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Data Privacy And Security Challenges In AI-Driven Cloud Health Systems: A Regulatory Perspective

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Abstract

AI systems in the cloud pose a significant challenge as many of them are human-centered and involve sensitive health information. Patients have been increasingly concerned about healthcare cloud technology and data communication services. Although the cloud still presents new opportunities for data storage, computing, and transmission in healthcare, it can also expose users in the health sector to episodes or scenarios that produce unintended outcomes, and even harm when misuse occurs. Evidence suggests that the cloud environment suffers from basic vulnerabilities such as ongoing attacks on confidential data. In addition, health AI systems are increasingly scrutinized in the wake of numerous AI scandals and fraudulent scandals in numerous industries. AI designs and tools that lack transparency and explainability, which black-box results that violate accountability obligations, untested algorithms that unfairly affect people's lives, and systems based on scraped or socially questionable information are some examples of AI use gone wrong. These examples represent opportunities for human researchers and engineers at big companies to stray from proper AI design, deployment, and use paths intentionally, thus resulting in harmful outcomes.

AI is prepared in a way that monitors, groups, seeks unusual samples, and signals alerts using past health data and behavior. The cloud is a versatile data repository and AI enhancer for health, but it processes data off-premise, away from the direct control of patients and actual data owners. Patients have clouded data streams, coupled with AI health systems, thus losing important algorithmic control semantics. They cannot define what data of theirs are used for what purpose, by whose algorithm, when, where, and how. Developer-oriented data abstraction trends make many patient-focused algorithms work directly with durable storage, scope, and type mechanisms rather than referencing individual data points. Patients' data can be reused in ways that violate patients' own expected purposes. Audits, permissions, shackles, and compensations are explicit governance measures that need to be securely and formally established, monitored, enforced, and updated.

Keywords: AI in Healthcare, Cloud Computing Security, Health Data Privacy, HIPAA Compliance, GDPR in Healthcare, Data Governance, Cybersecurity in Cloud Systems, AI Ethics in Health, Patient Data Protection, Regulatory Compliance, Privacy-Preserving AI, Medical Data Breaches, Healthcare Regulations, Cloud Health Infrastructure, Data Anonymization Techniques.

1. Introduction

To meet demands and improve users' quality of care, healthcare organizations, cloud service providers, and telecommunication carriers are moving toward a cloud-based health system. Being at the intersection of the major data-driven fields, the new norm of the data-driven healthcare health system, in which personal health data will be processed by global players in the cloud, creates a fundamental shift in data privacy. Such constantly available data aggregators and interpreters result in shifts in data control, where patients no longer have actual custody over their health data. Consequently, the concern towards health data privacy increases, especially after a few significant data leaks affecting multinational consolidators that provide cloud-based services. Aligned with this trend, various parties are striving to balance public health interests with privacy concerns, resulting in a series of laws and regulations. Nevertheless, realizing the goal of fine-grained regulatory data control is challenging.

Most regulations concerning AI in health deeply elaborate on accountability, fairness, and control when dealing with re-used personal health data. However, debating on prohibition instead of preventing regulated data use first hand, it is previously suggested that AI products processing cloud health should undergo different regulatory standards which differ to what is currently in practice. To complement the analysis about the suitability of the current policy without introducing profound significant changes, the response to the increased concern of data misuse, with an emphasis on the transnational impacts, was worked with a proposition on how to make incremental improvements to strengthen the protective power of existing regulations without addressing procedural changes. That fundamental change can hardly be achieved, the identification of an AI-driven cloud-based health system as a potential highly-intrusive AI product justifies proactive regulatory actions on prohibiting regulated data use in the first place. Methods to achieve such regulatory ambitions are proposed.

First of all, both AI-driven health systems and the majority of software that fall into the definition in the regulations can be excluded from the definition of AI-based products, thus beyond the authority of the existing regulations. In addition, even if it is presumed that this system and software could be defined as transportation means, none of this software nor the information to enter is of European origin.

1.1. Background and Significance

With much excitement and great expectations, Artificial Intelligence (AI) is entering the health services sector. Cloud computing technologies enable the coordination of cloud-based eHealth platforms where AI algorithms support data challenges. AI allows reassessing the volume, variety, and veracity of data, thereby converting it into knowledge. The latter enhances decision-making for improved and timely health services. However, to make this ecosystem of advanced technologies beneficial for patients, healthcare professionals, hospitals, and governments, patient data privacy and cybersecurity are pivotal challenges to the adoption of these systems.

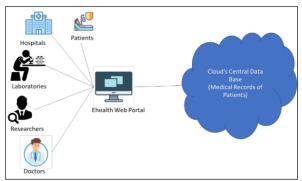


Fig 1: Data Privacy and Security Challenges in AI-Driven Cloud Health Systems.

Health information must remain protected. A secondary but equally critical challenge is to assure data and algorithm security against stealthy and random accesses. Cybersecurity threats to eHealth systems can block benefit provision, and compliance with regulations could also be non-observance of ethics and rights. Even starting with official and acceptable objectives, systems based on personal information could divide societies or finally destroy democracy. All systems might lead to biased conclusions due to biased training data. The deliverable solutions would be sub-optimal, leading to suboptimal decision-making. A major worry is that under a negative scenario, safe decisions could be generated, e.g., to deny a person health care or insurance coverage. Such systems could be manipulated and re-diagnosed intentionally. In this case, the system would mislead the users by creating reachable paths. Enactment of AI and cloud-based eHealth systems must closely consider state of the art laws, regulations, ethics, and rights because of the potential harm to the patients and society.

Fake concerns of scientific revolutions have happened throughout history. However, AI-based cloud health systems could be genuinely momentous, improbable, and unforeseeable. The delivery of this unprecedented power must be with prudence. Privacy and security requirements concerning patient data gathered from sensor-enabled devices and machine learning algorithms must be with proponent maturity and competence. Governments must define and enforce legislation for the health service. Trustable certification of AI implementations is a novel topic on the agenda of the regulatory authorities. AI adoption would enforce further efforts in these domains; the opposite could lead to undesired and disastrous scenarios.

