

Blockchain Technology & the Potential for Its Use in Healthcare

A visionary approach

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COLOR SPACE POST

A privately owned, Consumer Led Health Company.

1. Who We Are / Executive summary

Color Space Post - Consumer Led Health, is a US health start-up leveraging the blockchain to create a new healthcare infrastructure to service consumers and the health industry.

We believe:

- healthcare is unsustainable on current trajectories.
- in a consumer centric ecosystem where individuals manage their own health.
- in a future where medical treatment is individualized and privacy is paramount.
- blockchain implementation is eminently achievable and has great potential to; store records, help democratize health, empower the consumer to self-manage, spur savings, and unlock additional value and data, driving healthcare discoveries for years to come.

2. Introduction

Healthcare is intrinsically different to other industries. Healthcare is intimate and pervades every element of life often demanding extreme privacy. When one's health is failing, it can be traumatic, affecting one's mental state, finances and one's friends and family. Color Space Post believes healthcare access and affordability is on a downward trajectory, and the prospective integration of blockchain technology has the potential to re-set the current trends. The role of government in supporting the integration of this technology and in-turn, re-setting healthcare for a new era, becomes vitally important.

In relation to the forementioned, this paper explores;

- Why a consumer centric approach must be the basis for blockchain technology rollout in health. We explore where the consumer currently sits in health, and why consumer-centricity will solve future sustainability issues in healthcare (Section 3)
- Health from a data perspective to look at blockchain technology's data application (Section 4)
- The role of blockchain technology in facilitating this radical new future of healthcare - it's applications, and opportunities - including the role of government (Section 5 and 6)
 - NOTE – when blockchain is referred to in this paper, it refers in general terms to the technology of a distributed database held in time-stamped valid transaction blocks, linked to previous ones in a chain.
- Challenges raised by blockchain (Section 7)

We hope that this paper brings clarity to why putting the consumer at the center of our blockchain approach (answering the "why" of blockchain first), will support a revolutionary and sustainable healthcare model.

3. Healthcare today

3.1. *Consumer centricity*

The direction of every industry on earth - and one that health has resisted, is one where the consumer sits at the very centre of every element of their journey - not as a passenger. Whether banking, retail, or entertainment, consumers have been driving the agenda for change and businesses realise that to remain relevant they must respond. Industries and companies that have failed to adapt to the changing needs and demands of consumers, have disappeared. Companies that tried to maintain their competitive advantage, being afraid to challenge the status quo, have failed.

Arguments against a similar revolutionary approach in healthcare have focused on the technical and specialized nature of health¹. However these arguments have failed to hold muster in other industries. Even though health is unique, the same forces of transparency, autonomy, consumer centricity, empowerment, and living in the Information Age with knowledge a few clicks away, means that health will radically evolve like all other industries - in its own way.

We see consumers as people. Not as patients². In 2016, when people refer to consumer- or patient-centricity, they believe in a system that improves its customer service and customer oriented approach. They refer to a stepwise change, which respects that our customers have increased rights are demanding more from their providers. They realise that consumers now share stories (especially horror ones) and that their reputations are at risk if they fail to improve their approach. They also realise that a more customer centric approach will benefit them financially.

¹ "Health is different". "We must protect the patient (from themselves?)". "We don't want to upset the clinicians" and "it has always been this way".

² We favor the term consumer, as the word "patient" comes from its use as an adjective, and is an establishment term to describe how an individual must be while waiting for care - we consider it pejorative and incompatible with the future that we propose

However this definition and approach has only delivered minimal improvements in our industry oriented healthcare system. We continue to entrust our data to proprietary systems incompatible with others. Consumers are still not able to determine their own healthcare journey and are often at the whim of their providers. Consumers still lack access to their full medical records. Consumers lack the freedom to explore alternate health and bespoke approaches suited to what they believe their needs are. Health is often available only when and where the provider is, often causing inconvenience and duplication. We believe this mentality and approach is holding us back somewhat from the next healthcare evolution.

We believe that a consumer centric implementation of blockchain technology will drive the healthcare industry into the future with consequent positive outcomes and benefits for all associated parties. However to achieve this future, it is critical to explore why the current system is unsustainable.

