

# Ethical And Regulatory Challenges Of Ai In Life Sciences And Healthcare

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Cite this paper as: Gopalakrishnan Mahadevan (2023) Ethical And Regulatory Challenges Of Ai In Life Sciences And Healthcare. *Frontiers in Health Informatics, Vol.12*

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The current research focuses at analyzing the ethical and legal aspects concerning the use of Artificial Intelligence in the field of life sciences and healthcare. As a rapidly growing field, it is also important in the area of patient care, diagnosis, and treatment, several ethics arise which includes privacy and data security, biases in AI, and black box decision making. Such challenges put regulatory bodies in a dilemma when attempting to design guidelines that will help in safe and effective use of AI. In this research it reflects the need for international guidelines that take care of ethical factors such as justice, responsiveness, and confidentiality. It would imply that there is a need to embrace international cooperation and work such that risks may be prevented and the positive impact of AI is increased in the healthcare sector.

**Keywords:** *Artificial Intelligence, Healthcare, Ethical Challenges, Regulatory Compliance.*

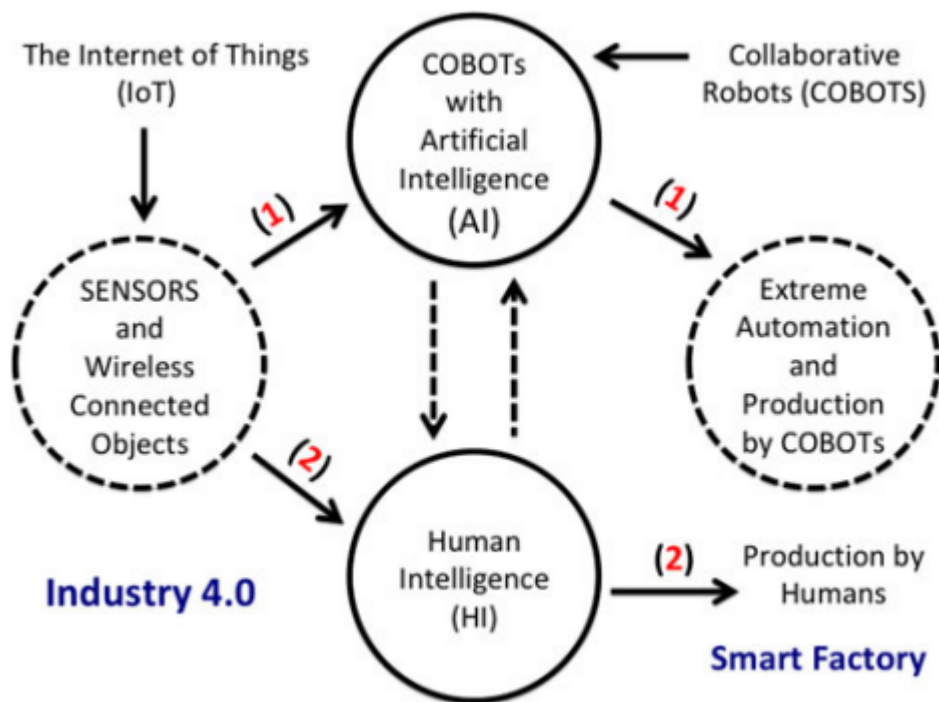
## 1. Introduction

The use of Artificial Intelligence in life sciences and healthcare has the potential of enhancing the health systems significantly in aspects of patient management, diagnosis, and treatment. There are certain critical ethical and regulatory problems that appear as AI technologies develop. Such limitations include patient privacy, data security, issues with algorithms and Artificial Intelligence and the ability of AI to make decisions on its own. Even the governing boards are struggling with how to set guidelines for the use of AI in healthcare that would be satisfactory for both the patients and the doctors or any other health care providers. In this research the purpose is to analyse the ethical and legal issues of AI in life sciences and in healthcare with the expectation of having a concept on how to handle the incorporation of such a delicate and sensitive area of human life.

