

HEALTHCHAIN: TOWARDS UNIVERSAL HEALTH COVERAGE IN SUDAN: A BLOCKCHAIN ENABLED HEALTH SUPPLY MANAGEMENT SYSTEM IMPROVING ACCESS, EFFICIENCY AND TRANSPARENCY

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ABSTRACT

This White Paper demonstrates the basic foundations for a *HealthChain*: A blockchain-enabled supply chain management system to solve the challenges that are facing the health systems in Lower and Middle-Income Countries (LMICs). The paper is presented to materialise joint collaboration between UNDP and UNICEF on innovative solutions for sustainable development.

The invention of Blockchain has hit the World with its potential in different sectors. Although it was initially designed to back up the transactions of BitCoin (the first digital currency) its potential applications expanded to other industries. These include the global supply chain and shipping industry, where earlier indications from Maersk (the shipping container giant) show that its implementation has meant a reduction of approximately 25% in operating costs and greater time efficiency.

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Health supply chain management, especially in LMICs, is facing great challenges related to regulations, management and structure, multiple tiers and poor forecasts and irregularity of funding and purchasing. These challenges have led to frequent stockout and sometimes waste of medicine, health supplies and commodities. The ambitious SDG3 targets and related strategies on achieving Universal Health Coverage will not be attainable with the current status of health supply chain management. Additionally, the increase in global counterfeit medicines and supplies hit almost US\$400 billion, putting additional pressures on health systems and global health agencies.

The National Medical Supplies Fund in Sudan is the entity responsible for the public procurement and distribution of medicines in Sudan. In 2011, as part of a reform, electronic procurement was introduced. Although some success was achieved, the problems related to poor forecasts, stockouts and wastage remained unsolved.

HealthChain is a blockchain enabled health supply management system that will include all the stakeholders along the supply chain, from manufacturers, global shippers and handlers, customs and other regulators, to in-country buyers, distributors and dispatchers. Through its development stack (protocol, network and application layers) and the transactions of the information, documents, receipts and execution of work through smart contracts, *HealthChain* is capable of addressing most of the current challenges. This will lead to greater efficiencies, increased collaboration, better pricing and overall improved equity and access to essential medicines, technologies and other health supplies.

UNDP and UNICEF (and potentially other global health agencies) are in a unique position to leverage and shape the global supply market. A recent partnership on Sustainable Procurement in the Health Sector (SPHS) that aimed to promote the use of efficient materials, reduce waste, and prioritise products with low carbon footprints, can create cost savings and environmental and health benefits, demonstrated the power of partnership and joint action.

In order for *HealthChain* to be implemented effectively, the current global, regional and national regulations, guidelines and policies will need to be updated to allow for innovation to grow at scale, without jeopardising the safety, accessibility and affordability of the medicines, technologies and other health supplies. A multi-stakeholders collaboration, including multilaterals, academia, global philanthropy and governments, is crucial for the piloting and further scale up.

INTRODUCTION

The World Health Organization (WHO) defines access to essential medicines and technologies as one of the building blocks of health systems in LMICs (WHO, 2007). Nevertheless, WHO estimated that by 2007, about half of the African population (around 270 million people) still lacked regular access to most essential medicines (WHO, 2007). A well-functioning health supply system is the backbone of a well performing health system (Yadav, 2015). The exemplary supply chain system is one that can guarantee regular and consistent access to essential medicines, vaccines and health products in all health facilities and at the service delivery points (Yadav, 2015). Nevertheless, most health supply chain systems in LMICs are not even close to being well-functioning.

Additionally, globalisation, increased population size in LMICs and increased corruption have added additional complexities to health supply chain systems. The supply chain system is not just a central purchasing authority that owns a fleet of trucks and warehouses to enable it to perform the purchasing and distribution of commodities. Rather, it is a complex ecosystem of organisations, individuals, vendors and suppliers, transporters, regulators, port authorities and other staff that share information, resources and execute processes to ensure that products and commodities are delivered from the production point to the end-user (Yadav, 2015). Health supply chains do not only deliver medicines and equipment to service delivery points or peripheral health facilities, but also return useful information on needs, demand and consumption that will help proper and informed procurement planning (Yadav, 2015).

In addition to the intrinsic factors affecting the success of health supply chain systems, there are extrinsic factors that increasingly challenge health and pharmaceutical procurement, even in developed countries; these factors are the fake or counterfeit drugs. WHO estimates that the global market of counterfeit medicines has increased, reaching US\$200 billion per year (Yadav, 2015). Even the most sophisticated health supply chain systems do not have the capacity to authenticate and validate all the drugs procured and consumed along its chain (Waxman et al., 2015).

STRUCTURE OF HEALTH SUPPLY CHAIN SYSTEMS IN LMICS

While there are some differences depending on the country and population size, technology utilisation and use, infrastructure and health system advancement, even a simpler structure involves a complex combination of manufacturers, importers, distributors, wholesalers and retailers. There are also many other systems involved, including transportation, fleet management, warehousing, etc. This is in addition to overarching authorities, such as customs, regulators, monitors and consumers' societies (Waxman et al., 2015). In most LMICs, and mainly in Africa, the government takes the responsibility for the major procurement of medicines for public and private sector distribution; this is through a central agency, usually known as the Central Medical Stores (CMS) (Yadav, 2015). CMSs are responsible for procurement forecasts and planning, purchasing, clearance and distribution. The purchasing process is very complicated and usually takes place once a year, in some instances once every two years; requests for tendering usually starts 12 months before the anticipated time of arrival of these health commodities and medicines in the ports. Once they have arrived, the CMS then liaises with the customs' authorities for clearance; this requires the involvement of the central pharmaceutical regulatory and the Standardization and Metrology authorities to ensure the safety and quality of the commodities. In most countries, the mandate of the CMS is distribution to regional or district health levels, while distribution to hospitals and

other health facilities is done through local or regional distribution systems. Figure 1 below elaborates on the most common processes:

