GBA HEALTHCARE WORKING GROUP

BLOCKCHAIN ETHICAL DESIGN FRAMEWORK FOR HEALTHCARE GBA

NOVEMBER 2020

THE GOVERNMENT BLOCKCHAIN ASSOCIATION



"The GBA has over 50 Working Groups that are exploring how blockchain technology will affect everything from banking to supply chain to identity management. The GBA Healthcare Working Group is a dedicated team of professionals who have volunteered their time and expertise to produce this whitepaper. At this time in history, an ethical framework for utilizing blockchain technology in the healthcare sector is not only helpful, but vitally essential." -Gerard Dache Executive Director, GBA

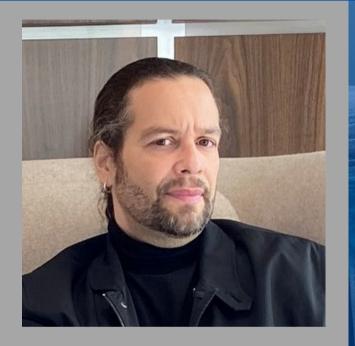


The GBA Healthcare Working Group (HWG) focuses on applications of blockchain technology to the needs of the healthcare sector.

GBA

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WHITEPAPER: BLOCKCHAIN ETHICAL DESIGN FRAMEWORK IN HEALTHCARE

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ABSTRACT

The named authors are members of the Government Blockchain Association (GBA) Healthcare Working Group (HWG) and have contributed content to this whitepaper as a service to the public.

Purpose: The purpose of this whitepaper is to:

- Illustrate the current landscape of blockchain technology and
 - identify innovations that demonstrate use in health information technology (HIT) or in sectors that impact the healthcare service delivery market.
- Describe the need for ethical design approaches in building and deploying blockchain-featured technologies in the HIT infrastructure.
 - o identify potential ethical issues of blockchain used during health service delivery
 - $\circ~$ discuss potential ethical issues for stakeholders across the healthcare ecosystem including regulatory and compliance segments
- Propose a conceptual framework of blockchain ethics as it applies specifically to its design, implementation and use in healthcare.
- Create an outline from which the Ethical Design Framework for Blockchain Applications in Healthcare will be developed by the GBA HWG.
- Raise awareness and stimulate further debate on the ethics of blockchain in the HIT and healthcare governance and regulatory communities.

Methodology/approach: The paper employs literature research and experiential information from GBA HWG members whose roles encompass healthcare leadership, practitioners and technology professionals in the U.S. and Europe, primarily.

Findings: There is a significant lack of guidance on building or using blockchain applications ethically in healthcare settings; ethical design of blockchain-featured healthcare applications is essential for technology adoption. The authors propose a theoretical framework of blockchain ethics focusing on design, build and use in HIT applications. This framework can be matured into practice by healthcare stakeholders when coupled with decision points for their unique environments, business models and service verticals. Additionally, the authors recommend measures for stakeholders to facilitate adequate governance of ethical blockchain policies, implementations and future HIT research directions within their systems.

Value: This work provides reasonable systematic research on blockchain ethics as it applies to the unique scenarios and use cases for healthcare. The authors identify key research questions of blockchain ethics and propose the first theoretical framework of blockchain ethics addressing the specific and diverse needs of healthcare. This study also contributes to the understanding of blockchain technology and its societal impacts.

Keywords: Ethics, Ethical Design Framework, Information society, Decentralization, Discourse ethics, Blockchain, Disruptive technology, Peer-to-peer network/file sharing, Society and ethics, Emerging technology, Healthcare Blockchain



INTRODUCTION

It has been widely considered that Blockchain has the potential to transform digital service delivery, data management, and the exchange of value in ways that we have not seen in human technology since the mass adoption of the internet. Since the first real-world blockchain application, Bitcoin, launched in 2009,¹ blockchain technology has demonstrated its security, reliability, and transparency in recording data transactions — and, in so doing, transferring value -- in a tamper-evident way.²

While blockchain adoption has witnessed steady growth in many sectors over the past several years preceding this writing,³ the occurrence of the COVID-19 global pandemic in 2020 has triggered an unprecedented interest in, and exponential adoption of, blockchain-featured technology.⁴⁻⁶

Three specific domains that have shown recent, massive increases in blockchain implementation are supply chain management,⁷ financial services delivery,⁸ and the life-sciences;⁹ however, this movement coupled with global enthusiasm for rapid, large-scale adoption also poses several challenges in the areas of quality assurance, long-term sustainability and ethical viability.¹⁰ Considering current industry trends in the adoption of this novel technology for many uses, the need to identify regulatory, developmental, and ethical guidelines is extremely important.¹¹

The implementation of solutions using blockchain raises ethical concerns that require clear, intentional coordination to ensure they are socially valuable and ethical. This is especially important because of the cross-connection of use cases in the finance, supply chain, digital identity (DID) and data ownership arenas, and how blockchain adoption in those verticals could impact the healthcare industry in service delivery, revenue generation and patient safety.¹² Because of the broad implications of how blockchain can affect different industries, communities and even individuals in the global neighborhood, reaching agreement on a global ethics strategy has become more important than ever.

