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Leveraging Blockchain Technology to Enhance Supply Chain Management in Healthcare: An Exploration of Challenges and Opportunities in the Health Supply Chain

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Background: Effective supply chain management is a challenge in every sector, but in healthcare there is added complexity and risk as a compromised supply chain in healthcare can directly impact patient safety and health outcomes. One potential solution for improving security, integrity, data provenance, and functionality of the health supply chain is blockchain technology.

Objectives: Provide an overview of the opportunities and challenges associated with blockchain adoption and deployment for the health supply chain, with a focus on the pharmaceutical supply, medical device and supplies, Internet of Healthy Things (IoHT), and public health sectors.

Methods: A narrative review was conducted of the academic literature, grey literature, and industry publications, in addition to identifying and characterizing select stakeholders engaged in exploring blockchain solutions for the health supply chain.

Results: Critical challenges in protecting the integrity of the health supply chain appear well suited for adoption of blockchain technology. Use cases are emerging, including using blockchain to combat counterfeit medicines,

securing medical devices, optimizing functionality of IoHT, and improving the public health supply chain. Despite these clear opportunities, most blockchain initiatives remain in proof-of-concept or pilot phase.

Conclusion: Blockchain technology has the unrealized promise to help improve the health supply chain, but further study, evaluation and alignment with policy mechanisms is needed.

INTRODUCTION

Globalization, increased adoption of information systems and related technology, and a sector populated with multiple actors in various jurisdictions, have given rise to a complex and self-proliferating health supply chain. Numerous efforts to protect supply chains in the broader context of all commodities and goods have been undertaken, including the United States (US) National Strategy for Global Supply Chain Security[1], which is a White House initiative to: "promote efficient and secure services" and "foster resilience".[1,2] While this federal strategy on supply chain security is important for any industry, a compromised supply chain in healthcare is of particular importance as it can result in a number of failures in healthcare delivery that directly impact patient safety and health outcomes. These include the threat of failing to secure and distribute lifesaving commodities, adverse events associated with supply chain breaches, and increased morbidity and mortality in the end-user or patient.

The pharmaceutical supply chain is one of the verticals most prominently considered when developing technology-driven solutions and use cases.[3] For example, the global market for fake, substandard, counterfeit, and grey market medicines accounts for up to $200 billion per year.[4] Studies have uncovered a host of pharmaceutical products, medical devices, and biologics, that have been subject to counterfeiting in World Bank categorized low, middle-income, and high-income countries indicating that the entire drug supply chain is susceptible to this transnational form of pharmaceutical crime.[5-8] Coupled with international growth of the pharmaceutical market and a rise in global drug sales, the emergence of various forms of technology and digital health platforms has given rise not only to supply chain solutions but also vulnerabilities.[3] Efforts to secure and modernize the supply chain have thus far focused on technologies such as radio frequency identification (RFID) chips with ownership transfer, mobile applications to track drug pedigree (e.g., m-pedigree), and other product verification solutions.[2,3]

In addition to pharmaceutical falsification, improving security and mitigating vulnerabilities in the vertical space of medical commodities and devices is a priority area. The medical device industry is particularly important, given the rise in connected devices and mobile health (mHealth) applications. For example, patients with implantable cardiac devices have been rendered vulnerable due to gaping security holes, illustrating challenges associated with the growth of the Internet of Healthy Things (IoHT) and how its development and adoption has far outpaced security requirements.[9,10] In response to challenges as with the cybersecurity vulnerability identified in the pacemakers, government agencies and regulators are taking steps to increase awareness of the risks to the general public and healthcare ecosystem in the IoHT.[9] Relatedly, rising healthcare costs tied to medical supplies are forcing healthcare systems to reexamine basic operating assumptions. While these processes would allow systems to better capitalize on a health system environment with large volumes of supply chain data, it still would not fully leverage it for supply chain optimization.

