Convergence of eco-system technologies: Potential for Hybrid Electronic Health Record (EHR) systems combining distributed ledgers and the Internet of Medical Things towards delivering value-based Healthcare

by

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SUBMITTED TO THE SYSTEM DESIGN AND MANAGEMENT PROGRAM IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE IN

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ABSTRACT

The Healthcare industry, just like any industry, is constantly racing to stay abreast with pace of technological innovations, especially at such a time where the industry is experiencing a strain on the global healthcare infrastructure. Specifically, the evolution of record management systems in the healthcare system has taken a slow and gradual transformation with each stage of transformation carrying over certain aspects and functions of previous stages. A survey of record management practices reveals that record management begun with paper-based records that have since partially been replaced with centralized Electronic Health Records (EHR). With the advent of Electronic Health Records enabled by distributed ledgers, we continue to see the inclusion of traditional paper-based functions beyond centralized EHR functions. Electronic data sharing in the healthcare ecosystem is constrained by interoperability challenges with different providers choosing to implement systems that respond to increasing their productivity. Prioritizing a patient-focused strategy during implementation of EHRs forces providers to implement systems that are more interoperable.

A system engineering approach was adopted to guide the development and valuation of candidate architectures from Stakeholder analysis to concept generation and enumeration. Nine (9) key design decisions were selected with their combinations yielding 512 feasible hybrid architectures. In this paper, we proposed a hybrid EHR solution combining distributed ledger technologies and Internet of Medical Things, which contributes towards providing value-based healthcare. Leveraging properties of distributed ledgers and IoMT, the hybrid solution interconnects various data sources for health records to provide real-time record creation and monitoring whilst enabling data sharing and management in a secure manner.

Thesis Supervisor: Dr. Bryan R. Moser
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Looking back at the past two years and what has transpired, I can only be thankful for the circumstances and the people who crossed my path. As the saying goes "That, which does not kill you, makes you stronger!" Indeed my time at MIT, not only made me stronger but brought me to the realization that as human beings we have so much potential and are capable of anything, with the right attitude and mindset.

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1 Motivation

In the wake of growing strains on global healthcare infrastructure coupled with the pressure to continuously transform the healthcare industry to provide better services, products and value to patients, the concept of value-based healthcare is proving effective in how healthcare is designed and managed given its patient-centricity focus. Value-based healthcare, a data-driven model, promises to deliver improved healthcare system outcomes to patients at lower costs. Through a joint collaboration between the World Economic Forum and the Boston Consulting Group (BCG), Value in Healthcare initiative, they make an argument in their working paper ("Value in Healthcare Laying the Foundation for Health-System Transformation," 2017a) for the potential of value-based healthcare in aligning stakeholders around delivering value to patients. The paper further highlights four key enablers towards supporting patient-centric models: *Outcomes data, leveraging health data for clinical innovation, changing the payment model as a mechanism of creating incentives for all healthcare providers to focus on value,* and *improving coordination across the health system*.

Research projections, (Prasad, 2016), indicate that the number of connected devices is expected to be more than 50 billion by 2020, with 30% of these expected in healthcare. The growing number of connected devices is proportional to the growing innovations transforming the healthcare industry. Notable innovations include but are not limited to innovations that apply machine learning to study and map effects of diseases on our genes by making inferences, forming hypotheses using larger sets of data; application of machine learning techniques to cell line engineering, drug discovery and clinical cell therapies; AI-based diagnostic tools for patients using web and mobile-bases platforms; use of artificial intelligence-enable tools for patient-trial matching and reduction of the time to market for potentially life-saving drugs; and application of artificial intelligence to providing accurate medical image processing analysis. Nonetheless, many of these interventions are implemented in silos denying the healthcare industry the opportunity to leverage synergies from these technological innovations and potentially leapfrog through the harmonization of these interventions.

Another concern of existing healthcare investments, beyond fragmented solutions, is the absence of patient-centric interventions. Patient-centered care focuses on understanding the patient needs and ensuring that these same needs drive what is measured and how healthcare performance is assessed. This concern has led to evolution of value-based care, a unique model of designing and managing patient-centric healthcare systems.

The potential for blockchain technologies in revolutionizing data security, through the use of distributed ledgers, offers unique opportunities for transforming the digital healthcare landscape. Security and integrity of patient data, data sources inclusive, is crucial for the success of existing and future healthcare digitization interventions towards sustainably and efficiently deliver data-driven healthcare. Mainstream IT solutions generally focus on improving clinical decision making, information management, communication among service providers, costs and access to care. Overtime, sophisticated technology-centric solutions are coming in to interface with humans and allow for error-free diagnosis and procedures.

Over the past years, we have seen a few uses cases of blockchain technologies in transforming healthcare services and processes notably (1) Estonia's digital health success that was built on an underlying ID card infrastructure, powered by Blockchain technologies, which used for secure authentication as well as standardization of processes and applications in the digital health ecosystem; and (2) MedRec, a network solution to patient control of medical information and identity. These will be covered in greater detail in later sections.

In their article on The Truth about Blockchain, (Lansiti Marco & Lakhani R. Karim, 2017) argue that while blockchain is not viewed as disruptive rather a foundational technology, it has the potential to influence the impact of other technology-led innovations. Their claim is based on the premise that the blockchain technologies do not change traditional business models but rather offer foundations for economic and societal system. From a system thinking perspective, blockchain technologies can be viewed as foundational technologies that create a shared platform for storing, accessing and sharing patient data.

The objective of this research is to evaluate the shift from current innovations, specific to health record management, that focus on real-time, outcome-based care to a new generation of connected intelligent solutions that revolve around predictive and preventive care centered on the patient. This paper will assess the potential for converging various technologies, processes, practices in delivering patient-centered healthcare. Secondly, this work intends to analyze the benefits of technology convergence and how this convergence can be achieved.

1.1 Broad research questions

This research work attempts to examine potential systemic benefits of converging distributed ledger technologies with Internet of Medical Things (IoMT) into mainstream healthcare digitization efforts of health records.

- Beyond the obvious benefits of distributed ledgers and the IoMT, such as data integrity, interoperability, security and patient trust in managing and sharing electronic health records among health providers, what other benefits emerge from the convergence/hybrid of these technologies?
- In what ways can the adoption of a hybrid solution, *distributed ledgers and IoMT*, potentially lead to overcoming the tradeoff between patient-centric services and healthcare provider-centered models? How does the adoption of this hybrid solution does promote patient-led co-creation interventions?
- How can this hybrid solution allow us to implement and sustain healthcare systems differently from incremental and conventional systems that require large upfront capital investments?
- Where can a hybrid EHR architecture combining distributed ledger and IoMT technologies provide capabilities not readily enabled by pre-existing technologies?
- Can the hybrid solution allow for scalability and flexibility to capture future user needs?

- How can the risks of applying blockchain technology be minimized? Can the implementation of a distributed public ledger and IoMT cause short-term disruptions that would they correct overtime?

2 Literature review

This thesis spurs out of keen interest in the role of emerging eco-system technologies towards transforming the healthcare industry. In this section, we explore the evolution of the healthcare industry, particularly healthcare records management, trends of technological innovations that have transformed the industry, prevalent and emergent challenges that come with the adoption of these innovations as well as opportunities for delivering patient-centric care.

2.1 Global Healthcare industry outlook

The healthcare industry, sometimes referred to as the medical industry, is an eco-system of practitioners that provide medical goods and services for preventive, curative and palliative care towards maintaining and re-establishing health of individuals. In their assessment of the healthcare sector, (Ledesma, Mcculloh, Wieck, & Yang, n.d.), categorize the healthcare ecosystem into six main industries: *pharmaceuticals, biotechnology, equipment, distribution, facilities and managed healthcare*. The healthcare industry is viewed as a complex system with multiple actors, competing objectives and priorities yet their convergence towards a common goal is essential to transforming healthcare delivery.

2.1.1 Trends of technological innovations in transforming the healthcare industry

2.1.1.1 Traditional healthcare system

(Lyons, n.d.) highlights how traditional health care systems were characterized by archaic practices of cupping, bleeding and purging, persisting as mainstays of the practitioner. In some cases, use of dangerous medical treatment methods ("Information - 18th Century Medicine," n.d.). such as Lobotomy, a practice of drilling holes into the patient's head and destroying tissues around the frontal lobe as a treatment of mental disorders; crushing of tobacco and inserting it into the rectum using a tube to treat headaches, colds, and respiratory issues which would stop blood circulation and poison the heart; and long-held beliefs that bacteria, germs and viruses weren't the cause of any disease and as such did not need to sterilize medical tools.

Beyond traditional medical practices, information sharing and processing was mostly manual with medical records primarily based on closed bookkeeping, using paper-based repositories that made access and sharing of patient data cumbersome. (Shortliffe, 1999)confirms this hypothesis in his paper noting that traditional paper records arose in the 19^{th} century as highly personalized "lab notebook" that clinicians used to record observations and plans to remind them of pertinent details when they met the patient next. In her article, *The Medical Record (R) evolution*, (McClanahan, 2012) highlights that purpose of the medical record originated to document the patient's medical history, with physicians completing their hand-written notes after a patient's visit. Until then medical paper records were never assumed to support communication among healthcare providers. As such, referral processes were tedious as they were mainly manual and costly given the levels of duplication that manifested across the entire value chain.

(Cleanwater compliance, n.d.) further presents incidents where paper records put patients at risk citing data breaches in recent years where the privacy of hundreds of thousands of patients were jeopardized when medical records, billing statements, registration information and accounting records strewn in the streets when doors of the vehicle transporting them flew open because the doors weren't properly secured. Another incident investigated by (HIPAA, n.d.), involved medical records containing medical diagnoses, health insurance information and social security numbers that were not properly disposed of and discovered in a dumpster in Springfield, Ohio.

In his article, (O'Connor Stephen, 2015) argues that manual records present a set of challenges that hinder medical organizations from improving their productivity and enhancing patient experience. These challenges include portability, security that may be compromised, difficulty tracing where patient information was compromised along the value chain, inefficiencies in retrieving information and most importantly lack of clarity and precision.

2.1.1.2 Current healthcare system

Overtime, with the proliferation of technological innovations, advancements in the healthcare industry have evolved from simple, basic solutions to complex, sophisticated solutions. Healthcare practitioners are increasingly relying on technology solutions to reduce their costs and improve the quality of services from coordinating appointments and procedures, sharing results, to monitoring and involving patients in their treatment plan. Nonetheless, similar to other products and services, the lifecycle of healthcare innovations evolves over four stages: Early phase, innovation phase, maturity phase and decline phase. In his paper, (Meskó, n.d.) covers trends that are shaping the future of healthcare as well as their lifecycle stages.

