VACCINE TRACEABILITY SUPERVISION PLATFORM USING BLOCKCHAIN TECHNOLOGY

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MASTER OF SCIENCE

IN DIGITAL INNOVATION AND FINANCIAL TECHNOLOGY

GRADUATE SCHOOL

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AN INDEPENDENT STUDY SUBMITTED TO CHIANG MAI UNIVERSITY IN PARTIAL FULFILLMENT OF THE REQUREMENTS FOR THE DEGREE OF MASTER OF SCIENCE
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26 October 2022

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Yuwen Ding

หัวข้อการค้นคว้าอิสระ	แพลตฟอร์มกำกับดูแลการตรวจสอบย้อนกลับของวัคซีนภายใต้ระบบบล็อคเชน
ผู้เขียน	นางยูเหวิน ดิง
ปริญญา	วิทยาศาสตรมหาบัณฑิต (นวัตกรรมดิจิทัลและเทคโนโลยีการเงิน)
อาจารย์ที่ปรึกษา	อาจารย์ ดร.ธีรพจน์ จันทรศุภแสง

บทคัดย่อ

การค้นคว้าอิสระนี้ ได้ทำการศึกษาและสำรวจความสำคัญของการกำกับดูแลและการตรวจสอบย้อนกลับของกระบวนการการผลิต การขนส่ง และการบริหารจัดการวัคซีนโควิด-19 (COVID-19) โดยมีประเทศจีนเป็นกรณีศึกษาโดยเฉพาะ ทั้งนี้ เพื่อให้รัฐบาลและประชาชนชาวจีนสามารถมั่นใจและไว้วางใจในวัคซีนที่จะได้รับและจะผลิตต่อไปได้ ในการนี้ เพื่อให้การบริหารจัดการวัคซีนดังกล่าวสามารถเพิ่มทั้งความปลอดภัยและประสิทธิภาพของวัคซีนโควิด-19 ได้ ประเทศจีนจึงได้มีการนำกระบวนการแปลงเป็นดิจิทัล เทคโนโลยีบล็อกเชน และการแปลงเป็นดิจิทัลของห่วงโซ่อุปทานมาประยุกต์ใช้ในการออกแบบแพลตฟอร์มกำกับดูแล และการตรวจสอบย้อนกลับของวัคซีนโควิด-19 (COVID-19) เพื่อสร้างระบบที่แข็งแกร่งสำหรับกระบวนการการผลิต เพื่อให้การผลิต การขนส่งและการบริหารจัดการวัคซีนโควิด-19 และเป็นไปตามระเบียบข้อบังคับขององค์การอนามัยโลก (WHO: World Health Organization) แต่ถึงอย่างไรก็ตาม การเปลี่ยนแปลงระบบการผลิตของวัคซีนโควิด-19 (COVID-19) สู่รูปแบบดิจิทัล (Digitalization) นั้นไม่ใช่กระบวนการที่ง่าย อีกทั้ง ยังมีค่าใช้จ่ายที่ค่อนข้างสูง แต่เนื่องจากสถานการณ์ของโลกในอนาคตกำลังประสบปัญหาการแพร่ระบาดในลักษณะเดียวกันเป็นจำนวนเพิ่มมากขึ้น ดังนั้น จึงจำเป็นอย่างยิ่งที่จะต้องมีการประยุกต์ใช้เทคโนโลยีบล็อกเชน (Blockchain Technology) ในทันที เพื่อให้รัฐบาลและประชาชนชาวจีนมั่นใจได้ว่ากระบวนการการผลิต การขนส่งและการบริหารจัดการวัคซีนโควิด-19 นั้น ได้รับการปรับปรุงอย่างทันสมัยและต่อเนื่อง อีกทั้ง แพลตฟอร์มสำหรับการกำกับดูแลและการตรวจสอบย้อนกลับของกระบวนการการผลิต การขนส่ง และการบริหารจัดการวัคซีนโควิด-19 (COVID-19) นั้น นับเป็นสิ่งสำคัญและจำเป็น

Independence Study Title	Vaccine Traceability Supervision Platform Using Blockchain Technology
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ABSTRACT

This Independent Study investigates the extreme importance of being able to track and trace the production, transport and administration of COVID-19 vaccines with particular reference to China. Governments and their people have to be very confident that they can trust the vaccines that have been and will continue to be produced. China following World Health Organization protocols has established a robust system that it is in the process of digitization, Blockchain Technology, and the digitization of the supply chain and how it is managed would enhance both the safety and efficacy of these COVID-19 vaccines. However, digitization of all facets of COVID-19 vaccines is not a simple process and is also very costly but as the world looks as though it will in the future experience even more pandemics of a similar nature it is essential to utilize Blockchain Technology immediately and ensure it is continuously updated.

Key Words

COVID-19, Blockchain Technology, Digitization, Traceability, Vaccine Safety

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LIST OF ABBREVIATIONS

ASEAN	Association of Southeast Asian States
ASF	African Swine Fever
COVAC	COVID-19 Vaccination and Mitigation Initiative
COVAX	COVID-19 Vaccines Global Access
DSCSA	Drug Supply Chain Security Act
EMA	European Medicines Agency
EU	European Union
EUL/PQ	Emergency Use Listing Procedure
GAVI	GAVI, The Vaccine Alliance
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
ICSR	Individual Case Study Report
MERS	Middle East Respiratory Syndrome
mRNA	Messenger Ribonucleic Acid
NRTI	Nucleoside Reverse Transcriptase Inhibitors
OECD	Organization for Economic Cooperation and Development
P2P	Patient to Patient
QR	Quick Response Code
SARS	Severe Acute Respiratory Syndrome
UNICEF	United Nations Children's Fund
USFDA	United States Federal Drug Agency
WB	World Bank
WHO	World Health Organization

CHAPTER 1

INTRODUCTION

1.1 Background

The COVID-19 or SARS-CoV-2 as it is officially referred to was first discovered or at least made public in Wuhan on the 31st of December 2019, the first reported case outside China was reported in Thailand on the 13th of January 2020 and on the 11th of March 2020 the World Health officially declared COVID-19 to be a pandemic. As of the 27th of April 2022, some 512 million of the world's population have caught COVID and 6.23 million have either died from COVID or COVID related illnesses. In the US as of the same date 81.2 million people have caught COVID and 992,000 have died. By way of contrast "only" 532,563 people in China have caught COVID (nearly 70 percent in just the province of Hubei but in Tibet only 12 persons since the pandemic began has caught COVID) and "only" 14,250 people have died from COVID. Some 93.1% of China's population have been fully vaccinated against COVID compared to only 61.2% of the population in the US. The independent study has not been prepared to praise China and denigrate the US but it is important to provide some factual evidence as a backdrop to the study. Many of the alleged scientific studies about China covering up the impact of the pandemic on its population and "prosperous liberal democracies" being more transparent is not helpful to this independent study[1]. As an underlying methodological issue, it has to be remembered that an independent study of this nature is a rapidly evolving study and what may have been an accurate generalization today is not necessarily an accurate generation tomorrow. However, it is argued traceability issues are anchored in processes that are not simply time-bound[1].

[1] *It has to be noted that these numbers everywhere including China are becoming somewhat less significant because of the virus mutations that are becoming more infectious but less deadly. The Omicron variant has resulted in fewer deaths than the previous Alpha and Delta variants but the "R" factor is almost double that of these variants.*

There are only a handful of countries, largely relatively remote island states in the South Pacific that have not recorded any COVID cases but for the most part they are isolated from the rest of the world. There when this research project has been conceived it needs to be clearly stated that the extant issues vis-à-vis traceability are very global in nature. While there are parallels with traceability of foodstuffs (the 2008 Melamine Milk Scandal in China) most of the issues associated with food safety have not necessarily had a global impact. In the context of foodstuffs food safety, nutrition and food security are inextricably linked. To put in the context of this study people who were affected by such scandals as those associated with infant food formula do not necessarily impact on the global population but being able to trace vaccines in supply chain management with COVID vaccines is a global issue. If such vaccines do not enable the effective management of this pandemic, irrespective as to what may or may not transpire with sound or unsound practices, then it will be very difficult to ensure COVID becomes an endemic virus rather than continue as a pandemic.

COVID-19 virus part of the coronavirus ribonucleic acid virus family has generated a worldwide pandemic being very easy to spread and pushing a lot of pressure on the healthcare system and on levels of the society. Against this background, the COVID-19 vaccine (2019-nCoV vaccine), the birth of a COVID-19 vaccine is an active and effective means of epidemic prevention. On January 24, 2020, the Chinese Center for Disease Control and Prevention successfully isolated China’s first strain of COVID-19 strain. On March 16, the recombinant new crown vaccine was approved to start clinical trials. On April 13, China's COVID-19 vaccine entered phase II clinical trials; on the same day, an expert group composed of more than 120 scientists, doctors, funders and manufacturers around the world issued a public declaration, promising to coordinate under the World Health Organization, and work together to speed up the research and development of the new crown vaccine. On June 19th, China's first COVID-19 vaccine was approved to start clinical trials. On October 8, China signed an agreement with the Global Alliance for Vaccines and Immunization to formally join the "New Coronary Pneumonia Vaccine Implementation Plan”.

As of February 25, 2021, the number of COVID-19 vaccines that have been conditionally marketed in China has reached four, including three inactivated vaccines and one adenovirus vector vaccine. On June 15, 2021, according to data released by the National Health Commission, my country's new crown vaccination has exceeded 900 million doses, covering more than 600 million people, and the number of vaccination doses and the number of people covered ranks first in the world[2].

Figure 1.1 Covid-19 virus ravages the world

1.2 Problem

Due to the vaccination of a large number of people, the subsequent vaccine management and traceability issues also urgently need to be well taken seriously. How to combine advanced digital methods? Relying on modern Internet of Things, cloud computing, AI intelligence, big data decision analysis and blockchain, with business as the core, to manage the whole process of vaccine. The whole process of dynamic supervision of cold chain, vaccine circulation management, and the whole process of vaccination management, Vaccine traceability, big data decision analysis and other businesses are deeply integrated[3]. Blockchain can improve the efficiency and transparency of COVID-19 vaccine distribution and ensure the traceability and strict review of storage and delivery conditions.

Figure 1.2 Positive impact of Covid-19 vaccine on global outbreak

The extant question is the traceability of vaccines used to ward off the ravages of COVID-19 or indeed any viral infection and why is this an important issue. The answer in these turbulent times is that irrespective as to what political system people that have to be vaccinated live in or what are the dominant political cultural narratives people have the right to know what the vaccines, they are receiving out of sheer necessity will result not only in an effective response to any virus-induced pandemic but they will not be harmed either in the short-term or over the longer-term by agreeing to be vaccinated. People to be vaccinated need to know the name (ID) of the vaccine, date, name (ID) of vaccine, batch or lot, name (ID) of vaccinator, and location (setting) of vaccination. Without this real-time knowledge it is not altogether surprising that there is somewhat less confidence in what may transpire if these vaccines are less officious than they would otherwise be.

Despite the prevalence of anti-vaxxers in the global community especially from largely politically very conservative groups in Western liberal democracies who are also generally likely to be quite racist, sexist and homophobic it would appear that most people in the world have or will opt to be vaccinated against COVID-19.[2] The issue here is that while the vaccine rollout has been very impressive in prosperous countries of the world or those some lower middle income countries (Cambodia for instance has leveraged its good relationship with China, its ability to access vaccines supplied by COVAC, but also

[2] *Vaccine hesitancy has been associated with specific groups in many societies that are opposed to the narratives used by scientific experts, technocratic politicians, and civil society groups who eschew the use of science and social inclusion as they attempt to facilitate greater levels of social cohesions.*

taking advantage of countries who are trying to rival China) but not necessarily in other lower middle countries (for instance Vietnam has resisted using vaccines supplied by China including on a gifting basis because of historical animosity towards China resulting in significantly lower vaccination rates than in neighboring Cambodia or the Lao PDR). However, it is on the African continent where the vaccine rollout has been very slow and many or most people living in Africa also want to be vaccinated: they do not care where the vaccines come from or the technologies utilized in their production[4].

Generally speaking, no wants to die from COVID-19 whether directly or indirectly. The indirect impacts have been quantified by the World Bank in an early December 2021 assessment of the impact of the pandemic on the world's poor. It has estimated that more than 1.5 billion people globally have fallen back into poverty (that is more than the population of either China or India) although comparing and contrasting China and India there have been significantly smaller numbers of people economically impacted in China than India. We have one estimate from Thailand where because tourism has been adversely affected it may well be that people living in or the near poor might have doubled although Thailand's poverty rate which prior to the pandemic was the lowest in the ASEAN region outside of Singapore, Malaysia and Brunei. The social impacts are in a range of areas from an increase in domestic violence, poorer formal learning outcomes right across the educational sector, to more pronounced forms of disassociation among largely poorer and vulnerable groups or middle-income groups that have been forced to dispose of fungible assets.

However, unlike in the past where there were people who were opposed to any form of vaccination for a myriad of cultural, religious, and "quasi-scientific" reasons social media did not exist. For instance, one only has to compare the 1918 so-called "Spanish flu" which resulted in the deaths of between 17 million and 100 million depending on what methodology is used but more than 500 million were infected, there was no internet or even television and there were not the same information flows that are currently occurring globally. With COVID-19 people are being encouraged with most narratives to vaccinate or perish but here the politics of effacious and effective vaccines has occupied main stage. There is some fear that many of the new vaccines, especially the mRNA vaccines Pfizer and Moderna being the two major vaccines, while appearing officious in

laboratory settings might be less effective in real life and of equal importance perhaps harmful in the long-run[3].

