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A BLOCKCHAIN AND IOT BASED FRAMEWORK OF MEDICAL COMPLIANCE FOR ADR REDUCTION

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ABSTRACT The current study proposes a framework which can be used to reduce ADR, which is a critical phenomenon all over the world causing too many irreconcilable clinical damages and fatal incidents. The framework proposed in this study uses Blockchain's immutable property where all the health and medicine related transactions are recorded. Use of IoT technology helps to get sensory information like temperature, bio-metric measurement of individuals to authorize people as well as maintaining certain standards. When applied in real life this framework would make the healthcare system more secure. This framework also helps in any postmortem analysis for fatal incidents.

KEYWORDS : ADR, Blockchain, Medical Compliance, IoT, ADE

1. INTRODUCTION

Previous studies have shown that many patients expire due to wrong administration of drugs and intravenous injections. Hence, numerous prevention mechanisms have been placed to avoid occurrence of adverse drug reactions (ADRs). There has been increasing focus in recent years on quality assurance in drug treatment, audits in adverse drug reactions after incorrect physician recommendation, pharmacy counterfeits or nurse administration [1]. These measures have reduced the occurrence of fatal adverse drug events (ADEs).

A recent Johns Hopkins University study [2] claimed that close to 0.3 million people die every year in the United States of America (USA) deaths per year due to medical error and it has been the third leading cause of death in the USA. Studies have shown that adverse drug reactions cause 3 to 7% of all hospitalizations in most countries. Out of the hospitalization cases which happen due to ADR, close to 20% of them become severe [3]. Although only 5% cases of ADRs are reported and considered as major side effect [4]. Hence, it drags down the actual figure of ADRs. Regulatory bodies are bringing in active surveillance approaches to evaluate the risk of medicine in the post-market phase of the new medicines. The development of pharmacovigilance market in Europe is also credited to rising number of adverse drug reactions, and increasing demand in end-use industry.

Blockchain provides a platform of distributed ledger which securely bridges healthcare records among various stakeholders and institutions. Its major advantage is real-time recording of transactions and giving a tamper-proof distributed ledger. Blockchain can record, store and share data real time with different people and institutions. Blockchain time stamps every transaction and the record becomes a perpetual one which has no chance to be altered later [5].

Blockchain technology has numerous possible roles in the healthcare industry. The spectacular growth of Blockchain applications has the potential to assist in maintaining population health and medical records. Mettler [6] exemplified probable impacts, objectives and potentials associated with Blockchain technologies in healthcare. Yue [7] proposed a Blockchain application that enables a patient to possess, regulate and exchange personal information effortlessly but securely allowing third party organizations to access anonymized health information using secure multifactor computing. MIT has prepared a platform built on Blockchain where medical data can be saved and stored in an encrypted and secured format and researchers [8] have suggested to use such a platform for storage of any medical information. Researchers [9] have advocated a data sharing framework built on Blockchain that adequately resolves the access control problems related to sensitive data in cloud storage by means of immutability and autonomy properties of Blockchain. Many researchers [10] have suggested to store and exchange patient information using Blockchain and few others [11] recommended Blockchain network to prepare an inter-organizational medical health prediction model. Some researchers have suggested that Blockchain provide a well-organized infrastructure which can exchange and make use of information smoothly creating enhanced healthcare system, while keeping patient data rights and not negotiating on secrecy or safety of sensitive patient information [12]. Electronic medical records (EMR) are mentioned through private and permissioned Blockchain network built on Hyperledger Fabric [13] or Ethereum [14]. More secured EMR framework was proposed by Zhang and Lin [15]. Blockchain can also be used to prevent medications by deception or fraud [16]. Blockchain can also support in clinical research by removing fuzzed information or reducing the under-reporting of unwanted outcomes [17].

Internet of Things (IoT) has enhanced the omnipresence of the interactivity among devices and also between devices and humans thereby bringing in a vastly distributed network [18]. In this study we are proposing a Blockchain and IoT based framework which will address the following –

- An automated process where medicines would come out from vending machines only when there is consensus of authenticity and whether the patient needs that medication
- The automated process will also open the fail-safe lock of intravenous injection if the person is authorized and
- The whole process would be automated. Only in special cases a jury of doctors would give the final verdict if this drug should be administered or not.

2. Literature Review:

With an emphasis on adverse drug reactions (ADRs) or medical compliance, the authors found the following peer-reviewed journal papers (or academic works) as pertinent to Blockchain + IoT (or digital tech) in healthcare/pharmacovigilance.

Praveen in 2023 [19] published an article which is directly relevant to combining Blockchain + IoT for pharmacovigilance. The studies of Rajora in 2023 [20] help for the supply chain or traceability part. Muniappan et al. in 2024 [21] written an article about devices but this article is very useful for post-market surveillance architecture. Mishra & Gupta in 2024 [22] described how Blockchain prevents counterfeit drugs, which can reduce ADR due to poor-quality medicines. The extensive review work done by Avunoori et al. (2025) [23] covers how Blockchain especially smart contracts can automate compliance or reporting in pharmacovigilance. The bibliometric analysis of Litvinova et al. (2024) [24] gives a broader picture of how digital technologies including Blockchain and IoT are being applied in ADR management. Mazhar et al. in 2025 [25] included Generative AI with IoT and Blockchain to explain the fallacies of modern-day architectures for solving these issues.