2. Overview of AI in Healthcare

AI evolves in healthcare to reduce costs, improve the quality of provided services, and optimize clinical workflows using patient data. The last decade has experienced a growing interest in AI technologies for healthcare applications. AI is a branch of computer science that aims to create intelligent systems that mimic human-like behavior. In particular, healthcare applications help to understand how AI-based systems can be effectively utilized to aid clinical decision-making. Medical imaging is one of the main areas of development, whereby various AI-driven systems are used to aid radiologists in identifying lesions of interest within acquired medical images.

AI systems are extraordinarily promising, with applicable niches in many healthcare domains, extending from diagnostics to personalized medicine, patient risk assessment, and early treatment betterment. A range of methods is available to analyze various types of medical data. Nevertheless, while currently growing and providing interesting solutions, these kinds of tools have not yet reached maturity and use. Potential roadblocks preventing a smooth clinical integration of AI-based tools regard a general lack of knowledge on AI-related techniques, data and infrastructure issues, low technological literacy of medical users, and difficulties in interpreting AI-produced information. Concerning the general lack of knowledge about AI systems, it is important to understand how AI works and how it differs from standard statistical analysis. This has consequences at several levels: where to invest, which workforce to recruit, and how to make strategic decisions and assess possible business opportunities in the healthcare domain.

AI-based systems are today often protected by intellectual property rights, explaining their predictions as a black box. Moreover, often-users have limited responsibility and awareness of biases that provide inequitable discrimination based on gender, race, and region. The second aspect of understanding the limits and the processing of data is strictly related to privacy and ownership issues of patient data, which presently are ambiguous. The most advanced AI applications can consume big amounts of data to "train" predictive models, following the adage "more data, more successful AI" along with "better data, more successful AI." A common challenge today regards data and infrastructure issues, as it is often difficult to obtain medical data for innovation in content reading, non-curated, or not explorable, generalist datasets.

2.1. Research Design

The regulatory landscape for health data protection is developing rapidly. In light of this gap, the paper will analyze the regulatory data security and privacy challenges posed by AI-based cloud health systems through a legal lens. This analysis will highlight the blind spots and inefficiencies in existing regulations, which are leading to a global race to the bottom in the protection of health data privacy and security. A set of regulatory solutions will then be proposed, aimed at providing a lucid reference framework for the design of future regulations for cloud health systems and regulatory harmonization. Existing regulations protecting health data privacy, security, and other associated rights were reviewed and analyzed. Consistent with the monitoring of the rapid evolution of AI-driven cloud health systems, many new technologies, applications, and use cases have been identified. It was also observed that existing regulations are inadequate or missing for these new technologies, applications, and use cases. Seven blind spots and inefficiencies in existing regulations were identified, and an analysis of the regulatory aspects of existing cloud health systems in five regions/locations was conducted. Existing cloud health systems were classified into three types, and the data protection and privacy implications of each type were analyzed. Existing regulations were observed to be blind and ineffective in protecting cloud health systems, and a regulatory analysis of the data privacy and security concerns of existing cloud health systems was conducted.

As discussed previously, existing regulations protecting health data privacy, security, and other associated rights were reviewed and analyzed. This analysis was conducted in light of the rapid development of new technologies, applications, and use cases that store, process, transfer, and monetize a large amount of highly sensitive health data on the cloud. Efforts were made to review and identify up-to-date regulations worldwide that are applicable to these technologies, applications, and use cases. Unfortunately, despite painstaking efforts, it was observed that a great number of AI-driven cloud technologies, applications, and use cases were simply not covered by existing regulations. It is a timely reminder of how inadequate or even nonexistent regulations are for a great number of technologies and applications. Other new technologies, particularly those that are more widely used at a household level, were also envisioned to be at risk, because the need for consent, pseudonymization, and privacy protection regarding an IoT health device or the use of gene editing on a baby is much less explicit than that for a cloud-based AI-powered heart rate risk screening application.

Equ 1: Differential Privacy Equation.

- M = randomized algorithm (mechanism)
- D_1, D_2 = neighboring datasets
- ε = privacy loss parameter
- S = subset of outputs

$\Pr[\mathcal{M}(D_1) \in S] \leq e^{\epsilon} \cdot \Pr[\mathcal{M}(D_2) \in S]$

3. Data Privacy Concerns

The unprecedented availability of vast volumes of health data has motivated numerous public and private stakeholders to explore the implementation of AI to produce cheap and actionable insights that improve patient outcomes, health system performance and drug discovery. The deployment of AI-driven methodologies to mine health data, however, entails several key ethical concerns, all of which revolve around the privacy and agency of patients and the risks of unsolicited data use and sharing. Concerns regarding privacy can be divided in two broad clusters. The first concerns the substantive threat to health information privacy posed by access to, use and control of patient data in private hands. Concerns regarding the availability of health data to private custodians such as technology companies delivering its AI models have become more acute and nuanced in the general wake of recent public-private partnerships to implement AI in health systems, some of which provide poor guarantees of privacy protection. To this end, researchers have called for much greater systemic oversight of big data health research at the national and supranational levels, through more detail on the design of appropriated legal safeguards and structural recommendations that encourage custodians to prioritize privacy and patient agency in health AI projects rather than access and exploitation of such data for profit reasons. There is a continuum between rights and obligations regarding patient agency, in that, unlike other forms of personal data with strong marketing relevance, health data are voluminous and dispersed. Custodians are thus in a unique position of power with respect to patients. They should be structurally encouraged to mitigate the risk of competing goals related to the potential profit from re-analysis and secondary trading of health data. The other cluster of privacy concerns relate to external risk of privacy breaches through AI-driven means, especially in terms of complex algorithms that make modifications to patient health data to "de-identify" or "anonymize" it. Such modifications are a central part of many data-sharing protocols aiming to comply with legal policies that mandate the protection of patient privacy. New algorithms have demonstrated their capability to amplify ordinary modification processes and bring forth effective de-anonymization methods. Moreover, the data reproduced through algorithms may still retain sufficient identifying information to allow health system tracing and linking back to patients without the aid of references.

