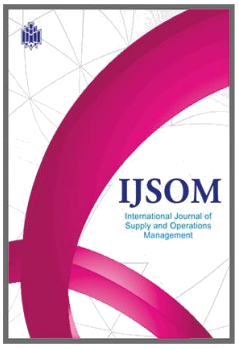
International Journal of Supply and Operations Management

IJSOM

November 2022, Volume 9, Issue 4, pp. 379-397
ISSN-Print: 2383-1359
ISSN-Online: 2383-2525
www.ijsom.com



Theoretical Block chain Architecture Model (t-BAM) to Control Covid-19 Related Counterfeit Medical Products across Supply Chain

Ashok Kumar Peepliwal [a,*], Sandeep Narula [a], Rahul Sharma [a], Chandu Bonde [b] and Khushboo Jain [c]

[a] *IIHMR University, Prabhudayal Marg, BudhsinghPura, Sanganer, Jaipur, Rajasthan, India*

[b] *School of Pharmaceutical Management, Babulde Banks of Tapi River,Mumbai-Agra Road, Shirpur Dist: Dhule, Maharashtra, India*

[c] *Clinical Intelligence & Analytics, Akna Medical Pvt. Ltd., Karnataka , India*

Abstract

Covid-19 pandemic affected millions of people across the globe. Healthcare professionals need various kind of medical product like drugs, vaccines, other biologicals, and diagnostic equipment to combat pandemics. Fake vendors introduced falsified medical products in national and international markets during pandemic. These counterfeit products are life threatening due to inferiority in quality and available in noncompliance of label claim. Europol confiscated 34,000 counterfeit surgical masks in just one coordinated assignment of fake goods. The data for the unauthorized medical product sell is higher than expectation during this Covid-19 pandemic. World Health Organization reported that up to $200 billion worth of counterfeit pharmaceutical products are sold globally every year. It is a challenge to track and trace counterfeit medical products because these products must pass through many complicated distribution channels which allows opportunity for counterfeit drugs to enter in supply chain. In current supply chain methods, central authorities control transacted data among parties. Multiple intermediates needed to enable activities and creating trust. In this scenario, there is chance of manipulation in data fabrication. Block chain protects supply chain and maintain a shared source of data information. Trust enabled by cryptographic algorithms and immutability of data preserved in Block chain. In this paper, a Theoretical Block chain Architecture Model (t-BAM) proposed using hyper ledger Fabric as a Block chain platform and Byzantine Fault Tolerance (BFT) Algorithm for mutual consensus in supply chain of medical products during COVID-19 pandemic. This model validated for immutability, Mutual consensus, Transparency and Accountability, Privacy and Security, Temperature and Humidity control parameters.

Keywords: Covid-19; t-BAM; Fabric Hyperledger; Supply Chain; BFT.

1. Introduction

Covid-19 pandemic affected millions of people across the world. Healthcare professionals need various kind of medical product like drugs, vaccines, other biologicals, and diagnostic equipment to combat the pandemic. It's indeed important to procure medical products from authentic manufacturers, wholesalers, retailers to control of Corona infection because the quality products can give better safety and efficacy.

Corresponding author email address: apeepliwal@gmail.com
DOI: 10.22034/ijsom.2021.108656.1848

During this pandemic, fake vendor enters in supply chain and attempt to capture the market by selling counterfeit medical products. It is a challenge for Regulatory and Governments to control such falsified products. Urgency to control corona pandemic forced authorities to purchase the medical products without manufacturing site audits. Regulators know the associated risks with such procurements but due to political pressure, authorities generally go for fast-track approvals of new medical products. Europol (the Eu's law enforcement agency) confiscated 34,000 counterfeit surgical masks in just one coordinated assignment of fake goods (europol.europa.eu, 2021).

Data for unauthorized medical product sell is higher than expectation. Published data reveals that a firm from Europe ordered protective mask and disinfectant from a company in Singapore. The deal cost €6.6 million ($7.3 million) worth — which never arrived. German government lost millions of masks expecting from Kenya. A recent fraud happened in Netherlands, recalled millions of defective masks bought from China (Business-standard, 2020).

Deccan herald (2020) stated that trafficking and sale of fake or defective medicines enrich criminal groups and endangers health while draining away vital industry and tax revenues. The sale of counterfeit drugs and smuggled goods will not only deteriorate the current condition of public health, but it affects the economy too.

As per World Health Organization (WHO), 1 in 10 counterfeit medical products are in circulation in low-and middle-income countries and tens of thousands of deaths occur due to fake drugs in the world. WHO also reported that up to $200 billion worth of counterfeit pharmaceutical products are sold globally every year and 50% of these drugs are purchased online (Daniela 2017, Clark 2015). It also mentioned that counterfeit medicines market is worth a whopping $75 billion (Tim et al., 2015). It has been warned world that China and India are reportedly leading sources of counterfeit medicines distributed globally" stating that "approximately 20 per cent of drugs sold in Indian market are counterfeit and could represent a serious threat to patient health and safety" (Mackey et al., 2011).

COVID-19 pandemic outbreak in which falsified drugs entry is increasing in the supply chain, and it is a threatening to public health at domestic as well as international markets. Many cases reported in India and an initiative taken by Pangaea, coordinated by Interpol, seized false pharmaceutical products worth of US$ 14 million across countries in a week and arrested 121 people (Yadav, 2020).

Drug track and trace (2020) raised the issue and expressed that counterfeit medical products supplies are murdering patients not only in one country but worldwide.

It is challenging to control counterfeit medical products because these products must pass through many complicated distribution channels which allows opportunity for counterfeit drugs to enter at any point of authentic supply chain. Supply-chain aims to collect, access, analyze data and supply-chain system must collect each product information from production to delivery point. It covers entire visibility for all stakeholders involved (Simchi et. Al., 2001)

In traditional supply-chain methods, manufacturing, marketing, logistics, distribution, planning, and procuring organizations act independently. Stakeholders of supply-chain have their own objectives and often conflicting too. Traditional supply chain has certain limitations like (Bushra et al., 2018; Srai et al., 2015; Themistocleous et al.; and Foerstl et al., 2017)

- Limited visibility and lack of coordination
- Distorted information demand by customers across the material path
- Delays due to various planning cycles
- Limited accessibility of each point
- Limited view of supply chain
- Unsynchronized responses across multiple peers etc.

A supply chain consisting two or more partners interconnected in a chain by flow of goods, data information, and financial transactions (Tsay et al., 1999).
National Informatics Center (Government of India) has developed, designed, and implemented a portal for drug tracking and traceability, called Drug Authentication and Verification (DAVA) but it does not cover entire functionality as Blockchain do. DAVA does not allow visibility of every transacted events to all stakeholders with timestamp where multiple intermediates involved in multilocation and multi-product scenario. It also not a secure monitoring system to track and trace supply chain which may ensure temperature compliance additionally. With innovative and advance technology like Blockchain, limitations of existing supply chain methods can be overcome..

Blockchain technology expanded its applications in other industries too apart from bitcoin. Blockchain records product information registry and able to monitor possession of medical products at different points of supply chain. It allows smart contracts among all stakeholders to diagnose the problems and to provide timely solution (Bahga, 2016)

Blockchain based models can improve more visibility, better optimization of process, better demand/supply forecasting, more transparency and tracing of real time unseen problems during supply chain process (Field, 2017)

It will also help in inventory management and reduce fraud, errors as well as waste by optimizing transit and shipping cost too (Iansiti et al., 2017)

Blockchain comprises two main things, distributed ledger and data structure i.e. linked with number of blocks embedded with transacting information where each block interconnected to previous one by their hash and a cryptographic signature. It provides a complete tamperproof system where no one can alter an earlier block transaction without recreating the entire blockchain and its impossible. Blockchain technology enables and enhance the implementation of collaborative supply chain structures for better supply execution in a smart way (Norta, 2017).

The main objectives of this model to provide a tamperproof and immutable supply chain model to pharmaceutical industry who can monitor and trace transit of medical products from its origin to end user.

In Paper, Theoretical Blockchain Architecture Model (t-BAM) presented, and Hyperledger Fabric system used in model. A Hyperledger Fabric designed for active nodes and dormant nodes to control the supply chain of medical products from its origin to end users. Byzantine Fault Tolerance applied for smart contracts among nodes. Pharmaceutical Industry, Regulatory, Governments, Auditors, and Inspectors will be beneficiated from presented t-BAM to control medical product's quality and safety for Covid-19 patients.

2. Blockchain in Supply Chain of Medical Products

Blockchain especially focusses where people or businesses express frustration or mention that consumer service of business performance that customer service of business performance suffer. It records the medical product journey of raw materials, compounds, or components through each step of supply chain in a chronological order from source to consumer or patient (Aburto et al, 2007; and Youness et al.,2018).

All participants (Raw material vendor, Manufacturer, Logistics, Distributer, and Retailer) can make an entry of log information of medical products on to a blockchain ledger by direct data entry or by data transfer from sensors connected to Internet of Things (IoT). The updated ledger is visible to all active and authentic nodes on Hyperledger Fabric system. It could be identified by blockchain operators who are authorized to access and determine the malfunctioning, environmental breakdown, tampering, and material information during the supply chain (Marucheck et al., 2011). In this way, Blockchain technology secure record transactions/information among various parties in chronological order.