1.3 Supplier/Customer Pain Points

In the broader context by attempting to ensure the efficacy of COVID-19 Vaccine Traceability it is necessary to raise the following issues:

1) Is it possible for truly global monitoring and is a new specialized body necessary?
2) Such a system requires much background work such as creating proper IT infrastructures, training and education with high costs involved and would these costs be prohibitive for all stakeholders (defined here as both the state, vaccine recipients and companies producing the vaccines)?
3) There are many anticipated technical challenges and how could these be addressed?
4) What occurs when there are also provisions for non-digital alternatives to tracking COVID-19 especially in many low income and middle income countries?
5) Where some countries might not be very cooperative in ensuring the transparency of their vaccine manufacturing and administration are there possible ways to address such cases to ensure global safety?
6) Are there real prospects of the COVID-19 pandemic eventually leading to a global standardization of supply?

These are issues that must be discussed in the context of whether blockchain technology that follows the path of a vaccine, from manufacturer down to individual patient, should be transparent. As it argued in this Independent Study this is what

[3] *Of course, this is vigorously denied by such vaccine manufacturers but in the past such manufacturers have been as much interested in maximizing profits – as you would expect them to be – as in promoting the health and wellness of people.*

traceability is all about and in is discussed at more length in preceding sections. But here it is necessary to address each of these six issues, albeit very briefly[4].

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1.4 Business Opportunities

This independent study will critically analyze the efficacy of blockchain technology that effectively enables individuals to trace the specific vaccine they have been vaccinated with. Most of the empirical evidence will come from China but where useful and relevant examples will be drawn from around the globe. The underlying thesis is that as newly developed vaccines are ensuring this terrible pandemic will be defeated or at least managed as well as possible and people can benefit enormously from the technological advances in the world. It holds out the possibility that ordinary people with access to at least a smart hand-held device (approximately 80 percent of the world's population according to the most recent data) will be empowered in ways they would not otherwise be empowered: knowledge is power in this context, even if it is either individualized or collectivized.

Technically, through the organic connection of all parties, digital trust is finally established. Blockchain technology allows multiple parties to manage and share decentralized databases. These participants can create and share negotiable transparent rules together. Therefore, blockchain may be an ideal infrastructure for a supply chain management platform, as it covers two key prerequisites for establishing digital trust:

The blockchain is not unique to anyone, but provides a general standardized protocol. All participants in the supply chain can join and share relevant data. The data on the blockchain cannot be tampered with, so it cannot be deleted. If there is information, you can only continue to add additional information, which makes each participant who writes new data have a higher sense of responsibility

Another important advantage is that it is relatively simple to manage read/write access permissions on the blockchain. In this way, some participants have read-only access (cannot write), and participants with write access can determine who and what information to share with. This forms a platform that can provide complete tracking information for each project in near real-time and provide other information as needed. Therefore, it is argued that the blockchain-based supply chain management platform is efficient and reliable. It needs to make every effort to create an innovative model of

"Internet + Immunization Program" and continuously promote the standardized and safe vaccination of vaccine work to maintain national public safety.

1.5 Job to be Done

In relation to the first issue, it is generally argued that a new specialized body for the global monitoring of adverse events (COVID-19 like Ebola or HIV/AIDS is classified as an adverse event) but the WHO has a database known as Vigibase for such purposes already. Data in this base is available free-of-charge to all member countries and currently there are 142 member countries and 29 associated members, representing more than 75% of the world's countries and 90% of the world's population. The US along with China are of course members and it is pertinent to note that this database, which was established in 1957 following the Thalidomide Tragedy) has seen China as the leading reporter of vaccines leading to adverse reactions, almost 10,000 submissions in 2014. This database is able to include reports of adverse events resulting from the use of vaccines but is only as effective as countries ability and willingness to share relevant data. The European Centre for Disease Prevention and Control already coordinates antibiotic consumption surveillance and this relies on national vaccine registries so in theory the same could apply to COVID vaccines although the array of antibiotics available both on prescription and under the table are in quite a different category to COVID vaccines. There have been few reports of people seeking to be vaccinated multiple times when not considered effective against COVID but antibiotic use and abuse is largely a market-based decision: to date COVID vaccines cannot be purchased by-and-large but some people line up for a ridiculous number of jabs (there are some reports of people being vaccinated on a monthly basis) but there are few limits to the types and quantities of antibiotics that can be used.

The second issue relates to IT infrastructures, training, education, and if necessary enforced sanctions against those who might abuse vaccine use. There are open-source solutions for national vaccine registries and supranational support to develop lean and mean national systems in countries lacking such systems. Via GAVI and COVAX, which strive for the equitable distribution of vaccines some allow some of their funds to be used for needed infrastructure and health systems such as information systems for monitoring.

China as a member of COVAX has extended such assistance to lower middle income countries in the region most notably the Lao PDR and Cambodia but is not averse to extending such assistance to other non-regional low income countries. Additionally, the Uppsala Monitoring System (USM) that is part of the WHO architecture provides a web-based system Vigiflow for the management of individual case safety reporting (ICSR) on national pharmacovigilance and vaccine surveillance processes to all members of the WHO program. This service is based on the interoperability (refers to timely and secure access, integration and use of electronic health data that can be used to optimize health outcomes for individuals and populations) and can be linked to reporting apps and to web-forms allowing direct input from health professionals and patients. COVID-19 represents an opportunity for all countries to make progress in resolving longstanding issues.

There are some technical issues that have to be addressed. Drug utilization monitoring in many countries is based on reimbursement claims but not every large country such as China. Because COVID-19 vaccines are generally distributed free-of-charge as with most recommended vaccines they may not turn up in these administrative databases. In countries where there are robust systems in place to fight against medicinal falsifications, these systems may provide an additional outcome to better manage COVID-19 vaccines' supply chains. Interchangeable information for identifying the vaccine is crucial to the exchange of information as identified in the introductory section.

At this juncture there is no mandatory 2D barcoding if the vaccines supplied to low- and middle-income countries via UNICEF or GAVI for quite some time. The consequence of this is that tracking who is vaccinated and who is not cannot be effectively traced. Because there is an absence of reliable and internationally verifiable information of the vaccination status of the country (Myanmar at present but especially since the military coup in early 2021) non-traceability compromises the sustainable approach to tracing that is crucial. Tolerating the distribution of vaccines without proper identification is not acceptable because these products require capacity to analyze the medium to long-term effect of different vaccines, at micro and macro societal levels both economically and socially. The distributors of Pfizer and Moderna claim to have assessed these impacts but this is errant nonsense and the problem remains that in less than transparent management regimes archaic forms of supply chain management.

Blockchain benefits which re analyzed below could theoretically follow the whole path of the vaccine. For the supply chain from manufacturer through wholesaler to community pharmacist or immunization center, regulations in place to fight against medicinal product falsification should be used. These regulations require standardized product identification by utilizing GS1 *Datamatrix* data carrier. Blockchain technology requires at least the same identifications as for the fight against medicinal product falsification: name (ID) of subject of care, date, name (ID) of vaccine, name (ID) of vaccination, and location (setting of vaccination).

Already the first COVID-19 vaccinations have been rolled out for over 16 months and in the first phase, if there is only one or two vaccines distribution can be highly centralized, prioritized and supervised. This is one of the comparative advantages China has but in countries with a fairly wide range of choices such as Cambodia this is more difficult. Thus, there can be chaotic distribution of vaccine batches and there can be leftovers. Vietnam represents a good example of this because while the Government was keen to accept Sinopharm and Sinovac the general population was not. But even if Vietnam has the ability and will to overcome this problem distribution of vaccines will become more complex in the near future if and when multiple vaccines come to the market, with extra cold channels and normal refrigeration channels allowing multiple methods of distribution.[6] Remediating such an unmonitored stage is very difficult.

It has already been seen that some countries might not be very cooperative in ensuring the transparency of their vaccine manufacturing and administration but unless there is equity in delivering vaccines (for instance in Indonesia the government has been reluctant to deliver vaccines to the West Papua indigenous people living in Irian Jaya because the latter are seeking autonomy and this is also a problem in Myanmar). These countries are more vulnerable to falsified medicines and racketeer sale of vaccines. Early in 2021 the Government of Thailand refused to accede to demands by private hospitals to procure and administer vaccines on a fee basis for those able and willing to pay to be vaccinated. Bad management is sometimes a major issue but Thailand cannot be accused

[6] *Cold chain storage facilities render the equal distribution of COVID-19 vaccines highly unequal because many low income countries simply do not have such facilities in any great numbers. Despite all the hubris this is also one of the reasons China developed vaccines that did not require sophisticated cold chain storage facilities.*

of bad management: slowness with vaccine rollouts is one thing but the government did provide a sensible rationale as to why it would not support the private sector. The litmus test is whether there is lower acceptance of vaccinations by people living in such countries. However, it can be seen in countries such as the US or even smaller countries such as New Zealand some groups clearly do not accept the requirement to vaccinate. New Zealand has managed to generally avoid the major problems that have beset the US, especially among the Afro-American population and some working-class males and to a lesser extent females.

1.6 Business Canvas

Table 1.1 Business Model Canvas

<table>
<tr>
<td rowspan="2">Key partners
● Industry experts
● Users establishing partnerships
● Competent government departments</td>
<td>Key activities
● Research on User Behavior
● User demand research
● Business model validation
● Software platform R&D
● Market promotion and customer expansion</td>
<td rowspan="2">Value Proposition
● Serve the government's vaccine safety supervision
● Improve vaccination safety
● Enhance public recognition of vaccination safety
● Better service experience for the public</td>
<td>Customer relationships
● Building partnerships with customers
● Timely track the flow of vaccine
● Public use of mobile applications</td>
<td rowspan="2">Customer Segments
● Vaccine manufacturer
● Health committ
● Centers for Disease Control and Prevention at all levels
● hospital
● Community Health Centre
● Township Health Center</td>
</tr>
<tr>
<td>Key Resources
● Innovation
● Blockchain</td>
<td>Channels
● Direct sales, door-to-door customer visits
● Organize academic conferences through industry associations
● Local cooperative dealers
● Publicity of typical media cases</td>
</tr>
<tr>
<td colspan="3">Cost structure
● Marketing cost
● Personnel cost expenditure in R&D cost
● Site rental fee
● Cloud platform resource expenditure
● Investment in fixed assets such as office equipment</td>
<td colspan="2">Revenue streams
● Project cost of government users
● Annual maintenance fee paid by the customer
● Platform entry fees paid by vaccine manufacturers</td>
</tr>
</table>

CHAPTER 2

LITERATURE REVIEW

2.1 Research Works

Countries around the world are innovating in vaccine certificate storage technology[5]. However, we must move from the putative benefits of Blockchain technology to pilot programs to assess whether they can be upscaled and replicated across the whole vaccine supply chain system. A most recent pilot was undertaken between IBM, KPMG, MERCK and Walmart in the US that is worth examining in closer detail[7]. This pilot that was implemented in 2020 was designed to allow for rapid alerts between supply chain partners if a medication recall were to occur, with granular identification of the impacted lot. It was noted at the time the notification process is highly manual and fragmented using various disparate systems, and thereby increasing the response time and number of patients impacted by the recall. The specificity enabled by the marking serialized product in addition to using blockchain technology to quickly identify the location of recalled lots and notify relevant supply chain partners, that would eliminate unnecessary communication and prevent the valid product from being quarantined resulting in pharmaceutical waste and of course financial loss to all supply chain partners.

This must be seen not in the context of COVID-19 vaccines per se but rather the Drug Supply Chain Security Act (DSCSA) that was passed more than eight years ago in 2013 in the US where a staggering 50% of the population take some form of prescription medication for various ailments and medical conditions and the fact that its aging population will double from about 52 million in 2018 to 95 million by 2060[6]. The stated intention at the time was to follow through on critical steps to build an electronic, inoperable system by late 2023 whereby members of the

[7] *Companies like IBM have been quick to realize the financial benefits of supporting such investments and through it innovative approach has managed to recoup some of the losses it incurred over the past decade.*

pharmaceutical supply chain will be required to verify, track and trace prescription drugs as they are distributed in the US.

It is claimed that in the US various organizations and government entities have been collaborating to ensure medications are safe, officious and are produced according to the highest quality ingredients[7]. It is and was also a reaction to pharmaceutical manufactures in countries such as India, Turkey, Mexico and to some extent countries such as Thailand who have been successful in developing high quality pharmaceutical products much cheaper than those produced in the US. This of course led to large American companies MERCK being one of them along with Pfizer attempting to accuse companies elsewhere in the world of intellectual property theft, which of course there was some such activity although American companies are not wholly innocent when it comes to such practices themselves. Anyway, working on the assumption these companies had the noblest of intentions and were and are not simply profit orientated there was a recognition of the need for continuously evaluating and pursuing enhanced manufacturing, distribution, regulatory and technological approaches to advance innovative solutions.

Through the use of iterative processes, it has been argued that the integrity of the supply chain can be improved by the rapid identification and elimination of counterfeit medication, isolation of substandard ingredients and preventing product diversion and entry from grey markets (refers to the trade in products through distribution channels not authorized by the manufacturer or by the IP owner: a good case in point are the Indian drug companies that produce cheap but effective cloned erectile dysfunction medications thereby undercutting the original manufacturers of Viagra and Cialis in the US)[8].