3.1. Patient Consent and Data Ownership

The cloud computing paradigm allows to overcome the local storage and processing limits of traditional systems by allowing data owners to outsource large datasets to remote platforms and leverage upon their size and advanced computing capabilities. The adoption of cloud computing is particularly appealing for Health Systems, as transitioning from local storage to cloud systems involves huge economic savings on the hardware side. However, this transition also raises ethical, legal, and regulatory challenges in the light of the growing sophistication of health data processing tools and AI technologies. In this context, data

privacy and security are one the main challenges for global health cloud systems. Data privacy refers to the proper management of the information an individual provides in order for it to be analyzed and interpreted. In AI-oriented health systems, data privacy implies obtaining appropriate consents from patients; making sure that the right data are actually used for the desired prediction or analysis and that there is no risk that private information could be inferred from anonymized data. At last, patients have to be guaranteed that their data will not be commercialized by the provider company. Data security generally refers to measures preventing unauthorized access to a dataset in order to protect it from potential leaking, hacking, breaches or attacks. In AI-driven health systems, security entails controlling who can access health data, ensuring that the information obtained from a dataset cannot be turned into information about the individuals it was derived from, and being protected against malicious attacks that manipulate the invisible data processing chain.

3.2. Data Breaches and Vulnerabilities

One of the greatest dangers of AI is related to security and necessary software updating. Several AI methods don't provide enough knowledge on how the output is generated. If vulnerabilities emerge in such systems, they could be exploited by adversaries and become troublesome and hazardous for patients. An AI model might give a wrong output due to hardware or software faults or due to adversarial intrusion or due to chance. At the same time, an AI system can fail due to a faulty choice of design or an inadequate training set, without any obvious intentional action. Such faults can cause much harm to patients, e.g. a broken decision system that suggests a prescription with a wrong dosage to be given. An erroneous AI system might misinterpret imaging exams, e.g. showing a malign feature as a benign one. These faults can be attributed to the software rather than the users, or to the users of the software rather than to the developers. The malfunction of the software isn't a satisfactory defense in a litigation. AI products qualified as 'high-risk' systems such as those intended for health are subject to stricter requirements. Here is a list of requirements that AI should meet: Adequate risk assessment and risk mitigation systems.



Fig 2: Data Breaches and Vulnerabilities in Healthcare system.

A 'good' AI system uses high-quality datasets for training and testing. If an AI is trained on wrong or biased data, it is at best useless and often harmful, much more than a classical method with untrained parameters. To overcome this problem, AI has to log its activity, and keep a record of its train-test datasets and hyperparameters. Through this documentation, data protection authorities, civil society and possibly patients themselves can review if a hospital is compliant with all these requirements. AI shall provide clear and adequate information to users, explaining the limitations and assumptions made. AI systems intended for health, medical devices and therefore all high-risk systems shall have high levels of robustness, security and accuracy, and need to be tested and certified as such.

4. Security Challenges

The significant growth in digital health system adoption continues to raise privacy and security concerns over the management of sensitive patient data. Security vulnerabilities exist within both the cloud infrastructure hosting health applications and services or within AI algorithms. The growth of cloud computing, combined with the value of the health data generated, collected and processed by health systems has driven a fundamental shift from the traditional local storage on-premise systems to the new cloud-based digital health tools. The positive shift towards cloud-based health systems, offering many advantages and compelling use cases, is marred by ongoing security and privacy issues.

A range of high-profile cloud data breaches makes the digital health systems more interesting targets for attackers. While cloud vulnerabilities can be mitigated, the prolific deployment of AI-driven algorithms creates new privacy and security challenges. On the one hand, AI algorithms used within medical imaging services are trained internally, then accessed externally. Such models often include sensitive features that can be exploited to leak private patient data back to the service user. On the other hand, black-box AI methods are being accepted in peer-reviewed journals and translated into clinical systems without adequate regulatory oversight or transparency, leading to a potential threat to patient safety and security. Health systems may publish AI-driven algorithms externally, allowing unlimited access to other organizations. AI algorithms operating without oversight can result in erroneous processing of person identifiers linked to patient safety and security. Techniques exist to reverse engineer decision logic from AI algorithms, allowing ways for association attacks on patient safety. In other cases, constructed symbolic rules have been successfully used to recover data and infer the details of individual patients

underlying the analysis. Ensuring accountability and responsibility is required to minimize the risks of inference attacks. Currently AI development teams work in silo, without knowledge sharing and logging exposure to AI black-boxes. Third parties lack required capabilities, rules, and policies to operate within compliant boundaries. Consequently, they may be unaware of model risks and become the weak link in the AI chain.