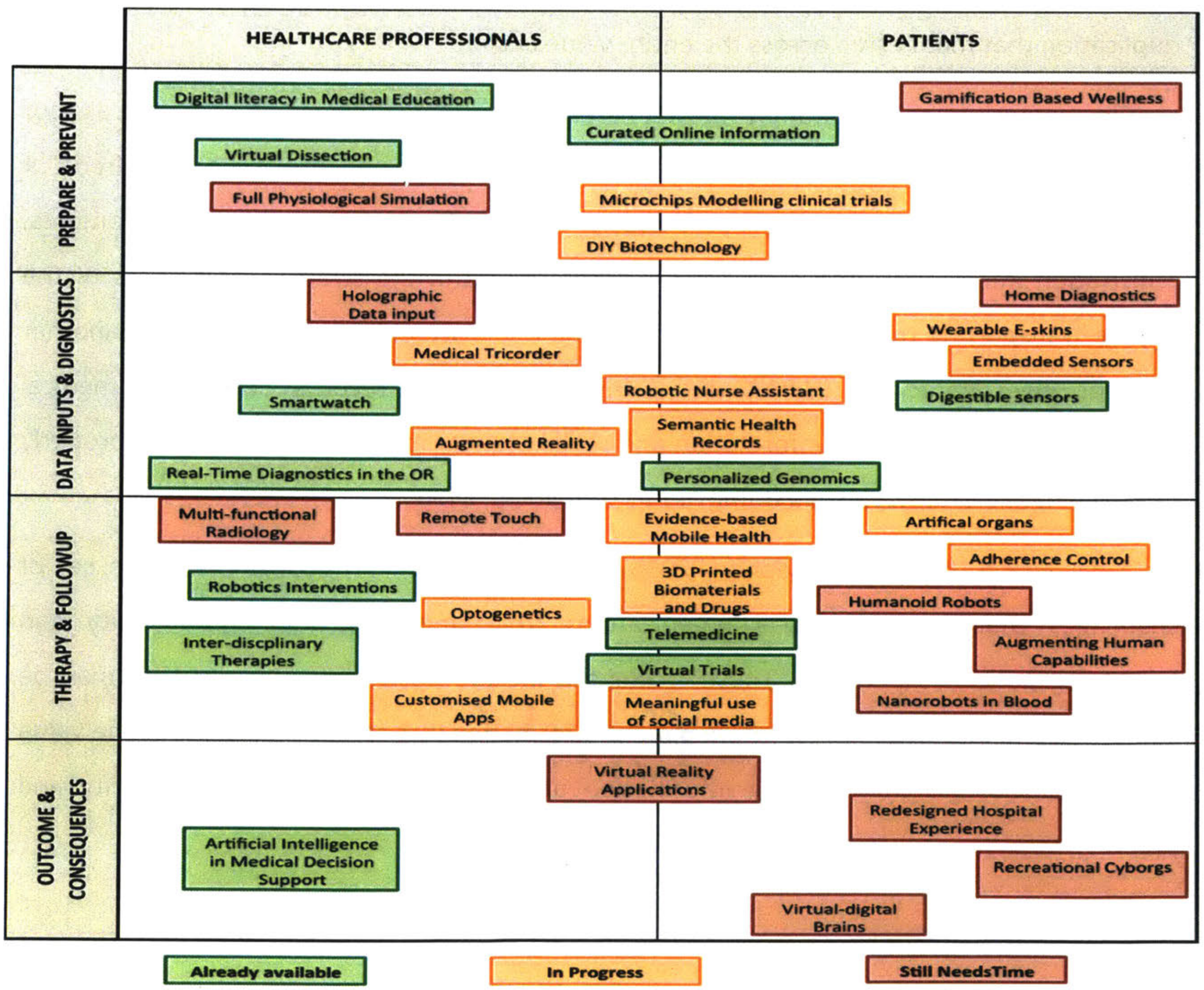

Figure 1: Trends shaping the future of Medicine

Figure 1 depicts maturity stages of technologies with the potential to transform the healthcare industry. A quick glance at these technologies reveals majority are data-driven applications, hence the urgent need to develop a solution that leverages the data generated by these applications to create and capture value for the patient. As healthcare needs evolve, so do the processes and tools used to deliver healthcare services mainly data management trends in the healthcare industry ranging from cognitive computing, cloud-based, interoperable electronic health records to Internet of Things applications. This section takes a deep dive into evolution of existing technologies that are changing data management, health record management and interoperability of data-driven applications in the healthcare industry.

Information systems have overtime evolved from segregated systems to Enterprise Resource Planning solutions that aggregate patient data into one system, integrating the needs for mission-critical business operations such as administration, finance, human resource management, revenue and admissions services, healthcare specific scheduling, claims management & billing and enterprise intelligence to mention but a few. In their paper, (Mucheleka & Halonen, 2015) contend that despite their wide adoption and usage towards increased productivity, ERP systems have proven to be (1) less flexible given that they are designed to follow strict routines with no alternatives, (2) vendor-dependent thus inhibiting innovation and becoming costly to maintain, (3) single points of failure for an organization given their centralized capability. Further innovations have led to development of Enterprise Data Warehouses to complement ERP solutions with decision support functions.

Electronic medical records were introduced to address challenges specific to paper-based records: legibility of records, coordination of practitioners and cumbersome data collection. (Charles A, 2008) emphasizes the development of a universal system of electronic medical records that allows access to patient information whilst providing privacy, security and autonomy of patient information. He suggests that the primary goal of a universal EMR should be access, with cost-effectiveness treated as a secondary goal that would result from better outcomes that reduce hospitalizations and lower the overall utilization of healthcare resources.

In their paper, *A Survey of Big Data in Healthcare Industry*, (Khatri & Shrivastava, 2016) suggest a common platform for health analytics. They outline existing big data initiatives in healthcare such as (1) IBM Watson offering cognitive computing power applied to stored heterogeneous data from different sources; (2) Google Research in collaboration with Stanford Pande Lab conducted experiments by gathering a huge collection of publicly available data to achieve significant improvement over simple machine learning algorithms for drug discovery; and (3) the Human Brain Project that collects information, through neuromedicine, about brain diseases by aggregating medical records from multiple resources. Even with the adoption of these solutions, they note persistent challenge such as lack of a standardized approach of storing unstructured data, noisiness of large volumes of data makes it difficult to extract useful information, complexity of genomic data that is worsened by combining it with standard clinical data, data acquisition limitations of existing electronic health records to mention but a few.

The Internet of Medical Things (IoMT) was recently coined as a connected network infrastructure of medical devices and applications that communicates with various healthcare IT systems through online computer networks. The premise of this innovation is that all devices are equipped with Wi-Fi capabilities facilitating machine-to-machine communication. With the growing number of an aging population that continues to strain the healthcare system, IoMT adoption promises the relief in dealing with the parachuting costs of care for the aging population. IoMT has the potential of interconnecting and allowing data exchange across various healthcare applications. Technology innovations transforming the healthcare industry, captured in Figure 1 are prime candidates for IoMT. In his article, *How Technology is Transforming Health Care,* (Topol, 2013a) delves into applications transforming health care notably genome sequencing to support preventative healthcare by determining what conditions to be watched for in an individual; wearable tech, such as Google Glass, used by healthcare providers to improve and administer timely, accurate patient-care through improved communication with patients; microchips used to model clinical trials replacing the use of animals and hence improving the accuracy of these trials due to heir capability to emulate bodily systems; digestible sensors that come in form of pills are ingested by individuals to monitor bodily systems and wirelessly transmit information to any storage device *(computer or smartphone); and* cloud-based provider relationship management software, such as ReferralMD that supports communication, between healthcare practitioners managing a patient's physician referral network through a centralized referral CRM solution.

While Artificial Intelligence (AI) technologies are still in their infancy stages, they hold promises to revolutionize the healthcare industry from remote patient monitoring, enabling scheduling priorities based on severity of symptoms by monitoring symptoms, AI for Nurse staffing for different shifts to chat-bots that connect patients to the right contacts, to helping patients refill prescription or pay bills.

Sometimes referred to as a mutual distributed ledger, blockchain technologies are independent, transparent and permanent databases coexisting in multiple locations and shared by a community of users. Current use cases of distributed ledger technologies span the entire healthcare continuum including:

- Decentralized content management system for health care data across providers. These content management systems facilitate data exchange, synchronization, reconciliation and interoperability enabled by blockchain-enabled systems that are cryptographically secured and irrevocable. Blockchain technologies eliminate the burden and cost of data reconciliation. Successful application of distributed ledgers in securing health records include Estonia's partnership with Guardtime, a private security company, to secure the health records of Estonia's citizens; Patientory that securely stores and manages health information in real time across healthcare providers to mention but a few;
- Claims adjudication and billing management through automation of processes such as Gem Health, a network of application and shared infrastructure used for health claims management addressing issues of real-time transparency of health claims, rate of payment and provider reimbursements. Gem's platform, GemOS, is built on a blockchain-based ecosystem for exchanging enterprise data peer-to-peer, both within

and across organizations, while creating unique global identifiers for data assets in order to track them between systems. These identifiers link together and register the locations of all the data belonging to a person or asset on a blockchain, along with the necessary consents and sharing policies;

- Drug supply chain integrity using a chain-of-custody log, tracking the supply chain of drugs to minimize counterfeited drugs. Smart contracts and private keys are then used to build in proof of ownership along the supply chain. Case in point is iSolve LCC that partnered with Biopharma to build an Advanced Digital Ledger Technology to manage the drug development lifecycle through the creation of a smart marketplace for all healthcare providers;
- Pharma Clinical Trials and Population Health Research – Block chain based systems enable time-stamped immutable records of clinical trials, protocols addressing issues of outcome switching, data snooping and selective reporting, hence reducing incidence of fraud and error in clinical trial records; and
- Cyber Security and Healthcare Internet of Things (IoT) – blockchain enabled systems are critical to support the evolving Internet of Medical Things (IoMT) ecosystem; and
- Advanced health care data ledgers storing beyond patient care data but various other types of health care-related data such as genomic and precision medicine data, patient care plans, pharmaceutical supply chain data and clinical trials data from various patient-based technologies and EMRs.

The above list is not exhaustive and goes along way to indicate how the healthcare industry is realizing more and more innovations that are drastically changing the way patient care is provided. However, for purposes of this research work, we limit the following sections to evaluating the potential of a hybrid solution that converges distributed ledgers with the Internet of Medical Things to transform Health Records Management eco-system.

2.1.1.3 Future of healthcare

In his article, (Topol, 2013b), a cardiologist, geneticist and researcher advocates for super-convergence of various technologies currently transforming the healthcare industry, thanks to the maturation of digital world technologies – the ubiquity of smartphones, bandwidth, pervasive connectivity and social networking.

Deloitte makes a further argument for the theory of convergence, highlighting that the convergence of powerful trends – new technologies, the demand for value, a growing health economy and government as an influencer – have the potential to transform the healthcare market in four areas: Everywhere care, Wellness & Preventive care, Personalized care, and Aging, chronic & End-of-Life care.

(Haughom, n.d.) in his article of *"The Rising Healthcare Revolution"* emphasizes the role data-driven healthcare will into leapfrogging the healthcare industry. He lays out the possibilities of personalized patient care enabled by the effective use and analysis of the vast amounts of data collected in the process of managing health and wellbeing of people.

2.1.2 Healthcare expenditures

(Deloitte, 2018) estimates global healthcare spending to increase at an annual rate of 4.1% in 2017-2021, up from just 1.3% in 2012-2016. Global healthcare spending is projected to reach $8.7 trillion by 2020. Estimates from the Council for Affordable Quality healthcare indicate that the commercial healthcare industry spends billions, annually, collecting and maintaining provider data. In its whitepaper, *"Defining the Provider Data Dilemma: Challenges, Opportunities and Call for Industry Collaboration*, the council makes an argument for provider data as a driver for the most fundamental processes of the healthcare industry, and yet access to high-quality provider data remains elusive. Hence the Council for Affordable Quality Healthcare recommends a unified approach towards collecting, maintaining and disseminating accurate and timely provider data as critical towards improving the quality and cost of healthcare delivery. This white paper further emphasizes multi-stakeholder alignment as a key step towards avoiding fragmented investments.

Specific to implementation of Electronic Health Record (EHR) solutions, billions of investments are spent in building integrated epic EHR systems. In the MarketsandMarkets (M&M) paper, *"U.S. Electronic Medical Records Market, 2010-2015 (Market Share, Winning Strategies and Adoption Trends)"*, spending in healthcare-related information technology is projected to rise more than 16 percent every year. Mayo clinic invested $1.5 billion to develop an integrated EHR system. Statistics below, from Statista, indicate that the digital health market is expected to reach 206 billion US dollars by 2020.