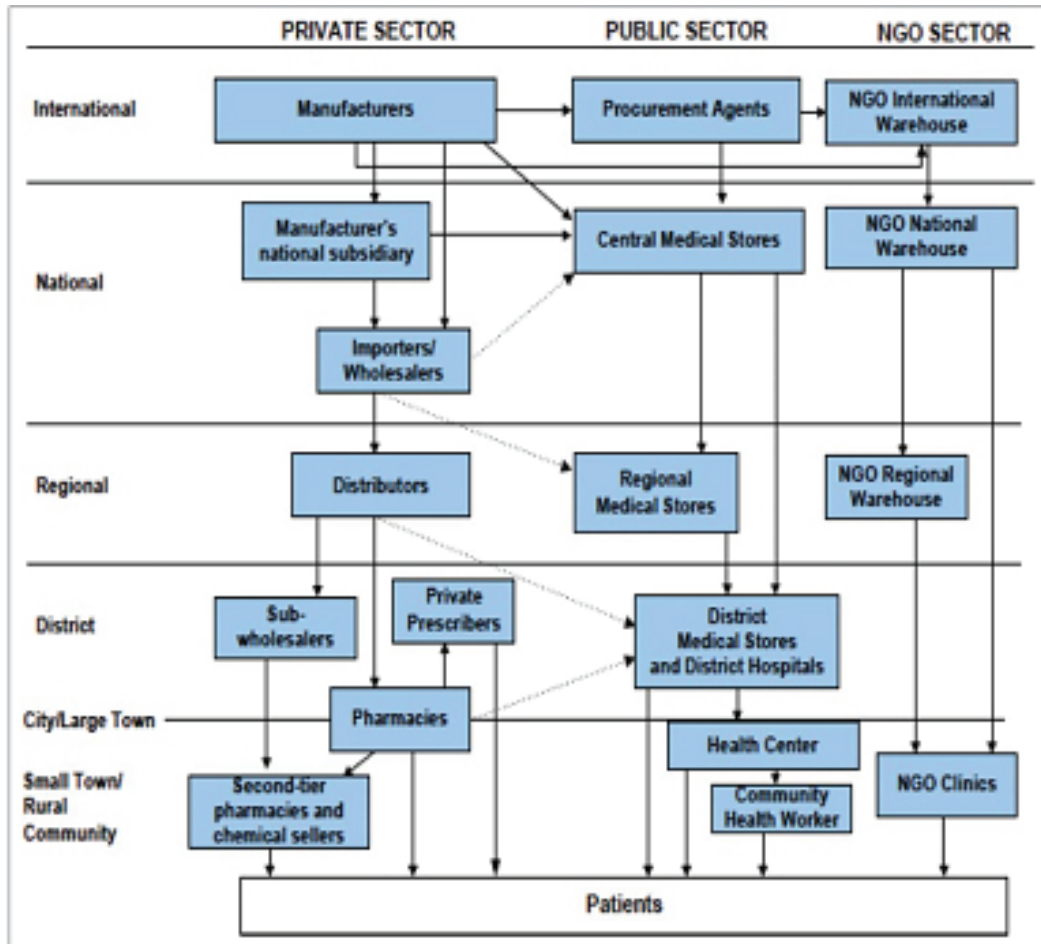


FIGURE 1 Health supply chain systems in developing countries

Source: Adapted from WHO, 2017

This system design creates multiple layers (tiers) of management and distribution of the health commodities and medicines, with many bottlenecks and inefficiencies created as a result of poor capacity, especially at the peripheral levels. The flow of information upwards and downwards in the system is very weak if not non-existent, which further contributes to the failure of the system.

The complexity is further exacerbated when there is relief and humanitarian operations in the country, with NGOs and other humanitarian agencies managing their own health supply chain systems. In most cases, these go in parallel to the national health supply system. This complexity generates many challenges, as demonstrated below.

CHALLENGES FACING THE PUBLIC HEALTH SUPPLY MANAGEMENT SYSTEMS IN LMICS

Loose accountability

The complex purchasing, importation, clearance, storage and distribution structure that involves multiple tiers in most LMICs creates a sense of diffuse accountability and inability or resistance to take responsibility; this is because of the fragmentation of the system and overlapping of responsibilities between CMS and health management staff at the district or facility level. The resulting stockout of essential medicines and commodities, or wastage of such important elements, further exacerbates the fear of responsibility, coupled with poor incentives. This is in addition to the failure of the system.

Corruption

In most of the countries, the responsibility of the CMS is to manage public purchasing, management of its own warehousing, and distribution of health supplies and medicines to the regional and district health levels. From there, the management of these supplies is under the jurisdiction of other departments in the district or regional health departments; the CMS has no authority on warehousing processes, including inventory building and verification. This loose and overlapping in accountability also contributes to the corruption and leakage of these publicly procured items to the private or black markets (Yadav, 2015).

Multiple levels of complexity with poor information flow

In most LMICs, there are at least three tiers or levels of administrative management of the health supplies and commodities: warehousing, distribution, and inventory management. The important flow and collection of information from one tier to another is very weak, and this results in the bullwhip effect phenomenon (Figure 2). Due to the long lead times, small variations in patient demand become amplified as the information passed along the various levels of the stock decision-making, from health facility to the district health department to the regional health authority to the CMS, and then procurement from the manufacturer. The result would be either an over-estimation of demand leading to waste, or under-estimation leading to stockout.