The four stakeholder companies concluded that blockchain technology with its shareable ledger, immutable data, and inherent ability to track drug provenance (contaminated substandard ingredients such as what the WSJ in 2008 accused China of manufacturing heparin that is used for treating medical emergencies such as various thrombosis and pulmonary embolisms, would demonstrate how digital transformation would assist in further development[9].

Such companies are very interested in the implementation and continuous iterations of a technological nature and how they might or should evolve. The end-user is a stakeholder in such a digital landscape because if some adverse event as those associated with the Thalidomide Disaster back in the late 1950s were to re-occur this is also not good for the bottom line of the corporate's financial ledger. Of course, there is no need to denigrate such companies because they are profit-orientated because if they did not spend some of their own capital on research and development it is doubtful that especially mRNA vaccines would have seen the light of day so quickly.

The solutions that were proposed in anticipation of benefits based on the blockchain-enabled technologies were as follows:

- Enable inoperability between supply chain partners in an in immutable, distributed ledger
- Provision of a single, shared source of truth associated with pharmaceutical product movement
- Elimination of sources of suspect or illegitimate activity
- Improve patient safety in the event of product recall

The emphasis was also on practical learning and securing stakeholder buy in with existing pharmaceutical trading partners and the establishment of a deeper understanding of the required process-level interaction and also to enhance supply chain security. Viewed in the context of the ensuring COVID pandemic these are laudable goals. It is here we can turn to the test results where five areas – drug provenance and data privacy, increased patient safety, reporting, recall functionality blockchain evaluation and governance (this is focused on in the next section, value beyond compliance, and future considerations and enhancements – are discussed.

To be effective a drug's provenance needs to be accurately captured in the blockchain through recording shipment, receive and dispense actions against serialized product data to create a continuous link of product movement (process of digitally converting an object into a stream of bytes to rectify the opacity of abstract data). It also needs to be demonstrated that data privacy can be maintained among network participants with limited one up, one down permissioned view (parameters

include national security issues, shortage of personnel, lack of coordination, shortage of suppliers, limited capacity, vaccine damage, gaps in rural areas or between deprived and non-deprived urban and peri-urban areas, and misinformation about vaccines and tracking).

Increased patient safety which should be of paramount concern has four areas that need to be addressed[10]. The first area is that the product must be open for investigation and recalls can quickly be sent to and received by network participants, who have or have previously possessed the impacted product (s). It needs to be demonstrated that network participant can quickly identify products subject to an alert that are or have been in their possession through the product security of the solution. It also needs to be demonstrated that products cannot be dispensed more than once, which will reduce the potential of dispensing counterfeit products. And lastly the ability to restrict shipping or dispensing of product that is subject to an alert for investigation or recall by challenging the product status to non-saleable.

Recall functionality at present is expensive and time consuming, with a lack of standardized processes and alert mechanism between trading partners. In the context of a recall, companies must rely on collaborating to quickly identify recalled product and communicate to downstream partners with the impact product lot. Currently, due to the lack of inoperability and visibility to lot-level information, it can take up to 3 days to identify impacted product and alert downstream partners with the information[11]. A significant outcome of the pilot project was that by utilizing blockchain technology, the processes would be exponentially expedited. Using blockchain technology, partners may be altered in as little as ten seconds. This is where blockchain technology is in a league of its own. Imagine reducing such information to "nano-seconds" and the potential for a highly positive impact on traceability but also critical time spent on vaccine alerts.

Blockchain technology offers a decentralized, trusted way to share information across networks participants, providing a path to comply with DSCSA 2023 interoperability requirements. The Pilot also demonstrated minimal complexity associated with the integration of stakeholders' existing operational systems used in packaging and distribution, which translates to reducing the individual burden of

achieving interoperability. Blockchain is an advanced technology requiring industry participation, with potential to advance interactions in the pharmaceutical supply chain. Pursuing a blockchain-based solution can enable DSCSA compliance while enabling new business models.

The complexity of moving towards a blockchain solution is in building consensus for governance models. It is only possible to adopt blockchain as an underpinning technology if an equitable governance model is established with no single establishment gaining an undue advantage from controlling the blockchain network. Therefore, it is important to develop a defined industry governance framework associated with the blockchain network itself as well as data standards for information exchange such as GS1, integration requirements and solution triggers. An inherent benefit of blockchain is that it enables trust in a decentralized manner – trust is established by the network itself and the network participants, and not by a single or third party. Since the network is governed by industry participants and not a single party, the network members can collectively establish standards which the network then executes and operates by[12].

2.2 Cross Border E-Commerce

The vaccine distribution policy of EU countries is to ensure that the internal vaccination rate of EU member states is the main goal, and the export is mainly to middle and high-income countries[13]. As of July 21, 2021, more than 522 million doses of the new crown vaccine have been allocated to the European Union and European Economic Area countries under the joint procurement strategy and programs that emphasize internal coordination and sharing [17]. The main export destinations of EU vaccines include: Japan (72 million doses), the United Kingdom (19 million doses), Canada (18 million doses), Mexico (10 million doses), and Saudi Arabia (7 million doses). It is worth noting that most of these countries are relatively wealthy countries, excluding those developing countries that are relatively poor and are in urgent need of vaccine assistance.

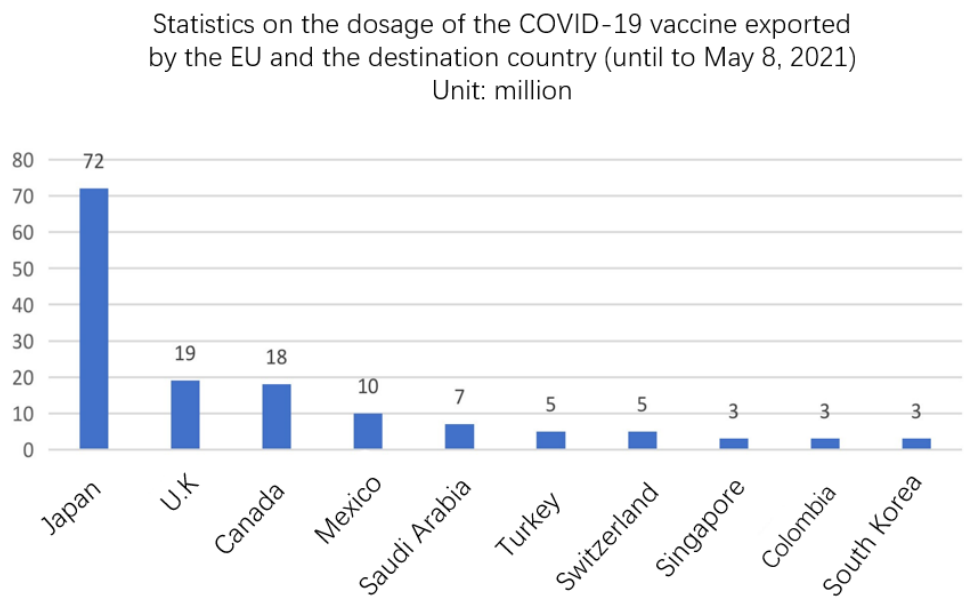


Figure 2.1 Statistics on the dosage of the COVID-19 vaccine exported by the EU and the destination county

As can be seen from the following comparison chart of vaccine production and export of major countries in the world, as of May 2021, China's vaccine production and export volume are both at the world's leading level, ranking first among major countries. China’s vaccine exports are 227% of Europe’s vaccine exports and 84 times that of the United States. At the same time, China's vaccine exports accounted for the production ratio far exceeding the level of the United States and the European Union. From a regional perspective, China's vaccine exports are mainly concentrated in three regions: Southeast Asia, Latin America and Africa. Compared with other vaccine exporting countries, China's contribution to Latin America and Africa is particularly prominent. China has direct vaccine distribution and cooperation relationships with 18 Latin American countries. China has donated more than 1 million doses of COVID-19 vaccine to the region and exported nearly 280 million doses. in Africa, 31 countries have accepted vaccines purchased and donated from China, and this number is steadily increasing.

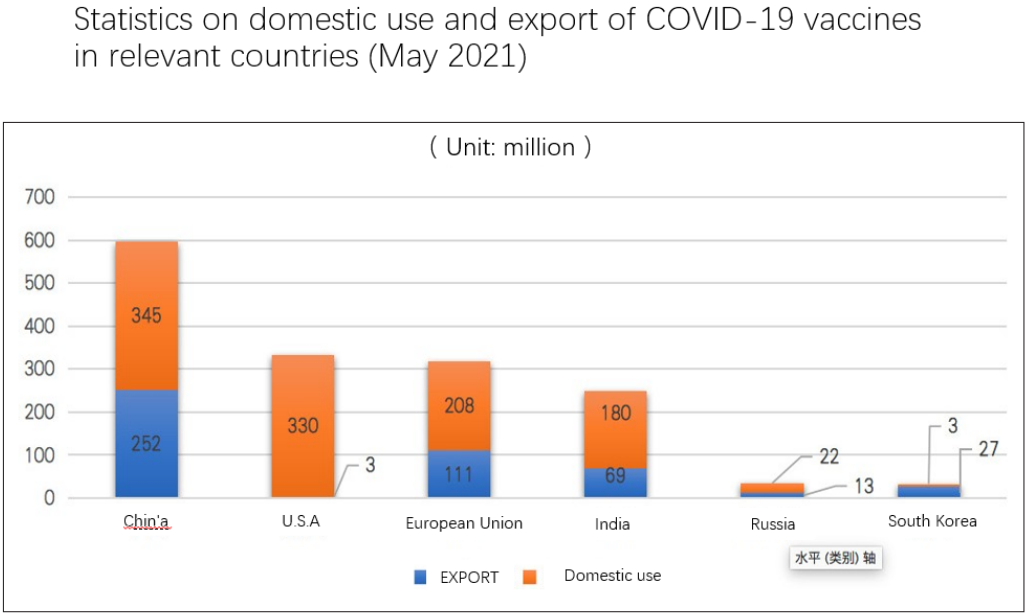


Figure 2.2 Statistics on domestic use and export of COVID-19 vaccines in relevant countries

The other vaccine manufacturers included in the table are India, Russia and South Korea but do not include Thailand which earlier in 2021 exported Astra Zeneca to most of the other ASEAN countries. Indeed, it was this export commitment that created supply chain issues in Thailand because with the pandemic appearing to be of a minor nature compared to the Philippines, Malaysia and Indonesia (although Thailand also exported some of its Astra Zeneca to Vietnam). In this respect Thailand was not totally dissimilar to India that was also exporting to other countries until the pandemic hit very hard in late January of 2021. Russia would like to export more vaccines to other countries but unlike China is not prepared to donate such vaccines in the same quantities. Turkey is also another producer of vaccines although at the moment it does not export to other countries.

The wave of the future is that many countries want to be able to produce their own vaccines but this might be largely aspirational. A country such as Australia claims it has the technical and financial capacity and of course the political will via its current government to manufacture its own vaccines and become an export hub to the South Pacific. Perhaps there are geopolitical rivalries involved here although it is interesting to note that Fiji which is a close ally of China but also it maintains reasonable relations with

Australia opted to be supplied with Astra Zeneca both Australia and New Zealand secured for it even though China was able and willing to supply Sinopharm and Sinovac. India of course which is the largest overall manufacturer of pharmaceutical products in the world will continue to develop its production capacity because such products constitute 12.5% of India's export revenue[14].

The issue here though is not who is the largest exporter of vaccines in the world but the fact that unless there is real traceability with all vaccines produced to tackle COVID-19 it will be far more difficult to tackle the pandemic. Being able to track and trace all COVID-19 vaccines irrespective as to their type of where they are manufactured is a major issue that the world is starting to grasp but has yet to operationalize. The ideal scenario is where any vaccine can be tracked and traced rapidly because COVID-19 does not slow down to allow blockchain technology to catch up, we can see that the latest variant of the pandemic Omnicom is being transmitted more than three times as fast as either the Alpha and Delta variant, but do we know this will be the last wave before the pandemic becomes more of an epidemic or the "new normal"? This is absolutely an impossible question to answer and to date even the South African medical experts who first identified this latest variant admit they cannot yet provide definitive answers.

This last point is very relevant as we are living in an age of uncertainty that has not existed in the modern history of the world especially since the end of World War Two in 1945. The historian is better able to grapple with this than the computer scientist and this is clearly evident in the "blind faith" some proponents of blockchain technology would argue. Their world is a world of technical neutrality and this independent study does not dismiss this argument but it also has to be juxtaposed against a world where technology is not philosophically neutral but rather dependent on human activity. There is an increasing interest in and use of Artificial Intelligence (AI) but this study remains skeptical of the capacity of AI to render human agency irrelevant. It is here that behavioral psychologists might think they have the answer of the reification of human consciousness reduces us all to "slaves of the machine" (the master is the machine and we humans are it slaves) but this borders on the phantasmagoria of those who think we live in a brave

new world. It is highly doubtful that Xi Jinping thinks his leadership of the Chinese Communist Party makes him a slave to the Party[8].

