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Review Articles

Blockchain for Digital Health: Prospects and Challenges

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Abstract

An open distributed ledger system, blockchain records digital transactions and offers the potential to disruptively transform the way we conduct biomedical research, provide health care, and perform economic transactions. This expert review provides the overarching background, key definitions, prospects and socio-technical challenges at the intersection of blockchain and digital health. In addition, we discuss the tenets of next-generation technology policy for blockchain, drawing from the field of responsible innovation.

Keywords: blockchain, digital health, emerging technology governance, technology and society, critical policy studies, responsible innovation

A Disruptive Technology on the Rise

What would you think if we were to tell you that there is a technology with the potential to disruptively transform the way we conduct biomedical research and provide health care as well as the way we perform economic transactions, not to mention how we relate to each other in society? Besides questioning the real-world feasibility and efficiency of the claim, one of the first thoughts would surely be that this technology should not fall in the hands of a single entity, be it a person, group, network, or institution. And what would you say if we were to tell you further that not only this technology exists, but it should not be controlled by one or more appointed experts, and rather it can only be governed democratically, and in particular, by people whose lives will be affected? (Sarewitz, 2015, 2016). Then, further questions would arise, such as the ends to which such governance occurs, who designs the technology governance frames in the first place, whether the governors are elected or appointed, among other crucial questions at the interface of technology and democracy (Sclove, 2020). Indeed, an emerging technology with crosscutting corollaries in biomedical sciences, health care, economic, and quotidian life warrants critically informed governance.

Blockchain Meets Digital Health

Prospects and challenges

This technology exists, and is called blockchain. It has multiple potentials that can impact on digital health technology and social innovation trajectories. *But what is blockchain exactly?*

An open distributed ledger system, blockchain is a technology that records digital transactions. In its simplest form, it is reminiscent of the traditional paper-based ledgers with each block corresponding to a page. Each transaction is verified and registered in the block. After several transactions have been registered, and the block is full, the system creates a new block. Before starting to enter transactions in the new block, the system generates a random number based on the content (i.e., the registered transactions) of the prior block. This random number, known as the ''hash value,'' is the first entry in the new block. It is the hash value that ''chains'' the blocks together, thus creating a blockchain. Importantly, any

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attempt to modify transactions that have been entered into a prior block will result in a mismatch between the content of the prior block and the hash value entered in the next one, rendering the change invalid. The ledger is thus immutable, that is, cannot be modified once it is created. And this is precisely where the versatile societal and technical potentials of the blockchain rest.

The blockchain is a distributed system because an identical copy of the blockchain is stored in many computers, providing the required redundancy to avoid single point failures. Blockchain is also decentralized because the architecture of the system does not permit verification and storage of transaction data by a single agent (Gatto, 2018).

Since the ledgers are immutable, the blockchain ensures the integrity and nonrepudiation of transactions. This attribute guarantees trust among distributed agents unknown to each other, thus rendering intermediaries obsolete. In the finance sector, this might mean that institutions such as banks are likely becoming redundant; this has led to emergence of digital cryptocurrencies such as Bitcoin (Nakamoto, 2008).

An important add-on to a blockchain is computer protocols, known as smart contracts, which can be integrated into a blockchain to trigger an action when predefined conditions occur. The combination of blockchain with smart contracts, in platforms such as Ethereum, has rendered blockchain a horizontal technology that serves as an enabler for innovation, and has attracted the interest and investment of many stakeholders from diverse sectors including, and beyond, finance and financial technology (Fintech). For instance, blockchain is anticipated to promote the implementation of the Internet of Things as well as artificial intelligence (AI) applications (Kojouri, 2019). Even more important is the prospect offered by blockchain for data governance. In this context, the public sector in Estonia is already exploring the reduced costs and improved efficiency in provision of a great majority (99%) of public services as e-services (Martinson and PWC, 2019).

In an increasingly digital world, blockchain offers an option for a decentralized solution to the problem of digital data storage and governance with prospects for improved security. With health care becoming increasingly data-centric, blockchain-driven solutions that have been proven efficient in other data-driven industries have started finding applications in the domains of health care and biomedical sciences as well.

The most widespread application of blockchain in digital health is in the field of electronic health records (EHRs). Highly granular medical information stored in EHRs improves medical decision-making, especially in emergencies. However, security concerns pose a formidable challenge to the EHRs since they should be safeguarded from the third parties (such as insurance companies) who may have an interest in EHRs. Here, blockchain not only provides the necessary security but also puts the patient in control of her/his data. The storage of such voluminous data on a blockchain is expensive, however, and thus, solutions have been developed where the data are stored not on the blockchain *per se* but in external databases. In this case, the blockchain hosts only the metadata related, for example, to ownership and permission, and not the data in its entirety, thus serving as a gatekeeper to the latter (Leeming et al., 2019). Such innovative arrangements could also reduce the high costs associated with high energy consumption in data storage and governance solutions as the blockchain technology moves toward the field of digital health.

