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RESEARCH ARTICLE

A Comprehensive Study on the Integration of Robotic Technology in Medical Applications considering Legal Frameworks & Ethical Concerns

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ABSTRACT

The medical industry is one of the rapidly growing sectors, considering the advances achieved in the last century. In this paper, a brief exploration of the integration of robotic technology in medical applications has been done, with light on the legal and ethical aspects. The role of robotics in healthcare has been expanded over time, enhancing surgical assistance, rehabilitation, and personal care through innovation and Artificial Intelligence (AI). The paper explores diverse healthcare robot applications, emphasizing their impact on patient care and medical practices. The legal frameworks and ethical implications are also analyzed in this paper, with case studies like domestic robotics and automation in personal care providing insights into real-world experiences. In addition, the regulatory landscape has also been explored with the civil liabilities of smart robots in Jordanian legislation, with attention to cybersecurity and governance issues. Upcoming technologies and the future potential of medical robotics, including nanorobots, and the need for ongoing research and robust regulation to maximize benefits have also been explored.

Keywords: Healthcare robotics, Ethical issues, Legal regulations, Medical technology, AI in medicine, Robotic surgery, Cybersecurity in healthcare.

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INTRODUCTION

The integration of robotic technology in the healthcare industry is transforming the entire landscape by enhancing surgical precision, aiding in rehabilitation, and providing personal care. With the latest trends and advancements in artificial intelligence and machine learning, the integration of robotic technology in the healthcare domain has become easier than ever before, opening a new wave of innovations and technological marvels in this domain, expanding the enhancing surgical precision, aiding in rehabilitation, and providing personal care.

Role of Robotics in Healthcare

The role of robotics in healthcare is highly transformative, offering advancements in the industry by providing a reliable system for complex procedures that were considered to be risky. It also helps in assisting in tasks that are more on the passive side and are repetitive in nature, by reducing the load on the healthcare service providers and improving patient care. Thus, robotics can play a crucial role in improving and advancing the healthcare industry by enhancing overall medical efficiency and by automating recurring tasks.

It is important to provide a proper definition for robotics in healthcare, as the same will prove crucial for legal clarity and avoiding ambiguity.[1] One of the popularly accepted definitions states that 'systems able to perform coordinated mechatronic actions (force or movement exertions) based on processing information acquired through sensor technology, to support the functioning of impaired individuals, medical interventions, care and rehabilitation of patients and also individuals in prevention programs'.[2]

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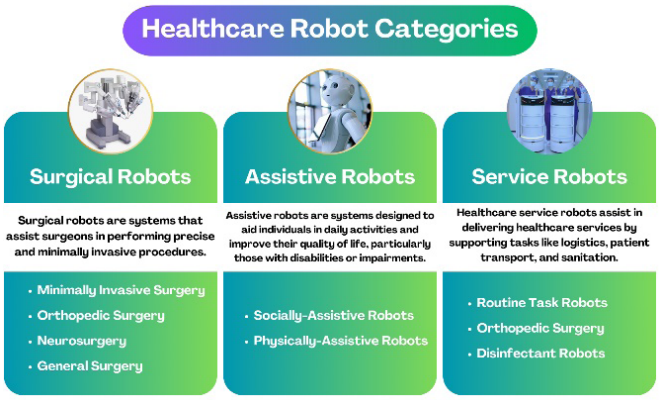

Figure 1: Categories of healthcare robots based on function

Applications of Robotics in Healthcare

Here are several key areas where robotics is making a significant impact in the healthcare industry:

