A Blockchain-Based Solution for COVID-19 Vaccine Distribution

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IEEE DOI 10.1109/EMR.2022.3145656

Abstract—*The COVID-19 vaccine distribution chain faced multiple challenges associated with the lack of production capacity, security issues, and miscommunication between different actors. Blockchain technology has been shown to solve the security and miscommunication issues in other industries. We first identify distribution chain challenges via literature reviews and primary interviews. Case studies that solved these challenges in other industries also served as a source. This information allowed us to devise a blockchain framework for the vaccine distribution chain and evaluate its application feasibility. We present the framework using data flow diagrams. The proposed framework helps minimize the circulation of counterfeit vaccines and vaccination records, improves communication between stakeholders in the distribution chain, increases supply chain security, and simplifies vaccine inventorying and handling processes.*

Key words: Blockchain framework, data flow diagrams (DFDs), vaccine supply chain

1. INTRODUCTION

IN December 2019, a novel variant of coronavirus, which could infect humans, was found in Wuhan, China [Mackenzie and Smith, 2020]. The rapid spread of the virus and its fatal nature due to the induction of major respiratory illness in the sick have forced nations to impose strict quarantines for all citizens. The prolonged quarantine has forced many small and medium businesses to close, causing an increase in the unemployment level across the globe [Jones, 2021]. The development of a vaccine to battle this virus has thus become a critical task to prevent future deaths and restore the global economy [Graham, 2020].

The U.S. Food and Drug Administration had authorized three vaccines for safe vaccination of the U.S. population. Getting these vaccines to U.S. citizens as quickly as possible became a number one presidential priority [The White House, 2021].

A supply chain is all the steps that are involved in creating the product from raw materials and then delivering it to the customer. This includes the movement and transformation of raw materials into the product, and transportation and distribution of the products to the end customer. The supply chain for vaccines is referred to as the *cold chain*, due to the fact that vaccines have to be transported at specific temperatures in order to maintain their efficacy. Maintaining the cold chain requires the use of special transportation and storage facilities, personnel training, and efficient management procedures [Ylanmui, 2020].

1.1 Overview of the Postproduction Cold Chain

We only focus on supply chain activities after the vaccine has already been manufactured and is ready to be packaged at the producer's facilities, which we will refer to as the vaccine distribution chain (see Figure 1). The vaccine distribution chain of the Pfizer-

BioNTech mRNA COVID vaccine—from here the *vaccine*—is our focus.

After vaccines are manufactured, Pfizer organizes them into special thermal boxes with dry ice to keep vaccine batches cold and maintain their efficacy. These thermal boxes are then shipped by FedEx or UPS—third-party logistics providers—directly to the point-of-use site. The location and the temperature sensor inside each box allow Pfizer to identify any harm that could have led to spoilage of the vaccines. Upon arrival at the administration site, the thermal box can maintain the required -70 °C temperature for up to 10 days if left unopened [Pfizer, 2021].

At the administration site, the vaccine coordinator (VC) manages the vaccines. The VC is responsible for inventorying the incoming shipment and placing each batch in a special refrigerator or freezer. The VC has to record the daily minimum and maximum temperatures reached by each of the vaccine storage freezers. They also perform weekly inventory balance calculations.

Before the administration site is allowed to submit an order for new vaccine shipment, the VC must complete a full inventory recount [Oklahoma State Department of Health, 2017]. The final step in the vaccine distribution chain is the administration of the vaccine to the patient. After the doctor prepares a dose and issues it to the patient he has to create and submit a proper COVID-19 Vaccination instance to the Vaccine Administration Management System (VAMS) [Centers for Disease Control and Prevention, 2021b].

Based on the CDC guidelines, the vaccine's provider has to record various information about the vaccine, patient, and the issuing doctor and submit them to VAMS [Centers for Disease Control and Prevention, 2021a].