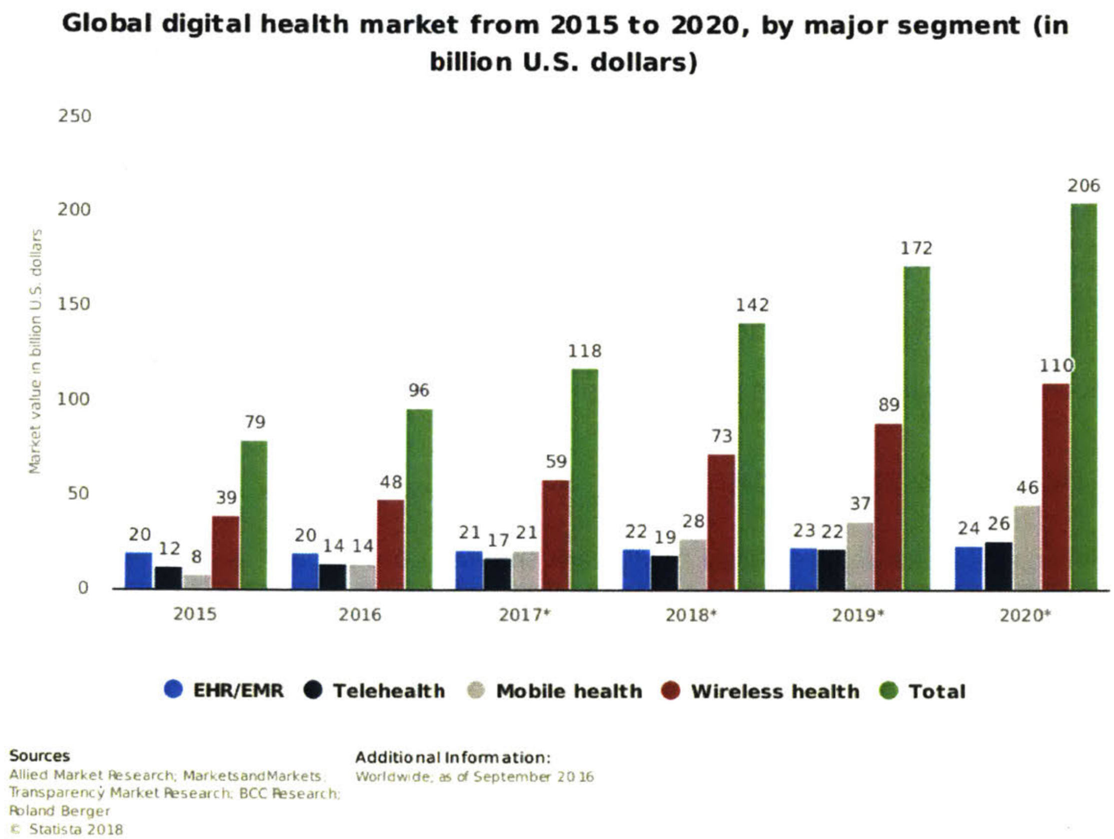

Figure 2: Global digital health market from 2015 to 2020 (Source: Statista 2018)

While the costs of operating blockchain technology are not known as these are dependent on computing power necessary to process transactions, adopting an interoperable solution will curb rising healthcare costs that are a result of monopolized EHR solutions.

2.1.3 Regulatory landscape

The current regulatory environment for the healthcare industry is heavily focused on patient and drug safety, guarding health/medical records against pervasive and persistent cyber risks, automated tracking and analysis of existing healthcare ecosystem relationships to minimize fraud and abuse. The approach used by Food and Drug Administration (FDA) towards regulating digital health is a continuous effort as they grapple with differentiating digital health tools that are regulated as devices and those that are not. This kind of approach constrains innovations due to lengthy FDA approvals coupled with discretionary regulatory measures that are well known to the industry.

Regulatory issues stemming from legal concerns around data protection are covered by a number of instruments notably: *Health Insurance Portability and Accountability Act (HIPAA); Health Information Technology for Economic and Clinical Health (HITECH)*, and *21st Century Cures Act*. (Back, 2017) in his article, *Blockchain Applications in Healthcare: Unlocking a future of untapped potential,* talks about how data sharing and privacy laws have resulted in gross inefficiencies, industry-wide fragmentation and the prevention of real innovation in healthcare. He cites HIPAA as a tool designed to protect health information by imposing strict rules on healthcare providers, but remains a large impediment to efficient patient care due to the cumbersome process of accessing patient medical records. On the other hand, HITECH promotes adoption and meaningful use of health information technology including health records and private, secure electronic health information exchange. 21st Century Cures Act has various provisions the support the flow and exchange of electronic health information.

When it comes to the much needed regulations that are required to realize far-reaching transformation in the health care industry, current research lacks tangible recommendations on what kind of regulation should be enforced that will continue to support continuous innovation in healthcare.

2.1.4 Challenges

In their work, (Pronovost, Ravitz, & Grant, 2017), explain the lack of a systems engineering approach in implementing technology driven solutions within the healthcare industry, with practitioners opting for siloed technologies that result in a constellation of technologies that rarely connect, to the detriment of patient safety, quality and value.

More so, with the evolution of various healthcare systems, some challenges prevail while new challenges emerge with the proliferation of innovations in the healthcare industry. (Deloitte, 2018) summarizes the six (6) top challenges facing healthcare eco-system as (1) Creating positive margin in an uncertain and changing health economy, (2) Responding to health policy and complex regulations, (3) Investing in exponential technologies to reduce costs, increase access and improve care, (4) Strategically moving from volume to value, (5) Engaging with consumers and improving the patient experience, and (6) Engaging with consumers and improving the patient experience.

At a micro scale, (Baldwin, Singh, Sittig, & Giardina, 2017) identify pitfalls of patient portals and health applications designed to improve quality care by engaging patients as active participants in their care. Some of these pitfalls include but are not limited to difficulties navigating these apps; patients struggling to understand their medical information because they lack understanding of what standard, normal benchmarks are.

Specifically, traditional database management solutions used for Electronic Medical Records (EMRs) in the healthcare industry have limitations due to their centralized nature of management making it impossible to integrate independently managed healthcare applications. Secondly, beyond integration, owners of these solutions want to own their data without ceding control to another authority. These systems provide limited capability of information exchange between systems and usually require a designated individual to enable the process of transferring information resulting in delays and decreased quality of healthcare services. Third, with traditional databases, system administrators with access to the information can modify records Last but not least; centralized systems are the epitome of single-point-of-failure.

The key prevailing challenges in healthcare are interoperability and coordinated patient-centric care. Interoperability issues stem from the fragmented nature of healthcare digitization efforts across the industry as well as the fast emergence of innovations that results into duplication. The shift from provider-centric care model to patient-centered care remains a challenge, as providers prefer the volume-based care that is tied to quantity as opposed to quality of care.

2.1.5 Summary of literature review

Despite advancements in the healthcare industry, from wearables to genome sequencing and regenerative medicine, these siloed efforts contribute to industry-wide fragmentation, restricting the levels of innovation that could possibly create a fundamental transformation in the industry. Most research indicates the potential for distributed ledgers to address these challenges, however, this possibility comes with its own set of drawbacks such as (1) transparency and confidentiality as a result of everyone in the ecosystem being able to see everything; and (2) speed and scalability that is highly depended on the number of nodes in a block-chain network. More so, there's little research on the potential for the convergence of blockchain technologies with other emerging technologies such as Internet of Medical Things, machine learning and artificial intelligence in overhauling the healthcare industry. As healthcare becomes more consumer-oriented, implementation of a hybrid solution of distributed ledgers and IoMT has the potential to revolutionize the healthcare industry by offering personalized patient-centric care with an emphasis on overall health of the populations and early intervention for preventive healthcare.

The literature review on the potential of distributed ledgers presented in this paper is not intended to be exhaustive. We attempt to map out the evolution of healthcare delivery systems and the future of the healthcare industry. This paper further attempts to understand how the combination of two ecosystem-centered technologies, distributed ledgers and Internet of Medical Things, can be leveraged to revolutionize the healthcare eco-system. We believe that as the industry sees a proliferation of disruptive innovations, they continue to seek ways of converging these technologies to ensure meaningful, efficient, secure and cost-effective healthcare delivery.

3 Healthcare as a Distributed Ledger System

With the growing emphasis to shift towards value-based healthcare, comes the urgent need to share medical data among healthcare practitioners whilst ensuring data integrity and protecting patient privacy. The proliferation of various healthcare innovations has brought distributed ledgers to the limelight as prime candidates with the potential to transform Electronic Health Records. Notable examples include (Ekblaw, Azaria, Halamka, & Lippman, 2016) work on MedRec, a prototype blockchain system used for Electronic Health Records to address issues of fragmentation, slow access to medical data; system interoperability; patient agency; and data quality and quantity for medical research. Implementation of various blockchain uses cases has led to a number of benefits ranging from:

- Offering a decentralized health data backbone for digital health solutions allowing easy access and sharing of medical records without ceding control, and enabling real-time processing by eliminating intermediaries;
- Offering an immutable audit trail that guarantees that medical records cannot be altered by anyone other than the owner of the data, improve claim auditing and fraud detection, traceable and time stamped patient-generate data and clinical research protocols that can be used to personalize health care interventions;
- Enabling verification of legitimacy of records to support claim qualification, medical research data and supply-chain manufacturing process; and
- Minimizing the security risks of patient data record keeping since patient data is stored on a decentralized network, and increases safety of medical records using Public Key Encryption methods.

Frost & Sullivan highlight the implementation challenges of blockchain in Healthcare as:

- Conflicting interests among incumbent health data players;
- Standardization and terminology issues with already disparate terminologies;
- Finding the scalability trade-off between required computing energy and network types;
- Threat of substitute from emerging DLT; and
- Integration concerns: Technical, Operational, governance and economic challenges.

Distributed ledgers as a foundation of interoperability enable collaboration and bolster innovation in medical research. Distributed ledgers also address security, privacy and reliability concerns related to integration and exchange of medical data among various health devices, applications and solutions. As outlined in the Literature Review section, a number of Healthcare systems have attempted to implement and use blockchain technologies with the objective of managing and maintaining integrity and security of records. In the section we compare two of those systems: Estonia's Keyless Signature Infrastructure and MIT MedRec System.

3.1 Estonia's case study

Estonia's Keyless Signature Infrastructure (KSI) is used for different industries, but this paper focuses on its use in Estonia's healthcare sector. Much as Estonia's KSI is built using blockchain technologies; the global architecture resembles a centralized architecture. Estonia uses an Electronic Health Record nationwide system to create a common record that can be accessed online for every patient by integrating data from various healthcare providers. Contrary to blockchain's underlying technology, distributed ledgers, e-Health Record functions more like a centralized database aggregating data from the different providers and presenting it into a standard format using the e-Patient portal.

The figure below depicts a high-level formal Architecture of Estonia's Health Information Exchange platform. Blockchain as a system is essential as a database that connects other databases in a distributed form. Benchmarking Estonia's healthcare system built using blockchain technologies, the blockchain system has three elements: X-Road, Services and Distributed information systems.

X-Road is a secure data transport backbone, also referred to as the distributed enterprise service bus for inter-organizational data exchange. X-Road interconnects healthcare providers and implements a secure, unified Electronic Health Record.

Distributed Information Systems function as the secure, scalable, independent storage components of the system. These systems are responsible for achieving consensus. Data can be stored in either public or private blockchain cloud that uses cryptographic methods to protect medical records.

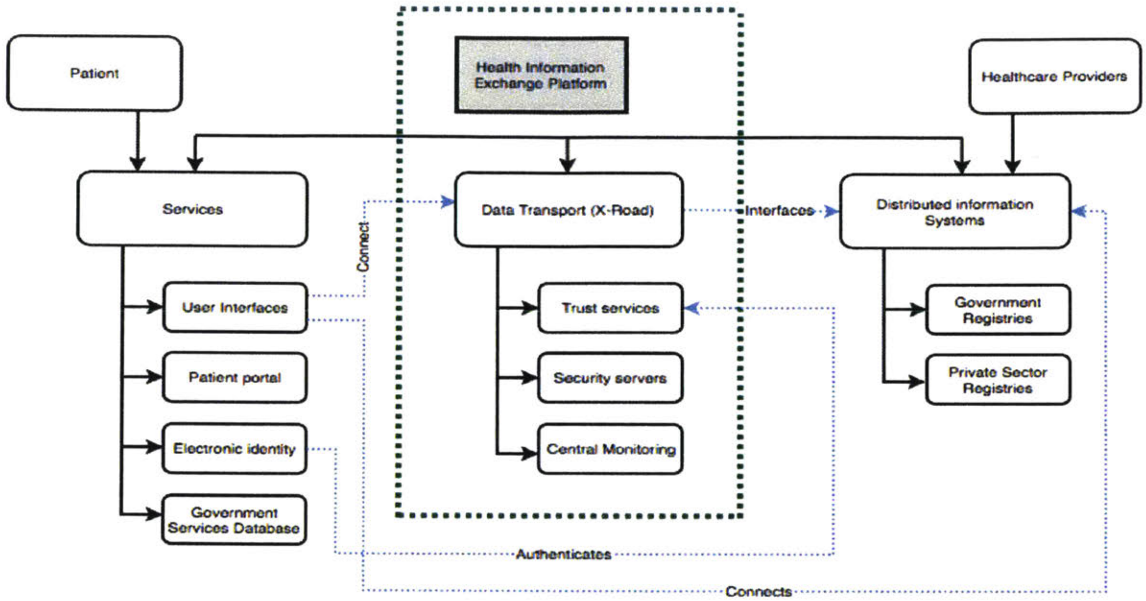

Figure 3: High-level architectural decomposition of Estonia's Health Information System

("Estonian EHR Case Study," n.d.) outlines the key functions of Estonian National Health Information System.

