Blockchain for Healthcare: Promises, Challenges and Prospects

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https://www.blockchain-healthcare.org/

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Project aims and objectives

This project will

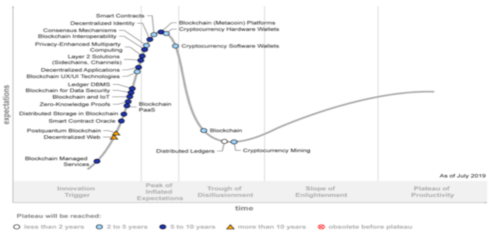
- identify the state of the art in blockchain tech and healthcare applications worldwide, and explore prospects for the use in the UK up to 10 years hence
- map the legal, ethical, technical and governance dimensions of these applications, drawing on experience in other sectors
- ascertain the **potential benefits, risks and challenges** associated with these applications along each of dimension (legal, ethical, tech, governance)
- consider the potential **significance, implications and prospects** for utilising blockchain in healthcare

Outline

1. Where are we now and where are we headed?
2. The 'promise' of blockchain for healthcare
3. Challenges (Risks directly related to challenges)
4. Prospects
5. Under what conditions and for what kinds of problem, does blockchain offer a real and unique solution?
6. Does blockchain-based patient records management fit the profile of (5)?
7. Conclusion

1. **Where are we now and where are we heading?**

Blockchain in 2019 - trough of disillusionment



Where is blockchain for healthcare now?

- Interest in developing blockchain applications for healthcare began around 2016.
- Despite considerable activity and excitement, blockchain for healthcare is still largely an **immature technology** for which applications remain **systematically unproven**
- Considerable recent and on-going activity focused on developing a **concrete 'use case' and establishing 'proof of concept'** (Mac)
- Where implementation has occurred, widespread adoption and take up not (yet) achieved (Estonian e-health exception)

What is the direction of travel?

- Investment and development led largely by the **private sector** healthcare organisations. No significant **public sector investment** in the UK or USA in blockchain generally, nor for healthcare
- Current US activity focused on creation of **consortia and networks** of shared interests. On-going exploration and experimentation of B2B use cases (see later)
- **Continuing interest and optimism** continues, despite the rise, failure and significant number of ICO scams) albeit much more **muted.** Hype has faded. Widely recognised that progress will require hard graft, trial and error, and a more sober appraisal of what is achievable in practice.
- But substantial investment in sector by **venture capitalists** reflects their **belief that there is real value** associated with the sector, with potential to bring a level of expertise not available via crowdfunding (via ICOs)

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2. The blockchain for healthcare promise

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The blockchain for healthcare promise

The ‘opportunities’ (or ‘promises’) of blockchain in healthcare contexts through the generation of significant improvements in healthcare delivery in the form of:

- better quality **medical care** (ie clinical decisions) and more effective (public) illness and **disease prevention** (ie population health monitoring and more rapid, more accurate response)
- more efficient and effective **healthcare administration**
- improvements in the efficiency and quality of **medical and healthcare research**

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Better, more accessible data = better healthcare

- All these opportunities rely on the blockchains to establsh and maintain **databases** comprised of **better data** (ie more accurate, trustworthy, reliable, secure) while enabling **more fine-grained and timely access** then is currently possible
- This data can then be used to **inform decisions** - for care, administration and to inform and drive research
- But to fulfil this promise, must establish **proof of value** ie demonstrate that blockchain offers real and significant value to healthcare by ‘solving’ real, practical healthcare need in ways that justify the costs of implementing and maintaining DLT systems

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3. Challenges

What challenges must be overcome if blockchain is to deliver on its promise for healthcare?