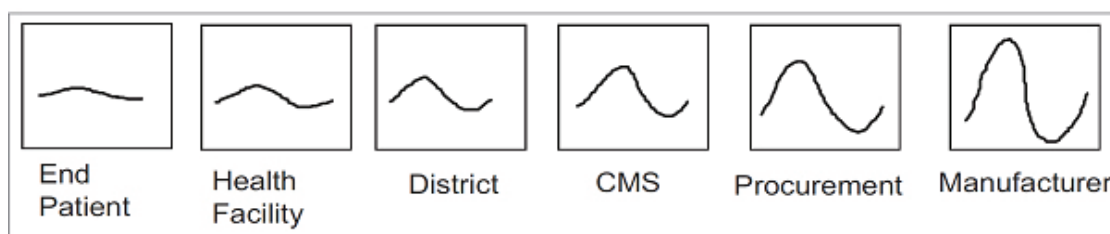


FIGURE 2 The bullwhip effect fluctuation in the demand along the supply chain tiers

Source: Yadav, 2015

Long time intervals for replenishment

Because of the very long procurement process, this is only done once a year. Improper procurement planning, especially in the absence of reliable information and data from the tiers below, delays the compilation and order placement process. Such delays can lead to stockout, which will have disastrous effects on the health outcomes of the population in LMICs. With the delay in procurement, the rest of the supply chain processes are also delayed (clearance, transportation, warehousing and distribution).

Pooled procurement of medicines and other health commodities

The WHO supports LMICs in accessing essential medicines, medical equipment and other health supplies at an affordable price and of good quality (WHO, 2007). The WHO encourages pooled procurement practices, especially among groups of countries who share some sort of political uniformity (i.e., regional political constituencies). The Global WHO meeting on multi-country pooled procurement of medicines and other health supplies, recommended that strong and high level political commitment is a prerequisite for pooled procurement programmes to facilitate the challenges of different regulations, standardisations and registration issues (WHO, 2007).

Figure 3 below illustrates the various models of cooperation between countries engaged in pooled procurement practices (WHO, 2007).

Obviously, the level of complexity in the supply chain management, even the purchasing side, increased with pooled regional or multi-country procurement. The number of stakeholders increases by a number equal to the number of countries participating. Additionally, the differences in regulations, processes, procurement practices and tiers at national level would require a very strong system with real time provision and sharing of information along the chain.

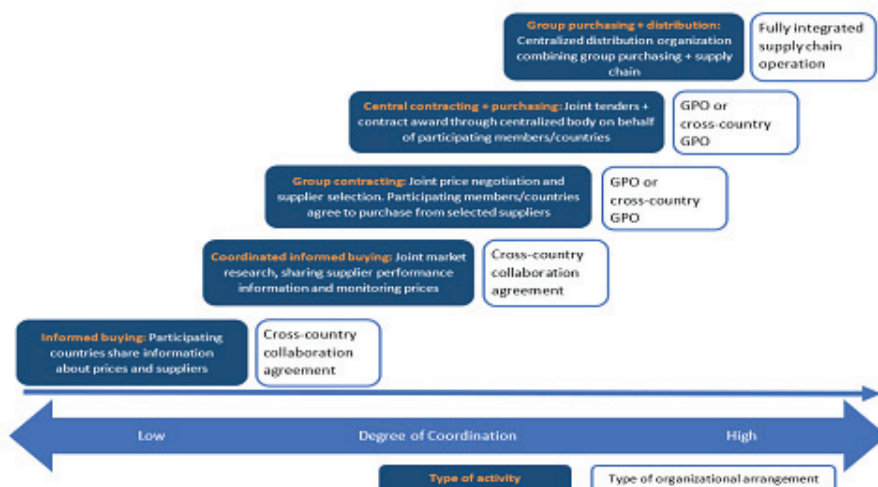


FIGURE 3 Modalities of cooperation in pooled procurement practices

Source: Adapted from Espin et al., 2016

Medicines and other health supply chain management in Sudan

The forecast, procurement and distribution of medicines and other consumables for the public sector in Sudan is managed by the National Medical Supplies Fund (NMSF), which is the successor of the National Authority for Central Medical Supplies Public Corporation (NMSF, 2015). The NMSF conducted reforms in 2011, aimed at streamlining business processes and modernising the tendering process with the introduction of the Electronic Procurement (e-procurement) and electronic tendering process (NMSF, 2015). With the first process completed in 2015, a 4% saving was made; increased transparency and reduced timing were also achieved. Nevertheless, procurement is just one step in any supply chain management system, so no major progress was made in the compilation of forecasts (which was done only through consultation with major public providers), transportation and tracking, storage and warehousing management, and fighting counterfeit medicine. The *HealthChain* will provide an ultimate solution and strong tool for gaining many benefits simultaneously, as explained in the next sections.

HEALTHCHAIN: A BLOCKCHAIN FOR A HEALTH SUPPLY CHAIN: RATIONALE

What is a blockchain or Distributed Ledger Technology (DLT)?

Blockchain is a distributed, cloud-based network that provides a secure, immutable and trusted platform for exchange of values, IP content and/or other personal or institutional records. Developed initially to support the BitCoin platform that allowed the online exchange of value without an intermediary, its potential was quickly realised to include in most industries and sectors (Shrier and Pentland, 2016:5–6). When data are added to the blockchain, it is done chronologically. Each block contains the relevant encrypted data, which is referred to as a hash, and the hash of a previous block. The kind of data contained within a block depends on the type of blockchain being utilised. Figure 4 below illustrates the decentralised nature of blockchain.

