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Challenges & Opportunities for Blockchain Powered Healthcare Systems: *A Review*

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Abstract

Blockchain, the technology that began with Bitcoin in 2009, today promises to provide the safe, interoperable sharing of real-time data between providers, payers and patients in the healthcare industry. Majorly, blockchain's automated data verification capabilities, in particular, are able to resolve many of the trust issues regarding pulling data from disparate sources. Applications of the technology in healthcare shows promise for solving issues such as its used in EHR distribution of data and nationwide interoperability. The use of blockchain in healthcare is expected to reinvent the ecosystem in limitless ways to benefit the patient and advancements in treatments, outcomes, security and costs. In effect, blockchain technology has the potential to transform healthcare delivery, placing patient at the center of the healthcare ecosystems and the capability to increase the security, privacy, and interoperability of healthcare data. It's envisaged that this technology is expected to provide a new model for health information exchanges (HIE) by making electronic medical records more efficient, disintermediated, and secure. One of blockchain technology's core offerings that make it a no-brainer for supply chains across industries is its immutable, time-stamped, tamper-proof ledger, accessible by its all or pre-approved participants. In this review paper we're to step through how blockchain aid in the providing efficiency, security and privacy to management of patient care.

Keywords: Blockchain, supply chain, provenance, traceability, security, counterfeit

1. INTRODUCTION

Blockchain is a decentralized and distributed digital ledger that is used to record transactions across many computers so that the record cannot be altered retroactively without the altercation of all subsequent blocks and the collusion of networks (Rabah, 2016a, 2016b). Further, it's a distributed tamperproof database that can be shared and maintained by multiple parties. Through the use of technology known as "cryptography," data can be stored in "blocks" in a manner that only the intended users can open and read or view but not alter in case of integrity. Cryptographic controls ensure the basic information security (CIA) together with the tenert of information assurance (CIA and A & NR). Each participant connected to the blockchain network has a secret private key and a public key that acts as an openly visible identifier. The pair is cryptographically linked such that identification is possible in only one direction using the private key. As such, one must have the private key in order to unlock a participant's identity to uncover what information on the blockchain is relevant to their profile**.** Thus, there is definitely a role for blockchain in the future of healthcare. In fact, technologists and healthcare providers and professionals across the globe view blockchain technology as a crucial way to streamline the sharing of medical records in a secure way to protect patients' personal data (or privacy) from hackers, insiders and outsiders, and give patients more control over their information.

In effect, blockchain technology has the potential to transform healthcare delivery, placing patient at the center of the healthcare ecosystems and the capability to increase the security, privacy, and interoperability of healthcare data. It's envisaged that this technology is expected to provide a new model for health information exchanges (HIE) by making electronic medical records more efficient, disintermediated, and secure.

Furthermore, the arrival of blockchain in healthcare has great implications in future of healthcare services that spans a gamut, including patient medical records, clinical trials, master patient index, healthcare supply chain, and revenue cycle management among others. Moreover, the potential to establish a longitudinal health secure record for patients, which is also securely accessible to all of their clinicians, could be supported by blockchain – and this of course, is expected to significantly increase patient quality care. More-so, the traceable nature of blockchain transactions could reduce improper billing, prevent unauthorized staff members from accessing patient records outside of their purview, and even address issues such as counterfeit drugs and inappropriate prescribing.

Blockchain technology, in our view, could also be applied in the context of high-tech precision medicine and to population health. Population health has been defined as "the health outcomes of a group of individuals, including the distribution of such outcomes within the group". It is an approach to health that aims to improve the health of an entire human population. Thus, importance of population health powered by blockchain technology can provide the means to aggregate and identify where data are – so that organizations can access patient data on a large scale. This, in conjunction with advancement of interoperability and security are of paramount importance in healthcare – and blockchain technology is being considered as a resource that can significantly increase the efficacy in this important area of healthcare (Ross & Kieffer, 2017).

Just to figure-out the complexity and chaos that informs the current healthcare systems; for example, currently, there are 26 different electronic medical records systems in use in Boston city alone, and each with its own language for representing and sharing data. More-so, critical information are often scattered across multiple facilities, and in most cases, isn't accessible when it is needed most – a situation encountered by medical practitioners and plays out every day around the US and other parts of the world – costing money and sometimes even lives. This is a clear problem that that is tailor-made for a blockchain technology to solve. For blockchain in healthcare, we can envisage a case when a doctor sees a patient or writes a new prescription, the patient agrees to have a reference or "pointer" added to a blockchain. Now instead of payments, this blockchain would record critical medical information in a virtual incorruptible cryptographic database, maintained by network of computers that is accessible to anyone running the software (Rabah, 2016a, 2016b). Thus, every pointer a doctor logs on the blockchain would become part of a patient's record, no matter which electronic systems the doctor is using – in effect, and the beauty of this, any caregiver could in essence use it without worrying about incompatibility issues. However, before we can see an industry-wide evolution in medical records, a new technical infrastructure – a custom-built "healthcare blockchain" – must be put in place (Orcutt, 2017).