1.2 Distribution Issues and the Blockchain

The issues of the current vaccine distribution process can be broadly categorized into four categories: i) physical limitations—such as lack of manufacturers and manufacturing capacity, low supply of raw materials, lack of nurses and facilities [Sell, 2021]; ii) communication issues—such as inaccurate vaccine distribution planning ([Lee, 2020]; [Alam, 2021]), lack of communication between stakeholders [Segal, 2021]; iii) security concerns—such as cyberattacks [Person, 2019], misinformation of the public and counterfeit vaccines and records ([UNODC, 2021]; [Hopkins and Córdoba, 2021]; [Bernaert, 2021]; [Pawlowski, 2021]); and iv) efficiency difficulties—such as mishandling [Murakami, 2021], lack of digitization [IIF, 2021], and lack of a unified database [Kenen, 2021].

Blockchain technology may help address some of these issues, specifically communication, security, and inefficiency challenges. The blockchain is a distributed ledger technology that has been shown to overcome security and communication problems in a variety of industries. A blockchain solution for the vaccine supply chain could enhance user trust in the vaccine and encourage them to get vaccinated. It could also decrease vaccine management and distribution costs for the manufacturers, distributors, and providers.

The goal here is to identify the key communication and security challenges facing vaccine distributors and providers, determine how blockchain could alleviate these challenges, and finally design and present a blockchain solution for vaccine distribution.

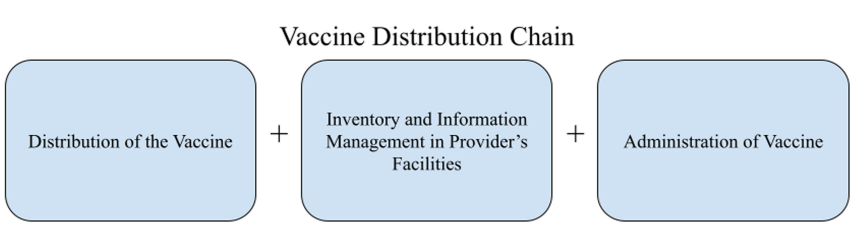

Figure 1. Steps in the vaccine distribution chain.

2. Background Information

2.1 Overview of Blockchain and Its Merits in Supply Chain

Blockchain technology is a decentralized digital ledger system that records information and makes it almost impossible to modify the content that was previously published to it. The technology utilizes a linked-list structure using cryptography to secure the privacy of the information. It is then distributed over a peer-to-peer (P2P) network utilizing a specific consensus mechanism to maintain the order of the verified transactions added to the ledger [Wright, 2008].

This emerging technology has attracted significant industrial interest—from banking to healthcare to consumer goods—due to its transparency and reliability. The application of blockchain in the industry can help reduce costs associated with data discrepancies in a company's information systems [Longo, 2019]. This technology orders transactions and groups them in a constrained-size structure named block. The network nodes or peers are responsible for linking the blocks to each other in chronological order, with every block containing the hash of the previous block to create a *chain* of information-carrying blocks linked to each other, hence providing the name *blockchain.*

Blockchain's decentralized data ledger supports data transparency and homogeneity and simplifies cooperation and communication between different actors. It allows users to see changes in the ledger, in almost real time [IBM, 2021a].

Blockchains can increase security and trust in multiactor chains due to the immutability of records and the ability to encrypt any sensitive data, as well as clearly verify ownership transfer along the whole supply chain [Thomas, 2021]. Another element of blockchain is smart contracts that automate transactions and business processes that reduce the chance of human error and allow for the creation of autonomous, self-improving systems [Queiroz and Wamba, 2019].

2.2 Blockchain-Based Solution for Vaccination Supply Chain Blockchain has been used to monitor the conditions of shipments and quickly record shipping violations on the chain [Alkhoori, 2021]. This simplifies the process of shipment inspection and allows for quick identification and evaluation of damage incurred by the shipped goods. The use of Internet-of-Things (IoT) devices and smart contracts allows for trustworthiness and accountability.

High-level blockchain architectures for vaccine delivery from the manufacturer to the provider have been developed with entity-relationship diagrams showcasing the relationship between the stakeholders and the system, and the algorithm functions—the smart contracts—executed by the system [Musamih, 2021].