Responding to the potential of blockchain innovation, several countries have published their own national blockchain strategy. ^{13,14} Numerous governments and international organizations have also taken clear steps towards either blockchain adoption or approving legislation facilitating the development of blockchain technology. Like artificial intelligence (AI), 5th generation wireless (5G), or the Internet of Things (IoT), it has become evident that blockchain technology will continue to be a key player in the development of solutions offering secure transaction of digital assets and information in the 21st century.¹⁵

The **GBA Healthcare Working Group**, a consortium of technologists, innovators and healthcare professionals with a deep understanding of the healthcare industry on many levels, has written this white paper to illustrate the need for further ethical development and deployment of blockchain technology as it pertains to healthcare applications. The goal of this exposition is to promote the evolution of a *global blockchain ethics ecosystem*, and to serve as a call-to-action for all relevant stakeholders such as federal and state agencies, not-for-profit institutions, industry representatives, social partners, researchers, and the like. This treatise is not meant to be prescriptive in tone; rather, it is meant to spark ideas, conversation and self-assessment on the concepts that should be considered when a healthcare practice or governing entity decides to incorporate blockchain innovations into their regulatory, corporate or consumer ecosystems.



GOVERNANCE

Physicians may deal with a great variety of perplexing ethical challenges in the practice of medicine, regardless of discipline or specialty, even in a small medical organization. While the ethical conundrums in healthcare are numerous, there is considerable guidance available to help caregivers navigate the often-tumultuous landscape of health service delivery. In contrast, there is extraordinarily little guidance available regarding the ethical implementation and use of blockchain-featured technology innovations in the treatment of health service consumers, especially in the U.S.

Given the rapid exponential technological advancements we are experiencing globally, a framework for the ethical design of blockchain technology in HIT systems and solutions is critical to instill confidence in the technology, encourage adoption and drive responsible proliferation.^{16,17}

Having a proactive approach towards policy governance is a key driver for success in any industry, however for healthcare systems deploying blockchain technology, it is a leadership imperative.¹⁸ Understanding enterprise ethical risks and assigning an ethics advisory board tasked with providing guidance, leadership and oversight is highly desirable. The benefits of establishing a state-of-the-art ethics governance program within an organization's HIT ecosystem will reduce liability risks, ensure long term sustainability and create competent management tools for enterprise transformation.^{19,20} It will be incumbent on each healthcare system ethics governance team to customize their strategy based on their unique needs and specific blockchain use cases.

To illustrate the importance of employing a thoughtful and consistent approach to ethical governance of blockchain innovations and policies, consider these examples of critical ethical scenarios when using blockchain:

<u>Data control</u> - Federal healthcare regulations like the *Trusted Exchange Framework and Common Agreement* (TEFCA)²¹ and the *Health Insurance Portability and Accountability Act* (HIPAA, 45 CFR 164) require providers to allow patients more access to their health information and have provided guidelines for doing so, but these regulations still tend to be restrictive to the individual. Current protocols fall short of addressing the complex debate establishing ownership of healthcare information between caregivers and their patients and often do not consider ethical best practices regarding advanced data sharing between these groups.²² Blockchain applications can facilitate data access in several ways by allowing transparency of transactions through distribution of a common ledger²³ and allowing for the application of granular consent on predefined data sets,²⁴ so the review of compliance requirements for health data handling is important for a service provider to determine if these innovations are viable for their system.

<u>Data privacy</u> - Creating and applying adequate privacy policies are not only necessary for health service providers to meet regulatory requirements but are also essential because keeping patient data private is ethically the right thing to do. While regulations like TEFCA and HIPAA provide guidance on many aspects of handling protected health information (PHI) but are still nebulous about data access, recent legislative landmarks like the California Consumer Protection Act (CCPA)²⁵ and the EU's General Data Protection Regulation (GDPR)²⁶ have very stringent guidelines regarding a patient's (or consumer's) right to specific levels of data privacy, including the right to have their data forgotten (i.e., deleted). When



considering the use of blockchain for applications that handle patient data, stakeholders and policy makers should review how the intersection of some of these rules might affect ethical design and implementation. For example, HIPAA allows de-identified or limited data sets to be issued from a covered entity to a researcher under a Data Use Agreement.²⁷ While this practice is legal, the ethics of omitting information from the patient about this practice, or misleading the patient unintentionally or otherwise, deserves scrutiny from organizational leadership.

<u>Data Trustworthiness</u> - Digital health platforms intended for personalized healthcare (pHealth) offer a wide range of services that have a strong potential to impact privacy and trust. Some of these services can include virtual applications, blockchain innovations, dynamic algorithms, AI, and so-called Big Data analysis.¹⁹ Users of these services can be a person or patient, health care professional, unregulated health service provider or a secondary user such as a researcher. Compared to pHealth, traditional health services built on digital platforms create an extremely complex information system from legal, regulatory, information processing, privacy and trust points of view.¹⁹ This translates to multiple potential points of failure.

<u>Data Aggregation</u> – many health applications used to predict and prevent personal health risks often require a wide spectrum of health-related information collected from different sources (for example, a combination of the content from a patient's electronic health record, their own PHI, and personal data created by a wearable health monitoring tool).²⁸ The collection and use of large, complex data sets from disparate sources raises meaningful ethical and privacy concerns about the authenticity, entirety, accuracy and validity of the data, especially if it is stored or transacted on a blockchain.²⁹

Other examples of ethical questions worthy of examination in the healthcare continuum include, but are not limited to:

- Data monetization and commoditization who gets to directly benefit from data and how?
- Data Ownership who owns data generated by clinicians about their patients? To what degree can the owner(s) capitalize on the benefit of ownership of this data?²²
- Hyper-efficiency and potential job loss what processes will see benefit and how does it impact the workforce?
- Cybercrime & related vulnerabilities³⁰ how might blockchain applications increase the capability of nefarious or illegal activity? How might it negatively impact patient safety? 30)
- Activity reorienting the clinician's role back to care how might blockchain innovations create workflow efficiencies so that physicians spend more time caring for patients and less time in front of a computer?

