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Blockchain in healthcare – a blessing in disguise

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ABSTRACT

Technology transformation is on the sweep. And Blockchain is another technology marvel impacting several fields including healthcare. Patient Centered Outcomes Research and Precision Medicine Initiatives are in the forefront and blockchain can add value to these initiatives. Blockchain is a peer-to-peer distributed ledger technology for a new generation of transactional applications that establishes transparency, trust and audit trail. Its framework comprises three components: distributed network, shared ledger and digital transactions. This technology provides scalability, security and data privacy allowing patients, researchers and healthcare community to access shared, accurate and comprehensive health data which includes data from mobile applications, EMRs, Wearable sensors, document and images. Also, it works with standard algorithms and protocols for cryptography and data encryption. Another advantage of block chain is built-in fault tolerance and disaster recovery. The paper provides overview of the technology and its impact in healthcare domain.

INTRODUCTION

Healthcare industry always rides on rough waters – trying to strike a balance between regulating costs and timeline without comprising quality. Market disruptive technologies are playing the role of a savior and evolution of the industry is guided by technology. The eye of regulation being the most important factor in healthcare, industry leaders must ensure transforming technology into use cases which meets regulatory requirements.

Blockchain is a platform that eases the dependence on a single, centralized authority, yet still supports secure transactions directly between interacting entities. It offers decentralization, immutability, and consensus via cryptography. This technology provides the foundations for several application domains including healthcare.

There has been a recent push towards patient-driven interoperability, in which health data exchange is patient-mediated and patient-driven. The shift towards patient-centered interoperability is an important trend that has the potential to lay new groundwork for data sharing in healthcare. Patient-centered interoperability, however, brings with it new challenges and requirements around security and privacy, technology, incentives, and governance that must be addressed for this type of data sharing to succeed at scale, and many of these challenges are still not solved for traditional interoperability. Thus, it is appropriate to look for novel or disruptive interventions that could be applicable in facilitating the shift to patient-centered interoperability. Such interventions could ease the tension between the advantages of data liquidity—clinical, research, operational—and the substantial barriers to interoperability that define the landscape of health data sharing.

CURRENT STATUS

In the healthcare sector, critical patient data and information remains scattered across different departments and systems. Due to this, crucial data is not accessible and handily available in times of need. The existing healthcare ecosystem cannot be considered complete as multiple players in the system do not have a system in place for smooth process management. Moreover, inadequate handling exchange of information is a concern too and looks forward for solutions in these areas.

The misuse of available data is preventing healthcare organizations from delivering appropriate patient care and high-quality services for the sake of better health. Despite being efficient in terms of economy, these organizations are not able to fulfill the needs of patients. Following are a few stats from resources that emphasize on this fact:

- Certain % of clinical trials across the globe are unreported
- Up to 40% of healthcare provider data records are filled up with errors or misleading information



- Healthcare data breaches in organizations are estimated to cost around \$380 per record in the current times. This amount is expected to increase with the passing of time.

Many healthcare facilities today are still dependent on outdated systems for keeping patient records. These systems hold the functionality of keeping local records of the patient data. This can make it difficult for the doctor to diagnose which is time-consuming for the doctor and tedious for the patients too. Due to this, the cost of maintaining a patient-oriented business is increased considerably.

Issues prevailing in the current healthcare sector are not limited. They keep on growing with high-intensity with time. The need for a technically advanced system is undeniable. Consider the problem of drug counterfeiting which leads to losses of around \$200 million. It could be diminished dramatically if a system with accurate tracking features is put into place in the supply chain.

Another time-consuming and tedious process that results in high costs in the healthcare industry is Health Information Exchange. Since patients don't have any control over their data, the chances of identity thefts, financial data crimes and spamming are increasing every day.

Despite having gadgets like computers and mobile phones at every healthcare facility these days, we're still not able to collect, analyze, secure and exchange data seamlessly. Therefore, the healthcare system today not only needs an advance system rather it also needs a system that is smooth, transparent, economically efficient and easily operable.

BLOCKCHAIN

Blockchain is one of the most disruptive technologies that has taken the world by storm these days. This is a type of shared distributed digital ledger, which allows every event that a piece of data undergoes - whether it is viewed, used or changed - to be recorded indelibly. As each event occurs, information on the event is added as a 'block' connected - in sequence - to the one recording the previous event. As the data in the blockchain is recorded on a distributed, peer-to-peer basis, it creates an ever-growing, permanent record that cannot be altered retroactively; nor can the sequence of blocks be changed without it affecting all subsequent blocks. This means that it can provide a robust method of confirming data integrity as well as a permanent log of all events undergone. It could also allow the use of distributed health databases that need to be rapidly synchronized each time there is transaction.