3.2. Unsustainable HealthCare

It is clear that healthcare is now at a crossroads. The sustainability of healthcare globally, with its increasing proportion of GDP,ⁱ is at risk. Beyond the aging population straining our health resources (the rectangularisation of society away from the traditional age pyramid), we believe the two largest causes for this increase in health spending over recent decades have been the proliferation of inefficiency/waste (to be qualified) and chronic health conditions.

3.2.1. Inefficiency & Waste

Although it is not clear, what is the right amount of GDP to spend on healthcare, it probable that national healthcare spend below 5% does not buy a population adequate health (although this is not universally agreed)ⁱⁱ.³ However above certain percentages, even as we spend more on healthcare, there is an obvious decoupling of expenditure from outcomes⁴.ⁱⁱⁱ Put differently, when we plot health outcome measures vs. expenditure, the outcome improvement one achieves with the additional investment of GDP has failed to translate into meaningful improvement health outcomes. The US, it has been argued, with ~17% of GDP focused on health, may not be receiving value for money, with probable waste and fraud. In fact when compared to other developed economies, the US has, by some measurements, inferior health outcomes.^{iv}

This suggests that we are spending money in the wrong places – inefficiencies and waste.^v Whether it is because of the practice of defensive medicine, high administration costs, expensive treatment mixes, duplication, fraud, drug costs, pharmacy costs, or lack of pricing regulation and transparency, the challenge all Payors face in this regard is how to make a significant change in the way they approach healthcare to find savings and ensure they are spending where it counts. We believe to make thus change, we must leverage technology and move the paradigm of health to one that is less focused on paying for the inputs (whose value for money are difficult to measure and reign in), and completely focused one rewarding and paying for outcomes. This is extremely challenging today with our current healthcare construct.

3.2.2. Chronic health

The second issue straining our healthcare budgets is the massive movement of health care costs to the chronic side of health from the acute setting. Chronic diseases are estimated to contribute in excess of 80% of health costs. Beyond the fact that diseases that used to kill us quickly can now be lived with for many years, including cardiovascular disease, HIV, and certain carcinomas, one of the reasons for soaring costs in our estimation, is because we continue to approach these life long conditions in the same way we have always managed them: as acute conditions in acute facilities like hospitals (completely unsuitable for managing chronic health, although perfect for acute care and surgery), through robust clinician involvement, and through regular in person reviews.

3.3. Self-care

Consumers are often disempowered through the belief that health is too complex. As consumers, we have been culturally inculcated to rely on the doctor (often in hospital settings rather than in our home) with minimal questioning or input. It is true that consumers often lack the knowledge and adequate health literacy to self-manage their conditions, and for the most part require hands-on support. It is also true that many consumers do not follow clinical advice and are non-compliant with their therapies. However it is worth exploring why consumers are illiterate in health, and why for the most part consumers are ill equipped to self-manage their chronic health issues in today's construct.

Anyone can identify a health consumer - often from a distance - as they lug giant imaging printouts (of which they have no skill to read and understand and rarely receive the accompanying report) between appointments. Beyond these huge x-rays however, consumers are for the large part left out of the data, records and clinical results when it comes to their health. If one is lucky enough to receive a copy of the pathology results, most of these formats

³ Many emerging economies find themselves in this predicament and their national health statistics include lower longevity, and infant mortality

⁴ ~8-10%, although this is not universally accepted

haven't advanced in many years in their decipherability - and are as difficult for a layperson to interpret as ever.⁵ Consumers are therefore completely reliant on clinicians to interpret their data. The only way we will put a dent in healthcare costs is to empower consumers with the correct data and tools to lead their management and take on much greater responsibility and accountability.

However, today, with limited tools at our disposal to self-manage our ongoing health issues which are consuming the healthcare budget - we are asking the impossible. Sure consumer health related apps including disease management tools, are proliferating, however without one's record encompassing all the elements that are required to diagnose, investigate and manage our health, the utilization and power of such tools will remain stunted.

4. Data – the full human picture

4.1. Consumer health data

Consumers have sometimes been deemed unreliable, and often their reports are considered fictitious, not to be trusted. In clinical practice today, there is a different value put on symptoms (a term used to describe what the consumer tells the clinician) to signs (relevant things found upon examination and enquiry by the clinician).⁶

Yet increasingly, research is demonstrating the critical role consumers can play in their health. Numerous reviews have shown value and medical accuracy of many consumer websites^{vi}, where individuals with similar conditions, share tips and self-management advice (especially in rarer conditions). Other studies have demonstrated that consumers once educated about their condition and self-management, can improve their health outcomes at reduced cost to the healthcare system^{vii}. There is clearly a greater role the consumer can play in their healthcare both from a management perspective and from contributing valuable data, which is underutilized today.