2.3 Research Status in China

On June 1, 2005, the formal promulgation and implementation of the "Conditions for the Administration of Vaccine Circulation and Vaccination" by the State Council changed the unified management mode of vaccine use, one of the main ones being: the opening of vaccine procurement channels. However, vaccines are not ordinary drugs, not to mention ordinary commodities. Any mistakes in the procurement, selection and use of vaccines will lead to serious consequences. Under the traditional vaccine management mode, it is required to report the difference analysis between the planned amount and actual amount of Category I vaccine in the previous year level by level at the beginning of each year. At the same time, it is required to report the monthly reports on the use and inventory of various vaccines level by level, and use the data of the monthly report on vaccination to verify the use of vaccines. So that managers can master the demand and use of various vaccines and provide a reliable basis for the formulation of disease prevention strategies[15].

Taking Jiangsu Province as an example, although some districts or cities have implemented a single vaccine management information system, it is not a whole process concept, and it has not completely replaced manual work. There are many problems, such as heavy workload and untimely data processing. Therefore, the whole process vaccine management and safety monitoring platform is still nearly blank. About 80% of drugs and vaccines are circulated and stored under the condition of almost no detection, and the phenomenon of "chain breaking" often occurs.

An analysis report on the current situation of vaccine management in the immunization program of Guangxi Province shows that poor management is the main

[8] *The proponents of Blockchain Technology over-estimate the degree of creativity and innovation they purport to bring to the scientific and technological advance of human civilization over the past 20 years. A more nuanced understanding of historical dynamics would render such computer scientists more relevant than they think they are.*

reason for vaccine waste through the analysis of vaccine use, distribution and scrapping. As the vaccines under the national immunization program are purchased by the government and distributed to all regions for use free of charge, cities, counties and towns generally lack effective management means for immunization program vaccines. Even in some regions, the procedures for receiving and distributing vaccines have been simplified by themselves. The receipt of vaccine delivery and the absence of signature of vaccine reception often occur. In addition, because of poor management, the validity period of the vaccines distributed is too short, or the vaccines cannot be used on children within the validity period, a large number of vaccines are scrapped, which is also the main reason for the loss. Some domestic scholars analyzed the problems in vaccine management from the aspects of vaccine supply channels, supervision and implementation, but failed to fundamentally propose solutions to the serious loss of vaccines. Based on the successful experience of foreign vaccine management, the establishment of a whole process vaccine traceability management and monitoring system to master the current situation of vaccine use around the country has become one of the main means to reduce vaccine waste.

CHAPTER 3

LAW AND REGULATION ISSUES

3.1 Introduction

Traceability of vaccines from production to administration has always been a concern of both the World Health Organization and most national governments including the Government of the People's Republic of China. This traceability dates back to the 1950s when vaccines were developed against a range of highly infectious diseases, most notably polio, smallpox, yellow fever, whopping cough, measles, diphtheria, HIV/AIDS and the various strains of influenzas (related of course to COVID-19). However, as their impact was often geographically specific and were more of an epidemic nature than a pandemic nature regulatory framework did not gain the traction they have with the current pandemic. We have to go back to the "Spanish" influenza pandemic immediately following the end of World War One to witness a global pandemic on the scale of COVID-19: this was long before the WHO was established after World War Two with the foundation of the United Nations. What this chapter examines is the regulatory framework that the WHO has developed, which of course China is a member, and then examines China's laws and regulations as they relate to COVID-19 vaccines. It is here that the IS makes the linkage with the efficacy of Blockchain Technology.

3.2 The WHO Regulatory Framework

Enabling decisions on COVID-19 vaccines by the national regulatory authorities in a time-efficient manner should be based on available evidence and should not compromise the existing processes of regulatory decision-making. National drug regulatory authorities (NRAs) should conduct an appropriate review of the available data and information and should document the extent of the evidence in support of the regulatory decision on whether to authorize or reject the product. Regulatory alignment

and collaboration are critical in facilitating rapid and equitable access to safe and effective vaccines meeting international standards[16].

Predictability of regulatory requirements and early communication of expectations to manufacturers of COVID-19 vaccines informs and facilitates preparation of submissions; countries may refer to considerations for evaluation of COVID-19 vaccines published by WHO, the European Medicines Agency (EMA) and stringent regulatory authorities (SRAs) such as, the United States Food and Drug Administration (FDA) and others as they become available. In addition to these, WHO has issued a product-specific roadmap that is intended to serve as a model for subsequent product-specific vaccine evaluations, provided there is agreement from the manufacturers and the regulators concerned.

New information, linked to development, authorization, use and safety monitoring on COVID-19 vaccines is evolving. WHO publishes regulatory updates on COVID-19 diagnostics, treatments and vaccines for NRAs, regional pharmaceutical advisors, regulatory networks and associated stakeholders. Access of countries to product-specific information related to WHO procedures of emergency use listing or prequalification (EUL/PQ) of COVID-19 products will be further facilitated; furthermore, documentation related to COVID-19 vaccine evaluation is being published by some SRAs with the aim of increasing transparency of regulatory decisions and maintaining public trust. The efficiency and effectiveness of the national regulatory process to authorize COVID-19 vaccines can be enhanced by the following general principles and approaches adapted from WHO guidance and modified to fit the national context

3.3 Laws related to COVID-19 vaccine

Target group estimation: ensuring a sound legal basis for regulatory decisions related to COVID-19 vaccines;

Regulatory alignment and consistency: aligning national regulatory requirements for COVID-19 vaccine submissions with global best practice, such as WHO

recommendations and/or recommendations of SRAs and applying them in a consistent and predictable manner;

Regulatory flexibility: reducing time for regulatory approval by defining emergency pathways and modifying procedures, such as reviewing the submissions and other relevant evidence on a rolling basis;

Regulatory cooperation: establishing links and cooperation agreements to support the regulatory process by joint review and sharing the tasks with neighboring NRAs and/or supporting NRAs;

Regulatory reliance: applying principles of reliance and recognition to decisions and evidence made available by WHO EUL/PQ procedures and by SRAs to allow efficient use of resources;

Regulatory agility: adopting proactive search, review and use of the published evidence on COVID-19 vaccines with the aim of supporting regulatory decisions, in particular decisions based on reliance and recognition;

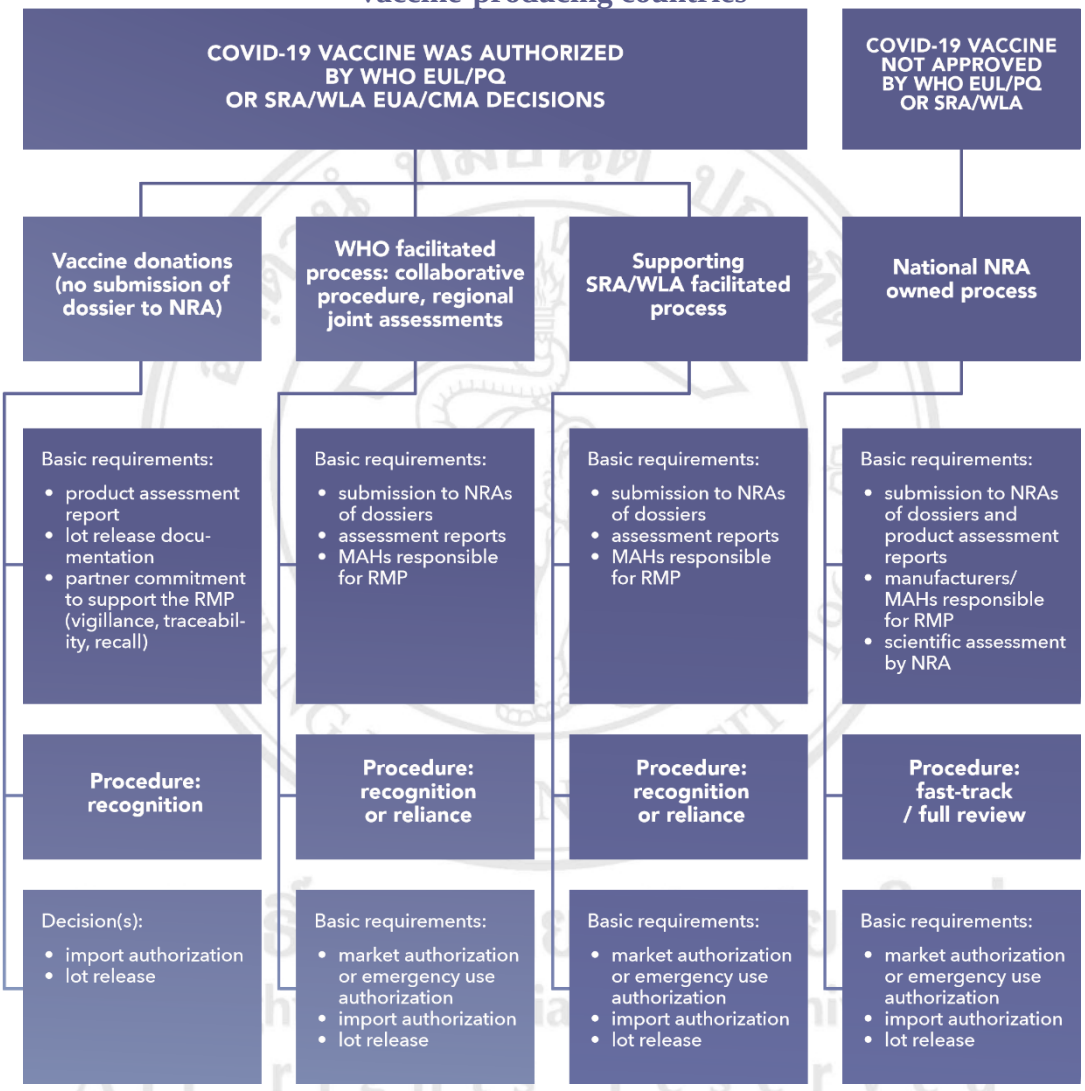
Regulatory transparency: ensuring transparency of regulatory decisions and of the available supporting evidence to maintain public trust in the regulatory process and in the quality and safety of vaccine

3.4 Application case of COVID-19 vaccine law

Pathways for emergency regulatory approval should be in place and should have been tested in advance to check that they function properly when needed. An assessment should be undertaken of the additional human, financial and infrastructure resources required and such resources mobilized promptly. To protect patients and ensure no substandard or falsified products enter the country, it is critical that existing national legislation relating to importation covers all products including donations. This legislation should be enforced by the NRA as well as customs and other relevant authorities.

Figure 2 outlines options for pathways for emergency regulatory approval of COVID-19 vaccines depending on prior received authorization by WHO EUL/PQ or by an SRA or WHO-Listed Authority (WLA).

Figure 2.
Pathways for emergency regulatory approval of COVID-19 vaccines in non-vaccine-producing countries



EUA/CMA = emergency use authorization/conditional market authorization; MAH = market authorization holder; RMP = risk management plan.

Figure 3.1 Pathways for emergency regulatory approval of COVID-19 vaccines in non-vaccine-producing countries

The options draw upon the WHO Guidelines on regulatory preparedness for provision of the marketing authorization of human pandemic influenza vaccines in non-vaccine-producing countries and the WHO-UNICEF Joint statement on vaccine donations as well as the principles of regulatory effectiveness and efficiency outlined above and the basic requirements of the regulatory process for COVID-19 vaccines. The lot release of vaccines by regulatory authorities is part of the regulation of vaccines and involves the independent assessment of each lot of a licensed vaccine before it is released for use. This assessment is based, at a minimum, on the review of the manufacturer's summary protocol; it may be supplemented by other documents, such as the release certificate from the responsible NRA or national control laboratory in the country of origin and, in some circumstances, by independent testing. WHO advises that vaccines procured from assured sources, for example WHO prequalified vaccines, vaccines listed as EUL, or vaccines approved by SRAs/WLAs, need not be tested again by receiving countries, as they have been tested and released already by NRAs with stable, formal approaches for vaccine approval The WHO operational tool for efficient and effective lot release of COVID-19 vaccines provides detailed guidance on lot release options.

Lot release of COVID-19 vaccines during the pandemic can be based on reliance and recognition and should be done quickly (ideally within two days) through review of the minimum set of documents. Traceability of COVID-19 vaccines is important for managing distribution of vaccine batches/ lots, individual vaccine administration schedules and safety monitoring. Core data elements include the name of the product, batch number and the expiry date. Making available stickers, containing printed batch/lot information may facilitate further documentation of traceability data. Traceability data elements should be integrated into: 1) logistics management documents and information systems to trace distribution and manage potential product recalls; 2) patient vaccination records, information leaflets, and vaccination reminders to inform patients of the vaccine received so that a series is completed with the same product; 3) adverse event reporting and investigation forms; 4) vaccination uptake and coverage monitoring systems; and 5) COVID-19 disease notification/investigation forms.

Two-dimensional bar codes are already included on the secondary packaging of vaccines and medicines in many markets to facilitate traceability, and WHO recommends

that this use case be applied for COVID-19 vaccines. Attempt to extend traceability technology to the vial level would only be optional (and support future operational research) if it does not compromise statutory information on the vial label. A WHO model label for vials and packaging for Covid 19 vaccines is available in the public domain. However, the bar codes and the model labels do not ensure full traceability and have not been financially costed by health financial specialists although the economic benefits could be quantifiable.