Hence, effective management of the health supply chain is critical to ensuring optimal patient safety and population health level outcomes—a task that paradoxically relies on but fails to fully utilize cutting-edge technology and innovation. Failures in the health supply chain evidenced by the transnational trade in fake medicines, medicine shortages and stock outs, and security vulnerabilities in connected medical devices, illustrate the high stakes nature of this sector relative to some industries.[3,5] As such, solutions must address and balance optimizing supply chain management and ensuring supply chain efficiency and risk reduction. In all healthcare verticals improving resilience, integrity, data provenance, and functionality of the health supply chain are essential.[11]

What is the common denominator to address these challenges? All of these and more critical challenges in healthcare could be addressed with superior supply chain management practices that are digitally enabled by blockchain technology.[12] For the purposes of this perspective piece, we define a supply chain as the end-to-end process from sourced raw material to final product sold to a customer. Areas within healthcare primed for improvements in supply chain management that we focus on in this paper include: *pharmaceuticals*, *medical devices and supplies*, *IoHT*, and *public health*. This perspective aims to raise awareness of opportunities for blockchain uptake in these health supply chain areas with a particular focus on the pharmaceutical supply chain, and also ask critical questions of what blockchain elements are crucial for future adoption and implementation.

"PHARMA-CHAIN": BLOCKCHAIN FOR THE PHARMACEUTICAL SUPPLY CHAIN?

A serious and well recognized threat to the pharmaceutical supply chain is the infiltration of the combined category of substandard and falsified (SF) medicines; these are also referred to as counterfeit medicines but often taking on a different legal meaning.[5,13-14] Collectively, these different forms of compromised and fake medicines can manifest as a result of importing substandard drugs without local approval, poor manufacturing practices or improper storage, theft and diversion of drugs, and the infiltration of poor quality or fake products into grey markets (i.e., business conducted outside of legitimate channels).[15] The World Health Organization (WHO) estimates this combined market at $75 billion per year,[13] but estimates range up to $200 billion.[4] The pharmaceutical supply chain and healthcare system are particularly susceptible to disruption in countries like Vietnam, where the vast majority (i.e., 90%) of drug expenditures are contingent upon imported sources.[16]

However, supply chain vulnerabilities are not limited to low-income markets or those heavily reliant upon drug importation. As an example, in 2012 the US Food and Drug Administration (FDA) notified nearly 1,000 healthcare facilities and practitioners in 48 states and 2 US territories that they might have purchased and administered fake versions of the blockbuster anti-cancer drug Avastin® (bevacizumab).[17] The legislative response to these threats in the US is the Drug Supply Chain Security Act (DSCSA).[18] In a 10-year time frame, the DSCSA requires "medication tracking and tracing; serialization, verification, and detection of suspicious products; and strict guidelines for wholesaler licensing and reporting."[15,19] Outside of the US, related efforts are underway with the Falsified Medicines Directive in the European Union (EU)[20] and the Council of Europe's MEDICRIME Convention,[21] along with local anti-counterfeiting laws in various countries.

When exploring the role of blockchain in securing and optimizing supply chain management for the manufacture, distribution, and dispensing of pharmaceutical products, the initial questions that should be posed are: would blockchain technology represent improvement over existing supply chain and anti-counterfeiting systems and databases? Does it offer functionality or processes unavailable with centralized databases and legacy systems? How can a blockchain interact with existing supply chain data (e.g., RFID, Global Standards One (GS-1), Electronic Product Code Information Services (EPCIS), etc.) and anti-counterfeiting technology? And finally, does it offer a compliance and regulatory solution that can mitigate risk but also better ensure compliance and patient safety that can benefit *both* manufactures and consumers? Answers to these questions should be the foundation of initial evaluations of blockchain design elements and feasibility studies to develop robust use cases, while also localizing within the context of the different challenges faced by supply chains in varying jurisdictions (e.g., EU parallel trade, markets with poor pharmaceutical governance). With the example of DSCSA, each regulatory component should map to blockchain capabilities for it to be a viable solution. In the case of the pharmaceutical supply chain, possible DSCSA-blockchain policy and technology alignment is illustrated in Table 1.

Several organizations are actively exploring the use of blockchain for pharmaceutical supply chain management by developing use cases, simulation models, and prototyping blockchain solutions. Leading the thought process around this development is The Center for Supply Chain

Table 1. Blockchain applicability for DSCSA key requirements

Key Requirement	Blockchain Applicability	Compatible
Product identification	Unique product identifier can be required with contributed information validated as a side chain	**YES**
Product tracing	Allows manufacturers, distributors and dispensers to provide tracing information in shared ledger with automatic verification of important information	**YES**
Product verification	Creates system and open solution to verify product identifier and other contributed information	**YES**
Detection and response	Allows public and private actors to report and detect drugs suspected as counterfeit, unapproved, or dangerous	**YES**
Notification	Creates shared system to notify FDA and other stakeholders if an illegitimate drug is found	**YES**
Information requirement	Can create shared ledger of product and transaction information including verification of licensure information	**YES**