4.2. All data

Historically, and still today, we view health at the organ level rather than at the level of the individual. We assume that disease and its treatment start and finish at the organ and fail to recognize the human being in his/her entirety. This mentality starts early in medical education - where health is taught in systems (cardiovascular), clinicians specialize in systems (e.g. gastrointestinal) and wards in hospitals are based around the organ system. In practice this is exemplified by our management approach where people are often managed one organ at a time and those with multiple morbidities or systemic conditions affecting multiple organs e.g. rheumatoid arthritis - need to move around to multiple specialists (often not co-located) to support them with their medical needs.

We are becoming aware, that consumers are more complex than an organ – and the need to holistically consider and manage people is becoming apparent. Even though our current lens of health is a narrow one, since 1948, the WHO's definition of health has been urging an even more inclusive view.⁷

Even though it would be a major step forward to integrate just the basic health data, advocating a more holistic view of the individual, would suggest that we need more than just clinical health data alone.

Consumers seek help at a multitude of health practitioners including alternative ones. They join gyms and seek mental health support away from the clinic and hospital. They try and fail consumer health programs or courses, and they may even seek religious counselling, which has never been integrated nor considered part of a person's health. Consumers may have a genome mapped, and pathology and microbiology assessments done (often repeatedly) by different providers. It is not uncommon for a consumer presenting to emergency departments to have a "full set of bloods" done and "routine" x-rays, as access to test results that may have only been performed the previous day, aren't accessible. All of this data is incredibly important – and yet is fragmented and inaccessible. There is also no current way for anyone, including government, to help pool the data - or coerce providers to cooperate. In addition, there is no way for individuals, even if they have access to their data sets, to fully integrate them, as most options for storage rely on commercial organizations with complex permissions,

⁵ E.g. for people with diabetes who actually understand what an 8% HbA1c result means, interpreting the new measurement – mmol/mol – is incredibly challenging

⁶ However, amongst other research demonstrating the value of patient reported outcomes, a recent British longitudinal study - the UK Biobank⁶, when exploring the predictors of mortality in their cohort, found that many of those factors with the highest correlation to mortality were based on symptoms that patients could describe themselves - i.e. symptoms without requiring an intervening clinician to diagnose (for example walking speed) - challenging the notion that only clinical based signs and diagnoses are important.

⁷ Health is "a state of complete physical, mental, and social wellbeing and not merely the absence of disease and infirmity

questions from the consumer regarding safety, accessibility, longevity of data, privacy and the intent of the organization.⁸

Today, as an example, when faced with two people who must be supported or encouraged to self manage their diabetes, we offer generic management solutions for them and wonder with frustration why consumers don't heed our advice - enforcing our paternalistic belief system for health. What we fail to see is that their belief and religious systems, their underlying mental health and social status, their finances, and their desires, are incredibly important and powerful drivers of health behavior.

If we take this consumer centered approach and could link and incorporate these disparate data sets, add in consumer health behavior, and find ways to understand what drives consumers – we might be able to better support, advise, and impact their health outcomes, even more convincingly than today.

4.3. Data security

In addition, the current approach to storage of our important data raises important issues on security of this vast data set. In recent years, data breaches have demonstrated the challenge and liability in anyone maintaining even a part of someone's record. With Anthem and Premera's breaches approaching the 100 million mark, it is estimated that health breaches comprised up to 42% of all data breaches in 2014.^{viii} According to some estimates, the impact goes beyond just the lost privacy - the average cost to an individual of medical identity fraud is close to \$13,500.^{ix} Data is proving to be a liability. In fact, not only do those entrusted with our data often lack the hack-safe facilities to keep it private, recent breaches question whether our current approach to data storage is outdated. There needs to be another way. Government's could take a leadership role in facilitating protocol formation, digitization of records, standards, transfer of data to a safer format and encourage innovation in storage, access and integration.⁹

5. Blockchain in healthcare

Maybe a starting point in healthcare lies in supporting the evolution to a state where we own and can access our own health and life record in its entirety. Where technology start-ups and incumbents leverage technology, knowledge, and a complete view of the consumer.¹⁰ Only then, can we support a consumer's journey, because we can create bespoke advice, through prompting the consumer when and how to self-manage, when they are on track and when not, and when they require professional help.