## 2. Literature Review

### 2.1 Big Data with Artificial Intelligence and the Internet of Things

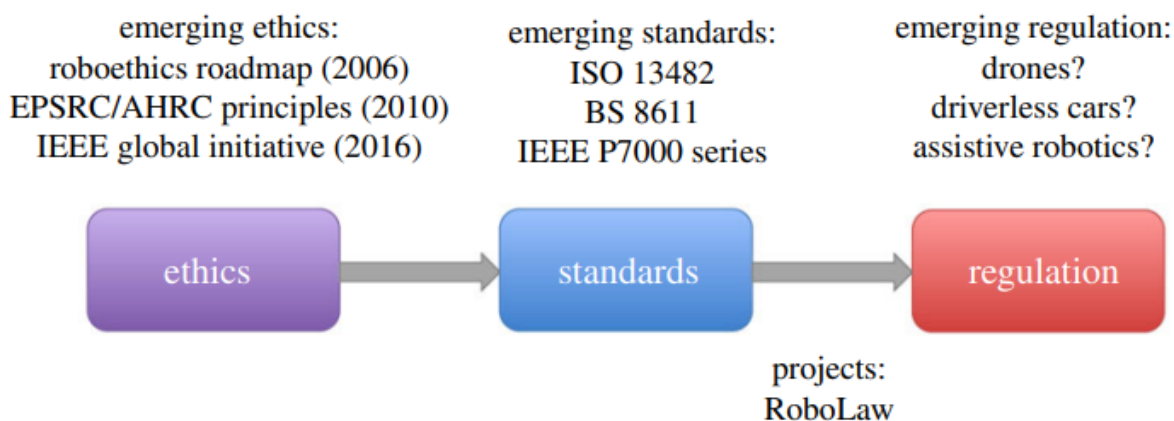
According to the author Özdemir *et al.* 2018, it states that in this research it was intended to identify the ethical and legal issues of AI in life sciences and healthcare with regards to the use of AI in patient care, compliance, and ethical use. It actually focused upon how AI technologies are being implemented by firms within the healthcare industry and the challenges arising from lack of adequate regulation, and also ethics such as those of Great Britain including issues to do with algorithm bias and accountability. Among the issues it has highlighted was that AI has made a positive impact to the patient mainly through outcome improvement but the two key challenges that were pointed out include regulatory compliance and ethical issues. The overall research indicated that the emergence of AI in health-care services is increasingly growing faster than the legal systems leading to disparities in the use as well as the lagging behind in implementing legislations on the use of such systems. There were issues in the areas of ethics such as reporting the information, being accountable for the information and protecting the identity of the patients. It is because there is no extensive regulatory framework for AI, for healthcare worldwide that has been established. Challenges for the future research will be to focus on creating a comprehensive framework and ethical standards regarding the use of AI in the provision of health care.