4.1. Cybersecurity Threats

Healthcare organizations have become prime targets for cybercriminals, particularly in the era of constant electronic exchange of ePHI data. With an increasing reliance on cloud-based health systems, the stakes have risen even further, introducing a slew of new vulnerabilities. Yet new technologies have also brought enterprise-grade preventative measures within reach of organizations of all sizes, and the trend toward in-house ePHI encryption allows organizations to maintain control over sensitive data. In addition to relatively mundane healthcare data breaches driven by human error or contractor indiscretion, threat vectors exist that capitalize on advanced capabilities like deep-fakes. Emerging vulnerabilities linked to the rapid deployment of AI in the health domain also raise questions over the adequacy of traditional HIPAA protections. This rapidly evolving digital landscape invites the possibility of exploitation at unprecedented scale and sophistication, propelling the urgency for effective regulations and responses. Given the multitude of existing and developing vulnerabilities and threat vectors, the various regnant models and structures of regulation, and the potential of existing oversight authorities to insert themselves into this complex discourse, it is imperative that effective guidelines, principles, and regulations for AI in cloud health systems be established in a timely manner and with a degree of cooperation across interest groups sufficient to ensure their efficacy. The opportunities for malicious actors posed by the digital transformation of healthcare have burgeoned simultaneously across both the private sector and the nation states operating within a rapidly changing geopolitical context. This raises questions over the adequacy of existing adversarial-based regulatory responses. The proliferation of the Internet of Things (IoT) has ushered in an increasing number of 'smart' personal health devices that provide awareness and monitoring. There is an implicit expectation that health devices will manage and safeguard that health data in ways similar to applicationlevel encryption frameworks. However, the potential exists for new vulnerability classes that have the potential to expose ePHI to criminal actors who can exploit existing tooling to sidestep conventional protective measures. Such vulnerabilities may be exploited by security experts and 'hacktivists' for benign ethical and political purposes, or by knowledge workers from lowcost international labour markets to perpetrate 'click-worker' frauds at enterprise scale.

4.2. Access Control Mechanisms

As an example of regulatory attention afforded to access control mechanisms, the European Union's Free Flow of Non-Personal Data (FFD) directive and the EU's 2020 Data Governance Act (DGA) are examined below. These two acts are establishing an important regulatory framework for ensuring and encouraging data-sharing of data in a secure way. Both texts have implications for the increasingly AI driven cloud health systems by enhancing access control and prohibiting free-riding censorship of data.

The European Data Economy is fueled by the explosion of data driven economic activities, i.e., data-driven services that access previously untapped data sources and charge service fees for value-generating actions like data-analysis, predictions, valuations and pragmatic incentives. In the age of big data, smart objects, AI and Cloud computing, data proliferation presents tremendous potentials and challenges. A common worry is that, as data is the new gold, data monopolies could arise. Unfettered concentration of data could hinder innovation, price out new competitors and limit consumers' and businesses' choices. Competing concerns exist on whether data should be retrieved from hands of market giants and returned to primary custodians such as individuals and information producers. Indeed, the problem of "refus de données" or censorship of data sharing by data custodians is as important as data monopolies.

Europeans consider data an asset that they create by default. The EU's GDPR tries to restore this asset back to individuals or data subjects ("my data, my rules"). However, its fundamental approach is rights-centric, which might be tricky as it requires data subjects to take actions to exercise their rights. It also regards data as a subjective attribute or vector, leaving data context and modalities unregulated. Hence, the GDPR is a necessary but not sufficient regime for the next generation of data economy. It does not operate on unjustes copza, potentially causing inappropriate redistributions or excessive enforcement. For example, it may prohibit Naloxone training programs because of concerns that overdose reversal data could be used against the narcotics community by law enforcement.

5. Regulatory Frameworks

Given the speed at which health data technologies are being developed, the current regulatory landscape needs several changes to keep up with evolving technologies and the greater scrutiny they are facing. The FDA may need to focus more on premarket regulation. This push on regulation may need to involve re-examining the scope of the definition of a medical device by Congress. Additionally, greater guidelines about the software and source code writing process of tools and algorithms regulating software tools across categories will need to be examined. Ultimately, to effectively implement the broad range of options being discussed to regulate emerging tools in health technology, the regulators will need adequate funding, resources, staffing, and equipment for the future capabilities of these technologies to be fully addressed. Regulatory and legal challenges for AI and beyond need to be addressed on local, national, and international levels. Implementing effective AI-based health policy and regulation necessitates active communication and collaboration among organizations and institutions across medical specialties and sectors. Accordingly, AI in the healthcare system should be monitored continuously after it is designed and legally commercialized and those who are legally responsible for AI features need to be verified on a regular basis. Public health agencies, national health authorities, and regulatory bodies need to better regulate current evidence generation and evaluation, and care delivery approaches concerning the growing demand for new AI tools in healthcare. Moreover, healthcare stakeholders should develop a strategy to implement AI in healthcare to address AI-related cost, having a sound AI infrastructure, and integration of AI systems into the workflow of care providers.

5.1. HIPAA Compliance

Health organizations are legally bound under the Health Insurance Portability and Accountability Act (HIPAA) to apply privacy and security safeguards to the application and storage of patient medical records. The HIPAA Privacy Rule applies to either a "covered entity" or a "business associate" of the covered entity and establishes a national set of standards for the protection of health information. The minimal data set rule inherently produces a trade-off between privacy and data utility. The rule prevents levels of data sharing that could be beneficial. Hence it is necessary to have an alternative framework that allows for the adoption of data sharing technologies while still preserving the rights of the patients. Studies show how the quantitative privacy guarantee of differential privacy can be harmoniously combined with the computationally intensive approaches of cloud architecture.



Fig 3: HIPAA compliant.

Any Covered Entity must comply with the privacy and security regulations of HIPAA. A Covered Entity is a health plan, health care provider, or health care clearinghouse. An important part of compliance is the completion of a Risk Assessment. A Risk Assessment includes analyzing the Covered Entity's storage, creation, transmission, and debunking of ePHI. A risk assessment helps decide what safeguards should be implemented around ePHI. Any solution that the organization uses to store ePHI should have undergone a comprehensive risk assessment.

The HIPAA Security Rule requires unique user IDs and automatic log-off options for workstations that access ePHI. Keeping workstations logged-on in public areas and not physically securing them can create a HIPAA violation. Covered Entities also run the risk of noncompliance if they implement a patient portal but do not properly regulate its use and access. Sending email to patients without knowing the system the portal is built on can create vulnerabilities for the portal that could lead to hacking.