3. Hyperledger Fabric System Network in t-BAM

Blockchain-council (2020) describes blockchain application or platform and Hyperledger platform which will be created to allow interoperability of all participants with updates of location, timestamp, names, quantity of products, temperature control and insertion/deletion of information. There are different tools available to create the blockchain platform on which entire supply chain parties interconnected and can transfer the information peer to peer.

Building a Blockchain application from the scratch is a complicated process; but is done by the developers with very ease (Kim et al., 2018). In paper, Theoretical Blockchain Architecture Model (t-BAM) presented with Hyperledger Fabric application system which is an open-source collaborative effort developed for advancing of cross-industry blockchain technologies. This is hosted by the Linux Foundation and Technology and Supply chain of medical products is a system of people, organization, performance activity, updating, information, monitoring, and resources involved in the movement of medical products from manufacturer to end user, patient (Marija et al., 2020).

Hyperledger Fabric is a peer-to-peer network of virtual computers that any developer utilizes it to run the distributed application. The Hyperledger fabric system has advantage over the public ledger blockchain. Hyperledger is also a distributed ledger as depicted in Figure 1 (nodes may vary from 1,2,3,4 to ……n) but it does not allow all nodes to access the updated ledgers of all nodes.

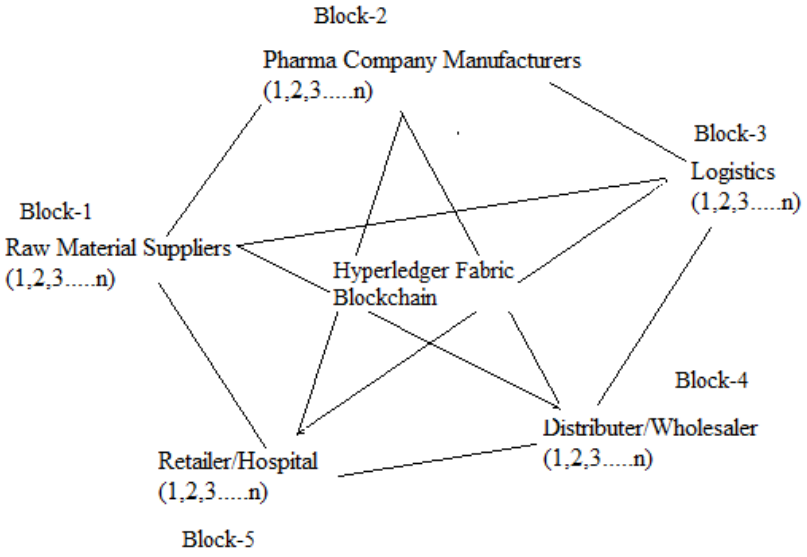


Figure 1. Hyperledger Fabric System Network for Pharma-Stakeholders (Marija et al., 2020)

It provides only the active nodes of this system may be able to verify the ledger. It gives the confidentiality, data protection and privacy among the active and dormant nodes. The design of the Hyperledger Fabric activity among all pharma related stakeholders and analysis of proposed system execution of different supply routes from raw material supplier to manufacturer to retailer presented in Table 1.

Table 1. Hyperledger Fabric Activity Design Among Pharma-Stakeholders

Supply chain network (Route)	Raw material supplier (Number)	Pharma Company Manufacturers (Number)	Logistics (Number)	Distributer (Number)	Retailer (Number)	Active nodes
I	2	5	9	112	12	Node number 2,5,9,112,12 is active, and rests are dormant
II	1	19	22	18	21	Node number 1,19,22,18,21 is active, and rests are dormant
III	31	2	8	19	3	Node number 31,2,8,19,3 is active, and rests are dormant
IV	10	43	23	1	2	Node number 2,5,9,112,12 is active, and rests are dormant

Route I of supply chain network results when pharma company manufacture number 5 receives raw material from raw material supplier number 2 and transports medical product using logistics number 9 to distributers. Among distributers, company number 5 distributes to distributer number 112 from where retailer number 12 get medical products. Now under Hyperledger Fabric in supply chain network route number I, only 2,5,9,112,12 nodes are active, and rest nodes of ledger are dormant. The transaction of data information in shared ledger will be accessed by these nodes only due to smart contract achieved on blockchain using Byzantine Fault Tolerance Consensus Mechanism. Thus, confidentiality and privacy of information is maintained among stakeholders. Each node can trace the updated transactions in chain. The data will be shared only among active nodes by Hyperledger Fabric Network system and privacy of data assured. Other supply chain network route from II to IV and their different stakeholder from manufacturers to retailers (2,3,4…..n) work in a way similar to route I as described above in Table 1. These network systems can be automatically executed and operated

when conditions are met like smart contracts under consensus mechanism using algorithm Byzantine Fault Algorithm described (Lei et al., 2018) in Figure 6.

4. Theoretical Blockchain Architecture Model (t-BAM) for Medical Products

Block chain is the chain of "n" numbers of nodes connected to each other with encrypted information. It is a decentralized digital ledger to record and transfer the data in a secure, fast, and transparent way. The block chain based drug supply chain will depend on manufacturers, wholesalers, pharmacists and even patients too.

In a block chain based supply chain of the medical products, all medical devices, packets, bottles, and other containers of medical products are labelled with serial numbers and QR codes. These QR codes/serial numbers are scanned and recorded using IOT devices on block chain at every point along its journey from manufacturing unit to hospital/pharmacy or even patient also. In addition to that, even manufacturing inputs, like chemical ingredients, process, shipment, quality control/quality assessment parameters, no. of medical products dispatched/received can be tracked and linked to all partners in the decentralized ledger called block chain.

To enhance the visibility like location and temperature of the medical products during the transit, IOT devices can be further added as technical tools which unauthorized any unwanted tampering in the data and information encrypted. The IOT devices records the accurate information during the medical products shipment from one location to another with data integrity. The entire process from manufacture to sale, the system will be controlled by block chain. It records each step of the transit and every change of hand. The Block chain in context of this model based on the distributed ledger depicted in the Figure 2. In this, every stakeholder of chain system interconnected to each other and updated information of medical products are visible, traced and relevant data can be accessed anytime by any authorized nodes (Raw Material Supplier, Manufacturer, Logistics, Distributer, Retailer and at last patient)

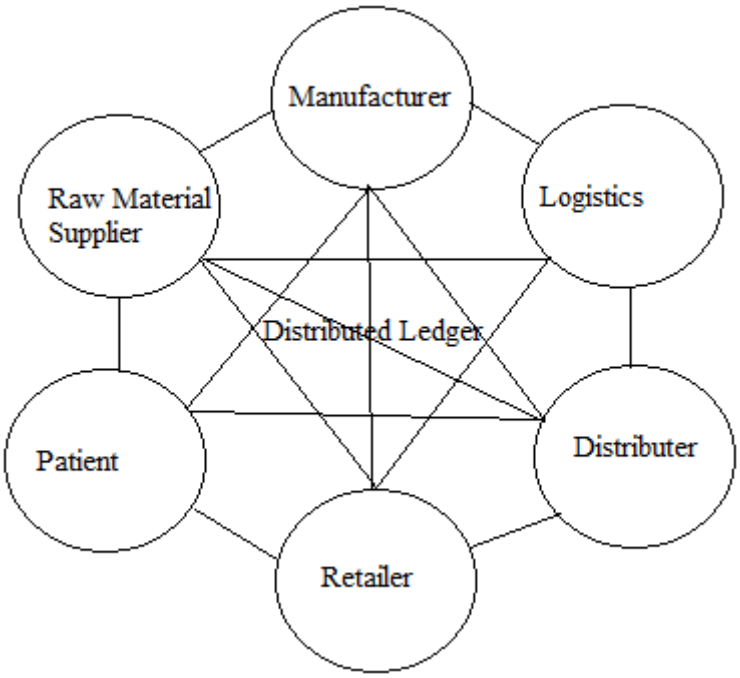


Figure 2. Distributed Ledger of Supply chain Pharma-Stakeholders (Srivastava et al., 2019)

The blocks are created on block chain platform from 1 to 5 which corresponds to different stakeholders like Raw Material Producer, Manufacturer, Logistics, Distributor and Retailer, respectively. These stakeholders are connected throughout a chain with hash values against input data and it is result of Secure Hash Algorithm256 (SHA256) technique. The hash value of previous block to be added to input data of next block and generating the new hash value of the current block, now this blocks hash value added to the input data of the next block; and process continues with progression of blocks. In figure 1, raw material producer (Block-1) is a genesis block, and input data transaction generates Block-1 hash value with SHA256 hash technique. This hash value will be included in transaction data of manufacturer (Block-2) resulting in generation of new hash. Block-2 hash value will be combined in input data of logistics (Block-3) to generate fingerprint or hash values of Block-3. This hash value added to input transaction of Distributer (Block-4) and generates Block-4 hash. Block-4 hash value added to text/input data of Retailer (Block-5) by generating hash of Block-5. This previous hash of old block helps to generate hash of new block and with same the principle, stakeholder's blocks are interconnected to one another which is depicted in given Figure 3.