In addition to this short, incomplete list, ethical development and use of blockchain in healthcare requires stakeholders to understand cross-sector issues related to the application of this technology. The impact of industries that intersect healthcare and adopt blockchain technologies (e.g. finance + cryptocurrencies, supply chain + track/trace) should be understood and considered when establishing an ethical approach to blockchain usage. Blockchain education is especially important to guide policymakers and regulators in forming a governance model for ethical policy creation and solution adoption.³¹



Currently, there is a dearth of advice available to healthcare leadership to help define potential ethical concerns so that steps can be taken to ensure the responsible, fair and equitable creation, distribution and use of blockchain featured technology.

The GBA is a strong advocate for ethical blockchain technology deployment and aims to develop a comprehensive Ethical Blockchain Framework that can serve as a catalyst for all relevant stakeholders globally. In addition to this white paper, the framework will include Blockchain Code of Conduct Guidelines, Ethics Principles and Values and an Ethics Implementation Toolkit.

The Blockchain Ethics Implementation Toolkit includes a template for:

- Blockchain Code of Ethics,
- Blockchain Bill of Rights,
- Blockchain Ethics Policy,
- Blockchain Ethical Principles,
- Blockchain Ethics Education Program,
- Blockchain Ethics Certification, and
- Blockchain Ethics Risk Assessment

These tools would serve as guidelines for governments or organizations to develop a *de novo* blockchain ethics program, or to update their existing ethics or compliance programs when deploying blockchain technology in healthcare ecosystems.

BARRIERS & THREATS

While blockchain in combination with other innovations like AI and IoT has promising potential to transform healthcare, adoption of blockchain in healthcare is still in the beginning stages.³² While there are many small-scale (and an increasing number of large-scale) implementations, there are many existing obstacles that need to be surmounted for the innovation to be employed in more health service organizations.

In addition to logical or technical constraints, behavioral, and philosophical hurdles exist within the unique environment of healthcare.³³ These must be proactively identified and addressed to ensure successful, ethically responsible blockchain adoption can occur. It is also useful to remember that within the myriad of sub-verticals in the healthcare continuum, there are constraints and hurdles specific to their discipline that may not apply to others. For example, an impediment that may interfere with blockchain adoption for a small practice may not be a problem for a large practice. A threat to adoption in a Behavioral Health organization may not be a threat in an Orthopedic organization, and so on.

For this document, we will separate these impediments into two categories: **barriers** - obstacles that can slow adoption, and **threats** – obstacles that can kill adoption.



Barriers

It has been the experience of the authors that the adoption of new processes within the workflow of a healthcare organization's service delivery strategy **requires a major cultural shift**, especially among providers. Healthcare organizations and regulators often rely on precedence and status quo when making decisions on how –or whether-- to implement, use or govern new tools; and for many groups, change is often met with apprehension and fear. To be fair, decision-makers use the historical success of an initiative along with empirical evidence to gauge whether its success will continue;³⁴ however, innovations often lack a long track record to do this (a condition that also factors as a potential threat to adoption, but more on this later).

Cultural norms could be challenged with the use of novel technology, and it all depends largely on the type of blockchain innovation that a health system considers. Digital ID technology, which can employ blockchain mechanisms to establish self-sovereignty and autonomy, may challenge status quo regarding acceptable identification methods for a healthcare practice.³⁵ In each case, entities may need to examine their cultural readiness to support implementation of novel technologies like blockchain-featured applications.³⁶

We advocate awareness that cultural barriers are a fundamental precursor to overcoming many other barriers to blockchain adoption in healthcare for what might be obvious reasons: unless a unified, organizational commitment to embracing the innovation initiative is in place, blockchain adoption for healthcare can be very challenging.

Procedural roadblocks to blockchain adoption are very much tied to cultural readiness. An organization's adherence to outdated, systemwide procedures that inhibit making full use of blockchain innovations could stunt progress and slow acceptance.³⁷ These obstacles could include archaic technological procedures, outdated policies, mission-inefficient directives, and other considerations that would not benefit the implementing or use of blockchain.

Depending on the type of blockchain architecture, infrastructure and usage, historical procedures for technology implementation, governance and use may need to be reviewed regularly, with a willingness for the entity to change approach if it is found to be more responsible or ethically beneficial.

Procedural changes might conflict with current practices, but failure to incorporate them into current policy might limit the utility of some blockchain solutions.

Outdated federal and state regulations that place unnecessarily prohibitive restrictions on the use of innovations like blockchain or reduce the potential value an organization could realize by implementing the innovation (i.e. by limiting reimbursement models or requiring expensive oversight mechanisms) are impediments regularly encountered in healthcare technology advancement.³⁸

While some federal statues like the U.S. Physician Self-Referral Law (commonly known as the Stark Law) and the Anti-Kickback Statute have been relaxed in the wake of the COVID-19 pandemic in an effort to encourage collaboration and speed up innovation development⁷⁸, existing regulations must be reviewed and revised, and in some cases changed altogether, to consider the full scope of end to end



management of PII (personally identifiable information) and to sustain the growth of innovation in this process. It is no longer sufficient to simply define how PII data is stored and transmitted. With technologies coupled with blockchain like IoT and AI, it is important to consider how data is captured at the source and transmitted with privacy and security embedded, and bias eliminated.³⁹

Ethical principles should also be considered in all aspects of healthcare law, risk management, finance, and organizational operation from a regulatory perspective. This needs to be addressed in every value chain across the healthcare ecosystem to encourage participation by physicians, hospitals, insurers, drug and device manufacturers, pharmacies and others in adoption of blockchain. Health care providers need greater flexibility to implement novel technologies and practices that will help to improve the quality of patient outcomes and facilitate the transformation of our health system from volume-based to value-based care.

