelligent medical devices become omnipresent, they bring not only promises of remarkable transformations in the health arena but also unprecedented ethical challenges that stakeholders must proactively grapple with to maximize the benefits and minimize the harm. From chatbots to surgery robots to surgical skill assessment systems, trust and ethical considerations are central to real-world usability, acceptance, and impact. For example, in a clinical context, real-world practitioners may behave differently than in an experimental setting. Consider a general surgeon who must make a split-second choice: to either trust/take the advice of a collaborative AI system or go against it. If the AI-driven system provides an improper recommendation, the consequences can be catastrophic on various fronts. Here, the discussion about duty and attribution of responsibility for bad health outcomes comes to the forefront. These ethical and legal challenges underscore the need for responsible and trustworthy AI in healthcare.

Emerging smart medical devices provide innovative access to otherwise limited health insights, which raises questions about what individuals actually assess during benefits of their data being aggregated and used by intelligent devices. Intimate aspects of health that trigger desire for privacy are revealed through data collection for disease prediction.

Such devices collect, assemble, and manipulate vast amounts of personal health data that can be vulnerable to lengthy exposure and secondary invasive use or speculate on individuals who have not provided consent. Certain AI algorithms learn from historical data, incorporating biases present in society. Their use in medical practice can reinforce or even exacerbate existing healthcare disparities among groups, especially among those defined by sensitive attributes such as race/ethnicity, sex, and age. Bias has already been shown to exist in existing devices and is being studied further. As future smart devices become real-world practices, appropriate bias control mechanisms to ensure robustness, fairness, transparency, and explanations are needed to maximize the potential of AI-enhanced health technology and to counter inequities.

12.6.1. Patient Privacy and Data Security

Machine learning models rely heavily on vast quantities of data to train on, resulting in the ability to produce real-world applications. Medical devices that utilize AI components often require vast amounts of data so the real-world applicability of training them is often not safe. Security concerns regarding patient privacy and security arise from two sides. The first is the concerns surrounding the sensitive information that is often collected from patients. The second is the concern for possible hacking potentials that might allow for the information to be accessed.

AI-based mobile technology devices present patients with the ability to monitor their health state without requiring a clinical visit. However, AI-based tools must be used with caution, as the patient's health information, including video images and sensitive biometric data, are often permanently collected and stored on cloud interfaces. Consequently, the unique data that are stored will be highly sought after by hackers, as the potential creation of misinformation using this data is nearly impossible. The increased use of social media platforms that store highly sensitive health information literally invites hackers to retrieve valuable data. Furthermore, poor or inadequate data storage infrastructures create what is referred to as "unsound" medical technologies.

When employing AI-related healthcare tools, patients may be exposed to unscrupulous collection of personal health data, including other physical or psychological disabilities. Thus, the responsibility lies with developers, who should either publicly state to the user what that data, in addition to health information, is being collected, or limit the data being collected. When releasing tools for free to the public, developers must know that patient data may be forwarded to third parties for profit. Therefore, users or patients should carefully read any privacy policies established to know whether they consent to any data transfers before utilizing the tool. Ultimately, data anonymity should be prioritized as a rule for developers, especially regarding vulnerable populations.

12.6.2. Bias and Fairness in AI Algorithms

AI-driven smart medical devices are trained using medical, environmental, patient demographic, and lifestyle data. If patient demographic variables, such as age, gender, race, and ethnicity, are included in the training data set, it logically follows that the resulting AI model may include bias. More critically, biomedical datasets do not capture the diversity of certain subpopulations, which can then inadvertently lead to biased AI algorithms, whether noisy or spurious, with fairness concerns such as in healthcare due to the consequences of using AI-based medical devices for critical diagnostic or therapeutic decisions. Such biased algorithms can worsen existing health inequalities. Improving fairness in high-stakes settings, such as healthcare, is risky because misuse or unintended consequences of biased predictions from these algorithms can have life-threatening implications. The emergence of increasing health disparities detected in racially and ethnically marginalized groups has already been linked to the influence of biased clinical AI algorithms. Additionally, biased medical algorithms can further shade public trust in AI-based technologies.

Fairness in AI is a complex and flexible notion. What is fair and unfair varies across communities and even among individuals. Even among fairness-aware computer scientists, there is no single definition of fairness that is not contentious. Broadly speaking, fairness algorithms are based on the intuition that it is unfair to treat similar individuals differently. Fairness attributes may encompass proportional probabilities, risk parity, negative discrimination, calibration, and equal odds in regards to sensitive demographics like group or individual parity. There are various fairness definitions and metrics. However, there are inherent trade-offs between competing definitions, for example, balancing fairness and discrimination.