Blockchain solutions for managing vaccine storage at the provider level have also been recommended [Kahn, 2021]. The solution was similar to existing systems that track cold chain upkeep for chemotherapy drugs, blood supplies, and ophthalmological drops. The results showed lessened medicine waste.

Blockchain solutions for broad vaccine distribution chains, from manufacturing to inoculation have been proposed—however, they did not explicitly address the components required at each layer to maintain such a system (e.g., see [Yong, 2020]; [Carniel, 2021]).

These blockchain solutions for vaccine distribution included elements of machine learning for forecasting and management [Yong, 2020]. Various actor roles and actor data requirements were also evaluated to offer a suitable decentralized application (dapp) for registering a vaccination instance [Carniel, 2021].

Research completed to date has focused either on developing blockchain frameworks to streamline the effectiveness of vaccine distribution from the manufacturer to the provider or on solutions for the providers' facilities. However, they do not offer an overview of a framework to encompass all parties. Some do present a working solution to assist all stakeholders and have commented on the data flows, user roles, and machine learning algorithms that can improve those systems for the public but did not mention the blockchain components required to develop such solutions.

We will bridge this gap in research and practice by developing a blockchain framework to encompass the needs of multiple stakeholders in the distribution network. We will showcase the components necessary to maintain such a framework, describe how the framework will be integrated into the current vaccine distribution chain, function it will perform, and present the information flows within the proposed system.

3. Methodology

Blockchain architecture is introduced to alleviate the most pressing issues in the vaccine distribution chain. We initially identify key challenges in the vaccine distribution chain through preliminary research and stakeholder interviews. We then exemplify how blockchain could alleviate these challenges and evaluate framework validity with a blockchain expert. Finally, we showcase the finalized blockchain framework, its layers, and its components, as well as present how this model will be embedded into the vaccine distribution chain.

We performed primary and secondary research to identify the distribution chain challenges, their causes, and their impact. Secondary research was found in news articles and publications dating from December 2019 to August 2021. This list of challenges was then confirmed, disproved, and expanded through four interviews with vaccine distribution stakeholders—one individual overseeing and coordinating the distribution of vaccines in Massachusetts, and three vaccine providers, two working in hospitals in the U.S. and one working in Italy.

During the interviews, we also identified the key processes that particular stakeholder has to carry out as part of their job; these processes were then transformed into *use case descriptions* required to develop *data flow diagrams* (DFDs) for the proposed system.

The next step of the methodology was to determine whether a blockchain solution could, in theory, solve the issues identified by the vaccine distribution chain stakeholders. We identified existent blockchain supply chain solutions, which were used to tackle similar challenges in other industries. We analyzed these case studies and determined which components these solutions consisted of at each of the framework layers and concluded contributing blockchain merits.

To validate that the potential blockchain solution will successfully target distribution chain challenges, we performed an interview with a blockchain expert. The expert we consulted had experience working with IBM and designing decentralized solutions for supply chain management in two different industry sectors.

To ensure that we produce an economically and environmentally feasible solution, we also asked the expert if they could envision a faster or cheaper solution for dealing with that particular challenge. The expert suggested a different component combination from the proposed design. Despite the solution proposed being viable, it was not the most computationally effective, resource conscious, or legally feasible choice to deal with those challenges. Having confirmed the future blockchain components with an expert, we provided a general description for each of the future components, as well as the justification of their merit for the vaccine distribution chain. The final list of components was then presented in a general layer framework layout.

The final step of the methodology was to present the proposed framework via a process model, to show how this blockchain system will be embedded in the existing vaccine distribution chain. The purpose of this step was to detail the business processes or functions that the system will perform, what data passes from and to these functions, as well as who is responsible for contributing the required data to the chain. To define the system's external entities, processes, data flows, and data storages, we reviewed the system use cases gathered during stakeholder interviews.