- **Surgical Robots:** This is one of the most commonly used applications of robotics in healthcare, wherein the use of multiple robotic arms will be utilized for carrying out complex surgical procedures with the utmost precision, flexibility, and control than conventional techniques.[3]
- **Rehabilitation Robots:** Assistive robots that will help in achieving physical therapy and recovery for patients with mobility impairments, such as stroke survivors. They provide consistent and precise therapeutic exercises, providing faster and more efficient rehabilitation.
- **Robotic Prosthetics:** These are advanced prosthetics that mimic natural limb movements, which can be controlled by analyzing the signals from the signals obtained from the patient, enhancing the quality of life for users.
- **Robotic Nursing Assistants:** These are hospital environment based robots that help in tasks like lifting and transferring patients from beds to wheelchairs, thus decreasing the strain on nurses and caregivers and preventing accidents.
- **Telemedicine & Remote Monitoring:** These are specialized robots that facilitate remote consultations and monitoring of patients, enabling healthcare professionals to monitor the patients in real-time across distances, delivering healthcare to the hard-to-reach or underserved areas.
- **Pharmacy Automation:** The handling of medication as per the prescription, dispensing and packaging of the same without the margin for errors and improving the efficiency with timely delivery and data entry of the same makes a proper ecosystem for pharmacies and hospitals.
- **Robotics in Geriatrics:** These are specialized social robots that are designed to provide companionship and cognitive stimulation for elderly people, improving their mental health and reducing loneliness.
- **Laboratory Automation:** Similar to pharmacy automation robots, these work in the automation of the laboratories based in hospitals and further. These are mainly deployed for automation of repetitive tasks such as sample handling, testing, and analysis, improving efficiency and accuracy.
- **Disinfection and Sterilisation Robots:** Autonomous robots that can perform routine cleaning tasks such as UV disinfection, cleaning, and maintaining hygiene standards of healthcare facilities.
- **Logistics and Supply Chain Management:** These are industry-trained robots that can handle tasks like delivering supplies, medications, and equipment to different departments of the hospital environment, optimizing resource utilization and reducing wait times.
- **Robotic Exoskeletons:** Specialised wearable exoskeleton-based robots for patients with spinal cord injuries or other mobility impairments, enabling them to perform normal physical activities by providing them strength and stability, facilitating rehabilitation and enhancing mobility.

Evolution of Robotics in Medicine

The integration of robotic technology in healthcare and medicine has been done early on, mainly to assist in surgical procedures. One of the first notable instances of the same is the Automated Endoscopic System for Optimal Positioning (AESOP), which was approved by the Food and Drugs Administration (FDA) in 1994 and was developed to help surgeons navigate endoscopic cameras during minimally invasive surgeries, with precision and stability.[4] Robotic surgery has been one of the popular applications of robotics in healthcare. The same has evolved largely over the years into more sophisticated systems with significant improvements.

The currently available technology allows surgeons to perform complex procedures with enhanced precision, dexterity, and control with systems like the da Vinci Surgical System. We have seen significant improvements in teleoperated and autonomous robotic systems, wherein the former provides high-definition 3D visualization that replicates the surgeon's arm movements and the latter performs tasks independently based on programmed instructions and real-time data from the surgical environment using advanced machine learning algorithms coupled with computer vision technology.[5]

Healthcare Robots: A Qualitative Exploration

The emergence of robotics is transforming industries across domains, and with the integration of AI, these systems can learn from their environment and human interactions to provide better results with accuracy and efficiency. A qualitative approach of various stakeholders such as engineers, system developers, suppliers, academics, and users of healthcare robots was done to understand the interdependence of social and technical systems within the ecosystem.[6] There is a wide opportunity available in terms of improving the safety, quality and efficiency of healthcare robots. Some of the barriers that are prevailing for the implementation of these dedicated robotic systems into healthcare are:

- **Lack of Clear Demand:** As the demand for the utilization of advanced healthcare robots is difficult to understand due to limited awareness and understanding of the potential

benefits, it becomes difficult for manufacturers to create a market for the products.

- **Learning Curve and Adaptability:** The stringent procedure protocols to be followed in the medical sector leave a heavy impact on the adaptability of new technologies into the ecosystem, making it difficult to integrate. Even though the integration has been done successfully, the learning curve will be huge for the healthcare professionals, where many of the personnels associated will hesitate to adopt the novel technologies just to counter the learning curve.
- **Disruption of Workflow:** The integration of robotic technology will disrupt the currently existing workflow and will require significant organization and distribution of work among healthcare professionals.
- **Legal and Ethical Considerations:** Since the integration of robotics in healthcare needs dedicated legal frameworks to be implemented along with a series of approvals and regulatory affairs to be followed, it is difficult to integrate with the current ecosystem.

In addition to the discussed challenges regarding the integration of healthcare robots in the clinical setting, there are socio technical challenges as well to overcome the implementation of the same in the healthcare ecosystem. This happens mainly in designing robotic systems that can adapt to various healthcare environments, ensuring the comfort of both the patient and the healthcare service provider.

