PharmaChain 2.0: A Blockchain Framework for Secure Remote Monitoring of Drug Environmental Parameters in Pharmaceutical Cold Supply Chain

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***Abstract*—Cold chain logistics play an important aspect in storing, preserving and transporting of cargo which is highly sensitive to environmental parameters surrounding it. Not handling these medicinal products in the recommended environment either during transportation or storage can cause adverse effects such as degradation of potency of the drug, the stability of drugs and in some cases may even lead to serious consequences on the health and well being of the consumer. Once a product leaves the supplier and enters the cold supply chain, monitoring and controlling the surroundings of the shipment will be a difficult task which can be resolved by using latest technologies like Internet of Things (IoT). However, due to the resource constraints of such IoT devices, it is very easy to manipulate the data and provide falsified information by any adversary in order to disrupt the system. Hence, a robust architecture called PharmaChain 2.0, which is capable of efficiently and securely monitor and control the ambient parameters of shipments in cold chain using IoT, and a cloud architecture and IoT friendly Proof-of-Authentication consensus based blockchain technologies to increase confidence of safe consumption for end consumers.**

***Keywords*—** Pharmaceutical Supply Chain, Blockchain, Distributed Ledger Technology, Counterfeit Medicine, Remote Monitoring and Control, Secure and Verifiable Log

I. Introduction

Currently, an increasing number of drugs and vaccines need a special temperature-controlled handling which is also called cold supply chain. These special drugs need to be kept at precise temperature ranges from the point of leaving the manufacturer site till it is safely dispensed to the consumers. Most of such cold chain drugs are required to be maintained in an environment between 2° to 8°C. One of the most widely used insulin types for diabetes, and some dermatological drugs, especially injectable, come under this category [1], [2]. Many vaccines like COVID-19 require freezing temperatures around -70°C to store for long term. Such medicines when exposed to temperatures out of the recommended ranges can lead to reduction in efficacy of drug, early expiry of drugs and may even become fatal to the consumer [3]. Due to globalization and the number of entities involved, pharmaceutical supply chains are complex and maintaining and keeping track of all the interactions between these entities will be very difficult. The tangled nature of these pharmaceutical supply chains obscures the consumers' visibility into the drug's life cycle which in turn reduces the confidence of consumption. Such threats are more dangerous in the case of cold supply chains and can lead to life threatening situations for the consumer. A typical cold supply chain in pharmaceutical industry is shown in Fig. 1. Monitoring of such temperature-controlled drugs should be done at all aspects of the drug's life cycle, which may include:

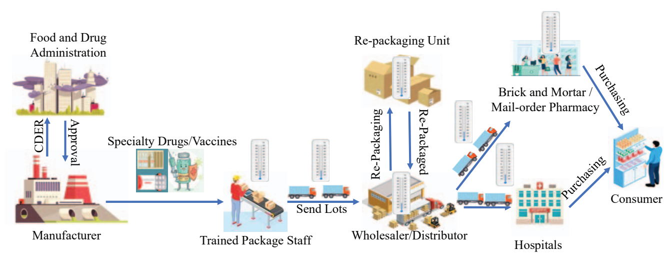

Fig. 1. Goods Flow in Typical Cold Supply Chain.

- Monitoring and controlling the temperature during storage of medicines in warehouses.
- Maintaining the temperature ranges during the transportation of drugs.
- Packaging should be taken care following all recommended procedures.
- Pharmacies and care sites should be properly equipped to maintain the medication temperature until dispensed.

Advancements in different technological components have helped in increasing the transparency and control of the cold supply chain in the pharmaceutical industry. The Internet of Things (IoT) is one such technology which can help in continuous monitoring and controlling of environmental parameters for specialty drugs. A typical IoT architecture consists of three layers: A sensory layer which consists of different sensors and has their unique identity and makes use of different Information and Communication capabilities to exchange data in the IoT network. A network layer which consists of gateways and routers to collect data from the sensing layer and delegate to cloud layer for further processing. IoT devices are resource constrained and cannot provide needed computations on the data being analyzed, hence a typical IoT architecture consists of a cloud layer which can provide required computational and storage capabilities. IoT has been many application domains in the form of Internet-of-Medical-Things (IoMT) and Internet-of-Agro-Things (IoAT) making smart healthcare and smart agriculture possible [4], [5]. As IoT devices are resource constrained, managing security of the data by implementing complex encryption and decryption techniques is not a feasible solution. The blockchain is one such technology which can help in providing data security and integrity.

