

Ethical Issues Regarding the Digitalization and Interoperability of Health Services

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ABSTRACT

The COVID-19 epidemic has expedited the ongoing process of digitalizing the healthcare industry. Nevertheless, there are substantial concerns surrounding the matters of personal data security and the transfer of sensitive information between systems in the digital/eHealth domain.

Purpose: This research aims to analyse the ethical concerns that arise from the digitalization and interoperability of health services.

Methods: To address this matter, a comprehensive examination of the existing body of literature is undertaken, focusing on digitization, digital applications, and emerging technologies in the healthcare industry. Additionally, the concept of interoperability and the ethical dilemmas arising from it, particularly in relation to specific patient groups, are explored. The analysis highlights significant concerns pertaining to information technology law, safeguarding personal data, maintaining the confidentiality of sensitive information, ensuring the quality and attributes of information management in the healthcare industry, and promoting access and proficiency of healthcare professionals in handling this data. These ethical quandaries hold more significance within particular patient cohorts, including as those with psychiatric disorders and impairments, unidentifiable people like refugees and immigrants, and patients hailing from disadvantaged demographics.

Conclusion: Given the facts provided, it is crucial to prioritise the training of healthcare workers, the creation of patient-centred safe health information systems to address cyber security concerns, and the establishment of a digital health governance framework.

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Introduction

The use of digital technology and the digital environment has novel prospects for identifying healthcare requirements and providing comprehensive healthcare services, encompassing preventive measures, health promotion, therapeutic treatments, and self-management. Consequently, they possess the capacity to revolutionise healthcare services in manners that can aid in achieving health system objectives. The characteristics and outcomes of digital health services might differ significantly in each instance, highlighting the intricacy of evaluating their impact. The adoption, use, and reimbursement of new digital health services within the healthcare system are determined by

evaluating their performance in relation to the objectives of the health system. New digital health services are evaluated based on their alignment with the overarching goals of the health system, which encompass quality, accessibility, efficiency, and equity. The outcome of the digitalization of healthcare services will be heavily influenced by the calibre of the procedure and the individuals participating. This includes those who utilise digital health services, such as professionals, care recipients, and citizens, as well as those who create and develop these services, health service providers, and governmental entities. To achieve successful digital transformations, it is crucial to comprehend the two primary components involved: 'health service' and 'digital technology', across all levels. In this context, careful attention is necessary for the comprehensive process of their creation, manufacture, funding, implementation, and assessment [1].

eHealth systems prioritise the needs of patients and utilise contemporary information systems and technology to effectively integrate and coordinate the delivery of healthcare. Electronic systems in the field of e-Health encompass various components, including

- a) Electronic Health Records, which are typically connected to a registration system within a hospital network,
- b) a health identification number that serves as a distinct identifier for citizens, professionals, and organisations,
- c) Electronic Prescribing, which involves the clinician fulfilling medical prescriptions for patients through the pharmacy while adhering to privacy, security, and data protection regulation

The epidemic has accelerated the progress of digital transformation in the health industry. The Greek Ministry of Health, in collaboration with the Ministry of Digital Governance, has developed the “Business Intelligence System NHS” (BI-Health). This advanced information system improves the Ministry of Health’s management of stable Management Information by simplifying procedures, enhancing resource management, and providing detailed control over operational and financial data. Amidst the pandemic, all participating entities (such as EODY and hospitals) implemented system upgrades to enable real-time monitoring of nursing organisations’ inventory. This was done to promptly remedy any shortages in personal protective equipment. The Individual Electronic Health Record (IEHR) was developed to provide patients and healthcare providers with access to patients’ medical histories [2].

Nevertheless, there are substantial apprehensions regarding personal data security and the transmission of delicate information across digital/eHealth systems. Within this framework, several studies have specifically examined the ethical dilemmas that emerge in relation to the interoperability of information systems [3-5].

This work addresses the aforementioned concerns. The primary objective of this study is to analyse ethical quandaries related to the digitization and interoperability of health services. The primary aims of this study are as follows

- a) to investigate emerging technologies and the process of digitising health service provision,
- b) to recognise ethical dilemmas that arise from the digitalization and integration of health systems,
- c) to propose practical strategies for effectively addressing these challenges.