Blockchain technology offers a way to bring this consumer centered approach to our health. Blockchain is a way to ensure our full record, beyond our narrow definition of health, is owned by the individual, can be securely stored with privacy, security, safety, and verification embedded in the protocol, and can be shared, accessed and interpreted when necessary.

Blockchain offers a cryptographic way to store and access a verified list of transactions, data, information, results, and procedures, not relying on one storage facility, instead distributed across numerous nodes that instantaneously verify the data to ensure records aren't lost, misplaced, tampered, falsified or exposed to hacking. This rest of this paper rather than defining blockchain and its technical elements, will focus on use cases that leverage the power of the technology and demonstrate how it could add greatly to our evolving healthcare for the better.¹¹

⁸ Today there have been some minor moves towards interoperability, however when data is stored in incompatible formats, and whilst we still see all the parts of our health care system as silos without considering their intersection - we will not move towards a complete picture.

⁹ To close off this section, it is important to note, that we have written in generalities in our examples to make a point. We offer no suggestion here that providers across the industry do not have a critical and ongoing role to play in delivering excellence in health delivery, support, products, and other services to consumers. We are also not questioning the intent of anyone in healthcare - who we believe are mostly motivated by clinical excellence, patient health, and adhering to legislation. We are suggesting however that the way health is structured, encourages behaviours, actions and approaches that don't always lead to the best consumer health outcome. This paper suggests that blockchain will enable enterprise and providers to provide a newer, more finessed and personalized role, one that is more future proof, innovative, health advancement generating, and sustainable.

¹⁰ This would include all our 'omes - genome, biome, micro biome etc., all patient led data including consumer health apps, our likes and dislikes, and other important socio-economic data - all to support a truly holistic view.

¹¹ Of note, blockchain doesn't necessarily do away with existing infrastructure, record systems, databases, software packages or clinical records. Clinicians and hospitals would continue to use whatever proprietary software they wanted to manage their patients, however the backend of data, would be linked into the blockchain cryptographically.

6. Use cases in how blockchain will revolutionize healthcare

6.1. GOVERNMENT & PAYOR PERSPECTIVE

6.1.1. Linkages across government services

Often the same consumers who require medical support e.g. Medicaid, are also recipients of other government services - including housing, and social benefits. Currently the linkages and flow of data between these are incomplete. It can be difficult to obtain a full perspective on the consumer without the use of resource heavy multidisciplinary teams whose use is often restricted to the most complex cases – meaning millions miss out on help with this holistic perspective.

Blockchain data integration could help integrate all elements of a consumer's life for them through their data, and allow algorithms, personnel when appropriate, and even themselves, their families and caregivers, insights into their needs, helping them determine how to move their lives forward and address their concerns and the issues holding them back. Blockchain addresses concerns about privacy, and as these are consumer led, the wealth and breadth of data it could encompass could be vast.

It is often assumed that two individuals with similar financial and health challenges require the same services, but through this data integration, the nuances of each individual can be revealed ensuring more bespoke delivery of services. In addition, consumers could be empowered to better choose the right services for them. In certain jurisdictions (e.g. Australia) aged care and disability pensions are increasing being procured by consumers – rather than government. Consumers receive a budget based on their determined needs for housing, nursing care, services, meals, and transport. Rather than governments procuring generic services for the consumers, consumers have greater choice in how they spend their budget - reducing costs while improving the relevance of their services, while reducing the government's involvement in the day-to-day activities of the individual.

Although there is legitimate fear in this full integration from a consumer perspective, much of the process with blockchain could happen automatically through smart contracts, computer intelligence, and appropriate consumer input rather than needing to be reviewed at the granular level by governments.

6.1.2. Pooled real time population risk

One of the critical advantages of blockchain in the transparency it brings to data for some creative research, extensive analysis, and actuarial insurance management.

Patterns of illness, public health issues, ZIP related analyses on areas with specific needs, rich clinical information, and robust cohort based analyses, are just a starting point for this extensive data set, increasing the likelihood of massive value generation and medical discoveries.