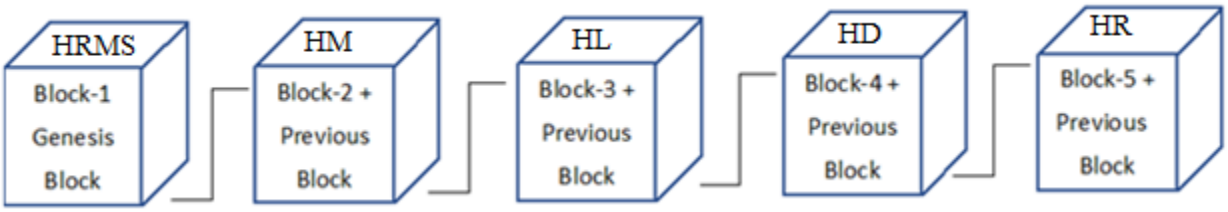


Figure 3. Block chain Architecture Model for Supply Chain of Medical Products (Khizar et al., 2020)

Pharma-stakeholders transact data information and give inputs to blocks. As a result of transactions, hash values are generated against change in data information. The process of generating corresponding hash values is given in Table 2 to Table 6 with subsequent change of data in each block.

Block-1 presents raw material supplier data and all details of raw material supplying to pharmaceutical companies for manufacturing of medical products encrypted in block. The specific string of data requires a signature which is generated by cryptographic hash functions. Once all details of raw material; embedded in the form of text/data which converted into a 64-digit string (fingerprint) output by SHA256 hashing technique. However, various techniques are available but online SHA-256 (https://emn178.github.io/online-tools/sha256.html) has been used in this paper to generate hash to present t-BAM for fingerprint generation. As per inputs data of block-1, new hash has generated represents as:

"000ed212b9ff1603baa24ea4cb85f560f071b27437906bbfbf73f9941a5a2131"

Every string of data has only one unique hash representing fingerprint of that data string which is continuously updated on shared ledger platform. These hash values are also referred as Merkle Tree/fingerprint of transacted data Fingerprint of Block-1 data given in Table 2.

Table 2. Genesis of Blockchain Hash Values against the Hash Keys or Input Data Text of Block-1

Block-1 (Raw Material Supplier)		**Transaction data Hash**
Input Text/Data	(Raw Material Supplier Transaction Data: TRMS1) Name and address of Vendor (Raw Material Supplier Transaction Data: TRMS2) Name of Raw Material (Raw Material Supplier Transaction Data: TRMS3) Method of production (Raw Material Supplier Transaction Data: TRMS4) Batch number/Serial No. (Raw Material Supplier Transaction Data: TRMS5) Certificate of Analysis (Raw Material Supplier Transaction Data: TRMS6) Purchase Order No. (Raw Material Supplier Transaction Data: TRMS7) Manufacturing date (Raw Material Supplier Transaction Data: TRMS8) Expiry date (Raw Material Supplier Transaction Data: TRMS9) Shipper Number (Raw Material Supplier Transaction Data: TRMS10) Destination Location	HRMS1 HRMS2 HRMS3 HRMS4 HRMS5 HRMS6 HRMS7 HRMS8 HRMS9 HRMS10
Genesis Hash	A signature starting with at least *ten consecutive zeroes, then a Block* qualify to be added to the blockchain	
New Hash	000ed212b9ff1603baa24ea4cb85f560f071b27437906bbfbf73f9941a5a2131 (**HRMS:** Hash of Raw Material Supplier includer Hash from HRMS1 to HRMS10)	

Block-2 represents the manufacturer of medical products. The manufacturer produces various kind of medical products and the information related to "X" medical products are stored in the blocks in form of data/text (64 String).

Block-2 links with block-1 because hash of previous block carry forwarded to next block-2. In block-2, previous hash as

"000ed212b9ff1603baa24ea4cb85f560f071b27437906bbfbf73f9941a5a2131"

added to the block-2 information and new hash of block-2 generated as

"e4e959eebbc14b64e7862595acd79d3a90917349d4be42d4908cd0c31d97b7bf"

which is indicated in Table 3 with transacted data information by manufacturer.

It is observed that both hash values are entirely different. These signatures link blocks and generate a blockchain system in a unique way. As input data changes with time, hash value also changes accordingly, and these changes can be made only by authorized personnel of the manufacture (Block-2) to whom private key has assigned.

Table 3. Genesis of Blockchain Hash Values against the Hash Keys or Input Data Text of Block-2

Block-2(Manufacturer)		**Transaction data Hash**
Input Text/Data + **Previous Hash (HRMS)**	(Manufacturer Transaction Data: TM1) Name and address of Manufacturer (Manufacturer Transaction Data: TM2) **Name of the Drug Product** (Manufacturer Transaction Data: TM3) **Name of raw material supplier Quantity of the product** (Manufacturer Transaction Data: TM4) **List of the Active Ingredients** (Manufacturer Transaction Data: TM5) Date of Manufacturing (Manufacturer Transaction Data: TM6) Date of expiry (Manufacturer Transaction Data: TM7) Price of Product (Manufacturer Transaction Data: TM8) Batch number (Manufacturer Transaction Data: TM9) Storage conditions	HM1 HM2 HM3 HM4 HM5 HM6 HM7 HM8 HM9
	000ed212b9ff1603baa24ea4cb85f560f071b27437906bbfbf73f9941a5a2131	
New Hash (HM)	e4e959eebbc14b64e7862595acd79d3a90917349d4be42d4908cd0c31d97b7bf (**HM:** Hash of Manufacturer include Hash from HM1 to HR9+Block-1, HRMS hash)	

Block-3 deals with logistics system and its always essential that logistics system should be rigorous, tamper free, transparent. It is a challenging task to transport life-saving medical products from one place to another without hampering the quality of the product, but the information encrypted in form of hash, then it is very hard to penetrate supply chain at any point of time without authentic blockchain partner. Here block-3 carry forward the previous hash of block-2 as:

"e4e959eebbc14b64e7862595acd79d3a90917349d4be42d4908cd0c31d97b7bf"

into the input data of logistic vendor, Block-3 created new hash given as:

"687182ac2ae2850e19c2de96179ce2dfbc7b8e3925344660f76b02fcc1ea78cc"

It is depicted in Table 4 with all relevant data transaction made by Logistics.

Merkle Tree of Data Transactions in Logistic Block-3 presented in Figure 4 and transaction data from TL1 to TL10 updated in shared ledger on block chain logistic channel and corresponding Hash values (HL1 to HL10) against input data (TL1 to TL10) generated on Hyperledger Fabric Network. These Hash values (HL1 to HL10) and previous hash value of block-2 (HM) will generate next hash value that is called fingerprints of Logistic Block-3 (HL). Here, this block also embedded previous block information on shared ledger because Block-2 transacted data hash (HM) is part of new hash of Block-3. In this way, previous block is interconnected to next one with updated information which is accessible as and when needed by all partners of Block chain.

Table 4. Genesis of Blockchain Hash Values against the Hash Keys or Input Data Text of Block-3

Block-3(Logistics)		**Transaction Data Hash**
Input Text/Data + **Previous Hash (HM)**	(Logistic Transaction Data: TL1) Name of logistics (Logistic Transaction Data: TL2) Travel Permission (Logistic Transaction Data: TL3) Name of Medical Product Manufacturer (Logistic Transaction Data: TL4) Registration no. (Logistic Transaction Data: TL5) Number of Medical Products (Logistic Transaction Data: TL6) Batch number (Logistic Transaction Data: TL7) Date of dispatch (Logistic Transaction Data: TL8) Delivery Point (Country/State/District/Region/Local area) (Logistic Transaction Data: TL9) Delivery date and time (Logistic Transaction Data: TL10) Temperature logger (Calibration date, next Calibration date)	HL1 HL2 HL3 HL4 HL5 HL6 HL7 HL8 HL9 HL10
	e4e959eebbc14b64e7862595acd79d3a90917349d4be42d4908cd0c31d97b7bf	
New Hash (HL)	687182ac2ae2850e19c2de96179ce2dfbc7b8e3925344660f76b02fcc1ea78cc (**HL:** Hash of Logistics include Hash from HL1 to HL10+Block-2 Hash, HM)	