This was one of the major issues with the Pfizer nRMA vaccine because initially it was only produced taking into account the logistical and storage capacities of upper middle income and the OECD economies of the world, thereby denying poorer countries the opportunity to take advantage of these supposedly superior vaccines. However, into the breech stepped China with its non nRMA vaccines – Sinopharm and Sinovac – which did not need to be stored at between minuses 40C to 80C and had a longer storage life (up to 12 months versus 3 months). There were also attempts to discredit China's supply of its non nRMA vaccines to developing countries including in the region such as Cambodia, Lao PDR and Myanmar by critics of China seeking to "weaponize" the world struggle against this pandemic.

3.5 China's Rules and Regulations

As of the middle of April 2022 China had produced 4,951.4 billion vaccines from Sinopharm Sinovac, Anhui Zhifel, and Can Sino or 42.2 percent of all COVID-19 vaccines have produced, according to WHO estimates of 11,715.3 billion since July 2021. It has been reported from Cambodia that Chinese public health authorities provided significant assistance to Cambodian public health authorities to ensure not only has more than 90 percent of the total population been vaccinated but the importance of demonstrating to people they could trust the efficacy of the Chinese supplied vaccines. As mentioned elsewhere in this Chapter it has been quite clearly demonstrated that China has consistently followed WHO protocols and is not the outlier in this respect it has made out to be by its critics. So, what specific rules and regulations has China prepared and implemented to bolster its claim that it considers vaccine traceability not only enhances

the efficacy of the vaccine but also its safety? This question has to be asked in the context that the Chinese government like other responsible governments is concerned with the health and welfare of its own citizens as it is with citizens in other countries who have received its COVID-19 vaccines[17].

It might come as a surprise but China was the first country in the world in 2019 to develop a real law in this context known as the Vaccine Administration Law of the People's Republic of China. This law was designed not only to standardize research into vaccine traceability but ensure the efficacy and safety of the vaccine. Specifically Measures for the Supervision Over and Preparation of not simply Pharmaceutical Production but also Provisions for the Lot Release of Biological Products were incorporated in this Law. Of the eleven guidelines for vaccines, five of them specifically relate to COVID-19 vaccines including the inactivated vaccines, recombination adenovirus vaccines, recombinant subunit vaccines, and the mRNA vaccines. Clearly this suggests that Chinese virologists possessed technical knowledge in relation to the mRNA vaccines some time before the first reported cases in Wuhan. Indeed, Chinese technical knowledge in this respect can be traced back as far as the SARS outbreak in 20039.

It is evident if one could read the technical and scientific papers published in China over the past decade that Chinese experts were acutely aware of issues associated with vaccine production, distribution, storage and physical administration. What of course what not as well developed were approaches consistent with the application of Blockchain Technology: they were still in their infancy. Thus, it can be clearly argued that China has a framework both ground in rules and regulations that would, indeed has enabled it to track and trace the efficacy and safety of COVID-19 vaccines. As can be demonstrated in countries where China has contributed significant quantities of its inactivated vaccines it has provided a considerable degree of technical support and capacity building. It is correct that political rivals such as the US and to a lesser extent the EU have also provided quite a lot of similar support but the recombination adenovirus vaccines and especially the mRNA require substantially more technical support because the supply chain from

[9] *It should come as no surprise that interest groups politically opposed to China have been doing all they can to discredit not simply the government but also scientific and technical experts by implying either China is involved in massive cover ups and/or less "advanced" than their counterparts in Western societies.*

the center of production to the administration of the vaccine is a lot more problematic. Logistical issues to one side simply the storage facilities require far more expensive and sophisticated infrastructure than the vaccines supplied by China.

CHAPTER 4

DATA ANALYTIC

4.1 Economic and Financial data

There is a significant opportunity and need to enhance transparency and trust in an increasingly complex pharmaceutical supply chain. With these factors as a backdrop, the Drug Supply Chain Security Act (DSCSA) was signed into law in 2013, with the intention to allow the pharmaceutical trading partners to collaborate on improving patient safety. The law outlines critical steps to build an electronic, interoperable system by November 27, 2023, where members of the pharmaceutical supply chain are required to verify, track and trace prescription drugs as they are distributed in the United States.

In addition, I have also paid attention to the vaccination situation in various countries. The number of vaccinations in China is far ahead in the world. On June 19, 2021, the number of vaccinations in China exceeded 1 billion doses, which is more than one-third of the global vaccination number. The vaccination rate of more than 20 million doses in a single day in China has attracted widespread attention from the international community.

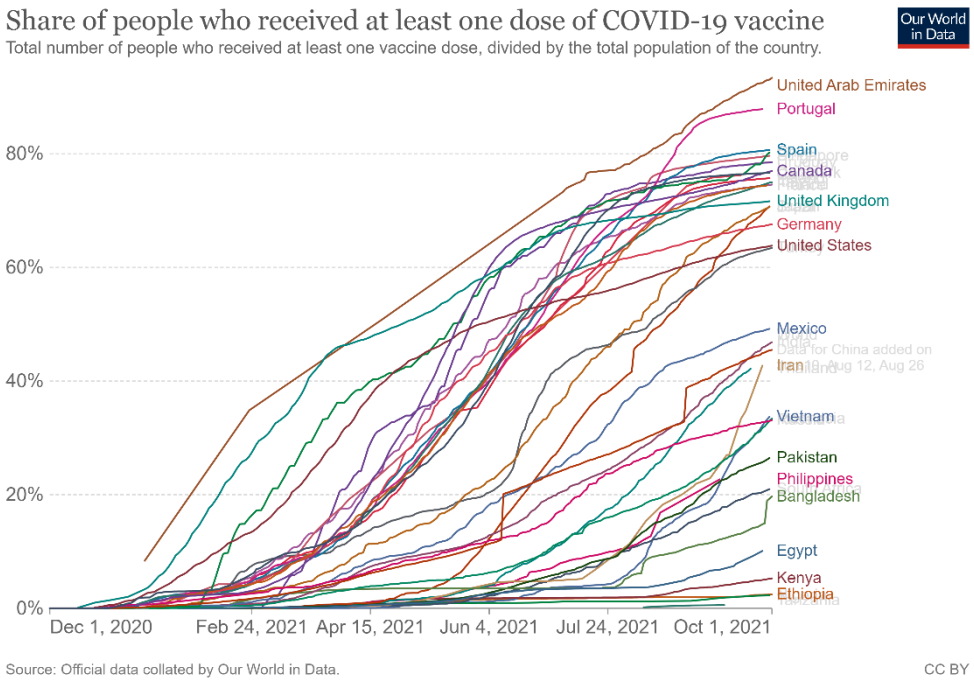


Figure 4.1 Share of people who received at least one dose of COVID-19 vaccine

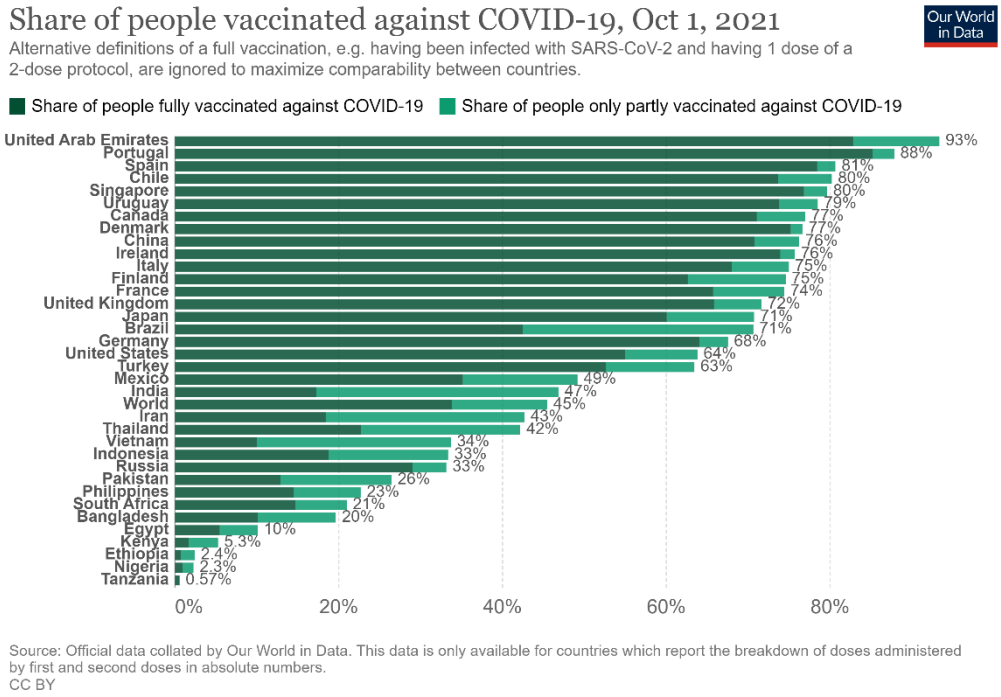


Figure 4.2 Share of people vaccinated against COVID-19

Behind the strong vaccination rate, the traceability and recording of vaccines, as well as the recall of problem vaccines, are also very important. On June 21, 2021, Su Lacuo, Deputy Secretary-General of the Food and Drug Administration of Thailand, signed and issued an emergency reminder notice about the Kexing vaccine with registration number 1C 3/64 (NBC). The report stated that the production batch number was C202105079, For Kexing vaccine with registration number 1C 3/64 (NBC), production date 10.05.2021, and expiration date 09.11.2021, coagulation material is generated in the vaccine storage bottle, and the coagulation material cannot be dissipated after shaking the bottle. This situation arises from the fact that during the storage and transportation of the vaccine, the temperature is not controlled according to the temperature approved at the time of registration (2-8 degrees Celsius), and this temperature is to ensure that consumers can obtain good quality, effective and safe vaccines.

4.2 Related Cases

However, there is something amiss in all of the analysis concerning vaccine storage. In larger cities and towns of developing countries and this also includes an upper middle-income country such as Thailand, the efficacy under which vaccines were produced and tested in the first place ignores the realities for communities in rural areas. While such communities are more than likely nowadays to have access to electricity and are generally connected to the rest of the world here, I want to describe the situation in Erawan District of Loei Province some 600 km from Bangkok that borders neighboring Lao PDR to illustrate a real-life example.

In late August 2021 the Governor of Loei Province announced that all people over the age of 70 and those otherwise vulnerable should be vaccinated immediately with Sinovac as the Government after a rather slow start was able to roll out its vaccination program in the province. While there was no direct coercion it was subtly suggested that if people loved the Nation, Monarchy and Buddhism and also themselves and their family, relatives, friends and the community they should be vaccinated immediately. In fact, the Governor did not have to worry because people were generally very happy to be

vaccinated: there are very few anti-vaxxers in rural communities or indeed anywhere in Thailand. The irony is that while people in Western Europe and the US were out on the streets to protect the vaccination rollout (but of course there were other issues on the agenda including strident critiques of the incumbent ruling party/s) in Thailand or at least Bangkok some groups were also demonstrating against the government because they sought among other things to encourage a more rapid rollout of the vaccination program.

Village people from all villages within the district (the population is just under 40,000) flocked to the temporary vaccination center set up at the District Office. Local staff from the Erawan District Hospital (district hospitals in Thailand are much better equipped than provincial hospitals in neighboring Lao PDR, Myanmar or Cambodia and are generally better than prefectural hospitals in China) were out in force to administer the Sinovac. It may sound surprising but the health workers (medical doctors and nurses and community health workers) all took time out to explain to villagers how Sinovac was manufactured in China, transported to Thailand by plane, stored in optimal storage facilities of between 2C and 8C, transported by road to the provincial capital and then distributed to each district in the province, and what could be the possible effects of the vaccine on some people.

However, the most interesting part of the exercise is that the traceability of the vaccine being administered was explained to all villagers in a language they could understand and surprisingly a video produced by the manufacturer in China dubbed in the Thai language was shown and many people watched it with an interest. The video explained how the supply chain could be traced from its manufacture in China to its arrival in Thailand. It was clearly explained that each batch had a bar code and serial number with details of when it was produced and transported to Thailand. The video went on to explain that the technology was available – blockchain was not mentioned although the laboratory technician from the District Hospital was able to explain to those interested how track and trace could work – to follow the vaccine on its journey from the production floor to the physical center where it would be administered. Several villagers described this as a bit of propaganda but most found this interesting and possibly useful.

A major concern expressed was what would happen if people fell ill as a result of being vaccinated. It was freely acknowledged that this might occur in some instances but

the evidence to date, including from China itself or across the border in the Lao PDR and Cambodia, clearly suggested that the impacts were quite minimal and could generally be mitigated quite easily. By way of contrast, and here local staff were not engaged in a propaganda war, stated that the mRNA vaccines were supposedly more effective but had more side effects. Some people were asked why they did not have a choice then to which the spokesperson for the Provincial Department of Health explained such vaccines were not freely available in Thailand because wealthier countries in the world were hoarding as much of the NRNA vaccines as they could.

However, people should not worry because the vaccine rollout was proceeding very well in China as it was in the Lao PDR and Cambodia or indeed other countries that were benefiting from China gifting significant quantities of its vaccines to many countries that were poorer than Thailand. Although this did not prevent at least one person who described himself as an opponent of the current government asking why Vietnam or at least many Vietnamese people were refusing to be vaccinated with the Chinese vaccines. The usual diatribe about Vietnamese antipathy to Chinese occupied center stage for a little while but the assembled group soon returned to discussing the advantages of China supporting Thailand's vaccine rollout. It needs to be noted in this region of Thailand people are generally pro-China or at the very least not antagonistic to all or most things China.