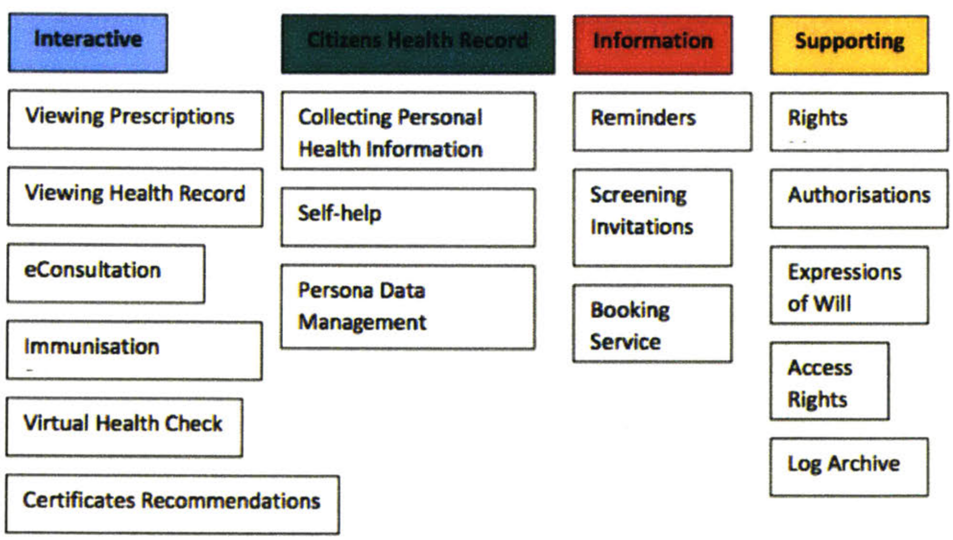

Figure 4: Principal and Internal functions of Estonia's National Health Information System

Estonia's National Health Information system has four (4) categories of functions: Interactive, Citizen Health Record, Information and supporting functions. One of the architectural decisions undertaken for the development of Estonia's Health Information System was integrate through a central system. Due to that, this system is limited in data exchange capabilities.

3.2 MedRec

MedRec is an open-source system that prioritizes patient agency, giving a transparent and accessible view of a patient's medical history through the creation of decentralized content management systems for healthcare data. (Ekblaw et al., 2016) make a case for MedRec as an alternative solution to addressing the fact that traditional centralized EHR systems are not designed to manage the complexities of multi-institutional, lifetime medical records. A second element that MedRec tries to address is the shift from provider stewardship to patients. In doing so, MedRec replaces centralized intermediaries with a distributed access and validation system. The system integrates with existing data storage solutions owned by various providers, thus enabling interoperability.

MedRec's platform architecture allows research and clinical community to participate by linking medical researchers to the larger data sets that exist across different organizations. Medical researchers mine this data in exchange for access to anonymised data that would be used beyond supporting decision making to further medical research. MedRec 1.0 started off as a small-private blockchain with later versions, MedRec 2.0 adopting a more advanced peer-to-peer private blockchain model that uses votes to admit new members. Figure 5 maps MedRec 2.0 architecture.

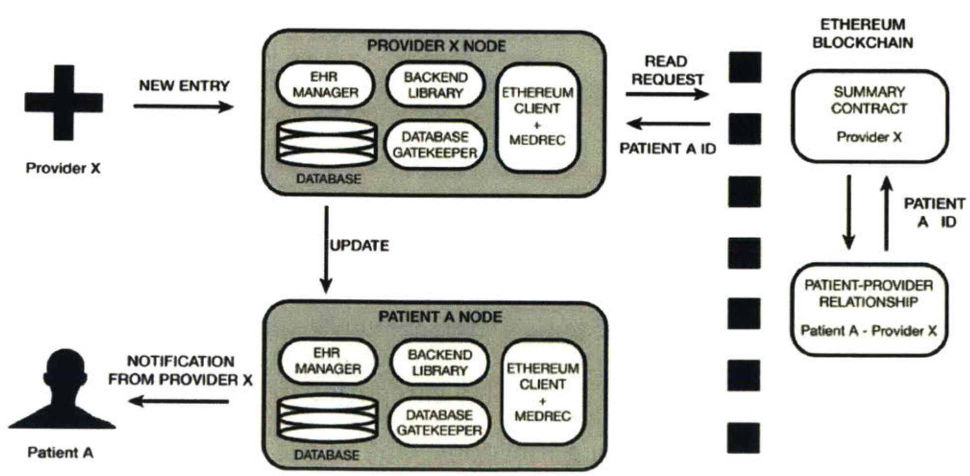

Figure 5: MedRec 2.0 Architecture

MedRec's Technical documentation points out a key architectural modification between 1.0 and 2.0 as the need to bypass the blockchain for patient notifications. Blockchain storage is restricted to creation and modification of identities and relationships rather tan their metadata. This means a third party can view the relationship between two parties but will not have details on the interaction, in terms of content and frequency, between any two parties. MedRec 2.0 is a network solution to managing distribution and access to patient records, with the patient controlling permissions on who accesses and uses their health data.

MedRec uses smart contracts to link patients and providers by encoding pointers that are used to locate and authenticate locations of existing medical records. This means that MedRec doesn't store any records, but rather encodes metadata that will be used to identify and access records securely.

4 Internet of Medical Things as a System

The Internet of Medical Things (IoMT) is a combination of medical devices and applications using networking technologies. IoMT is particularly a technology of interest given its ability to facilitate the delivery of personalized, value-based care. IoMT can support healthcare providers to collect and monitor patients' vital signs and adherence to treatment plans and prescriptions in real-time. While IoMT is currently used to facilitate workflow optimization, inventory management and medical device integration, the focus of this section is on medical device integration.

Benefits of IoMT include remote monitoring coupled with greater patient involvement; telemedicine capability that minimizes physical trips to the doctor - doctors still get compensated based on the value-care delivery model; behavioral modification triggered by reminders for medication, diet and exercise.

The System Architecture below, Figure 6, depicts a high level architecture of a Healthcare IoT system. Sensors are viewed as the objects of the system and are connected over a communication infrastructure.

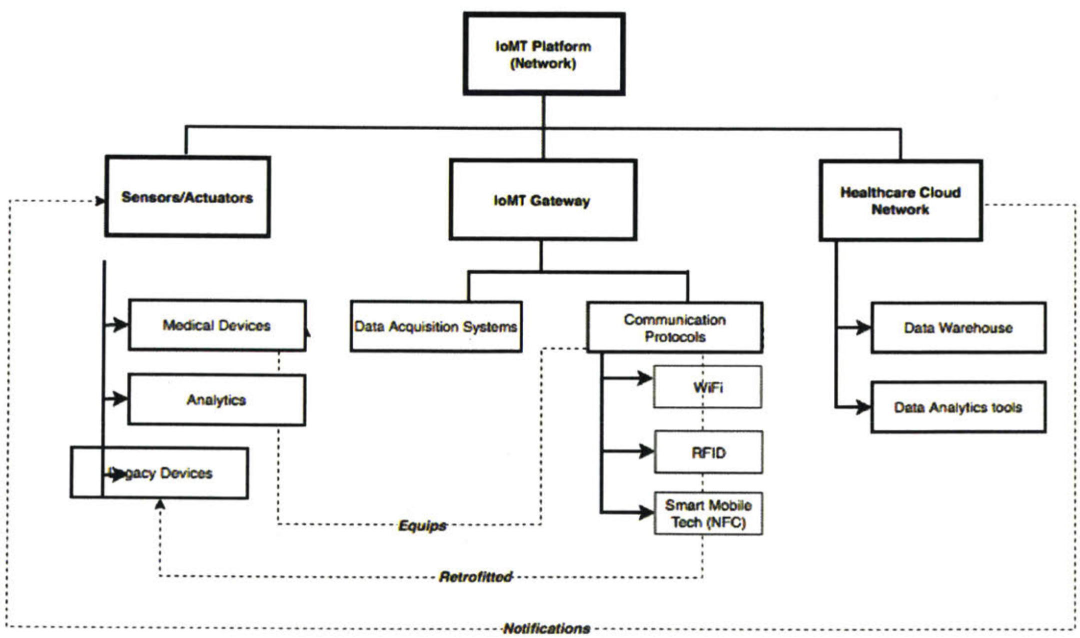

Figure 6: Formal decomposition of IoMT Architecture

Level 1 of the healthcare IoMT architecture has three components: the IoMT Gateway, Sensors and the Cloud. The IoMT gateway, just like its name, is responsible for connecting various sensor-embedded healthcare devices and applications to the cloud network. Sensors are equipped to the various healthcare devices, applications to collect data and channel it to a centralized or decentralized data warehouse. Whereas the Cloud Network stores and processes sensory data, uses various artificial intelligence and machine learning algorithms to provide data analytics services.

While IoMT has benefits that make it a worth investment, this technology still has fundamental challenges of security vulnerabilities. These two main challenges include security and privacy. Addressing these challenges requires designing robust access control mechanisms that preserves privacy.

5 Convergence: System of Systems Architecture

This section provides a framework for architecting the System of Systems healthcare ecosystem. The proposed solution is a network of medical devices and application connected to a distributed ledger system that allows for secure access and sharing of health data for better diagnostics, improved communication between healthcare providers and patient and improved decision making.

5.1 Stakeholder Value Network

Healthcare delivery business models include value-based care and fee-for-service models. Value-based care encourages medical practitioners to provide quality services, necessitating a whole-of-value-chain follow up that simply does not start and stop with when a patient visits a hospital. Whereas the latter, fee-for-service, is volume-based, reimbursing providers for the services they delivered. This model does not account for provider efficiency or effectiveness.

The World Economic Forum (WEF) Journal, ("Value in Healthcare Laying the Foundation for Health-System Transformation," 2017b) outlines three ways value-based healthcare aligns stakeholders around delivering value to patients through: (1) Systematically measuring health outcomes that matter to patients; (2) Tracking outcomes and costs; (3) Tailoring interventions to improve value.

The table below details the various healthcare stakeholders, their needs and contributions towards strengthening data-driven healthcare ecosystems.