12.7. Technological Innovations

The rapid adoption of concepts like smart medical devices has introduced myriad specialized devices creating a technology ecosystem associated with health monitoring, intervention, and management. This technological boom not only envisages minimally invasive software or hardware devices but also aims at making the quotidian monitoring of patients while ensuring data privacy. This section outlines the advancements in disciplines like machine learning, data integration with the Internet of Things ecosystem, and data privacy.

Machine Learning Advancements

Machine learning and artificial intelligence-led innovations have resulted in important development and commercial uptake of new tools. Powerful tools for miniaturization, computation, and interactive devices capable of producing clinical information and being regulated as devices have also been pioneered. Novel and complex data that is being generated should drive significant innovation in health-directed technology. Data that is collected from clinical interventions using complex technologies is being used to produce novel tools for real-time dynamic assessments of critical pathways and transitions. These devices are often intended as supplemental or adjunct tools to healthcare professionals with the intention of augmenting their capabilities in recognizing and responding to patient needs. Indeed, the continued evolution and incorporation of advanced technology-capable devices into clinical applications should allow for reduction in task saturation, enhancement of the capabilities of healthcare professionals and their staffs, reduction of healthcare costs, and improvements in overall patient care and safety.

12.7.1. Machine Learning Advancements

Machine learning technology is presently undergoing many advancements. Deep learning, particularly when applied to CT and MRI imaging, is rapidly leading to generally usable AI applications in radiologic imaging. While most of the currently approved and "in production" applications are still "mini-AIs" (i.e., statistical and rule-based algorithms), the wide range of deep learning tools is quickly leading to more sophisticated applications utilizing a range of ML technologies, particularly in image classification. All of these applications are presently "profiler" AIs: They speed access to information but do not contain the complete chain of logic necessary for decision support. Instead, the AI acts as a profiler to alert interested humans that there is suspicious information in the dataset.

Generalizable decision support AIs that work selectively across unlimited categories, questions, and datasets of interest are the long-term goal. Such an AI would be able to label, search, sift, and select images—pick out potentially important items on an image—without being given any prior knowledge about the dataset. It could find a blood vessel anomaly or a gastroenterologist having a bad hair day, on completely different images, without being told anything about them in advance. It could qualitatively or quantitatively analyze the content of any combination of images previously described in natural language and/or visual pattern terms. The decisions fed back to radiologists, referring physicians, and other users would indicate which images were of interest. For other stakeholders, the decision feedback would inform them about monitoring, compliance, happiness, and shared knowledge of the general public about selected areas of interest.

12.7.2. Integration with IoT

Advancements in computer and software technologies centered around the emergence of the IoT promise crucial innovations to medical devices that will prove impactful in the next decade. Smart medical devices will become key nodes in networks of monitoring to help automate and optimize tasks for medical and surgical providers. They will serve as vehicles to deliver therapy customized to the individual patient and enhance what a clinical care center is able to provide to the patient at home. The automation of care in clinical facilities and at home will create infrastructure and knowledge integration barriers that will increasingly need to be crossed should the full potential of these devices be realized. Smart medical devices will need to support automation in patient assessment outside the clinical environment, but also provide the ability to seamlessly notify the clinician when intervention or specialized care is needed without burdening the clinical infrastructure. This will allow the device to not only support collection of data for short- or long-term clinical monitoring, but also augment clinical diagnostics.

Additionally, in connection with the anticipated innovations of medical care available remotely, smart medical devices will become capable of funding the patient's compliance with advisory guidelines for clinical interactions. It is possible that financially supporting the goals of both patients and clinical staff via smart devices guided by machine learning methods will help these devices create a prevention-first interaction paradigm, enforcing preventive therapy goals proactively rather than in an additive caregiving process during routine clinical encounters. Data managed by these devices will be shared appropriately with care teams across disparate medical infrastructure.

12.7.3. Blockchain for Health Data Security

Artificial intelligence is a leading enabler of smart medical devices, revealing insights dense and subtle, accurate and actionable. But healthcare data can be difficult to protect, posing an important threat to its use in machine learning algorithms. One solution, blockchain technology, offers unique solutions. Both blockchain and AI can be used individually to protect health data, but using these technologies in tandem has been conceptualized to offer the most security, efficiency, and power to healthcare systems. Using actual trials and case studies, this section explores both traditional and hybrid applications of integrating AI, blockchain, and IoT devices in the health technology space. Blockchain systems offer security benefits that traditional computing devices cannot match because of blockchain's unique properties. Hackers cannot access or modify blockchain data because of its decentralized and distributed nature. Personal health information is sensitive information and is some of the most sought-after data blocks of hackers. Yet holding this data in centralized data banks is unavoidable today—

medical facilities and developers alike rely on it for device production, training, and usage. For AI-based embedded systems, however, such large storage within easy access may be unnecessary; instead, data may be streamed and ingested as needed. In these scenarios, integrating edge computing may make more sense for real-time processing than blockchain. However, AI-based processing is often needed across vast amounts of historical data with minimal processing delays. Blockchain offers an opportunity to cue these models to implement functions like alerting. Blockchains can be tuned to minimize data stream processing within specified latencies in this hybrid approach.