Studies (https://www.c4scs.org/), a non-profit organization created to help explore the feasibility of blockchain adoption through a virtual pilot study[22] with participation of various stakeholders from across the pharmaceutical supply chain. It is also engaged in ongoing research efforts around simulating reference models of DSCSA and blockchain compatibility and compliance. Additionally, technical professional organizations, such as IEEE Standards Association (http://standards.ieee.org/) have convened workshops, webinars, and now operate a Supply Chain/Clinical Trials Technology Implementation Industry Connections program to explore frameworks for standards of interoperability between blockchain and existing legacy systems to enhance patient safety in both the pharmaceutical supply and clinical trials sectors. Concurrently, a number of companies are similarly working towards these same goals, but from different perspectives of developing use cases, exploring projects with manufacturers, and extending blockchain models used in other industries (e.g., food supply chains)[23] to pharmaceuticals and related healthcare uses (Table 2).

Overall, assessing how blockchain technology might better secure the pharmaceutical supply chain, while concomitantly addressing the need to combat the decades long public health challenge of SF medications, has been a case study that has received multi-stakeholder interest in the shared spheres of the technology, public health, and healthcare community of blockchain researchers and entrepreneurs. While a project like MediLedger (https://www.mediledger.com/) represents a collaborative approach between multiple companies in Table 2, the practical and real-world application of blockchain to this problem remains unclear and requires further maturation.

BEYOND PHARMACEUTICAL SUPPLY CHAIN: OTHER POTENTIAL BLOCKCHAIN APPLICATIONS IN HEALTHCARE

Moving beyond pharmaceuticals and the drug supply chain, blockchain applications are beginning to mature in other healthcare verticals, many of which are technology-focused and heavily regulated. Arguably the most mature healthcare sectors moving forward with blockchain adoption are the clinical trial stakeholders, healthcare records and data management providers and entities, and as aforementioned, the pharmaceutical supply chain. However, areas for blockchain growth that align with the fundamental principles of improving data management and integrity of the health supply chain exist in areas of medical devices and supplies, IoHT, and public health applications, which are explored in brief below.

Medical Devices and Medical Supplies

Recently, almost half a million patients with implantable cardiac pacemakers were identified as needing a vital firmware update due to a security flaw exposing their device to potential manipulation by hackers.[9] This follows other instances, including the recall of the Symbiq™ Infusion System, after it was discovered that Hospira's smart pumps could be accessed and controlled through a hospital network by unauthorized users to change patients' dosages.[24] As the employment of connected and digitally-enabled medical devices becomes more prevalent, their opportune use as well as their vulnerabilities become more pronounced. In response to requirements for medical devices to bear a Unique Device Identifier (UDI) by the FDA and the EU, blockchain has the potential to reduce costs and improve patient safety, and combat medical device counterfeiting due to its efficiencies and accountability around trust.[25,26] Use of blockchain could also enhance preventive maintenance of devices via deployment of

automated smart contracts.[27] In one university-industry partnership involving Edinburgh Napier University, National Health Service (NHS) National Services Scotland and Spiritus Development with support by The Data Lab and Scottish Funding Council, an effort is underway to use blockchain technology to support the medical device supply chain to track devices through their lifecycle.[28] The aim of the pilot is also to monitor the patient care pathway for opportunities to leverage analytics to improve safety and efficiency (e.g., improved response times for device recalls and field notices issued by responsible companies and agencies).[28]

Table 2. Selected companies exploring blockchain for health supply chain management

Company	Features	Website
Block Verify	Extending anti-counterfeit solutions from luxury valuables to medications	http://www.blockverify.io
Chronicled	Partnered with The LinkLab for a blockchain-supported DSCSA compliance platform	https://www.chronicled.com
IBM Blockchain	Early work with supply chain management in food products with multiple partners	https://www.ibm.com/blockchain/supply-chain
FarmaTrust	UK org developing blockchain solution for pharmaceutical supply chain, Initial Coin Offering (ICO) primarily for European market	https://www.farmatrust.com
iSolve	Advanced Digital Ledger Technology, BlockRx ICO primarily for U.S. market	http://isolve.io
Modum	Blend of blockchain and sensors, MOD token Initial Token Offering (ITO)	http://modum.io
OriginTrail	Recognized by Walmart Food Safety, partnered with Yimishiji; TRAC token	https://origintrail.io
Provenance	UK org starting with chain-of-custody for food; positioned to extend	https://www.provenance.org
T-Mining	Belgians partnered with NxtPort for container shipping; adaptable tech	http://t-mining.be
The LinkLab	Knowledge resource, development partner, partnered with Chronicled	http://www.thelinklab.com
VeChain	Combining blockchain and IoT; food/drug forays in roadmap; VEN/VET token	https://www.vechain.com
Walton	Early phase to use RFID and IoT; goals to scale to business ecosystem; WTC token	https://www.waltonchain.org