The working of a blockchain relies on three major principles that have existed for long. Compiled working of these principles allows blockchain to provide secure and safe digital relationships.

- **Private key cryptography**—In private key cryptography, a secret key is used as a variable along with an algorithm to encrypt and decrypt the code. The key is kept secret even when the algorithm is not. In a blockchain, a reference of the secure digital identity is created, however, the transactions are on the open network.
- **Distributed ledgers**—A distributed ledger also known as a shared ledger is referred to as a consensus of shared records. In DLT, the ledger is updated in real time and no central authority is held responsible to maintain the ledger. Instead, network participants keep the ledger updated. Any changes made in the ledgers are reflected within seconds.
- **Authentication**—Authentication is a process that proves genuineness. In a Blockchain, all the transactions are authenticated before getting added to the chain. This process takes place through algorithms that validate and verify all the transactions. Once the information is encrypted and digitally signed and stored, the authenticity is sealed.

Healthcare firms, technology innovators and the members of overall healthcare sector are looking out for ways to find out what's possible in the current times and what blockchain could do to make healthcare better and affordable in the future. Blockchain allows the creation and sharing of a single common database of health information. This system would be accessible by all the entities involved in the process no matter which electronic medical system they use. This offers higher security and transparency while allowing doctors find more time to spend on patient care and their treatment. Moreover, it will also enable better sharing of statistics of researches which, in turn, would facilitate clinical trials and treatment therapies for any rare disease. In a healthcare system, smooth data sharing between healthcare solution providers can lead to accuracy in diagnosis, effective treatments, and cost-effective ecosystem. The day-to-day growth of patient data requires proper utilization of resources in order to make the most effective utilization of the insights discovered through it.



Blockchain for healthcare allows multiple entities of the healthcare ecosystem to stay in sync and share data on a commonly distributed ledger. With such a system in place, the participants can share and keep a track of their data and other activities happening in the system without having to look out for additional options for integrity and security. As per the requirements and access permissions for the network participants, two types of blockchains can be used:

Permissioned Blockchains

These type of blockchains, as the name suggests allowing real-time data to be shared between the participants of the network only on a permissioned basis. A permissioned blockchain is a closed network where all the participants involved in the system have access to the network. It is built and used inside organizations and enterprises in order to exchange information and make transactions securely. Once a transaction is processed through consensus, it will be treated as a permanent record and get added as a new block to the existing blockchain.

Permission less Blockchains

Permissionless blockchains provide access to anybody for creating an address of their own and begin interacting with the network. One of the most popular examples of a permissionless system is the internet which allows anyone to create their own website. Similarly, in a permissionless blockchain, anyone on the network can interact with other participants on the same network by creating their address on the network.

Among the two of these, private or permissioned blockchains can be effectively used in healthcare in order to make the right decisions within the healthcare ecosystem. The use of Blockchain technology in healthcare holds a lot of potentials as it is being explored further. Holding properties like immutability, trust lessness and decentralization, the distributed technology of blockchain provides the healthcare sector with opportunities to detect fraud, reduce operational costs, smoothen processes, remove duplication of work and apply transparency in the healthcare ecosystem.

Frost & Sullivan research for Blockchain Technology in Global Healthcare, 2017–2025 states that- “Blockchain technology may not be the panacea for healthcare industry challenges, but it holds the potential to save billions of dollars by optimizing current workflows and disintermediating some high-cost gatekeepers.”