4. Blockchain Framework for Vaccine Distribution

In this section, we present the findings and analyses of data collected, an overview of the framework that will help alleviate vaccine distribution challenges, and some of the framework's limitations and issues. The key challenges in the vaccine distribution chain were identified. These include planning and communication issues due to system discrepancies, circulation of counterfeit vaccines and records, cyberattacks, vaccine mishandling issues at provider's facilities, lack of digitization in provider's facilities, poor vaccine packaging, small number of manufacturers, and inadequate legislative policies.

4.1 Proposed Blockchain Framework Blockchain solutions have a framework structure that is composed of several architecture layers. Each layer identifies how blockchain will interact with various physical components or users. The general blockchain framework was derived from several sources ([Liu, 2020]; [Tan, 2020]). The framework is summarized diagrammatically in Figure 2.

Six layers exist perception, network, data, blockchain, application, and user layers.

The *Perception Layer* defines the set of sensors to monitor the status of supply chain logistics. The perception layer includes quick response (QR) codes and smart containers. The QR code component is required to deal with the counterfeit vaccines issue. Similar to Bumble Bee Seafood QR-coded fish [Bumble Bee, 2020], our solution involves individual QR codes for each vaccine vial and every vaccine batch to help battle counterfeit vaccine issues. The smart containers can safely digitize the hospital cold chain storage system, improving the facility's environmental footprint and decreasing the likelihood of vaccine spoilage.

The data and information gathered by the perception layer are transmitted to the blockchain network or to a particular node via the *Network Layer*, which consists of different communication channels including 4G/5G, Bluetooth, and TCP/IP ([Liu, 2020]; [Tan, 2020]). Our network layer consists of the 4G/5G Network and standard TCP/IP. 4G/5G Network connects the smart containers to the blockchain, ensuring that the critical temperature data are published to the blockchain even in case of a power outage and when the vials are being transported from the manufacturer to the distributor's or provider's facilities. Utilizing smart containers connected to the blockchain through a 4G Network derives from the CryptoCargo use case [Alkhoori, 2021], as a feasibility check. The second component, TCP/IP, will be used to connect participating distribution chain stakeholders' computer devices to the blockchain network and allow them to post information to it.

The *Data Layer* determines whether the information transmitted to the blockchain will be processed on-chain, off-chain, or in a hybrid manner—some parts processed and stored on-chain and other parts off-chain [Liu, 2020]. Since we will not be storing or transferring the sensitive and byte-heavy medical record data within this system, the optimal solution will be to complete and store all transactions on-chain—this was reinforced by the blockchain expert.

This solution will also help prevent transfer issues and inefficiencies when integrating on-chain and off-chain data storage. Transparently storing all the data on-chain will allow all actors to use one unique decentralized database and will help solve miscommunication issues between different stakeholders. A fast consensus protocol like the Proof of Authority will allow all transactions to be published to the chain in almost real time.

The *Blockchain Layer* is a *rule book* dictating what comprises the block within the blockchain, how the system will verify the new block's legitimacy, how to aggregate data on the distributed ledger, access permissions for the blockchain, and how those permissions will interact with the blockchain. This layer also contains the programmed algorithms—smart contracts—that make the system capable of performing logic and actions that enable supply chain automation [Liu, 2020].

The P2P Network chosen for this layer will be a consortium network. Since there are multiple stakeholders, we default to either public or consortium network alternatives. With expert consultation, it was determined that a consortium network will likely jointly optimize transaction speed and energy efficiency. A consortium network will use *proof of authority* as a consensus mechanism; this mechanism typically provides a more efficient data verification mechanism than *proof of work* or *proof of stake*.

This layer will also contain cryptography to ensure the immutability of past records. These records will be easily accessible through a mobile or a web user interface. Decentralized applications (dapps) will also allow the stakeholders to publish or view information on the blockchain after verifying their identity. These capabilities are similar to other permissioned blockchains such as Bumble Bee seafood [Bumble Bee, 2020], Vitalpass [Auna Health, 2021], DARPAs military messenger [Rabbitte, 2019], and IBM Health Pass [IBM, 2021b].

