BLOCKCHAIN TECHNOLOGY AND THE NEW ECONOMICS OF HEALTHCARE

This report by the RMIT Blockchain Innovation Hub is in partnership with DB Results. It was funded under the Victorian Medical Research Acceleration Fund.

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Executive Summary

In this report we examine some of the implications of blockchain technology for the healthcare sector, with a focus on the coordination of trusted data. We propose that blockchain—understood as a new technology of trust—might propel an institutional re-organisation of the healthcare industry away from hierarchical governance towards digital platform governance.

We begin our analysis by introducing the economic problem of the healthcare system. Healthcare decisions must be made under uncertainty. The data used in this process is dynamic, fragmented and often untrusted. The institutional structure of the healthcare industry—siloed but hierarchical organisation—is in part a response to the costs of producing, coordinating, and creating trust in that data. Blockchain technology opens new organisational possibilities in solving these healthcare data problems, and therefore suggests a re-organisation of the sector.

Blockchain technology, and distributed ledger technologies more broadly, are institutional technologies. Blockchains leverage economic incentives, cryptography and peer-to-peer networking to facilitate distributed programmable ledgers of information to be governed by computer networks. Blockchain technology is being applied in healthcare in four major areas: decentralised medical records, data markets for scientific research, tracing of devices and pharmaceuticals in supply chains and insurance. In many of these applications the promise of blockchain is as an alternative governance infrastructure for the production and coordination of data.

What does blockchain mean for the healthcare sector? The impact of blockchain in healthcare shouldn't be understood as simple cost reductions within existing organisational structures. More deeply, blockchain looks to catalyse a fundamental institutional re-organisation between data governance in firms, governments, markets and blockchains. The extent of this re-organisation relates to how much of the large hierarchical structures in health (e.g. hospitals) are the result of solving trust problems (within existing technological constraints). We propose that the impact of blockchains is to de-hierarchialise the healthcare industry, pushing data governance towards digital platforms.

New platform-based digital healthcare infrastructure might help to ameliorate Australia's healthcare productivity crisis by better coordinating the inputs into the healthcare discovery problem. That is, blockchain is new foundational infrastructure on which entrepreneurial solutions to healthcare problems may be discovered.

Table of Contents

1. Introduction

Healthcare is a large and growing part of the Australian economy. Valued at about $180 billion, the health sector is just over 10 percent of the Australian GDP.[1] Moreover, with a real growth rate of 4.5 percent in public health spending over the past decade (combining both Federal and State), the healthcare sector is a growing percentage of economic expenditure and production. Health is a normal economic good, and therefore as societies become wealthier, they consume more health services. This points to both structural shifts in the economy, with increasing economic activity in this sector, and also to an ever-growing burden on public finance. Without further tax increases, the growing costs of healthcare will need to be met with increased productivity through cost savings, improved operational efficiency, and better use of technology and automation.

A key driver of improved productivity in healthcare is new technology. Research and development (R&D) spending in health in Australia, which drives such innovation, is around $6.5 billion, accounting for about one-fifth of total R&D spending.[2] Of that total, public funding of research in the healthcare sector in Australia is $1.6 billion in 2019 (combining the MRFF, NHMRC, and ARC).[3] The healthcare sector spends about 3.6% on R&D, which is higher than the 2.2% of R&D spending in the whole economy.[4] Healthcare is both an economically large sector and a relatively high R&D sector.

The problem is that healthcare innovation is mostly focused on *inputs* into health production. We innovate on better devices and equipment, new drugs, or better understanding of health sciences. All of this is important, and requires ongoing investment and application. A real productivity revolution in Australian healthcare, however, will also require innovation in the *economic coordination of healthcare production*—in the basic administrative infrastructure of the healthcare industry.

The institutional infrastructure of the healthcare sector manages the vast, complex and dynamic flow of data through the healthcare production process. These institutional processes and technologies track patient identity, patient records, licensing and permissioning of access, credentialing of medical professionals, calibration of machines, device authentication, quality

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[1] Australian Institute of Health and Welfare, 2018, <https://www.aihw.gov.au/reports/health-welfare-expenditure/health-expenditure-australia-2016-17/contents/data-visualisation>.
[2] Research Australia, 2016, <https://researchaustralia.org/tag/rd-expenditure>.
[3] Research Australia, 2017/18 Pre Budget Submission, 2016, <https://treasury.gov.au/sites/default/files/2019-03/C2016-052_Research-Australia.pdf>.
[4] The Conversation, Infographic: How Much Does Australia Spend on Science and Research?, 2016, < https://theconversation.com/infographic-how-much-does-australia-spend-on-science-and-research-61094>.

assurance of drugs, and all the other aspects of information updating, record-keeping, auditing and contracting that is crucial for safe and productive delivery of health services.

Healthcare innovation has so far focused largely on innovation in inputs—in seeking better drugs, devices, procedures—with less focus on innovation in underlying institutional infrastructure. If we are to achieve the sort of long-term productivity improvements in healthcare that are needed to ensure high-quality decision making, which enables the health sector to deliver ever-higher quality services to ever-more people, then we need to drive innovation in basic industry infrastructure too. This new healthcare infrastructure will be institutional and will involve developing new ways of ordering and coordinating exchange of data between potentially untrusted parties (patients, hospitals, funders) and increasingly complex health service supply chains.

While blockchain technology is most famous for powering cryptocurrencies (e.g. bitcoin) it should be understood more broadly as a fundamental leap in distributed ledger technology.[5] Blockchain technology enables ledgers of information to be recorded and programmed through decentralised networks of computers. Institutional technologies such as blockchains need to be understood differently to industrial technologies (e.g. 3D printers, steam engines). Institutional technologies compete and complement other institutional technologies (e.g. hierarchical firms, nation states) to solve problems of trust. Indeed, blockchains can be understood to industrialise trust.[6] The study of blockchain as an institutional technology is known as institutional cryptoeconomics, and draws primarily on institutional economics and transaction cost economics (see Section 4 below).[7]

Blockchain technology is a new frontier in institutional innovation in healthcare. This paper will explore how blockchain can be used as a tool to propel institutional innovation in the health sector. We propose that blockchain will fundamentally shift the institutional structure of the health sector, moving from a landscape of centralised hierarchies towards more decentralised platforms. This shift from healthcare hierarchy to platform comes through the transfer of data property rights from

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[5] Nakamoto, Satoshi 2008, "Bitcoin: A Peer-to-peer Electronic Cash System." <https://bitcoin.org/bitcoin.pdf>

[6] See Berg, Chris, Sinclair Davidson, and Jason Potts, 2019, *The Blockchain Economy: An Introduction to Institutional Cryptoeconomics*. Cheltenham: Edward Elgar.

[7] See Allen, Darcy WE, Chris Berg, Mikayla Novak, Brendan Markey-Towler, and Jason Potts, fortchoming. "Blockchain and the Evolution of Institutional Technologies: Implications for Innovation Policy." *Research Policy*, no. 1; Berg, Chris, Sinclair Davidson, and Jason Potts, 2019, *The Blockchain Economy: An Introduction to Institutional Cryptoeconomics*. Cheltenham: Edward Elgar; Davidson, Sinclair, Primavera De Filippi, and Jason Potts, 2018, "Blockchains and the Economic Institutions of Capitalism." *Journal of Institutional Economics* vol. 13, no. 4, pp 639-58.

organisations to individuals, and the incentives that a new platform brings in terms of entrepreneurial competition to solve health problems.

We proceed as follows. In Section 2 we outline the general framework through which we view the healthcare industry. The healthcare sector faces a data problem—not just an allocation of physical resources problem—where the 'cost of trust' in data as it moves through the production process is a significant proportion of the cost of healthcare.[8] In Section 3 we examine the historical experience and public policy issues of applying technologies to public health, with a focus on digital medical health records in Australia. In Section 4 we first introduce blockchain technology as a governance technology and then outline the field of institutional cryptoeconomics that studies its relationship to existing structures of governance. In Section 5 we review the applications of blockchain in healthcare, including medical records, clinical trials, healthcare supply chains and insurance. In Section 6 we look to the future. What does a platform revolution in healthcare, underpinned by blockchain technology, look like? We argue that there will be a fundamental transformation of the industrial architecture of healthcare service delivery based on digital platforms. Blockchain furnishes the base administrative layer for that, and we anticipate future healthcare services to be built on top of this infrastructure. We conclude in Section 7.

2. Healthcare decisions and data problems

By observing the political machinations around healthcare it would be easy to conclude that the healthcare ecosystem is made up of physical things such as hospital beds, drugs, doctors, medical clinics and equipment. If we see healthcare from this lens, then the solution to healthcare problems are to both increase spending in health-related services, and to better allocate health resources to their most desired use. In this section we outline an alternative and somewhat contrasting view of the fundamental problem preventing a rapid productivity increase in healthcare. We propose that the healthcare industry faces a more fundamental problem of coordinating trusted data through its people, organisations and processes. Trusted data is necessary to make the various medical decisions under uncertainty. The healthcare system isn't just made of physical things, it is a complex data production and coordination process.