Decentralized Ledger

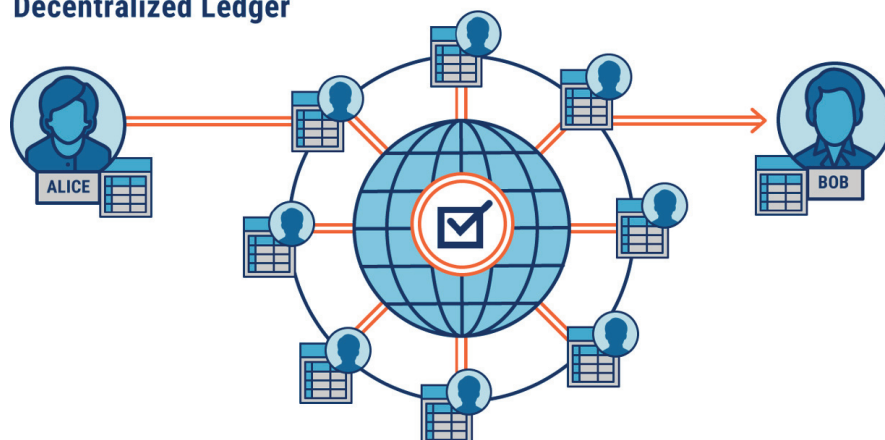


FIGURE 4 Basic structure of a blockchain decentralised network

Source: Oxford University, 2018

The basic structure of blockchain is of three layers:

1. the foundational protocol layer that gives the basic commands through which the network operates;
2. the network layer, which enables the various members of the blockchain to get connected; and
3. the application network, which is the interface (Dresher, 2017).

The Blockchain development stack is illustrated in Figure 5.

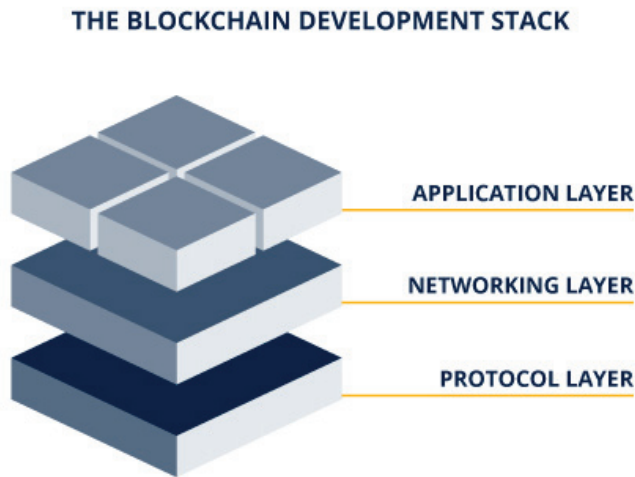


FIGURE 5 Blockchain layers

Source: Oxford University, 2018

In terms of public access, blockchain networks are either open or closed. The public access is further divided into permissionless, which means any member can access and execute a transaction, or permissioned, where certain members enjoy such privileges (Hileman and Rauchs, 2017:20). In addition, some enterprises have developed closed blockchain networks.

Would blockchain provide a solution for Health Supply Chain Management?

To answer this question, it is important to consider the features that blockchain provides vis-à-vis the problems and challenges currently facing the health supply chain management in LMICs. We will try to use the Oxford University Blockchain Strategy framework, which outlines the following key questions or criteria (Oxford University, 2018).

Is there a predictable, repeatable process that lends itself well to automation?

This is a definitive feature of Health Supply Management Systems in all countries. Governments, or even the private sector, do not set up an entire system and operations for a one-time procurement and distribution process. In addition, the function of a proper supply system is to predict needs based on the information collected along the chain. The current automation practices are limited to some application systems that were developed to support the bidders' registration, tendering and exchange of documents. However, these systems do not integrate with other stakeholders' systems (suppliers and customers) nor do they provide any information on the status of the procured and distributed commodities.

Is there an ongoing or long-running transaction or process, rather than a process that only occurs once?

The health supply chain includes forecasting and planning the required medicines and health supplies, then sourcing (including acquiring information about suppliers and prices), tendering, contract allocation and signing, and eventually delivering, transportation, arrival at the port of entry, customs clearance, warehousing (CMS) and distribution to the regional or district levels. All of these processes involve numerous challenges and often encounter delays.

Are there multiple stakeholders in this process or value chain?

Similar to any other supply chain, the health supply chain process is a lengthy, multi-faceted and multi-stakeholder process. Stakeholders involve manufacturers, suppliers, transporters, handling and clearance agents, CMS agents (including warehouse management), distributors (including fleet and other operational aspects), regional or district health management staff, local transporters, and finally, health facilities where supplies are finally dispatched to the end user.

Is the role of reconciling disparate data usually played by one party or a limited number of parties?

The health supply chain includes multiple data sources for the chain management. First, the requesting agency or entity (e.g., CMS) would have its own data inventory of these health supplies, then the distributors (who might have their own lists), followed by the regional and district health management with another layer of data source, and finally, the health facilities where the supplies reach the end users. Using blockchain would eliminate all redundancies and improve efficiency.

Is there an element of value transfer?

There are multiple values being transferred through the supply chain process. First, is the actual value of the supplies being managed (commodities, medicines, food, etc.). In addition, the time that is currently wasted in tracking and auditing the transactions is also a valuable asset that would be saved.

Is there value in an immutable record? Or is an immutable record a requirement?