The blockchain layer will also contain various smart contracts. Smart contracts will be used to tackle the variety of outlined vaccine supply chain challenges. Some smart contracts will dictate how stakeholders' legacy applications will connect to the blockchain allowing for a unified database for all actors. This will allow for instantaneous data discrepancy identification. Other smart contracts will be used to program the QR code readers and help VCs manage and update hospital inventory records.

The smart container cold storage system interactions with the blockchain are to be driven by smart contracts. The mishandling and counterfeit vaccine distribution issues will also be addressed through smart contracts that require authorized user signatures along the different steps of the distribution chain.

A blockchain's *Application Layer* defines the rules for blockchain to interact with already existing solutions. For example, a blockchain solution for vaccine distribution management will probably have to

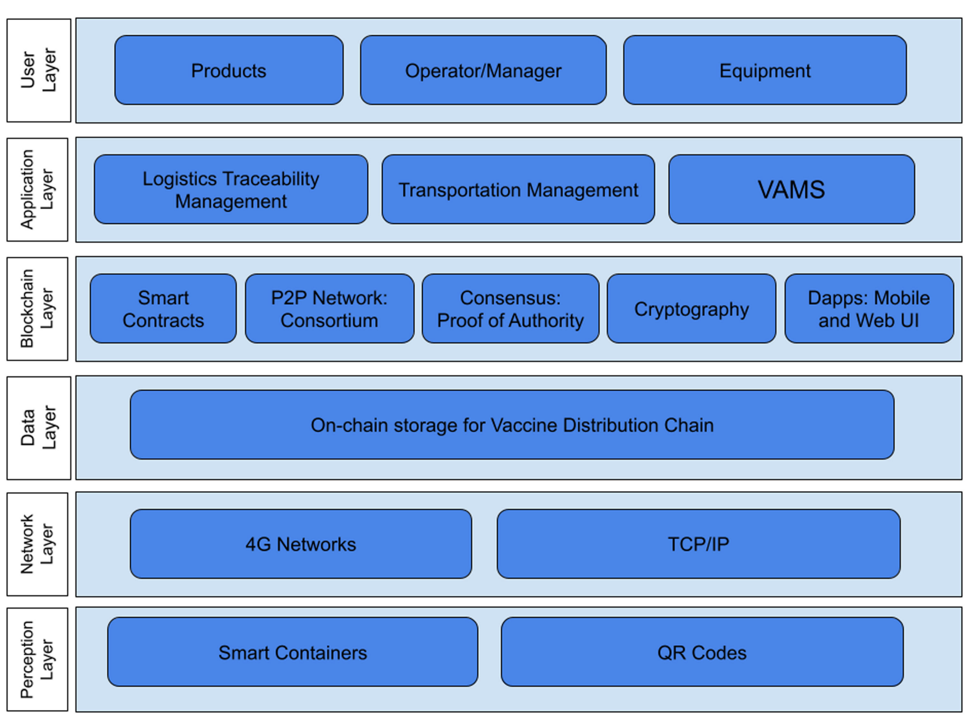

Figure 2. Proposed blockchain framework.

integrate with the hospital's VAMS ([Liu, 2020]; [Tan, 2020]).

For the application layer, we seek to integrate logistics traceability, transportation management systems, and VAMS currently used by providers, distributors, and manufacturers. Similar to IBMs Transparent Supply Chain Solutions [IBM, 2021c], our solution will include the integration of legacy systems. It will help track the batches en route and ensure that upon their arrival—after being inventoried by the provider—the inventory data are visible on the blockchain. This will help address some miscommunication challenges and help create a decentralized real-time unified distribution chain database for all stakeholders.

The *User Layer* is used to define how the three general participant types—products, operators, and equipment—in the blockchain interact with the system. The product—a vaccine vial—interaction rules identify the one-to-one relationship between each QR code and each vial, many vials and a given production batch, and a volume of batches in each given shipment.

The manager component of this layer will define the authority of each of the participating stakeholders. For example, what data they can publish to the chain and when they can do it. This authority validation helps ensure that no unauthorized or false data is published to the chain.