Currently, individuals, IT vendors, consulting firms and pharmas are also included in the organizations that are expected to be using this digital technology to their advantage. For example, Google and IBM are developing blockchain tools with more focus now directed towards interests in healthcare services. Some of these proto-type devices could, for example, be a client proto-type global, blockchain-based patient identifier that could be linked to hospital records as well as data from other sources like employees' wellness programs and wearable health monitors. There is no denying that blockchain is a new and important strategic resource for healthcare solutions.

In fact, the US Office of the National Coordinator for Health Information Technology of late has issued a shared nationwide interoperability roadmap, which seeks to define critical policy and technical components required for nationwide interoperability that should include:

- Ubiquitous, secure network infrastructure
- Verifiable identity and authentication of all participants
- Consistent representation of authorization to access electronic health information, and several other requirements.

The only thing limiting the realization of the dream is that current technologies do not fully address these requirements, because they encounter problems related to security, privacy, and full ecosystems interoperability.

Moreover, today when we think about all the data held in the EHR, the question that pops-up, what do you put in it? Genomic data, hospital records, immunization records, lab results – well, there is an enormous amount of data that can be held in EHR. However, with blockchain, everything you have in relation to your health records can easily be put into the blockchain, in which case, the patient has ability to manage their own health record – in away, the patient can go to a doctor, and with token in his possession, allow the doctor to access his personal records. This should eliminate the often bothersome questions the doctors ask like "what medicine are you taking? What is your wearable telling you?" By giving patients control over their data, the technology could enable better privacy protections, more efficiency and easier information exchange.

Clinical Health Data Exchange and Interoperability

In bringing in the blockchain into healthcare realm, data exchange is typically the most crucial topic that needs to be tackled in the first place. Blockchain powered healthcare information systems is expected to provide technology solutions to currently existing challenges, including healthcare data interoperability, security, privacy and integrity, portable user-owned data among others. In fundamental way, blockchain would enable data exchange systems that are cryptographically secured and irrevocable. This should give rise to seamless access to historic and real-time patient data, while eliminating the burden and cost of data reconciliation. For example, the recent collaboration between the Estonian eHealth foundation, and the Guardtime, the data centric security company to secure the health records of one million Estonia citizens, using its proprietary Keyless Signature Infrastructure (KSI) – is a classic example of application of blockchain technology. However, due to currently existing complexities surrounding data ownership and governance structure for healthcare data exchange between public-private entities – however, it would be difficulty to replicate the Estonian scenario globally.

Claims Adjudication and Patient Billing Management

Current existing patient billing management systems are at best complex and prone to manipulation by the service providers – today, an estimated 50% of healthcare costs are fraudulent, resulting from excessive billing or billing for non-performed services. For example, in US alone, Medicare fraud caused around $30 million in losses in 2016 (Das, 2017). It's believed that the advent of blockchain powered healthcare systems is expected to provide realistic solutions or minimizing the medical billing-related frauds – through automation of the majority of the claim adjudication and payment processing activities – that is, blockchain systems would help eliminate the need for intermediaries – and thus, reduce the administrative costs and time for providers and payers. It could also have significant ramifications or improving some of the huge logistical information tracking hurdles of reliability-centered maintenance (RCM) functions. Recently, Capital One in collaboration with Gem Health, have successfully developed a blockchain application platforms for enterprises to provide blockchain-based healthcare claims managements solutions.

To drive the point home, in one of the study, it was found that physician practices spend about $70 billion in 2012 on bureaucratic paperwork. Further, hospitals spent and an estimated $74 billion on Billing and Insurance-related (BIR), and other institutions, such as nursing homes, home healthcare agencies, prescription drug and medical supply companies, have spent an estimated $94 billion on these money chasing tasks. In a similar manner, private insurers spent $198 billion on BIR, whereas public insurers, e.g., Medicare and other government-sponsored programs, spent $35 billion on such activities. In another study conducted by NIH in 2014 by a group of physicians and health policy researchers with ties to USCFS and Harvard Medical School found that, in 2012, an estimated $375 billion went into waste in Billing and Insurance (BIR)-related paperwork. It was observed that 80% of the $471 that is spend on BIR activities is embedded waste – resulting from the inefficiencies due to financing systems (de Brantes, 2017).