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Challenges: obstacles & normative conflict

The challenges must be overcome to deliver on the promises of blockchain for healthcare are **multi-faceted.** I have divided them into:

(a) **obstacles** that must be overcome to facilitate the successful implementation of DLT into healthcare to solve real healthcare problems (and might be overcome)

(b) **resolving normative tensions** to identify acceptable compromises between competing objectives and values that arise in seeking to apply DLT to real-world settings

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Obstacles to overcome in order to realise the promise of blockchain for healthcare

1. The adoption challenge
2. The interoperability and standardisation challenge
3. The (internal) blockchain governance challenge
4. The data security challenge
5. The quality, safety and data integrity challenge
6. The human factors and fallibility challenge

(a) The adoption challenge

- Overcoming organisational risks to justify cost of adoption
- Building a network of participants and stakeholders
- User acceptance: clinicians, patients, administrators
- Preserving and sustaining core professional and ethical norms and adherence with legal requirements

(b) Interoperability and standardisation challenge

Much of the 'promise' of blockchain lies in its capacity to manage access to records (and to share the data contained therein) simply and seamlessly, overcoming the current 'siloed' approach.

To achieve the greatest benefits of DLT, *full* interoperability required at 3 levels

(a) *foundational* interoperability, ie allowing data exchange from one IT system to another;

(b) *structural* interoperability, ie allowing the exchange of data which has been structured and formatted so that the purpose and meaning of data is preserved and unaltered

(c) *semantic* interoperability: the ability of two or more systems to exchange information and to *use* the information that has been exchanged

Interoperability thus depends upon the shared use of common standards at the relevant level.

- Most promising use cases in practice are all concerned with sharing 'back office' functions, where high level of interoperability realistically achievable at all three levels.
- Yet dangers of lack of functional interoperability due to emergence of multiple blockchain platforms in healthcare that might block the flow of transactions across platforms (Flannery 2019)

(c) Internal governance challenge

- Although internal governance challenges acute for permissionless blockchains, permissioned blockchains also raise serious internal governance challenges
- Successful collaboration of healthcare organisations via DLT systems requires effective governance to **manage complex interests** - some shared common interest, but also considerable divergence
- Merely identifying set of shared common interests across multiple organisations is not sufficient to establish a 'minimum viable network'
- Because the interests of participants are unlikely to be *wholly* aligned, how to devise an implement appropriate internal governance structure, ie binding policies that prescribe how decisions about how the network will operate, whether and how to effect changes?
- Challenge **not yet fully grasped** because still early stage of development: governance challenges often only apparent when conflict and tension between the partners surfaces in specific cases – esp due to changing circumstances

(d) The data security challenge

- ensuring the **security** of **off-chain data** that is referenced in the blockchain ledger is vital. Data security of blockchain storage does *not* apply to off-chain data (serious limitation to practical achievability of blockchain promise)
- problem of '**data leakage' or 'escape'**: although blockchain promises selective data sharing through access controls intended to ensure privacy and confidentiality of records, it does **not** address the possibility that – once data is revealed, those with access will generally be able to copy and extract the data and store it perpetually (Finck 2019: 115).
  - *"When data is to be downloaded from the ledger, most of the benefits of using DLTs to initially store and sell it are lost."* (Finck 2019: 139).
  - Though privacy-preserving computations to ensure that data is not downloaded and remains anonymous might be possible

(e) The quality, safety and data integrity challenge:

Because healthcare settings are safety critical, it is vital that DLTs are not implemented unless and until patient safety can be assured.

•**USA**: appears to be a lack of attention to rigorous testing, validation and verification to provide the necessary assurances, even in safety critical settings

eg Flannery (2019) argues that DLT experiments should be approached within a framework of **medical research protocols** to enable robust data collection, conformity with ethical standards and data collection and review.