Finally, the equipment component of this layer will define data published by the freezer units and how that data will be appended to the blockchain. These components help define what information each of the network participants will contribute to the system, thus playing a role in the solving of all distribution chain challenges.

4.2 Process Model In this section, we present two DFDs that identify system's functional tasks, informational inputs for these tasks, and informational outputs.

Figure 3 shows the three external entities—vaccine manufacturers, vaccine providers, and smart containers—and the information each of them contributes to the blockchain via the context level DFD.

Figure 4 introduces the six functional tasks—represented by the *F#* in Figure 4—performed by the system and the types of data that will be stored on-chain—represented by the S# in Figure 4—via Level 0 DFD. This level is the highest level of DFD; multiple levels exist and are not shown here.

Next, we offer a description for each functional task, the informational inputs they require, and the outputs they produce.

The first function of the vaccine distribution blockchain solution is to produce a vial record for each manufactured vaccine. Vial record information would include the date manufactured (timestamp), vial QR code, and the manufacturer's signature confirming they produced the vaccine. The vaccine manufacturer should be able to select multiple vial records and group them into a single batch record.

Once the batch is packaged, the system will timestamp when it was

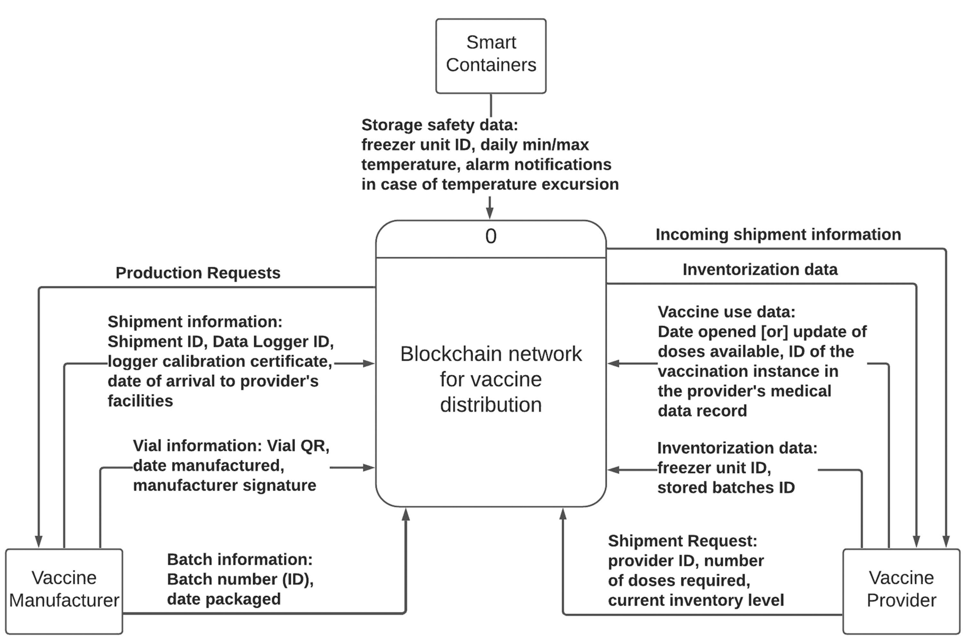

Figure 3. Context DFD for a vaccine distribution blockchain solution.

created and assign the batch a unique number. Multiple batches will compose a single shipment. The manufacturer will add shipment identification (ID) to that record, the data logger ID—used to track the temperature of that shipment— and a proof of calibration for that data logger. Thus, if a data logger flagged a temperature excursion en route, all the batches in this shipment and all vaccines within these batches will be automatically flagged as *spoilage* by the system. Each shipment record is composed of multiple batch records, which are composed of multiple vial records, and all of them are stored on-chain allowing for full traceability in the system—see S1, S2, and S3 on Figure 4 for the vial, batch, and shipment records, respectively.

After vaccines are shipped, managers will be able to track them until they arrive at the targeted hospital facility. Arrival date and shipment location information are added to the blockchain through integration with the distributor transportation management system. This information is available to any hospital whose ID is listed as a recipient of the upcoming shipment. After the vaccines are delivered to the hospital, the provider will use the blockchain solution to record vaccine inventory. The VC will record the ID of the freezer units together with the IDs of the batches that are stored within each of the storage units.