Innovation, Artificial Intelligence and Robotics

Although the idea of robots handling surgeries and assisting healthcare professionals seems uneasy, the same exists and is being used widely across the healthcare domain for several applications.[7] The innovation happening in this domain is phenomenal compared to the last couple of decades, as we have achieved milestones in terms of the technological advancements we have achieved in terms of integrating advanced AI models with medical robotics, making it more intelligent and adaptable as per the real-time situation. These also help in making the system's accuracy better, enhancing efficiency, and personalized care. Some of the most advanced and automated robotic systems have been explored in this section:[8]

The da Vinci® Surgical Robot

One of the most popularly known brand names within the healthcare robotics industry is a state-of-the-art robotic system dedicated to facilitating complex procedures using minimally invasive means,[9] improving surgical outcomes and enhancing the precision and safety of the procedures. It comes with a high-definition 3D vision, coupled with a magnified view and precise instrument control for procedures like Nephrectomy for kidney conditions, Coronary artery bypass, Hernia repair, etc.

- **Xenex Germ-Zapping Robot:** As the name suggests, by leveraging the power of pulsed xenon UV light, the robot acts as an advanced disinfection system designed to eliminate harmful pathogens in healthcare settings.[10]

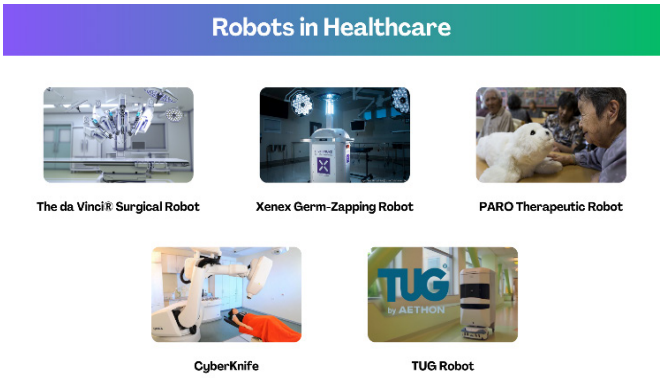

Figure 2: Robots in Healthcare Industry

It provides a rapid, effective, and automated solution to combat harmful pathogens in hospitals and other healthcare environments like research laboratories and clinics.

- **PARO Therapeutic Robot:** This is a different type of robotic solution as compared to the others in the list, as it is a social robot designed to provide emotional and psychological support to patients, such as geriatric patients, patients with dementia, mental healthcare support and pediatric patients.[11]
- **CyberKnife:** CyberKnife is a state-of-the-art robotic radiosurgery system that delivers high doses of radiation with sub-millimeter accuracy.[12] This minimizes damage to surrounding healthy tissues and makes it less invasive compared to the traditional methods. It is used in treating cancer and other medical conditions, such as brain tumors, spine and spinal cord tumors, lung cancer, prostate cancer, and liver and pancreatic tumors, with high precision.
- **TUG Robot:** An autonomous mobile robot designed for material transport within the healthcare ecosystem, streamlining operations by delivering medications, supplies, lab specimens, and more, making the system more streamlined, providing better efficiency in less time and reducing the pressure on the healthcare service providers.[13]

Ethical Implications of Medical Robotics

Although AI and robotics are groundbreaking innovations promising advancements in diagnostics, treatment, and patient care in the healthcare sector, there have been major ethical concerns regarding the use and integration of these technologies with age-old medical procedures. Over the years, there have been many criticisms against the proper implementation of robotic technology in medical procedures, but the same has decreased due to the promising advantages over the conventional methods and risk analysis that shows a positive ratio compared to not using the same. The integration of AI is also facing the same issue currently with the advancement and leaps the same has taken in the last couple of years. Some of the important parameters to look forward to in the ethical perspective of healthcare are as follows:[14]

- **Privacy and Data Security:** With data becoming the most important resource in the digital world we are living in,

the use and management of data, its privacy and security has to be taken care of while considering the integration of AI and AI-based robotic technologies, especially in the healthcare sector, as the data here is highly sensitive.