Table 1: Key Stakeholder needs, inputs and outputs

Stakeholders	Needs	Inputs	Outputs
Patients	▪ Quality and coordinated personalized care ▪ Reduced healthcare costs ▪ Patient engagement using personal healthcare applications and devices ▪ Easy, secure access to personalized care ▪ Predictive healthcare management ▪ Privacy and security of patient data ▪ Interoperability of medical devices and applications ▪ Improved diagnoses through continuous monitoring and improved analytics ▪ Remote service delivery ▪ Elimination of fraud and errors in medical insurance and billing processes	▪ Medical records ▪ Personalized care ▪ Consumer protection ▪ Emotional support ▪ Health coverage plans ▪ Subsidies Medical devices and apps ▪ Clinical tests	▪ Money ▪ Personal Data ▪ Influence/buy-in
Providers (Physicians, labs, pharmacists, drug manufacturers)	▪ Efficient and coordinated care and medical record management ▪ Access to historical medical data and prescriptions ▪ Increased profitability ▪ Predictive care management ▪ FDA approval ▪ Accuracy and reliability of medical electronic devices	▪ Healthcare plans ▪ Investment ▪ Knowledge ▪ Policies and Regulations	▪ Controlled healthcare costs (lower) ▪ Better health outcomes ▪ Personalized healthcare data

	▪ Real-time remote monitoring of patient progression ▪ Automated verification of complex processes and/or products ▪ Improved health data analytics to support decision making		▪ ▪ Jobs/wages
Payers	▪ Faster and efficient claims payments	▪ Employee contributions ▪ Subsidies	▪ Health Insurance plans
Governments/ Regulators	▪ Universal quality healthcare ▪ Predictive healthcare management ▪ Licensing ▪ Consumer protection in terms of privacy, security and environmental health hazards	▪ Knowledge (Information on healthcare outcomes and interventions)	▪ Emergency response ▪ Policies ▪ Regulations ▪ Healthcare subsidies
Communities	▪ Better Health outcomes ▪ Disease prevention	▪ Health awareness ▪ Jobs/wages	▪ Information on outbreaks
Medical Device Manufacturers	▪ Volume Purchasing ▪ Testing and validating electronic medical devices ▪ Productivity of electronic medical devices ▪ FDA approvals	▪ Consumer preference information ▪ Data trends ▪ Revenues	▪ Medical devices
Solution providers	▪ Volume Purchasing ▪ FDA approvals ▪ Health information exchange	▪ Data Integration and analytics ▪ Investments ▪ Revenues	▪ Solutions/systems

The stakeholder value network diagram maps out the various value exchanges between the Patient (as the focal stakeholder) and other stakeholders along the healthcare value chain.

In (Helander, 2014), assessment of *Healthcare system as a value network,* she maps out three (3) direct value functions: *Profit, Volume and Safeguard;* as well as *Development, Network, Scout* as indirect value functions in the healthcare system.

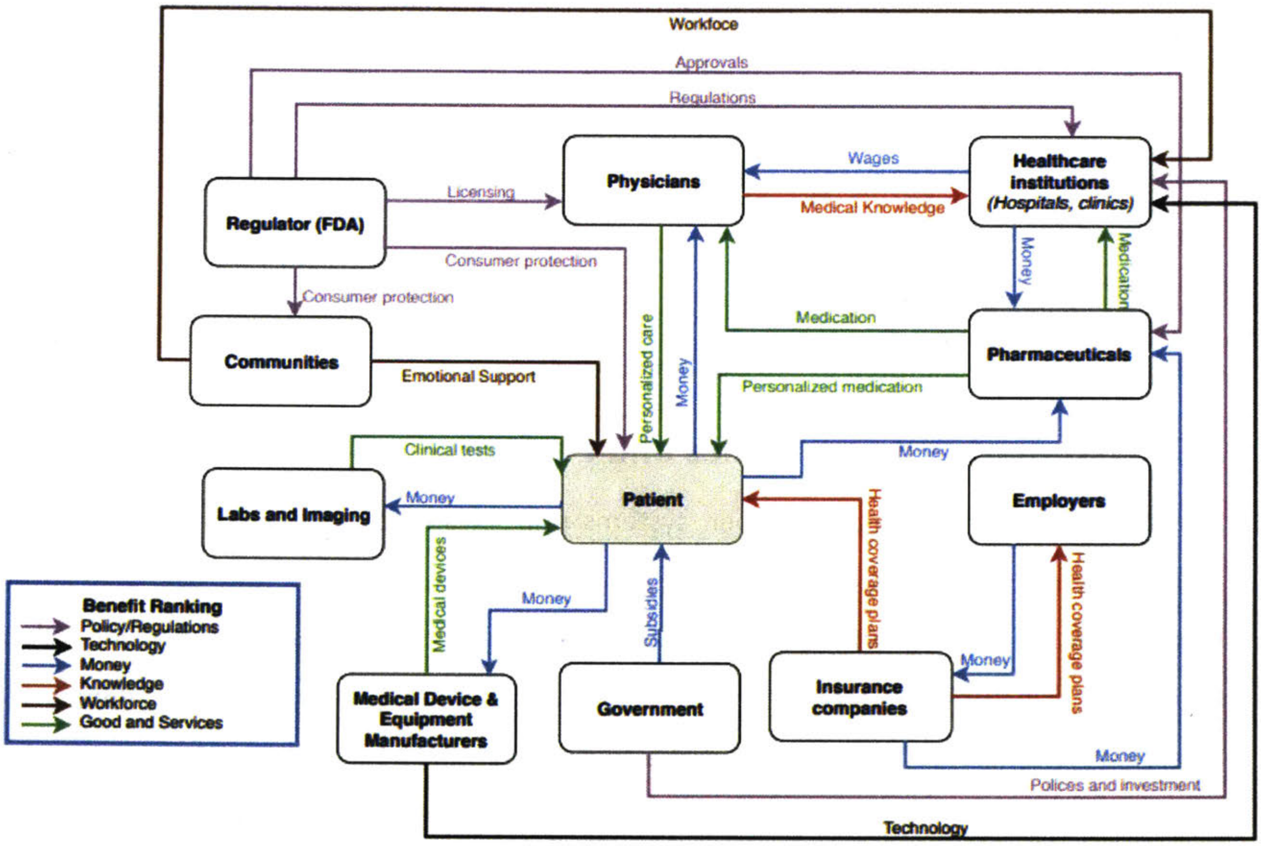

Figure 7: Stakeholder Value Network Map for Healthcare industry

Data-driven healthcare is essential to transforming the way health care is provided, but most importantly a key attribute towards personalizing value-based care. The Stakeholder Value Network depicts the needs of specific stakeholders from the exchange that happens with other stakeholders. Our system Architecture will focus on satisfying the needs of the patient primarily, and the eco-system as a whole.

5.2 System Problem Statement

To provide coordinated and personalized healthcare

By creating, managing, exchanging, interconnecting and integrating Electronic Health Records in an efficient and secure manner

Using hybrid record management systems that process real-time patient-generated data

The System Problem Statement is derived from the value delivery to the patient - the primary beneficiary of the system. The primary value of this system is patient-centered care whose business model is value-based care. This paper intends to take a holistic approach towards patient needs, necessitating the convergence of data across the healthcare eco-system.

In the following section, a set of criteria is proposed that will be used to evaluate the multiple concepts generated in subsequent sections.

5.3 System of systems: Illities and Performance metrics

Drawing from Azani's suggested open systems principles, this section reviews those system Illities required to evaluate probable hybrid architecture combining the use of distributed ledgers and the Internet of Medical Things (IoMT). The measures used will provide value for patients and in turn the other stakeholders, which ultimately drive systemic change. These performance measures are considered at a macro level, further work would be required prior to implementation to integrate micro-level performance measures.

- **Open platform** – The proposed EHR architecture should be an open platform that interconnects various healthcare applications and devices to facilitate interoperability and integration.
- **Holistic** – Given the focus on eco-system interventions, a holistic architecture is necessary to address both component elements of the platform as well as the interactions that exist or emerge between these component systems.
- **Synergism**– Synergy between the various components is an essential factor towards supporting data exchange across healthcare providers whilst minimizing duplication.

- **Reconfigurable** – The hybrid EHR architecture must possess the ability to adapt to future needs and technology trends, combining multiple concept to deliver an architecture that responds to evolving needs.
- **Accessibility** – Not only should health records be readily available but easy to locate, retrieve and translate. This means storing records in standardized and structured formats that a patient with limited physician expertise can understand.
- **Connectivity** – given that hybrid architectures embody a system-of-systems design that integrates various medical systems, devices and app/solutions, its important that the underlying architecture promotes connectability of independent modular systems.
- **Scalability**: Hybrid EHR architectures interconnecting various medical devices and applicable ought to scalable both in terms of required computing resources as well as expansion of the architecture.
- **Availability**: The primary objective of implementing EHR is to avail healthcare data in the easiest way possible. Hybrid architectures of EHR systems must exhibit this illity, making healthcare data readily available to authorized users.
- **Reliability** – Health records need to be relied upon as accurate in order to support valid decision-making. Inaccurate records lead to inadequate/irrelevant decision-making.
- **Quality**: Value-based healthcare is highly dependent on the quality of the data that ultimately translates into quality of healthcare services provides, which is essential for healthcare reimbursements.
- **Integrity** - Preventing unauthorized access and modification of health records throughout their lifespan.
- **Interoperability**: Probably the most important illity when evaluating hybrid architectures of blockchain-enabled EHRs. Connecting medical things necessitates that these various application and systems can communicate and exchange data seamlessly.
- **Authenticity** – Value-based healthcare is heavily data-driven, necessitating that health records and their source/origination is authentic and verifiable.
- **Patient safety –** This illity not only applies to medical devices, specifically wearables and microchips inserted in the human bodies, but to the entire spectrum of prevention,

reporting and medical analysis that could potentially lead to adverse effects. Decision support functions of the hybrid EHR architecture should emphasize patient safety.

- **Maintainability** of various systems and applications necessitating a change on one interface to be adapted by all other parties.

5.3.1 Performance-related metrics

The following metrics are developed based on assumptions of what would be the main bottlenecks to performance of the hybrid system towards delivering value-based care to the patient. These include both qualitative and quantitative metrics:

i. **Implementability** – Is the hybrid architecture implementable from a design perspective? Does the architecture provide for a sound cost/benefit analysis that justifies its implementation?

ii. **Processing speeds** assesses the number of transactions per seconds and whether any latency is experienced during the processing of transactions.

iii. **Number of peer nodes** evaluates the capacity to host multiple stakeholder transactions without affecting the quality and availability of records.

iv. **Availability** focuses not only on percentage uptime but also at a macro level on the permissions provided for relevant stakeholders to view and/or edit the records.

v. **Quality care-metrics** – Such metrics promote patient-centered care and involvement of patients in clinical decision making. Quality care metrics include assessing patient satisfaction regarding their experience during treatment and post-treatment, outcomes are documented and measured.

vi. **Bundled care** focuses on the full chain of care from diagnosis to treatment and recovery. This concept measures health outcomes by considering a patient's entire medical condition as opposed to just a segment of a health system.

vii. **Real-time data reporting and collection:** Efficiency of data-driven healthcare is dependent on the ability to collect and report patient-generated data in real time. This metric favors digitally collected data as opposed to self-reported data.

viii. **Automated autonomous action:** Automatic text reminders of post-treatment plans, Apps to guide though personalized care plan and alerts for caregivers. Activity monitoring of chronic diseases (blood glucose, tidal volume, weight) to provide remote analysis and triage.

ix. **Security:** Medical data is sensitive in its form necessitating the need to provide secure access to data and transactions.

x. **Diversity of healthcare providers**: This focuses on the nature and type of healthcare providers integrated into the EHR systems. Most EHRs are developed to integrate a section of providers in the healthcare providers. Whole-of-ecosystem EHRs should integrate all providers along the value chain.

5.4 Morphological Matrix

This section reviews the key design considerations undertaken is developing three types of Health Record Management systems: Paper-based records, centralized electronic record management systems and distributed-ledger electronic record management systems. While these architectures may not be universally agreed upon, we attempt to capture the key design consideration for purposes of depicting each of these models.

EHRs are a set of computer-based tools that facilitate users to access and process health data containing historical and current patient information.

5.4.1 Paper-based records

Traditional paper-based record keeping systems are prevalent in healthcare organizations, particularly in rural settings. The healthcare eco-system is yet to overhaul this system of record keeping given that even for those providers that choose alternative electronic means still employ an element of paper-based records.

The table below depicts a functional decomposition of the key processes/functions entailed in traditional paper-based record keeping practices. Highlighted boxes represent the combination of best options of each decision that make up the preferred architecture for paper records systems.