The inventory data are updated every time provider performs inoculation. After performing inoculation, the nurse will scan the vial QR and the system will automatically issue a timestamp for when the vial was opened—if it was just opened—or update the information on how many shots are still available in the vial—if it was an already opened vial.

The vaccine dose ID will be cross-referenced in the hospital's VAMS, validating that a vaccine shot was actually issued at that point. The inventory data of unused vaccines will be automatically updated by the smart containers. Each container will submit its own ID and the daily minimum and maximum temperature inside the chamber, to the blockchain. The updated inventory data will be directed to information storage S4—*Inventory database*.

Finally, the system allows providers to submit order requests for more vaccines. This information is sent directly to the manufacturer in Pfizer's case; however, in other systems, it may be directed to the distributor first. The system may be programmed to issue shipment requests on behalf of hospitals automatically, when certain inventory level thresholds are reached, or it could be done manually.

To create a shipment request, the provider has to submit their ID, the number of doses required, as well as their current inventory database from S4. This information is then processed and submitted to the manufacturer in the form of a production request. The logistics traceability solution integrated into the blockchain will allow the system to automatically transform this request into a production plan for effective just-in-time delivery.

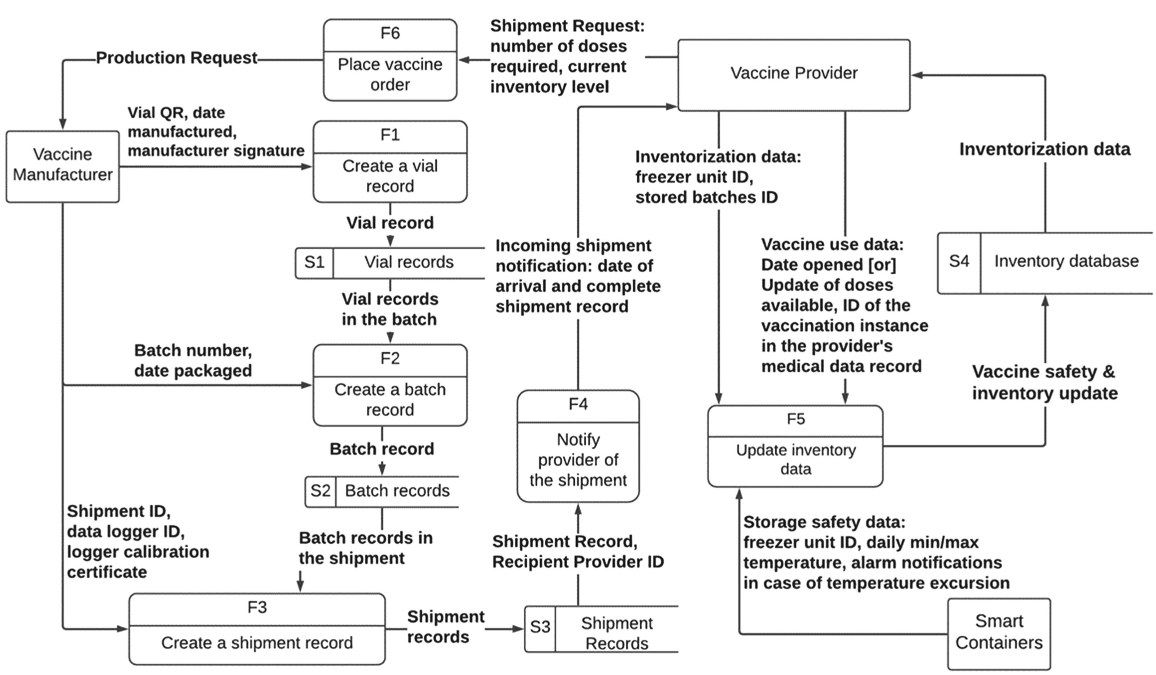

Figure 4. Level 0 DFD for a vaccine distribution blockchain solution.