- **Algorithmic Bias and Fairness:** AI algorithms can perpetuate biases as per the data in which the model has been trained. Diverse datasets and continuous monitoring are necessary to ensure the proper functioning of these systems without giving any biases and to be fair in the results put forth by the AI model.
- **Transparency and Accountability:** The decision-making process of the AI models should be transparent with clear responsibility explained as a framework, especially in the healthcare sector, where the stakes are high. Explainable AI techniques can enhance trust and accountability by providing a clear path the model has taken to come up with a particular result.
- **Ethical Guidelines and Frameworks:** As robotics and AI technology are novel considering the current ethical guidelines and frameworks, the same has to be improvised to accommodate these technologies without interfering with the existing ones, which will be an upcoming challenge, although we have seen many attempts that have been discussed in this paper.
- **Impact on Healthcare Professionals:** The introduction of robotics and AI has redefined the healthcare sector, shifting the role of healthcare professionals in the hospital ecosystem. The demand for these professionals to overcome the learning curve with new skills and responsibilities has been prevailing. The need for interdisciplinary collaboration is high as the technology integration strengthens.
- **Regulatory and Legal Challenges:** Developing a globally adaptable regulatory framework addressing legal challenges like liability and intellectual property has become inevitable. These innovations have to be democratized across the globe, ensuring equitable access to AI and robotic technologies to all.

Case Study: Project RoboLaw

RoboLaw is a project commissioned by the European Commission under the Seventh Framework Programme (FP7), which aims to explore and address the regulatory challenges posed by the rapid innovation, integration and development of robotics and artificial intelligence in society.[16] There is a requirement for proper regulatory frameworks in robotics and their applications due to their profound impact on economies and societal structures. Many geographical powers have invested heavily on the research, development and integration of robotic technology for strategic advantages, influencing labor markets and income distribution. Ethical considerations are another major factor discussed in the RoboLaw project, wherein, the same can guide the development and implementation of robotic technologies to align with societal values and principles.

Another major concern to be taken care of is the transformation of human vulnerabilities and capabilities, making it

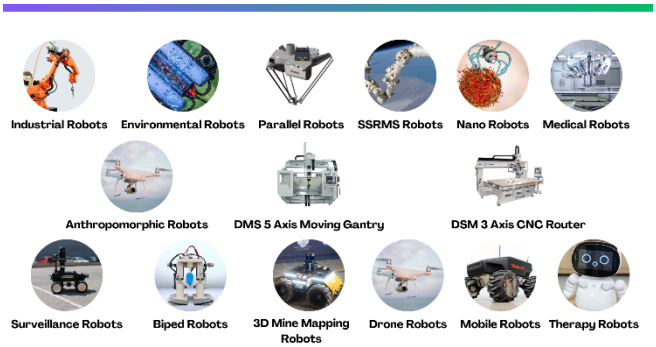

Figure 3: Parameters of robots: Application and type

necessary to introduce careful policy decisions to balance out the risks and benefits, protecting fundamental rights and freedoms. Liability laws are one of the challenges that will significantly influence the development and deployment of new technologies, making it important to have a clear and fair liability framework that can promote the growth of socially beneficial robotic applications while mitigating the associated risks. Some of the recommendations to be considered while drafting a framework for the regulation of robotic technology for socially beneficial areas are proactive policy stances in regulating robotics to ensure that technologies develop in line with the EU (European Union) values and principles. Creating a clear and transparent regulatory environment for the successful development, integration and deployment of robotic technology, and finally, the generalization of findings to other emerging technologies, ensuring a comprehensive and adaptable regulatory framework.

Case Study: Responsible Domestic Robotics

This case study focuses on the ethical implications of domestic robots and the deployment of the same into society, which has become somewhat inevitable as technology develops in this sector.[17] Some of the major concerns include privacy, consent and integration of human values that have to be contributed into the design aspect of these technologies. Responsible research and innovation in the design and development of domestic robots should look forward to ethical considerations.

The study focuses on different aspects and implications that have to be considered while using these robotic technologies for domestic purposes. Privacy and consent have been some of the major concerns that were raised, which addresses issues such as challenges in human-robot interactions and the need to have a robot interaction protocol as a part of the design implication. Responsible research and innovation is another area, which addresses continuous reflection and interaction with a range of stakeholders guided by ethical principles and societal needs and a sense of responsibility to make a positive impact on society.