5.2. GDPR Implications

In response to the rapid rise of new technologies, a great deal of regulation has recently been made. As a result, many countries have established laws, guidelines, and best practices to assist in the building and deployment of AI systems. In particular, the General Data Protection Regulation (GDPR) was established in the EU and came into force on May 25, 2018.

Even though the GDPR came into force prior to the dramatic rise in the number and scope of solutions penalized by AI, the GDPR covers many aspects of data processing approaches made available through AI systems. During the development, deployment, and operation of AI systems, a producer and a provider typically share one or more datasets on which the services of the AI systems rely. Although it is essential to ensure the quality and durability of this dataset, a greater concern is the shared dataset because it may involve personal data of individuals. The GDPR provides rules to ensure the privacy protection of individuals by regulating how companies collect, share, and use personal data. One of the primary subjects of the GDPR is a dataset containing the personal data of individuals.

The GDPR specifies rules on processing personal data and provides the rights of individuals in data protection. In addition, the GDPR specifies the roles and responsibilities of the parties involved in the processing of personal data. Some parties involved in processing personal data are the data controller, the data processor, the data subjects, and the supervisory authority. Those roles correspond to the relationships that data controllers and data processors build with data subjects, and ultimately the supervisory authority. Each party involved possesses specific rights and obligations specified in the GDPR. If a party breaches the rules specified in the GDPR, it will result in different legal consequences ranging from a warning to a ban on processing personal data.

5.3. International Regulations

The EU and the U.S. have made great strides in terms of laws governing the development and implementation of AI systems. Although both nations have made great progress on their own, there is still a need for international regulations. Countries need to create a framework model that addresses the specific common challenges and needs of both low-income and underdeveloped countries.

The EU's 2023 AI Act applies to both public and private sectors, and provides some degree of safety based on the risk-based approach of its requirements. It covers a wide range of AI systems, allowing stricter regulatory regimes where necessary. In contrast, the U.S. has adopted a more decentralized, sector-specific approach to AI regulation. Because of the multi-national nature of the technology industry, harmonizing regulations is vital to not only facilitate continued innovation in the sector, but also to ensure the safety of humans.

Equ 2: Risk Assessment Function.

Where:

- R = Risk
- P = Probability of data breach
- R = P imes I
- I = Impact (severity) of breach

6. Ethical Considerations

The ethical and legal framework for health data regulation crosses three interrelated domains: data privacy, data protection, and data ownership. The guidelines set the baseline for legal compliance with data protection law. Areas not covered by this baseline include inadequate transparency and accountability mechanisms for health data use, the risks posed by non-compliance with the policy toolkit, and insufficiency of civil law remedies. In all but the first area, there has yet to be an assessment of whether and how the implementations would address these concerns effectively. Further, given that industry-driven codes of conduct are more likely to regulate mere aspects of health privacy than the entire ecosystem, it would be prudent to proceed along these lines with caution.

There is an increasing awareness of the data privacy and related ethical challenges raised by technology in the health domain. Lacunae in regulation, particularly concerning the need for greater transparency over datasets, were observed before the pandemic. Considerations around data ethics by the data-driven health community, along with an active push for data protection by design by regulators, have emerged as being paramount for the responsible development of health-related applications. A dual challenge of education and ethics remains in balancing the potential for health data use with an understanding of its privacy risks in a way that passes the scrutiny of the most stringent regulators.



Fig 4: Ethical Considerations of AI healthcare systems.

The challenges for privacy purists abound and include the access, use, and control of patient data in private hands. Serious calls for greater systemic oversight of big data health research as an emerging site for major privacy concerns have been made. Considerations of professional ethics and clinical duty of care require privacy safeguards that, in the context of degraded health and health data privacy, may compromise the use of data by developers to monitor health globally and optimise patient safety. Structural reforms are needed to encourage the data custodianship of the private custodians of patient data and lock the provider into the development of responsible models while also allowing patients to freely exercise their rights to transfer, access, rectify, delete, and object to the use of health data.

6.1. Bias and Discrimination

The importance of ensuring ethical and socially responsible machine learning algorithms has never been greater. However, significant challenges remain regarding algorithm bias in healthcare. The next twenty years will bring incredible advances in artificial intelligence, but these systems need to be developed responsibly, and how they are trained and vetted before deployment is crucial. Large language models can generate fluent text and reason intelligently about both trivial and sophisticated topics. The excitement is palpable, with major companies racing to integrate these new capabilities into their consumer products and open-source versions proliferating. Simultaneously, public interest in these advances has skyrocketed, with concern over how such tools will be used and whether they could introduce biases or lead to harmful recommendations. These concerns were raised in healthcare years ago when algorithms trained on clinical data were shown to unintentionally disadvantage demographic groups in treatment recommendations. Five years on, it is apparent that despite efforts spent on understanding the reasons for bias and how to avoid it, there remains a lot to be done.

Healthcare data is not representative of the patient population because they are collected and curated based on the healthcare system that generates them, which can be idiosyncratic. For example, data awarded by economics will miss care received outside of the system or before a patient joins it. This is important for new arrival refugees. When designing algorithms to predict outcomes, it should be known what data proportionally registered in every age cohort. However, even if there is a good data and model creation process, algorithm use will complicate the question of whether results are inaccurate, albeit on different

groups. For example, a model used to predict a heart attack risk via widely accepted risk factors such as sex, age, blood pressure, smoking, or family history of disease will yield incorrect results for young women with high blood pressure and no family history, while being accurate for older men similarly healthy. Therefore, it is necessary to include the error interpretation stage to say that the algorithm is not inaccurate. Recognizing why evaluations will no longer be binary and instead arrive at several outcomes that correlate finely with the degree of accuracy and the combination of reasons makes it complicated to estimate and communicate error-wrongness.

