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Blockchain Technology Holds Promise for Health IT

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As blockchain and distributed ledger technology (DLT) continue to develop, there are growing opportunities to apply this technology to solve the challenges and needs of managing health information.

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However, in such a highly regulated field, success will depend on a clear understanding and consideration of the legal, policy, cultural, and operational implications of this breakthrough technology as it applies to health care. This article will explain the basics of this technology, identify promising applications, and explore the top legal and policy considerations at the intersection of blockchain technology and health information.

Why Now? Setting the Stage in the Evolving Health IT Landscape

The change on the horizon is palpable. An explosion of innovation in the health IT marketplace has rapidly infused technology into every aspect of the health care sector and—not surprisingly—every aspect of our daily lives. Doctors maintain records electronically and receive alerts to remind them about preventative tests or treatment options. Wearable monitors track our steps and sleep quality. College students have video visits with their primary care physicians back home. Patients manage chronic conditions by using digital tools to track blood pressure or blood glucose level, and these digital tools can automatically alert the patients, their doctors, or their caregivers about a significant change.

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And all of these advances have the same goals in common: increasing efficiency, decreasing health care costs, improving patient engagement, and ultimately facilitating better health outcomes.

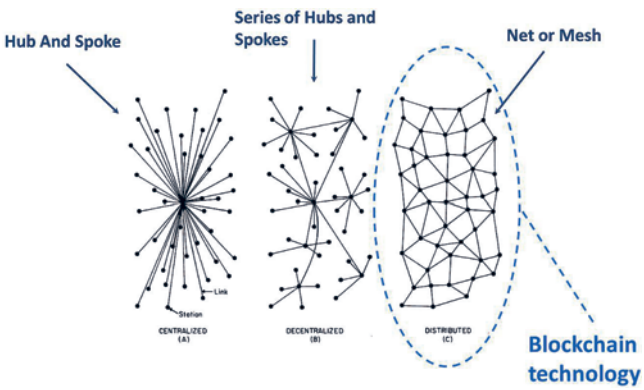
But these advances haven't happened in a vacuum. Significant legislative, regulatory, and policy incentives have catalyzed this burgeoning movement. With laws like the Health Information Technology for Economic and Clinical Health Act of 2009 and the Medicare Access and CHIP Reauthorization Act of 2015, programs like President Obama's Precision Medicine Initiative, and HHS's health care delivery system reform efforts, health IT has rapidly become the foundation for clinical care improvements, innovative research, and health care cost savings.

But in spite of these advances, health care data remains siloed and electronic health systems don't talk to each other. Problems exist with interoperability at all levels, including governance, security, reliability, and patient matching. In the midst of all these challenges is blockchain technology—which could be an important tool to help address these issues. The key will be to develop the technology in tandem with the policy and governance structures that support its success.

What Is Blockchain?

Blockchain technology is an innovative approach to transmitting and keeping track of pieces of information. A blockchain is a computer program that is used to track transactions (for example, the transfer of assets, entry into contracts, or exchanges of information).

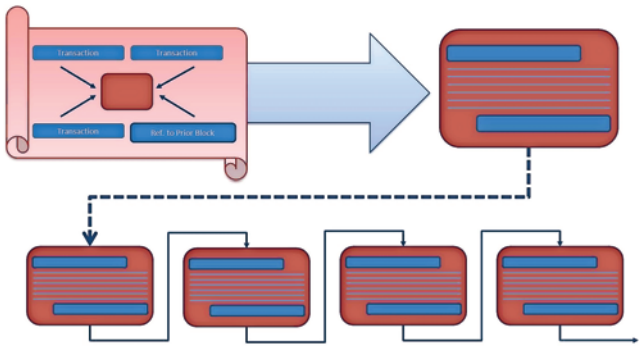
Blockchains are typically stored using distributed ledger technology (DLT). While it is possible to have a blockchain stored on a single computer, the value of the technology increases exponentially through the use of DLT. Each computer in a particular blockchain network is able to communicate with the other computers in the network to ensure that all versions of the blockchain contain exactly the same information.



Original Image: Paul Baran, *On Distributed Communications: Introduction to Distributed Communications Networks* (RAND Corp. 1964) (original image altered to add notations).

Data can be stored on a blockchain in a form that is completely accessible to everyone (such as the blockchain behind the virtual currency Bitcoin), but more and more industries are recognizing the value of ''permissioned'' blockchains. In a permissioned system, only certain computers are given access to the blockchain network, and information on the network is stored in encrypted form to ensure that each record is only accessible by users with specific authorization. Each user of the blockchain network receives a unique digital access code (created using a method known as ''public key/private key technology''). A user would be able to use this code to access only the information that she is authorized to see.

The concepts behind blockchain and DLT have been known in the computing industry for years, but Bitcoin was the first widely adopted use case. The Bitcoin blockchain is simply a ledger showing all Bitcoin transactions. But blockchain and DLT have much broader application than simply tracking virtual assets—including the potential to track health information.