Another challenge related to the implementation of blockchain in EHRs is the lack of interoperability between blockchains from different providers and services, which creates obstacles in effective sharing of medical data (Siyal et al., 2019). Notably, the immutability of blockchain ledgers can be a disadvantage within the context of the new General Data Protection Regulation (GDPR) of the European Union, which foresees that citizens have the right to have their data deleted (European Commission, 2016).

On the biomedical research front, blockchain combined with smart contracts is bringing accuracy and transparency to several issues related to data governance in clinical trials, ranging from data privacy and integrity to sharing and recording (Nugent et al., 2016). Here, apart from the security challenges, there are issues related to expensive and limited scalability of blockchain and the required standardization. Regulatory agencies and clinical trial registries are expected to set rules for blockchain applications in clinical trials. The same holds for research conducted with real-world data (RWD), where blockchain is anticipated to leverage it by providing secure platforms for storage and governance of RWD.

With biomedical research being a centerpiece of drug discovery and development, blockchain applications have an impact on pharmaceutical research as well. By offering the promise of secure, unbiased, and transparent collection and registration of data, blockchain warrants further evaluation by drug regulators in a context of prevention of potential manipulation of data by clinical trial sponsors or other parties. Furthermore, the immutability of registered data renders the utility of blockchain in logistics obvious. In the pharmaceutical supply chain, the technology can be used to secure compliance with the regulatory framework, and to enhance the efficiency and transparency of all stages, from drug origin, composition and manufacturing to storage, transportation, and delivery. For instance, blockchain has been implemented in China for recording and tracking of materials, such as protective gowns and masks used in the SARS-CoV-2 epidemic (blockchain.news, 2020).

In the health insurance sector, blockchain is poised to reduce costs, improve risk assessment, and enhance client trust. Moreover, the technology can reduce fraud by improving the efficiency and transparency of the claim submission and processing (Deloitte, 2016). Considering the volume of transactions in the insurance industry, the current processing speed of transactions in a blockchain is extremely low (only a few hundredths of a credit card) indicating that the main challenges here are speed and scalability (Yoon, 2019).

In the entrepreneurship field, the significance of blockchain as a horizontal enabler of innovation becomes apparent by the increasing number of startup firms that transform various aspects of health care, ranging from management of health care data and patient data monetization to the management of genomic data and health care cryptocurrencies. Indicatively, the rising adoption of blockchain technology in health care is anticipated to reach a value of more than $1.6 billion in 2025 (Global Market Insights, 2019).

Importantly, blockchain can catalyze not only technological but also social developments in digital health. First, by engaging citizens in governance of their health-related data, blockchain can empower citizens and enhance individual and social responsibility. Here, it is important to note that the empowerment of the citizens may harbor implications for the public. In the case of digital health, for example, the more empowered the citizens are, the less capable the central authority for scalable actions will be, for example, in the case of acutely required high stakes public health interventions. In essence, empowerment confers power on human agents, and at the same time, calls for social responsibility of the empowered individuals. Second, blockchain reshapes the relationships among technological platforms. For instance, in digital health, information commons such as public biobanks and free/libre open-source software (FLOSS) play an ever-important role. Our group has recently shown how blockchain technology can be used in the interface between public biobanks and FLOSS to protect them from the free-riding problem and guarantee their sustainability without hampering their operational framework. Blockchain could also provide the technological substrate for health data cooperatives and similar social arrangements, where citizens own and control their biodata (Evangelatos et al., 2020).

Outlook

Although still faced with challenges, blockchain technology has an enormous potential to catalyze both technological and social innovation, turning the promise of digital health into a reality. By reshaping both the technological and social environment, the rise of blockchain in digital health can help reduce the disparity between the enormous technical progress and investments versus our currently inadequate understanding of the social dimensions of emerging technologies through commensurate investments in the latter knowledge domain.

Furthermore, blockchain and emerging technologies are a broad opportunity and invitation to be cognizant that it is not the technologies that result in social change *per se*, but the often opaque human values and power asymmetries embedded in technology design, translation, and implementation (Özdemir, 2020; Sclove, 2020; Von Schomberg and Hankins, 2019). In this context, scholars in the field of critical policy studies inquire about not only ‘‘what’’ we do in science but also ‘‘how’’ we do science and govern new technologies, by asking questions specifically relating to knowledge frames (i.e., epistemology—*how do we know what we know?*), for example, on public engagement in science, technology, and innovation. By examining both the blockchain technology actors (e.g., scientists) and technology narrators (regulators, social scientists), we can then be poised to make critically informed decisions to steer the blockchain innovation trajectory toward outcomes that are broadly relevant, experiential, and socially just, and by extension, securing robust gains toward better health and better lives (Garvey, 2019; Guston, 2019; Özdemir, 2019).

Finally, although technological platforms such as blockchain might initially be understood as Fintech relevant only to the financial sector, they have crosscutting broader relevance for the health care sector as well. Existing scholarship in the field of emerging technology governance can help transfer Fintech innovations to the domain of health care and biomedical sciences in ways that are critically informed and consistent with responsible innovation.

Disclaimer

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Abbreviations Used

EHR = electronic health record
Fintech = Financial technology
FLOSS = free/libre open-source software
GDPR = General Data Protection Regulation
RWD = real-world data