Fragmentation of responsibilities across the stakeholders in diversifying the roles within the robotic community will help in creating an open ecosystem for better practices inclusive of human values and ethical concerns, which can be

overlooked by a framework of unified ethical standards that helps in addressing the fragmented community as a whole. Considering human values in the design of domestic robots becomes important with the third wave of Human-Computer Interaction (HCI), which gives importance to human values (including cultural and social aspects) in the technology design. Value-sensitive design acts as a key framework, which aims to incorporate moral values into technological design, research and development, making it more aligned with conservative human rights. Finally, the challenges and criticisms include prioritizing the values during the design process and the need for a more practical approach and implementation of the domestic robots in the design as well as the development stage.

Legal Frameworks of Medical Robotics

Building a proper legal framework for medical robots is one of the most challenging tasks for any nation or organization across the globe due to the high stakes in healthcare as well as the ethical implications of robotic technology.[18] But, drafting a proper legal framework for the same is inevitable as the merits of using robotic technology in healthcare are increasing day by day, with better capabilities and precision.[19] This makes complex procedures more streamlined and simplified, improving the overall healthcare ecosystem. Some of the factors to be considered while drafting a legal framework for healthcare robots are mentioned below:

- **Intellectual Property (IP):** Patents and Copyrights come under intellectual properties for robotic technology and the use of the same in the healthcare sector.[20] Due to some public policies and morality, patents may rarely be denied for robots accounting for public security and morality or that may harm the environment. There are also some exclusions to certain medical treatments and diagnostic procedures, wherein robots designed for these purposes often face challenges in patent eligibility. Coming to copyright, there is a chance of unresolved ownership issues, which involves understanding whether human corporations can own content created by robots or if robots can have any form of IP right attributed to them.
- **Jurisdictional Compliance:** Some of the established regulatory agencies across the globe are listed below:
  - Food and Drug Administration (FDA): Regulatory agency for the United States that oversees the regulation of medical robots via stringent safety and efficacy standards before market approval.
  - European Medicines Agency (EMA): The regulatory agency for the European Union along with corresponding national bodies regulate medical devices, including robots, ensuring that they meet EU Medical Device Regulations (MDR).
  - Medicines and Healthcare products Regulatory Agency (MHRA): Regulatory agency for the United Kingdom that regulates the safety and performance of medical robots under post-Brexit frameworks.
- **Approval Process:** The approval process involves clinical trials with both premarket approvals and post-market surveillance. Premarket approvals, especially for medical robots, include rigorous clinical trials to demonstrate their safety and effectiveness with multiple phases of testing and review to meet regulatory standards. In post-market surveillance, medical robots are subject to ongoing surveillance to track performance and address any safety concerns that arise even after approval from the regulatory agencies.
- **Specialized Regulations:** This includes classifying risk based on the device category from low-risk (e.g., assistive robots) to high-risk (e.g., surgical robots). Higher-risk classifications involve more stringent regulatory requirements. Software as a Medical Device (SaMD) refers to the software utilized in healthcare robots and is also regulated under specific frameworks.
- **Ethical and Legal Considerations:** Patient safety and consent is an important aspect to be taken care of which should focus on informed consent from the patient with proper transparency about the use of robots in their treatment.[21] There should be proper human oversight while deciding on what has to be automated and what decision has to be made in critical situations, maintaining patient autonomy and preventing over-reliance on robots. The quality of care provided should be of utmost value with standards and protocols ensuring consistent and high-quality care across different settings. Accountability and responsibility for the performance and outcomes of medical robots are important, delineating roles for developers, healthcare providers, and operators. Finally, privacy and data protection should be ensured especially while handling medical data, where the system must comply with health data protection laws, such as HIPAA in the US and GDPR in the EU. Keeping the patient data confidential should be the responsibility of all the included stakeholders handling the data.
- **Liability and Safety:** Properly defining the liability especially in case of any accident or malfunction, distinguishing between the responsibilities of manufacturers, healthcare providers, and operators. Risk management is another aspect wherein insurance policies can evolve to cover the specific risks associated with medical robots. Structuring a proper safety standard in compliance with the medical standards involving operational safety mandating regular updates and maintenance checks is important. Understanding the perfect balance between humans, robots and the interactions between them should be architectured properly by integrating safety especially in the medical setting, preventing accidents and ensuring smooth integration into healthcare practices.
- **Cybersecurity:** Securing medical robots against potential cyber threats by ensuring robust cybersecurity measures to protect against hacking and data breaches coupled with proper regulatory requirements by setting up minimum cyber standards for medical robots that enforce protection and update timely to address evolving threats.[22]

Data protection for sensitive data handling in compliance with the data laws proposed by the authorized authority ensures secure collection, storage, and processing of patient information.