UK: Various recent policies and regulations for digital health technologies

- NHS standards that ensure new technologies are (1) **clinically effective** and (2) **offer economic value** (NHS England + Public Health England + Digital Health London + MedCity)
- NHS Digital **Clinical Safety Regulations** (DCBO129 and DCBO160) recently introduced under s 250 of the Health and Social Care Act 2012 mandating **clinical risk management processes** to ensure patient safety where deployment and use of a new Health IT System or in respect to the modification or decommissioning of an existing system
- Before digital healthcare providers can provide services, they must secure **CQC registration** for the regulated activities they intend to deliver. Must satisfy CQC that the care and treatment to be provided will meet the requirements of the Health and Social Care Act and associated regulations
- NHS Digital offers **functional test and assurance services** for health IT systems

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(f) **The human factors and fallibility challenge**

- Even if adoption challenge is overcome – these systems must interact with **humans ie fallible agents**, with multiple and sometimes conflicting needs, interests and motives, and with highly varying levels of technological competence, and capacity for decision-making to safeguard their own interests
- Eg. Even if patients are willing to engage actively in decision-making that affects their own health (including health data sharing) **mistakes are inevitable and unavoidable**. Applies to all those working in healthcare (clinicians, adminstrators, care workers)
- Implementation complex socio-technical systems that utilise DLT into real world contexts must successfully respond to the vagaries of human behaviour and decision-making.
- Mistakes and human failure have potential to reduce or otherwise undermine the achievement of the anticipated benefits.

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Challenges II:
Normative tensions that require satisfactory resolution

1. Performance and scalability vs security and resilience
2. Privacy and confidentiality vs transparency and accountability
3. Social vs computational trust: the 'computational trust' paradox

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i. Performance and scalability vs security and resilience

- Blockchains cannot (yet) provide high levels of ledger security and resilience while processing high volume of transactions at scale and speed
- Instead, **trade-off required**: greater security and resilience to attack provided by more computationally and time intensive consensus protocols for validating transactions. But this reduces transaction throughput and hence operational performance
- Also, large data cannot be stored effectively on permissionless blockchains. Instead, blockchain can enable source integrity by creating a tamper-proof append only ledger that can be mathematically verified and audited, via automated creation of a transaction event index, but the data itself must be stored off-chain.

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ii. Privacy and confidentiality vs transparency and accountability

Transparency of blockchains (esp permissionless blockchains) fundamentally at odds with the private and confidential nature of

- patient information. EU data protection law prohibits sharing without a lawful basis (which includes, but is not limited to, consent by the data subject); and
- business records confidentiality (of healthcare organisations)
- EU data protection law confers a set of data protection rights on data subjects, which DLTs must demonstrate that respect and accommodate
- Designing a blockchain based technological system that demonstrates fidelity to legal obligations, rights and duties, and yet can be flexibly altered to fit dynamic legal rights and obligations **and** professional, clinical and patient norms and expectations, as these evolve and change over time, is a **serious** challenge in real world settings

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*iii. Social vs computational trust: **the 'computational trust' paradox***

- Emergence of healthcare blockchain consortia seeking to build technical system to generate shared benefits from cooperation via blockchain systems by driving efficiencies via secure shared administrative records/functions
- Use of computational consensus mechanisms to verify transactions and maintain a single shared ledger across a distributed network of computers obviates the need for each participant to maintain and reconcile its own ledger and records - should **generate considerable administrative savings** that benefits all network participants

But generates what I call the **'computational trust' paradox:** ie

But, to achieve this, each participant must

(a) trust in the integrity, quality and security of the **underlying substantive information** underpinning the events and transactions that are validated by the blockchain system and appended to the shared ledger, and

(b) be **wiling to contribute their records** and resources to maintaining the ledger (discussed later).

- Hence the operation of a shared repository of records exposes each participant to **vulnerabilities of the data (and processes of collection) contributed by fellow partners**.
- **Paradox:** reliance on computational trust **heightens the importance and need for social trust**, in order for network participants to generate and reap the gains from co-operation that permissioned blockchain systems make possible

Question: Can blockchain systems be designed and implemented to achieve the appropriate combination, balance and dynamic interaction b/n social and computational trust?

4. Prospects

What are the future prospects of blockchain for healthcare in the US and UK?