The blockchain can be simply defined as a data structure which is formed of hash connected blocks of data and provides certain characteristics like immutability, security and distributed data architecture. The blockchain was designed initially as a financial solution but due to its characteristics like immutability, security and consensus based updates. However, it has been explored as potential applications in many different fields including IoT [6]. A common shared ledger is the one important logical component in the blockchain which helps every node to have its own copy of the transaction ledger. This also avoids centralized controlling of the data. The consensus mechanism is a set of rules which are accepted across the entire network and which every node must follow to verify and approve the transactions coming to the blockchain. This is very much needed in a distributed environment for un-trusted entities to agree upon the newly generated blocks [7]. Two of the commonly used consensus mechanisms are Proof-of-Work (PoW), and Proof-of-Stake (PoS). As one size doesn't fit all, the original blockchain solution is resource intensive and cannot be readily used in IoT applications. Hence, a consensus mechanism, Prrof-of-Authentication (PoAh), which is IoT friendly is designed in [8]. In the current proposed PharmaChain 2.0, we made use of the PoAh consensus protocol to achieve lower computational requirements and higher scalability of the system while providing desired security.

The rest of the paper is organized in the following sections: Section III provides an overview of prior related research work. Section II discusses the novel features of the proposed PharmaChain 2.0. Section IV presents an architectural overview of the proposed PharmaChain 2.0. Section V discusses the algorithms behind PharmaChain 2.0. Section VI gives an insight into the implementation validation details of the proposed PharmaChain 2.0. Section VII provides the conclusion along with future scope.

II. Novel Contributions

A. Problems Addressed in Current Paper

Problems addressed in current cold supply chains are:

- Centralized authorities can be eliminated which will in turn remove adversaries.
- Security and integrity of the data shared can be provided without much overhead on the IoT nodes.
- Security attacks such as False Data Injection (FDI) and Denial-of-Service (DoS) can be prevented.
- Instead of a central entity hosting the entire data and serving client requests, a P2P network can increase response times.
- Preventing data from unauthorized modifications and present information directly to consumer.
- Increasing consumer confidence by increasing trust in the network.

B. Novel Solutions Proposed

PharmaChain proposed in [9] is a counterfeit detection solution with violation log based on Ethereum private blockchain and utilizes hybrid smart contracts to ensure the authenticity of incoming data into the network. However, block validation time is approximately 5.6 seconds and the cost of operations is also high compared to the solution proposed in the current paper. Novel solutions proposed in PharmaChain 2.0 are:

- Near real-time data will be propagated in the P2P network. Hence, prompt action can be taken to prevent decreases in drug efficacy.
- Consensus in the proposed P2P network will make the system more robust to different security threats.
- PharmaChain 2.0 makes use of IoT systems to provide continuous monitoring and control throughout the drug life cycle in supply chain.
- Data security is provided by using the immutable characteristic of blockchain.
- PharmaChain 2.0 provides a cost-efficient infrastructure which can be adapted in large scale as cold supply chains are huge.

III. Related Prior Research

The blockchain has been an emerging technology which has provided very promising solutions in many aspects of Smart City applications [10] like Smart Agriculture [11], [12], Smart Healthcare [13], [14] and others. One of the main characteristics of the blockchain is immutability and shared ledger which makes it a viable solution for addressing issues in supply chains. Different studies are being conducted in using the blockchain as a solution for supply chain transparency and ensuring safety of the shipments.