Table 2: Morphological Matrix for functional decomposition of paper records

Processes	Configurations					
	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6
Capturing	Hand-written	Type written	X-Rays images	All		
Record Processing	Manual record abstraction	Manual chart matching	Hybrid			
Filing & searching	Alphabeticall y	Numerically	Alphanumeri c	Terminal-digit		
Storing	Centralized	Decentralize d				
Securing	Administrativ e practices	Physical security	Hybrid (All)			
Sharing	Physical distribution (Paper mail)	Faxing	Emailing	Hybrid		
Retrieval & tracking	Out guides/ signing out records	Requisition slips	Record tracking			
Disposal	Shredding	Pulping	Burning	Cutting	Dumping	Imaging
Backing up (Duplicates)	Photocopying	Scanning	Carbon copy paper	Hybrid (Carbon copy and Scanned document)		

The processes of capturing records using traditional paper-based record systems could either be handwritten notes from providers, or typewritten records as a way of minimizing illegible records, or X-rays results for body imaging records. In most health organizations, the process of capturing paper-based health records is a combination of hand-written, typewritten and x-ray results.

Common methods of manually processing medical records include: manual record abstraction, and manual chart matching. Manual record abstraction requires manually searching medical records and identifying required data. Whereas manual chart matching involves comparing information on different charts to find similarities or discrepancies.

Filing, sharing and searching for records follows alphabetical, numeric, terminal digit or alphanumeric format. Alphabetically filing medical records is not recommended given that it's the least secure method of filing medical records. Numeric filing involves filing medical records using a number ordering system based of patients' Medical Record Numbers. Alternatively, terminal digit filing can be used to file medical records using reverse numeric filing systems. This involves using numbers, just like the numeric filing system. Another method is the alphanumeric filing system, which is a combination of letters and numbers.

Paper record systems can either be centralized or decentralized in nature. With decentralized health record systems, patient records are filed independently across various providers or units within an organization. This implies that the records might not be necessarily uniform across the board, given that each hosting entity stores information that is most relevant to their needs. Whereas with Centralized health record systems, all patient records are consolidated together into a single folder or location.

Paper-based health records are secured using traditional methods of locks, keys and access codes. Paper records are stored in files/folders that are placed in open-shelves. Some health organizations dedicate storage facilities for health records that is not only equipped with locks and keys but also secure these facilities with personnel to man the shelves/cabinets storing health records; and cameras to control access to the storage facility.

Common methods of sharing of paper records among healthcare providers include paper mail, faxing and emailing. Copies of the original paper records are made and either mailed or faxed to another provider. In some instances the original records are scanned and emailed to the patient or provider. Alternatively, printed or photocopied hard copy records are given to the patient to deliver another provider.

Methods for retrieving and tracking paper-based health records include out guides, requisitions and tracking of records. However, these methods have limitations when it comes to ascertaining whether or not there has been misuse of the records. The use of out guides necessitates medical records are signed out and placed where the record was removed. However, users with malicious intent can obtain access to the records without necessarily using an out guide. It's worthy to note that access to paper-based health records is limited to location and working hours.

The process of disposing paper records takes different forms: shredding, pulping, burning, cutting, dumping and sometimes a hybrid of either shredding and burning, dumping and burning, or cutting and burning. The choice of which method to use largely depends on the sensitivity of the records. An alternative disposition method for paper records is imaging which involves converting paper records to digital images and then the physical records are destroyed.

In order to backup paper records, various options are used including photocopying original records, scanning paper records to keep a digital version on a disk, or the original method of capturing health record is make on paper supported by carbon paper to simultaneously create a copy (or multiple copies) of the original record.

By and large, paper-based systems have displayed inherent challenges that constrain the delivery of improved healthcare. These challenges include illegibility of hand-written records, difficulty searching records, non standardized abbreviation. A key design constraint of paper records is their inability to support value-based, patient-centric healthcare.

5.4.2 Centralized EHR

As paper-based patient records made it increasingly difficult to deliver faster and efficient healthcare, their obsolescence led to the invention of electronic medical record management practices. The birth of EHRs stemmed from the need to streamline access to patient records, and consolidate patient information into one record as a way of reducing errors and their continuous propagation. Current EHRs systems are not fully computerized, maintaining dual repositories – paper-based and electronic databases to support different tasks. The table below depicts a functional breakdown of the key functions of Electronic Health Record Systems.

Table 3: Morphological matrix - Functional decomposition of Centralized EHR systems

Parameters	Configurations					
	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6
Creating	Document imaging (Scanning)	Electronically (Computer or Type writer)	Diagnostic imaging (X-Rays)	Voice-recording	All	
Filing/Classification	Alphabetically	Numerically	Alphanumeric	Terminal-digit		
Records retention scheduling	Automated	Manual				
Storing	Centralized	Decentralized				
Access control	Discretionary Access Control	Mandatory Access Control	Role-based Access Control	All		
Data Exchange	Electronically	Manual (Printing)	Hybrid			
Securing/Protecting	Administrative practices	Physical security	Technical security	Hybrid (All)		
Disposal	Archiving	Purge	Reformatting	Physical destruction (Cutting, crushing, shredding)	Chemical recycling	Degaussing
Billing	Value-based reimbursement	Fee-for-service				
Backing up (Duplicates)	Full backup	Differential backup	Incremental backup			
Reporting	Statistical reporting	Historical reporting	Hybrid			
Disaster Recovery	Air drying	Backing up				

Given that most EHRs are not fully computerized, the function of capturing/creating health records involves methods used for capturing paper-based records, direct input into the record system (electronically) as well as methods used to convert paper records into electronic records such as scanning and image capturing.

Classification of electronic health records takes a similar approach as traditional paper-based records. This filing system is transposed into the Electronic filing system to ensure consistency between electronic and physical records.

Records retention scheduling can either be automated or manual. The starting point is organizations creating policies for retention and disposal of records, deciding the duration the various types of records remain active. Automation of records destruction involves automated notifications to users about documents that will soon become inactive or archived prior to any automated action being undertaken. Whereas, the manual process requires that record owners conduct periodic reviews to determine which documents should be archived.

Access control mechanisms limit who views/accesses and manipulates electronic health records. Access control mechanisms relevant to EHR include Discretionary Access Control (DAC), Mandatory Access Control (MAC) and Role-based Access control (RBAC). (Bakker, 2004) distinguishes DAC as an access control mechanism based on a user's identity and authorization; MAC provides access based on security classification of users; whereas RBAC is an access control mechanism that provides access to an EHR system based on users' role and privileges in an organization.

Providers frequently require patients to share their previous medical records to support their current diagnoses. Data exchange mechanisms frequently used for providers that are not using the same EHR system are manual in nature, which involves printing copies of the records. This form of sharing medical records among providers doesn't happen in real-time and is insecure, making it less inefficient. Alternative mechanisms include faxing or emailing a patient's medical historical. For physicians on a centralized EHR system, sharing of medical records using EHR systems done electronically through three models: push, pull and view. The Push model involves one-way sharing of medical data between two parties (medical providers) over a secure network/system. Pull models involved one provider querying information from another provider, whereas, the view model enables a provider to view data from another provider's record. Worthy to note that push, pull and view models operate on a centralized premise that only allows two parties to transact without any other party viewing these interactions.

Techniques for securing Electronic health records as highlighted by (Kruse, Smith, Vanderlinden, & Nealand, 2017) and recommended by HIPPA are categorized into: *Technical, Administrative and Physical safeguards*. Technical methods for securing electronic health records entail Firewalls, Encryption mechanisms, Audit trails and Access controls (such as PIN numbers and passwords. Physical safeguards prevent or limit unauthorized access to hardware housing the Electronic health records system such as combination locks, secured doors etc.; whereas, administrative safeguards entail policies, practices and procedures for security that combine elements of technical and physical safeguards.

Disposal of electronic health records takes multiple forms with reformatting used for digital electronic media; whereas, cutting, crushing, shredding and chemical recycling is used for magnetic and optical audio-visual media. Degaussing is a process the demagnetized magnetic media to erase recorded data. These disposal methods are applied to copies contained in system backups and offsite storage.

Traditional systems use a fee-for service model for billing, whereas overtime a shift towards value-based reimbursements has been introduced as the healthcare system transitions into patient-centered healthcare delivery.

Backup options for centralized EHRs range from full to differential to incremental backups. Full backups regularly make a copy of all the data stored in the centralized ledger; differential backup only copies data that has ben modified since the last full backup process; whereas, incremental backup processes build off the differential backup concept by copying all the data that was modified since the last full or differential backup.

Reporting functions in centralized EHR systems can either be statistical or historical reporting. Statistical reporting aggregates quantitative patient data whereas historical reporting is more qualitative.

Given that current centralized EHR systems manage hard copy and electronic records, disaster recovery mechanisms for these types of records involver air drying and backing up respectively.

The adoption of electronic health records comes with added functionality (or options) not necessarily available through traditional paper-based record keeping practices. These added functionalities include patient support through access control and decision support functions. Most of the functions described above support patient empowerment, thus contributing greatly to delivering value-based, patient-centric healthcare. However, this option has limitations too mainly around security and privacy of patient records, interoperability of healthcare systems and application.

5.4.3 Distributed EHR

The architecture of a distributed-ledger, shared ledger, EHR system places emphasis on how healthcare data is stored, shared and secured in a decentralized manner. Unlike centralized HER systems, multiple copies of a ledger are available and can either be accessed by a trusted group of network participants (permissioned system) or anyone (permissionless system). Additionally, while traditional paper-based EHRs systems could potentially have more than one copy of a ledger distributed across providers, modifications of the original ledger are not necessarily reflected across the multiple copies.

In the next section, we detail the various processes undertaken in managing and maintaining a distributed HER system:

Table 4: Morphological Matrix - Functional decomposition of Distributed EHR systems

Parameters	Configurations				
	Option 1	Option 2	Option 3	Option 4	Option 5
Creating	Document imaging (Scanning)	Direct input	Real-time automated entry (sensor data collection)	Voice recording	All
Connecting	Physical	Virtually	Hybrid		
Storing	Decentralized	Distributed	N/A	N/A	N/A

Monitoring	Real-time	Adhoc (event triggered)	N/A	N/A	N/A
Data Exchange	Permissionless	Permission-based data distribution (Smart contracting)	N/A	N/A	N/A
Access control	Consensus mechanisms (Proof-of-work)	Identity verification	N/A	N/A	N/A
Reporting	Objective	Subjective			
Clinical Decision Support	Knowledge-based	Machine learning	N/A	N/A	N/A
Data Analysis	Historical Analysis	Episodic Analytics	Preventive Analytics	Predictive analysis	All

Beyond the methods used to capture or create records in traditional centralized EHR systems, automated capturing of data from sensor-embedded devices or applications is method used when using IoMT to connect medical devices to Health IT systems such as EHR systems.

The hybrid architecture uses IoMT technologies to connect medical devices using wireless technologies (virtually), while other systems and healthcare solutions are physically interconnected to the distributed EHR.

Much as the hybrid system is a distributed ledger in nature, another method of storing health records is the decentralized method. In many cases distributed-ledgers are interchanges with decentralized systems. However, for purposes of this work, we distinguish decentralized storage mechanisms from distributed storage by the fact that decentralized systems have pockets of centralized systems interconnected. Unlike traditional paper-based record management systems and centralized EHRs, the concept of distributed or decentralized EHRs does away with intermediaries, central parties, responsible for exchanging data across the network of providers.

Monitoring of distributed EHRs can be done in real time as IoMT connects and captures data instantaneously. Alternatively, monitoring can be done in an adhoc manner with triggers built-in to alert providers when their urgent and immediate attention is required.

Data exchange mechanisms within a distributed or decentralized ledger are distinguished by either the ability for anyone to access the ledger or only participating nodes in the network. Smart contracts support data exchange or redistribution of digital assets among parties based on pre-established rules. Sharing of data on distributed-ledger EHRs involves identical copies of the ledger distributed across the participants and every time the original is updated, the modifications are automatically displayed in the distributed copies.

Access control for participating nodes within permissioned systems, which are built on trust of the network participants, will only need to undergo identity verification to access data on the distributed ledger. Whereas, for permissionless systems, where anyone can join the network at their will, consensus mechanisms, such as Proof of work, are employed prior to adding or sharing data.

Reporting mechanisms for hybrid EHR system can be categorized as either subjective or objective reporting. Objective reporting stems from the ability of sensor-enabled devices to automatically report healthcare data in real time and based on detections in body changes. Whereas subjective reporting is dependent on how best a patient can articulate symptoms.