Policymakers and organizational stakeholders must make informed decisions when introducing new technological tools or innovative approaches into their ecosystem. Without **education about blockchain from a technical and/or a practical approach**, leadership will lack the understanding of the technology, and the context of how it can be useful (or not) in achieving their organizational mission might not be apparent.³¹

Because of the decade-long "hype cycle" of blockchain that has created conflicting reports about what blockchain innovations can and cannot do, empty and broken blockchain promises are prominent in the media.⁴⁰ This is mostly attributable to the mixed review of cryptocurrency, the first real-world example of a working blockchain solution that targeted the finance sector globally.⁴¹ While the value of educational directives within an organization are driven by its culture, independent instruction on blockchain technology and its use cases is available through organizations like the GBA and others.

Threats

As digital technologies become an integral part of our daily lives and are deeply embedded into every industry, it is important for all participants of the blockchain ecosystem to have trust. **Blockchain applications in the HIT space are relatively new** and few to the market, and have not had the benefit of measurable, long term use to demonstrate reliability, feasibility and safety.⁴² Many innovators are still offering use cases in healthcare, especially when being applied to complex or unique healthcare-specific workflows and processes.⁴² The lack of empirical evidence that reassures potential adopters of the positive and reproducible characteristics of blockchain featured technologies -- evidence that needs to be collected over time -- constitutes a potential threat to speedy adoption and the creation of trust until more participants enter the space and contribute favorable reports of its efficacy and safety.³²

Besides trustworthiness, the need to show Return on Investment (ROI) by many for-profit participants in the industry could threaten adoption. Innovations are often experimental and may not always be a revenue generating enterprise, especially during initiation. An organization that maintains a progressive approach to implementing blockchain without requiring an immediate financial return, or alternately, in defining its ROI proposition in non-financial terms³⁴ (e.g., does this solution improve patient outcomes or contribute to the scientific community in mutually beneficial ways?) A progressive approach may have greater success in acceptance and understanding of value of the technology.



Healthcare service providers may not have the in-house skill set needed to build, maintain and improve on bleeding edge innovations that are introduced into their existing enterprises, but organizations can outsource these services from "platform-as-a-service" blockchain products or customization from professional service organizations.⁴³ A LinkedIn report specified that blockchain is the #1 demanded hard skill required in the workforce for 2020.⁴⁴ Consequently, **lack of appropriate technical resources could** make adoption of these technologies challenging to sustain. Historically, and with some exceptions, healthcare technology does not implement novel solutions because the talent pool needed to make them work is limited, and these advancements often lack crucial interoperability with the systems they have in place.⁴⁵ To mitigate this potential hazard, there is need for technical and human resource development to achieve long-term sustainability of blockchain solutions.

Just as the placement of outdated federal and state regulations pose a potential barrier to blockchain adoption in healthcare, **lack of speedy regulatory guidance** could kill acceptance in many organizations for the long term. It is our experience that the healthcare industry has been slow to adopt many technology innovations because the regulatory mandates and compliance rules -- particularly regarding physician reimbursement or cost responsibility -- are archaic, and the legislative process to adapt to new technologies is slow. Policymakers should recognize the effect that the slow legislative process has on the adoption of novel technologies like blockchain as it relates to healthcare.

On the Fence

The novelty of blockchain also raises concerns for **interoperability** with in-production systems that a health organization uses. There are concerns that these solutions could profoundly impact data security, privacy and patient health.⁴⁵ Because of the expense alone, most organizations are reluctant to introduce new technologies that do not work well with the systems they have in place. Adding the potential of increased risk to patient safety elevates the question of interoperability to a *barrier* in some cases, and a *threat* to others when it comes to blockchain adoption. Blockchain can promote interoperability with some technologies but must still be recognized in cross relation to other roadblocks in the barrier-threat conversation.

Despite the recent increase in collaboration and the outcry for cooperation in many industries utilizing technology innovations like blockchain, **some participants in the healthcare continuum do not want to share data, especially between providers and payers**.⁴⁶ In some business cases where siloed data is considered to give a competitive advantage, practices may not want to use innovations that foster decentralized data storage or auditable transparency of transactions¹⁵ for fear of losing their ability to compete for the same customers or resources. To limit liability in other cases, some healthcare organizations depend on administrative inefficiencies as a source of revenue, which could also be considered unethical practice, and therefore would not be successful candidates to use blockchain in a sustainable and valuable way. Depending how deeply rooted these sentiments are in organizational culture, the lack of desire to employ systems capable of decentralized sharing of data could be a barrier or a threat to blockchain adoption.



The Need for Blockchain Ethics

To achieve large-scale adoption and sustainability of blockchain technologies, we advocate for a structured, proactive and holistic approach in developing the ethical framework. Moving from a belief mindset to an ethics-by-design mindset can be conducive to building a culture of ethics and ensure long term sustainability.

One way to proactively approach ethical uses for blockchain is to develop a scenario based ethical dilemma across various value chains in healthcare areas (namely non-pharma, pharma, medical device, etc.) and provide guidelines for asking the right questions to make ethically appropriate decisions.

A principle based ethical framework alone is not sufficient to ensure proper implementation. There must be guardrails around these ethical principles that will enable the healthcare community to ask critical questions when faced with an ethically challenging situation. People need to be educated to understand the ethical implications for various business scenarios. Technology and human behaviors should be considered collectively for ethical decision making.

Additionally, the societal perspective and impact on the global environment will also have to be considered in any effort mirroring other digital ethical frameworks (for example, those for Ethical Deployment of AI).

Having a balanced, cross-disciplinary approach when developing ethics programs will ensure that ethical principles are embedded into all legal, risk, financial, operational and human resource aspects of those organizations and their policies.