CryptoCargo [15] makes use of the Ethereum blockchain to increase transparency and ensure real-time operations of the pharmaceutical supply chain. The proposed architecture in CryptoCargo makes use of smart contracts to build this decentralized application. Violations in environmental parameters are also captured in the proposed architecture. However, the processing time of the current work PharmaChain 2.0 is much lower and the cost of maintaining the network is lower as there are no mining fees, unlike the Ethereum used in CryptoCargo. Other Ethereum based solutions for pharmaceutical supply chain are proposed in [16]–[19] which make use of smart contracts and also provide off-chain storage solutions for large amounts of data. These solutions do not monitor the environmental parameters while the shipment is in transport, which is vital for cold supply chain as the efficacy is impacted if drugs are mishandled. Another solution proposed based on smart contracts to defeat counterfeits in the pharmaceutical supply chain is proposed in [20]. However, a proof of concept is proposed in this paper whereas implementation and analysis of feasibility of solution are not presented. CryptoPharmacy [21] is another application which makes use of NEM blockchain in order to ease the process of selling and buying easier as multiple entities are involved in the supply chain. The application makes use of native tokens of NEM blockchain to make purchases. Similar to the previous solution, CryptoPharmacy also doesn't consider monitoring the drugs during transport which can be an issue for cold supply chains. DrugLedger in [22] proposed a model using UTXO workflow for pharmaceutical supply chains. However monitoring and controlling of the drugs in supply chain is not considered. A hyperledger fabric blockchain based solution for counterfeit detection is proposed in [23], but monitoring of the drugs is not considered in this model.

IV. Architectural Overview of PharmaChain 2.0

An architectural overview of the proposed PharmaChain 2.0 is shown in Fig. 2. The main components in the proposed architecture of PharmaChain 2.0 are: End nodes which are placed near the drug shipments during their movement within the supply chain and mainly consist of sensors and actuators. End nodes are responsible for sensing the environmental parameters around the drugs during the process of transportation. Along with that, actuators help in controlling the devices to maintain the temperature, light and humidity within the recommended levels. Typically drugs with similar specialized conditions will be shipped together. Hence, it is assumed one node for each transportation truck is sufficient to monitor and control the environmental parameters. These end nodes are capable of connecting to the Internet and send the data over to the edge devices.

Unlike end nodes, edge devices have higher storage capabilities and can perform lightweight computations. These edge devices act as bridge between the end nodes and cloud layer. Edge devices consume data coming from nearest end nodes and will be sent to the cloud for further processing. In the proposed PharmaChain 2.0, edge nodes will perform the pre-defined conditional checks on the environmental data received and if any violations in the environmental parameters compared to the recommended range are detected, they will be reported to the blockchain. The reported transactions will generate an immutable log into the blockchain network which can be accessed by the consumer for verifying the safety of product. Along with that, data from edge devices will also be sent to the cloud using

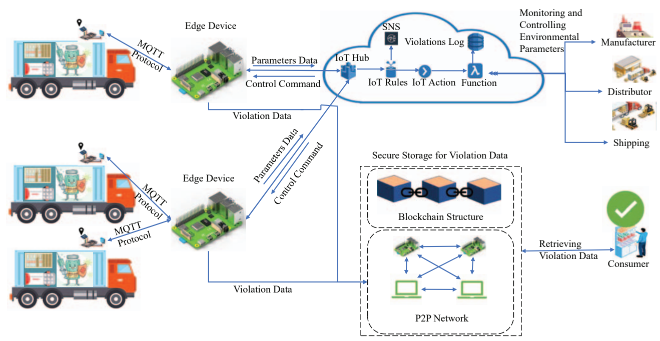

Fig. 2. Architectural Overview of Proposed PharmaChain 2.0.

which the entities participating in the supply chain can take prompt actions by controlling the actuators.

A cloud layer is used in PharmaChain 2.0 for delivering the alerts and controlling the actuators of the end node by the participating entities of the cold supply chain like manufacturers, distributors and 3-PL Shipping companies. The cloud layer consumes data from the edge devices and generates alerts based on predefined conditions by using Simple Notification Services (SNS) which will be delivered to the entities in real-time. In response to the alert, control commands can be sent by the entities to actuators at the end node to safeguard the drugs from long exposure to the unfavorable conditions which could deter the efficacy.

The blockchain Layer consists of the P2P nodes deployed and managed by the multiple entities of the cold supply chain. PharmaChain 2.0 uses the Proof-of-Authentication (PoAh) consensus protocol which ensures the near real-time processing of transactions along with reducing the computational requirements and making it more suitable for resource constrained environments like the IoT. Edge nodes can also participate as the nodes of the proposed P2P network for performing mining operations. Once the violation of a data transaction is published to the P2P network, one of the miner nodes will pick up the transaction and generate a block which will eventually be added to the chain. This blockchain chain ledger with connected blocks acts as the immutable log which provides a single source of truth about the violations during the drug life cycle throughout the cold supply chain.