The Clinical Decision Support (CDS) capability supports physicians in making informed decisions. This function can be categorized into: knowledge-based, and non-knowledge-based CDS. Knowledge-based CDS leverage consolidated health records to create rules of IF-THEN functions to avoid any unsafe interactions. Whereas non-knowledge-based CDS is supported by machine learning technologies to adopt a combination of mining episodic & historical data with patterns in clinical data to support predictive care.

Data analysis of hybrid EHR systems provides beyond historical and episodic analytics to provide predictive analytics based on clinical research coupled with historical health records.

The hybrid solution offers added functionality over existing EHRs, these include: patient control over data, interoperability of healthcare solutions through data exchange and connecting functions, easier and efficient data exchange, better analytics and improved information security and privacy protections. EHR functions such as retrieval & tracking, scheduling, billing, disposal, backing up and securing are not enumerated in the morphological matrix since they would be similar to any candidate EHR architecture.

Securing, verification, validation and authorization functions are commonly achieved through a consensus mechanism that requires all participating nodes to reach a consensus. Therefore, these functions are not captured in the matrix as the mechanisms (options) are already captured in access control function.

5.5 Tradespace analysis

The concept generation efforts, combining architectural options for the distributed EHR and the best architecture from both the traditional paper-based health record systems and the centralized EHR, led to the generation of 512 possible hybrid architectures for EHR systems. Out of the nine (9) architectural decisions, eight (8) were selected given their sensitivity to the final EHR hybrid design and direct link to overall goals of the hybrid system.

As a way of filtering invalid designs, a number of rules that constrain certain decisions/functions from coexisting were identified, such as:

- Health records that are created though document imaging or diagnostic imaging or direct input into the systems do not allow for real-time automated monitoring;
- Permission-based data exchanges only required identity verification as a mechanism of controlling access to the EHR; and
- Voice recording of health records cannot be considered objective reporting of patient symptoms.

Down-selection of concepts is tied to the primary goal of the system, which is to interconnect and exchange healthcare records in a secure manner. With these set of rules applied to the initial set of 3200 concepts, the resulting matrix has 512 candidate architectures that could potentially address our primary stakeholder needs. However, based on the system problem statement, and performance metrics highlighted in Section 5.3.1, we chose eight (8) candidate architectures to explore further.

Table 5: Concept Enumeration of Hybrid EHR Architecture

Decisions	Options	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5	Concept 6	Concept 7	Concept 8
Creating	All	X	X	X	X	X	X	X	X
Storing	Distributed	X	X	X	X	X	X	X	X
	Centralized								
Monitoring	Real-time	X		X		X		X	
	Adhoc		X		X		X		X
Data Exchange	Permissionless	X	X					X	X
	Permissioned			X	X	X	X		
Access Control	Proof of Work	X	X					X	X
	Identity verification			X	X	X	X		
Reporting	Objective	X		X		X	X		
	Subjective		X		X			X	X
Clinical Decision support	Knowledge-based	X	X	X	X	X			
	Machine Learning					X	X	X	X
Data Analysis	All	X	X	X	X	X	X	X	X

Each of the candidate architectures is evaluated based on its ability to deliver value using the performance criteria. Interoperability being central to the hybrid EHR architecture, it is worth noting that two tensions exist: Accessibility and Security. While it is desired that electronic health records are easily accessible to patients and providers, ensuring access to health records does not pose a challenge of misuse is always a difficult tradeoff.

Weighting was assigned to each candidate architecture using percentiles for accessibility and security. Based on assigned weighting, we map these candidate architectures on the Tradespace in Figure 8. The Tradespace includes two additional architectures beyond the down selected hybrid EHR: paper-based health records and Centralized EHR. The two are chosen as the best-in class for their respective categories.

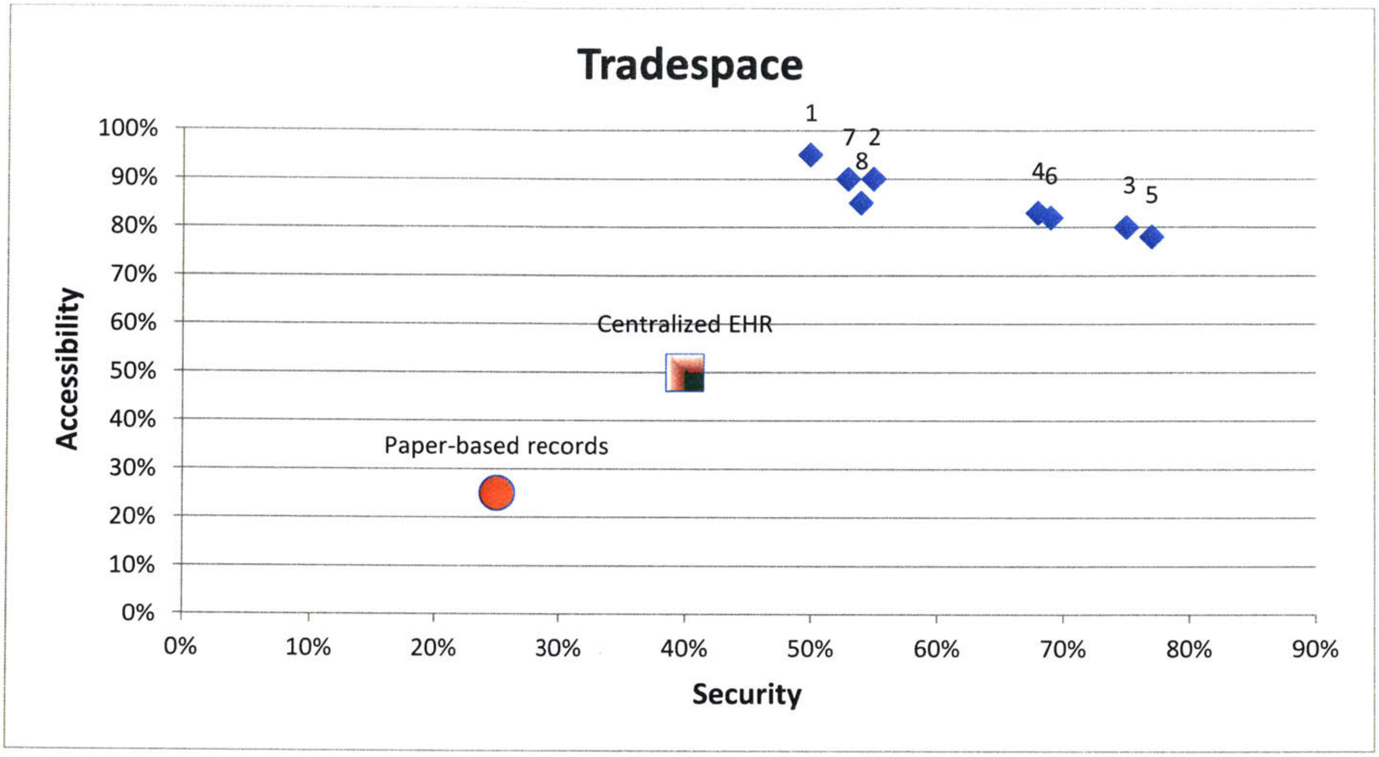

Figure 8: Tradespace exploration for Hybrid Distributed EHR Architecture

The Tradespace exploration is conducted for two metrics: Accessibility and Security. These two metrics are inherent tradeoffs for interoperability a key design parameter for this hybrid solution. Interoperability dictates the need to integrate as many providers, third party solution vendors, creating a significant amount of data. These vast amounts of data necessitate high computing resources, thus requiring highly scalable storage to handle high volumes of data. In essence this leads to another tradeoff: scalability versus operational costs. However, for this work we focus on the accessibility-security tradeoff.

The optimal architectures for distributed-ledger EHR solutions that respond to the System Problem Statement are reflected along the Pareto frontier. Highly accessible records are not necessarily highly secure and the reverse is true. As such, given the sensitivity of health records, high security levels are prioritized with fairly easy access to these records. The candidate architectures on the Pareto curve strike a good balance between ensuring health records are readily accessible by authorized entities whilst ensuring high levels of security.

6 Proposed Solution

Patient-centric EHR solutions are a crucial aspect towards delivering value-based healthcare, a concept that has evolved from value being attached to cost but to primarily quality of healthcare. In the previous sections we evaluated different candidate architectures that converge distributed-ledger technologies with the Internet of Medical Things to deliver personalized healthcare by leveraging interconnected, real-time Electronic Health Records. These hybrid architectures support the creation and management of Electronic Health Records that represent a universal record that is secure and accessible.

Distributed ledger technologies have the potential to resolve issues of immutability, transparency and health data interoperability. Whereas, the Internet of Medical Things (IoMT) connects various medical devices and applications, enabling machine-to-machine communication to providing a more personalized form of healthcare. Specific to Electronic Health Records, IoMT supports providers to collect real-time data and analyze it in a manner that allows for timely personalized care. To achieve value-based healthcare, interoperability of a plethora of applications and systems in healthcare in a secure and seamless manner is key.

Current EHR systems are dependent on direct and/or manual input of records into the system. This implies that such data capturing and creation mechanisms are prone to error. Erroneous input into the system trickles down into subsequent functions of EHR systems leading to misdiagnoses that threaten patient safety, failing to deliver any value but risks to the patient. More like the Garbage-In, Garbage-Out concept. The capability of a hybrid EHR architecture to capture and monitor vital signs in real-time to a large extent minimizes the potential for erroneous input. We talk about minimizing and not elimination of erroneous input mainly because there still exists a controversy on the accuracy of data captured from sensor-based medical devices with some arguing that the numbers and/or results are sometimes inaccurate (off by insignificant values).

6.1 Proposed hybrid architecture

In reviewing the key decisions that guided the concept enumeration exercise, we attempt to review functions of each technology in isolation of the other technology. The main functions of distributed ledgers include Records creation, classification, storing, tracking, data exchange/sharing, securing, analysis, and disposal. Whereas functions for IoMT technologies include real-time data capturing, interconnecting, analyzing, transmitting, data exchange, monitoring, storing, and decision-making and access control. We tend to see an overlap in some of these functions due to the choice of converging these two technologies towards designing an efficient EHR system. The choice of options for decisions that overlap takes into account the most effective and non-conflicting options.

Considering the Tradespace analysis, hybrid distributed-ledger EHR solutions that embody a permissioned model are the recommended architectures. Permissioned EHR systems are private ecosystems that provide access to a select group of providers that have expressed common interest and contribute towards providing bundled care for patients.

In down selecting the recommended candidate architectures, concepts 3, 4 5 and 6 strike a fair balance between making health data accessible in a highly secure manner. Further along, concepts 4 and 6 are eliminated by the subjectivity of the reporting function as well as Adhoc-monitoring capabilities. Subjectivity of patient reporting is purely based on how the patient perceives and communicates symptoms of illness. With the IoMT capabilities, personal healthcare devices such as wearables detect and transmit data about body changes in real-time providing a more objective manner of reporting symptoms. As such concepts 3 and 5 embody this capability and are preferred over concepts 4 and 5. Concepts 3 and 5 differ in their clinical decision support capabilities. Concept 3 uses knowledge-based decision support whereas Concept 5 adopts machine-learning based clinical decision support. In order to leverage both decision-support functions, a hybrid of concepts 3 and 5 is the recommended architecture for the distributed EHR architecture. Figure 9 depicts the recommended hybrid architecture from the Functional perspective.