12.8. Market Analysis

Within the past two decades, the start of new ventures is gaining momentum at an unprecedented level. The upcoming trends in smart devices witness a multi-trillion economy engendered by unprecedented investment trends, government incentives, home automation needs, cyber threat preparedness, and lifestyles caterwauling for emerging smart devices. Over the years Smart Medical Device Technologies have equipped healthcare practitioners to manage various tasks in the hospital and for the patients. With AI technology being leveraged, Smart Medical Device Technologies offer a plethora of features to automate preparation, diagnosis, treatment, testing, monitoring, and reporting with precision, speed, accuracy, and control. The convergence in AI-Smart Medical Device Technologies has the potential to radically reshape the landscape of technology in large sectors including health care. These systems proffer intelligent data-backed insights for physicians to take exquisite patient-centric preventive measures, induce elaborate therapy procedures, devise personalized rehabilitation processes, forecast chances of readmission, and orchestrate elaborate surgical procedures and aftercare for surgical patients.

Investment Trends

Smart medical devices have gained substantial ground in the market constituting a significant share from unconnected medical devices. Industry experts in the field believe that AI-driven smart medical devices will yield the largest customer growth compared to other device segments and will reach nearly $37 billion in 2025. This would indicate a compound annual growth rate of over 36%. Healthcare professionals and industry experts across the globe project massive private equity investments in current and future AI-enabled medical devices due to growing consumer demands and consumer difficulties in receiving timely effective medical attention. In such a rapidly-growing digital healthcare landscape, Private Equity players are quickly venturing into artificial intelligence-enabled healthcare innovations mired in the paradigm shift toward disruptive healthcare technologies. These AI-enabled technologies emanate various benefits of convenience and efficiency by using personal devices for health services rather than visiting the hospital. AI in the healthcare industry is gaining the attention of streamed investment strategies enabled by advanced predictive analytics and the desire for better healthcare services.

12.8.1. Investment Trends

Medical devices are a key factor in the provision of healthcare services and a means to assess the progress of medical science, technology, and manufacturing industry in any country. The global medical devices market is projected to reach around USD 294 billion and grow at a CAGR of almost 9.5% by 2025. The market for medical devices powered by Artificial Intelligence (AI) specifically is witnessing massive investment trends with an estimated value of USD 1.6 billion in 2020. The AI in Medical Devices Market is expected to reach USD 6 billion by 2027, growing at a CAGR of 36.2% during the forecast period.

Investment in AI and robotics first boomed with the creation of the internet, with computer vision investing 36 billion dollars. The reason for investment trends in AI investment is the highlighted need of a better-predicting ability and data analysis. AI has been introduced into the life science arena, acting as the catalyst for change within the market. The AI paradigm teaches lessons about agility, focusing on non-incremental change, recognition of the self-disruption cycle, and in culture. By implementing real technological change at all levels of investment, the AI industry can better justify its valuation, get a return for investors, and ensure that AI continues to embark on a winning streak of technology breakthroughs in the years to come. This will in turn, help enable profitable development funds to create transformational change in the sectors.

12.8.2. Key Players in the Market

Artificial intelligence (AI) has gained prominence across various industries due to its ability to solve a wide range of complex problems. It is a new kind of intelligent approach aimed at resolving problems and automating activities in ways that are comparable to – or even better than – human capabilities. Big data and AI are revolutionizing the healthcare landscape by overcoming traditional challenges such as an aging population, a global increase in chronic diseases, increasing patient volume, and high medical costs. Customer service, solution, and product development, digitization and data analytics, intellectual property, and marketing and promotion account for the main revenue sources of the AI in the healthcare market. To meet growing customer and operational demands, healthcare organizations are increasingly relying on AI technologies and solutions to create innovative solutions. Major players in the AI in healthcare market are Microsoft, IBM, Siemens Healthineers, Google, and NVIDIA. Their core competencies in AI and machine learning (ML) drive innovations across various business functions including research and development, manufacturing, and sales and marketing. Increased research activities across new therapeutics and hospitals and clinical laboratory centers investing heavily to fund ML technologies and solutions development projects are expected to fuel the AI in healthcare industry growth. Rising popularity of social media is shifting the patients' and consumers' interest toward apps developed from AI technologies, resulting in more demand for these apps for diagnosis. Moreover, increasing demand for remote monitoring of patients during surgical procedures, rising number of chronic disease patients owing to sedentary lifestyle, and growing need for cost optimization are augmenting the AI in healthcare market expansion.