V. Proposed Algorithms for PharmaChain 2.0

Steps in the proposed violated data log generation algorithm are shown clearly in Algorithm 1. Initially end nodes will use different sensors to capture environmental parameters which include temperature, humidity, luminosity and GPS location and will send the data to the edge device for further processing. The algorithm is subdivided into three procedures, one each for the edge, cloud and blockchain layers. In the edge layer, edge devices after checking for any violations out of recommended ranges send the data to the cloud for generating alerts to the entities in the cold supply chain. Along with that a transaction is prepared and published to the P2P blockchain network. In the cloud procedure, after receiving the violation data, an alert will be generate by Simple Notification Service (SNS) which is a native IoT cloud function. These alerts are received by the participating entities to take prompt decisions. In the blockchain procedure, after receiving the transaction, it is added to the unconfirmed transaction pool. Miner nodes in the blockchain network will pickup the transactions and generate a new block after performing Proof-of-Authentication consensus mechanism. The newly mined block will be published to the blockchain network and is added to the ledger at all the nodes, thus creating an immutable trail of logs.

Algorithm 1 Proposed Violation Data Log Generation Algorithm For PharmaChain 2.0

Input: Temperature, Humidity, Luminosity and GPS Position data from End node
Output: Violation data transaction published to blockchain network and cloud layer

End node E prepares a message E_{msg} with all the environmental parameters Temperature (temp), Humidity (hum), Luminosity (lum) and GPS position data(gps)
Prepared message is published to the topic τ of edge device using light weight pub-sub protocol
E.Publish(τ,E_{msg}(temp,Hum,lum,GPS))
Edge device E_e consumes the messages sent by the end nodes
E$_e$.consume(τ)

Phase 1 – Edge Device Processing

procedure Edge Device Processing
  for Every message E_{msg} **do**
    Check the pre-defined conditions on Temperature, Humidity, Luminosity
    if Any Violation Detected **then**
      Publish violation data V_E to both cloud
      E$_e$.Publish(V_E)
      Prepare and send transaction to blockchain network
      Tx $\leftarrow$ E$_e$.prepareTransaction(V_E)
      E$_e$.generateTransaction(Tx)
    end if
  end for
end procedure

Phase 2 – Cloud Layer Processing

procedure Cloud Layer Processing
  for Every Violation Data V_E received **do**
    Consume the message
    IoTHub.consume(V_E)
    Generate an alert using SNS (Simple Notification Service) to the registered entities
    SNS.generateAlert(V_E)
  end for
end procedure

Phase 3 – Blockchain Layer Processing

procedure Blockchain Layer Processing
  Generated transaction is received into unconfirmed transactions pool (UTx)
  UTx.append(Tx)
  Miner picks transaction from UTx pool and creates a block
  Mining performed based on PoAh consensus protocol
  New block is added to the chain at all the participating nodes in the network creating an immutable violation data log
end procedure

Steps of entities controlling environmental parameters around the shipment during transport are shown in Algorithm 2. Alerts generated by the cloud layer are monitored by all the participating entities. The entity which is responsible for the shipment will prepare a control command with the instructions and sends it to the cloud layer. The cloud layer, after further processing the command, will generate instructions required for the end node to turn ON/OFF the actuators and publish to the edge devices. Edge devices use the less computationally demanding pub-sub communication protocol to deliver the instructions to the corresponding end node, which in turn processes them to control the actuators to achieve desired temperature, humidity or the light.