Health supply chain management, especially in the public sector, needs to be properly managed against mis-use and fraud; this should be done through an audit process. Most of the current records are kept in an electronic inventory or database, which is prone to tampering. A blockchain-based supply chain would provide an immutable, distributed ledger that would satisfy these requirements. Any attempts to tamper with the data stored along the blockchain would invalidate the entire chain, and the tampering would be recognised. This would increase trust in the Health Supply Management System and reduce corruption.

HEALTHCHAIN AND THE SUSTAINABLE DEVELOPMENT GOALS (SDGS)

Strong Health Systems (SDG3)

All the targets under SDG3 depend on strong, resilient and sustainable health systems, and other systems, that enable positive health outcomes. The WHO identifies access to essential medicines and technologies as one of the building blocks of health systems. In the LMICs, where the health systems are fragmented and weak, health supply chain management is one of the areas that can demonstrate many efficiencies through proper forecasting and utilisation of regularly accessible health supplies.

The Heads of State issued a Political Declaration towards Universal Health Coverage (UHC) in September 2019; this reemphasised the need to progressively provide one billion additional people by 2023 with quality essential health services and quality, safe, effective, affordable and essential medicines (UNGA, 2019). The Global Action Plan (GAP) for SDG3, which includes a dozen UN agencies, Funds and Programmes and other multilaterals, calls for aligned efforts and financing, and accelerating progress in areas including R&D of innovation and access, data and digital health that provides a political premise for the *HealthChain* to be explored as a potential solution and accelerator towards Universal Health Coverage and the achievement of the SDGs.

Social Justice and Equity (SDG 10)

The *HealthChain* system will allow an equitable distribution of health supplies, medicines and vaccines; this is because the information sharing along the chain would make a sound prediction of the needs and evidence-based decision-making of distribution according to the needs of the population, not the demand.

Sustainability in health procurement (SDG13)

With the increasing tendency in the public health sector procurement towards ensuring environmental preservation and reduction of the carbon footprint through operations, the *HealthChain* will facilitate the exchange and sharing of information about the commitments of the manufacturers and their countries, efficient shipping routes, and reduced paper work.

Fighting corruption and fostering collaboration (SDGs 16 and 17)

The immutable, single record of truth provided by the *HealthChain* will make it almost impossible to commit fraud and corruption in health procurement and distribution. The whole record of the operation would be available for public audit and review. The availability of real time information and exchange of such information will further increase collaboration among countries (buyers) and global manufacturers and their governments. This will lead to better pricing and quality, more commitment and shared values (Figure 5).

Blockchain: One Truth Across Networks for the Supply Chain

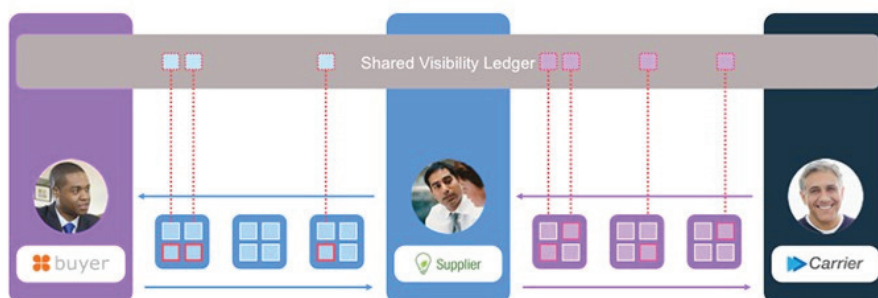


FIGURE 6 Data visibility in a blockchain enabled supply chain

Source: Khaitan, 2017

Fighting counterfeit drugs and other health commodities

The increase in global counterfeit or fake drugs and other health commodities has increased to almost US\$431 billion per year and is still increasing; this is especially true of online sales where 10–70% are selling fake medicines (WHO, 2019). The risks vary from contaminated products to sub-optimal or increased therapeutic dose, leading to an estimated one million deaths per year (WHO, 2019). Other global problems include Antimicrobial Resistance (AMR) and loss of financial and human capital. A blockchain based health supply chain management will contribute to the reduction of this problem as it will be more practical to trace the authenticity and quality of medicines across the chain.

In line with WHO strategic priority on strengthening regional and country regulatory systems for proper delivery of medicines and medical supplies towards Universal Health Coverage (WHO, 2019), the system will also facilitate regulatory functions and monitoring by central authorities. This is because the system will provide a unique product identifier that can be easily checked for validity.

Even in public health emergencies, such as emerging diseases and pandemics that require different and speedy working modalities than the “business as usual” practices, the regulations that ensure the quality of medicines, vaccines and other equipment are often ignored for the sake of fast delivery of the supplies to address those emergencies (WHO, 2019). The system has the capacity to ensure the authenticity and safety of the medicines and other products used.

Proof of Concept (CoP)

Global handling and shipping companies, such as the giant *Maersk* (which manages global shipping and handling with offices and staff all over the World), are working on a blockchain system with IBM for their global networks (Carson et al., 2018). For supply chains where participants are not known or trusted, blockchain technology can add trust, transparency, and traceability. Almost by definition, these supply chains are complex, multi-tiered, involve many parties, and operate in a regulated environment that demands a higher level of traceability.

Improvement of the current systems

It is important to understand and distinguish that *HealthChain* is not a substitute for the NMSF; rather it modernises it to the greatest extent possible and increases its mandate on the overall public sector health supply chain management. It will help to streamline not only the procurement and distribution processes by the public and private sectors, but would also accommodate medicines and health supplies procured, for instance, by the humanitarian sector.