Figure 1. Illustrative Healthcare Blockchain Ecosystem

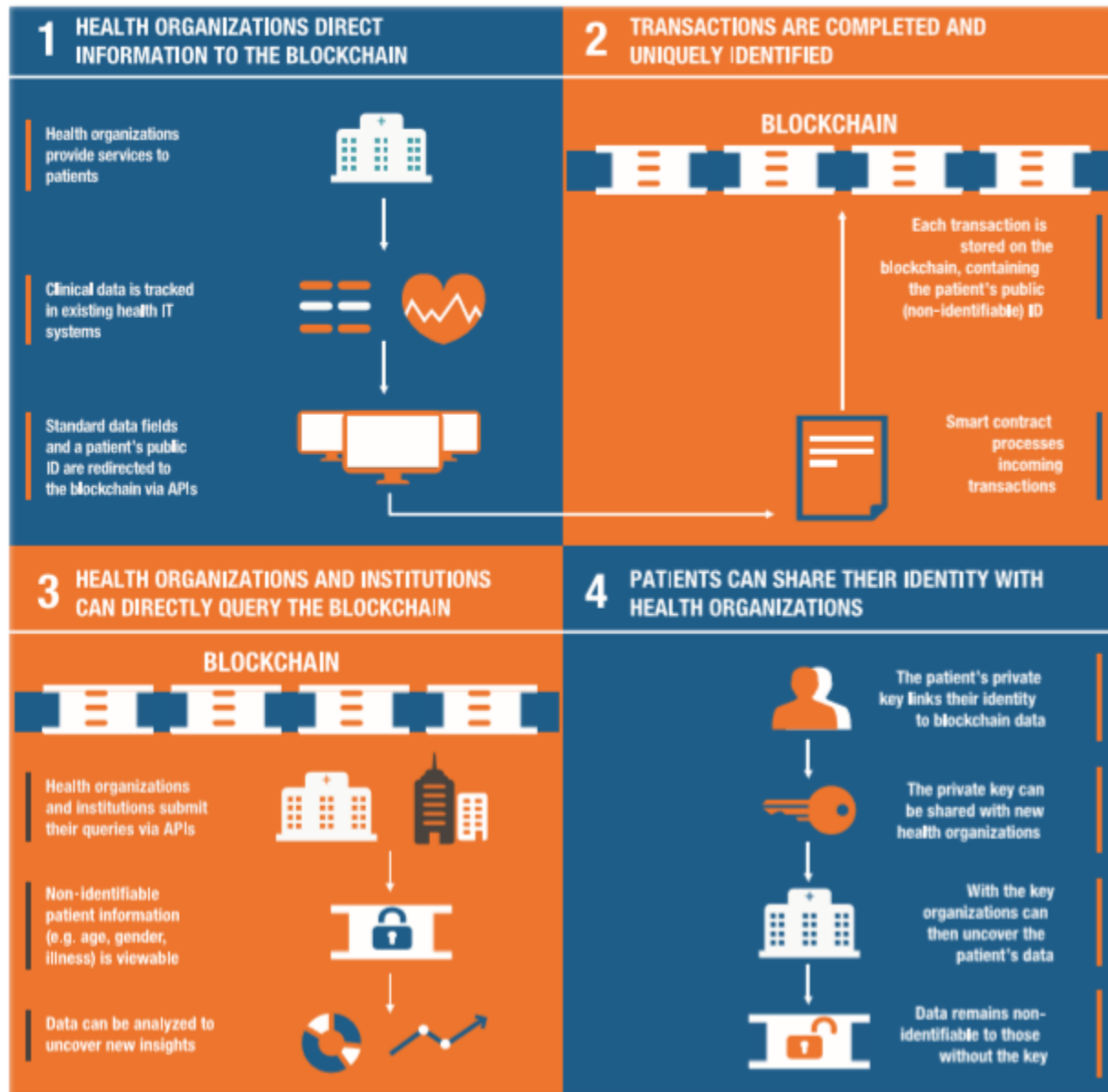


Image courtesy: Deloitte



ADVANTAGES OF BLOCKCHAIN

INTEGRITY

Blockchain's distributed ledger and immutable transactions helps ensure data integrity while encryption of data enhances data security across the network. With the implementation of Blockchain technology, multiple instances of obsolete patient data with various stakeholders are replaced with single source of up-to-date information of patient information. Patient is the custodial owner of data controlling who has access to PHI information.

SECURITY

Security in healthcare industry encompasses various aspects based on integrity of data maintained in an organization. Tampering and security breach of healthcare data is a growing concern for many healthcare organizations. It is difficult to tamper with data present in blockchain as it requires validation from different nodes in the chain. Blockchain offers inbuilt security features as the data in blockchain is encrypted with private key of the sender and only intended recipient can decrypt data using key from the sender.

INTEROPERABILITY

Today healthcare organizations are at different maturity levels as far as interoperability of healthcare data is concerned. There are some organizations who are exploring use of FHIR, while several organizations are using the CDA standard for data exchange and some share data using HL7 2.X standard. Varying data standards across organizations is another challenge which reduces which hamper Quality scores interoperability. Blockchain helps overcome this challenge by accessing data through APIs. With transfer of data through APIs, blockchain achieves standardization of data format, which is used to transmit data irrespective of the capabilities of EHRs to communicate different HL7 versions.