Algorithm 2 Proposed Control Algorithm For PharmaChain 2.0

```
for Each violation alert received do
    Alert is reviewed by the responsible entity in the cold supply chain network
    Control command CC_e for actuator is prepared by the entity
    CC_e ← Entity.prepareCommand(Control Instructions)
    Control command is published to the cloud layer
    Entity.publish(CC_e)
    Cloud Layer processes the command and prepares control instructions for end node
    CC_e^+ ← IoTHub.process(CC_e)
    Cloud layer published the processed control command to the edge devices
    IoTHub.publish(CC_e^+)
    Edge devices will send control instructions to the corresponding end devices
    for Received Control Instructions by End Node e do
        e.consume(CC_e^+))
        Process and turn ON/OFF the actuators
        e.process(CC_e^+))
    end for
end for
```

VI. Implementation and Validation

A. Implementation

End nodes which are placed at the location of shipment to monitor environmental parameters are shown in Fig. 3. NodeMCU ESP8266 IoT platform is used as the end node. It is chosen because of its capability to connect to Wi-Fi and support of different sensor interfaces. Main environmental parameters considered in the implemented prototype of PharmaChain 2.0 are temperature, humidity, ambient light and GPS coordinates. For sensing ambient temperature and relative humidity, a DHT11 sensor is used. Ambient light is sensed using a TEMT6000 ambient light sensor and GT-U7 GPS Modules are used for capturing the location data.

A Raspberry Pi 4 Model B with 4GB of RAM is used as the edge node which also acts as the distributed nodes of the proposed PharmaChain 2.0 blockchain. The cluster of implemented blockchain nodes is shown in Fig. 4.

Edge nodes participating in the blockchain network are shown in Fig. 5. A four node network is implemented for the proposed PharmaChain 2.0. Among the four nodes two nodes act as miner nodes which are responsible for creating blocks from the unconfirmed transactions from the transaction pool and perform PoaAh consensus before publishing it to the network.

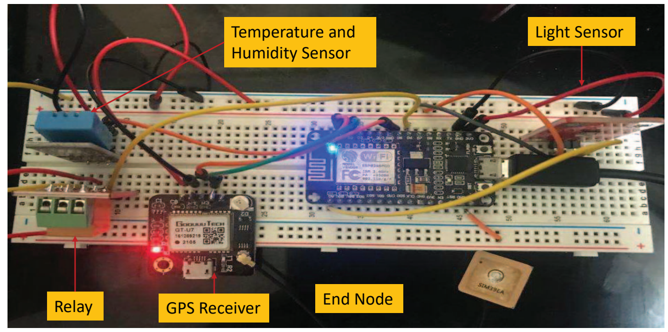

Fig. 3. Implemented End Node for Proposed PharmaChain 2.0.

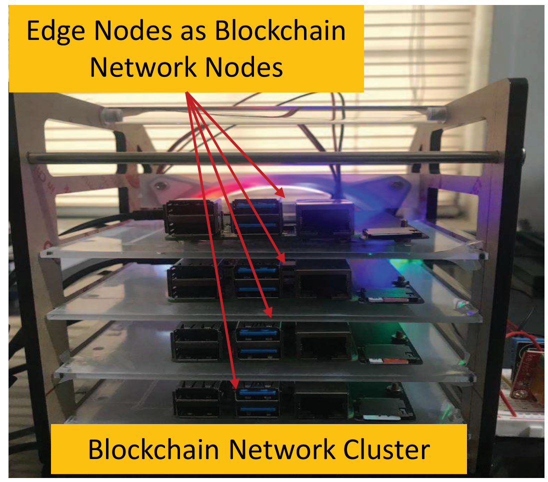

Fig. 4. Implemented Blockchain Network Cluster for Proposed PharmaChain 2.0.

Violation data being added to the blockchain ledger are shown in Fig. 6. Data from the end node along with all the overhead details of shipment and vaccine information is shown clearly in the log for the consumer.

B. PharmaChain 2.0 Validation

Security and timing analysis is performed on the proposed PharmaChain 2.0 to check the adaptability and scalability in real-world applications.

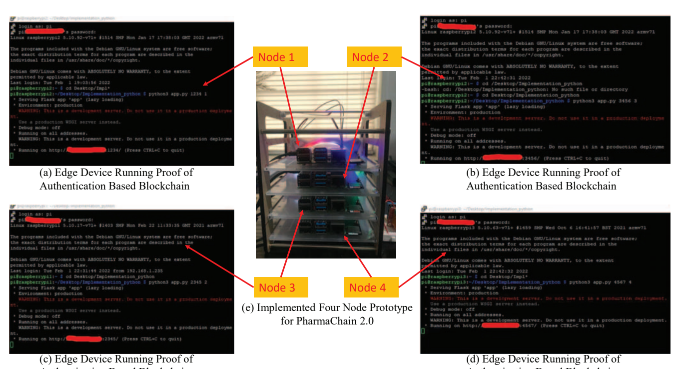

Fig. 5. Edge Nodes Participating in Blockchain Network Operations.