Through the entire healthcare sector practitioners must make choices about how to treat (or prevent) health problems. While diagnoses and the selection of potential remedies are always made with some level of uncertainty, those practitioners draw on medical and other knowledge to improve

[8] Davidson, Sinclair, Mikayla Novak, and Jason Potts, 2018, "The cost of trust: A pilot study." *The Journal of the British Blockchain Association* vol. 1, no. 2, pp. 1-7.

those choices. They draw on the existing body of medical knowledge that has been built up over centuries (i.e. medical science, clinical trials) and their own tacit experience of similar circumstances (e.g. what they have seen in the past). Practitioners must also place this knowledge within the context of the unique factors surrounding the individual patient (e.g. their medical history and preferences).

The parties who make decisions in the healthcare sector (both practitioners and patients) do not hold the entire set of potentially relevant information to their decision-making. Data about the patient, other patients, potential side effects, new drugs, long-term preferences and so on, are not easily accessible or contained in one place. Furthermore, interpreting that data is both highly contextual and subjective. This data must be shared and ordered between different parties who produce that information through time. The producers and holders of that information include patients, medical researchers, drug companies and doctors. Before we more closely analyse how this information is coordinated, however, it is useful to pinpoint three general characteristics of the nature of healthcare data: that the data is dynamic, fragmented and potentially untrustworthy. These characteristics speak to the underlying transaction costs of what forms of organisation and what institutional and administrative infrastructure will best coordinate that information.

First, healthcare data changes through time—it is *dynamic*. The dynamics have multiple sources. First, there is a continual stream of remarkable inventions in health delivery such as pharmaceuticals, medical devices and clinical trial breakthroughs. Humanity's stock of medical scientific knowledge is also being built and refuted. Second, patients constantly change. As patients age they build up an identity of different attributes medical conditions, hereditary history, potentially harmful lifestyle habits and so on. These features define the potential paths of medical action but are not necessarily observable to the patient or to the practitioner. Both medical knowledge and the patient information are needed to improve decision making. Furthermore, that data must continuously re-coordinated between each of the different parties. As we will see below, over time modern healthcare systems have developed organisational structures to ameliorate issues of dynamic information, for instance regularly updating the data assigned to a patient identity (we can also see Australia's My Health Record in this context).

Second, healthcare data is produced in many locations—it is *fragmented*. The data necessary to make healthcare decisions is recorded in many different organisations and geographical locations. Some information is produced through the scientific community, other information through tests, and other information through the observations of medical professionals. Compounding this is that the information is produced over a long period of time—a lifetime or more—with the potential for information loss. Given the current institutional structure of the healthcare industry the data is also fragmented in the sense that it is siloed within hierarchical organisations that are not easily visible or accessible externally. Lack of accessibility may come from a practical or transaction cost perspective.[9] Data fragmentation is a common feature of economic and social processes because knowledge is often distributed across individuals and is not easily aggregated. Fragmentation is particularly troubling from the perspective that healthcare is an 'o-ring' production function.[10] One missing piece of data might radically change a healthcare decision and therefore the outcome of the healthcare process for a given patient (this example speaks both to data fragmentation and the concept of data completeness).

Third, healthcare data is often *untrusted*. The healthcare data that practitioners and patients use to make their decisions must not only be produced over time (because it is dynamic) and collated for decision making (to ameliorate fragmentation) but that data must be trusted by the parties making those decisions. To have value, healthcare data must not only be produced and captured, but it must be trusted. We can pinpoint a number of ways the trust in data breaks down. First, there often legitimacy concerns over how a particular piece of data was produced (on what machine, when, under what conditions and so on). Second, there are concerns over what data is being withheld by other parties (including the patient) for a wide range of reasons (e.g. embarrassment or potential insurance implications). Moreover, as organisational distance increases—and as data crosses those boundaries—trust in the data declines. From the perspective of a medical practitioner, data they recently produced themselves may be more trustworthy than data produced by others in the past. For these reasons healthcare practitioners must constantly assess whether the data they observe is legitimate and can be trusted (or is the complete information set), and they may decide to re-collect the data within their organisation or within other organisations they rely on. These issues are all further exacerbated by questions of legal liability and the large implications of healthcare decisions (including because of the o-ring production function properties of healthcare as described previously).

These characteristics of healthcare data are important for understanding healthcare through the lens of institutional analysis. Drawing on these characteristics we can better understand how data is organised, utilised and coordinated, including within the context of the technologies available. Our focus on the healthcare problem is that it is an institutional governance problem over data that flows through the healthcare process. We know that there are many transaction costs in producing and

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[9] More deeply, accessibility may be limited because of entrenched rents within the system that wish to maintain information asymmetries (where one party holds more information than another). That is, there may be incentives for parties to withhold healthcare data from others.

[10] Kremer, M. (1993). The O-ring theory of economic development. *The Quarterly Journal of Economics*, 108(3), 551-575.

maintaining healthcare data that can potentially be remedied through economic organisation—for instance, through regulation of the production of data through the coercive power of the state, or through the management of ledgers of healthcare records within practices or hospitals, or even more recently efforts to centralise health records through government control.

Following the new institutional economics literature including Nobel Laureates Ronald Coase, Oliver Williamson and Elinor Ostrom, we can examine the healthcare system from the perspective of comparative institutional economics to ask what institutions are most effective at lowering the costs of coordinating healthcare data. This is the *new economics of healthcare*: analysing the economic organisation of the healthcare sector based on the coordination of trusted data under uncertainty and the capacity of different institutions to economise on those transaction costs. This is a *new* economics because it shifts the focus from the physical allocation of healthcare resources within constrained budgets—including applied statistics to understand changes within the system—towards a more exchange- and contract-focused analysis of healthcare.

The new economics of healthcare asks different questions. These questions come from a different understanding of economic systems, with a focus on the lens of institutional theory, mainline economics, uncertainty and technological change. For instance, what is the most effective way to govern the coordination of healthcare data? Should we organise and coordinate healthcare data through centralised government registries, private ledgers held by organisations such as hospitals, develop spot markets for data between hospitals, clinics and patients, or hand data directly to individuals? Furthermore, these questions emphasise the effect of technological change on the structure of the healthcare system, including the invention of technologies of trust. How does blockchain technology change the comparative efficacy of different governance structures? Effective governance changes through time as new technologies change the capacity of different governance structures to outcompete the others—organisational structures shift as the microstructure of transaction costs changes. Before we examine the potential of blockchain, in the following section we explore the history of technological adoption of electronic medical records in an Australian context.

3. Applying technology as health public priority: Experience and issues in Australia

Technology is deeply entrenched in the logistical, operational and organisational systems of health care providers—such as general practices, medical specialists and hospitals—and have extended to key allied branches of the primary and acute care health sector such as aged care, dentistry and mental health services. More recently, new technologies are being increasingly and regularly used by individual Australians to monitor their vital and other health statistics through wearables (e.g. FitBit health trackers) and similar technologies. There are numerous reasons shaping the uptake of technology in health. One reason is a potential increase in expectations by Australians with respect to quality service provision in health. As noted by the Australian Digital Health Agency

> Australians want a health system which puts people first – giving more choice, control and transparency. They want better access to mobile digital health services for the whole community – not just those who are experienced users of new technology. They want their health information to be confidential and secure, protected from cyber criminals and from any unauthorised access.[11]

From the standpoint of health care provision, doctors, nurses, general practitioners and specialists alike seek means to obtain patients' health information accurately and in real-time, and to provide care without undue administrative burdens (including contending with paper-based medical records). Implementing new information and communication technologies (ICT) in healthcare settings is commonly referred to as "e-health"—described by the World Health Organisation as "the combined use of electronic communication and information technology in the health sector".[12] Expanding upon this generic definition, e-health is depicted as

> the health care components delivered, enabled or supported through the use of information and communications technology. It includes: clinical communications between healthcare providers; patient access to specialist services via online consultation and a range of online tools and resources; and, professionals' access to information databases and decision support tools.[13]

One major area of e-health is the application of ICTs to develop integrated patient medical records. These applications have often sought to provide a common digital platform of medical data and information to be used across the health sector, and in a portable manner consistent with a given patient's treatment journey. The technical attributes of experiments in ICT-enabled patient medical records vary, and may be generally categorised as possessing either (relatively) centralised or decentralised attributes.[14] A critical distinction between these two categories is the extent to which data is held in one single site, whether organisationally or technologically. As indicated in the next section, the advent of blockchain has significant implications with respect to the feasibility of *radically decentralised* patient medical record-keeping.

[11] Australian Digital Health Agency (ADHA) (2017). Safe, seamless and secure: evolving health and care to meet the needs of modern Australia – Australia's National Digital Health Strategy. ADHA: Canberra, p. 3.
[12] WHO, cited in Australian Healthcare and Hospitals Association 2015, p. 2
[13] Ibid.
[14] Parliament of Australia (2017). *My Health Record System*. Senate. Community Affairs References Committee: Canberra, p. 11.