**Figure 1: Industry 4.0 and the Smart Factory**  
(Source: <https://www.liebertpub.com>)

**2.2 Ethical governance is essential to building trust in robotics systems**

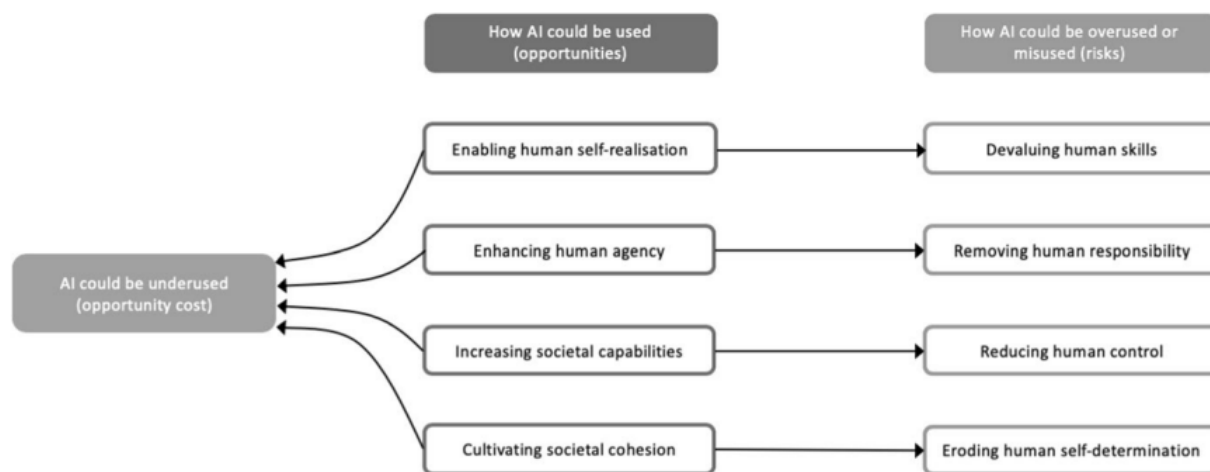
According to the author Winfield *et al.* 2018, it states that the aim of this research was to explore the significant approaches on ethical decision making in robotics and artificial intelligence and propose how such Hubs will be created to increase public confidence and responsible advances in robotics and artificial intelligence systems. The objective was to establish a strategic plan to align ethical principles, standards, rules and the public in the ethical steering of artificial intelligence and robotics. The research brings to light the necessity of ethical measures for the enhancement of trust in the Intelligent Autonomous System, and the research revealed that there is a continued growth and development of ethical principles for AI while the gap between it and implementations was noticed. The results have suggested that there is a necessity for more complex and effective management decision-making processes which should include stakeholders from different organizations. A research gap that has been found out is that while there is increased awareness on ethical governance frameworks, the practice has not been well up to the expectations. In the scenario of AI and Robotics further research should be conducted with the focus of establishing better, transparent and functional models of addressing the societies and Ethical issues in accordance with the technologies.



**Figure 2: Linking ethics, standards and regulation**  
(Source: <https://royalsocietypublishing.org>)

### 2.3 An Ethical Framework for a Good AI Society

According to the author Floridi *et al.*2018, it states that the aim of this research was to provide recommendations regarding foundational principles needed for the formation of a “Good AI Society” based on the reflection of opportunities and risks accompanying AI. The objective was to determine and outline five general ethical principles for AI respectively to present specific recommendations to the relevant stakeholders to follow and enforce healthy AI practices. The outcomes mentioned ethical governance as a significant priority and highlighted the benefits of integrating different stakeholders in developing a sustainable environment for AI-related activities. The principles and recommendations mentioned above if implemented would build a good foundation for a positive outlook to AI. The outcomes revealed that despite some advancements being made, specific policies and procedures remain short. The research gap that was noticed was a lack of addressed framework and a concrete solution that would help the global stakeholders in AI regulation work in unity. Future work also consists of a more comprehensive study of establishing international coherent, coherent AI policies, which is to ensure the moral use of AI at a large scale.



**Figure 3: Overview of the four core opportunities offered by AI**  
(Source: <https://media.springernature.com>)

## 3. Methods

### 3.1 Data Acquisition and Sources in Healthcare AI

The information and data for this research has been gathered from existing secondary sources, which includes books, peer-reviewed journals, articles, government reports, industry reports, and online websites. The resources that have been collected were gathered with much focus on the research area of Ethical and regulatory challenges of AI in life Sciences and Healthcare. Research works and significant analysis will provide a better perspective on the use of AI in healthcare, along with any critical issues of morality and legislation. There will be some theoretical frameworks based on the books written by renowned professionals in the field of healthcare AI and ethics. It states that from the government official sites and health organizations, official policies and measures concerning the deployment of AI in the sector will be gathered. Industry reports released by technology sectors and healthcare organizations will show how the practice of AI is done and the issues related to it (Cath *et al.*2018). In accordance with it, articles from standard peer-reviewed online journals that are focused in healthcare technology will provide advancement and will help to gather current information and will also help in performing better analysis and gathering of results based on the research topic.