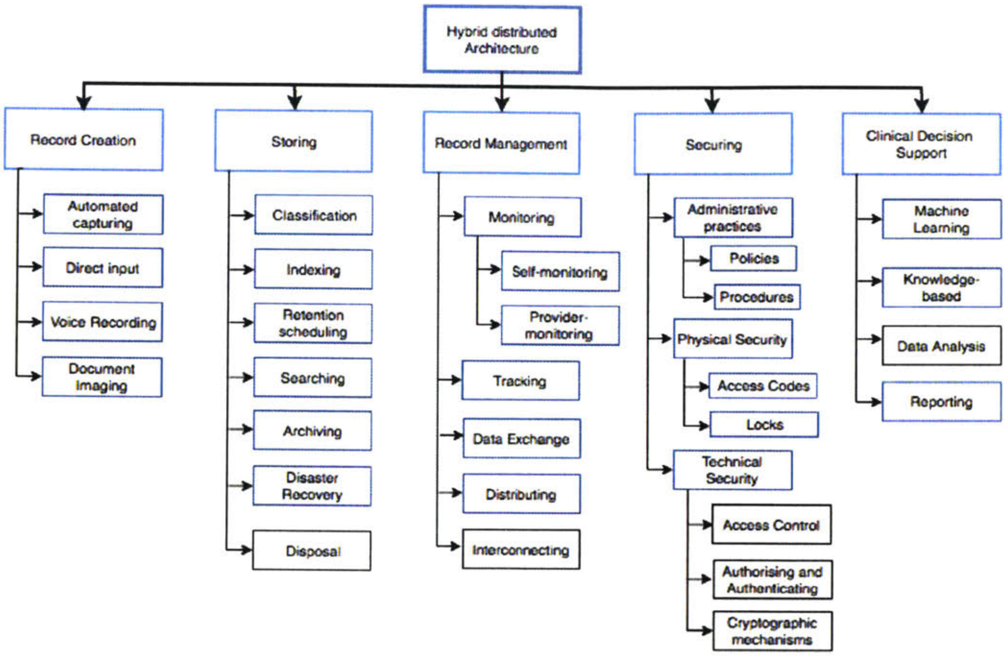

Figure 9: Proposed Functional architecture for Hybrid distributed-ledger EHR system

Following the 7 ± 2 rule, we categorize the system architecture into two levels, with some functions going further to level 3 to delineate which options have been selected for overlapping functions of both IoMT and distributed ledger technologies.

Given the literature review conducted and analysis conducted for the potential for a combination of eco-system technologies to transform EHRs towards delivering value-based healthcare, the following section reviews how the recommended hybrid architecture responds to some of the initial research motivation and questions.

First, the literature review exercise reveals that majority of EHR systems today are provider-centric, with records created, managed and exchanged in a manner that prioritizes provider needs, giving them more control over patient records. The shift from centralized EHR to a hybrid-distributed EHR presents a tradeoff between patient-centricity and provider-centered models. Distributed-ledger technologies allow distribution of control to patients via decentralization enabled by consensus algorithms. In addition, IoMT enables a shift of power from providers and caregivers to patients by empowering patients to monitor and participate in the decision-making process and care management.

Second, in the context of value-based healthcare models, access to personalized health data incentivizes providers to create value for patients, while the patient maintains control over which providers access and use their health data. The notion of value-based healthcare embodies a participatory model of healthcare that involves empowered patients rethinking their lifestyles to take charge of their health. Patient-led co-creation of preventive interventions is only possible if patients are central to the design and development of these interventions. The hybrid architecture places strong emphasis on the clinical decision support functionality, which relies on patients' medical history and current symptoms. Without a patient's consent to using their historical and episodic data, the possibility of this functionality is null. Additionally, with patients controlling access and use of their data, emerges the inclination to participate in the decision making process. The ability to share in the decision-making process is an aspect of value co-creation for healthcare service delivery. This hybrid solution will have the potential to store a plethora of data that is critical for research and can be used by public health researchers to identify population health risks and development new medication in a timely manner. The vast amounts of data produced are used for clinical research towards personalized healthcare, serving as an opportunity to collaborate when patients release their metadata.

Third, a hybrid solution for distributed EHR systems addresses issues of fragmentation that have plugged conventional systems, instilling shared interests and responsibility from stakeholders of a hybrid solution. However, hybrid solutions do require large upfront capital investments to implement them. Nonetheless, sustainability of hybrid solutions as opposed to conventional systems stems from (1) shared interests from all stakeholders; and (2) the vendor-neutrality design element prioritized when designing hybrid solutions.

Fourth, the convergence of these two technologies, distributed ledgers and IoMT, gives birth to new a functionality that would not necessarily be available using any single technology. An obvious emergent functionality from the convergence includes real-time patient self-management. In general, patients start to self-care when they detect visible/tangible symptoms, however with the convergence of IoMT, patients are able to monitor vital signs, before they get out of hand, and undertake preventative healthcare measures.

6.2 Benefits

The proposed hybrid EHR architecture offers a number of benefits over centralized EHR solutions and alternative hybrid architectures that were evaluated in the previous sections. These include but are not limited to:

- Comprehensive Clinical Decision Support functions that ultimately translate into predictive and personalized care;
- Supports bundled care through real-time capturing and monitoring of patients' progress leading to better healthcare outcomes;
- Enables data exchange between parties, thus removing the need for an intermediary. This could potentially translate into reduced costs, better scalability and faster time to market.
- Provides greater transparency with the use of audit trails that reveal modifications and their origination. Beyond audit trails, modifications are not made until consensus is established making it more difficult to initiate fraudulent or malicious intentions;
- Reduced medical errors as a result of the objectivity of health data collected from medical devices in combination with conventional subjective way of reporting symptoms;
- The use of IoMT to interconnect medical devices, applications and solutions ensures integrity from data generation to analysis with minimal human intervention. It is imperative that the data being used for clinical decision support functions data hasn't been tampered with as this directly translates into the predictions and decisions made;
- Given that the proposed hybrid architecture is built on a permissioned system, participants are incentivized not to deliberately undertake malicious acts as their identities are revealed;
- By and large, a patient controlling their medical records translates into an empowered patient that understands their medical health and actively contributes to preventive activities; and
- Real-time early diagnosis made possible through continuous remote monitoring coupled with real-time analysis of data from sensor-embedded medical devices. This is particularly important for patients with chronic conditions.

6.3 Future challenges

The key challenges that need to be addressed prior to implementing the hybrid architecture include:

i. **High costs** due to computing resources required for efficiently processing and maintaining records overtime. In general, investments into technological solutions such as the hybrid distributed EHR system tend to be high and absorbed by the healthcare providers, yet patients realize the most benefits of such system. This results into reluctance and resistance from healthcare providers to invest.

ii. **Scalability** of distributed systems can be infinite and thus increases the complexity of the system as it expands. If the hybrid system is not designed as an open platform that is vendor-neutral, the result will be a system that is less flexible to capturing future expansion needs. As second aspect of scalability is the **exponential growth rate of data** necessitating robust data mining and analysis tools.

iii. **Customer experience**, from both patient and provider perspectives, is crucial towards adoption of this hybrid architecture. This architecture creates a platform with enormous amounts of data that providers need to leverage for quality service delivery and with support of Decision Support system deliver personalized healthcare. The absence of providers mastering the art of using such systems will deprive the patient of the benefits. From an end user perspective, creating user-friendly interfaces is key to deriving driving buy-in and ultimately adoption.

iv. **Cultural and Mindset change** concerning health data that is viewed as proprietary data inhibiting health information exchange. Providers that control data and feel entitled to it, charge hefty fees for integration making it impossible for public health researchers to design timely interventions and for other providers to exchange data. Secondly, for a longtime healthcare is viewed as an in-person (face-to-face) intervention. The introduction of remote monitoring and diagnosis will require progressive cultural shifts.

v. A bigger problem is unstructured data that comprises a big chunk of health data stored in EHR systems. This necessitates standardization of health date prior to implementation of an industry-wide hybrid EHR solution. Unstructured data is usually recorded as free text, such as physician notes, with significant difference in the way data is represented.

7 Conclusion

In a large eco-system, such as the health industry, third party approvals are a major impediment to efficiency along the value chain of healthcare delivery. More so, medical records are at risk of misuse due to access provided to another party who does not necessarily provide added value to the exchanges across the network. Secondly, centralized authorizations take away from the ability to exchange value among stakeholders in a manner that encourages mutual benefits. Third, third party providers extract a fee for their services thus increasing the costs of healthcare across the board.

Adopting a distributed EHR system, not only addresses issues of seamless data exchange, costly healthcare and security of health data but also greatly contributes towards delivering value-based healthcare through provision of real-time data used to personalize care. As we enter into a technology revolution, value-based care continues to drive growth opportunities for emerging eco-system technologies.

The lack of interoperability across providers denies the industry the potential to deliver value-based healthcare. Thus, EHR solutions built on distributed ledgers with IoMT capabilities offer the industry a foundation for delivering value-based healthcare. It is recommended that implementation of a hybrid EHR that is distributed in nature connecting medical devices and solutions takes on a gradual, progressive approach as we transition from provider-centric EHR systems to patient-centered EHR systems.

7.1 Insights

Using systems engineering approach to create a hybrid EHR architecture has been beneficial in many ways. This systematic approach involved identification of stakeholder goals and needs for an architecture that converges foundational eco-system technologies; and determining functions that address stakeholder needs enabling lesser duplication of components and sub-systems. As discussed in previous sections, both distributed ledgers and IoMT shared a number of functionalities. This implies that designing the architecture from a form perspective would introduce multiple duplications at the component level. Conducting this assessment from a function perspective enabled understanding which functions overlap and/or components that might deliver the function better than the other.

Secondly, undertaking a systems thinking approach revealed two potential parallel roadmaps for implementing the recommended Hybrid EHR architecture: Transformational and leapfrogging roadmaps. While the initial thinking was to design a system that would leapfrog the healthcare industry, it became apparent during the concept enumeration exercise that leapfrogging an entire eco-system might not be the best roadmap given other aspects of technology readiness, costs and security that need to be taken into consideration for a complex industry such as healthcare. While it is possible to create a solution that leapfrogs the industry, it might take time and inhibit the industry from benefiting from other technologies that do not necessarily have the potential to radically transform the industry. As such, we separate architectural decisions into those that are capable of transitioning through standard stages and those that can be leapfrogged. Architectural decisions capable of leapfrogging include real-time collection of health records through the use IoMT and storage technologies.

7.2 Future research areas

In assessing the potential for a hybrid-distributed EHR towards transforming healthcare record management, several thrusts for future research that are not covered in this research work have been identified. First, given the focus of this work, research efforts were limited on conducting a financial model that looks into the Implementability, from a cost perspective, of the proposed solution. There is a need to conduct a detailed cost-benefit analysis of investing into hybrid distributed-ledger EHR systems. Much as the focus is on patient-centric solutions that create value for the patient, this assessment needs to take into account providers that will be shouldering investment and operational costs so as to garner their buy-in and adoption.

Secondly, this research work was not able to conduct a comprehensive Tradespace analysis for the various concept generated for the hybrid architecture. The absence of a target eco-system that would provide quantitative data used to conduct the analysis affected the ability to conduct an in-depth assessment. In addition, mapping out a detailed Tradespace of potential hybrid architectures should take into account other trades such as scalability versus cost as well as personalized care versus operational costs. More so, inputs from key stakeholders in scoring utility functions for the various architectural decisions should be considered.

Third, conducting a more general study on the potential of including other eco-system and/or complementary technologies such as Artificial Intelligence, data analytics that bolster IoMT and distributed ledger technologies.

Fourth, a separate study needs to be undertaken on the effect of regulation on emerging technologies and vice versa in the context of healthcare. This study should propose specific regulatory instruments that need to be in place to foster adoption of technological innovation in the healthcare industry. Distributed ledger and IoMT technologies are regarded early-stage emerging technologies and as such the current regulations do not necessarily control and support their implementation. A thorough assessment conducted jointly by the industry and regulators is required to determine the kinds of regulations needed and for what purposes.

Fifth, while the focus of this research work was on value-based healthcare, an in depth analysis on a hybrid model that differentiates which providers are reimbursed using on value-based model or fee-for-service model would be beneficial towards garnering buy-in for a shift away from a complete fee-for-service model. Alternatively, a hybrid of these models would focus on what portions of reimbursements should be accounted for using value-based models, with the remaining portion taking on a fee-for-structure option.

Last but not least, this research was not able to respond to the research question around risks presented by implementing a hybrid architecture that converges two foundation eco-system technologies. This would have been a fundamental element to consider in down-selecting some of the candidate architectures that were proposed and determining whether those disruptions would correct overtime.

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