There is an extensive literature seeking to identify the benefits associated with electronic patient medical records. The Victorian Auditor-General has suggested these benefits include: better treatment information at time of patient admission; reduced medication errors and adverse drug reactions; reduced duplicated, invasive or expensive tests; reduced delays in patient discharge, due to more timely availability of test results and completion of discharge summaries; reduced hospitalisation or additional bed-days associated with adverse events taking place within hospitals; reduced clinical administrative tasks, resulting in more time spent with patient care; improved communication between clinicians and the community; and improved data entry for auditing and clinical research purposes.[15]

An application wherein electronic patient medical records are widely expected to yield benefits is in relation to drug prescriptions. Errors in drug prescriptions for patients has been suggested to be an important causal factor underlying avoidable hospital admissions, leading to adverse patient health outcomes and a strain on health resources. It has been estimated that the potential cost of unsafe or erroneous medication-related hospital admissions was about $1.2 billion, whereas the Australian National Digital Health Strategy report indicated that incomplete and inaccurate medicines information contributes toward two million adverse drug events annually in Australia.[16] The digital management of more accurate prescription data, delivered to providers in real-time, would be expected to reduce the human and financial costs associated with medication errors.

Even among some health providers today there is a considerable reliance upon paper records to establish patients' medical histories, which include past diagnoses and medical treatment solutions (including drug prescriptions). As noted in a 2013 report by the Victorian Auditor-General, "patient clinical information was mainly handwritten, stored in folders, and filed in medical records held at hospitals. This approach often resulted in lost or illegible patient notes, time delays when retrieving and transporting files, and prescribing errors due to a lack of clarity within paper medication charts and pathology and radiology orders."[17] As will be discussed later in this section, the benefits of patient

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[15] Victorian Auditor-General (2013). *Clinical ICT Systems in the Victorian Public Health Sector*. https://www.audit.vic.gov.au/sites/default/files/20131030-Clinical-ICT-Systems.pdf (accessed 30 August 2019), p. 3.

[16] See Hambleton, Steven J. and Aloizos, John (2019). Australia's digital health journey. *The Medical Journal of Australia* 210 (6): S5-S6.
See ADHA, ibid.

[17] Ibid, p. 3.

medical records would seem inversely proportional to the non-trivial costs associated with maintaining legacy, largely paper-based, records.[18]

There is a long history of governmental initiatives in Australia to establish electronic medical records of patents' history. In the mid- to late-1990s the federal government accorded greater recognition to the need for it to play a role in facilitating the trialling and roll-out of patient medical record digital innovations, in conjunction with the states and the private sector. Following a House of Representatives Committee report in 1997 on the desirability of a national electronic patient medical record, the commonwealth and states agreed to the establishment of the National Health Information Management Advisory Committee (NHIMAC) a year later. This body, which included a National Electronic Health Records Taskforce sub-committee, was tasked to work collaboratively in developing standards and policies for nationally-consistent health identifiers and patient medical records. Within the overarching "Health Connect" strategy, a Better Medication Management System (BMMS)—a system intended to create personal electronic health records with linked prescription records with doctors and pharmacies—was trialled in various jurisdictions through the mid-2000s.[19]

The NHIMAC initiative was superseded by a National E-Health Transition Authority (NEHTA), which was established in 2004. This new body, jointly funded by federal, state and territory governments, aimed to "advance the e-health agenda through development of e-health standards, clinical technologies and patient and provider identifiers."[20] One of the achievements of NEHTA was to launch the Personally Controlled Electronic Health Record (PCEHR) in 2012, containing clinical documents, test results, information added by the individuals, and Medicare, Pharmaceutical Benefits Scheme and immunisation data.[21] In June 2014 it was estimated that about 1.7 million people and over 7,000 health care provider organisations (including most public hospitals in Queensland) were registered to use the PCEHR.[22]

In 2014 the then federal Health Minister Peter Dutton commission a review into PCEHR, with the subsequent final review recommending a change to a patient "opt-out" rather than "opt-in" system. In addition to accepting this change, the commonwealth renamed the PCEHR as the "My Health Record" and rendered governance changes including the establishment of the Australian Digital

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[18] Paolucci, Francesco, Ergas, Henry, Hannan, Terry and Aarts, Jos (2010). The effectiveness of health informatics. In Stèfane M. Kabene (ed.), *Healthcare and the Effect of Technology: Developments, Challenges and Advancements*, pp. 13-37. Medical Information Science Reference: Hershey, PA.
[19] Jolly, Rhonda (2011). *The e health revolution – easier said than done*. Parliament of Australia, Department of Parliamentary Services. Parliamentary Library Research Paper No. 3.
[20] Ibid, p. 24.
[21] Hambleton and Aloizos, ibid.
[22] See Productivity Commission (PC) (2015). *Efficiency in Health*. Commission Research Paper. PC: Canberra.

Health Agency in July 2016.[23] In 2017 a National Digital Health Strategy was outlined, in consultation with states, territories and other interested parties, with a view to ensuring comprehensive utilisation of digital health records. Specifically, the Strategy enunciated an objective of ensuring, by 2022, all health care providers would be able to contribute to, and use health information, in My Health Record, on behalf of their patients.[24]

Given their significant role in the provision and financing of health care provision, including the public hospital system, it is unsurprising that Australian state and territory governments have also been active in the development of electronic patient medical records. Take, for example, the experience of Victoria in this rapidly-changing policy space. The Bracks Government initiated the "HealthSMART" electronic health project, with an initial funding allocation of $323 million and a due date of 2007. The object of the project was to adopt common core ICT systems for Victorian health services and metropolitan community health service providers, operate those systems in a shared service arrangement, and fund a program of works to implement the strategy in approximately half of the mentioned agencies.[25] Following investigations by the Victorian Ombudsman and a review by the Victorian Government the HealthSMART project was abandoned in 2012.[26]

Subsequent to the HealthSMART experience, the Victorian Government has continued to work developing the governance and operational infrastructures necessary to facilitate electronic patient health records. In July 2016 a new protocol was developed to promote data security within the Victorian public sector, including with applicability to patient records. The Victorian Protective Data Security Framework (VPDSF) builds on mandatory ICT security standards, as delineated in legislation, with compliance and assurance activities so that public sector entities continuously assess their protective data security management in line with the VPDSF. These policy developments are encompassed by a broader privacy architecture developed by successive Victorian Governments, including establishment of the Office of the Victorian Information Commissioner (OVIC) and the Charter of Human Rights and Responsibilities which confers a right to privacy to Victorians.

[23] Hambleton and Aloizos, ibid.
[24] ADHA, ibid.
[25] Victorian Government (2013). Ministerial Review of Victorian Health Sector Information and Communication Technology. https://www2.health.vic.gov.au/about/publications/researchandreports/ministerial-review-of-victorian-health-sector-information-and-communication-technology (accessed 30 August 2019).
[26] Victorian Auditor-General (2017). ICT Strategic Planning in the Health Sector. https://www.audit.vic.gov.au/sites/default/files/20170524-Health-ICT-Planning.pdf (accessed 30 August 2019).

In late 2016 the Victorian Government approved a new "Digitising Health" strategy for the state, consistent with a previously-issued Statewide Health ICT Strategic Framework.[27] One of the key focus areas of the strategy is to replace "legacy and paper-based systems with up-to-date patient administration and departmental systems (such as for theatre, radiology and pathology) and expanding the deployment of electronic medical record systems, including medications management, to reduce the reliance on paper-based systems when delivering clinical care."[28] This was followed by an announcement, in April 2018, that the Government would roll out a regime of linked electronic medical records across the Peter MacCallum Cancer Centre, Melbourne Health and Royal Women's Hospital.[29] The Government has indicated that this initiative is expected to save Victoria $34.1 million per annum once operational, and that previous electronic record trials at the Royal Children's Hospital helped reduce prescription and administrators errors as well as promoted child immunisation rates.

The success of electronic patient medical records in Australia may be attested by the fact that over 6 million Australians are participating in the federal My Health Record (as at January 2019), a significant increase compared to its predecessor.[30] Surveys have also indicated that most Australians would be willing to digitise their medical records, provided appropriate privacy and other safeguards (e.g. record anonymisation) are in place.[31] However, the practical experience of implementation and uptake for electronic patient medical records—both in Australia and overseas—have been hampered by logistical failures and inflated budgetary costs, in turn suggesting considerable scope for improvement.

A major problem affecting the adoption of electronic patient medical records by patients and providers alike has been the lack of consistency across providers. Interoperability—or the ability of IT systems to communicate and interpret data consistently across organisational and institutional boundaries—is seen as a major determinant of the efficacy and productivity of electronic patient medical records and e-health in general.

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[27] Victorian Government (2016). Digitising Health – How Information and Communications Technology Will Enable Person-Centred Health and Wellbeing within Victoria. https://www2.health.vic.gov.au/about/publications/policiesandguidelines/digitising-health (accessed 30 August 2019).