COST OF MAINTENANCE

Maintenance of a typical healthcare information system involves various operations including but not limited to performing backup storage services, having recovery mechanisms in place and ensuring up to date fields. In case of blockchain, data is distributed across the network and there is no single point of failure leading to inherent backup mechanism.

Also, a single version of data is copied on every node of the blockchain. This reduces transaction volume that occurs between each information system reducing the burden on the healthcare ecosystem.

UNIVERSAL ACCESS

Managing access to patient data across healthcare entities is a challenge where Blockchain can help. Blockchain ensures that required data is present at every node and is available for use to the authorized entities based on the access rights provided through smart contracts or other mechanisms.

DATA PRIVACY

The goal of HIPAA is to keep personally identifiable information (PII) and personal health information (PHI) private and secure. HIPAA limits how and under what circumstances this data may be used without patient authorization. A blockchain solution could assist with HIPAA compliance by segregating and encrypting patient identity, PII and PHI into discrete units, accessible at any time by those who have authorization to do so. In addition, blockchains are an ideal platform for regulatory compliance because they establish a trusted audit trail that can be verified in real-time. Blockchains don't merely track compliance; they also streamline enforcement and discourage fraudulent behavior from the beginning.

DISASTER RECOVERY

Blockchain removes the need for a centralised infrastructure as the distributed ledger automatically synchronises and runs across all nodes in the network by design. As a result, Disaster Recovery (DR) is essentially built in, eliminating the need for a synchronised DR plan. The inability to alter entries in the ledger also contributes to the overall security of the blockchain, improving resilience against malicious attacks.



POTENTIAL OPPORTUNITIES:

There are existing use cases where blockchain potentially offers an advance or opportunity:

SUPPLY CHAINS:

Different industrial sectors are already exploring the potential of blockchain in enhancing integrity and traceability in the supply chains [8]. With modern medicines commanding premium prices, pharmaceuticals are an attractive prospect for counterfeiters. Although an anti-counterfeiting system based on QR codes already exists in Europe, it has some fallibilities; blockchain could add a further layer of integrity for guaranteeing product integrity. India has teamed up with Oracle, Apollo Hospitals and Strides Pharma to track drug supply chain using blockchain solutions.

Oracle's blockchain software permanently registers a drug's record in the manufacturer's drug supply chain (serial number, labelling, scanning), leaving no scope for record tampering. From here on, at every point of hand change, it records the drug's movement – from manufacturer to logistics, from stockist to hospital, or from pharmacy to consumer. In case of a fake drug, the software will detect irregularity and notify the concerned nodal point. Besides, Oracle IoT will provide options to track critical information such as chemical ingredients of the drug or maintenance of temperature control in case of life saving drugs or vaccines.

DRUG VERIFICATION:

The ability to verify the authenticity of drugs at the point of dispensing, (e.g. community or hospital pharmacy) is an example of cross-sectoral use of blockchains with the pharmaceutical industry. While there are already many examples of blockchain use for secure supply chain within the industry and its suppliers, there are only few at the caregiver level. Yet, information such as a medication's authenticity, its expiry date and special requirements such as handling conditions or the ability to organize product recalls, is vital and would enhance patient safety.

REIMBURSEMENT:

Payers, patients and healthcare providers could use and exchange data more easily to verify insurance coverage. By creating trusted relationships between all participants and by storing transactions and contracts on a shared ledger, blockchains would allow a consistent, automatic contract execution environment. This could sharply reduce the level – and cost – of administration.

CONTROLLED ACCESS:

Controlling the access to shared Electronic Health Records. Blockchain will contain references to the EHR data, while Smart Contracts will define and enforce access rules to EHR content. This will ensure that only authorized persons access the EHR data. In addition, the blockchain provides an irrevocable record of all events that the data has undergone. All these will enable population health management and research.

CLINICAL TRIALS:

Blockchain could help make clinical trials reliable at each step by keeping track and time-stamping at each phase of the trial (trial protocol, patient enrolment, data collection, trial monitoring and data management and analysis). This could reduce waste - a great deal of trial data is not captured - minimizing reporting errors and avoiding accusations of data manipulation or selective reporting. The COMPare Trials Project found that out of 67 trials they examined, only nine were correctly reported; 354 outcomes were not reported, and 357 new outcomes were silently added. This casts doubt upon the accuracy of medical information derived from clinical trials and the resulting care that patients receive. To create transparency and trust, those conducting clinical trials could use blockchain to record and time-stamp each event in the trial's protocol. This would prevent selective reporting, ensuring that reporting of trials is correct and not "spun" to achieve a desired outcome.