USA

- Current trend entails development of **permissionless blockchains** around **consortia of network of trusted healthcare organisations** with a **common interest** in a shared set of authoritative, secure records
- Motivation by desire generate efficiencies and responsiveness of back office processes and healthcare administration where duplication arising from lack of trust
- Reliance on permissioned blockchain systems that enable a shared common pool of records could generate **significant cost savings and efficiencies.**
- But, serious challenge to create appropriate incentive and governance structures that facilitates record sharing *and* the fair and acceptable distribution those savings (benefits) across the partners (see below)

UK

- National tax-payer funded healthcare system (NHS), beloved of patients and citizens
- Well-established pre-existing relationships so organisations are **not** considered **inherently untrustworthy**, nor are their records
- But some similarities in terms of the **cost reduction proposition** that might motivate clinical commissioning groups (CCGs) to consider blockchain tech.
- So, to the extent that that DLT-based systems have the potential to drive **serious cost savings**, then these might well be attractive to clinical commissioning groups.
- Eg The Guardtime/Instant Access Medical **MyPCR** application - to help patients manage chronic conditions. Cost savings arising from adherence to care plans can help avoid very expensive secondary conditions

Future prospects driven by quest for administrative efficiencies

- The prospect of very **substantial cost savings** (while improving service and care delivery processes, or at least without introducing greater inefficiencies) likely to be primary driver for continued interest and experimental adoption
- In the USA, reliance on mathematical consensus protocols to verify the admissibility of transactions to the ledger where those transactions might otherwise be regarded as **inherently untrustworthy** may also help nurture momentum in finding DLT based approaches in healthcare

5. Under what conditions, and for what kinds of problems, does blockchain offer a **real and unique** solution?

Blockchain as a technological solution in search of a problem

What are the problems that blockchain is uniquely suited to solving?

- Initial activity motivated by a desire to play with the cool new toy (tech-driven)
- But novelty has now worn off with realisation that implementing blockchain technologies into real world practice is considerably more difficult than the rhetoric and fanfare associated with its emergence
- To succeed, 'genuine problems' or 'real needs' in healthcare or other domains must be identified which blockchain technologies have a realistic prospect of actually 'solving' or meeting?

My provisional theory

- There are **two core functions** that blockchain technology can help provide and offer real value, thereby potentially meeting a genuine need:

(1) Mathematically verified and auditable tracking and trace function

(2) **Record pooling:** create and secure store a set of **shared records** between a **network** of **partners**, that serves as a trustworthy, **single authoritative database of records** which

- authorised partners can **contribute records to**, and
- can be accessed by individual partners via the application of **technological access management** implemented via permissioned blockchain protocols

(1) Mathematically verified and auditable track and trace function

- Blockchain can promote the **value of security**, providing assurance about the 'source integrity' of an item of data via the creation of a mathematically verifiable, tamper-proof and highly secure, **real-time audit trail** of the item of data to which it attaches (thus offering reliable and verifiable evidence of the item's handling and movement)
- Applied in this way, blockchain is essentially a **reference system**, rather than a storage system. Hence virtually any type of data can be referenced, with the b-ch serving as an index of what information exists, who has access to it, where it can be found, and when it was created.
- Eg KSI service offered by Guardtime. All data that is sent to Guardtime for signature is hashed, and only the audit marker (hash) is stored on the blockchain (hence scalable and fast).

(2) 'Record pooling': creating a shared authoritative database + technological access management

- USA: On-going trend towards building healthcare consortia seeking shared benefit via blockchain
- Under what conditions is can **collective value** be generated for a limited number of authorised partners by creating a pool of authoritative, synchronised records (and index) among them via technologically enabled access controls?
- I posit that there IS real potential for shared value creation such a permissioned blockchain where 6 (rather demanding) **conditions** are met:

1. Common interest in shared records

- **Condition 1: common interest in shared records.**

Shared records of specific phenomena in which all network partners have a **common interest** (although the nature and extent of their interest might be variable, although the greater the divergence, then potentially greater challenges for internal governance of the network) in which the **nature of their interests are broadly aligned** (and I suspect also rough parity in magnitude of interests)