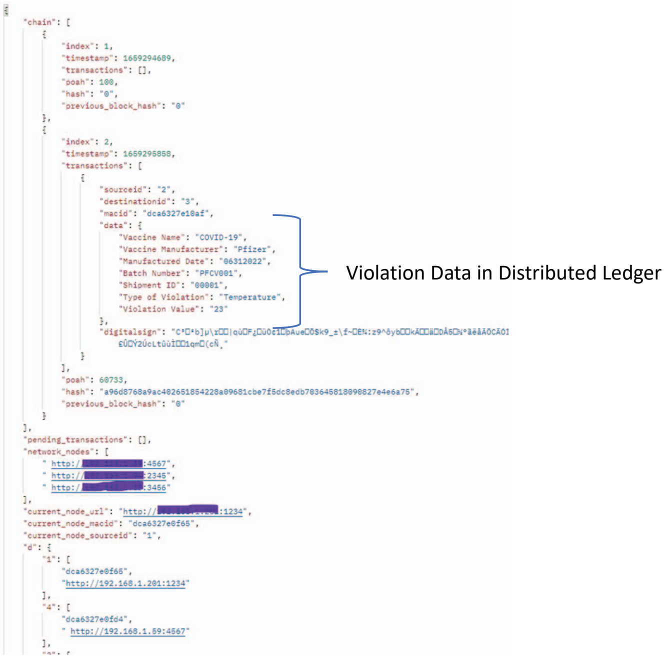

Fig. 6. Violation Data from End Node is Added to Ledger.

1) Security Analysis: **Threat 1**: False Data Injection (FDI), when an adversary is trying to introduce false data into the blockchain network.
Solution: PharmaChain 2.0 makes use of the PoAh consensus protocol which performs device authentication using digital signature as first level of security and MACID checking as secondary authentication. As the private keys of the edge devices are stored at a secure file location of the device, it is unlikely for the adversary to get access and generate false data transactions. If the digital signature or the MACID doesn't match, such transactions will be discarded by the miner and not added to ledger.
Threat 2: Data Integrity Attack where an adversary controls one of the node in the blockchain and tries to modify the data within its ledger.
Solution: PharmaChain 2.0 makes use of the blockchain ledger structure. When an adversary corrupts the data in one of the transactions, it will corrupt the entire block and changes the hash pointer, thereby invalidating the entire chain. As the distributed peer nodes have their own copy, they will be able to identify and punish the adversary within the network.

2) Scalability Analysis: Transaction time is defined as the time taken by the edge device to prepare and broadcast the violation data transaction to the blockchain network. To measure the average transaction time of the edge device, 100 different transactions are generated and the time taken to prepare the transactions and publishing them to the blockchain network is measured. All readings from 100 transactions are shown in Fig. 7. It can be clearly seen that the average time for generating and publishing the transaction is 173.39ms, which is small.

Block time is defined as the time taken by the mining node in the blockchain network to perform consensus and publish a new block to the network. To measure average block time, 100 new blocks are mined by the miner and the time taken for each block generation is considered for the average block time. Block times for each block can be seen in Fig. 8. The average block time is measured to be 148.89ms which is acceptable for the current application.

As many devices can be connected to one edge device, throughput is another parameter which can be used to measure how many end nodes can be assigned to each edge device. To measure the throughput of the edge device, a load test is performed with 10 threads sending 10 requests within 10 seconds, which results in 100 transactions in a short time of 10 seconds. Throughput measured from the load test can be seen in Fig. 9. Throughput is computed to be nearly 0.8 Transaction/Sec with only 1% of failed transactions. Hence, the proposed edge nodes can handle up to 100 end nodes each and provide high scalability considering the application of cold supply chain.