12.8.3. Future Market Projections

The 36 billion dollars market in 2022 is expected to grow to 100 billion dollars by 2032, for an impressive 10% CAGR. Nearly 100 medical device companies are publicly traded, two-thirds of these companies in the USA where small and mid-size companies abound. An increasing number of foreign companies are establishing headquarters in the USA, seeking to take advantage of this fertile ecosystem. Venture capitalists are attracted by the low cost of entry and the high potential for return.

The long-term outlook for the medical device market as a whole is mixed, with 2023 likely experiencing its own recession as a result of the pandemic. What is different this time is that the pandemic created unprecedented demand for some devices, like in-home diagnostics, consumer wearables, RFID tagging of patients, automated real-time alerts to caregivers of serious patient condition changes, and home monitoring devices that measure oxygen levels and heart function remotely. All of these higher demands succor a sense of urgency for continued innovation, especially with automating manual processes. Advanced innovation, though slower, keeps demand going for devices that support the aging US population, such as joint replacements, minimally invasive surgical devices, and implantable devices. Spending is also expected to rise as innovation increases and private payers return to traditional payment strategies, especially for robotic-assisted surgical devices that reduce time in hospital and lead to better outcomes. The aging population, which leads to higher demand for healthcare services, is also expected to raise public spending as well, particularly for diagnostic imaging, patient monitoring, and drug delivery devices.

12.9. Conclusion

We can see that significant fertile ground is present for advancements and growth of intelligent automatic medical device technologies in the not-too-distant future. Recently introduced devices, which are neural network based or are deploying knowledge models supplementary to neural networks, and which intelligently distinguish between normal physiological conditions and pre-symptomatic or asymptomatic clinical conditions, are pointing the way for growing research attention and corporate investments in rapidly developing smart-age intelligent medical devices. It is anticipated that commercial growth and advances on the subject will include not only intelligent medical devices for adult human beings, but also for children, infants, newborn, and fetal subjects, as well development of intelligent medical devices for animal species as intelligent veterinary device technologies, as well intelligent development encompassing acceleration of intelligent photonic device and wireless radio wave sensor device technologies for developing smart-age intelligent medical device – for growing area of sleep stage scoping, including sleep deprivation and sleep apnea, as well device deployments in hospitals, clinics and other specialized non-home destinations, including for geriatric patients as well, who have difficulty in undertaking planned sleep stage scoping in home, non-specialized locations.

Trends in future include development of specialty deployment miniature intelligent sensors such as smart-age intelligent wearable or sticker adhesive non-invasive sensor patch devices, and specialty deployment miniature intelligent sensors including internal implantable non-invasive internal sensor devices which are deploying intelligent non-invasive photonic sensor technology, as well continuing to accelerate research in increased utilization use of intelligent multi-sensor correlated input for enhancing sensitivity and specificity of intelligent non-invasive patient status sensing. Another important trend area includes intelligent device auto-crew composition, task allocation, identification cadence, and addressing capability and other strategies to remove medical personnel workload in a crowded telehealth-telemedicine environment.

12.9.1. Future Trends

"Emerging trends and future directions in AI-driven smart medical device technologies" manuscript presents emerging trends and future directions in AI-driven smart medical device technologies, focusing on global healthcare industry pulses and introducing an innovative concept of patient-centric preventive personalized medicine. AI is becoming the key technology in the current phase of the Fourth Industrial Revolution. Global trends, products, and patents in AI from different stakeholders suggest their expectation and investment momentum in AI technology. In the global healthcare scope, using semantic engines with diverse AI algorithms, innovative value chains and ecosystem paradigm shifts in the drug, diagnostic, individual therapy, and healthcare market were explored. Current global trends and future outlook in AI-driven smart medical device system evolution were described. Products and patents in software, algorithms, and hardware systems imply a digital transformation in the healthcare industry. Future smart medical device systems and products should be expanded to a software-with-a-device model in the medical sectors, combining a complex algorithm, software application, and smart connected hardware in the consumer area. They should also enable a patient-centric and customer-oriented innovative consumer experience with a new business model via different partnerships. AI will be becoming a key technology for the digital transformation, a complex tool, and a bridge to expand into a software-with-a-device model. In the Fourth Industrial Revolution era, the evolutionary game of smart medical device technologies will continue and accelerate healthcare market growth.

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