MEDICAL DATA MANAGEMENT:

Because blockchain can simplify the exchange of data across authorized parties, it can be applied in healthcare to enhance the management of electronic health records (EHRs). Current health information exchanges (HIEs) are hampered by several technology issues, including the need for an intermediary trust network, data interoperability issues and inconsistent rules and permissions.

These issues prevent the safe transfer and sharing of data. However, it is now possible for healthcare organizations to build blockchains based on data pulled from existing databases, creating a complete data picture and single source of truth.



This paves the way for an HIE that is patient-mediated. Patients would be the owners of their own data, accessible to each individual via the blockchain private key mechanisms. Patients could share this data with whomever they choose within their healthcare team. This would give patients and the caregivers of their choice a longitudinal history of their health.

BILLING MANAGEMENT:

While complex billing procedures can lead to unintentional inaccuracies, intentional medical billing fraud is a serious issue. In July 2017, a Medicare fraud task force charged more than 400 people, including dozens of doctors, with defrauding the government of \$1.3 billion. Current processes are incapable of detecting all instances of fraud. Blockchain's security and auditability make it an ideal choice for claims adjudication and payments processing, as well.

IMPLEMENTATION METHODOLOGY:

- **Mapping phase:**

Blockchain technology is evolving rapidly, and new developments emerge weekly. As the technology advances and new applications become possible, the Office of the National Coordinator can play a valuable role in convening stakeholders from health care providers, plans, life sciences companies, startups and academics to discuss progress, share lessons learned, and identify unanswered questions. To that end, HHS could develop a sensing mechanism to track promising new startups and establish a forum for connecting them to more established organizations to undertake experiments

- **Design phase:**

Blockchain experiments could help HHS to determine what the technology can readily accomplish. The experiment design should look to addressing holistic work stream problem sets with transactions crossing multiple parties from creation to archival storage. Creating the experiment early and following it through complete transaction cycles can help developers and policy makers to address friction points and identify areas of advantage prior to nationwide implementation.

- **Investment/financial consideration:**

The potential efficiencies, cost savings and increased security could save government and industry billions of dollars. In a resource constrained environment, however, existing capabilities or technologies could be leveraged for near-term benefits while targeted experiments can demonstrate where blockchain technology might create transformational, long-term value.

- **Guidelines/work instructions for blockchain in health care**

Guidelines for standardizing and storing data on the blockchain. Specifically, evaluating which information should be stored on or off the blockchain and the format in which it should be stored etc.

- **Review and monitoring phase:**

Constant monitoring is important since data security is a crucial aspect and triggers related to data security should be seriously reviewed. Adherence to auditing guidelines should be the goal. Reviewing available audit trail available in this phase.

- **Disaster recovery**

Blockchain offers a robust disaster recovery methodology. It removes the need for a centralized infrastructure as the distributed ledger automatically synchronizes and runs across all nodes in the network by design. As a result, Disaster Recovery (DR) is essentially built in, eliminating the need for a synchronized DR plan. The inability to alter entries in the ledger also contributes to the overall security of the blockchain, improving resilience against malicious attacks.

CHALLENGES

- **CHANGE MANAGEMENT AND GOVERNANCE TERMS OF BLOCKCHAIN ECOSYSTEMS**

Blockchain technology in healthcare is most likely to develop through the ecosystems created by partners that need to share and exchange health data, interacting regularly and facing a risk of potential disputes. With blockchain-based solutions, it is possible to build confidence; however, how these consortia of typically five to ten partners will be funded and governed efficiently remains unclear. All members of blockchain ecosystems will need to agree, at a minimum, on the governance structure for their collaboration at two levels:

ON AN IMPLEMENTATION LEVEL, this includes agreeing on how to integrate the different systems to the blockchain and encoding the business processes via smart contracts.

ON AN OPERATIONAL LEVEL, this will include:

- a) agreeing on where the blockchain system will be hosted;
- b) who runs the different components;
- c) what data needs to be shared;
- d) how and who has permission to do what; and
- e) agreeing on how to govern any potential changes to the lifecycle of existing processes.