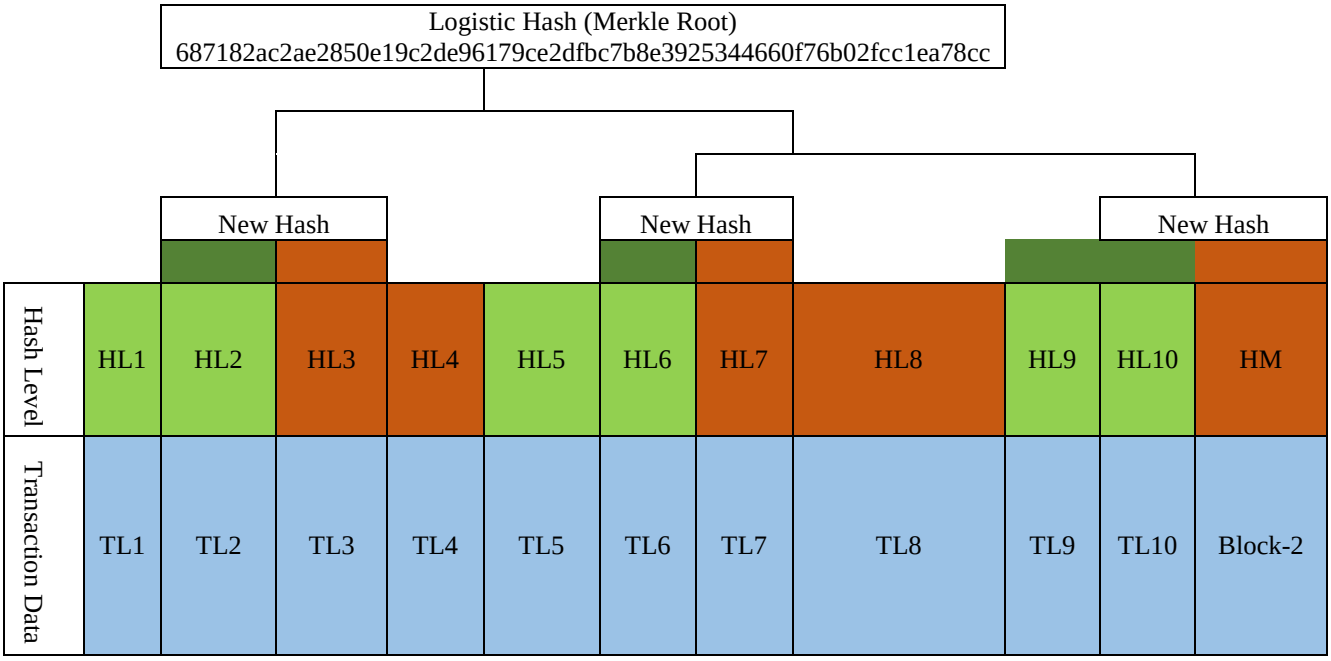


Figure 4: Merkle Tree Hash Root Algorithm of Logistic Data Transaction

Block-4 presents the distributer related data/information and different distributers have rights to sell medical products across the states/countries. These medical products are received, verified, stored, and sold to retailers. The previous hash as of block-3 given below

"687182ac2ae2850e19c2de96179ce2dfbc7b8e3925344660f76b02fcc1ea78cc3"

which is being added to block-4 and new hash for block-4 is generated as

"ed89b15c453f8ce76e1da5e1ac3f428af83574d222c28046b55e954c74e55667" as depicted in Table 5. In continuation to the different blocks, each block differs with each other in terms of different hash values which is also called the fingerprint of that block.

Table 5. Genesis of Blockchain Hash Values against the Hash Keys or Input Data Text of Block-4

Block-4 (Distributer)		**Transaction Data Hash**
Input Text/Data + Previous Hash (HL)	(Distributer Transaction Data: TD1) Name of Distributer (Distributer Transaction Data: TD2) Name of Logistics (Distributer Transaction Data: TD3) License No. of Distributer (Distributer Transaction Data: TD4) Name of Medical Product (Distributer Transaction Data: TD5) No. of Received Items (Distributer Transaction Data: TD6) Batch number (Distributer Transaction Data: TD7) Name of Manufacturer (Distributer Transaction Data: TD8) Name of Transporter (Distributer Transaction Data: TD9) Date of Dispatch (Distributer Transaction Data: TD10) Date of Delivery (Distributer Transaction Data: TD11) Product Quality (Distributer Transaction Data: TD12) Damage (If any)	HD1 HD2 HD3 HD4 HD5 HD6 HD7 HD8 HD9 HD10 HD11 HD12
	687182ac2ae2850e19c2de96179ce2dfbc7b8e3925344660f76b02fcc1ea78cc	
New Hash (HD)	ed89b15c453f8ce76e1da5e1ac3f428af83574d222c28046b55e954c74e55667 (**HD:** Hash of Distributer include Hash from HD1 to HD12+Block-3 Hash, HL)	

Block-5 represent the data of retailers from where patients are purchasing the medicines, and other medical products. The details of the products stored by retailers in the form of input text. The previous block-4 hash as:

"ed89b15c453f8ce76e1da5e1ac3f428af83574d222c28046b55e954c74e55667"

added to the data of Block-5 and generated new hash for this block-5 as

"4298df23461c537dca35a14d1908e089aec4b731a3c77cc0b0cc509759aeeb83" which is shown in Table 6.

Table 6. Genesis of Blockchain Hash Values against the Hash Keys or Input Data Text of Block-5

Block-5 (Retailer)		**Transaction Data Hash**
Input Text/Data + Previous Hash (HD)	(Retailer Transaction Data: TR1) Name of Retailer (Retailer Transaction Data: TR2) Name of Distributer (Retailer Transaction Data: TR3) Name of Manufacturer (Retailer Transaction Data: TR4) Name of Product (Retailer Transaction Data: TR5) Batch number (Retailer Transaction Data: TR6) Quantity of product (Retailer Transaction Data: TR7) Quality of Product (Retailer Transaction Data: TR8) Date of Dispatch from Distributer (Retailer Transaction Data: TR9) Date of Receipt (Retailer Transaction Data: TR10) Storage conditions	HR1 HR2 HR3 HR4 HR5 HR6 HR7 HR8 HR9 HR10
	ed89b15c453f8ce76e1da5e1ac3f428af83574d222c28046b55e954c74e55667	
New Hash (HR)	4298df23461c537dca35a14d1908e089aec4b731a3c77cc0b0cc509759aeeb83 (**HR:** Hash of Retailer include Hash from HR1 to HL10+Block-4 Hash, HD)	

The blockchain using different hash functions like MD5, ripmed160, SHA-1, SHA-256, Keccak-256 converts data into a fingerprint of that data. These fingerprint or cryptographic hash sometimes called digest which is kind of "signature" for a text or data file. The digest changes with the small change at any point of addition or deletion during the supply chain. All stakeholders can use Blockchain platform and perform their tasks. The login ID and passwords (private keys) help to stakeholders to access blockchain as given in Table 7.

Table 7. Hash Key, Private Key, Hash Function and Hash Values

Hash Key	**Private Key**	**Hash Function**	**Hash Value/Fingerprint of Text**
Insert Item—e.g., Individual ID, location, timestamp, current stakeholder	Login ID/Passwords	SHA-256	544fd93aca8f011bf3231d5dab309ffc8c8fc55bed0db1b3532a169b5f5f20fa
Update Item—e.g., ID, new location, new timestamp, new stakeholder			76e3f4e37925ffd2476ec030b5d53d8e24de58eab9033274258753bf33cb653e
Look Up Item—e.g., ID, retrieve locations, and retrieve stakeholders			04b48bcb63f8e8051e7d19ca64a0de8aaa20142929dc76802c3d138bf6c89c59

5. Control of Counterfeit Medical Products using t-BAM

During Covid-19 pandemic, falsified medical products are increasing in national and international market. False vendors are taking the advantages of government, regulators, and public health provider's urgency, and curious to generate fake medical products with similar packaging and labelling like original ones (Lukas et al., 2019). These fake medical products to be sold under the branded names as well as generics across the world. These malpractices can be prevented using presented t-BAM which offers a system of interoperability across disparate levels of stakeholders in supply chain. Blockchain prevents unauthorized medical products entry in market at regional and country level across borders. t-BAM

described in below given steps from 1-5 and provides a complete process of controlling counterfeit medical products in different countries across the globe.

Step-1: The block-1 of the raw material vendor update all raw material data information on shared distributed ledger. This block is a genesis block. These raw items supplied to different manufacturers from where medical products are being produced. The hash of block-1 generated against input text of this block is given below.

"000ed212b9ff1603baa24ea4cb85f560f071b27437906bbfbf73f9941a5a2131"

Step-2: The block-2 is manufacturer's data block and generating new hash against input data by manufacturer in connection with block-1 encryption. The hash for this block-2 contains:

Block-1 Hash	000ed212b9ff1603baa24ea4cb85f560f071b27437906bbfbf73f9941a5a2131
Block-2 Hash	e4e959eebbc14b64e7862595acd79d3a90917349d4be42d4908cd0c31d97b7bf

In block 2, we presumed that manufacturer produced 10,00,000 "X" medical products and released into global market. These 10 lakhs medical products information is stored in block-2 hash which includes hash of block-1 too. Now both blocks can access data that how much "X" medical products are produced from raw material.

Step-3: The block-3 represents logistics which has responsibility to transfer medical products from one place to another in a very systematic manner.

Block-2 Hash	e4e959eebbc14b64e7862595acd79d3a90917349d4be42d4908cd0c31d97b7bf
Block-3 Hash	687182ac2ae2850e19c2de96179ce2dfbc7b8e3925344660f76b02fcc1ea78cc

Now new hash of data of 10 lakhs "X" medical products generated in the world. The products supposed to be distributed throughout the world in USA, France, Italy, and Australia as in case of this t-BAM presentation with help of logistic system. The logistics also connected with earlier blocks, so data are visible to other block holders too in these country's partners. The logistics distributed definite quantity of "X" medical product to different distributers across the World in different countries as indicated in the given Table 8.