Case Study: Jordanian Legislation

This case study focuses on analyzing the legal framework for the civil liability of smart robots and other intelligent machines operating based on artificial intelligence within the general and proposed regulations of Jordanian Law. Article 291 of the Jordanian Civil Law explains the rules of liability for damage caused by things and machines, which includes robots and their application and liability. Additionally, Articles 291 and 292 state that "whoever has control over things (machines) requiring special care has a guarantee (i.e., compensation for the damage to the affected party)".[23] These laws define the liability of intelligent robots in case of any mis happenings, errors or malfunctioning that may cause damage to others. Although the jurisdiction presents a solid framework for robotic technology, it lacks a proper code of ethics for robotics, which can be easily introduced by amending the existing legal framework. Additionally, the case study suggests the addition of "artificial intelligence programmed activities" to Article 291 of the Jordanian Civil Code. The focus is also proposed to look into using objective liability standards to compensate for damages along with the necessity of obligatory insurance with registration and licensing of robots before their use.

Cybersecurity and Care Robots

A care robot (CRs) can be defined as "a system that is able to perform coordinated mechatronic actions (force or movement exertions) based on processing information acquired through sensor technology, to support the functioning of impaired individuals, medical interventions, care and rehabilitation of patients and also individuals in prevention programs".[24] It is used in various applications such as surgery, rehabilitation, assistance, therapy, etc. As CRs are becoming increasingly significant in healthcare, they pose significant cybersecurity risks. There is growing research on cybersecurity for CRs, but they mainly focus on general safety and risk rather than specific cybersecurity issues.

The currently applicable regulatory and legal frameworks have limitations that specify voluntary mandates on manufacturers and no mandates on the user. CRs have higher cybersecurity threats compared to other medical devices, including attacks on hardware, firmware, and communications, which can potentially cause both physical and psychological harm. The goal is to build an improved framework specifically addressing CR cybersecurity with a greater focus on user training and awareness, integrating ethical considerations into cybersecurity practices.[25] The development of CR-specific cybersecurity models and countermeasures is required for the wider adoption and protection of CRs from cybersecurity threats.

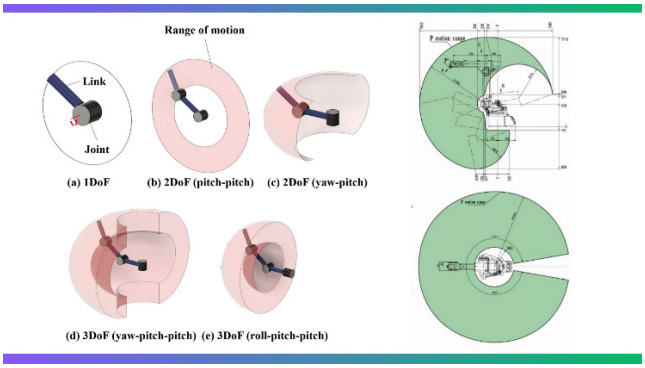

Figure 4: Parameters of Robots: Degree of Freedom and Motion Range

Robot Governance: Private Standards vs Public Policy-making

The development and enforcement of regulations and standards to control, manage and regulate the deployment and integration of robots for societal applications and interaction can be considered under robot governance.[26] Industry groups and technical experts with flexibility and rapid adaptation to technological advancements with a downside of prioritising industry interests and lack of formal enforcement mechanisms develop private standards. Public policy-making involves regulatory bodies creating frameworks that protect public interests, ensuring safety, fairness, and ethical considerations.

Examples of the former include ISO and IEEE standards for robotic safety and interoperability and examples of the latter include General Data Protection Regulation (GDPR) of the European Union that impacts the design and deployment of robots. The effective governance of robotic technology requires a harmonious integration of both approaches, leveraging the agility of private standards and the broad protections offered by public policymakers ensuring a balance of safe, ethical, and beneficial deployment of robotic technologies into the society.