[28] Ibid. p. v.

[29] Hennessy, The Hon Jill (2018). Electronic patient records to save lives. Minister for Health Press Release, 30 April. https://www.premier.vic.gov.au/wp-content/uploads/2018/04/180420-Electronic-Patient-Records-To-Save-Lives.pdf (accessed 30 August 2019).

[30] Hambleton and Aloizos, ibid.

[31] Productivity Commission (PC) (2017). *Data Availability and Use*. Inquiry Report NO. 82. PC: Canberra.

The available studies indicate there is considerable scope for improvement in terms of ICT interoperability in Australian health care. Recent research investigated the extent to which certain Victorian health care providers—namely, five major Melbourne metropolitan hospitals—shared complete and consistent information with one another.[32] In summary the authors found that "there is little uniformity in the current electronic clinical information systems being used by healthcare providers that have been widely adopted in an attempt to improve efficiencies relating to medical information."[33] Additionally, "the details of the health care information captured, stored and used is variable and site dependent" and "the overall variability in medical information quality across many categories has created information silos."[34] Similar criticisms have been levelled toward the multiplicity of electronic patient medical record experiments across and between levels of government as well as sectors. For example, an advisory report to the federal government in 2004 made the observation that "there were too many small, loosely coordinated e-health initiatives underway across the states and territories."[35]

A related problem inflicting the adoption of electronic patient medical records has been the potential, and in some circumstances the actuality, of data breaches compromising privacy protocols. An audit by the Victorian Auditor-General of security arrangements underpinning patients' hospital data found that "Victoria's public health system is highly vulnerable to the kind of cyberattacks recently experienced by the National Health Service (NHS) in England, in Singapore, and at a Melbourne-based cardiology provider, which resulted in stolen or unusable patient data and disrupted hospital services."[36] Weaknesses were uncovered with regard to password security and other user access controls, as well as potential points of compromise in the physical security of patient health records.

Concerns have been similarly raised about effectiveness of privacy protections surrounding federal initiatives, most prominently the My Health Record. A 2018 report indicated that the Office of the Australian Information Commissioner was assessing the unauthorised, third-party access of My Health

[32] Allen-Graham, Judith, Mitchell, Lauren, Heriot, Natalie, Armani, Roksana, Langton, David, Levinson, Michele, Young, Alan, Smith, Julian A., Kotsimbos, Tom and Wilson, John W (2018). Electronic health records and online health records: an asset or a liability under current conditions? Australian Health Review 42: 59-65.
[33] Ibid. p 63.
[34] Ibid.
[35] Boston Consulting Group (BCG), *National Health Information Management and Information and Communications Technology Strategy*, report prepared for the Australian Health Information Council, August 2004. Cited in Jolly (2011, p. 24).
[36] Victorian Auditor-General (2019). Security of Patients' Hospital Data. https://www.audit.vic.gov.au/sites/default/files/2019-05/29052019-Hospital-Data-Security.pdf (accessed 30 August 2019), p. 7.

Record data in 2016-17, relating to information pertaining to 100 people.[37] In a submission to the Senate inquiry into the My Health Record, the Centre for Digital Business pointed out the risks to security arising from the management of a centralised database of sensitive patient information which is, nonetheless, accessible to a large number of health care providers (such as the My Health Record). In essence, "having so many potential access point was a potential source of vulnerability for the system if those access points could not be properly secured."[38]

Other issues have been raised as potential obstacles to the seamless diffusion of electronic patient medical records. These include a lack of organisational and workforce capability to accommodate ICT innovations, stemming from antiquated computer software and a lack of labour skills and training. With respect to the My Health Record, Hambleton and Aloizos mention "low levels of specialist computerisation, inconsistent levels of readiness in public and private hospitals, and variable user experience and engagement in general practice," an observation which appears applicable to most attempts to implement electronic records in the health system.[39] Jurisdictions such as Victoria have devoted policy attention and funding toward redressing these concerns in recent years.[40]

It would be remiss for an analysis of the policy experience with electronic patient medical record innovation and management to not reflect upon the implementation difficulties in terms of the "opt-out" My Health Record protocols. Reports have indicated that more than 2.5 million Australians chose to opt out of the My Health Record before the (extended) deadline of late January 2019, in the wake of concerns raised by various groups about the technical integrity and security of patient records within the (centralised) platform.[41] From the perspective of groups such as the Australian Privacy Foundation, for example, "simplistic IT solutions that gather large amounts of raw, un-managed patient data, which can be matched with other data sources, which are onerous to use, and which are easily accessible over the internet, potentially by hackers, can create far more insidious problems than they solve."[42]

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[37] Sadler, Denham (2018). My Health Record an 'abuse of trust' https://www.innovationaus.com/2018/05/My-Health-Record-an-abuse-of-trust (accessed 30 August 2019).
[38] Parliament of Australia, ibid, p. 12.
[39] Ibid., p 56.
[40] ADHA, ibid.
[41] Knaus, Christopher (2019). More than 2.5 million people have opted out of My Health Record. The Guardian, 20 February. https://www.theguardian.com/australia-news/2019/feb/20/more-than-25-million-people-have-opted-out-of-my-health-record (accessed 30 August 2019).
[42] Australian Privacy Foundation (2019). My Health Record: What we and others think of My Health Record. https://privacy.org.au/campaigns/myhr/ (accessed 30 August 2019).

Given the survey evidence, as mentioned previously, that most Australians would be willing to have their (de-identified and secured) health information stored on an interoperable digital platform, the implementation difficulties in Australian e-health commend to it an assessment of the potential for new modes of (distributed) ledger management to ease the transition to the digitalisation of patient medical records.

4. Blockchain as a new institutional solution

Blockchain was invented in 2008 by pseudonymous Satoshi Nakamoto to facilitate the first decentralised digital currency, bitcoin.[43] The invention of blockchain was part of a long-term effort to create a native digital currency for the internet that didn't rely on third parties to generate trust in the ledger. In practice the Bitcoin blockchain is a chronological ledger of transactions governed by a decentralised and distributed network of computers. Blockchain ledgers do not necessarily need to contain records of monetary transactions, and have recently been applied to ledgers as diverse as property titles, data rights, government registries and supply chains. In this section we introduce blockchain and distributed ledger technology before briefly exploring how to understand the blockchain economy through the lens of institutional cryptoeconomics.

What exactly is a blockchain? Blockchains are decentralised ledgers maintained by networks of computers through the use of economic incentives. When Satoshi Nakamoto invented the bitcoin blockchain they combined several other technologies—including peer-to-peer networks, cryptographic hash functions, game theoretic incentives—into a new technology called a blockchain. This unique combination of technologies solved a long-standing 'consensus problem' that plagued decentralised ledgers. Decentralised ledgers sounded fantastic in theory (they are potentially more robust to attacks, censorship-resistant and immutable) but are a difficult engineering problem. In particular, if we are to have a decentralised and distributed ledger spread across and updated by a network of computers, how do those computers come to consensus over the state of the ledger? How can we ensure that all copies are the same? Who prevents fraudulent transactions from being added to the ledger? Previously all of these problems were partially solved through centralised third parties like governments, who held and updated the ledger, and were trusted by the stakeholders and participants associated with that ledger.

We're not used to thinking about ledgers in this way because almost all of the ledgers we use are centralised. If we want to transfer money we use banks. The bank determines who is entitled to send

[43] Nakamoto, Satoshi, Bitcoin: A Peer-to-Peer Electronic Cash System, 2008, <https://bitcoin.org/bitcoin.pdf>.

and receive money, and whether accounts have balances. To transfer property titles or licenses we go to the government. We pay a hefty fee for the local governments to transfer property from one party to another. The reality is that much of our modern economy is based on ledgers maintained by hierarchical, centralised third parties. These parties provide a coordinating role of trust to facilitate exchange. Centralised ledgers have institutional benefits: they are administratively convenient, they don't double-up on transaction processing, and theoretically, mistakes can be easily remedied.

The fundamental innovation of blockchains is that they potentially solve many of the problems that are currently solved through centralised intermediaries but they do so across a decentralised network. There is an enormous amount of innovation around blockchain and distributed ledger technologies, but it is useful here to outline how Satoshi Nakamoto solved the 'consensus problem'. In the case of a digital currency this is the 'double spend' problem, which is the equivalent of digital money counterfeiting. Bitcoin uses a consensus mechanism called 'proof of work'. In a proof of work blockchain, 'miners' solve difficult computational puzzles to validate and order transactions into blocks to update the ledger. Around every ten minutes, a miner wins the right to publish the next 'block' of transactions to the blockchain and is rewarded with freshly minted bitcoin. Their chance of winning is random but probabilistically related to how much computing power they contribute. The blockchain can be downloaded freely by anyone (it is simply a list of timestamped transactions) from the thousands of locations in which it is kept. For a malicious actor to change the ledger across the network they would have to gain 51% of the mining power (a '51% attack')—a feat that becomes more expensive as the network expands and becomes more decentralised.