From a health insurance and government perspective, with integrated data and robust time stamped longitudinal data sets, the ability to really determine risk, the value of varied medical interventions and approaches, and to be able to compare patient populations - adds real value for determining health costs, predicting these and eventually managing payments in more innovative ways.

6.1.3. Billing, Fraud and Savings

According to recent analyses, billing and insurance-related activities in US health care system totalled approximately \$471 billion in 2012^x with government paying for a significant part of that. In other analyses it has been estimated that a simplified financing system in the US could result in cost savings: >\$350 billion annually^{xi}, nearly 15% of health care spending, and processing costs can be up to 30% of the cost of a procedure.

In addition, Medicare and billing fraud is growing – increasing costs for the entire health system. *"Federal officials have created "strike forces" in Miami and eight other locations in recent years to better identify and prosecute suspects... The effort has led to charges against 2,900 people in the last decade, with the fraudulent billings totaling \$10 billion". "Wifredo A. Ferrer, the United States attorney in Miami. "Medicare fraud has infected every facet of our health care system." ^{xii}*

We believe blockchain technology could make a massive impact on both the administration costs and fraud. This could be achieved through smart contracts with payment automation – reducing the need for manual input, paper records, billing and follow-up – as interventions and treatment documentation occurs immediately and verifiably through the blockchain. This approach will also reduce fraud, through traceability, digitization, and the inability to change records retroactively. Blockchain, with its ability to see who has done what, and whose "fingerprints" are where in healthcare management, as well as offering opportunities to remotely monitor fraud, may help minimise the waste that occurs in these areas – drastically reducing costs and waste.

6.2. FUTURISTIC HEALTHCARE MODELS

6.2.1. Personalized healthcare

In the recent past, health has overly relied on clinical research backed by "gold standard" multicenter double-blinded controlled randomized studies. Clinical research's prima facie has been the assumption that there is an average person. It is predicated on people in both treatment arms being identical in their likelihood to respond to either of the two approaches based on factors we currently are aware of. However as knowledge of medicine, genomics, and other 'omics progress, we realise more and more how unique we each are. In a pharmaceutical cancer trial for example, one will note that even when longevity is achieved in a significant number of patients in a new therapeutic arm, there are still a percentage that don't respond or do worse with the new therapy. Nevertheless the therapy is approved for all patients - even while knowing maybe only 30% will respond positively.

In addition, some clinicians when asked about alternative therapies (e.g. nutraceuticals, or Chinese medicine) will quote large studies, which on average concluded that patients didn't respond to the intervention. However, again, when looking at individual data, there are indeed many patients who responded impressively, and those who didn't or actually worsened with the intervention. Yet we summarise the results by saying the treatment had no response for the average consumer.

Health isn't binary - and we health consumers are not all identical. What works for one, even when evidence exists, won't necessarily work for another.

The blockchain allows for a future of research factoring in what makes us each unique and applying n of 1 approach^{xiii} affordably and systematically (i.e. working out what is most suitable for a certain individual in a specific circumstance). In the future we may be able to better predict for example which anti-hypertensive therapy should be used in a particular patient - rather than the trial and error approach we have today in practice. Linking individual data may allow a whole new clinical approach which helps us adapt historical wisdom, and learn anew what works for who and really create a future of personalized medicine.

6.2.2. Pay for outcomes and smart contracts

Our healthcare system has struggled with the way providers in the system are rewarded for their efforts, inputs and impact. Regardless of the outcome, for the most part the consumer and the Payor pay the same for the intervention. Today, our healthcare system is stuck paying for inputs, ingredients, or interventions, and pays the same for them regardless of the health outcome.

New health interventions and therapeutics often promise to deliver better outcomes for consumers, often costing significantly more than the current standards of care, however, there are numerous examples of what appears to work in clinical research, sometimes fails in the real world.

Real world data analyses, have been promising to herald breakthroughs and new knowledge and proof of efficacy and outcomes. Yet these measurements, have struggled to become reality. Some of the challenges in implementing these include confounders, questionable data quality, expense, and funding.

Blockchain - a full data set, with smart contracts embedded within and patient reported outcomes overlaid, could make significant advances in this. Services delivered, could be automatically and partially paid for upon completion. The remaining payments could be finalized with agreed upon output measures - depending on the condition. Some examples -

- An emergency department (ER) visit that is only partially funded until it can be proven that the consumer discharged from hospital was well managed without requiring a return visit to the ER.
- Reduced payments might be considered if a patient after e.g. a simple appendectomy was readmitted with wound dehiscence, retained surgical tool or preventable infection.
- Hypertension management - where upon achieved upon blood pressure targets are achieved, the final payment of the service rendered is released.

