**Introduction**

The previous two decades of the information age saw the transition from paper to digital health records. The Clinton administration foresaw the change and passed the Health Insurance Portability and Accountability Act (HIPAA) in 1996, establishing modern security and privacy guidelines for personal health information [1]. More recently, the Affordable Care Act (ACA), the American Recovery and Reinvestment Act, and the Health Information Technology for Economic and Clinical Health (HITECH) Act passed under the Obama administration in 2009-10 sought to accelerate the transition to electronic health records (EHRs) [2]–[4]. The acts paid out more than $35 billion in subsidies and incentives from 2011 to 2016 to increase EHR adoption across the country [5]. The hope was the digitization of health data would reduce the cost of healthcare and modernize the US’ health data systems.

However, the acts were shortsighted in prioritizing EHR adoption and security over a unified, standardized, interoperable system [6]. Hospital systems, keen to cash in on incentives and weary of legal consequences for security flaws, built up proprietary silos to handle EHR data storage and retrieval [7]. The lack of interoperability guidelines meant these data silos largely adopted their own methods for segmenting and aggregating health data. While organizations such as Health Level Seven International curated medical data transaction standards, the complexity of medical data and particularly medical imaging data meant that the storage solutions adopted by hospital systems did not necessarily interoperate with other proprietary systems when transferring data [8]. As a result, in 2014 while more than 80% of office-based physicians had adopted EHRs, 15% of patients had to personally bring a test result to their physician and 5% had to repeat a test due to the unavailability of prior results [9], [10].

To mitigate these issues, new proposals have arisen to prioritize health data interoperability. The non-profit Health Level Seven International group proposed the Fast Healthcare Interoperability Resources (FHIR) standard to exchange resources based on an application programming interface (API) data format standard [11], [12]. The use of API’s is particularly important as hospital data has grown tremendously and become outsourced from local servers to cloud data centers [13]. Recent advancements in blockchain technology could enable a peer-to-peer network of medical data transfer that incentivizes interoperability and data security. Here, we will explore the difficulties associated with medical data transfer, with a particular focus on medical images, opportunities for FHIR API standards and blockchain networks to improve interoperability, and challenges in implementing these technologies while complying with government-mandated privacy standards.

# Background

Converting medical data to its digital format is no trivial task. Patient health data represents some of the most complex and sensitive information, and transitioning decades of paper-based records to digital formats is a monumental task. The 1996 HIPAA law mandated that patient medical information is only accessible to the patient and authorized representatives as denoted by the patient themselves [1]. As such, governments around the world sought to incentivize this transition by providing billions of dollars of subsidies with the promise of faster, cheaper, and better health care in the digital age. Ten years after 2009, when the HITECH and American Recovery and Reinvestment Acts were passed with EHR adoption incentives, EHR adoption doubled [4], [9]. As of writing this paper, 88% of office-based physicians have adopted EHRs. What the governments didn’t provide was a standardized system for indexing and segmenting the medical data; this was left to private industry. Eventually, the US government created the United States Core Data for Interoperability (USCDI) in 2016 via the 21st Century Cures Act that mandated the standards medical data and APIs must abide by. The USCDI falls under the US Office of the National Coordinator for Health Information Technology (ONC) and largely draws from commercially created standards and documentation [14]–[16].

The Logical Observation Identifies Names and Codes (LOINC) universal medical laboratory data standard was created in 1994 by the non-profit Regenstrief Institute to aid in increasing demand for electronic health databases [17]. It is publicly available with no cost and is cited by the US government in the USCDI documentation. It details the data types and medical terminology to be used in electronic healthcare data. The terminology is split between laboratory and clinical data. For medical images, which comprise a majority of health data by storage size and growth in the 21st century, the Digital Imaging and Communications in Medicine (DICOM) format is most widely used [18]. It details a metadata header with a 2D array of pixels that allows the images to be viewed and important information such as the imaging device and any necessary variables to appear in the header. Notably, DICOM does not store the raw data and the image cannot be re-processed once in DICOM format. For some referrals or consultations where re-rendering the raw image file is necessary, the exchange of DICOM images alone can be a severe downside. Additionally, to comply with HIPAA privacy requirements, the images must either be encrypted or anonymized before sending to cloud server storage, an increasing occurrence as medical data storage and particularly medical images increase in size [13], [19].

The most notable and widely used standard for medical data transfers in clinical settings is Health Level Seven International’s version 2 system. The standard defines a messaging system for exchanging information in a clinical workflow, ranging from patient administration to pharmacy & billing systems. It uses a non-XML syntax based around line segments and character delimiters. The HL7 version 2 standards are desired to be interoperable among all record keeping systems of a hospital workflow and is implemented in every major hospital system in the US [20], [21, p. 7]. Another medical data transfer initiative is Integrating the Health Enterprise (IHE), a non-profit organization created in 1998 to sponsor projects aiming to improve health information sharing. The organization has aided in the US Department of Veterans Affairs health system development and in developing a cross-enterprise document sharing (XDS) model using the LOINC and HL7 standards. They also developed a standard for retrieving medical documents across domains, called the ITI-43 transaction standard [10], [22].

The interoperability of EHRs between vendors and healthcare systems has become a major focus of the ONC in the US. However, as recently as 2019 the transfer of a patient’s EHR from one healthcare vendor to another is commonly done via fax or print copies sent via mail. Even for transferring a subset of results for a consultation or referral, the electronic exchange of these documents is only possible roughly 50% of the time, depending on if the different healthcare systems use a vendor with electronic health exchange capabilities between the two systems [8]. To overcome these challenges, the Radiological Society of North America (RSNA) developed the image share network, a clearinghouse-based system where participating healthcare systems send their medical images for sharing to the clearinghouse operator, who stores the images indexed by a cryptographic hash for 30 days. Personal Health Record (PHR) vendors are able to download the patient’s information after they authorize it by divulging the token needed to reproduce the hash. While this system eradicates the physical exchange of medical images, it introduces two new, centralized organizations with access to sensitive personal health information. Additionally, early results show that patients are not likely to view or authorize their medical images within the 30-day window, and the image share network is dominated by a small number of radiological centers, and a small number of PHR vendors (who can also act as a clearinghouse operator) control authorized retrieval of medical images [10], [23].

To help mitigate these issues, the Health Level Seven International group proposed the FHIR standard, first drafted in 2011 and officially published in 2017. The standard revolves around APIs to incentive the transfer of data between and within systems; it is built around resources, such as clinical observations, that can be aggregated into FHIR profiles. However, despite endorsements of the standard by the US government, FHIR is still dwarfed in adoption by HL7’s version 2 [11].

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