It was explained that people would be provided with an immediate certificate that the batch number and serial number and a QR code was provided so people could check for themselves the efficacy of such the claims that were being made. Some people complained they did not have access to the internet (over 95% of villagers own smart phones) but they were shown how to use the QR code to track and trace the batch that was used for their vaccination. Indeed, during the observation period of 35-50 minutes following the actual vaccination health workers provided assistance to those who wanted it to find details about the vaccine they had just received. It was not perfect but a good beginning.

On returning 20 days later the health workers once more explained how the QR code would work and this time round some people asked who stored the data: the manufacturer in China, the logistics company, the Ministry of Health at the national or

provincial level or the District Hospital or Community Health Centers (there are four in this district). At the conclusion of the second round of vaccinations each person vaccinated was handed a printed vaccination certificate with the QR code and all necessary serial and batch numbers of both vaccines were included. Under Thailand's mix-and-match program the second vaccination consisted of being vaccinated by the viral vector Astra Zeneca and similar data was provided from the point of storage in Thailand but not the production center in Thailand where it was mooted production would commence but from other Astra Zeneca production centers abroad. Thus, theoretically even end-consumers in a small district like Erawan could track and trace the vaccines they were administered with. Whether many have bothered to do so is a moot point because very few have experienced deleterious side effects.

By way of contrast a small coastal community in New Zealand that consists largely of an indigenous Maori population have not been advantaged in the way people in Erawan or elsewhere in Thailand have. New Zealand prided itself in the fact that it had effectively managed the pandemic better than most countries in the world. But of course, this is relatively easy when the nearest populated land mass is some 2,000 km distance and the country itself has a total population of just over 5 million people (smaller than some district level prefectures in China) because one can simply isolate the country from the outside world. China might have a "ring-of-steel" but New Zealand simply has vast tracts of ocean surrounding it. Anyway, New Zealand set out to demonstrate to the rest of the world how successful it was or would become during the pandemic and managed to convince itself it was doing very well. However, the narrative is not totally matched by the reality.

In this small coastal town of Kawhia 300 persons over the age of 18 were deemed eligible for vaccination back in later May 2021 but some refused as they still do today because they do not trust the government especially when the latter could not explain how the Pfizer vaccine (there are no choices in New Zealand: only Pfizer is currently accepted fully the government unlike neighboring Australia where all or most vaccines are accepted including Sinopharm and Sinovac) would work. They were especially concerned about what they were reading on social media platforms and refused to buy

into the government's position that they should only listen to the government, that the government was the most authoritative and reliable source of information.

When the government vaccination staff turned up many of the people lining up to be vaccinated request that they be provided with official information about when the vaccine was produced, how it was transported from the production facility to the airport, how long and in what type of container it was stored on arrival in New Zealand, where and when was it tested for quality, the logistics involved in the four hour road journey from the storage facility in Auckland (point of arrival), and what did the vaccination staff actually know about the efficacy of the vaccine. In response the vaccination staff said that the questions being asked were irrelevant and that the government was acting in the best interests of all people living in New Zealand. This greatly displeased at least 50 percent of the people who turned up to be vaccinated and they decided not to be vaccinated.

When the government learned of this it promised that all questions would be answered in due course but this was met with the riposte that such questions needed to be asked prior to vaccination not after vaccination. The government responded that most other people in New Zealand trusted the government to do the right thing, that the government had the real interests of the community at heart. This only inflamed matters with not only indigenous people in this community but many in other communities (15% of New Zealand's population is indigenous) also voiced the same concerns. The government then tried to compare and contest the "Asian" immigrant population that was and still is the most highly vaccinated population in the community. The popular media and especially social media were asking the question as the "Asian" immigrant population is the most highly educated population in New Zealand why were they not asking the same questions as some of the indigenous community.

The latter community argued that racism since the settler colonial occupation of 175 years ago was the root cause of the problem and whether this is correct or otherwise in beyond the scope of this paper. However, the questions they were asking must surely resonate with any concerned person and this is what blockchain technology could mitigate to a large extent. The government said it was committed to providing all the data being requested and as the digital vaccine certificates were rolled out people would be able to effectively track and trace, which of course is far better than not being able to do so.

However, to date the digital vaccine certificates do not provide the necessary QR code to track and trace unlike the digital vaccine certificated issued in either Thailand or Cambodia. In this respect New Zealand is in the same category as Vietnam and actually its strategy for managing the pandemic is not wholly dissimilar to that of either Vietnam or China: the difference is simply the scale and the nature of its political culture/s.

4.3 Relevant Social Issues

This independent study also would like to focus some of its attention on gender and blockchain technology[10]. Women aspiring to raise a family have to be even more sure than men that being vaccinated does not have long-lasting unmanageable impacts on themselves, their babies and the rest of the family. The Thalidomide Disaster had a highly unequal impact on women and men, both were impacted but it was the reproductive health of women that was by far the worst impact. Even today the effects of this disaster still reverberate through the community. While it is argued all women and men need to be cognizant of the impact that these COVID-19 vaccines including the least harmful inactivated virus vaccines have on their long-term health but women as the physical bearer of the next generation and those beyond need to be in a real position where they can track and trace the vaccine they were administered with.

For women of child-bearing age, indeed for any female that will be vaccinated including young female children they must be able to assess whether the vaccines they have been administered with will have any likely bearing on their reproductive capacity. If they were to have some major negative impact these women could choose to terminate the pregnancy to avoid a lifelong crisis, they had hoped childbearing would not result in. On the other side of the ledger are women who refuse to be vaccinated because their religious beliefs preclude them from being vaccinated or because if they are vaccinated and fall pregnant these same religious beliefs might well discourage them from such a practice. Perhaps this can be rationalized in some religions whereby women and men

[10] *Blockchain Technology like all other forms of technology is not wholly gender neutral and historically women while also benefiting from technological advances in the management of public health have also bore the brunt of technologies that impact more negatively on women than men.*

accept that their “God” or “Gods” test their faith through such afflictions. This is a long way from the logic of blockchain technology but it is an issue that cannot be ignored. Even in a relatively secular society like China there are some minorities that do not buy into the standard total narrative and can be difficult to deal with.

It is not only gender that is an issue in this whole debate. We also have to consider the plight of the physically and intellectually impaired because as human beings they have a bundle of rights and of course obligations that the majority of the population also have. Whether the COVID-19 vaccines irrespective of their technology will impact unfavorably upon these groups is really unknown at this point in time. Part of the reason is that the vaccines have only been made available on the “market” for just over 12 months and the impacts cannot be fully appreciated. But another important part of the reason is that there are new technologies involved. We do not simply know enough about the mRNA or Viral Vector Vaccines but we know most about the Inactivated Virus Vaccines because they have been developed over the course of the last century and incrementally, they certainly did far better than harm for the most part. The extant question is does any society want its physically and intellectually impaired population to experience more trials and tribulations than they do at present? The answer is probably no!

Thus, society has both a moral and practical duty to ensure that even these two groups can track and trace possible trajectories of harmful vaccines. It really is unreasonable to expect that such issues are well known but with blockchain technology it is possible to pre-empt disastrous outcomes. If negative impacts cannot be covered up by the medical profession, public health officials, the state or the producer of vaccines then we are on the right path. To be able to effectively track and trace not only the vaccine supply chain but access a plethora of data in such as short space in time is clearly a basic human right in the digital age that all human beings should be able to enjoy. As bizarre as it sounds blockchain technology represents an opportunity to uphold human rights and dignity not undermine them and goes way beyond the rhetorical assertions of those who disparage societies and their individuals with different norms and values. Viewed sociologically it ironically guaranteed diversity rather than simply homogeneity.

However, there is no doubt that if Xi Jinping thinks blockchain technology can assist in ensuring the Party is not undermined in China he will support such technology. This is where the legitimacy of the Party is enshrined. If the CCP can demonstrate it is managing the pandemic very well, not just in terms of public health outcomes but also economically and socially then he is a likely winner. Supporting blockchain technology to ensure vaccines can be tracked and traced at every link in the supply chain is an imperative for China. While it wants to manage the pandemic domestically very well it does not want to be held responsible for either the pandemic becoming any worse than it currently is or the future the negative impacts surface and are not quickly resolved.

CHAPTER 5

FINANCIAL PLAN

5.1 Project Investment

Table 5.1 Project Investment statement

Investment (Unit: Million yuan)

<table>
<tr><td colspan="2">Completed investment</td><td colspan="3">4</td></tr>
<tr><td colspan="2">Use of funds</td><td colspan="3">R&D, personnel costs, research costs, etc</td></tr>
<tr><td colspan="5">New investment budget and basis during the implementation of the project</td></tr>
<tr><td colspan="3">Total planned investment of the project</td><td colspan="2">30</td></tr>
<tr><td colspan="3">New investment amount of the project</td><td colspan="2">26</td></tr>
<tr><td>Investment in fixed assets</td><td>3</td><td>Working capital investment</td><td colspan="2">23</td></tr>
<tr><td colspan="5">Details of fund use direction (including fixed asset investment, construction in progress, R&D investment, management fees, etc.)</td></tr>
<tr><td colspan="5">Investment in fixed assets:

Project | Amount | Amount of money
PC | 200 | 1.0
Notebook PC | 30 | 0.24
The server | 20 | 0.20
GIS | 1 | 0.56
Blockchain | 1 | 1.0
Total | | 3.0</td></tr>
</table>

Working capital investment:	
Personnel expenses	13.5
Research fee	1.5
Site rental fee	2.5
Material cost	4.0
Other related expenses	1.5
Total	**23**

IRR=10.81

WACC=(E/V)×Re+(D/V)×Rd×(1-Tc)=9.5%

5.2 Financing Plan

Table 5.2 Project financing Plan

Project financing (planned new investment) (Unit: Million yuan)

New investment amount of the project	26
Self-raised by enterprises	20
bank loans	6

5.3 Economic benefit analysis of the project

Table 5.3 Economic benefit analysis of the project

	Sales revenue (million)	**Total cost (million)**	**Net profit (million)**	**Average number of employees**
Year 1	30	23	7	100
Year 2	42	31.35	10.65	145
Year 3	58.8	42.20	16.60	200
Analysis of relevant economic data:				

With the rapid development of the Internet of Things, enterprises, industries, governments and other organizations have more urgent requirements for the Internet of Things. According to estimates, in the next three years, the market size in this area can reach about 1.5 billion yuan, of which the annual target market share of this software can reach 30 million yuan to 280 million yuan.

Because version 1.0 has been developed for this project, software testing is currently under way; It has been officially used in Jinan CDC. It is estimated that mass production and sales can start in the second half of 2022; Start mass production and sales in 2023. This project has advanced technology, obvious product advantages, flexible marketing methods and guaranteed technical services, so once the product is successfully developed, the market sales prospects will be very broad.

Therefore, the production and sales volume of the products of this project are equivalent. 2022-2023 is the project input period; From 2023 to 2025, the sales revenue will expand due to the gradual slowdown of investment. Our products have an exclusive advantage in technology, and at the same time, the working capital is also very sufficient. Therefore, the company has made a development plan within a reasonable range.

5.4 Tokenization

Every Blockchain has inherent financial characteristics. A suitable economic model is one of the essential elements of a Blockchain ecosystem and a key factor in its success.

After researching the economic models of most public Blockchain networks, we have found that the greatest adoption of large-scale applications on Blockchain Barrier: The cost of using Blockchain is directly related to token valuation. While token valuation typically rises as Blockchain usage grows, the cost of using Blockchain depends on whether a party wishes to conduct a payment transaction Or smart contract transactions. This does not even mention that the speculative behavior of investors and traders is a contributor to the value of the Blockchain. No business owner will run an application or business on the Blockchain or anywhere with unpredictable and volatile costs.

VAO tokens is name of our company's token, VAO tokens will be released through Ethereum's smart contracts for funding and will be a one-time offer, after which no new VAO tokens will be generated. VAO ICO is taking place in times of significant regulatory turbulence. In the midst of our ICO preparation process, the People's Bank of China halted all ICO related activities in China. VAO Project is a Thailand company. However, a major part of our business activities currently take place in Mainland China. In order to comply with the existing regulatory framework, as well as to mitigate the risks of future changes, we are making special provisions for VAO token circulation in regard to the China market. Below are the key features of these provisions.

All crypto activities (crypto payment processing, token issuance, circulation of exchange-listed tokens) will be held outside of China. VAO Project will develop a Blockchain-based, remotely hosted loyalty program that will be licensed to VAO China. Point issuance in VAO China loyalty program will be rigidly linked to VAO through a smart escrow contract in a 1:1 ratio. In other words, to issue 100 additional points for the VAO China loyalty program, VAO Project must first obtain 100 VAO tokens. Features and flexibility of the VAO China loyalty program will be in-line with the maximum allowable standard for loyalty programs currently operational in China, pending further regulation regarding crypto-activities. VAO tokens will be user-exchangeable to VAO China loyalty points through the VAO Project Co.,Ltd., but not vice versa.In other markets VAO tokens will be circulated in VAO loyalty programs directly, local regulations permitting.

5.5 Fund Raising Strategy

Pre ICO and ICO There will be 2 stages: first a pre ICO, then the ICO itself. Pre ICO will enable us to put together an ICO that is appropriate for the scope of the project and the opportunity.