6.2.3. Incentivizing those to improve health through smart contracts.

Many have tried, yet few have successfully managed to find sustainable ways of incentivizing people to improve behaviour, which are responsible for 69% of total US healthcare costs. One behavioural issue - poor medication adherence alone, costs the US more than \$100 billion annually in avoidable healthcare spending.^{xiv} One of the challenges of these motivational approaches beyond the expense of monitoring and follow-up, is the difficulty in personalising and evolving the incentive.

For some, financial motivators could help, however the same financial offers when applied to a different individual may fail to influence. The more we understand an individual's true motivators, drivers, belief systems, and intimately understand who they are, the more likely we are to predict and tailor incentives to help them achieve their goals - a person, rather than disease based approach.

Blockchain has the potential to embed smart contracts to incentivize, monitor and engage consumers through their health journey. Consumers could enrol into a program with their connected data and devices, to have payments linked to: immunization of at risk babies, verified weigh-ins at pharmacies for weight loss, gym

attendance, or medication adherence through smart pillboxes. This approach could reduce human intervention and manual checking, and allow consumers to personalize their journey to their needs.

6.2.4. Remote and autonomous diagnoses

Rare genetic and less common medical conditions are often missed because consumers fail to share all their symptoms (what does my back pain or tiredness have to do with my skin rash?). These could be integrated wisely through smart algorithms and tools, leveraging the wealth of personal data on the blockchain to hasten this discovery approach.

6.2.5. Autonomous programs looking at healthcare capacity and linking to consumer need

Hospitals on bypass. Extended waits for surgery. Surgeries cancelled with "no shows". Hospitals at capacity while waiting for nursing home beds to become available. MRI machines sitting idle due to gaps or cancellations. Ward beds empty on some days while at capacity on others. Emergency rooms full of patients waiting for beds to be freed-up on the ward.

Managing demand in our healthcare system is a challenge. Illness and need fluctuate greatly; at times overwhelming resources and at other times, underutilization means lost opportunity for treating people and generating revenue.

Blockchain could legitimately form the backbone of creating solutions by linking consumers, machinery, beds, and clinicians, in real time. With all data updated immediately, not only could the peaks and troughs be better managed, excess capacity could be more easily identified, helping to manage costs or treat additional customers. It also opens up opportunity for cross border sharing of medical resources (between states and countries) and ultimately benefit the consumers with greater availability of care when they need it. Delays, which cause suffering, distress, and sometimes morbidity and mortality, will be reduced.

Examples:

- A small rural hospital with excess capacity in its theatre and idle surgeons, being able to accept consumers from a neighboring town or provider
- Appointments for difficult to access specialists for remote individuals, becoming instantly available through this tool.

6.3. DATA ACCESS

6.3.1. Clinical research

Beyond the clear value that immense amounts of incorporated data brings to the research community, blockchain could open up clinical research in new previously unimagined ways.

One of the major costs of clinical research is the monitoring of sites, reviewing and verifying data, querying data anomalies, and following up consumers. In addition, from a safety perspective, it can often take significant time for data to be collated and analyzed, delaying identification of potential safety concerns.

Today, challenges with clinical data include data integrity, fraud, manipulated and redacted data, as well as unpublished results.

With inputting data directly into the blockchain for immediate verification – and at times concurrently from different sources (including directly from the consumer), it becomes more difficult to falsify or ignore data for publication purposes.

The blockchain also allows for more remote monitoring, greater patient reported outcome inputs and inputs of other parameters that have historically been difficult to collate. Blockchain technology can support enriching the data sets used in clinical research to see a much more holistic view of an intervention and make statements regarding the interventions benefits or harms. With blockchain's potential for significant research cost savings, the opportunity for new discoveries with innovative trial design, becomes possible.

6.3.2. Storage of genomics and user-generated data

Today there is a genomic 'arms race' in building massive proprietary databases of genomic data. These are considered to be incredibly important in our next evolution of healthcare - and access is vital. However, there are many concerned that these data may be restricted, or even used against consumers in excluding them from care or insurance coverage, due to identified genomic conditions or predispositions.

