ITU KALEIDOSCOPE
ATLANTA 2019

TECHNICAL AND LEGAL CHALLENGES FOR HEALTHCARE BLOCKCHAINS AND SMART CONTRACTS

Steven A. Wright MBA PhD JD
Georgia State University
swright22@gsu.edu

4-6 December
Atlanta, Georgia, USA

ITU

TECHNICAL AND LEGAL CHALLENGES FOR HEALTHCARE BLOCKCHAINS AND SMART CONTRACTS

- Blockchain Introduction
- Healthcare Blockchains
  - Data in Healthcare Blockchains
  - Actors in Healthcare Blockchains
- Technology Issues
  - Implementation Issues
  - Identity & Trust Issues
- Legal Issues
  - Entities
  - Public Law
  - Private Law
- Recommendations

- Blockchain technology usually associated with cryptocurrency (e.g. Bitcoin)
- Broad range of applications proposed (e.g. financial, health, IoT)
- Code as Law -> DAOs
- Nascent Standardization efforts (e.g. ISO TC 307)
- Open Source implementations (e.g. Hyperledger, Ethereum)

Healthcare Blockchains:

- Variety of Blockchain applications proposed in Healthcare:
  - Prevention of drug counterfeiting*, research/clinical trials, insurance claim adjudication, healthcare records, wearables, mhealth
  - Good fit applications ?– multiple (competing) parties, more trust adds value, intermediary elimination, visible/auditable data
- Beyond proposals, some are being implemented:
  - Primarily on Ethereum and Hyperledger
- Benefits claimed:
  - Decentralization, data security and privacy(?), health data ownership, availability, robustness, transparency and trust, data integrity

*The Drug Supply Chain Security Act (DSCSA) of 2013 requires the Food and Drug Administration (FDA) to develop standards and regulations for an interoperable electronic system to identify and trace medications. A number of pilot projects for this purpose have been developed using blockchain technologies (https://www.drstevenawright.com/pharmaceutical-supply-blockchains/).

Healthcare Blockchains: Data in Healthcare Blockchains

- Lots of data types across the healthcare blockchain proposals:
  - Financial, transaction records, consent forms, clinical trial records, **sensor data** (e.g. temperature), **medical** records, **personal** records
- Healthcare record categories / use cases:
  - Electronic Medical Records (EMRs) stored by healthcare provider
  - Personal Health Records (PHRs) store data collected by patients themselves (e.g. using wearables)
  - Electronic Health Records (EHRs) passed between healthcare providers
- Challenges:
  - Storage – Size of records
  - Privacy – access controls, confidentiality assurance mechanisms

Healthcare Blockchains: Actors in Healthcare Blockchains

- Depends on specific use cases
- Non fungible data value/ trustworthiness comes from who adds it (e.g. lab results from a qualified lab) – pseudonymous, permissionless transactions may not be needed?
- Stakeholders – patients healthcare professionals, regulatory agencies, legal systems, the public
- Special cases for access – minors, healthcare power of attorney, heirs after death
- Other Off chain systems for computation, storage, etc.
- Is the blockchain itself an actor?

Blockchain Technology Issues:

- Technology issues add risks impeding design and deployment
- Technology at early stage of adoption
  - only 2% of papers in one study were reporting on implementations
- Identified challenges include interoperability, security and privacy, scalability, speed and patient engagement
- Not just a technology exercise
  - Need to consider broader issues for requirements, e.g. organization, legal context
- Blockchain as trust machine – but who needs to trust whom for what purpose?

Blockchain Technology Issues: Implementation Issues

- Software has bugs
    - Cryptocurrency applications as an incentive stress test to find bugs
    - Security and performance bugs can take some time to fix
- Quality Metrics and benchmarks not yet agreed
    - What to measure, how to apply across different blockchain technologies
- Software engineering tools and methodologies still under development for blockchains
- Technology maturity

Blockchain Technology Issues: Identity & Trust Issues

- Blockchain sometimes referred to as trust machine, and most would consider trust important for healthcare applications

- What do we mean by trust in healthcare blockchain applications – is it the same sort of trust as in financial applications?

- Various Blockchains have limited capabilities across the security dimensions – confidentiality, availability, integrity, provenance, pseudonymity and selective disclosure – which are important for specific healthcare blockchain applications?

- Who do we need to trust and for what purpose in healthcare blockchain applications? What are the consequences of losing that trust?

ITU**KALEIDOSCOPE**
ATLANTA**2019**

Blockchain Legal Issues:

- Legal risks can impede the deployment of healthcare blockchains.
- Legal jurisdictions have geographic boundaries – blockchains do not -> may be impacted by laws of multiple jurisdictions.
- Blockchain code as law can violate, complement, supplement existing laws and substitute for law where none exist.
- Blockchain as trust machine, but legal systems also rely on trust.

Blockchain Legal Issues: Entities

- Law covers people and the things they own; legal risks associated with things revert back to the thing's owners.

- Legal "people" includes corporations, partnerships, LLCs, etc.

- Even in absence of other documentation, participants in blockchain could be considered in a partnership -> joint liability.

- Proposals to create independent Digital Autonomous Entities on blockchains:

  – Some claim possible within existing LLC enabling legislation

  – State specific Legislation, e.g. Vermont BBLLC statute (S.269 (Act 205) 2018 §4171-74).

- Under what circumstances would a Healthcare BBLLC make sense?

Blockchain Legal Issues: Public Law

- Blockchain specific legislation under consideration in many states
    - https://bit.ly/2OlWcJH
- General Statues impacting lots of software technology implementations
    - e.g. privacy legislation like GDPR requires corrections, but blockchains are immutable.
- Healthcare Specific laws and regulations
    - e.g. Privacy regulations specific to healthcare (e.g. HIPPA)
    - e.g. Medical device regulations
    - DSCSA

Blockchain Legal Issues: Private Law

- Contracts
  - "Smart contracts" executing on blockchains
  - Completeness / correctness / amiguity
- Torts (duties where no contract exists)
- Enforcement actions
  - By the blockchain (self executing smart contract)
  - Blockchain as arbitration
  - Legal actions on a blockchain?

Recommendations:

- Different approaches to reducing risks for deployment of healthcare blockchains.

- Availability of open source reduces cost/risk of experimentation with new technologies - provides a design pattern example for commercial implementations. More specific open source communities around selected healthcare blockchain applications may be helpful.

- Standards are particularly helpful for enabling interoperability. While TC 307 has started work, more remains to be done particularly around standardizing the healthcare record formats "healthcare tokens".

- Regulatory support through "sandboxes", etc. can help both the industry and its regulators understand the possibilities of the technology. More specific legislation/ regulation may then follow.

- Standardization (or perhaps parameterization) of smart contracts applicable to healthcare blockchains would be helpful if the use cases for those applications are well understood.

ITU KALEIDOSCOPE
ATLANTA 2019

Thank you