The process of converting information into a digital format and the subsequent changes that occur as a result of this conversion.

Digitalization refers to the complete interconnection of all sectors of the economy and society, along with the capacity to collect pertinent information through analysis and translate it into actionable steps. Modifications yield benefits and prospects; -however, they also give rise to novel obstacles [6]. The process of digitalization is not a completely novel occurrence, since data has been digitally handled and transmitted for over fifty years. An early instance of Electronic Data Exchange (EDI) was introduced in the 1960s [7]. The novel dimension of digitalization lies not in the mere use of information technology, but rather in the rapidity of transformation and the extent of interconnectedness. Previously, digitalization mostly focused on data administration and processing inside a company’s IT department. However, it now encompasses all departments and has transitioned from administrative and support functions to fundamental business activities. The impacts encompass alterations in marketing and

sales procedures, novel forms of collaboration and engagement, as well as freshly devised products and services [7].

Digitisation refers to the conversion of information or data into a digital format. It entails the conversion of analog/physical inputs into a digital format utilising bits and bytes. This produces code that may subsequently be utilised inside the framework of a process, product, or service. It pertains to the use of digital technology in the specific context of creating and providing a product or service. These digital technologies enable the reorganisation, production, and delivery of healthcare services in novel ways. Hence, digitalization is mostly an organisational and cultural process rather than a purely technical one [1].

Digital transformation is leveraging technology to significantly enhance the efficiency or scope of organisations. Digital transformation refers to the deliberate and ongoing process of advancing a firm, business model, concept process, or technique, both in terms of strategy and execution. Digital transformation refers to the profound overhaul of the whole corporate landscape brought about by the use of new internet-based technologies, which have a significant influence on society as a whole [6]. Another definition states that digital transformation, encompassing digitalisation, refers to the profound and expedited overhaul of business activities, processes, capabilities, and models to fully leverage the changes and opportunities presented by digital technologies and their impact on society in a strategic and prioritised manner [8].

Interoperability refers to the ability of different systems or devices to work together and exchange information in a seamless and efficient manner.

Interoperability refers to the capacity of several systems or components to communicate information and utilise it without any misinterpretation or loss. This definition is supported by references [9-11]. Interoperability refers to the ability to communicate and exchange information, enabling interactions between different entities. It is closely connected to integration, which involves the collaboration and coordination of organisational entities and their interactions. Interoperability plays a crucial role in supporting integration. Hence, it is imperative to ensure the interoperability and interaction of systems to effectively oversee and manage intricate organisations and steer their performance [10].

The European Medical Devices Regulation 2017/745 and the In Vitro Diagnostic Regulation 2017/746, which govern all medical devices in Europe, provide a definition of interoperability. Interoperability refers to the capability of two or more devices, including software, made by the same or different manufacturers, to

- (a) exchange information and utilise the exchanged information to perform a specific function accurately, without altering the data content, and/or
- (b) communicate with one another, and/or
- (c) collaborate as specified [13].

Interoperability, as defined by the Health Information and Management Systems Society (HIMSS), refers to the capacity of various information systems, devices, and applications to access, exchange, integrate, and share data in a coordinated manner. This capability extends across organisational, regional, and national boundaries, enabling timely and seamless portability of information. The ultimate goal is to optimise the health of individuals and

populations globally. Health data sharing architectures, application interfaces, and standards provide secure and authorised access to data throughout the whole healthcare system, across various care contexts, and including key stakeholders, including the person [13].