6.2. Transparency and Accountability

The ongoing pandemic has accelerated the shift to online and remote health services resulting in a boom in the generation and storage of health data. However, in the face of the potentially immense benefits of this large-scale digital health data, the rise of data privacy challenges is significant. In order to address these new governance challenges in a rapidly evolving technological landscape, the concept of a Health Data Governance Framework is endorsed comprising frictions between participation, privacy, accountability and transparency considerations. In this chapter, a specific regulatory perspective on transparency and accountability of AI-driven cloud health systems is elaborated upon.

Accountability and transparency are emphasised in laws and regulations governing AI systems, including the GDPR and the Act on the Prohibition of Discriminatory AI. The regulation of the latter explicitly states that the logical operations, including the parameters and weights, on which the outcome of the AI system is based must be transparent as well as the training data on which the AI model is trained, as far as it relates to a natural person that could be identified based on that information. Legal and regulatory analyses on how to ensure accountability and transparency of AI-driven health systems are limited. In this type of system, healthcare professionals may utilize AI-driven applications to analyse health data of patients. The outcomes of the health AI application systems are then used to support the decision making of the healthcare professional in pursuit of providing better healthcare for the patient. In such analysis, it is possible for a malfunctioning or biased AI application system to intervene with the decision making of the healthcare professional. In addition, the rigorous requirements set on AI systems necessitate the consideration of transparency and accountability challenges concerning the organization and processes of the relevant stakeholders in such systems. Countermeasures would especially need to be taken by the healthcare institutions which have direct ownership of the health data and implement the AI-driven health application systems in their operations.

7. Technological Solutions

In recent years, several technological solutions have emerged to enhance the privacy and security of patients' health information in AI-driven health systems, including de-identification, data sharing solutions, federated learning, and differential privacy. This is timely, as many data privacy breaches have arisen due to vulnerabilities inherent in health data infrastructure. Yet, these technological solutions have their own limitations, and for many there is uncertainty regarding whether they are practically deployable, or the degree to which they can enhance maintenance of privacy and security.

It is important to expect that AI and cloud computing will continue to be important for deal with vast volumes of health data, and thus the broader architecture for data sharing in the health sector needs to be positively adapted to ensure accountability and security. In the AI-based health landscape, protecting health information privacy is not only a matter of immersing emotion in protections against re identification and third-party access, but also a matter of addressing matters regarding the collection of health data in private hands and concerns regarding how that data may be used. Therefore, regulation of data privacy in AI-driven cloud health systems needs to proactively extend to the new architecture for health data sharing. In particular, it will be necessary to regulate and limit data collection in private hands, enhance oversight of the use privacy health data. The overall architecture for health data sharing, while perhaps well designed for cyber security against actor-on-actor malicious behaviour, needs to consider broader human behaviour factors than currently the case. Furthermore, the concept of health data security needs to move beyond focusing solely on the protection of data, to also consider accountability for how shared data are used.

7.1. Encryption Techniques

Encryption is the most effective approach for protecting privacy but it cannot be assured that every method of encryption is successful for data privacy. Mainly there are two types of encryption: symmetric and asymmetric. Symmetric encryption uses a single key established between the host and cloud and is used for encryption and decryption. The key must be common for protection of patient information. As an example of symmetric encryption. Similarly, data has to be decrypted while sharing with wife and kids which may be possible in conventional public key cryptography. The model proposed in text uses Identity-based encryption model which will help to encrypt reports in doctor identification features and allow decryption of data as per own identity. Healthcare environment requires sharing of patients' sensitive information. Cloud is a service model that can reduce the cost of the healthcare system but patients are hesitant in uploading data on cloud as a third party. This idea is to encrypt data at local premises as per patient desires before sharing with the cloud. This will provide flexibility in terms of privacy. The text proposes an Enhanced Attribute-based Encryption (EABE) based secure health cloud storage. EABE method will provide efficiency for storage and sharing of data while maintaining patient privacy and confidentiality.

Due to standardization and power of public key cryptography, Identity-based encryption (IBE) is proposed for patients to upload health related data in a privacy preserving manner. Users who want to store health records on the cloud post their ID, and the Public Key Generator (PKG) authenticates their identities through a database and generates their private keys using a mapping function. To share encrypted records with the doctor, the patient reverse calls the matching health service network (MHSN) system, submits a friend's ID and attributes and the MHSN retrieves a list of doctors which are prescribed the conditions verified from matching attributes. Asymmetric matching with different keys is designed and Role-Based Access Control (RBAC) is combined so that a safe and efficient MHSN is achieved. Main idea of the proposed system is to integrate matching as a use case together with privacy protection - based on the identity-based encryption, the MHSN healthcare matchmaking mechanism is unified with the information service, and privacy - preserving and secure retrieval are possible.

7.2. Anonymization Methods

The increasing demand for data protection and privacy guarantees, related to personal data, incentivizes the research community to innovate protection techniques that can offer different levels of protection guarantees. The research on data protection is massive, exploring options from simple local k-anonymization methods to complex global cryptographic techniques such as fully homomorphic encryption. Due to their associated complexities, exigencies, and potential risks, there are disparities in the adoption of the available protection techniques. However, addressing the growing concerns about the preservation of private data across end-to-end Data-Driven Pipelines has triggered an economic and technical incentive to put more effort into data privacy.

Anonymization is a process of removing information that could identify individuals from the dataset. The goal of anonymization is to retain the utility of information in the data while removing as much personal information as possible. The conventional anonymization techniques are designed to anonymize relational medical records by removing a large number of identifiers and doing other syntactic adjustments, whereas the electronic health records (EHRs) have unstructured formats, requiring semantic anonymization techniques.