4.3 Some Remaining Challenges

As with any technology or innovation, multiple challenges exist. These challenges can be technical, behavioral, financial, external environmental, and organizational, to name a few dimensions. We identify a couple here for managers and organizations to consider in this context.

One of the biggest challenges, blockchain cannot solve is the challenge of inadequate government and legislative policies. Due to the issue of packaging several doses of vaccine into one vial, Italian doctors would offer leftover doses to friends and family to avoid disposing of the vaccine after it had been punctured and if it was reaching its expiry and no patients were waiting to get vaccinated in the clinic. Italian media framed this story as a corruption scandal, prompting the government to take harsh measures, further complicating the process of obtaining the vaccine in the country. As a result of the media's influence on the public and politics, it is now mandatory in Italy for six people to be physically present in the hospital before the vaccine is opened. This small vignette exemplifies behavior and rules concerns related to limiting process effectiveness.

The list of challenges that were identified by the providers and distributors, but which could not be addressed with blockchain included issues related to the small number of vaccine manufacturers and the way these manufacturers package the vaccine. Since only three vaccines have been approved by the FDA, it is the responsibility of these manufacturers to vaccinate the whole population of the U.S., in addition to fulfilling all of the international orders. Vaccine packaging becomes an issue in rural areas where the number of patient visits per day may be low. In this environmental context, once the vial is punctured and one vaccine dose is issued, the hospital has to hope that more patients come in, otherwise, the other five doses are destroyed.

Blockchain cannot increase the number of factories or manufacturers of the vaccine and neither can it force manufacturers into changing their production line to package just one dose per vial. These are a number of contextual factors that are beyond the scope of our solution and these environmental contexts need to be explicitly considered when evaluating the performance of the vaccination system overall.

5. Conclusion

In this article overview, we initially identified key challenges faced by the vaccine distribution chain from stakeholders through primary interviews. We identified specific components of blockchain that may be used to address these challenges, presented a conceptually broad-based system that would be used for vaccine distribution, and to solve major existing challenges. To assess the practicality of the suggested framework, blockchain expert opinions were integrated into the development of the framework to provide external face validity of our framework.

A blockchain framework, using literature and exemplary practice, is then introduced for the vaccine distribution chain that can minimize the circulation of counterfeit vaccines and vaccination records, improve communication between stakeholders in the distribution chain, maximize the security of data, reduce the likelihood of a successful cyberattack, streamline the handling process of the vaccines in the provider's facilities, and assist providers in digitizing their facilities to avoid storage unit malfunctions.

A general limitation and challenges include the need for further empirical validation of the framework and the dynamic nature of the subject matter. The COVID-19 crisis is rapidly developing with new issues arising constantly. The issues discussed in this article are limited by the environmental context and time period; the solutions proposed focused on issues identified at that time. Additional stakeholder perspectives are needed given the complexity of the relationships that exist. While these will still confirm the previously identified issues in the vaccine distribution chain, additional issues and use cases that are idiosyncratic to a larger stakeholder set may result in uncovering other challenges.

Further blockchain framework reviews with stakeholders, blockchain experts, and system developers are still required. This will allow us to refine process models and help minimize costs of planning, creating, and deploying the solution as well as maximizing its efficiency.

The proposed solution also had a few limitations. The first major limitation is the inability of storing the patient's medical record on this particular chain. Due to the stringent requirements imposed by the HIPAA and state legislatures, a blockchain solution for medical records requires on-chain data encryption to ensure data privacy, as well as hybrid storage of data and a public P2P network to maximize the chain's security.

The second limitation of the blockchain solution is that it is unable to deal with the physical and organizational challenges often surrounding the vaccine distribution chain. It also cannot prevent governments from issuing rush policies to control the public's outrage or misinformation about certain issues surrounding vaccination.

The framework sets the stage for future considerations for cold chain distribution, vaccines, and other goods. The framework is general enough to work in these contexts and sets the stage for further customization depending on the product, urgency, and environmental constraints.

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