### 3.2 Preprocessing and Quality Assurance of Healthcare Data

In this research, the preprocessing and quality assurance of healthcare data will be centered on the validity, reliability and verifiability of the data that has been collected from different sources. This will provide an analysis of books, journals, articles and reports such as government and company reports and data from reputable online sources. A particular focus will be made to consider any sources of bias or inaccuracy in the data, especially as such data collection can differ in terms of the format, standard,

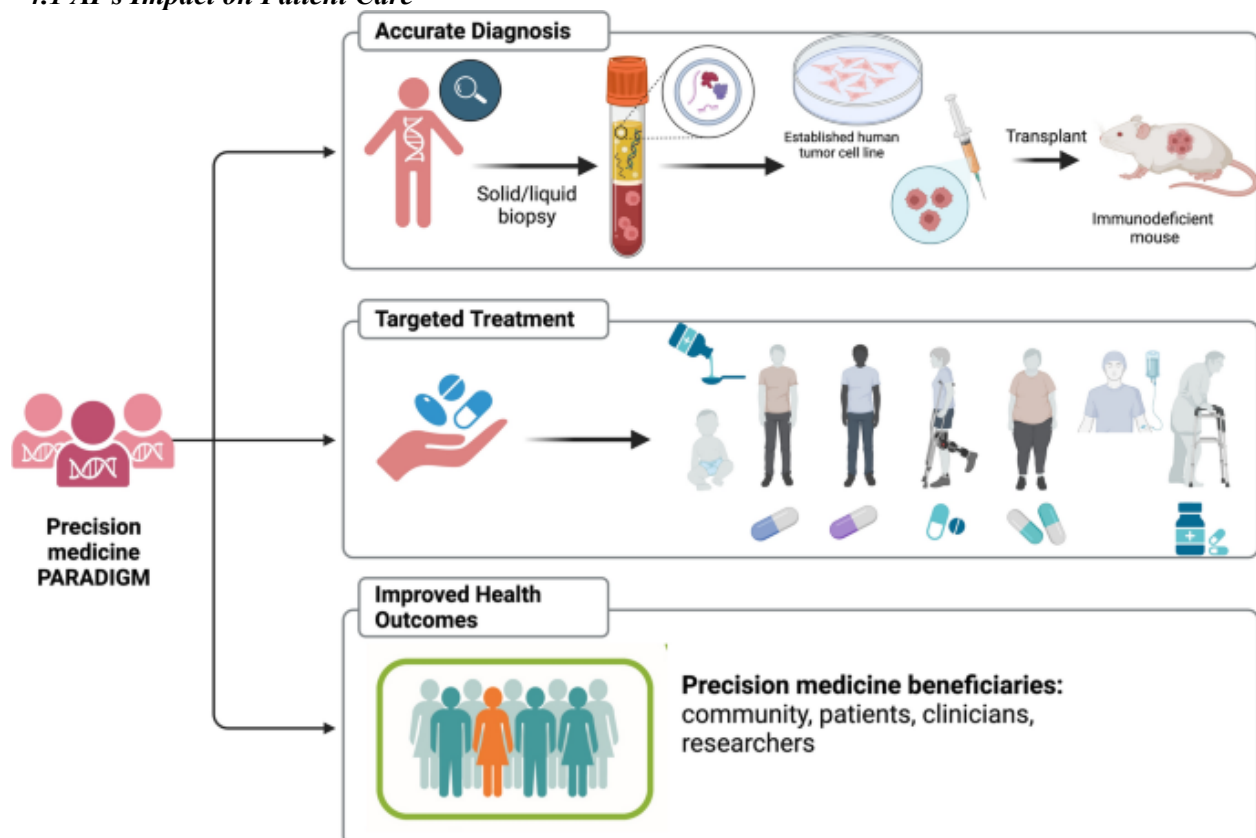
and source. The data will be reconstructed and aggregated with the goal of improving the comparison between the data which has been collected from a number of studies and from other publications. It will be done by verifying the reliability and the validity of the information and ensured that the information obtained is recent in response to the current development in the implementation of health care AI (Lin et al.2011). According to it, this will assist in ensuring that the data to be used for the research analysis of the ethical and regulatory issues on use of AI in healthcare will be relevant, credible and suitable for the qualitative research data.