Drug Supply Chain Integrity and Provenance

Another complexity that is currently weighing in on the medical drug supply industry is related to massive loss from counterfeit and pilfering. Provenance – tracking of assets across a supply chain – has emerged as an early application area for blockchain and solutions in the area – have been proposed by a number of healthcare technology service providers. Within one value chain – the pharmaceutical supply chain for drug products – many use cases exist across the board where there's an opportunity to leverage blockchain technology, because in this value chain there are many points where processes break down due to a lack of transparency and coordination in the entire supply chain network. Supply chain security is one aspect that has recently won attention, when the Drug Supply Chain Security Act (DSCSA) implemented in the US to, amongst others, fight the counterfeit drug problem. Based on current industry estimates, pharmaceutical companies incur an estimated annual loss of $200 billion due to counterfeit drugs globally. One of the core challenges of the industry is the assurance of the chemical composition of the drugs themselves. From manufacturing errors to complex supply chain processes, there are a number of things that can impact why a drug is either ill-made, spoils in a shipment, or entirely counterfeit.

The point is driven home, when say, you look at the realities of unit-level traceability in the supply chain, especially for a supply chain the size of that in the United States, there are exist mind boggling challenges especially with data exchange, challenges around trust for sharing data across the supply chain, and challenges for ensuring the immutability of the data associated with a product and the transactions associated with it. In the recent articles covering efforts in the investigation of the world counterfeit drug menace – it led to the seizure of counterfeit drugs valued at $74 million (Aboody & Lev, 2000), and on a large scale, an estimated annual loss of $200 million for pharmaceutical companies due to counterfeit drugs (Danzon, 1998). Such developments lead to deliberations about the level of sophistication of criminal organizations and effectiveness of the global operation for counterfeit drugs. This large scale operation of counterfeit drugs in the end damages the reputation of pharmaceutical companies and endangering the lives of patients.

It's estimated that 30% of drugs sold in developing countries are considered to be counterfeits. Counterfeit drugs are drugs that do not contain the active ingredients they are supposed to and consequently can harm patients. The World Health Organization (WHO, 2010) estimates worldwide sales of counterfeit medicines to $75 billion in 2010, a 90% rise in five years. However, it's envisaged that with the implementation of blockchain-based supply chain systems, could ensure a chain-of-custody log, with ability to track each step of the supply chain at the individual drug/product level. Moreover, additional add-on functionalities such as private keys and smart contracts could help to build in proof of ownership between different parties. This is very exciting to pharma industry, which with the help of blockchain for health, could be on the verge of solving a longtime problem: How to stop a flow of stolen or counterfeit pills from entering the supply chain and trickling down to patients. To-date, it's known that Pfizer is leading a group of companies to develop

MediLedger Project, which is creating blockchain tools to help manage pharmaceutical supply chains. Another company, Genetech, view blockchain as a logical extension of its efforts to assign unique traceable numbers to pharmaceutical products.

Other major areas of weakness in healthcare supply chain, which still require overhaul, is drug exchange channels – there are many links in the supply chain with multiple, incompatible legacy computer systems and so there is little visibility for manufacturers into end-customers sales by pharmacies. Components of this messy situation are:

- Pharmaceutical companies and pharmacy retailers are often involved in marketing alliances, involving rebates, co-paid ads, coupons and other costs to boost exposure for a product. Getting a clear picture of which drugs sell best is tricky.
- The product returns process is broken, leading to multiple rebates for the same batch of product and an unclear view of how many drugs are in the market. This makes it more difficult to discover counterfeit drugs.
- Third party companies are paid to provide research on the movement of pharmaceuticals, which is expense that could be cut completely with a blockchain-based tracking system linking all parties in the chain.

Pharma Clinical Trials Population Health Research

Clinical trials start with initial human testing on healthy volunteers followed by testing in a larger group of patients to establish safety and efficacy. Today, the world of clinical trials is complex and extremely mucky to say the least. It's currently estimated that 50% of clinical trials go unreported and investigators often fail to share their study results – e.g., nearly 90% of trials on ClinicalTrials.gov lack results. In effect, this ends up creating crucial safety issues for patients and also resulting in knowledge gaps for healthcare stakeholders and health policymakers. However, the arrival of blockchain-enable, time-stamped immutable records of clinical trials, protocols and results could potentially address the issues of outcome switching, data snooping and selective reporting – thus, reducing incidence of fraud and error in clinical trials records. Moreover, blockchain-based healthcare systems could end-up helping drive unprecedented collaboration between participants and researchers around innovation in medical research fields like precision medicine and population health management.