In order to attain this interoperability, firms must restrict heterogeneity. Heterogeneity may be classified into three distinct kinds: semantic, organisational, and technological [10]. The three types of heterogeneity are connected to the corresponding types of interoperability, as seen below

a) **Semantic Interoperability:** Semantic interoperability refers to the capacity of different systems to understand and exchange information with one other. Semantic heterogeneity refers to the challenges arising from differences in syntax and language, such as the interpretation of speech and the understanding of knowledge that may be developed and modified inside an organisation. This arises from the reality that systems are formulated, constructed, and used by diverse individuals, in various locations, at different points in time, with distinct objectives, and employing varied terminologies [10]. Semantic interoperability is closely associated with the notion of content and pertains to the human understanding of content rather than its mechanical interpretation. Interoperability at this level refers to a shared comprehension among individuals on the significance of the communicated material or information [9,11,12,14].

b) **Organisational (or Functional) Interoperability:** Organisational heterogeneity arises from variations in practices and business processes. Consequently, there may be inconsistencies in how identical activities are handled in separate units, leading to potential issues in their collaboration [10]. Organisational interoperability refers to the capacity of organisations to efficiently exchange and transmit relevant data, even while utilising diverse information systems inside distinct infrastructures, even spanning multiple geographical locations and cultural contexts. Organisational interoperability relies on the achievement of effective technical, syntactic, and semantic interoperability [9,14].

(c) **Technical Interoperability:** Technical interoperability refers to the capacity of different materials to transfer, transmit, and operate information that is incompatible due to technical heterogeneity [10]. Technical interoperability refers to the capacity of hardware/software components, systems, and platforms to facilitate communication across machines. Interoperability of this nature often emphasises communication protocols and the necessary infrastructure for their functioning [9,11,12,14,15].

Advantages of Interoperability

Interoperability is an essential element of contemporary health information technology. Interoperable systems facilitate the sharing and reusability of data, offering several possibilities for development and enhancement. Data silos are removed and data integration is automated, enabling the identification of hidden patterns. This allows for the application of new intelligence to patients and carers, resulting in value being created across the continuity of care [16]. Ensuring the interoperability of healthcare information systems is crucial for effectively exchanging vital data and using the extensive data produced for research, trend analysis, enhanced security, and cost reduction in healthcare [15].

The absence of interoperability is a significant barrier to the digitalization of healthcare. There is a widespread consensus that the digitization of healthcare holds immense promise, provided that data is liberated from isolated storage systems and facilitated

through seamless data flows, data sharing, and sophisticated data utilisation. Concrete illustrations of this potential encompass

- a) the utilisation of readily available patient-centered information can facilitate sophisticated clinical decision support in the realm of diagnosis and treatment,
- b) the coordination of care can be significantly enhanced through the exchange of data in standardised formats that can be comprehended by all parties involved,
- c) patients' ability to access their own health data empowers them to actively pursue favourable health outcomes. Operational data may optimise process and initiate improvement cycles that yield measurable benefits [13].

Patients/consumers should be in possession of healthcare information, which is the product of their direct and indirect payments for healthcare. The data obtained during consultations with a healthcare professional, including test results, diagnostic findings, and procedure outcomes, serves as the foundation for other physicians to comprehend a patient's health profile. Furthermore, it is necessary for other parties involved to have access to this healthcare data, since the information may be shared either through consented individual records or through anonymous datasets that are specific to certain groups. These institutions utilise the data to enhance returns, analyse and enhance treatment procedures, perform surveys and research on population health, discover instances of illnesses, and investigate other public health activities on a regional, national, and worldwide scale [16].

According to reports, the following advantages of interoperability are generally seen [11]

• **Easy Access to Patient Records:** patients often get treatment from a wide range of care providers, leading to the fragmentation of patient information in proprietary heterogeneous systems across healthcare companies. Consequently, essential information stored in these systems is not immediately available to offer a clear and full picture of the patient. Furthermore, patient information is frequently presented in non-standard, unstructured, and unencoded format (text), hence posing challenges to the exchange of information. Nevertheless, by means of healthcare information exchange and interoperability, practitioners may promptly retrieve longitudinal patient records held in diverse private systems. By furnishing care professionals with patient-specific information, this will enhance healthcare procedures and enable them to properly advise on a case. Also, with full interoperability in healthcare, patients may also have full access to fragmented medical records kept by each healthcare provider, which will allow for better management of their health. Interoperability ensures a smooth and uninterrupted flow of healthcare services. The primary advantage of interoperability in healthcare is to streamline access to health-related data held in diverse systems, irrespective of the geographic location of healthcare professionals and patients.