Finally, ethical frameworks are meant only as guiding principles. It will be essential for each organization to develop unique programs that are harmonized with their overall enterprise strategy. It is, therefore, important to design ethical programs in a manner that allows the organization to maintain excellence, competitive advantage, and the ability to foster innovation within their group or cohort.

OPPORTUNITIES

Blockchain technology has the potential to be a conduit for economic development. Moreover, the adoption of blockchain technology in the healthcare sector creates opportunities to provide solutions that benefit the good of society globally: thus, it can be surmised, one of the most profound opportunities for blockchain in healthcare is to provide tools and features that can help enact social good.⁴⁷

Features of the innovation can empower patients to secure and leverage their own data and can be used in development of technologies that seek to include unserved and underserved residents of the community with access to data-driven services. If deployed appropriately, not only can potential negative consequences be mitigated, but blockchain can become a key driver of digital transformation.⁴⁸ The ethical framework used in development and implementation efforts can serve as a blueprint for other novel complex technologies such as quantum and edge computing, 5G, IoT, IoMT, etc.^{49,50}



WHITEPAPER: BLOCKCHAIN ETHICAL DESIGN FRAMEWORK IN HEALTHCARE

In the wake of the COVID-19 pandemic of 2020, blockchain has already demonstrated a tremendous impact on the global economy. During this global health crisis, some countries have utilized blockchain as the preferred technology platform to manage COVID-19 related information given its unique benefits: access controls, data integrity, scalability, transaction speed, immutability, tamper-resistance, and automation.^{4,5,51} These blockchain innovations have also proven to be very useful in the scientific community for collaboration, coordination and security.

During this pandemic, we have observed trends of increased blockchain technology use in trade, crossborder financial transactions, mobile payments, supply chain, life sciences, e-government, health information exchanges and food safety.⁵²

Experts agree that the blockchain market will grow at an even higher compound annual growth rate (CAGR) than predicted before the coronavirus crisis. The total market size is expected to reach a valuation of \$176B by 2025 and \$3.1T by 2030⁵³ with a compound annual growth rate at or above 70% with slight variations in the healthcare market.⁵⁴

The recent initiatives to transition towards e-government and promote legislation designed to stimulate blockchain technology deployment in Asia, Australia, and the European Union are also expected to have a profound impact on voting, education, and digital currency use.⁵⁵ Additionally, the recent focus on blockchain technologies by the World Economic Forum, the United Nations and the World Bank have helped reduce misinformation and misconceptions related to this technology and have lessened resistance to adoption.⁴⁰

Finally, these international trends toward blockchain adoption have been influential in the United States, paving the way for municipalities, state and federal government⁵⁶ agencies to create blockchain innovation programs of their own.

We urge the blockchain community to leverage this favorable environment for innovation; there are substantial opportunities to apply blockchain to many compelling use cases in healthcare. Doing so may create efficiencies in health service delivery processes, establish paradigms of trust for healthcare consumers within the realm of data sharing,⁵⁷ and accelerate improvements to blockchain technology overall. However, it cannot be understated that there is an urgent, significant opportunity to develop state-of-the-art ethical frameworks that enhance stakeholder confidence, minimize the potential for victimization or objectification of vulnerable populations using blockchain solutions, and promote creation of a global blockchain ecosystem of excellence, sustainability and trust.⁵⁸

To achieve this, we encourage investing in ethics education, certification and talent development and having a clear accreditation process for organizations that have designed and implemented digital ethics programs.

Many of the examples mentioned in this section are opportunities where its use constitutes an uplift to the societal good, and so it is advantageous to consider them as having potential value, economically, socially and ethically.



Data Privacy and Ownership

Since blockchain technology offers significant advances in data security, Integrity, immutability, and transactional transparency, it is much easier for healthcare consumers to create, secure and manage their own health record data by using this innovation. While historically, so-called "patient portals" have granted patients a limited measure of access to their health data, implementing tools that allow patients greater control to access, view and use their health information creates opportunities for inclusion in the commercial use of PHI by the owner-subjects of the data.⁵⁹ In so doing, blockchain adopters in healthcare can participate in scenarios that demonstrate a benefit to the community and have ethical merit.

The fact that blockchain offers unique, scalable security features that permit granular consent rules and incorporates transactional transparency mechanisms that make data tamper-evident creates an opportunity for health service provider organizations to transfer a greater level of responsibility for personal data maintenance directly to their health consumer clients.

Health systems that promote transition of data custodianship to health consumers by implementing blockchain solutions to handle PHI may find public relations opportunities to demonstrate support for personal data ownership, a topic of significant global interest in multiple sectors including healthcare.²² This procedural change could also create financial efficiencies in healthcare by eliminating costly processes regarding patient data handling.⁶⁰

Public Health Initiatives

We regard the support of initiatives that attempt to provide services, guidance and information for public health and safety as a morally valuable enterprise, and therefore, worthwhile to approach from an ethical perspective since it relates to the greater good of a community. Pursuit of these programs should be considered with an ethical approach in mind to ensure all intended results are achieved, and that negative, unintended consequences are minimized.