Table 8. Distribution of "X" Medical Product Among Different Countries in World

State	**Distributers (D)**	**Quantity of "X" Medical Products (Lakhs)**
USA	UDR_1	1.5
	UDR_2	0.5
	UDR_3	0.5
France	FDR_1	1.5
	FDR_2	0.5
	FDR_3	0.5
Italy	IDR_1	1.5
	IDR_2	0.5
	IDR_3	0.5
Australia	ADR_1	1.5
	ADR_2	0.5
	ADR_3	0.5
Total (All distributers)		**10 Lakhs ("X" Medical Products)**

Step 4: The block-4 is representing the distributers and here block-4 represented as only one country that is USA which has three hypothetical distributers named as UDR_1, UDR_2, and UDR_3 in USA. Similarly, other blocks can also be created. Here in this paper, USA is taken as an example to understand whole system of controlling counterfeit products entry (if any) at any point against the original "X" medical products in supply chain under t-BAM. Distributer (UDR_1) has taken up in model as a distributer and following new hash value of distribute UDR_1 which includes the previous hash of Logistics(L_1) is given below:

Block-3 Hash	687182ac2ae2850e19c2de96179ce2dfbc7b8e3925344660f76b02fcc1ea78cc
Block-4 Hash	ed89b15c453f8ce76e1da5e1ac3f428af83574d222c28046b55e954c74e55667

This hash contains of USA division distributer (UDR_1) where 1,50,000 "X" medical products received from manufacturer. Similarly, USA distributers (UDR_2, UDR_3) and other countries (France, Italy, and Australia) distributers are accountable for 8,50,000 medical products. The hash values of these country distributers are also differing to each other.

Step.5: The retailers in USA is represented R_1, R_2, and R_3. The retailers (Block-5, Node no. 12) receiving 0.6 lakhs Covid-19 related medical products from distributor (Block-4, UDR_1) and data information is encrypted in block-5. Suppose three retailers (R_1, R_2 and R_3) received medical product from USA distributer (UDR_1) block-4 as presented in Table 9.

Table 9. Distribution of Number "X" Medical Products among Retailers (R_1, R_2, and R_3) in USA

State	**Retailers**	**Quantity of "X" Medical Product (Lakhs)**
Block-4 USA (UDR_1)	Retailer-R_1 (**Block-5**)	0.6
	Retailers-R_2	0.7
	Retailers-R_3	0.2
Total "X"Medical Products		**1.5 Lakhs**

The generated hash for Retailer-R_1 (Block-5) is given below:

Block-4 Hash	ed89b15c453f8ce76e1da5e1ac3f428af83574d222c28046b55e954c74e55667
Block-5 Hash	4298df23461c537dca35a14d1908e089aec4b731a3c77cc0b0cc509759aeeb83

In USA, R_1 (Retailer) is accountable for 0.6 lakhs "X" medical products and this retailer is connected to every peer of blockchain. Thus, R_1 is authorized to sell only 0.6 lakhs "X" medical product. Similarly, R_2 is accountable to sell 0.7 lakhs medical products, R_3 is for 0.2 lakhs "X" medical products. Other countries (France, Italy, and Australia) will be accounted for rest of 7,50,000 "X" medical products. Thus, complete 10 lakhs "X" medical product data will be shared through the blockchain in all countries. If any counterfeit of "X" medical product introduced at any level of supply chain, it will be easily tracked because that would not be part of the supply chain. The hackers try to succeed in entering of supply chain, but it would be easily tracked because public and private keys are with stakeholders of the Blockchain. A single dot (.) changes in block event transaction of supply chain, leads to changes entire fingerprints from manufacturer to end user and this will not be validated by all stakeholders.

Here, Raw material provider, Manufacturer, Logistics, Distributors, and Retailers are in connection to each other on Hyperledger Fabric platform. A fake retailer/vendor who is not a part of this blockchain (which covers the information of Block-2 to Block-5) is designed as Block-F in t-BAM. The following blocks from B_1, B_2, B_3, B_4, B_5 representing all stakeholder i.e. raw material vendor, manufacturer, logistics, distributer, and retailer, respectively. The block-5 relates with the retailer R_1 in USA. This retailer got 0.6 lakhs "X" medical products from manufacture as indicated in Figure 5.

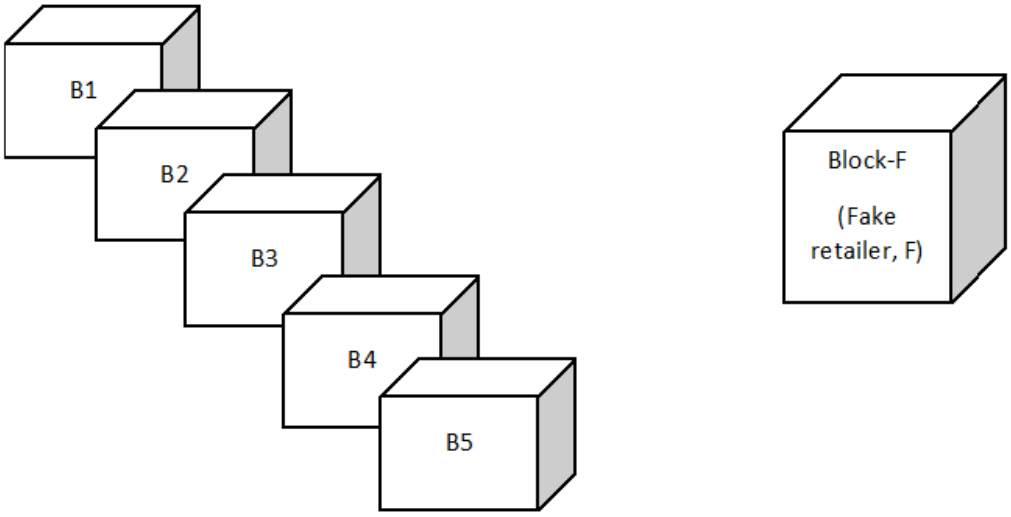


Figure 5. "X" Medical Products Blockchain and Fake Block-F (Soundarya et al., 2018)

If any retailer purchases fake drugs in name of "X" medical product from unauthorized market or fake manufacturer and start to sell. In such cases, regulatory may inspect the blockchain of "X" medical product where retailer B_5 (Name, Location, Quantity of "X" medical product purchased, Sold, and Balance) is the authorized one to have "X" medical product. If any other retailer like Block-F who is selling fake "X" medical product in USA, then regulators/ inspectors may investigate the Block-F whether it is part of "X" medical product Blockchain or not.
After investigating, they will certainly find that the Block-F is not the part of the Blockchain and is the fake/counterfeit medical product. Thus, the counterfeit "X" medical products may be traced and tracked at any point of supply chain in the market of different regions, different countries and control sell of unauthorized medical products during Covid-19 pandemic.

6. Consensus Mechanism in t-BAM: Byzantine Fault Tolerance

It is essential that a consensus should be achieved among all nodes of supply chain to make authentic transaction and ledger entry in a transparent way. As we know that Blockchain is a distributed ledger system which is secured, tamper free, verifiable due to consensus protocol which is a core part of Blockchain network. All nodes/actors of the chain should endorse the added transaction/information in their own ledger. It could be done using the consensus algorithm. However, various consensus algorithms i.e., Proof of Work (POW), Proof of Stake (POS), Proof of Burn (POB) and Byzantine Fault Tolerance (BFT) are used for consensus on nodes on Blockchain. Whenever the new information gets broadcasted to the blockchain network, actors or all partners have option either to include the information in their ledger or reject/ignore it (Leila et al., 2019). When majority of the actors are on the single state, consensus is achieved. In this paper, Byzantine Fault Tolerance algorithm-based consensus algorithm presented in connection of Hyperledger Fabric on Blockchain for mutual consensus and acceptability of all nodes. The Byzantine Fault Tolerance algorithm (in context of supply chain) for "X" medical product from manufacturer to retailer is given in Figure 6.

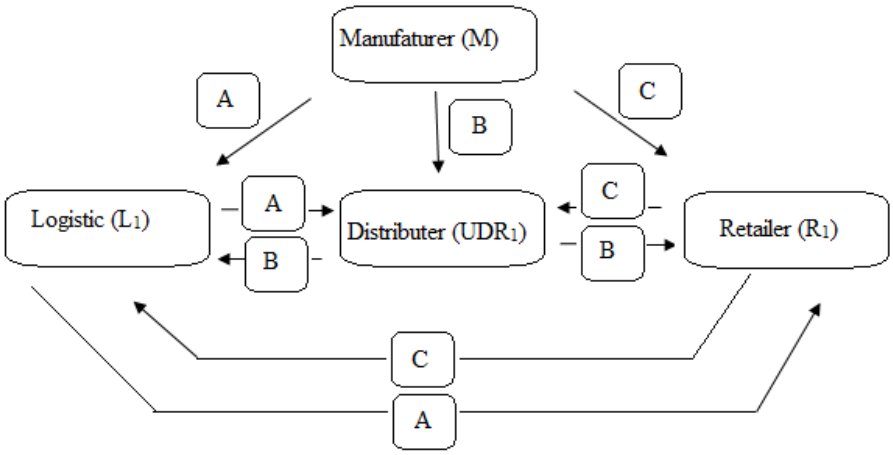


Figure 6. Byzantine Fault Tolerance Algorithm for Consensus (Lei et al., 2018)

The following steps (Description of Byzantine Fault Tolerance Algorithm for Mutual Consensus of Nodes) considered to achieve mutual consensus among active nodes (5, 9, 112, and 12) in t-BAM.