The blockchain may offer an alternate solution to these incredibly important data. Consumers could hold the data, choosing to share their data widely for research, and incorporate it into their other data sets, to benefit their needs. This democratization will ultimately cause organizations to center their approach to the consumer's need, driving meaningful consumer outcomes and benefit.

6.3.3. Emergency Healthcare

Unfortunately, consumers still present to emergency departments unknown to the clinicians or the hospital. Lacking any record on the individual, receiving poor verbal histories from a family member or care-giver with little information except a clutched plastic bag full of medicines grabbed from the individual's side bureau – is a regular occurrence resulting in suboptimal care, and even harm.

Blockchain could solve for this by allowing access to one's record in special emergency situations with the permission and signature of a hospital administrator, a next of kin (who had been previously listed as a key holder) and a clinician (depending on permission levels granted on the blockchain). Alternatively, special access keys adorned by consumers might also be considered as permission granted. This access, will reduce duplication of investigations, likely gain efficiencies in care management, and ultimately save lives.

The blockchain would also record who accessed the record, what procedures were done, and could allow consumers to designate the type of care they want - including advanced directives and do-not-resuscitate orders. Beyond ensuring the consumer's wishes are respected and considered legally binding (an area where legislation and governmental input could add immense value), immense expense and consumer discomfort during their last days could be avoided.

6.3.4. Remote consultations across the globe

Consumers are not only traveling more, they are seeking care across the nation and the globe. Whether it's the burgeoning medical tourism industry, self-insured seeking more affordable care, those seeking care for non-emergency healthcare like joint replacements and cosmetic surgery overseas, those traveling who require care whilst abroad or interstate, those seeking alternate therapies or specific expertise not available close to their home, or online telehealth - healthcare is moving from the traditional place of ones neighbourhood or city. In addition, consumers are parallel importing medications from low cost countries suppliers, and purchasing more health treatments and devices online or while traveling overseas.

This movement is causing the already fragmented records and lack of a true source of truth document to be compounded.

Blockchain - a record system which can be written to and accessed globally with appropriate permissions, a system which is portable and consumer driven - could solve for this with ease, enhancing the view of a consumer and also adding safety components like for example, warning consumers when they order a medication online which they might be allergic to.

6.4. MONITORING

6.4.1. Transparency of pharmaceutical supply chain and response rate for recalls

From a regulatory approach, transparency (with appropriate IP, and trade secrets kept private and secure) especially when applied to the supply chain of pharmaceutical ingredients - where they come from, who is manufacturing them, their approval and manufacturing approval status, could help streamline the monitoring approach of extremely important medications and products.

In addition, fraud, forgery, falsification of records, auditing of plants and equipment, manufacturers and processes - especially from an FDA or other regulator perspective, can be streamlined through blockchain. Certain processes can be audited remotely with this verifiable source of truth.

Recall of potentially fatal or unsecured products - even beyond the health arena, become much easier with the traceability that blockchain offers. Not only can unsafe ingredients be identified early, the consumer, often difficult to identify, can be found with ease. The blockchain, with the right permissions and accessibility for emergency situations, will ensure a more seamless regulatory and monitoring approach with consumer safety at the forefront.

6.4.2. IoT and the Blockchain

Pacemakers inserted into consumers require regular maintenance and monitoring to monitor for potential issues. Consequences for a failed device can be catastrophic. As with medical records, most devices and their software, increasingly broadcasting through the IoT (Internet of Things), sharing critical information and data, are often written with proprietary software requiring separate programs, and their own technological know-how to decipher and decode. In addition, with all the new devices streaming data continuously, including many consumer devices, the need to find a way to capture this data, and interpret it, is becoming urgent. Clinicians today are shying away from receiving step counts, blood sugar readings, blood pressure levels, and even electrocardiography via email or

remotely, because the streams are becoming unmanageable (as well as raising medico-legal questions on responsibility, culpability and the like). As a result, most of this data remains unanalyzed, and useless.¹²

The other questions raised are related to who will do the real-time monitoring when an IoE device sends a warning signal - a dangerously low blood sugar reading for example. Unless the consumer is paying for a monitoring service, which can be prohibitively expensive, the questions remain on who will be reviewing these results and integrating and interpreting them, and offering management advice - especially in emergencies. In addition, with some companies producing devices and then no longer supporting them, or going out of business, many consumers are left to their *own devices* (excuse the pun). It is impossible for this all to be managed without technological integration, linked computers, smart algorithms and the blockchain.