A fundamental benefit of using blockchain technology lies in the ability to share information more transparently with parties in a safe and traceable fashion. These specific features have been cited as advantageous in responding to the **COVID-19 pandemic** specifically but could be equally beneficial in any disaster or public health emergency response.^{61,62}

The coronavirus crisis has demonstrated a need to share real-time information between healthcare providers to promote early responsive quarantine policies and expedite implementing social distancing.⁶³ Leveraging blockchain technology to secure Health Information Exchange (HIE) consortiums can satisfy this need so that sharing of specific, proprietary data with regional health service providers may be done in a granular, auditable fashion.⁶⁴ Utilization of blockchain technology for HIE's can drive provincial participation, improve information-sharing and scalable collaboration in the scientific community, and support public health initiatives that track or address regional, national or global incidents.⁶⁴



Blockchain technology also provides opportunities for governments, public sector organizations, researchers, healthcare providers, and researchers to respond and manage public health crises like the COVID-19 pandemic using several mechanisms, including:⁶⁵

- 1. Outbreak tracking: to record and track immutable patient data
- 2. User privacy protection: gives ability to trace access as well as increase trust because of decentralization, data proofing and encryption
- 3. **Safe day-to-day operations:** provides reduced risk of virus attack; time-stamped data proofing which enables monitoring across surveillance networks and cross-border healthcare delivery systems
- 4. **Medical supply chain:** allows maintaining and tracking medical supplies, food, and pharmaceuticals
- 5. **Donation tracking:** via issuance of certificates and signatures to trace donations: when, where, volumes, and targeted receivers

Fraud Control

Government agencies, insurance companies and health service practices are targets of multi-billiondollar cyber-attacks that are often used to commit fraud, leverage waste and hijack value from the healthcare system.⁶⁶ Waste due to negligent or inefficient practices, and willful misuse of healthcare benefits and services are among the most prevalent deceptions, and these illegal activities are widely regarded as having an ethical impact on the healthcare industry and the communities it serves.⁶⁶

We assert that these agencies and organizations should evaluate blockchain to quickly and accurately spot suspicious activities or illicit participants and flag unsanctioned behaviors to prevent fraud and control waste. Blockchain features that facilitate transactional transparency and provide enhanced data security could be valuable to achieve this functionality and ensure resources and revenues are allocated and collected appropriately, however the application of an ethical design approach to these workflows supported with blockchain can expose potential vulnerabilities before they become a problem, allowing stakeholders to create mitigation strategies as appropriate.

The incidence of health care fraud remains at alarmingly high levels despite unprecedented attention in recent years from policymakers and law enforcement.⁶⁷ Major scams appear to be artfully designed to circumvent routine controls and may remain invisible for long periods. When they are discovered, it seems often to be more by luck than diligent governance. We offer that blockchain technology and smart contracts can create possible efficiencies in automation for information sharing, supply ordering, viewing drug or device supply chains, reducing time and errors with insurance reimbursement and other processes.⁶⁰

It was our collective experience that fraud control is more complex than is usually appreciated, and certain factors make it particularly difficult to accomplish in the healthcare industry, including lack of organizational training in fraud control. The social acceptability of government and insurance companies



as targets for fraud, and the degree of trust society places in health care providers also present challenges that could be addressed by using ethical design and implementation principles when creating blockchain solutions to eliminate fraud.

The Ethical Approach to Opportunity

Despite massive enthusiasm in [the] industry, [blockchain technologies] remain surrounded by severe concerns about invisible embedded politics.⁶⁸

Creation of an ethical construct for blockchain projects that examines not only the "what" we can do, but the "why", is essential to successful adoption, sustainability and responsible ownership of these novel innovations. The perspective of participants who may be affected positively or negatively (the "whom") should also be included in the assessment process to ensure that principles of inclusion and acknowledgement of human impact are factored appropriately.

Smart contracts also raise ethical questions regarding responsibility. Since the entire ecosystem is decentralized and operates autonomously, who will be responsible for any mistakes? The responsibility and moral obligations of the autonomous decision making of blockchain need to be rooted on ethical grounds.¹⁷

Depending on the type of blockchain solution, its architecture, design, user community and many other considerations, a healthcare organization must investigate as many scenarios as possible. Applying tools from the *GBA Blockchain Ethical Design Framework for Healthcare* gives needed context and guidance to health service organizations and policymakers, enabling researchers to streamline the process of due diligence. One tool from this framework helps organizations create a comprehensive *Digital Ethics Compliance Program* that includes some of the following elements:

- **Blockchain Ethics Course** curriculum designed to educate the participant on the unique ethical paradigms that affect healthcare service delivery, and how the implementation of blockchain featured solutions could impact positively or negatively.
- **Blockchain Ethics Accreditation Process** a useful tool for companies implementing blockchain technology to ensure stakeholders are properly educated and aware of the ramifications of employing blockchain innovations, and that they can continue to increase their knowledge and understanding as the technology, and the need for its features, evolve.
- **Blockchain Ethics Certification** empowers stakeholders with industry current knowledge of blockchain technologies and the use cases that are applicable to healthcare. This expertise can be used to demonstrate understanding of blockchain features, ethical impact to direct and indirect participants, and increase confidence among blockchain ecosystem participants for solution adoption.



FRAMEWORK DESIGN ELEMENTS

As we build blockchain solutions, the social effects of blockchain can be powerful and lasting. With the potential for such powerful impact, the design, application, and approach to the development and implementation of these technologies have long-term implications for society and individuals.

As of this writing, **there is no standard ethical approach** for the design, development and implementation of a blockchain platform for healthcare use cases; however, by borrowing from existing ethical frameworks, reviewing ethical guidelines already observed in healthcare service delivery, researching regulatory precedents and requirements, and studying concurrent ethical developments in other innovative fields like AI, we can compose guidance based on this foundation of knowledge.

Platforms that utilize blockchain technology do not operate in a vacuum, and as social media, and behavioral algorithms have shown, technology is not neutral. In fact, the capabilities of blockchain often work in tandem with other technologies such as AI, IoT, ML, or DIDs,^{69,70} just to name a few. When these combined innovations are deployed in a health services environment -- where adherence to stringent data-management regulations such as HIPAA, GDPR²⁶ or the HITECH Act⁷¹ are mandatory -- developers must look beyond the higher-level ethical theories of beneficence, non-maleficence, justice, and autonomy.