### 3.3 Ethical Frameworks and Guidelines for AI Model Development

The guidelines and regulations identifying the ethical concerns of developing an AI Model will be discussed in this research through books, journals, articles, government papers and guidelines presented by different authors. The paper will therefore aim at establishing steps and measures taken to ensure ethical AI that has been laid down in the provision of health care services. It is a chance to reconsider the approaches to open data, responsibility, equality, and confidentiality, including consent. Some of the issues of Ethics that shall be discussed include, Algorithmic Bias, Data Protectionism, and Automation of decision-making. This research will also consider the guidelines that govern regulations such as those provided by the government as well as other organizations with an emphasis in the healthcare industry (Califf et al.2015). It will also identify the major ethical issues and recommend how to overcome it by considering the guidelines that outline the best practice of ethical AI in models in the healthcare industry.

## 4. Results

### 4.1 AI's Impact on Patient Care



**Figure 4: Tribulations and Future Opportunities for Artificial Intelligence**

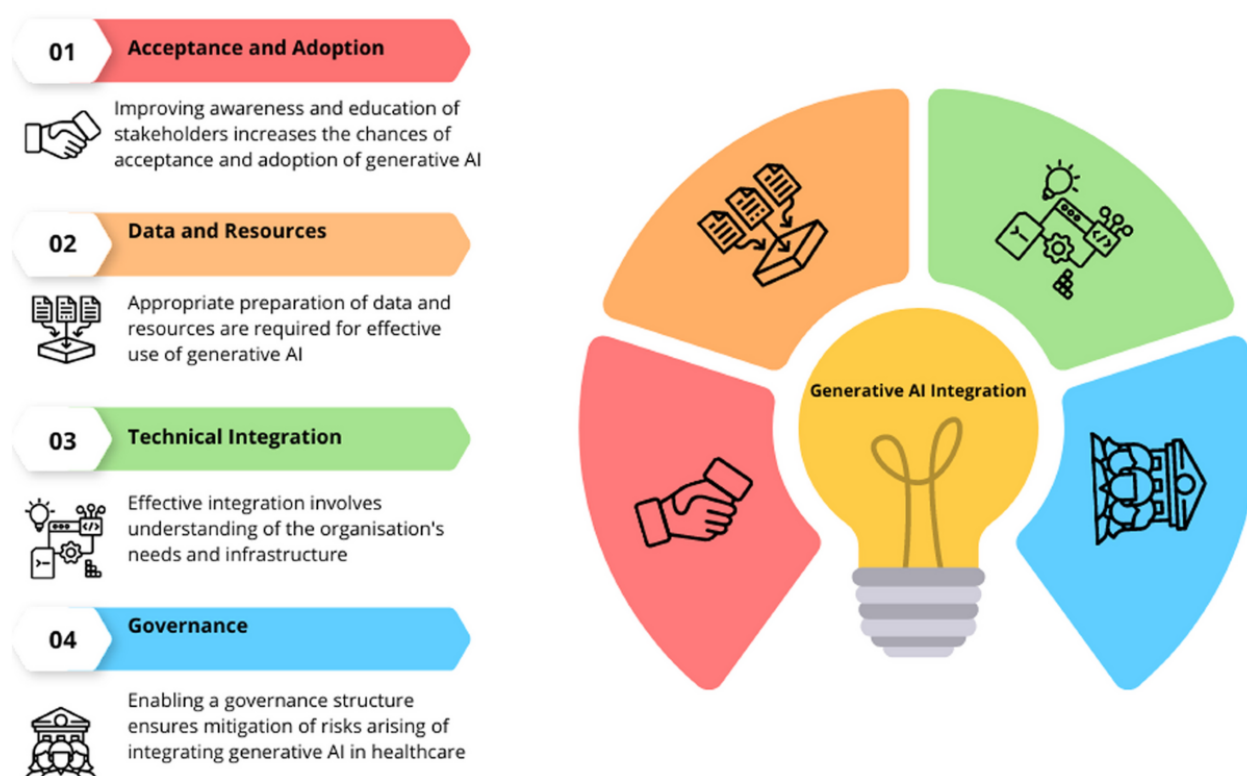
(Source: <https://media.springernature.com>)