8. Future Trends in AI and Cloud Health Systems

Advancements in artificial intelligence (AI) and cloud computing technologies are revolutionizing the healthcare sector by enabling the effective usage of a vast amount of patient information over cloud infrastructures and preventing data loss. AIenabled virtual healthcare assistants are playing a crucial role in assisting patients and healthcare providers through healthcare record processing and recommendation generation. Nevertheless, massive data breaches of AI-supported cloud health systems triggered by adversarial attacks harm patients and companies. Such security challenges and data protection regulation compliance issues of AI-based cloud health systems are surging. Countries have recently passed their own regulatory frameworks that bolster the data protection capability of traditional health IT systems. However, only a limited number of researchers have scrutinized the regulatory compliance issues of AI-based cloud health systems. In the scope of preventive health and AI-enabled healthcare services, advancements in AI, the cloud, and IoT technologies are well-known to revolutionize cloud health systems by proactively assisting patients with highly reliable and tailored healthcare services. According to robustness and perturbation, AI-based detection methods can be categorized as pixel and contextual methods. AI techniques and cloud infrastructures are widely embraced as the main enablers of cloud health systems. However, current state-of-the-art cloud health systems necessitate further improvement of trustworthiness indicators, which is critical for patients' acceptance of cloud health systems. AI techniques and cloud computing paradigms are well-known to transform traditional health systems into cloud-enabled health systems. Various innovative AI-enabled applications including health chatbots, smart wearable devices, smart health record management, and health services recommendation systems are attempted. Most of the AI-enabled health applications are narrow AIs capable of performing certain narrow tasks in very specific domains, with the health services recommendation system being their prime example.



Fig 5: Future Trends in AI and Cloud Health Systems.

8.1. Advancements in AI Technologies

Healthcare systems are facing an unprecedented explosion of medical data from various sources. This has stimulated the rapid development of various digital technologies to gather data, store, and process information to assess health and monitor individualized therapy progress. Thus, cloud-fog computation systems in combination with AI (Artificial Intelligence)-based tools are becoming a promising solution due to their ability to address and overcome the obstacles of standardization, interoperability, availability, and scalability. The integration of AI technologies is expected to have a significant impact on optimizing clinical workflows, improving patient safety, assisting in diagnosis and therapy, and supporting personalized treatment.

Cutting-edge AI technologies are currently revolutionizing healthcare by achieving remarkable successes in different fields of medicine. A smart learning system trained on different race-related datasets displayed exceptional performance in the identification of skin disease, outperforming static and predefined methods and offering a quick service through a mobile app. A model for breast cancer spread prediction achieved high AUC/TPR values, assisting doctors in precise analysis of the patient's case and potentially preventing complications. COVID-19 identification has been an important issue over the past three years, and both point-based cloud-based and transfer-learning-based models offered high-accuracy and timely solutions to reduce reliance on time-consuming detection tests. Regarding cancer imaging modalities, advanced technology showed high accuracy in improving diagnosis and providing valuable information to doctors, including tumor site, subtype, histology, and mutation.

In the past ten years, there has been an exponential growth of medical data and data security has been reshaped in healthcare. Privacy breaches in the health context or abuse of the information stored in health records can have far-reaching consequences.

Thus, strong security upgrades are urgently needed to guarantee the safe storage and handling of vast datasets. AI has a critical role in the management of health data. Currently, research efforts are focusing on the development of new methods to enhance the security and privacy of health data. These efforts cover three main approaches on in- and out-of-network threats in cloud-based infrastructures, as well as on model and data privacy threats in AI-based health systems. Driven by the rapid evolution of AI in healthcare, tools and applications are being developed in rapid succession throughout the world with often no regulatory approvals or oversight. The ethical concerns associated with the development and use of these tools are manifold.

8.2. Evolving Regulatory Landscape

There have been two key developments during the past year concerning international coordination of laws addressing privacy law issues in artificial intelligence (AI)-driven health systems. The need for better coordination and/or universalism of privacy standards and laws was mentioned as a major step that needs to be taken to manage privacy risks. A lack of coordination of laws, which may even result in conflicts, is a practical issue for global enterprise. It may lead to inconsistencies that could add operational difficulties, increase cost, and even challenge the profitability of the enterprise. Thus, nation-states may create better, clearer and/or controlling standards so that they will be relatively determined within global trade. International organizations may also pursue more universalism of privacy values among countries to increase welfare worldwide. However, this may raise a question of controlling power. Given the difficulty of coordination and universalism efforts taken in various international arenas, there is likely to be no easy or immediate solution to this issue.

A high-level conference entitled "Global Digital Health Standards" was held on September 28-29, 2022. The goal of the time was to develop a digital health strategy and a concerted global action plan toward a common vision of "one world connected digitally." In this connection, the creation of structures that establish rules and standards for global digital health is considered important. In line with this major motivation, discussions addressed how to democratize the possible rules and standards, what the incentive for individuals is to comply, how to open all the outputs of these discussions, and how to avoid the game of the past when individuals try to apply to each country different rules that benefit their interests.

9. Case Studies

Big data has been attracting widespread research interests. With dramatic developments of the Internet of Things (IoT), the networked sensor technologies are used to collect temporal and spatial data in large volume, detail and velocity. The rapid generation and collection of massive spatiotemporal data lead to significant opportunities and challenges across different areas. Health systems are part of the massive and complex IoT networks, producing various data types, structures, profiles, and sources in large volume and velocity across different spatiotemporal scales. IoT technologies offer a paradigm shift in the monitoring, management, prevention and intervention of general health and COVID-19. However, IoT can also introduce multiple data privacy and security threats to health systems, raising new non-foreseen socio-technical problems due to the complex interactions of multiple technologies, tasks, agents and stakeholders on personalized healthcare.