There are four key components to blockchain technology:

1. **Data Security:** All data is encrypted and access is limited by a public key/private key infrastructure.

2. **Distributed Ledger:** Unlike traditional approaches to storing information in a central location or holding an ''official'' copy, blocks are continually and instantaneously disseminated to every computer that participates in the blockchain network.

3. **Non-repudiation:** Blockchains are designed to preserve data quality, creating a complete and theoretically immutable record of transactions. Every computer in the blockchain network can verify that the information on its ledger is identical to the information on its peer computers.

4. **Real-Time Transactions:** Transactions are completed almost instantaneously, with prompt verification and updates across the entire blockchain network.

Blockchain and Health Care: Wave of the Future?

Critical pillars of the health IT infrastructure include identity, efficiency, protection, and trust. Blockchain has the potential to combine all of these core components to drive solutions in the health IT industry. Potential uses include:

1. **Longitudinal health records/interoperability.** Blockchain and DLT's greatest potential benefit is to support interoperability and the availability of a longitudinal patient record. Imagine a world with no more data silos, multiple patient portals, missing test results, or ''New Patient'' forms at every hospital and doctor's office. As a patient's health records are updated and those records (or notices that records have been cre-

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ated) are disseminated throughout the blockchain network, doctors and patients will have a more complete view of patient health information—and only those with permission would be able to view those new inputs. This capability could build on existing efforts of health information exchange (HIE) organizations. Patients can also play a role in validating records to support accurate patient matching.

2. **Patient-generated health data (PGHD).** In addition to compiling patient health data, blockchain can also serve to incorporate PGHD from remote monitoring devices and other mHealth tools. This can support patient engagement by providing up-to-date information that can be used for alerts and to record health trends, which are then made available to patients, caregivers, and doctors.

3. **Research.** Varying levels of access to the blockchain network could be granted or rescinded to physicians or researchers who conduct patient-centered outcomes or precision medicine research. Blockchain, along with the security and permissions that can be built into the technology, can support patients who wish to make such data available to researchers and clinicians for these purposes.

4. **Consent/permissions management.** Blockchain could facilitate patient consent and permission management to provide individuals with more ability to express their preferences. Patients could provide consent once—for varying degrees or levels of health care access—and change those permissions as necessary. This could also work for advance directives, which could be entered once and disseminated instantaneously to the blockchain network.

Open Questions Ahead: Rules of the Road for Blockchain and Health Care

No technological solution alone will solve our health care interoperability and data exchange challenges. Blockchain cannot solve policy questions, sort through cultural challenges or expectations, or define the rules of the road. As is the case with all health information exchange activities, much effort will need to go into resolving the policy and operational challenges of the technology. Significant effort must also go into establishing a governance structure that will not only take advantage of the technical capabilities, but will also align with the health care industry's legal framework and business needs. Some of the issues that the health care sector will need to grapple with are:

- **Access.** Who should have access to the blockchain network and for what purposes? Will this access be driven by patients, providers, or both? What level of control does the patient or their designee have to grant or limit access? Should there be limitations or criteria on participating entities, including innovators that help the patient visualize and interpret that data?

- **Data Usage.** Which uses of data should require patient permission? Does blockchain enable more patient control than required by law? Are there uses that should never be allowed? Should researchers be able to use aggregated and anonymized (or deidentified) data for research or other purposes with or without patient permission? Is notice required?

- **Governance.** Who makes the rules and sets up the blockchain? Who should—and will—take responsibility for creating the network, contracting with the software developers and providers, or establishing patient access portals? What are the roles for existing HIEs or networks? Who should be responsible for determining who does and does not get access?

- **Legal Framework.** What state laws apply? How do existing privacy and security laws apply to the use cases for blockchain in health care? Does the mix of protected and non-protected data need to be addressed? What about inclusion of ''sensitive'' health data or data about minors that requires added protections?

- **Enforcement.** Who will enforce the rules? What happens if a participant breaks the rules? What if the entity or entities that serve as the ''gatekeeper'' for the blockchain network break(s) the rules? Are new laws necessary for enforcement?

- **Individual Rights and Information.** What is the process for correcting errors in or adding information to a record? Could the individual make that update herself? Can individual rights under HIPAA be adequately addressed through blockchain?

- **Promoting Data Sharing/Limiting Information Blocking.** How do we incent the sharing of data to support patient care, research, and health care reform efforts? Are there ways to document when information blocking is occurring?

- **Security.** How can concerns about hacking be addressed by blockchain? How will new guidelines for security be addressed over time?

- **Privacy.** How do we align with existing privacy laws and expectations and address gaps in the legal frameworks? What are the concerns about privacy that must be addressed to build the trust of individuals and health care providers?

Where Do We Go From Here?

Security. Access. Efficiency. Trust. The varying uses of blockchain have the potential to address some of the issues currently plaguing the world of health care interoperability and the availability of health data. We must consider the value and opportunity of this technology along with the legal, policy, cultural, and operational implications. If change was on the horizon, then the horizon is now upon us.