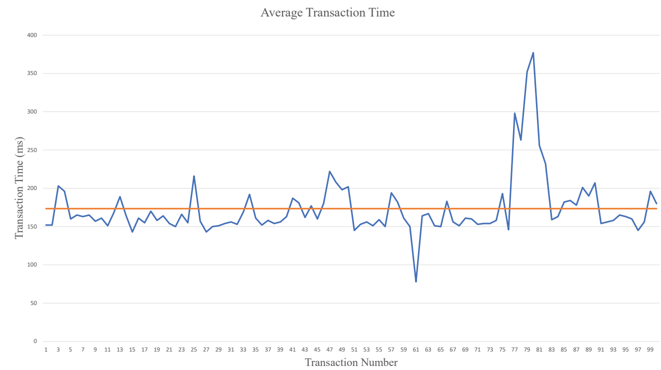

Fig. 7. Transaction Generation Time of Edge Node.

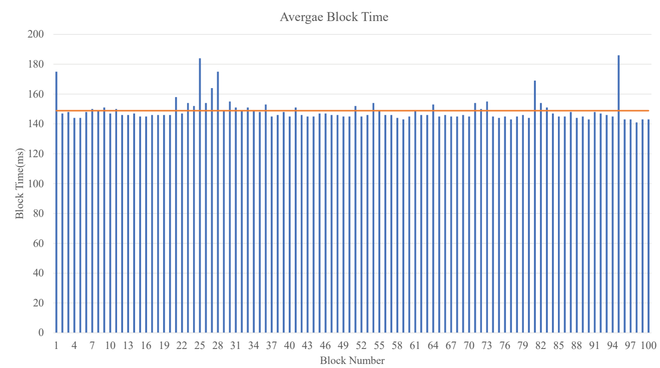

Fig. 8. Block Mining Time in Proposed PharmaChain 2.0.

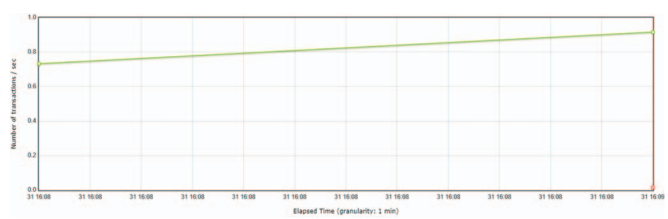

Fig. 9. Throughput of Edge Device in Proposed PharmaChain 2.0.

PharmaChain 2.0 is compared to prior research in Table I. It can be seen the proposed PharmaChain 2.0 has much lower transactions times even with the edge devices with limited computational and storage capabilities participating as network nodes of the blockchain. Average time combining both transaction generation time and block time is 322.28ms which is much shorter compared to the other solutions given in the table.

VII. Conclusion and Future Research

This paper presents a novel light-weight blockchain solution to ensure teh safe handling of medicines carried in cold supply chain.

TABLE I
COMPARISON OF PROPOSED PHARMACHAIN 2.0 WITH EXISTING SOLUTIONS

Parameter	CryptoCargo [15]	PharmaChain [9]	**Current Solution (PharmaChain 2.0)**
Blockchain	Ethereum	Ethereum	PoAh consensus based Blockchain
Consensus Protocol	Proof-of-Work (PoW)	Proof-of-Authority (PoA)	Proof-of-Authentication (PoAh)
Openness	Public	Private	Public
IoT Friendly Consensus	No	No	Yes
Average Time	43.36sec	5.6sec	322.28ms

The proposed PharmaChain 2.0 provides continuous monitoring and control capabilities for different entities in the Pharmaceutical Supply Chain to take prompt actions for shipments. It also provides a secure log of violations to the consumer to verify the safety of drugs before consumption. PharmaChain 2.0 works based on the light-weight consensus mechanism Proof-of-Authentication (PoAh) which is cost-efficient as no mining fees are involved and also not computationally intensive unlike other established consensus protocols. A proof of concept framework is implemented for PharmaChain 2.0 and analyzed for security, scalability and reliability. Results from the analysis show that the proposed architecture is an acceptable solution and provides near real-time data with only latency of 322.28ms. As a future work, anti-counterfeiting mechanisms will be included along with providing a user-friendly UI component for the application.

TABLE II
ANALYSIS SUMMARY OF PHARMACHAIN 2.0

	Transaction Time	**Block Time**	**Total Time**
PharmaChain 2.0	173.39ms	148.89ms	322.28ms

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