VAO token will be used to purchase VAO protected products (similar to loyalty program points). In terms of geography, we will start in China, but we'll grow outside of China as well. It's hard to predict the exact timing at this stage. This will also not be

limited to products that we sell ourselves: we plan to add other companies to the platform. These companies will also join the VAO coin system. We will encourage the use of VAO tokens in several ways: (1) We set up a seamless usage process for consumers. (2) We allow users to 'mine' tokens with a proof of purchase of VAO protected products. Buyers of products protected by VAO technology will receive some initial tokens when they start buying. We are reserving tokens at the ICO specifically for that. (3) Consumers using VAO will get better terms overall. This may include discounts, special offers, discounted purchases of VAO tokens, etc.

Excepted allocation of the VAO token: Total value: 6 million

Token sale: 50%

Reserve: 25%

Team, Advisor & Early Contributors: 10%

Foundation: 15%

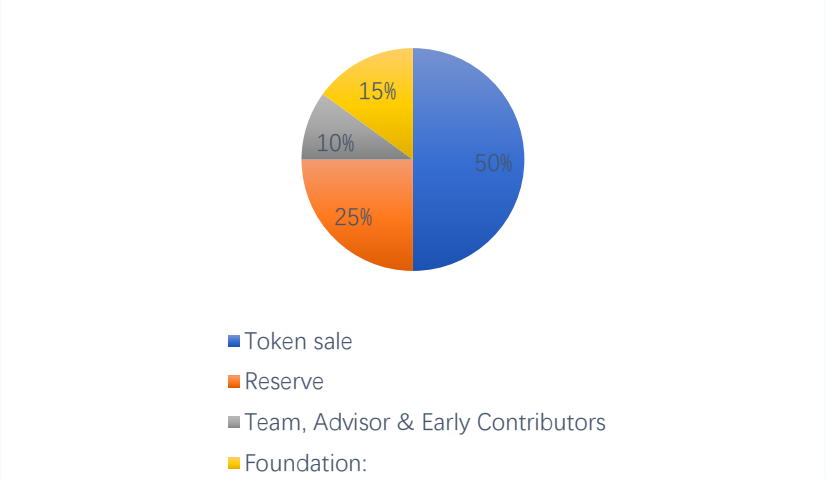


Figure 5.1 Fund Raising Strategy

CHAPTER 6

FINTECH

6.1 Block Chain Design

The proposed blockchain system for transparent COVID-19 vaccine tracking, distribution monitoring and administration is presented in Figure 6. It uses the distributed ledger for storing vaccine related data, while assuring data immutability to guarantee that the vaccines are transported safely to the beneficiaries and the administration is done correctly to the real recipient without abuses.

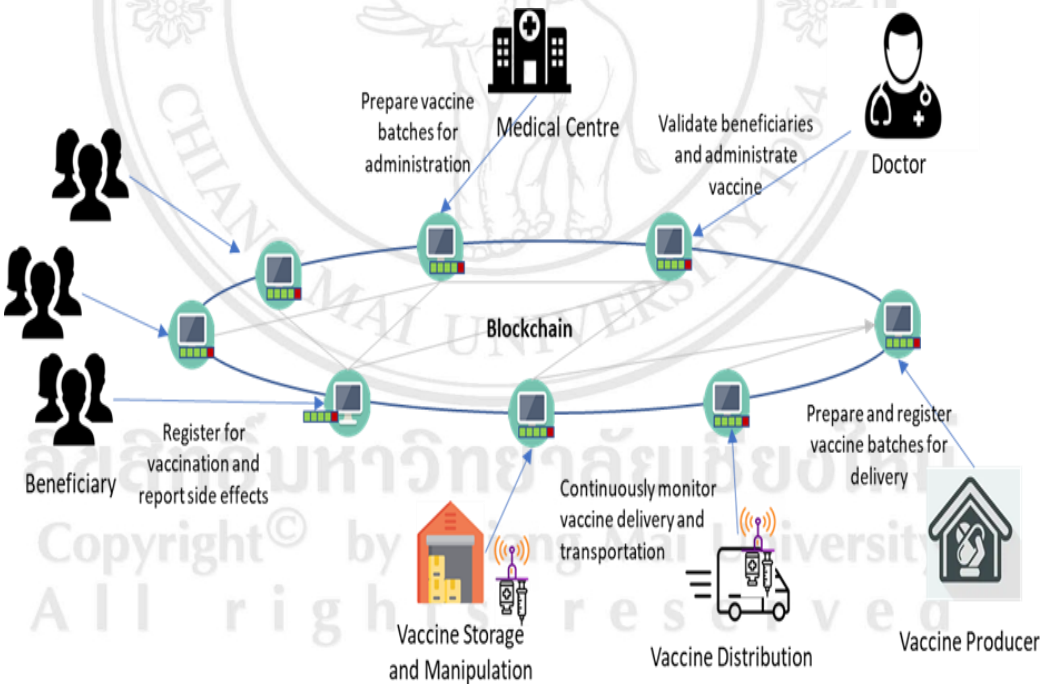


Figure 6.1 Blockchain system for transparent COVID-19 vaccine tracking, distribution monitoring and administration

The main actors of the proposed blockchain based system that act as peer network nodes are: i) the beneficiaries that register for vaccination, ii) the company that prepares and registers the vaccine batches/lots for transportation, iii) the IoT sensor devices that continuously monitor the vaccine delivery, storage and handling; iv) the medical centers that will receive the vaccine and prepare it for administration and v) the doctor who validates the beneficiary, delivery and storage conditions and administers the vaccine. All the actions are registered into the distributed ledger as immutable transactions which are stored in blocks that are replicated to all the peer actors in the chain. This will provide a high transparency of the vaccine handling operations enabling the tracking and registration of the COVID-19 vaccine as digital asset.

6.2 Blockchain Benefits

Blockchain is a distributed ledger technology that provides an immutable audit trail of transactions, allowing for transparency while maintaining data privacy, and uniting disparate sources of data from various stakeholders. Immutability of the data enables the technology to be considered for highly regulated industries such as healthcare. Another potential benefit that drives value is the capability of this technology to enable reconciliation in real time by confirming transactions without seeing the underlying data. This technology also has the potential to reduce costs, automate and eliminate manual processes and introduce a transparent supply chain among trading partners.

Figure 6.2 Summary of potential benefits associated with leveraging blockchain technology

For the pharmaceutical supply chain, this technology has the potential to enable a common, shared solution where manufacturers, distributors and dispensers can work together to solve key industry challenges and collectively set the stage for common standards and procedures to address DSCSA requirements. Establishing common technical standards for a blockchain solution enables interoperability and enhanced visibility for all supply chain participants, regardless of their involvement in the initial blockchain development process. With the use of a blockchain-enabled solution, this technology might be able to address the foundational requirement of track and trace for DSCSA in addition to establishing trust between trading partners.

Technically, through the organic connection of all parties, digital trust is finally established. Blockchain technology allows multiple parties to manage and share decentralized databases. These participants can create and share negotiable transparent rules together. Therefore, blockchain may be an ideal infrastructure for a supply chain management platform, as it covers two key prerequisites for establishing digital trust:

The blockchain is not unique to anyone but provides a general standardized protocol. All participants in the supply chain can join and share relevant data. The data on the blockchain cannot be tampered with, so it cannot be deleted. If there is information, you can only continue to add additional information, which makes each participant who writes new data have a higher sense of responsibility.

6.3 Blockchain Benefits Expanded

In this section the benefits of blockchain are expanded. Through the use of smart contracts and off-chain data, blockchain is capable of working with large amounts of data and enables scalability across multiple dimensions: participants, transaction volume, and product type. Smart contracts, or chain code, are digital representations of business-driven contracts that reside on the blockchain. Smart contracts define the relationship between two or more parties and can enable automation of business processes among network members which can eliminate operational inefficiencies by automation and provide

greater accuracy. For example, in future iterations a smart contract could enable automatic product re-ordering in the event that a product is damaged in transit or enable payment to be released from sender to recipient upon verified receipt of product.

A blockchain network purposefully may be designed to maximize the benefit of off-chain storage. For example, a blockchain network may utilize off-chain storage to store personal identifier information to facilitate compliance with HIPAA or used to facilitate the sharing of large files or documents. In addition, off- chain storage may be considered in order to maximize search query efficiency. However, network designers must ensure that the search capabilities enabled by the off-chain database adhere to the network's existing permission structure.

The cryptography innate to blockchain enables an immutable and verifiable chain of custody that can be used to support product investigation. Participants also have the ability to independently verify products without the need to contact the manufacturer or any other trading partners. This is a very important advantage of blockchain technology because of course manufacturers or other trading partners will generally trying to put a spin on the issue with the use of sophisticated PR specialists or in worst case scenarios attempt to buy off the most vocal critics if they can. Such approaches precede anything to do with blockchain technology or indeed the digital world. Will this make manufacturers more honest remains to be seen. Linking this to the claims and counter-claims of vaccine manufacturers there are concerted attempts by the manufacturers of mRNA such as Pfizer to use science to challenge assumptions concerning the efficacy and efficiency of the inactivated virus vaccines, notably Sinopharm and Sinovac.

This study does not buy into conspiracy theories but a systemic overview of many leading scientific journals, public health experts and especially virologists together with the social media sites outside of China are often seen calling into question whether China knows what it is doing when manufacturing vaccines. The "scientists" claim that neither Sinopharm nor Sinovac have undergone rigorous independent clinical trials whereas vaccines such as Pfizer and Moderna have despite both Sinopharm and Sinovac being approved by the WHO and even entry into countries such as the US. Public health experts might not be receiving "back-handers" from vaccine production companies at present although we cannot know for sure but let us assume they are not. One of the extant issues

here is that perhaps these public health experts know less about the pandemic landscape in China than they think they know and just assume all is not well in China. As for social media because free access is provided people can say what they like and my review of YouTube for instance shows many of the negative remarks about the Chinese vaccines are made by people who know little or nothing about China.

Instead, we should return to what can occur when combining blockchain with other technologies such as internet of things sensors (IoT) or ultra-high-resolution cameras, network stakeholders could establish a digital twin of a physical product on blockchain. The digital twin could be leveraged to represent an immutable record of product geolocation or temperature data and could also increase patient safety by ensuring that the product label has not been copied. If we once more put bias and prejudice to one side, we can more objectively look at what benefits blockchain technology has to offer.

6.4 Contemporary Technologies

Recent advancements of contemporary technologies such as the Internet of Things (IoT), machine learning, and blockchain pave the way for building more smart and innovative systems that can be adapted to different domains as is the case of the healthcare domain. The author proposes the use of IoT devices to monitor the location of the carrier, temperature, and humidity with the goal of optimizing and increasing vaccine coverage in remote regions and ensuring transparency in the overall process. Blockchain-based decentralized systems for addressing healthcare sector problems such as privacy and confidentiality of data are presented. Recent studies have pointed the possibilities of using blockchain in combating the COVID-19 pandemic most of them addressing the decentralized tracking of contracts and symptoms or for assuring security and immutability. Relevant use cases for blockchain technology in managing COVID-19 pandemic contact tracing, patient data sharing, supply chain management are overviewed.

Other studies have shown that blockchain can be used to develop trustful predictive systems that can help to contain the pandemic risks on a national territory to securely track the movements of residents in quarantine scenarios using IoT infrastructures.

Incentive-based approaches have been proposed to battle against the COVID-19 pandemic that uses blockchain to prevent information tampering and incentives for rewarding patients to remain in quarantine.

The whole-process vaccine traceability system solution, through the integrated platform management of the first-class vaccine and the second-class vaccine in the region, realizes the whole process monitoring of vaccine circulation and use, vaccine information traceability, temperature monitoring and over-temperature warning, as well as vaccine circulation and use. Management, immune planning, decision-making assistance, statistical analysis, and other functions. It can realize the supervision of the inspection, verification, vaccination, and other behaviors carried out by relevant personnel in the vaccine circulation process to ensure the quality of the vaccine and the safe vaccination. Reverse traceability of required vaccine information; traceability of temperature, flow direction, and compliance information during the entire process of the smallest packaged unit vaccine from production, circulation to the recipient can be realized. At the same time, according to vaccine inventory, loss, recall, procurement plan, cold chain equipment status, staff information, vaccine, classification, and correlation statistical analysis for disease epidemic data can be used to assist decision-making.

CONCLUSION

This Independent Study has covered a myriad of issues related to the efficacy of blockchain technology to effectively ensure that all COVID-19 vaccines irrespective as to where they are produced and, in the world, whether it be in China, India, Russia, the US, EU countries or even countries such as Cambodia or Senegal or type of vaccine – mRNA, Viral Vector or Inactivated Virus Vaccines – are fully traceable. When it is argued in this Study is that unless there is traceability on a global basis and everyone not just manufacturers, governments and entities responsible for vaccination whether public or private is able to trace all specific links in the supply chain from production to administration.

However, this is a very "tall order" given the social, political and economic characteristics of countries in the world. Intuitively it is argued that a country such as China or the US or smaller but highly developed countries such as Singapore or New Zealand or a country such as Thailand are better able to guarantee traceability than most of the lower middle incomes in the world. An attempt has been made to objectively analyze the extant issues associated with the overall objective of this Study. Rather the focus has been on what constitutes a transparent supply chain among trading partners or stakeholders as has been defined in this study because those that have or will be vaccinated are also included. This transparency starts with the shared ledger through to per missioning, smart contracts, trust, privacy, and modular processes.