Steps	**Byzantine Fault Tolerance Algorithm Description for Consensus**
Step 1	The Manufacturer sends informaiton A, B, C to L_1, UDR_1, R_1 respectively
Step 2	L_1 sends A information to L_1, UDR_1 UDR_1 sends B information to UDR_1, R_1 R_1 sends C information to L_1, R_1
Step 3	Majority (A,B,C) infortmation to L_1 Majority (A,B,C) information to UDR_1 Majority (A,B,C) infortmation to R_1
Consensus Achievement	Here it has observed that A,B,C are all different but the value majority (A,B,C) is the same for all three actors in the Blockchain. In this way, informations are verified by each node, everyone keeps the updating and correct version of the ledger updated at every partner. For more complex structure of several stakeholders and various manufacturers, the same BFT algorithm can be used. The consensus among the partners achieved maintaining the transparency of information or transaction during the supply chain of "X" Medical Product. Now all nodes have same value and thus consensus reached. The data transparency and authenticity developed without any uncertainty.
Agreement of Nodes	In this way, stakeholder are agreed mutually for suppyl of medical product "X=10 Lakhs" in Different countries.

6.1. Methodology of Consensus by Byzantine Fault Tolerance

All information about quantity of "X" medical products produced by manufacturer, encrypted in form of hash values in Block-2 (Node number-5). The transaction of information from manufacturer to other stakeholders like logistic, L_1(Node number 9), distributer, D_1(Node number 112 named as UDR_1 in country USA) and retailer, R_1(Node number 12 represented retailer in USA) received information through A, B, C respectively. Then L_1 sends A to UDR_1, R_1 and UDR_1 sends B to L_1, R_1.

Table 10. "X" Medical Producs at UDR_1 Distributer in USA

State	**Retailers**	**Quantity of "X" Medical Product (Lakhs)**
USA (UDR_1) (1.5 Lakhs Units)	Retailer-R_1	0.6
	Retailers-R_2	0.7
	Retailers-R_3	0.2
Total Medical Products		**1.5 Lakhs**

Node R_1 sends C to L_1, UDR_1. Majority (A,B,C) information of manufacturer passed to L_1, UDR_1, R_1 and each node also shared the information (A,B,C) to one another with the help of Byzantine Fault Tolerance. In this way, all nodes reached at a uniform mutual consensus and information shared by each other is accurate, transparent, reliable and authentic. Thus supplychain of the "X" medical product is an impervious chain under this model and fake conterfeit medical product can not be introduced at any level of supply chain.

7. Internet of Things (IOT) devices for Transit Temperature and Humidity Measurement

IOT devices like temperature sensitive probes, Data loggers are to be used with remote accession of recorded data during transit of "X" medical product supply chain. Any type of data variation due to changes of climatic conditions country to country or one place to another, can be accurately recorded and reported using t-BAM with timestamp and route used by stakeholder through which medical product passes. The configuration of IOT devices is Accuracy and Precision, Temperature Measurement Range, Humidity Measurement Range, and Power consumptions of devices (Daniel et al. 2020).

8. Validation of Proposed Theoretical Blockchain Architecture Model (t-BAM)

The Proposed model nodes actively participates in entire supply chain of medical product "X" from manufacturer (M) to retailer (R_1) in country USA through Logistics (L_1) and USA Distributer (UDR_1) who is assigned to distribute 1.5 Lakhs quantity of "X" medical Product only (using Byzantine Fault Tolerance Consensus Mechanism). UDR_1 delivers 0.6 lakhs to retailer (R_1) who is accountable to sell only 0.6 Lakhs "X" medical products. The supply chain channel of "X" medical

product depicted in Table 11 which participating active nodes presented in Hyperledger Fabric Network system of this model.

Table 11. Validation of Supply Chain Channel of "X" Medical Product from Manufacturer to end Retailer (R_1)

Block	Stakeholder	Hyperledger Fabric Route	Quantity of "X" Medical Product	Countries for Supply
Block-2	Manufacturer (M)	5	10 Lakhs	USA, France, Italy, Australia
Block-3	Logistics (L_1)	9	10 Lakhs	USA, France, Italy, Australia
Block-4	Distributer (UDR_1 in USA)	112	1.5 Lakhs	USA only
Block-5	Retailer (R_1) in USA)	12	0.6 Lakhs	USA Only

Validation of t-BAM model carried on various parameters i.e., Immutability, Mutual consensus, Transparency, Accountability, Privacy and Security, Temperature and Humidity.

8.1. Immutability

Immutability in Blockchain is relative and change of data cannot be possible. As we know, one block is linked with another by hash values. Hash values are generated against input texts using the Hash Algorithm (Secure Hash Algorithm 256) on blockchain during activities of stakeholders from manufacturer to end user. In this, changes are visible only for authentic active node, not to dormant nodes of chain on Hyperledger Fabric network as depicted in Table 1. None other than authentic node of blockchain can access ledger data. These data cannot be modified, altered, added, and deleted retroactively. If any malicious data inserted/modified, then nonce (guessing numbers to solve a puzzle for a new block creation) must be recalculated. In this process, entire chain fingerprint will be changed which is not acceptable by other nodes. To accept by all chain partners, change in fingerprint of all blocks to be made and it is next to impossible to modify hash values/fingerprint of entire blockchain system. It provides a secure and immutable environment to supply chain in blockchain system.

8.1.1. Process of Immutability

Data transaction updated in ledger of all stakeholders automatically in blocks. The events of each block consist a header and a body. Header comprises information required to link transactions to chain and updated related to consensus mechanism that is BFT in t-BAM. The body part of a block contains data elements of event happened on a specific date and time.

Block-2 encrypted data has fingerprint:

"e4e959eebbc14b64e7862595acd79d3a90917349d4be42d4908cd0c31d97b7bf"

and Block-3 encrypted data has fingerprint:

"687182ac2ae2850e19c2de96179ce2dfbc7b8e3925344660f76b02fcc1ea78cc".

Block-3 fingerprint includes block-3 data and hash value of Block-2. A little change in encrypted data of block-3 from capital letter to small letter in "Name of logistics (TL_1)" to "name of logistics (tL_1)" leads to change entire chain hash value initiating the change from block-3 onwards as depicted in Table 12.

New hash of block-3 will be "733094c18020a2e63f544870afd847d3c673df431d900771a02768c6c35dac35" which is entirely different from the previous hash of Block-3. A little change in only capital letter of "N" to "n" in Name only, transformed the entire hash value (64 string) of block 3 from correct hash "687182ac2ae2850e19c2de96179ce2dfbc7b8e3925344660f76b02fcc1ea78c" to incorrect hash "733094c18020a2e63f544870afd847d3c673df431d900771a02768c6c35dac35" which will not be acceptable by all nodes because of erroneous hash in blockchain. Because it resulted into change of entire subsequent block-4 and block-5 fingerprints which will not be authorized by node-4 and node-5. It fails entire blockchain system which cannot be achieved. Therefore, any insertion of medical products across supply chain is not possible and immutability of supply chain of "X" medical products.

Table 12. Change of Block-4 and 5 Fingerprints against Small alteration of Input Data in Logistic Block-3

Blocks	**Logistics/Block-3/Node-9**		**Acceptable Data**		**Acceptable data**	
Header	Previous Hash	Time Stamp	**Distributer/Block-4/Node-112**		**Retailer/Block-5/Node-12**	
	Merkle root	Nonce	Previous Hash	Time Stamp	Previous Hash	Time Stamp
	Transactions		Merkle root	Nonce	Merkle root	Nonce
Body	TL1 TL2 TL3		Transactions		Transactions	
	TL4 TL5 TL6		TD1 TD2 TD3		TR1 TR2 TR3	
	TL7 TL8 TL9		TD4 TD5 TD6		TR4 TR5 TR6	
Hash	687182ac2ae2850e 19c2de96179ce2dfbc 7b8e3925344660f76b02fcc1ea78c		TD7 TD8 TD9		TR7 TR8 TR9	
			ed89b15c453f8ce76e1da5e 1ac3f428af83574d222c280 46b55e954c74e55667		4298df23461c537dca 35a14d1908e089aec4 b731a3c77cc0b0cc509759aeeb83	
Data Change	Change N to n in Name of Logistics		Fingerprint Change		Fingerprint Change	
Acceptance	Not Acceptable data		Not Acceptable data		Not Acceptable data	
Block	**Logistics/Block-3/Node-9**		**Distributer/Block-4/Node-112**		**Retailer/Block-5/Node-12**	
Header	Previous Hash	Time Stamp	Previous Hash	Time Stamp	Previous Hash	Time Stamp
	Changed Merkle root	Nonce	Changed Merkle root	Nonce Recalculation	Changed Merkle root	Nonce Recalculation
	Transactions		Transactions		Transactions	
Body (tL1 in place of TL1)	tL1 TL2 TL3		TD1 TD2 TD3		TR1 TR2 TR3	
	TL4 TL5 TL6		TD4 TD5 TD6		TR4 TR5 TR6	
	TL7 TL8 TL9		TD7 TD8 TD9		TR7 TR8 TR9	
Changed Hash	733094c18020a2e63f544870afd847d3c673 df431d900771a02768c6c35dac35		ca978112ca1bbdcafac231b39a23dc4da78 6eff8147c4e72b9807785afee48bb		363cfe852dceb5d29c275ec5a39a856dd b3484dc0d189ce75549b3b8679ca4f5	
Immutability	Entire blocks hash changed, unacceptable by nodes, protects modification in data and provides Immutability					

8.2. Mutual Consensus Using Byzantine Fault Tolerance Algorithm (BFT)

In this model, smart contract achieved with Byzantine Fault Tolerance. All nodes are on same consortium and validate transactions across supplychain. Block-2 include imanufacturing information about quantity of "X=10 Lakhs" medical products and product information passed to logistic (L_1), distributer (UDR_1) and retailer (R_1) received through the A, B, C respectively.