The bitcoin blockchain is just one type of distributed ledger. Since 2008 we have seen a remarkable amount of innovation in similar distributed ledger technologies. We have seen continuing research and experiments by computer scientists, cryptographers and cryptoeconomists in new consensus mechanisms. These different mechanisms (e.g. proof of stake, proof of authority, delegated byzantine fault tolerance) trade off the properties of distributed ledgers in different ways (e.g. scalability, transaction costs, privacy, security, decentralisation and so on). These technical innovations are likely to overcome many of the present shortcomings of the technology, such as its speed and its environmental impact through electricity usage. But a technological invention is nothing without its entrepreneurial application.

There have been extensive entrepreneurial applications of blockchain and distributed ledger technologies across a wide range of industries and sectors including healthcare, supply chains, law, voting and energy markets. Blockchains and other distributed ledger technologies can be used for much more than simple currency transactions. The widespread application of blockchain is interesting because of the nature of the technology itself. Rather than a production technology, such as electricity or the steam engine, blockchain as an innovation operates at the level of institutions. Blockchain is a governance technology, more analogous to the invention of the joint stock company than the invention of the aeroplane. But institutional governance technologies are very rare. Therefore at the RMIT Blockchain Innovation Hub we've developed the foundational theory to understand how blockchain technology will shift the organisational structure of our economy and society—we call this methodological framework institutional cryptoeconomics.

Institutional cryptoeconomics has its foundations in the long-running field of institutional and transaction cost economics to understand how institutions constrain and facilitate human coordination and interaction. Institutional economics examines how governance structures overcome transaction costs. By transaction costs we mean the costs of searching, negotiating and enforcing our everyday exchanges. It costs time and money to find trading partners, to write contracts, and to ensure those contracts are completed successfully. The institutional cryptoeconomics view examines these dynamics in the context of blockchain technology as a new competing governance technology. Firms, markets, governments and blockchains are all alternative institutional arrangements used to solve economic problems. Firms might be more effective when there is need for hierarchical control under uncertainty, while markets might be better for aligning incentives. Institutional cryptoeconomics is the institutional analysis of the impact of blockchain technology on our existing governance structures, and at what margins our governance structures will shift from centralised firms and governments towards decentralised blockchains.

What is the institutional cryptoeconomics view of the healthcare sector? Recent analysis by the RMIT Blockchain Innovation Hub suggests that 35% of the global economy is dedicated to maintaining trust in its various forms. These are in roles such as managers, audits, courts enforcing contracts and so on. We suggest that this number might be even larger in the healthcare sector for processes such as monitoring, auditing, re-collecting data, ensuring its integrity through patient databases, protecting privacy. The healthcare sector has a vast number of ledgers of information that must be coordinated between distributed parties through time. Moreover, these ledgers tend to be held in centralised databases and locations such as hospitals, governments and general practices.

To the extent the economic organisation of the healthcare system is the result of solving data coordination and trust problems (what we suggest is a large amount) then we would expect a large shift in organisational governance utilising blockchain. That is, the vertical integration of healthcare services within large hierarchical organizations is often an attempt to overcome the transaction costs and coordination costs of dynamic, fragmented and often untrustworthy data. Even recent government attempts to create registries of healthcare data to overcome fragmentation solve the problems of healthcare data coordination through centralisation. From this perspective blockchain presents an interesting institutional alternative to managing healthcare data and for ensuring its integrity. Blockchain may not just supplement the technologies within our healthcare sector, but more deeply support some existing hierarchical organisation. The current state of blockchain in healthcare, which is the topic of the following section, represents an institutional discovery process: what processes and information that is currently maintained through centralised intermediaries could potentially be better organised using blockchain technology?

5. How blockchain is being used in healthcare

Blockchain has the potential to resolve the current healthcare provider interoperability, data privacy and security issues.[44] In this section, we introduce four potential use cases of blockchain in healthcare. Blockchain is currently being investigated by industry and academia for managing electronic health records (EHRs), facilitating clinical research and drug development trials, improving quality control of pharmaceuticals and medical equipment and optimising health insurance processes. Many blockchain healthcare startups raised capital in 2017-18 through initial coin offerings (ICOs).[45] Several of these projects have subsequently incorporated the use of tokens on their platforms to fulfil a particular utility function.

5.1. Managing Electronic Health Records

Managing EHR systems efficiently is increasingly important given the rapid increase of health data size and volume requiring storage and interpretation.[46] Blockchain-supported healthcare systems may allow healthcare professionals and patients to access updated records that are distributed in real-time in a transparent and secure manner. The viability of such projects, however, depends whether the

[44] See for an overview of academic literature, Drosatos, G and Kaldoudi, E, 2019, 'Blockchain Applications in the Biomedical Domain: A Scoping Review', Computational and Structural Biotechnology Journal, vol. 17, pp. 229-240, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6389656>.

[45] See, Kuraitis, V, Healthcare ICOs/Tokens-Medium, 2018, <https://docs.google.com/spreadsheets/d/1TANOZmuYtVhyn1C9PV6YLsOBlQNOEOBExB7u2_Kkork>; Miller, R, An Update on Healthcare ICOs, 2019, <https://medium.com/@bertcmiller/an-update-on-healthcare-icos-e7ae25cc85ff>.

[46] Hulsen, T, Jamuar, SS, Moody, AR, Karnes, JH, Varga, O, Hedensted, S, Spreafico, R, Hafler, DA and McKinney, EF, 2019, 'From Big Data to Precision Medicine', Frontiers in Medicine, <https://doi.org/10.3389/fmed.2019.00034>.

appropriate purpose, design and technical characteristics have been adopted.[47] Two major challenges—technical limitations and privacy laws—restrain the use of blockchain as an EHR management, storage and transfer system. In this section we discuss these challenges and examine some projects and research in this space.

Health data is generally not stored directly on blockchain. There are several reasons for this off-chain data storage. First, blockchain has technical limitations in processing high-frequency, high-volume transactions.[48] Second, privacy laws impose obligations on health service providers that hold health records to maintain patient confidentiality.[49] As such, storing identifiable health data on public or private blockchains can result in non-compliance with privacy laws. Rather than using blockchain as a data storage platform, blockchain is instead utilised as a notarisation, pointer mechanism and data exchange service. We outline some ways blockchain is used in these ways below.

- The Patient Data Network stores a unique, encrypted Medical Record Number for each patient at each provider, a link to the patient's profile and a hash of the profile data on the Hyperledger Fabric blockchain.[50] A hash of and a link to health record assets (e.g. procedure, medication, appointment information) will also be stored on the blockchain. No health data itself is stored on the blockchain.
- FHIRChain, which was developed in 2018 by Vanderbilt University engineers, stores and exchanges encrypted metadata referencing protected data stored off-chain.[51]
- PatientDirected.io utilises the Ethereum blockchain, and stores patient data events and limited metadata in secure IPFS pointers.[52]

Augmenting blockchain with other technologies, such as cloud infrastructure, enables off-chain data storage.[53] For instance, the Australian Federal Department of Health partnered with Agile Digital, Vault

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[47] Mackey, TK, Kuo, TT, Gummadi, B, Clauson, KA, Church, G, Grishin, G, Obbad, K, Barkovich, R and Palombini, M, 2019, ''Fit-for-purpose?' – Challenges and Opportunities for Applications of Blockchain Technology in the Future of Healthcare', BMC Medicine, <https://doi.org/10.1186/s12916-019-1296-7>.
[48] IBM, Blockchain: The Chain of Trust and its Potential to Transform Healthcare – Our Point of View, 2016, <www.healthit.gov/sites/default/files/8-31-blockchain-ibm_ideation-challenge_aug8.pdf>.
[49] See, Justice Connect, Privacy Guide - A Guide to Compliance with Privacy Laws in Australia, 2017, <https://www.nfplaw.org.au/sites/default/files/media/Privacy_Guide_Cth.pdf>.
[50] Lynch, M, A Secure and Transparent Network for Sharing Health Data using Hyperledger Composer Blockchain and HL7 FHIR, 2018, <https://medium.com/@micklynch_6905/the-patient-data-network-project-ef84a3d13781>.
[51] Zhang, P, White, J, Schmidt, DC, Lenz, G and Rosenbloom, ST, 2019, 'FHIRChain: Applying Blockchain to Securely and Scalably Share Clinical Data', Computational and Structural Biotechnology Journal, <https://doi.org/10.1016/j.csbj.2018.07.004>.
[52] PatientDirected.io, <https://www.patientdirected.io>.
[53] Xia, Q, Sifah, EB, Smahi, A, Amofa, S and Zhang, X, 2017, 'BBDS: Blockchain-Based Data Sharing for Electronic Medical Records in Cloud Environments', Information, vol. 8, pp. 44, <https://doi.org/10.3390/info8020044>.