Reaching an agreement on the implementation aspects should not offer major obstacles. There would be some migration and integration costs in connecting the systems of the different partners to the distributed ledger; however, this should not incur any great capital expenditure. Ultimately, costs would be distributed among all participants in the ecosystem and would be rapidly offset by the savings generated.

The real obstacles for blockchain to establish itself in healthcare probably lie in both agreeing on the ecosystems' operational governance and in managing the changes that this technology will bring to roles and processes.

- **BARRIERS TO HEALTH DATA SHARING**

Blockchain technology can help address some of the challenges currently facing health data access and sharing. However, there are also several challenges that this technology is not able to solve. Barriers such as unjustified health data localization requirements, lack of technical and semantic interoperability, low data quality and reliability must be overcome. Otherwise, it is unrealistic to believe that blockchain technology can achieve its full potential for healthcare.

Any comprehensive solution - or solutions - to the challenges posed by data management and sharing remains some way off. These are interrelated but distinct challenges, which need to be solved through a combination of policy and regulatory measures [11] and need to include a genuine shift to outcomes-based reimbursement models. Only then will healthcare providers and care professionals have enough incentives to capture health data in reusable formats and share it to improve patient outcomes and care delivery.

- **CHALLENGES IN INTEROPERABILITY**

Many blockchain implementations are proprietary, which jeopardizes exchanging blockchain data and establishing an open blockchain infrastructure and partner ecosystem. In addition, the position of blockchain within the healthcare interoperability stack needs to be more clearly defined. Standardization of blockchain APIs will typically occur when technology becomes more mature.

- **USE OF PUBLIC BLOCKCHAINS IN HEALTHCARE**

Public blockchains are completely decentralized, with the permissions to read and write data onto the blockchain shared equally by all connected users that come to a consensus before any data is stored. No user has special privileges on any decision and there are no controls over the users running the blockchain.

The role of public blockchains in the healthcare sector in supporting transactions taking place between unknown parties remains unclear. As previously highlighted, "permission less [public] blockchains are much more disruptive and difficult to fit into existing legal and business frameworks". European health systems are highly regulated, and several existing regulations could prevent public blockchains from being used in this sector. However, a public blockchain may be the only possible alternative where there is no ecosystem of actors eager to co-operate in finding a solution.

An alternative to public blockchains are the so-called consortium (or 'permissioned') blockchains. Anyone can be a user or a node of a public blockchain, while consortium blockchains are operated by a wider, but clearly defined, group. Like public blockchains there is no single actor trusted for operating the solution; this responsibility is shared among the consortium members. These are authorized to interact with the solution. In this case, trust relies on the ecosystem of actors (i.e. the consortium) operating the solution. Consortium blockchains are lighter on anonymity and transparency than public blockchains but can provide higher efficiency and greater privacy. The use cases for healthcare described in this paper rely on this kind of consortium blockchains; only partners will be able to access the blockchain and the transactions registered therein.



- **COMPLIANCE WITH PRIVACY REGULATIONS**

Compliance of blockchain implementations with privacy regulations need to be further analyzed and evaluated. For example, it is unclear which organization will be considered as the data controller when blockchains are typically characterized by distributed governance and the lack of a central authority. Another challenge how to implement the GDPR principle of “the right to be forgotten” in blockchain, where all transactions are immutable. This, and other privacy implications, requires further analysis.

CONCLUSION

Blockchain technology, while still nascent, presents numerous opportunities. A blockchain-enabled, trusted exchange of health information can provide longitudinal views of patients' health, generate new insights about population health, and support the move toward value-based care. With greater transparency, trust, and access to data, HHS can then also garner insights for better safety, effectiveness, quality, and security of foods, drugs, vaccines, and medical devices. The promise of blockchain has widespread implications for stakeholders in the health care ecosystem. Capitalizing on this technology has the potential to connect fragmented systems to generate insights and to better assess the value of care. In the long term, a nationwide blockchain network may improve efficiencies and support better health outcomes for patients.

REFERENCES

1. <https://blogs.thomsonreuters.com/answerson/Blockchain-technology>
2. <https://www.weforum.org/agenda/2016/06/blockchain-explained-simply>
3. <https://www2.deloitte.com/us/en/pages/public-sector>
4. <https://www.finance-monthly.com>
5. Blockchain Technology Use Cases in Healthcare - Peng Zhang, Douglas C. Schmidt, and Jules White, Gunther Lenz

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