• **Enhanced Comprehension of Medical Terminology:** the use of interoperability in healthcare will facilitate care providers in comprehending terms and concepts more easily when data is sent across different systems, while maintaining the integrity of the content's meaning. Thus, interoperability will assist improve healthcare since it assures that the right notions of medical language are offered in communication systems. Hence, clinicians may effortlessly scrutinise data from all interconnected systems for the purpose of diagnosis and decision-making.

• **Mitigating Medical Errors:** delivering healthcare frequently necessitates the transfer of treatment from one site and provider to another. Consequently, patient records are dispersed throughout several doctors' offices, laboratories, and hospitals. This procedure

is often plagued by mistakes due to a lack of interoperability among healthcare systems. To prevent medical mistakes, it is crucial to establish complete interoperability in healthcare. This involves formatting health-related data in a manner that enables various computer systems to comprehend both the structure and content of the transferred information.

• **Decreased Healthcare Expenditures:** The healthcare business is currently confronted with the significant obstacle of escalating expenses. Interoperability across health ICT systems, achieved via efficient data interchange and communication among many stakeholders in the healthcare network, is crucial for minimising healthcare expenses.

• **Incorporation of Health-related Records:** The healthcare system is a data-intensive operation that produces vast amounts of information from its several subsystems. Integrating information from self-developed apps can be challenging due to the lack of compatibility between individual programmes, which are often built independently and are based on distinct perspectives. Effective management of information in healthcare systems and organisations necessitates the joint effort of several parties, the capacity to transfer data easily, and the seamless integration of different sets of information. Interoperability guarantees that diverse apps, spanning across various healthcare institutions, are able to communicate and comprehend one another. Interoperability allows healthcare organisations to seamlessly incorporate information into various applications. Furthermore, interoperability enables a healthcare system to effortlessly interface with other healthcare providers, organisations, and entities on a nationwide scale.

• **Improved Assistance for the Management of Chronic Illnesses:** The treatment of chronic illnesses frequently necessitates the involvement of many physicians and healthcare providers. An interconnected healthcare system can facilitate patients' access to information that aids in the prevention of avoidable chronic illnesses, hence enhancing their ability to avoid such circumstances. Therefore, individuals have the ability to enhance their way of life in order to prevent the occurrence of chronic illnesses.

The advantages of interoperability for patients, healthcare practitioners, and other stakeholders are as follows: Patients can experience enhanced efficacy and security of the medicines they get, healthcare service that is timely and accessible, and complete care plans devised by professionals in one or many organisations. Furthermore, the capacity to work together across different countries might enhance and provide more efficient and current emergency medical assistance in foreign locations. The interoperability of pharmacy systems with primary care information systems enables the Electronic Transfer of Prescriptions (ETP). This facilitates the reduction of harmful drug interactions and transcription errors, leading to better clinical decisions and a higher quality of care. Timely access to selected health information for an individual is also improved, regardless of whether the ETP solution is connected to an electronic patient record.

Healthcare providers have the ability to increase the quality and safety of their treatment by improving coordination among different points of care. This can result in the acquisition of up-to-date patient safety information and evidence-based clinical recommendations, hence facilitating an improved decision-making process. Efficiencies can be achieved for patients and healthcare providers by minimising redundant data input, such as the need to enter identical demographic information at several sites.

Insurers might gain advantages from possible cost reductions due to less duplication of tests, early detection of diseases,

decreased expenses related to negative occurrences, and overall enhancements in outcomes for patients.

Interoperability standards may enhance the software business by facilitating a unified marketplace for digital healthcare, which in turn lowers the expenses associated with creating health information systems and fosters competitiveness in the market.

The adoption of healthcare interoperability standards can lead to increased efficiency, benefiting healthcare providers, individuals, and insurers. This facilitates quicker access to care, diagnosis, and treatment of illnesses, while also drastically decreasing costs [14].

Ethical Concerns Regarding the Interoperability of Health Information Systems

Research on ethical challenges with electronic health records identified confidentiality concerns since it may be able to re-identify participants or link participant information from other sources, particularly in small samples or in rare circumstances, notwithstanding recommendations. It is crucial to avoid using or presenting aggregated data analysis in ways that might worsen disparities or perpetuate social injustice [3]. Furthermore, while the integration of digital health and semantic/organizational interoperability helps improve healthcare, there are still obstacles to overcome in order to enhance user experience and satisfaction for both patients and clinicians. These challenges are primarily focused on reducing disparities in the adoption of health technology and enhancing access to telecare at a systemic and physician level [5].