All stakeholders of this channel are in same updated ledger mode with true updated informtion transmission on Hyperledger Fabric Network. Node numer 5 (M) passes data transaction of "10 lakhs X medical product" to node number 9 (L_1), node number 112 (UDR_1), and node number 12 (R_1). L_1 assigned to deliver 10 lakhs units to different countries (USA, France, Italy and Australia). Out of it, L_1 distributes 2.5 lakhs units to USA and it delivers 1.5 lakhs units to node number 112 (UDR_1) distributer. This UDR_1 delivers 1.5 Lakhs units of quanitty among different retailers (R_1, R_2, R_3) in USA. Block-5 or node number 12 presented as retailer R_1 who receives 0.6 lakhs unit of "X" product in model and confirmed by Byzantine Fault Tolerance Consensus mechanism depicted in Figure 6, This entire information of "X" product flow is updated on shared ledger of blockchain and every node is in mutual consensus as depicted in given Table 13. No unauthentic drug supplier can be part of such mechanism until every node permits. It provides immutability and security to supply chain for counterfiet medical product.

Table 13. Consensus Mechanism Flow of tranasction data by BFT

Block	Stakeholder	Hyperledger Fabric route	Information Channel	Encrypted "X" Product information of quantity	Every Node Consensus
Block-2	Manufacturer (M)	5	M send A to L_1 M sends B to UDR_1 M Sends C to R_1	10 Lakhs "X" products updated in Ledger of all	Yes (10 Lakhs)
Block-3	Logistics (L_1)	9	L_1 sends A to UDR_1 L1 sends A to R_1	10 Lakhs "X" products updated in Ledger of all	Yes (10 Lakhs)
Block-4	Distributer (UDR_1 in USA)	112	UDR_1 sends B to L_1 UDR_1 sends B to R_1	1.5 Lakhs Units of "X" products updated in ledger of all	Yes (1.5 Lakhs)
Block-5	Retailer (R_1) in USA)	12	R_1 sends C to UDR_1 R_1 sends C to L_1	0.6 Lakhs Units of "X" products updated in ledger of all	Yes (0.6 Lakhs)
A:B:C= 10 Lakhs "X" Products information **L_1**= 10 Lakhs "X" Product Information for transportation **UDR_1**= 1.5 Lakhs Units of "X" products **R_1**= 0.6 Lakhs Unit of "X" Products					

8.3. Transparency and Accountability

In presented t-BAM, transparency, and accountability of "X" medical is maintained throughout supply chain. All blocks on Hyperledger Fabric Network (Node 5, 9, 112, and 12) are updated with relevant transactions in real time manner and visible to each stakeholders of chain. Thus, transaction data are visible to all. The quantity of "X" medical product supplied till end retailer (R_1) in USA under this model, can be counted as depicted in depicted Table 14. No one can add any kind of counterfeit products in this blockchain and accountability of products is ensured.

8.4. Privacy and Security

The presented t-BAM is impervious to fake medical products in supply chain. The Hyperledger Fabric Networks itself provides accessibility to authorized stakeholders with public and private keys. See active and dormant nodes in Table 1. The Model presents active node route-I (5,9,112,12) and accessibility of fake vendors to introduce counterfeit medical products anywhere in supply chain (USA, France, Italy, and Australia) is protected. Any addition, deletion or modification leads to change the fingerprint of entire blockchain which will not be validated by active nodes due to transaction error and blockchain network fails. (See Table 12)

Table 14. Transparency and Accountability in t-BAM

Block-2 (M), Node 5	
Ledger Transaction	
Tx	**"X" Medical Product Units**
TX(M)	10 Lakhs
TX(L_1)	10 Lakhs
TX(UDR_1)	1.5 Lakhs
TX(R1)	0.6 Lakhs

Block-3 (L1), Node 9	
Ledger Transaction	
Tx	**"X" Medical Product Units**
TX(M)	10 Lakhs
TX(L_1)	10 Lakhs
TX(UDR_1)	1.5 Lakhs
TX(R_1)	0.6 Lakhs

Block-2 (UDR_1), Node 112	
Ledger Transaction	
Tx	**"X" Medical Product Units**
TX(M)	10 Lakhs
TX(L_1)	10 Lakhs
TX(UDR_1)	1.5 Lakhs
TX(R_1)	0.6 Lakhs

Block-2 (R1), Node 5	
Ledger Transaction	
Tx	**"X" Medical Product Units**
TX(M)	10 Lakhs
TX(L_1)	10 Lakhs
TX(UDR_1)	1.5 Lakhs
TX(R_1)	0.6 Lakhs

8.5. Temperature and Humidity Control

The transit temperature (T) and Relative humidity (RH) of "X" medical product can be measured on t-BAM and relevant information shared on distributed ledger which is visible to each partner. Any deviations in temperature and humidity acceptable range of medical products can be monitored and controlled. Cause of deviation and responsible stakeholder, can be held for practices due to which it happened. Below given Table 15 shows stakeholders in hand transit temperature and humidity data which can be accessed by transit stakeholders. The climatic condition variations can be observed, monitored as per data updated in ledger of all parties.

Table 15. Temperature (T) and Relative Humidity (RH) Data Transaction in t-BAM

Block-2 (M), Node 5	
T/RH Data Transaction	
Record Level	**Time, Date, T(°C)/ RH(%)**
TX(M)	Time1, Date 1, T1, RH1
TX(L_1)	Time2, Date 2, T2, RH2
TX(UDR_1)	Time3, Date 3, T3, RH3
TX(R_1)	Time4, Date 4, T4, RH4

Block-3 (L1), Node 9	
T/RH Data Transaction	
Record Level	**Time, Date, T(°C)/ RH(%)**
TX(M)	Time1 , Date 1, T1, RH1
TX(L_1)	Time2, Date 2, T2, RH2
TX(UDR_1)	Time3, Date 3, T3, RH3
TX(R_1)	Time4, Date 4, T4, RH4

Block-2 (UDR_1), Node 112	
T/RH Data Transaction	
Record Level	**Time, Date, T(°C)/ RH(%)**
TX(M)	Time1, Date 1, T1, RH1
TX(L_1)	Time2, Date 2, T2, RH2
TX(UDR_1)	Time3, Date 3, T3, RH3
TX(R_1)	Time4, Date 4, T4, RH4

Block-2 (R1), Node 5	
T/RH Data Transaction	
Record Level	**Time, Date, T(°C)/ RH(%)**
TX(M)	Time1, Date 1, T1, RH1
TX(L_1)	Time2, Date 2, T2, RH2
TX(UDR_1)	Time3, Date 3, T3, RH3
TX(R_1)	Time4, Date 4, T4, RH4

Block-2 records Time1, Date1, T1 and RH1 data on its ledger which is updated to other Blocks too. Similarly, other Block-3, Block-4, and Block-5 share updated product transit data transaction as Time2, Date 2, T2, RH2; Time3, Date 3, T3, RH3; Time4, Date 4, T4, RH4, respectively. These data stored on IOT (Data Loggers) which very much sensitive to record these parameters with accuracy/precision (+/- 1 to 3 °C), temperature range (-55°C to 125 °C), relative humidity range -30 to +80°C and 0 to 100% RH.

8.6. Track and Trace

This model provides complete visibility and effective coordination on product supply information on every stakeholder ledger. Table 15 presents time of dispatch from one node to another. In this model, Block-2 dispatches product "X" at Time1 and Date1. Similarly Block-3, Block-4, and Block-5 dispatch product "X" at different timing at Time2, Date2; Time3, Date3; and Time4, Date4; respectively. Transaction of dispatch and delivery data visible to all stakeholders who can access their product at any time across the supply chain to track and trace.