Systems and Gulanga in 2018 to develop a centralised, cloud-based system for storing de-identified My Health Record data for medical researcher access.[54] Retrieved patient data and subsequent experimental data is notarised on the Agile Digital Secure Health Data Research & Analytics blockchain platform. Raw data is secured on Vault System's ASD-certified Government cloud infrastructure. Non-cloud storage technologies are also used to store EHR data. Medicalchain stores health data off-chain in 'data lakes' or servers, which are located in the patient's jurisdiction.[55]

Interoperability of health data across technical systems is vital for the success of any project. Health data is generally stored across a dispersed network of healthcare providers in formats specific to the provider's record management system. Although government EHR systems such as the Blue Button[56] and My Health Record[57] empower patients to interact with their health data, patients do not have access to a complete patient record if information is siloed to health providers. Blockchain-based EHR systems must be able to share data in a way that enables interacting parties to understand the meaning and structure of the data.[58] Interoperability, or the way in which health data can be standardised and exchanged between health providers, is an essential focus for blockchain healthcare projects.[59] Research groups, such as those led by HIMSS and Hyperledger,[60] are working towards resolving interoperability issues and how to implement blockchain into existing IT infrastructure. Increased interoperability will ensure health data is consistent and can be effortlessly exchanged across health providers.

5.2. Enabling scientific research

Blockchain enables researchers and drug manufacturers to evolve from the traditional linear process of drug discovery, testing and approval to a model where health data is requested and

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[54] Agile Digital, Department of Health - Patient Privacy in Health Research Through Blockchain Technology, 2018, <https://agiledigital.com.au/clients/department-of-health>.
[55] Medicalchain, Frequently Asked Questions (FAQ), 2018, <https://www.reddit.com/r/medicalchain/comments/88l633/frequently_asked_questions_faq; Medicalchain Whitepaper 2.1, https://medicalchain.com/Medicalchain-Whitepaper-EN.pdf>.
[56] Blue Button, <https://www.healthit.gov/topic/health-it-initiatives/blue-button>.
[57] My Health Record, <https://www.myhealthrecord.gov.au>.
[58] Peterson, K, Deeduvanu, R, Kanjamala, P and Mayo, KB, 2016, A Blockchain-Based Approach to Health Information Exchange Networks, <www.healthit.gov/sites/default/files/12-55-blockchain-based-approach-final.pdf>.
[59] Gordon, WJ and Catalini, C, 2018, 'Blockchain Technology for Healthcare: Facilitating the Transition to Patient-Driven Interoperability', Computational and Structural Biotechnology Journal, vol. 16, pp. 224-230, <https://doi.org/10.1016/j.csbj.2018.06.003>.
[60] HIMSS, Interoperability & Health Information Exchange Committee, <www.himss.org/get-involved/committees/interoperability-hie>; Hyperledger, Hyperledger Announces the Hyperledger Healthcare Working Group, <www.hyperledger.org/blog/2016/10/03/hyperledger-announces-the-hyperledger-healthcare-working-group>.

exchanged in real-time. Blockchain has the potential to improve trust between stakeholders in the clinical trial process as well as data integrity and transparency.[61] It could reduce mismanagement of collected data by decreasing the number of intermediaries involved in the data collection process. Blockchain could also alleviate the ubiquitous issue of incomplete and inaccurate records collected during trials by providing a mechanism to track and trace information to its source. The ability of blockchain to facilitate transparency around health data usage further has the potential to disrupt the multi-billion dollar health data brokerage industry.[62] Blockchain-based solutions can provide opportunities to monetise health data, can increase patient engagement by improving informed consent procedures and can provide nuanced information about the quality of clinical trial data.

Trial researchers can engage potential participants through either interoperable EHR systems that link to a clinical trial portal, or through patient-centric platforms such as Health Wizz.[63] Researchers can specify participant criteria, for which the system can return a list of those who qualify as trial participants.[64] Patients can be reimbursed with tokens for sharing health data on platforms such as Enome, Patientory, Nebula Genomics, Encrypgen, Simply Vital Health, Iryo, HIT Foundation, AMChart PHR, and doc.ai.[65] These platforms utilise mobile or web apps to engage participants, manage informed consent and data transfer. For instance, MediBloc's first consumer product, mobile app 'YOL', lets Korea-based Android users to receive MEDX tokens for sharing their prescription data with third parties such as pharmaceutical and insurance companies.[66] Notably, MediBloc has established over 80 partnerships and joint research projects with prominent institutions, which has facilitated user adoption of the platform.[67]

Obtaining informed consent is a critical aspect of conducting clinical trials. Consent collection is a dynamic process that may require obtaining revised consent from research participants if new risks,

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61 Kleinaki, AS, Mytis-Gkometha, P, Drosatos, G, Efraimidis, PS and Kaldoudi, E, 2018, 'A Blockchain-Based Notarization Service for Biomedical Knowledge Retrieval', Computational and Structural Biotechnology Journal, vol. 16, pp. 288-297, <https://doi.org/10.1016/j.csbj.2018.08.002>.

62 Tanner, A, How Data Brokers Make Money Off Your Medical Records, 2016, <https://www.scientificamerican.com/article/how-data-brokers-make-money-off-your-medical-records>.

63 Health Wizz, <https://www.healthwizz.com>.

64 Benchoufi, M, Porcher, P and Ravaud, R, 2018, 'Blockchain Protocols in Clinical Trials: Transparency and Traceability of Consent', Version 5, <https://doi.org/10.12688/f1000research.10531.5>.

65 See: Enome, <https://www.enome.io>; Patientory, <https://patientory.com>; Nebula Genomics, <https://blog.nebula.org/dna-privacy>; Encrypgen, <https://encrypgen.com>; Simply Vital Health, <https://www.simplyvitalhealth.com>; Iryo, <https://iryo.io/#intro>; HIT Foundation, <https://hit.foundation>; Amchart PHR, <https://amchart.io/phr.html>; Doc.ai, <https://doc.ai>.

66 MediBloc, [BIG ANN] Introducing MediBloc's Very First Application, 'YOL', 2018, <https://medium.com/@MediBloc/big-ann-introducing-mediblocs-very-first-application-yol-f7f2e8fa2c4>.

67 MediBloc, MediBloc X Harvard Medical School Massachusetts General Hospital Research, 2018, <https://medium.com/@MediBloc/medibloc-x-harvard-medical-school-massachusetts-general-hospital-research-51f01e14d6e5>.

significant changes in research procedures or other trial issues occur. There are a number of ways blockchain can improve existing informed consent procedures.[68] Essentially, blockchain provides an immutable, time-stamped record of what the patient has been informed of and what they have consented to. An organisation's ethics committee has the potential to cryptographically acknowledge and store approvals for experiment protocols, and keep track of patient consent against particular protocols.[69] Obtaining informed consent with user-friendly interfaces has been trialled by Queen's University in 2018. BlockTrial, a permissioned blockchain, enabled patients to register in the study, apply permission settings and provide informed consent using the BlockTrial App.[70] Rati-Fi is a blockchain-supported platform that captures the doctor-patient appointment and records patient consent to procedures.[71]

Clinical trial records are often incomplete or erroneous, which significantly impacts the validity of final trial results.[72] To improve trial quality and patient safety at a reduced cost, IBM Canada and pharmaceutical company Boehringer Ingelheim (Canada) Ltd are developing a bookkeeping system for clinical trials.[73] Initial testing is likely to occur in post-marketing Phase IV studies.[74] Using blockchain to ensure accurate data collection may expedite drug development by reducing time spent on identifying trial errors. Improved trial procedures and bookkeeping mechanisms may ultimately contribute to a more transparent and efficient trial environment, which can lead to the higher quality research and drug development outcomes.

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[68] Benchoufi, M, Porcher, P and Ravaud, R, 2018, 'Blockchain Protocols in Clinical Trials: Transparency and Traceability of Consent', Version 5, <https://doi.org /10.12688/f1000research.10531.5>.
[69] Colleville, A, The Potential of Blockchain to Disrupt Clinical Research Data Management and Transparency, <https://www.bearingpoint.com/fr-africa/blogs/blog-life-sciences/the-potential-of-blockchain-to-disrupt-clinical-research-data-management-and-transparency>.
[70] Maslove, DM, Klein, J, Brohman, K and Martin, P, 2018, 'Using Blockchain Technology to Manage Clinical Trials Data: A Proof-of-Concept Study', JMIR Medical Informatics, vol. 6, <https://doi.org/10.2196/11949>.
[71] Rati-Fi, <https://rati-fi.com>.
[72] George, SL and Buyse, M, 2015, 'Data Fraud in Clinical Trials', Clinical Investigation, vol. 5, pp. 161-173, <https://doi.org/10.4155/cli.14.116>.
[73] Boehringer Ingelheim, Boehringer Ingelheim (Canada) Ltd. and IBM Canada Announce First of its Kind Collaboration to Integrate Blockchain Technology into Clinical Trials, 2019, <https://www.boehringer-ingelheim.ca/en/press-release/boehringer-ingelheim-canada-ltd-and-ibm-canada-announce-first-its-kind-collaboration>.
[74] Dearment, A, It's Not About What Blockchain Can Do in Healthcare, but What it's Already Doing, 2019, <https://medcitynews.com/2019/04/its-not-about-what-blockchain-can-do-in-healthcare-but-what-its-already-doing>.