A systematic review is conducted to identify the data privacy and security challenges in ADCHS with IoT integration at the network edge, aiming to give a comprehensive understanding of the protection governance. A regulatory framework based on the non-foreseen ethos is proposed for tackling the data privacy and security as an unknown issue in these complex and active adaptive socio-technical systems. Recent advances of IoT technologies across the cyber-physical-social space can be leveraged to anticipate the emergent data privacy and security risks and protect against unexpected incidents. Different from the existing review studies that primarily focus on the influence of data privacy and security breaches, this study can benefit the governments, industries, researchers, and citizens in the protection and governance of AI-based cloud health systems against unexpected data privacy and security threats.

Big data health systems have attracted widespread research attention. Patient data were considered at the personal, community, institutional or population level by leveraging various data types across different spatiotemporal scales. The rapid adoption of AI techniques has also changed the way of big data health analysis. Nevertheless, the extensive use of AI methods and technologies can raise unprecedented data privacy and security concerns. The data privacy and security challenges facing cloud-based AI-driven health systems have not received sufficient attention in health protection. Those challenges cannot be simply treated as a known issue with existing solutions and have the potential to lead to substantial problems and harms.

9.1. Successful Implementations

Developing countries and emerging economies are notoriously behind the more developed countries regarding the use of AI in healthcare systems. Some notable AI-driven Health Cloud Services are, therefore, primarily highlighted. The examples chosen in this section are two medication reminder services that have shown global popularity among various major applications to provide broader perspectives. Other services include AI-based teledermatology, depression diagnosis and management, pneumonia diagnosis, and diabetic retinopathy screening or monitoring, etc., which are primarily focused on one type of application.

MedCoach, a medication reminder Application, is a product of a US firm founded in 2006 in California. It has received approval from relevant health authorities and certification. The supporting infrastructures are primarily clinical experts and certified pharmacies. The platform is integrated with existing medical services and is cloud-based. The clients are healthcare organizations and skilled nursing facilities in various countries, and emerging economies like South Korea and Brazil are in its radar. The design holding the sensing devices in a plastic case is resident user-oriented, making it simple and easy to use. This may also be a reason why it could obtain patent protection in 2010.

MediSafe, another medication reminder Application, was founded in the US in 2013. It has received approval from relevant health authorities and was highlighted for its global reach. The platform is cloud-based, integrated with clinical experts and pharmacies. End-users are individual native users, family members, and organizations. The sensing devices include IoT pill bottles and image recognition-based pill box access and retrieval considering user-oriented and personal features. This kind of

design may be the reason for being chosen as one of the most innovative healthcare companies. The platform has recently engaged in AI-based pattern recognition and prediction of medication adherence.

Equ 3: Encryption Overhead Model.

Where:

- T_{enc} = encryption processing time
- T₀ = base time
- n = data size
- $T_{
 m enc} = T_0 + k \cdot \log(n)$ k = constant based on algorithm

9.2. Lessons

Learned from Failures

The regulation of AI-driven cloud health systems is still of utmost importance due to many lessons that were learned from notable failures regarding privacy concerns. The characteristics of health data, the way AI systems process information, and their transformative role in the health sector pose unique challenges that push traditional regulatory systems beyond their limits. No regulatory framework can adopt a "one-size-fits-all" approach. AI systems and their applications in healthcare employ so many unique characteristics and traits that regulatory frameworks should aim to be proportional and specific to the requirements of the AI systems regulated. Existing laws need to be adjusted to grant proper regulation to the types of AI with potentially severe consequences for individuals. Moreover, the data and the processing operations of the AI systems in place in AI-driven cloud health systems need to be shared with the regulators, so the approval and monitoring of the compliance of those systems with the law can be performed properly.

Regulators must look towards the future and anticipate the unforeseen developments so they can keep the pace with the upcoming innovative technologies. The current regulation of AI-driven cloud health systems is insufficient. The mechanisms for regulation and accountability aimed to control this novel technology are either nonoperational or too vague to be effective. However, there are some promising examples from the past. The regulations that were enacted by the aviation industry in the wake of several disastrous crashes may provide insights on how to approach regulating AI-driven cloud health systems.

10. Conclusion

AI may offer profound benefits to patients, caregivers, and those responsible for population health, conditioning a transformation of the healthcare system and delivering quality-of-life improvements that make it more equitable. However, to reap these benefits, important data privacy and security challenges need to be resolved. There is a critical window of opportunity for aligned action to address these issues while design features and programming routines are still being created. Public understanding of AI is limited for diverse reasons, including its complexity, rapid advance, inconsistent terminology, and obfuscatory industry language. AI is a scientific and engineering discipline that incorporates diverse technologies, including natural language processing, machine learning, computer vision, and modeling. Its potential applications within health systems include partnerships to improve care delivery. Concerns about the wise and ethical development and deployment of AI technologies have spawned a raft of questions spanning the disciplines, many of which pertain to data privacy and security.

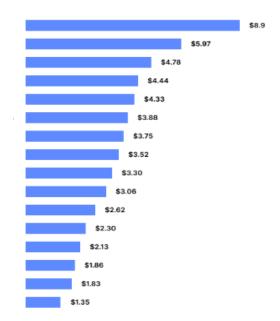


Fig 6: Data Privacy and Security Challenges in AI-Driven Cloud Health Systems.

Although public health agencies governing data privacy and security exist in Canada, commentary on AI in health systems has generally proceeded without mention of existing regulation, policy, or guidance from this discipline. This may be problematic because misleading and incorrect statements are being made about the boundaries of existing regulation, its applicability, and the robustness of protections. Understanding the capacity and limits of existing legislation and regulation is critical for genuine public debate and eventual good governance. While the ethical advantages and disadvantages of expert views on AI in health systems is an important topic, it is tangential to the goal of providing an overview of how AI systems using diverse data may be accommodated or regulated in Canada. Essential regulatory capabilities and principles for the appropriate use of data in AI decision-making systems across the spectrum of obstructive-excessive-co active data uses are identified. The implications of these proposals for data regulation in Canada and its jurisdictions are examined to understand how the regulation of AI-driven cloud health systems might evolve.

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