HEALTHCHAIN: FEATURES AND STRUCTURE

As explained in the introduction, the basic structure of the blockchain development stack is composed of three main layers: protocol layer, network layer and the application layer. For the protocol layer, the design is influenced by the following question: is it possible to use a public blockchain? Or is there a need for private implementation? What are the design expectations in terms of programmability, scalability, interoperability and payment structure (if any)? Are there developer's resources available, or will the development of the basic protocol rely on a robust, sustainable open source developer community? (Oxford University, 2018). Below is the preliminary vision of the *HealthChain* stack.

Protocol layer

The *HealthChain* will be a private implementation blockchain. The objective of the design is to improve efficiency, reduce costs and increase accountability. The stakeholders involved in the supply chain are defined entities or individuals who have very specific roles in the process. The design is managed by a central entity (i.e., Central Medical Stores) on behalf of the country (or central secretariat on behalf of several countries) for greater accountability. However, it is still possible that the records from this ledger could be exported and viewed by the public.

The design needs to have moderate speed because, although it is a private ledger, the number of the various users (nodes, miners and exchanges) could easily be in the thousands. For example, the supply chain blockchain needs to configure a smart contract component as it is an essential feature of smoothening delivery and payments after physical verification. Therefore, the programmability has to accommodate that feature.

Even when it is a private blockchain system, it will still be primarily used for the public benefit and will, therefore, require collaboration from a wide range of developers and institutions through an open-source community of developers from all over the world to support the development of the protocol; this is a demonstration of SDG 17. Furthermore, the open source will ensure the sustainability of the project, as it is established at zero cost and will continue to fix the bugs in the system.

From the basic design of the protocol, it should be able to demonstrate the “interoperability” feature of the blockchain. As the *HealthChain* will be operated by a wide range of stakeholders, including private sector (manufacturers) and public sector entities (customs, CMS, etc.), it is important that the protocol can be integrated with the different systems and software used by these institutions to ensure integrity and capturing of various information.

The other benefit of having an open source community of developers will be the possibility of protocol upgrades in the future being interoperable with the expected features of the so called “Fourth Industrial Revolution”. In this, Artificial Intelligence (AI), Internet of Things (IoT) powered by 5G Internet speed and based on “Big Data”, materialises and shapes the World.

Smart contract and proof of work

A key feature in the *HealthChain* protocol will be the Smart Contract (SC), which is basically an electronic record of terms and references of the specific purchase order (specifications, quantities, validity and date of delivery). When a manufacturer meets these terms through the Proof of Work (PoW), the SC automates the second part of the transaction, which is the payment of the specified amount against the purchase order. Similarly, for the distribution of supplies in the country, when the regional or district health management submits the supply request, the PoW here is the reconciliation report of the previously distributed commodities, coupled with the regional or district forecast report. Then, the SC (which will have different terms here) allows for the dispatch of the requested and agreed on quantities.

Network layer

The network of the *HealthChain* will be a viable structure and will include all the stakeholders that are relevant to the health supply chain. These will include manufacturers, global transporters and shippers, customs agents, local shippers, CMS staff, regional and district health management staff, health facilities administration, and the dispatchers at the pharmacy or dispensing windows.

The nodes in the *HealthChain* network should be run by staff members who are not involved directly in the various stages of the supply chain life cycle. For example, clerks and/or accountants who are currently managing payments could be turned into that role as payments will no longer need to be processed manually; SCs will substitute this excessive and slow paperwork. Writing access will be allocated to requesters, who would specify the needs, amounts and values (along the chain), and for the suppliers who would transfer these supplies on the *HealthChain* network. Reading privileges would be allocated for the handlers (who would review and verify the amounts) and for the regulators (customs or other border-control entities) who would need to ensure that fees are accurately calculated.

As there are various payments involved in the process, the blockchain needs to be integrated with SCs to facilitate and accelerate payment processes. If some of the ports of entry or warehousing use smart handling processes (robotic movers or cranes), the system needs to be configured so that once payments are received, the physical execution of the Proof of Work (delivery of supplies) is linked to the machines that implement the process.

The data could be stored on a cloud-based distributed system of the CMS computers in various locations; this would provide the infrastructure with a distributed, immutable system, and would facilitate the audit and review processes. The regulations would need to encompass various regulations in different locations, which could be difficult.

Application layer

The application is the interface part of the system where the stakeholders use and interact with the blockchain network. Therefore, almost all stakeholders will use the supply chain blockchain application. This would include requesters, vendors, manufacturers, shippers,

regulators and warehouse workers and distributors. The application should be simple and user-friendly, but also coupled with appropriate orientation or training.

Similar to any change, introducing blockchain in the current supply chain systems will require some changes in the organisational structure; it will also need the engagement of all staff to ensure acceptance. In the structure, some functions will no longer be needed, such as accountants, payment processors and contract designers, while others will be reduced in numbers, such as logistic officers and warehouse staff. Some functions will need to be created, for example, protocol developers and upgraders, system strategists and SC specialists.

For successful transition, it is important to anticipate and manage the stress and negative behaviour from all staff. First, very good communication throughout the process is key to ensure that staff are well briefed on the process and its value, then adequate training and human resources will be needed to ensure they are skilled to use the new system. Before fully operating the new system, it is important to pilot it first on a small scale to check for efficiency and to manage any problems that may arise.

Stakeholders along the *HealthChain* development stack

Due to the complexity of the health supply chain, various stakeholders are involved in the process from the cradle (manufacturing) to the grave (end use) of health supplies, medicines and commodities. Figure 6 below illustrates the proposed *HealthChain* development stack and the potential stakeholders.