ICMR: Ethical Considerations

The Indian Council of Medical Research (ICMR) has established ethical guidelines for the application of artificial intelligence (AI) in healthcare and biomedical research.[28] The 12 general principles in the ICMR National Ethical Guidelines, 2017 address most of the ethics related to biomedical and health research. ICMR recognized ethical principles of AI are:

- **Autonomy:** The application of AI technology in healthcare transfers the power of decision-making in the hands of AI. In order to regulate this circumstance, humans should have the authority over AI in healthcare and the medical decision-making and make sure that the AI technology does not interfere with the patient's autonomy.[29] The patients must be able to make informed decisions and consent on the use of AI technology in healthcare, given the right to choose or refuse to use AI healthcare technology.
- **Collaboration:** Ensuring of data quality involves collaboration with domain experts, including healthcare professionals and data scientists, to verify that the data used is relevant and accurate for the intended medical

applications. AI technology is vast and needs constant research and development experts for rapid changes in technologies and information. This interdisciplinary approach helps in addressing complex issues related to data quality and AI ethics.

- **Risk Minimisation and Safety:** Ensuring the safety of AI technologies through robust control mechanisms and secure systems is paramount. The Ethical Committee must work on measures to prevent misuse and ensure reliable functioning of AI tools. The cyber-attacks on AI technologies should also be taken into consideration so that the safety of private details can be ensured.
- **Accessibility and Equity and Inclusiveness:** The AI technology developers and concerned authorities must ensure fair and equitable distribution of the AI technology. This involves concentrating the distribution of AI technology more on the socially and economically backward citizens. Special considerations should be provided to the underprivileged and natives from a poor infrastructure background. This is to ensure that no such discrimination shall take place in the case of the distribution of AI technology.
- **Optimization and Data Quality:** The AI being training data for AI systems should be representative of the diverse populations that the technology will serve.[31] This means including data from various demographic groups to avoid biases that could lead to inaccurate or unfair outcomes in AI applications. Moreover, measures to identify and minimize biases in the data should be implemented, which can lead to discriminatory practices if not properly managed.
- **Non - Discrimination and Fairness:** The principle of fairness and equity must be profound in every stage of AI Technology.[32] In order to prevent inaccuracy or biases, it is the duty of the researchers to ensure that the population with which the AI technology is concerned shall be represented. Moreover, it is also necessary to ensure that the distribution of AI technology must be more focused on vulnerable groups like children, ethnic groups, persons with disabilities, etc. The active inclusiveness of women and minority communities must be ensured as well.
- **Validity:** The AI technologies must undergo rigorous clinical and field validation before being deployed in healthcare settings. This process involves testing the AI systems in real-world clinical environments to ensure that they perform accurately and effectively.[33] The validation process is essential for verifying that AI tools can safely be integrated into healthcare practices without causing harm to patients.
- **Data Scrutiny and Trustworthy:** Trustworthiness is the most desirable quality of any diagnostic or prognostic tool used in AI healthcare.[34] The AI tools in healthcare must abide by all laws and regulations and ensure adherence to ethical principles and values provided. The results provided by the AI healthcare systems must be explainable on scientific plausibility and reasoning. A well-explained AI tool in healthcare can increase the trust and confidence in AI over time.
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- **Data Privacy:** AI systems must be trained on high-quality, unbiased data to ensure their effectiveness and reliability. Stringent data protection measures should be implemented to safeguard patient information, including anonymization and adherence to privacy laws.

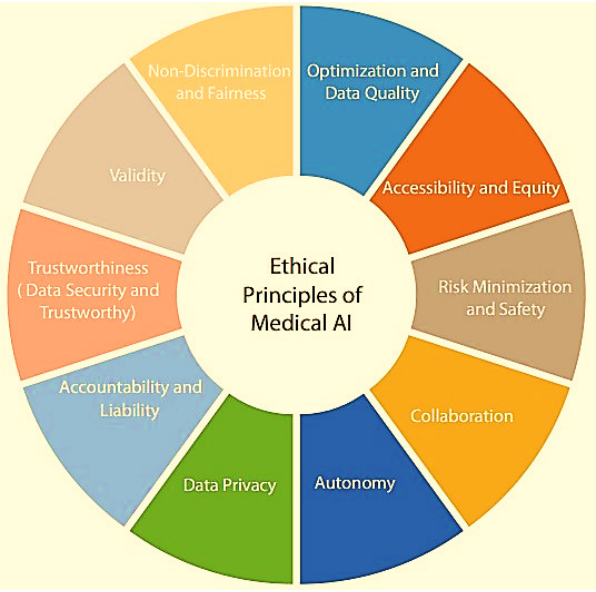

Figure 5: ICMR: Ethical Principles of Medical AI

ICMR: Legal Frameworks

The software as a medical device (SaMD), which is the AI technology for healthcare, has immense potential for improving the healthcare system and resources. However, such immense potential of AI technology also comes with challenges that should be taken care of by the regulatory bodies in the country.