5.3. Supply chains

Blockchain can be incorporated in healthcare supply chains in two major ways.[75] First, blockchain can be used as a quality assurance measure by tracking goods, such as pharmaceuticals, from genesis to delivery. Second, blockchain can be used for inventory management of healthcare providers, which enhances supply maintenance and reduces storage inefficiencies.

Pharmaceutical companies are estimated to lose over US$217 billion annually due to counterfeit drugs.[76] Deploying blockchain to track pharmaceutical drugs from origin to purchase has the potential to save up to US$43 billion in revenue for pharmaceutical companies.[77] Product provenance tracking for pharmaceuticals and medical equipment will involve utilising internet of things (IoT) devices in conjunction with blockchain.[78] IoT sensors may be used to track the physical location of goods, for which smart contracts may document the transfer of ownership and custody between parties.[79] Authenticating products along the supply chain may involve serialisation of products using unique sequences DNA in inks or packaging, quantum materials, or microprocessor chips.[80] Industry standards for blockchain supply chain logistics are currently being developed by the Blockchain in Transport Alliance.[81] Projects that are using blockchain to track pharmaceuticals across the supply chain include:

- In mid-2018, Microsoft and Adents launched Adents NovaTrack to track transactions across any global supply chain, with a particular focus on pharmaceutical goods.[82]

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[75] On blockchain supply chains more broadly see: Allen, DWE, Berg, C, Davidson, S, Novak, M and Potts, J, (forthcoming) 'International policy coordination for blockchain supply chains', *Asia and the Pacific Policy Studies*
Allen, DWE, Berg A and Markey-Towler, B (2019) 'Blockchain and supply chains: V-form organisations, value redistributions, de-commoditisation and quality proxies', *The Journal of the British Blockchain Association*, vol. 2, No. 1, pp. 57-65.
[76] PricewaterhouseCoopers, Fighting Counterfeit Pharmaceuticals: New Defenses for an Underestimated - and Growing - Menace, 2017, <https://www.strategyand.pwc.com/report/counterfeit-pharmaceuticals>.
[77] BIR Research, Global Blockchain in Healthcare Market: Focus on Industry Analysis and Opportunity Matrix - Analysis and Forecast, 2018-2025, 2018, <https://www.researchandmarkets.com/reports/4519297/global-blockchain-in-healthcare-market-focus-on>.
[78] For example, Modum, <https://modum.io/solutions/overview>.
[79] Liu, J and Cannistraci, P, 5 Supply Chain Use Cases for IoT, Blockchain, 2018, <https://deloitte.wsj.com/cio/2018/11/08/5-supply-chain-use-cases-for-iot-blockchain>.
[80] See: Making Pharmaceuticals Exhibition & Conference, Forensics DNA Technology Combined With Blockchain – To Achieve Completely Secure Pharma Supply Chains, 2019, <https://www.makingpharma.com/seminar/blockchain>; Young, R, Quantum IDs can Help us Fight Back Against Counterfeit Drugs, 2019, <https://www.wired.co.uk/article/medicine-quantum-id>; Postscapes, IoT Hardware Guide, <https://www.postscapes.com/internet-of-things-hardware>.
[81] Blockchain in Transport Alliance, <https://www.bita.studio>.
[82] Adents, <https://adents.com/adents-novatrack>.

- In early 2019, United States Food and Drug Administration approved a pilot project to use blockchain and IoT to track, monitor and verify prescription drug distribution across supply chains.[83]

- The MediLedger Project provides a drug serialisation solution to enable pharmaceutical sector compliance with US drug supply chain regulations.[84] Its working group members include major drug manufacturers and wholesalers AmerisourceBergen, Pfizer, Gilead, McKesson and Genentech.[85]

In addition to using blockchain and other complementary technologies to track goods from producer to consumer, blockchain can also be used to monitor a health provider's inventory of medical goods. For instance, in 2018 the National Institution for Transforming India partnered with Oracle and Apollo Hospitals to transfer the hospitals' inventory to a blockchain-based system to eliminate counterfeit pharmaceuticals and medical products.[86] Similar to its role in tracking during transportation, IoT can be used to monitor physical indicators such as temperature and location, which can be used to determine whether goods are appropriately stored.[87] The ability for blockchain to interact with real-time physical monitoring systems facilitates a more efficient transportation and storage system for medical goods.

5.4. Insurance

By incorporating blockchain into business processes, the insurance industry can potentially save billions of dollars by reducing administrative costs and enhancing claims management mechanisms. Deloitte has identified the following use cases for blockchain in the health insurance sector:[88]

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[83] US Food and Drug Administration, FDA News Release, 2019, <https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-adopt-more-modern-technologies-improving-security-drug-supply-chain-through>; US Federal Register, Pilot Project Program Under the Drug Supply Chain Security Act, 2019, <https://www.federalregister.gov/documents/2019/02/08/2019-01561/pilot-project-program-under-the-drug-supply-chain-security-act-program-announcement>.
[84] Ledger Insights, MediLedger: Pharmaceutical Industry's Blockchain Network, 2018, <https://www.ledgerinsights.com/mediledger-pharmaceutical-blockchain>.
[85] The MediLedger Project, <https://www.mediledger.com>.
[86] C&EN, India to Combat Fake Drugs with Blockchain, 2018, <https://cen.acs.org/pharmaceuticals/India-combat-fake-drugs-blockchain/96/i34>.
[87] Ji, Y, Zhang, J, Ma, J, Yang, C and Yao, X, BMPLS: Blockchain-Based Multi-level Privacy-Preserving Location Sharing Scheme for Telecare Medical Information Systems, 2018, Journal of Medical Systems, <https://doi.org/10.1007/s10916-018-0998-2>.
[88] Deloitte, Blockchain in Health and Life Insurance, <https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/blockchain-in-insurance.html>.

- Automatically collect and link relevant administrative records, and act on that data using smart contracts.
- Smart contracts can detect fraudulent or falsified claims or applications.[89]
- Improving the accuracy and relevance of health provider directories, which is presently costly for insurers to maintain.[90] ProCredEx and Hashed Health have partnered to create the Professional Credentials Exchange as a way of trading verified credentials information between healthcare organisations.[91]
- Simplifying the claims application process by providing easier access to medical records.

Prominent health insurers have joined collaborations to develop blockchain-based solutions. In 2019, IBM announced the Health Utility Network, an initiative to develop a blockchain-based healthcare data management system.[92] Network members include Aetna, Anthem, Health Care Service Corporation (HCSC), PNC Bank, Cigna and Sentara Healthcare. With three of five of the United States' top health insurers, the Health Utility Network is well placed to investigate insurance payment models and to develop a bundled payment system. The initiative is also researching how to enable greater patient control over data, facilitate secure and frictionless information exchange and maintain accurate healthcare provider directories. In 2018, the Synaptic Health Alliance launched a pilot project to determine how current information about healthcare providers can be made available to provider directories maintained by health insurers by using a permissioned blockchain.[93] Alliance members include Aetna, Ascension, Cognizant, Humana, MultiPlan, Optum, Quest Diagnostics and UnitedHealthcare.

In addition to health insurers collaborating on solutions, other projects are working on targeted solutions. Change Healthcare, for instance, is running a blockchain for claims processing and monitoring that enables organisations to track the real-time status of claims submission and

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[89] See, Gatteschi, V, Lamberti, F, Demartini, C, Pranteda, C and Santamaría, V, 2018, 'Blockchain and Smart Contracts for Insurance: Is the Technology Mature Enough?', Future Internet, <https://res.mdpi.com/futureinternet/futureinternet-10-00020/article_deploy/futureinternet-10-00020-v2.pdf>.
[90] CMS, Online Provider Directory Review Report, <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Year2_Final_1-19-18.pdf>.
[91] Hashed Health, ProCredEx Announces Launch of Partner Program with National Government Services, Spectrum Health System, WellCare, Accenture, and the Hardenbergh Group, 2018, <https://hashedhealth.com/procredex-dpp-announcement>.
[92] IBM, Aetna, Anthem, Health Care Service Corporation, PNC Bank and IBM announce collaboration to establish blockchain-based ecosystem for the healthcare industry, 2019, <https://newsroom.ibm.com/2019-01-24-Aetna-Anthem-Health-Care-Service-Corporation-PNC-Bank-and-IBM-announce-collaboration-to-establish-blockchain-based-ecosystem-for-the-healthcare-industry>.
[93] Synaptic Health Alliance, <https://www.synaptichealthalliance.com>.

remittance.[94] In 2018, the People's Insurance Company of China partnered with DNV GL and VeChain to develop a blockchain-based system to improve fraud detection, KYC compliance and claims processing.[95] In 2018 the world's first automated insurance claim was conducted in Singapore for pregnant women with gestational diabetes using the Vitana platform.[96] Projects with a target focus, such as facilitating claims processing, have the potential to act as an intermediary between consumer, payer and provider, or to merge with a health insurer to offer their services directly.