DSCSA: Drug Supply Chain Security Act, IoT: Internet of Things, RFID: radio frequency identification, UK: United Kingdom; U.S.: United States

Blockchain utilization also holds the promise to improve the value of care and reduce cost via enhanced supply chain management and interconnected clinical communities. To this end, Johns Hopkins Medicine (JHM) created a supply chain initiative focused on spine, joint, and blood management.[29] Focused on improving the value of care, JHM positioned this initiative as cost cutting with a "stuff not staff" philosophy to drill down on reducing supply expenditures and avoid staff reductions. The Armstrong Institute for Patient Safety and Quality (AIPSQ) was one of the highest-profile components to come out of this JHM initiative and the coordination of these interconnected efforts was observed to be a key element in its success (Figure 1). Cumulatively, the communities around spine, joint and blood management helped realize $5.6 million in cost savings from their physician-led clinical communities focused on supply chain management of medical supplies.[29]

Internet of Healthy Things

The IoHT is a subset of the Internet of Things (IoT) focused on health and wellness.[10] These "things" commonly include wearables, sensors, and standalone devices with utility including activity, sleep, cardiac function, and disease specific conditions (e.g., epilepsy). The vulnerabilities and opportunities with IoHT mimic those seen with medical devices, but IoHT often are associated with greater threats to data, security, and systems due to less rigorous requirements and testing relative to medical devices or devices that are less regulated (e.g., non-FDA approved applications and devices) and more consumer focused. The Trusted IoT Alliance (https://www.trusted-iot.org/), formed by multiple industry IoT stakeholders, aims to help navigate these hurdles by facilitating standard setting and other efforts centering around leveraging blockchain for "connecting and securing the next generation of IoT products".

Perhaps the first attempt at blockchain implementation with IoHT is by Bowhead Health (https://bowheadhealth.com/), which is based around a connected device that dispenses nutraceuticals. Incentivization of patient input of health data and habits is provided in the form of Anonymized Health Tokens (AHTs). While this is a similar incentivization model as proposed by other blockchain healthcare companies including: BurstIQ (https://www.burstiq.com), Healthcoin (https://www.healthcoin.com), ScriptDrop (http://www.scriptdrop.co), and Solaster (http://solasterhealth.com), Bowhead Health is one of the first blockchain companies in healthcare to pair with their own manufactured IoHT device. Assuming initial success, they also have in their roadmap to move from the less demanding wellness device to a medical device; this type of path to market entry could prove a trend in this space.

Public Health

Supply chain challenges in public health include disaster and emergency mitigation and management,[30] including protective supplies for healthcare workers during public health emergencies[31] and access to essential medications,[32] vaccines,[33,34] and immunizations.[35] In the context of access to essential and quality medicines, blockchain technology solutions overlap with use cases in the pharmaceutical supply chain and combatting SF medicines, but also extend to maintaining adequate supply at point of distribution (e.g., mitigating stock outs), curbing health systems-related corruption in medicines procurement, and catalyzing effective delivery of healthcare services and commodities. Blockchain technology in public health has also manifested as cryptocurrencies (e.g., digital currency like Bitcoin), which have been posited as alternative

forms of currency that can be used to better effectuate foreign aid and charity and as a means to reduce fraud and corruption in global health,[36] which can also intersect with disruptions and lack of resilience in supply chain integrity.