The findings gathered from the relevant resources such as books, journals, articles and online websites reveal that AI has revolutionized health care delivery systems in diagnosis, treatment, and the use of medicine based on individual patients' status. Application of artificial intelligence has gathered positive results through the determination of diseases like cancer and neurodegenerative diseases, in relation to receipt of image recognition and data analytics work. Machine learning is also concealing better prognosis of a patient's conditions thus enabling it to give the required treatment according to the patient.

Furthermore, self-developed knowledge supports the big number of patients ensuring proper handling and reducing the possibility of errors due to human factors (Boddington *et al.*2017). AI is capable of processing large volumes of data within a short time and this suits diagnosis most especially in emergency cases. It also states some specific issues that persist and consist of keeping the accuracy of the AI system across different patients' types and parameters. The application of AI in patient care is gradually increasing, though has to undergo periodic appraisal to determine how suitable and safe it is to be used in the actual clinical practice.

#### 4.2 Regulatory Compliance Challenges

## Generative AI-Translational Path

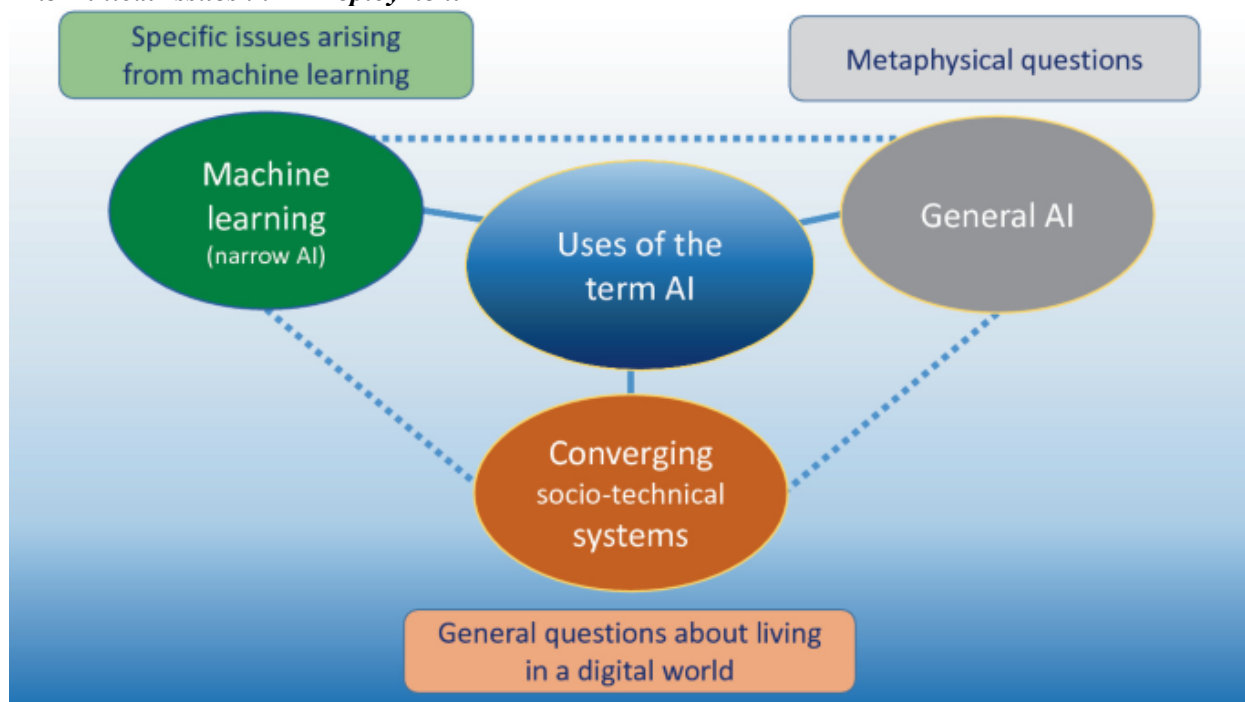