HealthChain and Stakeholders DIAGRAM

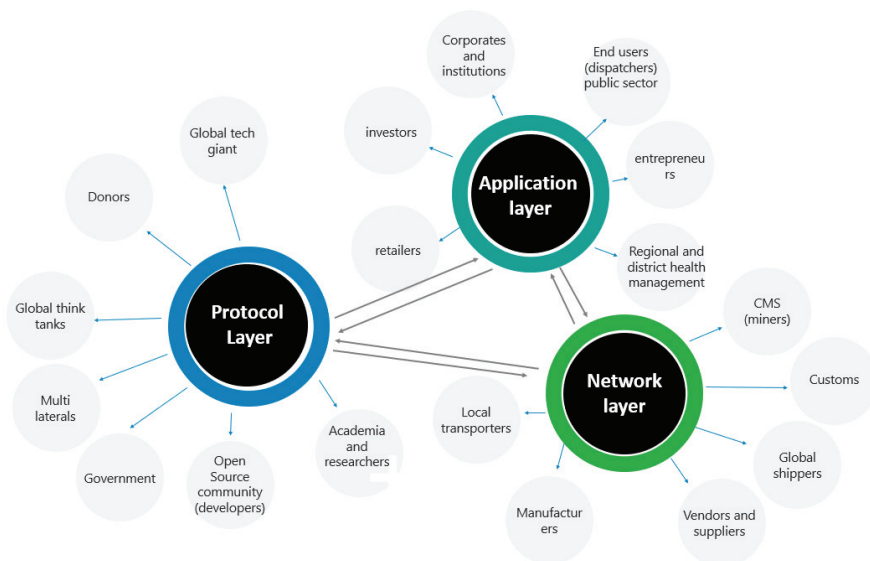


FIGURE 6 *HealthChain* basic development stack

Source: Devised by author

HEALTHCHAIN ECOSYSTEM MAP

Adapted from the Oxford Blockchain Ecosystem map, Table 1 below outlines examples of the stakeholders along the *HealthChain* development stack, their roles and motivation.

TABLE 1 *HealthChain* Ecosystem and stakeholders along the development stack

LAYER	STAKEHOLDER	ROLE	MOTIVATION
APPLICATION	Entrepreneurs and start ups	Build products and services	Driven by mission and profit
	Regional and district health authorities	Use of the technology to solve problems	Driven by accountability and improving performance
	Retailers and investors	Provision of capital to fuel growth	Financial
NETWORK	Exchanger and traders (most of the network)	Facilitate the transactions in the chain	Smoothing processes and profit
	CMS (miners)	Validate transactions	Equitable access to health supplies
PROTOCOL	Handlers	Moving of the supplies	Financial, reputation
	Developers	Set the protocol development map	Intellectual curiosity
	Academia	Drive the research and evidence	Knowledge
	Donors, multilaterals, government	Regulation, observation and support	Cost-efficiency, equity and prosperity

Source: Devised by author

HealthChain regulatory framework

The speed at which the blockchain and the DLT have evolved over the past few years has been much more progressive than the ability of the regulations and regulatory frameworks to adapt, even in developed countries. As a disruptive technology, the question of its regulation became elastic as technology changes exponentially. At the same time, social, economic and legal systems change incrementally (Borg and Schmebri, 2019). In most countries, there are national regulations that generally govern the registration, importation and handling of medicines, medical equipment and health supplies. In the United States for example, and following a nation-wide meningitis outbreak that was traced back to a pharmacy that engaged in drug manufacturing in violation of its state license, the Congress enacted the Drug Supply Chain Security Act (DSCSA).

It is therefore important to consider developing international guidelines and a regulatory framework for the *HealthChain*, after the pilot phase. It is advised that the regulatory framework is guided by the principles shown in Table 2; these would encourage innovation and at the same time protect the social, economic, health and other human and civil rights (adapted from the Oxford Blockchain Regulatory Framework).

TABLE 2 *HealthChain* regulatory framework

<i>Principle</i>	<i>Description</i>
Outcome focused	The desired outcome is the equitable access to medicines and health supplies, so the regulations should assess that the behaviour is aligned with this outcome.
Stakeholder protection	The interests of all stakeholders and parties are considered (private and public)
Building and fostering trust	The regulations, and actions around enforcing or applying them, should promote trust in the system, coupled with transparency, enabling a predictable and stable market and delivery of supplies.
Balanced competition	The regulations should support multiple competitive parties and promote “fairness”, avoiding monopoly and bias.
Promote innovation	New ideas should be permitted “an incubator to explore”, provided that the other elements of the regulatory framework are not adversely affected.
Respond to crisis	The regulations should be flexible enough to quickly respond to any unforeseen crisis and thus allow modification of policies.
Independent	The regulations should independent of the political process or dynamics in the country or region.

Source: Devised by author

It is important to engage in a deep discussion that encompasses all global political and other international partners in this process. Ideally, this discussion should be under the umbrella of the United Nations, through a dedicated global commission to outline a global policy. Stakeholders should include representatives from all those anticipated to be in the *HealthChain* at the global level, in addition to the International Health Agencies (WHO, GF, GAVI, PEPFAR, etc.), NGOs, academic institutions (law schools), global manufacturers and distributors, governments, CSOs, etc.

Additionally, the Interagency Pharmaceutical Coordination Group (IPC), involving advisors from UNICEF, UNFPA and WHO, needs to update the International Pharmaceutical Guidelines that were published in 1999 to encompass the changes in the international pharmaceutical market. These guidelines should also address the introduction of innovation and technology; this is providing opportunities but also challenges such as an explosion in online pharma, which is the main hub for the sales of counterfeit medicines and pharmaceutical commodities.