9. Conclusion

In this paper, an immutable, reliable, transparent, and realistic model; t-BAM presented to track and trace counterfeit medical products during supply chain in Covid-19 pandemic. Hyperledger Fabric as a Blockchain platform applied for active nodes of Node-5, Node-9, Node-112, and Node-12 in route-I. Byzantine Fault Tolerance (BFT) used to achieve consensus among manufacturer (Node-5), logistics (Node-9), (Node-112) USA distributer (UDR_1) and (Node-12) retailer (R_1). All transactions (TX) updated in ledger of each node. Node-112 (UDR_1) accountable for "X" medical product of. 2.5 lakh units. UDR_1 distributer distributes "X" medical products to three retailers in USA (R_1, R_2, and R_3) specifically 0.6 Lakh units to retailer (R_1) while other R_2, R_3 retailers are accountable for 0.9 lakhs medical products. Blockchain Architecture Model validated for Immutability (Table 12; Merkle Root change occurs with small change in data), Transparency and Accountability (Table 14; Ledger of nodes updated simultaneous to all transactions, visible to all), Consensus Mechanism (Table 13; all nodes are in uniform agreement and update data), Privacy and Security (Table 12; only public and private key holders of supply chain can access blockchain), Temperature and Humidity (Table 15; Climatic condition variations recording and maintenance), Track and Trace (Table 15; Tracking of product path with timestamp) parameters for supply chain. It was found that validation parameters provide an impervious environment to supply chain in presented t-BAM. The model will be beneficial for pharmaceutical companies, regulatory, government, auditors and inspecting agencies to control Covid-19 related counterfeit medical product during supply chain.

References

Aburto L., Weber L., (2007). Improved supply chain management based on hybrid demand forecasts. *Applied Soft Computing*, Vol. 7, pp. 136–144.

Bahga A., Madisetti V.K., (2016). Blockchain platform for industrial internet of things. *Journal of Software Engineering and Applications*, Vol. 9 (10), pp. 533-546.

Bushra M., (2018). Blockchain Technology in Supply Chain Management: A Review. *International Research Journal of Engineering and Technology*, Vol. 05 (6), pp. 2497-2500

Clark, F., (2015). Rise in online pharmacies sees counterfeit drugs go global. *Lancet*, (386), pp. 1327-1328.

Daniel L. W., Kendra N. W., Pillarisetti A., (2020). An Integrated Sensor Data Logging, Survey, and Analytics Platform for Field Research and Its Application in HAPIN, a Multi-Center Household Energy Intervention Trial. *Sustainability*, Vol. 12, pp. 1805-1807.

Daniela B., (2017) 1 in 10 Medical Products in Developing Countries Is Substandard or Falsified.2017. Available online: https://www.who.int/news-room/detail/28-11-2017-1-in-10-medical-productsin- developing-countries-is-substandard-or-falsified, Accessed Jan 2021.

Field A.M., (2017). Blockchain for freight?. *Journal of Commerce*, Vol. 18 (5), pp. 88-92.

Foerstl M. C., Schleper, Henke M., (2017). Purchasing and supply management: From efficiency to effectiveness in an integrated supply chain.

Funding, H.R. 20 Shocking Counterfeit Drugs Statistics. 2017. Available online: https://healthresearchfunding.org/20-shocking-counterfeit-drugs-statistics/, Accessed Jan 2021.

https://emn178.github.io/online-tools/sha256.html, Accessed July 2019.

https://www.blockchain-council.org/blockchain/top-10-tools-for-blockchain-development/, Accessed Feb 2020.

https://www.business-standard.com/article/pti-stories/netherlands-recalls-defective-masks-imported-from-china-120032900060_1.html, Accessed May 2020.

https://www.deccanherald.com/business/covid-19-surge-in-fraudulent-health-products-worldwide-warns-ficci-cascade-tracit-822301.html, Accessed May 2020.

https://www.drugtrackandtrace.com/solution-for-the-substandard-and-counterfeit-medicines/, Accessed May 2020.

Hyperledger Blockchain Metrix: https://www.hyperledger.org/learn/publications/blockchain-performance-metrics, Accessed Jan 2021.

Iansiti M., Lakhani K., (2017). The Truth about Blockchain. *Harvard Business Review*, Vol. 95 (1), pp. 118-127.

Khizar A., Muhammad A., Talha A. K., Wang-Cheol S., (2020). A Blockchain and Machine Learning-Based Drug Supply Chain management and Recommendation System for Smart Pharmaceutical Industry. *Electronics*, Vol 9 (852), pp. 1-31.

Kim H. M., Laskowski M., (2018). Toward an ontology-driven blockchain design for supply-chain provenance. *Intelligent System in Accounting Finance and Management*, Vol. 25 (1) pp. 18–27,

Lei K., Zhang Q., Limei X., Zhuyun Q., (2018) Reputation-Based Byzantine Fault-Tolerance for Consortium Blockchain, IEEE 24th International Conference on Parallel and Distributed Systems (ICPADS)

Leila I., Huned M., (2019). A Review of Blockchain Architecture and Consensus Protocols: Use Cases, Challenges, and Solutions. *Symmetry*, pp. 1198.

Lukas R., Kevin B.B., Daniel K. B., (2019). Substandard and Falsified Medicine Screening Technologies. AAPS Open, Vol 5 (2), pp. 1-12.

Mackey, T.K., & Liang, B.A. (2011). The global counterfeit drug trade: patient safety and public health risks. *Journal of Pharmaceutical Science*, 100, pp. 4571–4579.

Marija S.K., Lazar J.K., (2020). Hyperledger frameworks with a special focus on Hyperledger Fabric. *Military Technical Courier*, Vol. 68(3), pp. 639-663

Marucheck A., Greis N., Mena C., Cai L., (2011). Product safety and security in the global supply chain: Issues, challenges and research opportunities. *Journal of Operations Management,* Vol. 29 (7-8), pp. 707-720.

MATEC Web of Conferences 200.

Norta, A. (2017). Designing a smart-contract application layer for transacting decentralized autonomous organizations. In: Singh, M.; et al. (Ed.). Advances in Computing and Data Sciences, pp. 595−604.

Rise of fake 'Corona Cures' revealed in global counterfeit medicine https://www.europol.europa.eu/newsroom/news/rise-of-fake-%E2%80%98corona-cures%E2%80%99-revealed-in-global-counterfeit-medicine-operation, Accessed Jan 2021.

Simchi-Levi D., Kaminsky P., Simchi-Levi E., (2001) Designing and Managing the Supply Chain: Concept, Strategies, and Case Studies. *Journal of Business Logistics,* Vol 22(1), pp.259-261.

Soundarya. K., Pandey P., Dhanalakshmi R., (2018). A Counterfeit Solution for Pharma Supply Chain. *EAI Endorsed Transactions on Cloud Systems,* Vol. 3 (11), pp. 1-8

Srai J.S., Harrington T.S. , Alinaghian L., Phillips M., (2015). Evaluating the potential for the continuous processing of pharmaceutical products—a supply network perspective. *Chem Eng Process,* Vol. 97, pp. 248–258.

Srivastava S., Bhadauria A., Dhaneshwar S., Gupta S., (2019). Traceability and Transparency In Supply Chain Management System of Pharmaceutical Goods Through Block Chain International. *Journal of Scientific & Technology Research,* Vol 8 (12), pp. 3201-3206.

Temperature/humidity data loggers and chart recorder,https://sysmatec.ch/eE1_Temperature_Humidity_Logger.html, Accessed Jan 2021.

The Guardian. 10% of Drugs in Poor Countries Are Fake, Says WHO. 2017. Available online: https://www. theguardian.com/global-development/2017/nov/28/10-of-drugs-in-poor-countries-are-fake-says-who, Accessed Jan 2021.

Themistocleous M., Irani Z., Love P.E., (2004). Evaluating the integration of supply chain information systems: A case study. *European Journal of Operational Research*, Vol 159, pp. 393-405.

Tim, Bryan, Peter, & Thomas, K., (2015). Counterfeit Drug Penetration into Global Legitimate Medicine Supply Chains: A Global Assessment. *The American Journal of Tropical Medicine Hygiene*, Vol.92 (6), pp. 59 -67.

Track and Trace: Indian Pharma – Current and Future Applicability AMANINDER DHILLON JULY 17, 2019 https://medicinman.net/2019/07/track-and-trace-indian-pharma-current-and-future-applicability/ (Accessed Jan 2021)

Tsay A A., Nahmias S., Agrawal N. (1999). Modelling supply chain contracts: A review. In Tayur, S., Ganeshan, R., & Magazine, M. (Eds.) Quantitative models for supply chain management. US: Springer. pp. 299–336)

WHO (1999). Counterfeit drugs guidelines for the development of measures to combat counterfeit drugs. WHO/EDM/QSM/99.1. Geneva: WHO.

Yadav L., (2020). COVID-19 Pandemic leads to rise in circulation of counterfeit drugs, Policy Regulation. http://www.pharmabiz.com/ArticleDetails.aspx?aid=123851&sid=1, Accessed May 2020.

Youness T., Abdelali E. B., Houssine B., (2018). Supply Chain Management based on Blockchain: A Systematic Mapping Study, MATEC Web of Conferences 200, 00020 (2018), IWTSCE'18.