**Figure 5: Generative AI in healthcare**  
(Source: <https://media.springernature.com>)

The available data in existing resources has highlighted several models that are critical in regulatory compliances and holds issues that are encountered when incorporating AI in healthcare. Some of the challenges include the absence of a clear set of principles guiding the use of AI in various areas and compliance standards may vary depending on the geographical location (Cohen *et al.*2014). HIPAA in the US is a reference of such rules that do not consider the specifics of AI technologies, so it becomes a bit critical to provide assurance that the AI models are compliant with privacy, security, as well as ethical norms. The other challenge is that the current advancement in the application of AI makes it hard for the same regulatory authorities to provide prompt approval for the AI controlled medical devices and systems. Other issues include the lack of traced reasoning processes by the AI models, which is paramount in patients' safety and responsibility. It also states that there is a growing trend to create guidelines just for the purpose of regulating AI however, the capturing of a global healthcare system erecting barriers to the practice is still a major ideal.



#### 4.3 Ethical Issues in AI Deployment

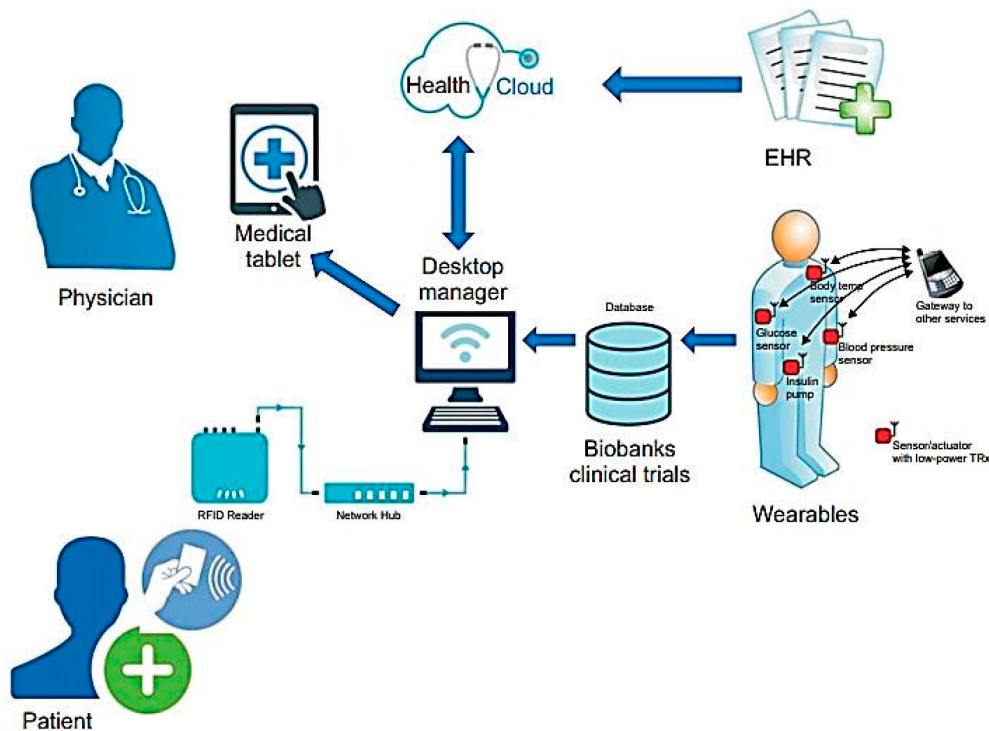


**Figure 6: Ethical Issues of AI**

(Source: <https://media.springernature.com>)