Data should possess the qualities of being discoverable, easily available, capable of interoperability, and reusable in order to enhance the transparency and reproducibility of research that relies on data. Furthermore, it is the duty of data custodians to guarantee that the data is suitable for its intended use, meaning that it satisfies the criteria for being comprehensive, compliant, and plausible, and that it adheres to the standards of research quality and honesty [3].

Looking at the issue of dentistry, it is observed that while the interoperability of electronic medical records data is vital for the ease and accuracy of health services, it might lead to ethical and legal concerns. In order to ensure the proper handling of medical data, it is essential that health facilities meet some fundamental criteria, such as obtaining patient permission, ensuring data security, and securely storing original electronic medical records [4].

Health professionals, particularly physicians, have a significant difficulty in ensuring the delivery of optimal medical treatment during their education, which includes the incorporation of the latest and most sophisticated technical advancements. The introduction of new healthcare technologies might result in a quick and incorrect "routineization." This refers to the social process where the notion of a new biomedical device changes as users become more accustomed with its use. Within the healthcare domain, the prevalence of technology has brought up an ethical quandary over the utilisation of the patient as a tool for averting death, so infringing against the core concept of medical ethics: autonomy. This occurs to such a degree that it becomes unimaginable for doctors to refrain from carrying out the therapy. Hence, the moral obligation arises from a source, influenced by the social mechanism and emerging technology. The moral duty has repercussions that extend to the patients themselves. Ensuring the proper utilisation of costly equipment and upholding ethical obligations for the use of new technology provide an immediate obstacle to maintaining patient autonomy and involvement in decisions that affect them [17,18].

Another pertinent matter that has been recognised pertains to the permission of participants in research endeavours [3]. Typically, participants in surveys have the option to give their consent willingly. This consent is based on comprehensive information about the research, which includes the potential advantages, risks, and effects on participants. For instance, it may involve costs for patients or increased workload for clinicians. Participants are also given the chance to ask questions and decline to participate in the survey if they choose not to. Nevertheless, in extensive programmes that utilise combined electronic health record data, it may be impractical or unworkable to get specific consent. In some circumstances, for low-risk research with great potential benefit, an opt-out strategy or waiver of study permission may be considered by a committee. Opt-out consent models necessitate the provision of clear and concise information about the study in a prompt, significant, and easily understandable manner. Additionally, individuals must be given the option to decline or retract their involvement, and there must be a well-developed strategy in place to safeguard confidentiality. It is essential for an opt-out method to be in accordance with both state and international legislation. Consent, whether expressed or inferred with opt-out procedures, has three essential components: competence, sufficient knowledge, and chances for deliberation.

Ethical Quandaries within Patient Cohorts

Individuals with cognitive impairments and mental illnesses

Mental health practitioners, particularly in low- and middle-income nations, encounter distinct ethical and professional obstacles in their routine clinical work with individuals suffering from mental illnesses. These challenges primarily involve infringements upon individual autonomy, particularly in cases of involuntary admission, the application of electroconvulsive therapy, and patients' limited understanding of prescribed psychiatric medications. Nevertheless, the suitability of prioritising individual autonomy has been challenged in settings where communal values are prominent, placing importance on community cohesion, and when the responsibility for providing mental health treatments mostly falls on the family. When only a select few have access to culturally relevant, evidence-based care that is less restrictive, carers may have to disregard the patient's individual autonomy in order to guarantee successful treatment or safeguard others [19].

Previous studies have concentrated on the ethical concerns surrounding the process of obtaining informed permission from individuals with cognitive disorders. Patients' cognitive limitations can impede their comprehension of therapy alternatives. Evaluating the cognitive capacity of individuals with cognitive impairment to comprehend treatment choices is essential for obtaining valid informed consent and should be guided by established guidelines. Hence, it is crucial to accurately identify patients whose capacity is uncertain, evaluate their competency, and ascertain their ability. Additionally, it is essential to rely on suitable alternate consent methods. This is of utmost importance [20]. Another aspect to consider is the ability of older patients, especially those with cognitive impairment, to provide informed consent in clinical trials [21,22]. This is also relevant for individuals with mental problems especially when dealing with sophisticated and/or high-risk research procedures [23,24].