Values are embedded in the solution framework: how the problem is defined and by whom, who is building the solution, how it gets programmed and implemented, who has access, and what rules are created have consequences in intentional and unintentional ways. In the applications and implementation of blockchain, it is critical to understand that seemingly innocuous design choices could have resounding ethical implications on people's lives.

Proper development of blockchain-enabled platforms must take a holistic approach to all relevant technologies employed within a healthcare technology solution, and the existing regulations that govern their use.

The **Blockchain Ethical Design Framework for Healthcare** collates available industry knowledge in this regard and expands on this information so it can be used by any healthcare industry group to conceive developmental best practices and set goals for responsible application function, all within the context of their unique organizational scenario. For brevity, this document will discuss one aspect of guidance, *The Design Phase*, within the Ethical Design Framework. There are several additional guide points to consider, and a more comprehensive list will be available in the full Framework.

The Design Phase

It is crucial to remember that *design precedes implementation*. Efforts taken during the design phase of a healthcare blockchain solution will influence all aspects of the solution development and implementation phases. The old adage, "measure twice, cut once" is particularly applicable at this stage because thoughtful, comprehensive assessment of the goals of a blockchain solution, how it is supposed to function and who it will impact during the design phase can mitigate dangerous outcomes, improve efficiency and instill confidence and trust within stakeholder groups.⁷²



The design phase of any blockchain-enabled solution must determine several key principles, three of which will be discussed here: identification of all participants in the blockchain ecosystem and their roles, the scope of the project, and identification & management of risks.

Part 1. Identification of Participants and Roles

The target participants in a blockchain solution and their roles & responsibilities within that system reflect that platform's purpose or intent. Each solution and its participants have its own objectives, and therefore, its own unique ethical considerations to be measured. For example, in a blockchain-featured medical records platform, a participant may have the *role* of Health Data Owner (or traditionally, a "patient"). The Health Data Owner's *responsibility* may be to manage the access of other participants in the ecosystem to the PHI they own, and/or to make determinations on how long access to their PHI should be given, and/or how much data should be made available to whom.

When applying the historic ethical framework, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*,⁷³ to our healthcare blockchain example, the "patient" role might want to allow enforcement of **respect for persons** (determination of accuracy and completeness of data), **justice** (preventing discrimination), **beneficence** (the promotion of their own well-being), and **prevention of malfeasance** (abuse or misuse of PHI), among other things. The concepts within this construct, while designed for research, can also be interpreted for non-research modalities.

While the *role* of the Health Data Owner is intrinsically linked to their own PHI, clearly the *responsibilities* to that PHI are not limited solely to the Health Data Owner. Consider this: another participant in our example of a blockchain ecosystem may have the *role* of Health Service Provider (or traditionally, a "physician"). If the blockchain solution is not properly developed or configured to give patients control regarding use of their health information, there may be unapproved access, affecting **autonomy**. Yet another participant in our example may have the *role* of Health Insurance Provider (or traditionally, a "payor"). In an improperly developed workflow, "payors" may make unfair judgments based on inaccurate information in the "patient's" medical record or may make decisions based on inherited bias within their discrete organization, thereby affecting **justice**.

Misapplication of data may lead to harmful, unnecessary procedures, affecting **beneficence**. A Health Data Owner's PHI may be improperly shared by hospital administrators, amplifying the chance of **malfeasance**.

This example attempts to demonstrate that the well-being of participants in the blockchain ecosystem, in this case, "patients", are affected simultaneously by multiple participants in disparate roles; moreover, participants are impacted by other participants' adherence to the responsibilities within their assigned roles. After defining all participants within a blockchain system along with their roles and responsibilities, a developer, stakeholder or policymaker may begin to appreciate the need for an appropriate ethical approach using tools from an ethical design framework as a guide.



Part 2. Scope of the Project

The intended scope of a healthcare blockchain project describes more than the anticipated benefits or intended functionality. Scope must consider multiple variables including, but not limited to, the type of information being exchanged, the amount of information being transacted, how the information is collected and used, how and where the information is stored and the duration it is kept in the platform.

The determination of scope often leads to unintended "mission creep." Prediction and planning are basic aspects of human nature; we tend to prepare for the future and the future is unknown. To plan, we require data; but acquiring custody of data, especially in the case of PHI, also introduces risk. For example, a stakeholder may want to collect and store participant addresses in case they want to geographically identify user groups later. If the plan to geographically identify participants is not a part of the project's direct scope, the risk of collecting, storing and safeguarding that data without an immediate need can categorize that dataset as an asset whose liability outweighs its benefit, at least in the near term.

Efficiently defining the scope of a project might require minimizing the data collected to only immediately relevant and necessary information. This concept of minimizing collected data is not simply a high-minded ethical principle, it is a requirement by law in many jurisdictions. Article 5 of the GDPR²⁶ requires that data be "relevant and limited to what is necessary in relation to the purposes for which they are processed." Understanding all relevant regulations is a part of the holistic approach developers must take when designing their systems. Sometimes "doing the right thing" is not only ethically sound; it is also a legal imperative.

Part 3. Identification & Management of Risks

A healthcare blockchain developer or stakeholder must identify and manage risks associated with the use of the innovation. This assessment can help identify acceptable risks while eliminating unnecessary risks, not only ethically but technically and functionally as well.⁷⁴ While risk could be identified in many aspects of the design process, let us consider examples surrounding an important aspect of any blockchain solution, *data*.

Risks involving data usage can originate from external or internal sources and can be amplified or diminished depending on the type of data (all systems that utilize PHI have uniquely inherent risks, for example, since PHI is itself a liability), the kinds of transaction methods applied and so on. While there are many risks regarding data use, we have observed that most can generally fall into two broad categories: 1) **Issues of Integrity** and 2) **Issues of Misuse**.