The specified ethical threats related to the use of AI in healthcare have been identified by the existing resources such as transparency, the manner in which machine learning models arrive at the recommendations is not usually easy to understand, Accountability where not only is it difficult for the general public to understand how a predictive model reaches its results but it may not be able to change the decision even when it has a difference in opinion with it. In the area of Fairness there are significant issues that AI may indirectly reinforce some of the bias that can be noticed in society. The first important dimension is creating algorithmic bias as it only reflect existing, trained data and as such, the machines that operate it may end up further harming patient groups that are already marginalized in the healthcare system (Stahl *et al.*2018). Another theme is the opacity of AI decisions thus the decision making process in AI is not easily clear especially to healthcare professionals and patients as to how an AI has arrived at a certain outcome, this provides the confidence of the people on these technologies. Also regarding the area of liability, it somewhere remains open as to which area is to be focused at when the AI system errors in its diagnosis or suggestions for treatment. Assigning or attributing the focus towards either the developers of the system, the medical practitioners using the system or the system itself is still a very critical issue. Also, the patient cooperation issue is significant as AI applications in healthcare require access to a large quantity of patients' SHI, to which the issues of data protection and informed consent are applied.

## 5. Discussion



**Figure 7: Healthcare Internet of Things (H-IoT)**

(Source: <https://www.mdpi.com>)

The result that has been provided shows information regarding the significant advancements adopted by AI in the medical participation and appreciation of the usefulness of the advanced AI in healthcare through early diagnosis, and even treatment to the patients. It states that like any other forms of research, it is important to meet legal and ethical standards in implementing this research. The absence of guidelines and policies relating to artificial intelligence in healthcare has disadvantages, such as uneven adoption process and possible delays in the approval procedure. There are areas which provide information regarding the ethical implications of prejudice in algorithms and the general effectivity, thus AI implementation is indeed required (Leenes *et al.*2017). Among the significant areas that are to be considered in this case are the following such as the issue of accountability of such an AI-based decision, and concern for patient privacy. These outcomes therefore impose the necessity for standard bearing setting and ethical policies in the practice of artificial intelligence in the health sector.

## 6. Future Directions

The policy considerations as regards to the future directions of AI in the healthcare industry should provide information that will be regarding the standards required across global territories for the efficient approval of AI systems. Hence, it is crucial to have policy frameworks involving policymakers, healthcare staff, and AI developers to develop virtuous, accountable and trusted AI algorithms. Ethical problems like what has happened in case of the biased algorithms and data privacy requires highly annotated guidelines and standard integration of fairness as well as transparency in the operations of the AI (Meskó *et al.*2018). Furthermore, the proper evaluation of effects and outcomes of the AI systems being used in real-life practicing environments in the healthcare sector is critical to determine the safety, efficiency, and fair operation across patients of different vulnerabilities and demographics.

## 7. Conclusion

AI is a promising tool in healthcare as it has the ability to provide improvement in the patients' care, diagnosis, and individual treatment plans. However, there are a number of ethical and regulatory questions that have to be solved for integrating AI such as the problem of algorithmic prejudice, the problem of AI explanation, the problem of AI responsibility and the problem of data protection. There is thus the lack of a well-defined set of legal requirements and rules of ethical conduct across world

regions of interest. It states that for AI to be implemented in a safe and fair manner, there should be a standard framework around the world, people and organizations should coordinate, and above all the AI that is developed should be tested regularly in practical settings. Addressing these issues will make it possible for AI to realize its potential value in the healthcare industry while ensuring the patients' trust.

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