The Indian Government has put efforts in providing a legal framework for the right functioning of AI technology in healthcare. The National Health Policy (2017) focuses on the integration of digital health and the establishment of the National Digital Health Authority for leveraging digital health technologies. The National Digital Health Blueprint (2019) focuses on developing a system of electronic health records based on international standards.[35]

The Digital Information Security in Healthcare Act (2018) provides the establishment of National and State eHealth Authorities and Health Information, which regulates the process of collection of data, storing, transmission, use

of digital health data and ensures reliability, data privacy, confidentiality and security of digital health data.[36]

The Medical Devices Act of 2017 and its amendment in 2020 has expanded the definition of the term 'medical devices' in the said act, by including any software or an accessory intended to use for medical purposes.[37]

The current Data Privacy Protection Act is the IT Act 2000. In the IT Act, section 43A states that "where a body corporate, possessing, dealing or handling any sensitive personal data or information in a computer resource which it owns, controls or operates, is negligent in implementing and maintaining reasonable security practices and procedures and thereby causes wrongful loss or wrongful gain to any person, such body corporate shall be liable to pay damages by way of compensation to the person so affected".[38] The Indian government is bringing a new healthcare data protection law - the Digital Information Security in Healthcare Act (DISHA) Bill and the Personal Data Protection (PDP).

CONCLUSION

The application, integration and development of robotic technology in the healthcare sector is inevitable, with the technological penetration happening already across different layers of the healthcare industry. As the stakes are high for any scope of error in the healthcare industry, the requirement for a proper legal framework with awareness about the ethical considerations has to be taken care of. There are different form factors as well as applications and functionalities of robotic technology in the healthcare industry, from self-care robots to advanced surgical assistive robots that are used for specialized and complex medical procedures. The Food and Drug Administration has set some of the established legal or regulatory frameworks (FDA) of the US, the European Medicines Agency (EMA) of the EU and the Medicines and Healthcare Products Regulatory Agency (MHRA) of the UK.

A brief exploration of case studies has been made to understand the necessity of adaptive regulations, ethical guidelines, and interdisciplinary collaboration to ensure safe, equitable, and effective deployment of robotics in healthcare. The effort of this paper to map the various legal frameworks set across the globe with a special focus on the Indian regulatory and legal frameworks set by ICMR (Indian Council of Medical Research). As the evolution of technology happens, ongoing research and thoughtful policy-making will play a major role in maximizing the benefits while mitigating risks, which will steer the future of healthcare robotic technology with better efficiency, improving the healthcare ecosystem as a whole.

Future Prospects

As robotic technology is a rapidly emerging technology, especially in the healthcare sector, there is a huge scope and opportunities for innovation and advancements in terms of the integration of advanced machine learning models or in terms of novel technology integration like improved battery technology or out of the box form factors that are more efficient and effective. Some of the key areas where it is expected to see growth are in the fields of robotic prosthetics and exoskeletons, personalized medicine and AI integration, telemedicine and remote surgery, and medical nanorobots, which will be explored further.

Medical Nanorobots

Miniature robots designed at the nanoscale with capabilities to perform specific tasks in medical applications, such as targeted drug delivery or therapy at the cellular or molecular level are called medical nanorobots.[39] They can utilize chemical and biological sensors for their functionality, which can be driven autonomously or semi-autonomously. They possess the capability to transform healthcare but require robust legal frameworks and ethical considerations. The three proposed laws of nanorobots are safety: must be safe and non-toxic to humans, effectiveness: perform allocated tasks efficiently and with minimal off-target effects and self-destruction, must disintegrate into harmless byproducts to prevent environmental contamination after completion of their allotted tasks.[40]

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