2. Semantic interoperability

- **Condition 2 – clear and settled agreement on semantic meaning of the records** ('semantic interoperability')
- The records attest to a set of activities that have a clear, unambiguous and **highly stable meaning over time**, for which there is little or no interpretative or semantic ambiguity
- eg administrative records for asset or process tracking, records of successful completion of university degree courses or other professional credentials
- In these circumstances, the information contained in the records can be computationally verified and thus considered **trustworthy:** hence can be **relied upon** as a basis for decision-making

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3. Significant benefits from single, shared longtitudinal record

- **Condition 3**: **Considerable value** arising from the maintaining **a single, accurate and reliable temporal record over time**:
- When availability of a **common trustworthy (**authoritative) **record of specific phenomenon over time,** that enables network partners easily to acquire an understanding of **the state of that phenomenon at a particular point in time** (past or present)**,** including **real-time updates**
- Eg what is the current state of X's professional credentials? Is Y accredited to perform a particular activity and is that accreditation still current? High value or sensitive product tracking such as prescription medication supply chain and dispensary tracking;

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4. Need to ensure validity of each shared record

- **Condition 4: Value and necessity of establishing validity of the shared record:** Each individual record may they lack certain properties and thus unreliable (eg forgery) AND the presence or absence of these properties can be easily and automatically evaluated by reference to clear, fixed and stable criteria (much more likely if those properties are stable and binary in character, rather than properties that can be present in degrees)**.**
- It these circumstances, the application of **distributed ledger consensus protocols can be applied to verify that the critical conditions for admission have been satisfied that can be automated and applied at scale (**otherwise, an ordinary shared data-base would suffice, no need for distributed consensus to validate)
- eg for Bitcoin, must establish that account holder actually holds sufficient Bitcoin to pay the recipient, and has not attempted to double-spend the same Bitcoin)

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5. Non-confidential nature of the underlying data

Condition 5 – Record does not contain confidential information or otherwise inherently sensitive information

- *Might* it be technologically possible to **design access controls** into the network architecture and protocols that **protect the privacy** of that information + enable access and sharing in ways that are consistent with **legal** and **ethical** duties?
- Even so, doesn't solve the data leakage problem

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6. Effective and legitimate technological governance + incentive structure

- **Condition 6: technical access mechanisms + underlying social governance and incentive structure facilitates contribution of records to the shared 'pool'**
- individual partners invited to contribute their commercial assets in the form of digitally recorded data (akin to private property) into a **shared pool of digital records** thereby **creating a new collective resource** (where previously none existed).
- Without the capacity for automated access management that can be designed into permissionless blockchains, there are **no incentives** for participates to contribute their records due to the **free rider problem** because access to the shared pool of records would non-excludable, ie open to all network participants, and also non-rivalrous (akin to a members-only recipe-sharing website) Hence, classical **'public good' problem**.

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Pooled records as collective (public) goods

Technological access management as a solution to the problem of the free rider

- A trustworthy pool of records = resource to which network partners contribute creates a public good (more akin to 'club good' b/c only partners have access)
- The classic 'problem of public goods' - due to 2 conditions: once a unit is produced, consumption of that good is (i) **non-excludable,** and (ii) **non-rivalrous**
- Thus, no incentives to produce or contribute units, hence market failure - the good will be under-produced - hence requires political decision and government regulation to generate production at collectively desired level
- But, because blockchains can incorporate fine-grained, automated access controls, they *partially* overcome the "free-rider" problem (but doesn't fully solve the non-rivalrous consumption problem due to the problem of data leakage and reuse).