6. The future of healthcare: From organisational hierarchy to digital platform

Healthcare has an industrial architecture that is more centralised than it would be in a world where all health-related data and information was completely trusted. The need to check, verify, audit, manage and monitor information—whether to guard against error, opportunism or fraud, and whether information about patients, health professionals, procedures, equipment, devices, drugs, scheduling, permissions—imposes not just significant costs to the delivery of healthcare serves but also imposes an industrial architecture that tends toward hierarchic centralisation in order to minimise these costs of trust by gathering disparate activities into one place.[97] This centralisation will in turn however tend to cause increased administrative complexity and bureaucratisation, and in further consequence will cause reduced innovation and competition. Blockchain technology therefore affects the economic organisation of healthcare in two ways: (1) it can lower the cost of trust, as a productivity gain from automation; but (2) in doing so, it also induces a shift in the industrial architecture of healthcare toward decentralisation and dehierachicalisation. It is this second aspect that promotes innovation and competition.

Technological innovation to lower the cost of trust in the information components of healthcare production—combining digitisation and decentralised ledger technologies—is the foundation of the next generation of economic infrastructure of the healthcare sector. This will be built on a blockchain-based digital administrative infrastructure for identity, records, permissions, access, contracting and control. The economics of a new technology that lowers the cost of trust predicts industrial re-organisation in the sector to shift from a largely centralised industrial architecture—dominated by

[94] Change Healthcare, <https://www.changehealthcare.com/innovation/blockchain>.
[95] VeChain Foundation, Peoples Insurance Company of China (PICC), One of the Largest Insurer Globally with $126 Billion Total Assets, is Opting to Embrace Blockchain Technology with the Help of DNV GL and VeChain, 2018, <https://medium.com/@vechainofficial/peoples-insurance-company-of-china-picc-one-of-the-largest-insurer-globally-with-126-billion-2570c60fd7c7>.
[96] Vitana, <http://www.vitana.sg>.
[97] Novak, M, Potts, J and Davidson, S, 2018, 'The Cost of Trust: A Pilot Study', Journal of the British Blockchain Association, vol. 1, no. 2, pp. 1-7, <https://doi.org/10.31585/jbba-1-2-(5)2018>.

large hierarchical organisations—toward a more decentralised industrial architecture built on one or many open digital platform(s).

One key structural change in the healthcare sector that blockchain innovation predicts is the shift in industrial organisation from hierarchy to platform. Another related prediction is a shift in the property rights of health data. In essence, where a centralised administrative hierarchy will tend to be most efficient when property rights of data (i.e. ownership and control) are vested with the organisation, on a decentralised platform economic efficiency will require a different arrangement, vesting property rights at the edge of the network,[98] which in this case means with the patient or consumer.[99] Put another way, to the extent that hospitals and other healthcare institutions are at least partially vertically integrated due to data coordination, we would expect a de-hierarchialisation of the health system towards decentralised healthcare data rights and a de-hierarchialisation of the sector.

Consider why this shift from hierarchy to platform, and from producer-side to consumer-side ownership and control of data, will likely be beneficial. We suggest there are at least 4 main benefits from this fundamental change in property rights:

1. It induces *entrepreneurial competition*. Lower coordination and integration costs (e.g. through open standards and APIs) lowers the costs of competitive entry into different points along the value chain. This might increase consumer service offerings or increase competition, bidding down prices to benefit consumers. This moves us from a healthcare sector centred on problem solving through centralised planning towards one centred on the provision of property rights that enables the mutual discovery of beneficial services and products.
2. The shift in property rights to consumer-side data creates *higher-powered incentives* for the production and upload of both higher quality data (e.g. cleaned and curated, with added meta-data) and increased quantity of data (e.g. from wearables). The incentives to upload this data will of course be discovered over time and will relate directly to the emergence of data markets and other related services from that data. More effective data property rights that have economic value might incentivise more data production that is of higher quality. Data markets can work through the same technologies as cryptocurrency transactions by being

[98] Alchian, A and Demsetz, H, 1972, 'Production, Information Cost, and Economic Organization', vol. 62, no. 5, pp. 777-795, American Economic Review, <https://www.jstor.org/stable/1815199>.
[99] Kostkova, P, et al, 2016, 'Who Owns the Data? Open Data for Healthcare', Frontiers in Public Health, vol. 4, <https://doi.org/10.3389/fpubh.2016.00007>; Mikk, K, Sleeper, H and Topol, E, 2017, 'The Pathway to Patient Data Ownership and Better Health', Journal of the American Medical Association, vol. 318, pp. 1433-1434, <https://doi.org/10.1001/jama.2017.12145>; Topol, E, 2015, 'The Patient Will See You Now: The Future of Medicine Is in Your Hands', Journal of the American Medical Association, vol. 11, pp. 689-690, <https://doi.org/10.5664/jcsm.4788>.

underpinned by a secure and decentralised economic infrastructure using blockchain and other distributed ledger technologies.

3. A blockchain-based data infrastructure platform furnishes a platform upon which to build Artificial Intelligence (AI), Internet of Things (IoT) and other digital and computational services. By providing an identity verification layer for machine-based payments, record-keeping, contracting and compliance, blockchain-based infrastructure will provide for digital automation of health services. In this way blockchain essentially powers-up other technologies to better resolve the fundamental healthcare data problem we outlined in Section 2.
4. The economic benefits in *productivity gains* through entrepreneurial competition, and better demand-side incentives enable scalability. This enables the healthcare industry to grow. This should not be viewed as a simple reduction in the cost of healthcare, but a rapid productivity improvement that enables scarce healthcare resources to be better used.

There are several reasons why this institutional transition from hierarchy to platform will be difficult, especially in the health sector. Those factors range with existing vested interests to collective action issues to regulatory barriers and constraints. There are several reasons why this is particularly difficult:

- There are issues around coordination problems, network effects, coordination games and collective action.

- There is a build-up of vested interests in existing industry frameworks. People who are receiving rents from the data property rights that they hold have strategic reasons to protect their positions.

- We are also going to see transitional issues around idiosyncratic capital investments that are built up within hierarchical organisation, sunk costs, human capital investments, pre-existing industry routines and business models that are all adapted to a centralised data model.

- There will be a range of new skills required. This means new investments in different skills and behaviours. We’re likely to see sectoral creative destruction as we move from one industry architecture to another.

- There is need for some political will given that the healthcare sector is tightly entangled with existing regulatory frameworks. For a decentralised healthcare architecture to work we’re going to require changes to existing policies that lock-in centralised systems of data management (and indeed require them to comply with domestic regulation).

Despite these institutional transition issues, we are optimistic that we will soon see the healthcare system shift towards platform governance. Data property rights will be decentralised down to individual control, which changes the incentives of how that data is produced, maintained and fed as inputs into healthcare decisions.

7. Conclusion

In this report we have outlined the potential for blockchain as a new technology of trust for the healthcare sector. We began by emphasising the need for a focus on healthcare as a trusted data coordination problem. The data required to make effective healthcare decisions has several general characteristics that makes it hard to coordinate: it is dynamic and changes through time, fragmented in terms of production and property rights, and often has issues of legitimacy from many different perspectives. This healthcare data must not only be produced (and people incentivised to capture this data) but it must also be coordinated between parts of the healthcare system.

Healthcare data faces a coordination and a governance problem. Drawing on new institutional economics we can see that the largely centralised healthcare institutions and organisations that make up the modern healthcare system are at least partly an attempt to economise on the transaction costs of the healthcare data problem. Large centralised hospitals have databases maintained centrally, governments hold records of medical licenses, and so on. But the structure and shape of a healthcare system changes through time as new technologies make new forms of economic organisation possible.

We introduced blockchain technology as a new alternative decentralised solution to healthcare problems. Blockchains and other distributed ledger technologies are technologies of governance and trust. They enable ledgers and records of information to be maintained through a network of computers in a decentralised way, rather than relying on hierarchical and potentially siloed data systems. There are numerous applications of blockchain being trialled in healthcare including decentralising medical records, data from clinical trials and the various pharmaceutical and medical device supply chains.

Blockchain has the potential to facilitate a fundamental shift in the governance of the healthcare sector. This institutional transition will be hard. We know this from the history of other sectors, and indeed the histories of economies themselves. Nevertheless, we argue that the future of healthcare will be through the evolution from centralised siloed hierarchical organisation towards decentralised healthcare platforms. This platform will be a digital platform powered using decentralised blockchain technologies to coordinate information about records, administration, permissions, intellectual property, licenses, events and so on. The healthcare process that occurs in a platform-based healthcare system will be more market- and contract-based and tailored to the individual preferences of the patient.

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