Cybersecurity and Healthcare IoT

Just as important for HIPAA requirements and data security, medical facilities and pharmacies would not have to send data back and forth to see it. They would merely have to point to the same common "health" ledger. Today, due to the poor IT infrastructure network security implementation in the enterprises means that there are numerous unreported network breaches taking place every year across the globe endangering organizations and individual personal data – occasionally, perpetuated by external hackers and internal attackers. According to Protenus Breach Barometer report, there were a total of 450 health data breaches in 2016, affecting over 27 million patients. It's important to note that insider attackers were responsible for 43%, while 27% was due to hacking and ransomware attack by external attackers. Furthermore, with increasing growth of connected healthcare devices, it will continue to be very challenging for existing health IT infrastructure and architecture to support the ever evolving IoMT (Internet of Medical Things) ecosystems. It is estimated that by 2020, there will be 20-30 billion healthcare IoT connected devices in use globally. However, intervention through blockchain-enable solutions is expected to potentially bridge the gap of device data interoperability while ensuring security, privacy and reliability around IoMT applications. Many companies are already actively working in this area, for example, Telstra (user biometrics and smart homes), IBM (cognitive IoT), and Tierion (industrial medical device preventive

maintenance). This level of security and scalability makes this incredibly appealing to the doctors and hospitals that need secure access to a patient's entire health history.

The Mechanics of Blockchain in Healthcare

Here let's look in summary at how we can use blockchain in healthcare service that could allow us to manage drug safety, that is:

- *Drug Traceability* provided by provenance where each transaction between drug manufacturers, wholesalers, pharmacists and patients can be tracked to verify and secure drug product information important for tackling issues such as counterfeit drugs.
- *Improvement and authentication of health records* and protocols on record sharing.
- *Detecting drugs* that, by error, do not contain the intended active ingredients they are meant to can lead to patient harm.
- *Smart contracts* where certain rule-based methods are created for patient data access. Here, permissions can be granted to selected health organizations.
- *Clinical trials* where altering or modifying data from clinical trials fraudulently can be eradicated.
- *Precision medicine* where patients, researchers and providers can collaborate to develop individualized care.
- *Genomics research* via access to genetic data secured on blockchain
- *Electronic health records (EHRs)*
- Nationwide *interoperability*
- *Recall management*, where one million people are killed each year worldwide from counterfeit drugs. Better tracking through the supply chain has significant effect at the human level.
- *Prescription drug abuse*, which is often made possible by disconnected healthcare records across hospitals, walk-in clinics, doctors and pharmacies.

Blockchain specific application to EHRs:

Blockchain can help enhance three major features of EHR systems which are:

- *Immutability via File Integrity* where each event on the blockchain has a unique hash corresponding to the contents of a record. This means users can verify if the contents of the record have been changed or not.
- *Cybersecurity via Data Access Management* where each hash may contain particular user permissions for doctors, patients, nurses or any authorised user or device. Therefore, only authorised personnel may access record information.
- *Interoperability via Collaborative Version Control* where each party has a record linked to the original record that is registered to the blockchain. This way, everyone who has the appropriate role and responsibility, can append information to the record avoiding issues such as inconsistent or duplicate records.

Current Market and industry trends in Blockchain

According to Statista (2016), the size of the blockchain technology market worldwide from 2017 to 2021 will be expected to grow to 2.3 billion U.S. dollars by 2021 from 339.5 million U.S. dollars in 2017. These estimated forecasts are based on an annual constant growth rate of 61.5%.

Factors driving the blockchain market include:

- Limited access to population health data.
- Inconsistent rules and permissions for accessing patient data.
- Varying data standards, which reduce interoperability as a consequence of non-compatibility between systems.
- Privacy and security such as confidentiality of protected health information and from hacking attacks.
- Fraud and abuse.
- Consumer engagement such in in the form of disease and management and clinical outcomes.

Factors inhibiting the growth of the blockchain market include:

- Immature infrastructure where most blockchain technology is untested and experimental.
- High development costs.
- Patient-controlled data can be risky.
- Scalability constraints in terms of tradeoff between volume of transaction and computer power for processing time of transactions.

CONCLUSIONS

Decentralized databases powered by blockchain promises to revolutionize medical records and healthcare service delivery, but not until the healthcare industry buys-in to the idea and gets to work. Blockchain technology applications in healthcare show promise for solving issues such as its use in EHR distribution, exchange of health data and nationwide interoperability. However, more research, trials and experiments must be carried out to ensure a secure and established system is implanted before using blockchain technology on a large scale in healthcare.

In effect, blockchain technology has the potential to transform healthcare delivery, placing patient at the center of the healthcare ecosystems and the capability to increase the security, privacy, and interoperability of healthcare data, not to mention reduction service delivery costs. It's envisaged that this technology will provide a new model for health information exchanges (HIE) by making electronic medical records more efficient, disintermediated, and secure. In fact, the nature of blockchain environment is also expected to smooth over issues of patient consent for data sharing – and which now is major obstacles of developing a health information exchange system.

Blockchain technology is expected to benefit patients interacting with healthcare systems by reducing their waiting times and avoiding repetitive registration processes. It will reduce manual paperwork and overheads and underlying costs by providing transparent and immutable personalised healthcare records that can be accessed from anywhere in the world, Universal EMR. It's hoped that blockchain will become the most innovative healthcare technology ever by creating a trusted peer-to-peer network for sharing information and value.

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