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Incentives to contribute to the pool

- Technologically created excludability opens up the potential to establish **incentives for individuals to contribute** to the development, maintenance and quality of the public good.
- Individuals can rationally be expected to contribute their records to the shared pool **if (and only if)** they believe that the value to them individually will outweigh the individual costs of contributing.
- Here lies the nub of '**creating appropriate incentive structures' challenge**: (to overcome the free rider problem and first mover 'disadvantage')

Creation of internal market among network participants

- Rather than simply contributing records into a shared pool which is then freely accessible by all network members, access can be controlled and conditions of access attached – eg **payment of an access fee**.
- In this way, **excludability** becomes practically possible through reliance on technical access control and this, in turn, opens up the possibility of creating an **internal market for records** which can then be bought and sold via the DLT-enabled exchange
- For example: **ProCredEx** - rather than a single shared authoritative database, creates **data sharing** and **synchronisation** system via the **pooling of authoritative records** that are **selectively shared**, based on a market-based exchange

Generation of network effects as pool size increases

- **Network effects** anticipated: the greater the size of the pool, the greater the benefit accruing to all members arising from access to the pool (eg the shared recipe database) while also reducing aggregate costs of production (only one person needs to write down the ultimate chocolate cake recipe and share it with others in the network)
- **But the benefit of network effects do *not* accrue solely to an individual contributor, but accrue to the benefit of the *collective*.**

First mover disadvantage - obverse of conventional platform economy effect

- Hence **first mover** within permissioned blockchains **faces a 'free rider' problem**, bearing the risks associated with early adoption, rather than the advantages associated with unilaterally capturing the benefit of network effects. (The extent to which the value of the collective pool is valuable to any individual partner is likely to vary, depending upon their particular context and circumstances)
- So, **the incentive structure is the reverse** of that arising from conventional 'digital platform economy' models (Search engines, social networks, ride-sharing etc) where the platform facilitates exchange between 'providers' and 'consumers at scale, typically enjoys a 'winner take all' logic associated with first mover advantage, unilaterally capturing the payoff of network effects
- For blockchain based pooled records, this is **reversed** because the **payoff** generated by the network effects is **shared among the network partners**

6. The prospect of blockchain-based patient records management

Do blockchain enabled Electronic Health Records (EHRs) meet the conditions set out in section 5?

Prospects for blockchain enabled EHRs?

Condition 1 is **partially met** – many stakeholders with a substantial interest in having access to the data contained in those records (clinicians and other treatment providers, medical researchers, pharma) but a wide range of intersecting interests that may not always be aligned, and sometimes conflicting

Condition 2 - clear and settled agreement on semantic meaning of the records appears very poorly met:

Condition 3 (very considerable value in having a single, accurate and reliable temporal record over time) is – by contrast - strongly met**.** Very considerable value for clinicians and for patients (and indeed for medical researchers) in a single, reliable and trustworthy longtitudinal care record for each individual patient over their life-course.

Prospects for blockchain enabled EHRs?

Condition 4 (inherent untrustworthiness of the data contained in the records) IS potentially present for some kinds of individual level health data, but this is likely to be highly variable depending upon context.

- Eg NHS probably a **very high level of trust** in patient records at one level, in that NHS clinical providers have high reputations for trustworthiness, and there are few incentives to falsify data.
- But problem of **data quality persists** – cannnot guarantee that all patient data was **reliably recorded.** Blockchain does not solve the **garbage in, garbage out** problem

Condition 5 is NOT met: the underlying data is highly sensitive. There are real risks for patients from the sharing of their intimate health data, in ways that might be used against them

Prospects for blockchain enabled EHRs muted

- So, patient records management does **not** appear to clearly meet **all** the conditions for which blockchain systems are likely to provide significant real value.
- Hence I am sceptical about whether the full range of promises associated with blockchain based patient-controlled medical records will come to pass.

5. Conclusion

What of my original hypothesis?

Original hypothesis

- My original hypothesis (for grant application):

"blockchain's promise in healthcare contexts cannot be realised unless and until significant and complex legal, ethical, technical and governance risks and challenges are addressed"

Revised thesis

- Following our investigations, I would now reformulate :

"The initial promise of blockchain in healthcare contexts will only be ***partially realised*** *because some of the multi-faceted challenges that arise in designing and implementing blockchain systems in healthcare contexts require the resolution of complex normative and practical trade-offs in real world healthcare contexts which* ***cannot be satisfactorily resolved by hard-coded solutions"***

Questions

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