It is argued all of these steps are necessary but unless there is trust and privacy, the former being important in all countries and the latter seemingly more important in "liberal democratic societies". Thus, in the context of China where it has the most sophisticated social credit digital app in the world it would seem that trust is the most important issue. People in China, and here it has to be noted this is not based on a detailed empirical investigation specific to this study but the insights gleaned from the fallout associated with the Melamine Milk Scandal in 2008, clearly demonstrate that people in China are

very concerned about all manufacturing processes that possibly impact upon their health and well-being.

This argument is not simply been made in the context of China but in any context where there is choice and the general populace have a relatively high degree of knowledge trust is very important. While trust in political culture is not simply restricted with groups in society with choice and knowledge it is argued here that where people do not feel they have choices or the necessary knowledge the state needs to facilitate the enabling environment.

In the "liberal" aka "prosperous" democratic societies it is often argued that such societies because they are less "centralized" than a society such as China (actually at present the only similar society is Vietnam but of course the Democratic People's Republic of Korea – North Korea – is ostensibly more centralized but it has not been focused upon in this study) and thereby better able to track and trace the passage of a vaccine through the supply management system. This study disputes such an assertion but rather argues trust in China is not simply engineered by the social credit system but is based on the legitimacy of the State and Party. Those who do not trust the State and Party are unlikely to trust any system that ensures traceability and blockchain technology in this context might mean it is less useful than has been suggested in this Study.

Governance issues are important and that is recognized in China and for instance taking Thailand as a regional example where trust is based on support for the Nation, Monarchy and Religion, despite some opposition to at least two of these institutions by-and-large people support these existing institutions. Indeed, it is in societies such as the US or quite a few EU countries where there is much less trust in the public institutions than in China or other non-Western societies. But the extant issue is that whether or not blockchain technology will ensure that trust is non-contestable because of all the processes involved which are non-dependent on different ideological values to those most societal members might subscribe to. It is here the Study has demonstrated hypothetically how traceability could work in China.

A person is fully vaccinated with one of the inactivated virus vaccines (Sinopharm or Sinovac) in Hohhot in Inner Mongolia but relocates either temporarily or permanently

to an Eastern Seaboard City such as Shanghai. S/he has learned through the "rumor mill" or even through official announcements that there are issues with some of the batches that were used during the time they were vaccinated. With a robust blockchain technological supply chain system in place this person could tap their app or go online and empirically view whether the batch or batches identified contain the data necessary to make an informed decision as to whether they should be revaccinated or seek medical advice. Ideally the State entity via the Social Credit App would notify the person concerned but the fact that blockchain technology enables to person from Hohhot to access details of when they were vaccinated and details of the specific batch to allay any fears they may have. While this might not yet be possible it is more likely to be rollout in China ahead of most other societies although it is claimed that in the US individual people are able to track and trace pharmaceutical medicines that have been prescribed. This maybe correct and the Study does not dispute this in the absence of detailed empirical evidence.

What has been demonstrated in this study is that blockchain technology when utilized to track and trace vaccine use can be scientific neutral: that the efficacy of a system based on truthfulness or otherwise of a supply chain management system does not have to be designed according to the ideological values of the designed. Rather it can be deigned based on the architecture highlighted in this Study and the very positive issue is that once designed if tampered with it can easily be detected and even the managers of this technology cannot simply redesign such a system.

Blockchain technology then is ideologically neutral and therefore can be utilized in societies or entities with quite different underlying norms and values. This is recognized in China and despite the hubris of critics who cast doubt on China either do not understand blockchain technology or are very selective as to what aspects of this technology they choose to focus on.

While trust issues can be adequately addressed in a robustly designed tracking and tracing of a specific vaccine there is an issue with privacy. Most people do not want to have private health issues circulating in the public domain for obvious reasons including possible discriminatory actions by providers of goods and services or in the field of housing, travel and employment. In China people have got used to the fact that poor social credit scores limit their options in many ways, an obvious example being inter-provincial

travel or access to some shopping centers or securing accommodation, that would not otherwise be a problem. However, as has been argued throughout this study the blockchain technology is not the only issue. This of course does not mean privacy issues are not important and that includes China, but they need to be addressed within the specific socio-cultural characteristics of each and every society.

This study recognizes the main characteristics of blockchain technology and the opportunities it brings to the COVID 19 pandemic as follows increased decentralization via a peer-to-peer (P2P) architecture whereby each member has access to the entire network (and I broaden this network to include people as consumers and not patients) and can participate in the verification and validation of transactions. The advantage of such an architecture concerning COVID-19 can be when independent stakeholders want to collaborate: they can do so without providing full control to a central authority but of course in the context of China this can be problematic.

There is scope for increased capacity in that all the P2P networks is that all data is stored in a vast network of geographically isolated computers as opposed to being stored in a few centralized servers. The capacity of such networks is always increasing, as a new node joins the network. It will also contribute to the network's total capacity. This increased capacity should be useful during the pandemic to store the vast amount of ever-growing data. Once again, the argument refers to patient but it is argued here incessantly that while the pandemic causes a lot of people to fall ill fewer than 10 per cent of those who are vaccinated are ill or have been ill so how can they be referred to as patients?

Blockchain networks are thought to offer far more transparency than other networks because the ledger is shared and is available for every member node to access. However, in healthcare there is often a tradeoff between providing transparency and maintaining privacy as has been stressed throughout this independent study. The miner with a complete ledger has all of the data in the network. In China the miner is of course the state via the Social Credit system but when describing mining and transparency the emphasis is largely on societies other than China.

Autonomy is based on there being no single central authority governing the transactions because all the member nodes of the blockchain can access the data and add

other data without any other external source watching. It is highly doubtful China would agree to such a level of autonomy but there is room for being corrected if this is not so. But in a broader context people from around the globe where there are no firewalls can use this blockchain technology during the pandemic to share both positive and negative experiences. This architecture can ensure in the absence of a firewall that users can choose who and who not they want to share their data with.

The blockchain network can quickly validate all the transactions and allows only valid transactions to enter into the network. Once the transaction has been entered into the network it cannot be rolled back or any transactions deleted. This characteristic described as persistency enables faster and ostensibly correct decision-making although political scientists would dispute this putative claim. It is probably more accurate to describe this as contributing to informed decision making. Proponents of blockchain technology are no doubt technical experts but decision-making even for the enhancement of traceability for COVID-19 vaccines does not simply rest with the architects of blockchain technology.

Immutability which has been described in some sections of the Independent Study ensures that once records are entered into the blockchain network they can never be removed or deleted. This characteristic ensures that all transactions are stored in the blockchain network forever. The clear advantage – and here I deal with the patient rather than the consumer – is that during the pandemic if a patient is referred to another doctor, the second doctor will have access to the entire patient's history. In existing systems where such technology does not exist or is only partially used this is not possible. Objectively speaking it is doubtful that China would embrace all the blockchain technology, but it is likely, indeed it has already embraced any characteristics if considers fit for purpose.

But it has to remembered that tracking and tracing vaccines used to ward off COVID-19 should be similar to any track and trace of any product, whether it be infant formula, processed meat products, beauty products, homecare safety products of motor vehicle manufacturing the difference resides in the fact that COVID-19 has demonstrated its potential to impact upon everyone in the world, irrespective of nationality, class, gender or ethnicity. Take the Melamine Milk scandal as the most relevant example for

China. Just who was affected? It was the infants of women who had chosen for a variety of reasons to jettison traditional practices of nutrition including of course breastfeeding although it is recognized that not all women are able to do so that were the most affected. Furthermore, it was women and their families who could not afford to purchase imported infant milk formula from countries such as Australia and New Zealand who were disproportionably impacted upon: so, in this instance class or rather socio-economic status had an important bearing. Nevertheless, women had a choice whereas with COVID-19 there are largely no choices although people can modify their behavior through mask wearing, social distancing, use of hand sanitizer and not engaging in high-risk related activities such as visiting bars or perhaps traveling on overcrowded public transport. Therefore, while the Blockchain Technology could be very useful the same Big Data requirements of tracking and tracing vaccine the supply chain is less important.

Staying in China African Swine Fever has decimated nearly half of China's domestic pig population and as of today a suitable vaccine regime to treat ASF has yet to be developed. However, ASF does not affect people in terms of food safety and consuming pigs with ASF while not recommended as with livestock that have been affected by foot-and-mouth disease is not life threatening. Of course, it has economic and financial impacts on farmers, trading intermediaries, meat processing companies, distributors, wholesalers and retailers and the end-consumer (reflected in price increases) but people are not going to die from either ASF or FMD. Moreover, outside of countries such as China, Vietnam, Cambodia, Lao PDR, Thailand and Myanmar pork is not widely consumed, For instance in countries such as Indonesia, Pakistan, Bangladesh, Iran and Saudi Arabia that are largely Muslim pork is only consumed in small quantities. So, the question is why would the same expansive blockchain technology need to be utilized as for COVID-19 vaccines?

Adverse events of a global nature such as the COVID-19 pandemic simply require a global response and for blockchain technology to be of any real use it has to address this issue: everyone in the world is potentially affected by COVID-19. The same cannot be said of Ebola, or MERS, indeed HIV/AIDS. Ebola and MERS have a regional basis to them just as SARS did back in 2003 in primarily East Asia. However, this argument needs

to be qualified because the answer to this question is not straight-forward as some of the proponents of blockchain technology might think it is.

We could take the example of the Flaviviruses – dengue, yellow fever, Japanese Encephalitis, Ross River Fever, or the West Nile Virus – that historically had their origins in the tropical and sub-tropical climatic zones of the world. Admittedly such viruses are endemic but with climate change and global warning these viruses are increasingly no longer restricted to such zones. At least one of the viruses, the Japanese Encephalitis virus currently affected one percent of the population with a very high fatality rate of 30 percent. Extrapolated globally if it were ever to regain pandemic status up to 95 million of the world's population could become affected and with a fatality rate of 30 percent this means over 20 million of the world's population could succumb to this virus. This would render this virus more horrific than COVID-19. Thus, if it were to assume a global nature would not the same imperative that could or should fuel the current pandemic also fuel such a pandemic?

The answer to that question is a clear yes. Tracking and tracing a such Flavivirus (and this includes dengue, yellow fever, West Nile Virus, and Ross River if they were ever to acquire pandemic status) would clearly benefit for blockchain technology. Taking the issue one step further HIV/AIDS is still a pandemic in Africa and was until the advent of antiretroviral medications to treat HIV/AIDS (ATV Therapies) in the late 1980s a virus that affected men that had sex with other men, men that frequented sex workers, men and women with multiple sexual partners a major public health issue in societies where sexual cultures were more liberal (e.g., America compared to Britain or Thailand to China).

But the pandemic did not affect all sexually active people and forms of "safe sex" (primarily condom use) and greater gender empowerment reduced this impact quite markedly. However, the point remains that men that have sex with other men irrespective as to what society they come from or women (and men) who provide paid sexual services were at risk and on the African continent are still at risk. But the fact remains that nearly half of infants born to mothers infected with HIV are resistant to one or more Reverse Transcriptive Inhibitors (NRTIs) but mothers need to know not simply in advance but also during ongoing treatment and during the post-treatment stage that these NRTIs are effective and if not why not. Being able to track and trace NRTIs would not only more

greatly empower women but save societies substantial amounts of human and financial resources that could be better utilized elsewhere for economically and socially productive purposes.

As a concluding comment this Independent Study concludes that blockchain technology if utilized correctly will be of great benefit for all stakeholders not simply in China that rely on vaccines produced in China. Being able to track and trace vaccines from production to administration and store all relevant data as also a proactive measure should there be vaccine failure or health issues that arise which were not anticipated during production and distribution. The real takeaway with this blockchain technology is that digitizing the vaccine supply chain management system is a vast improvement on non-digitized systems of traceability. Blockchain technology to track and trace vaccines was being developed prior to the COVID-19 pandemic but the pandemic has rapidly progressed developments to ensure this technology will benefit all stakeholders: the manufacturer if genuine does not want to produce problematic batches and the end-consumer, the person who is being vaccinated want to ensure the efficacy and effectiveness of the vaccine/s that have been administered to them.

The challenge for this Independent Study will be to decide how to secure buy-in from China's Health Authorities to use blockchain technology to develop at least a pilot project in one of the provinces or autonomous regions to test whether it is possible to develop a robust traceability system. Given that Yunnan is contiguous with provinces in Northern Thailand it might be possible to secure access to either the Xishuangbanna Dai Autonomous Prefecture or the Dehong Dai and Jingpo Autonomous Prefecture where there are a range of different national minority ethnic groups that are involved in cross-border movement to Myanmar, Thailand, Lao PDR, and Vietnam.

The hypothesis is that ensuring vaccine inclusiveness of smaller national minority ethnic groups is more difficult than for the Han majority in China but by focusing on Yunnan, which is politically far less sensitive than for instance the Xinjiang Uyghur Autonomous Region (furthermore the distance from Chiang Mai is too great) might be doable. With support from the University, it might be possible to persuade provincial and prefecture authorities in Yunnan to collaborate.

The major objective will be to demonstrate that China has both the ability and commitment to ensure vaccine traceability in this age of the COVID-19 pandemic includes all people in China. If the use of blockchain technology can demonstrate how effacious and potentially effective the supply chain management system has fully integrated traceability this is not only a contribution to China's management of the pandemic but also a regional and global example as to how traceability is not only useful and interesting but extremely important.

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APPENDICES

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