UNDP AND UNICEF POTENTIAL PARTNERSHIP AND COLLABORATION

UNICEF and UNDP launched a joint initiative in 2019 to encourage and foster innovation in the various areas that are relevant to the work of the two agencies. In this approach, the

two agencies are exploring partnerships with public and private institutions to bring in new solutions for the 21st century challenges that are hindering the achievement of their objectives and missions. The volume of annual health supplies and medicines procured by the two agencies (and potentially other multilaterals) offers a very good position to leverage and shape the global supply market by introducing innovation and technology and fostering public private partnership around them.

In 2018, out of the total US\$18 billion that was spent on the procurement of various commodities by various UN agencies, Funds and Programmes, US\$3 billion was used to procure pharmaceuticals, vaccines and other health commodities (Figure 7).

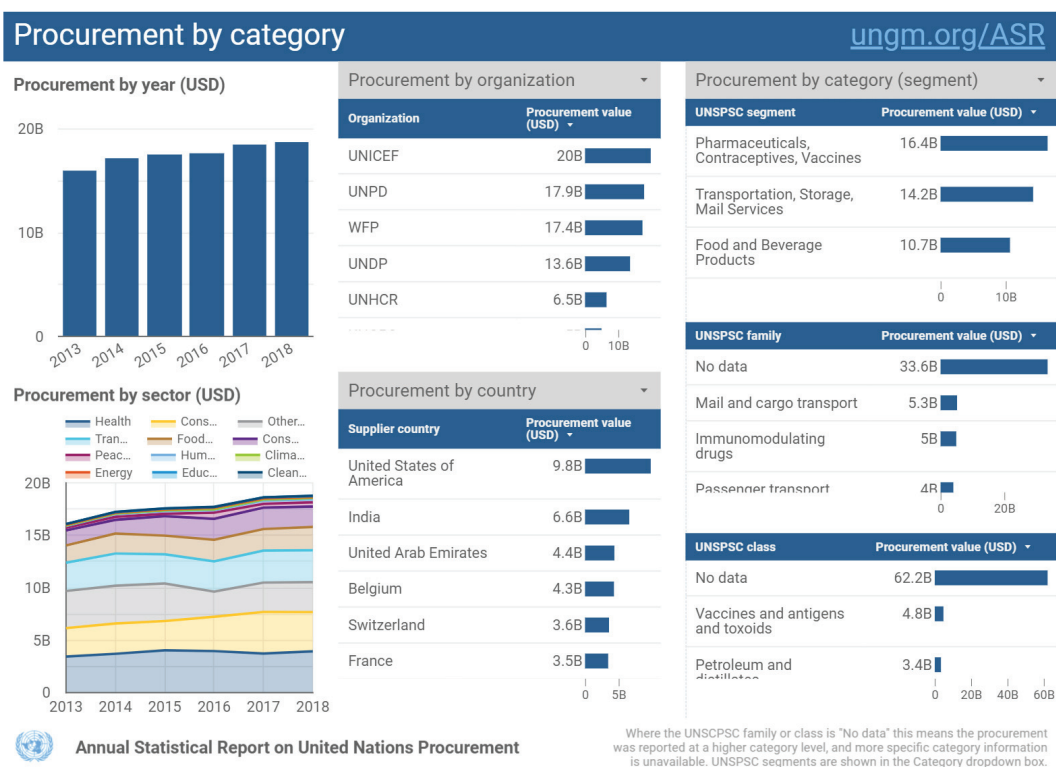


FIGURE 7 UN annual procurement by agency, sector and supplier (ungm.org)

Source: UNOPS, 2019

The Sustainable Procurement in the Health Sector (SPHS) is a multi-agency and multi-stakeholder partnership between various agencies and other multilaterals that procures large segments of global health supplies and commodities. It aims to promote the use of efficient materials, reduce waste, and prioritise products with low carbon footprints, and can create cost savings and environmental and health benefits. This unique partnership, although relatively young, was able to influence the production practices among major global pharmaceutical suppliers, including pharma industries from Europe, Asia and Africa, to introduce and implement practices that will reduce their carbon footprint and improve packaging and shipping procedures.

This example demonstrates the added value of partnership and working together to influence and shape the global market. *HealthChain* is another frontier that UNICEF and UNDP (and potentially other global health agencies) can use to leverage their procurement power to solve some of the complex challenges facing the current health supply management, especially in LMICs.

CONCLUSIONS AND THE WAY FORWARD

As iterated in the previous chapters, the *HealthChain* is a promising innovation that has many distinct advantages through leveraging technology, big data and potentially artificial intelligence to ensure wide and equitable access to medicines, health supplies and commodities. By design, the *HealthChain* will foster an unprecedented global collaboration between countries (SDG17) as it will ensure the protection of all parties' interests. Fighting corruption and improving efficiencies is a key definitive feature of the *HealthChain*, that also addresses the increasing global problem of counterfeit medicines and commodities, which further worsen health outcomes.

To move forward, the *HealthChain* will require an incubation within an innovation lab or any other initiative for a piloting phase through a joint effort and partnership (UN, Government, Academia and the private sector) to develop the basic protocols, build up the ecosystem (network and stakeholders) and run trials (with dummy transactions) to fix any bugs that might occur in the system. This would be followed by additional trials with real transactions on a small scale along the system, forecast and compilation of demand information from health facilities all the way to the national level, and then placement of a purchase order, allocation of the contract and delivery of the supplies. Throughout the pilot phase, the collaboration and communication between the various partners is key to ensure success, and to capture any bottlenecks or bugs. Training of the stakeholders along the chain is key during the pilot phase.

Once the pilot phase is successfully completed, the project can then be taken into scale and offered as a key development and technology solution, primarily to LMICs, but also to OECD countries that might wish to fix their current health supply chain systems.

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BIOGRAPHY

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