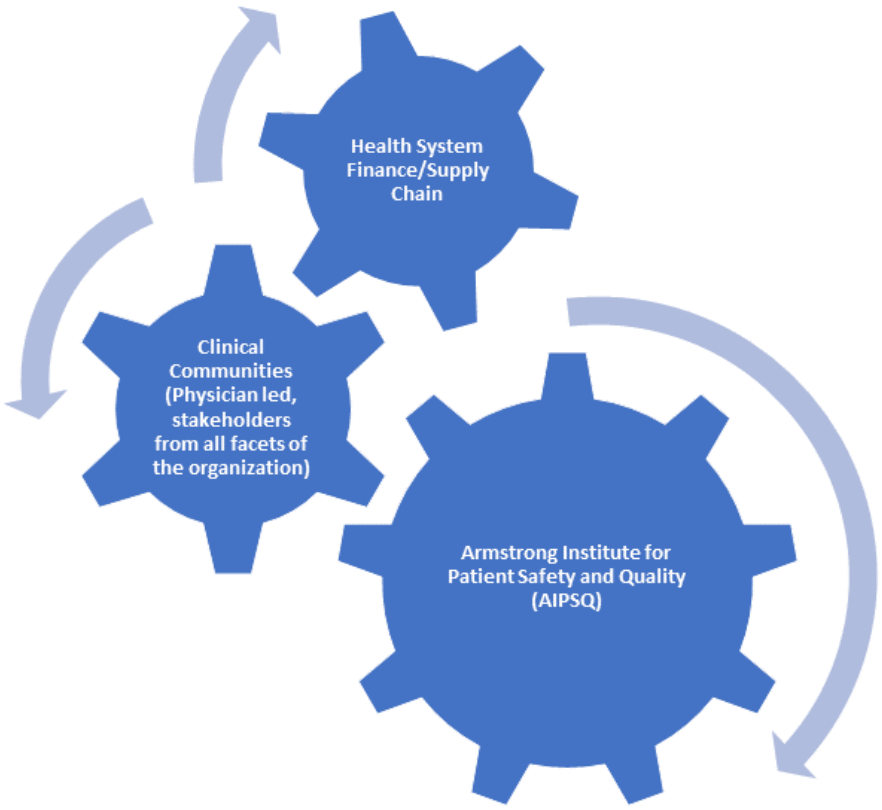

Figure 1. Coordination of Armstrong Institute for Patient Safety and Quality (AIPSQ) and health system supply chain through clinical communities. Adapted from Ishii et al.[29]

CONCLUSION

The purported benefits of blockchain technology for enhancing management of the supply chain include: 1) reducing or eliminating fraud and errors, 2) reducing delays from paperwork, 3) improving inventory management, 4) identifying issues more rapidly, 5) minimizing courier costs, and 6) increasing consumer and partner trust.[37] However, extending these potential benefits to acute challenges in the health supply chain remains an undelivered promise. Going forward, this will require greater research, investment, and deployment of solutions that can be evaluated rigorously for their actual impact on patient safety and population health outcomes. Numerous use cases in the health sector will also likely emerge. Two additional pharmaceutical sector examples that illustrate specific benefits that a blockchain-powered supply chain might offer are drug recall management and addressing prescription drug abuse (e.g., opioids). The capacity to utilize smart contracts to automate processes and reduce costs is also a crucial mechanism by which blockchain technology

could help achieve supply chain performance enhancement.

Equally challenging is the need to address privacy and data protection considerations unique to the healthcare sector as illustrated by the need to comply with policy frameworks such as Health Insurance Portability and Accountability Act (HIPAA) in the US and the General Data Protection Regulation (GDPR) in the EU. While many blockchain efforts for the health supply chain are still at the Proof of Concept (PoC) or pilot stage at present, more mature deployments are being explored across other industrial sectors that can be adopted for the healthcare sector and localized to policy incentives offered by national governments (e.g., compatibility with the DSCSA). Possibilities and opportunities for the health supply blockchain are seemingly endless, but only time will tell if the highly regulated and complex healthcare sector can fully leverage all the possibilities blockchain technology has to offer.

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The authors whose names are listed immediately below report the following details of affiliation or involvement in an organization or entity with a financial or non-financial interest in the subject matter or materials discussed in this manuscript.

KAC: Has served as a consultant for blockchain companies focused on healthcare and healthcare companies exploring blockchain solutions.
EAB: Has served as an invited speaker for healthcare blockchain companies.
TKM: Serves as the Co-Chair for the IEEE Standards Association Supply Chain/Clinical Trials Technology Implementation Industry Connections Program, is an invited participant in the DSCSA & Blockchain Study by the Center for Supply Chain Studies, and is a member of the Advisory Board for the company FarmaTrust a blockchain company developing technology for the pharmaceutical supply chain.

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Contributors
To fulfill of the criteria for authorship, every author of the manuscript has made substantial contributions to all of the work and participated sufficiently in the work to take public responsibility.

Supplemental materials
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