Within these two overarching classifications, ethical and other risk considerations can be traced broadly to six root issues: **Governance, Identity, Access, Verification and Authentication, Ownership of Data, and Security.** Together, these factors create a foundation for investigation, and comprise important aspects of the *Blockchain Ethical Design Framework for Healthcare*.

Once blockchain is selected as an appropriate technology, the Framework moves iteratively through a detailed analysis of the six root issues for ethical consideration within each of the two broader



categories. At every stage, guiding questions identify the effects of the design choices on the end users and communities.

- How is governance created and maintained?
- How is **identity** defined and established?
- How are inputs verified and transactions authenticated?
- How is access defined, granted, controlled and revoked?
- How is ownership of data defined, granted, and executed?
- How is **security** set up and guaranteed?⁷⁹

Blockchain Design Consequences

It is impossible to focus solely on one desired feature without understanding and accounting for the interaction of all the attributes of blockchain.⁷⁹ In the design process, to optimize the desired attributes of blockchain for a given application, compliance features must be built into the technology of the solution. As an example, a blockchain used to transact information pertaining to EU residents must include the capacity to address the right to be forgotten. In this manner, there will always be trade-offs which will result in functionally different blockchain systems.

While crypto-economic systems can increase financial inclusion and create innovative microeconomies, these structures could also create exploitative systems with perverse incentives or undermine existing payment and monetary systems that have the virtue of being understood and accepted within formal financial markets.⁷⁵ In each case, it is the responsibility of the stakeholders to identify and investigate all variables of use, participation, benefit and possible harm when planning the build, implementation and ownership of blockchain solutions. Since each organization that potentially adopts blockchain innovation has its own unique requirements, challenges, assets and goals, the most appropriate investigators of ethical risk are often internally sourced.

Codifying Negative Social Impacts

We have found that one potential consequence for end users of blockchain technology is the codification and exacerbation of existing negative social dynamics⁷⁹. Blockchain could be used as a tool to consolidate control over people or entities or to create secret agreements that circumvent laws and regulations. For example, a blockchain used to provide access to financial services that relies on members of a community to collectively verify a person's creditworthiness has vastly different effects on an end user from a blockchain that relies on a person's history of financial transactions, property ownership, and education record ⁷⁹. The first example runs the risk of codifying biases of the community, while the latter runs the risk of codifying the status quo. Without intentional design, a blockchain could run the risk of exacerbating disparities.

The Risks of Transparent or Immutable Personal Information

Transparency of PII could put someone at risk of exploitation, while transparency of ethnic or religious background, sexual orientation, or other identifiers could put a person at risk for persecution.^{79, 23} Should a political refugee, witness to a crime, or survivor of domestic abuse have the right to anonymity or to



create a new identity? Even if someone legally changed her name, it may be difficult to disassociate her biometrics from the old DID in the blockchain, if any were associated. Is there a minimally viable set of identifiers that should be used to create a DID to help mitigate these effects?⁷⁹

The Future of Blockchain in Healthcare

The demand for secure, scalable technology systems that facilitate collaboration, establish ownership and create trust in the healthcare space has reached a critical level. Based on current trends, it is our assertion that industry-wide demand is likely to continue to increase explosively for the foreseeable future. Watch for these factors and more to unfold beyond 2020:

- Blockchain technical skills training is on the rise and is expected to grow exponentially as different industries begin to trust and adopt blockchain innovation. Watch for an increase in available technical training for building on proprietary or unified platforms (Ethereum, Hyperledger, R3 Corda,) as well as foundational software development training using popular object-oriented languages for blockchain building. This will lead to higher availability of technical blockchain developers which will help mature the functionality of blockchain solutions and spur adoption.
- The Demand for Data Ownership will increase as consumers are becoming more familiar with the successful use of blockchain technology in other business verticals. Ultimately, the use of blockchain to demonstrate data origination, provide security and allow consumers to own and manage their data will become a coveted feature in technology offerings to the public. This will also be particularly impactful in adoption of DID and medical records on blockchain.
- The security, privacy and transparency of transactions that can be achieved with blockchain applications can bolster **greater adoption of Health Information Exchanges (HIEs),** giving confidence to participants that data about public health emergencies, local health trends, or information about patients common to metropolitan service areas (MSAs) of area health systems can be shared safely, and at the sharer's discretion.
- The modular and granular tracking and authorization capabilities in blockchain systems allow for **creative incentivization programs** for patients to participate in clinical trials, follow care plans (weight loss, smoking cessation, behavioral health) by tracking progress and offering rewards thru blockchain (micropayments).⁷⁷
- Blockchain in academic research shows promise in allowing secure collaboration, demonstration of chain of custody, and demonstrating ownership of intellectual property.
- **Other items**: The mobile healthcare revolution and the adoption of telemedicine, remote monitoring, and virtual service delivery creates opportunities for blockchain to offer security of transactions and portability of data.

Blockchain innovations show great promise in offering highly sought features and processes that can solve many of the urgent problems surrounding data use, ownership and access in healthcare; however these features can have significant negative impact if adoption is not planned deliberately, and with an ethical lens. The GBA encourages healthcare policymakers at the local, state, national and international



level and stakeholders for health service providers of all disciplines who are considering adoption of these promising technological advancements to utilize tools in the **Blockchain Ethical Design Framework for Healthcare**. We strive to offer tools and guidance, provide varying perspectives and context, and share information to assist the healthcare community in safely, responsibly and sustainably adopting blockchain, in keeping with our goal to help advance and refine blockchain technologies and solutions throughout the health services continuum.



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