The blockchain in these cases, as a source of data collation, can have built in smart contracts and triggers for this data, and help consumers interpret their findings - advising them on when to seek care. It pushes the responsibility back to our consumers with enabling and understandable information to empower them and their caregivers in their health journey.

Rather than scheduling review appointments regularly, and sometimes unnecessarily, for inserted pacemakers (as our example above began), in person reviews can occur when necessary as dictated by the data - advising when there are signs of wear and tear on a device, when batteries require replacement, and when certain data points are concerning. This is not only convenient for consumers; it can reduce unnecessary health costs.

7. Issues and Areas of Concern with Blockchain's Application in Health

As promising as blockchain opportunity is, the exuberance needs to be offset by the reality of this new and largely untested technology, and the areas that will need to be given consideration before mass adoption and rollout.

- 7.1. Utilising blockchain as another tool.** Blockchain is an incredible opportunity for completely reorganising our approach to healthcare. However, this technology can be hijacked as another tool for data storage and capture with an industry first approach, with scant consideration of the consumer. If this is the case, the blockchain technology, like digitization, will be hampered, and healthcare could risk becoming a laggard in blockchain's rollout. Ensuring we apply this new consumer centered mindset, will ensure blockchain heralds a revolutionary approach to health.
- 7.2. The integrity, security and privacy of data.** Risks of hacking, although potentially decreased, still exist, and cryptography, and security approaches are still evolving without an agreed upon standard. Government could potentially take an active role in this space helping support appropriate security standards.
- 7.3. Passwords.** Safeguarding the keys for access by the consumer is vital. Once a personal key or password is revealed in blockchain's current iteration, access to an immense trove of personal data could be considered catastrophic. Ensuring appropriate password and permission access, and identification processes to protect the data, is of paramount importance.
- 7.4. Lack of authority.** Health has historically been a regulatory rich environment. With a lack of central authority or regulatory approach in blockchain, consumers might be at risk. Governments could play a role in ensuring as this technology advances, that appropriate consumer protections are in-built.
- 7.5. Distribution concerns.** In Bitcoin, the amount of computing power is increasingly determining who is controls the latest version of the data. This however raises concerns on whether, beyond hacking, a large corporation or entity, by amassing huge computer power, may eventually take control of the entire chain putting at risk all the records contained. Legislation, leveraging inbuilt mechanisms of the blockchain, could help prevent this from occurring.
- 7.6. Data quality.** If erroneous data is established in one's blockchain, it can be impossible to erase. Validating the data and allowing one to hide or erase data (many are grappling with the right to be forgotten, and cached data) is important. Potential solutions could be inbuilt into the protocol formation - yet this still requires additional investigation.
- 7.7. Too much transparency.** Identification of people through their data, their visits to various websites, and other apparently secure online actions is becoming increasingly common. An area that therefore requires ongoing analysis and decision-making is how to achieve transparency, access to data, and privacy concurrently.

¹² In addition, finding meaning in someone's health data including even blood pressure, is a challenge without the wealth of other comorbid data, or day-to-day accompanying diaries to help interpret it - why was there a spike in blood pressure? What was the individual doing, feeling or thinking at the time when a certain measurement went awry?

- 7.8. **Sustainability** issues of the immense computer power currently required to mine and verify records needs to be solved to ensure this solution has a sustainable energy approach.
- 7.9. **Speed/Scalability** of the blockchain with an incredibly data rich set of information like healthcare records, is yet to be tested.

8. Conclusion

Blockchain offers a future state for healthcare that promises to center the individual in healthcare and help them discover and manage their own journey. It will herald a new global standard of storing, accessing and sharing data with ease interoperable ease. It promises a transparent, efficient, accountable, and innovative future across clinical practice, self-care and government services, leveraging data to anticipate and proactively manage issues. It promises to incorporate consumer reported outcomes and move us closer to personalised healthcare solutions and a payment system focused on outcomes rather than inputs. Even though there are still unanswered questions, which we are furiously working on, we believe, if we approach blockchain by truly starting with the consumer at the absolute center – we will have a world class sustainable healthcare system in which the consumer and their health, are the ultimate beneficiaries.

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