Unidentified Individuals Seeking Medical Treatment

Due to the absence of universally recognised definitions of migrant, the precision of the gathered data, as well as its definition and determination, varies across different nations. Each sovereign

nation compiles migration data pertaining to the legislative, political, and administrative requirements of the nation. While many Member States gather information on ethnic minorities, sometimes as a replacement for migratory status, others deem it superfluous or decline due to ideological, ethical, and security apprehensions over data safeguarding. Regarding data collecting, it is important to recognise that migrants encompass a diverse group consisting of several subpopulations, including illegal migrants, foreign students, unaccompanied kids, and regular migrants. This is crucial because subpopulations exhibit unique health issues, and even within these subpopulations, there will be significant variance in susceptibilities. The vocabulary employed in surveys may exhibit divergent interpretations among refugees and migrants. For instance, the notion of health may vary among distinct communities. Challenges may also occur as a result of the mobility of refugees and migrants as they adjust to settling in their host country. This makes it particularly challenging to monitor and gather statistics for certain subgroups [25,26].

Socioeconomically Marginalised Populations

Within the realm of digital health, disadvantaged individuals can be classified as underserved, including distant and rural communities, as well as specific subgroups within the population, based on the socio-economic disparity [18].

Currently, global healthcare is mostly governed by utilitarian principles, which prioritise actions that provide the maximum benefit. However, this approach may conflict with the needs of the most marginalised individuals. In order to tackle these difficulties, a distributive justice approach has been suggested as a suitable framework, emphasising prioritising, with the aim of giving priority to disadvantaged individuals when it comes to distributing the advantages of digital health. It is important to focus on how benefits are allocated among individuals, rather than just looking at the total amount of benefits. The proposed principles encompass the identification of disadvantages, such as the maximisation of the social value of digital healthcare. Additionally, it involves the design and implementation of digital healthcare technologies that cater to the needs of disadvantaged individuals through their active participation. Furthermore, it emphasises the integration of ethical obligations in the realm of digital healthcare [18,27].

The matter of patients' access to digital technologies and healthcare services should be simultaneously considered in this perspective [18,28]. No gains have been recorded about whether remote monitoring for the most disadvantaged offers increased access, from a utilitarian perspective. Remote communities frequently face a shortage of essential economic and technical infrastructure, while technology itself may favour population groups who possess sufficient levels of technological literacy. The incorporation of design ethics into the planning phase of digital healthcare technology is crucial in order to proactively address ethical implications and prevent any kind of discrimination in access.

Conclusions

The progressive advancement of technology can result in substantial advantages in the realm of healthcare, facilitated by the integration of health systems, comprehensive analysis of large datasets, and effective data management. Simultaneously, interoperability among systems presents notable ethical hazards about data accessibility, safeguarding of sensitive patient health data, and concerns over patient permission, particularly among specific demographic groups, in relation to data management. To tackle the issue mentioned above, it has been discovered

that including education for health professionals within their curriculum, as well as lifetime professional growth and learning, can have a positive impact on achieving the intended outcome. Simultaneously, it is imperative to include diverse stakeholders in the design and practical execution of digital health, ensuring that the system's structure aligns with particular requirements and adheres to effective governance within a comprehensive and standardised regulatory framework.

Effective governance should facilitate the advancement of digital health innovation to tackle the aforementioned concerns, encompassing accountability, privacy, evidence quality, data accessibility and sharing, and finally, trust. These are the essential conditions that can decide if digital health innovation can result in health benefits. In order to successfully implement any technique, it is imperative to guarantee the complete participation of all individuals or groups with an interest or influence in the matter. The focus on public participation and engagement of diverse stakeholders acknowledges the importance of ensuring that digital health benefits the public and allows for the involvement of many stakeholders in health-related decision-making.

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