3. Blockchain and IoT based Medical Compliance Framework

3.1 Blockchain Nodes

In this framework or architecture, a government health department will work as the regulator and the main Blockchain node or master-node. Master-nodes are typically more equipped than normal nodes. Master nodes also enable other events on the Blockchain apart from authenticating, storing and diffusing transactions, which are reliant on the nature of the events like leading voting, giving implementation of

protocol operations and applying the laws according to Blockchain [26]. Other nodes would be comprised of different hospital or similar healthcare providing institutions. Nodes are nothing but some device such as servers, computers or laptops. They create the Blockchain system. Every node on a Blockchain is linked and they continuously share the latest transactions such that all nodes stay updated. The nodes save, share and securely store the transactions, hence theoretically the nodes are the core of any Blockchain system.

3.2 Smart Contract

To enable, accomplish and impose the terms and conditions among untrusted participants, a smart contract works as a program or code that can be executed on the Blockchain system. Smart contracts consist of some already defined rules which are stored as digital assets in Blockchain system for the participating nodes [27]. There is no reliance on third parties as in the case of traditional contracts, hence operating or transaction costs become lower in case of smart contracts. Ethereum and Hyperledger are some of the renowned Blockchain platforms which are used to develop smart contracts [28]. In our framework, smart contracts would be the medicine administration rules for patients. The medicines would be decided based on the patient's age, medical history, the disease s/he is suffering from, the allergies s/he might have, the stage of the disease the patient is in etc. The smart contract rules will be designed to make them as much exhaustive as possible to make the process automated. But there would be exceptional scenarios which need to be handled manually, but still Blockchain would record that transaction. Expert opinion is such an exception where a jury of doctors would give the final verdict if this drug should be administered or not. But future audit would get the information from the Blockchain tamper-proof history. The medicines would come out from vending machines only there is consensus of authenticity and whether the patient needs that medication.

3.3 IoT Enabled Injections

The injections would be IoT or radio frequency identification (RFID) enabled. The RFID data would be automatically sent to Blockchain layer, which would reduce the manual error as there is no need to save it manually. The RFID tools help in designing full-proof safety locks or indicators that avert the unplanned or unauthorized use of the injections [29]. The system validates the users, the device and way the injections should be administered. These users can be hospital staff or the patient himself or a care provider. Based on these identities, the system through a wireless communication channel the steps to be taken with the help of an interface on a personal digital assistant (PDA). The Blockchain stores the transaction with timestamps as the RFID information is automatically stored in the Blockchain network.

3.4 Maintaining Coldchain

The requirement of developing cold chain was first suggested by Morley in 1976. He came up with the suggestion that World Health Organization (WHO) should develop a team within Expanded Program on Immunization (EPI) for monitoring three critical topics obliging WHO's drive of setting up global routine immunization services. These issues were improper arrangement in recording and observing the temperature of the delicate vaccines which are sensitive to heat, insufficiency to stock and supply vaccines and inadequacy of skilled people to properly keep and use vaccines. The staff in WHO adopted his suggestions and prepared a strategy to handle these challenges. They developed and distributed proper skill development documents, roadmaps and equipment of how to carry, supply and apply vaccines [30]. From the outset, WHO realized the necessity for a seamless system to measure and track temperature of vaccines in the cold chain. In the 1980s companies in the United States and Switzerland came up with a blue wax absorption methodology to visually observe and measure efficacy of cold chain [31].

Few medicines and vaccines are vulnerable to heat, light and freezing. Medicines should possess pair of fundamental features which are safety and efficacy. Some medicines lose their efficacy if they are not stored or transported at an appropriate temperature or condition. The strength and efficacy of these medicines might be lost because of exposure to light, for their thermo-sensitivity or due to extreme cold. From the manufacturing location to the consumption location coldchain keep and carries the vaccine at the advised temperature range. Freezers, cold stores and boxes and refrigerators transfer and preserve the medicines at proper temperature to keep the efficacy of the medicines for their logistics and supply chain starting from medicine production location to the point of use. The cold chain should not be broken at any point in time. It is the responsibility of health workers to maintain the cold chain in the medicine supply chain. They should closely monitor the transportation of medicine and vaccines both at urban and rural areas and even at the remotest healthcare centers during various vaccination programs as well as for regular treatments in hospitals or healthcare centers. The transportation staff should also be skilled and knowledgeable of handling the materials to maintain coldchain. This includes having appropriate and efficient logistics mechanisms to manage shipping, fuel, spare parts etc. Again, this would be managed through Blockchain and IoT. IoT devices attached to the medical box will send information if any time the temperature threshold has been crossed and the coldchain is broken. Blockchain will record this information and hence can be used for tracking and tracing the problem if it occurs.

3.5 Biometric Measurement to Identify Humans

Biometric identification corresponds to recognizing a human based on his or her unique physiological and behavioral parameters which can be called biometric identifiers [32]. As various physiological and behavioral features are exclusive for a human, biometrics offers a more consistent and dependable system of identity validation than any passcodes, pins, keys or any other traditional system [33]. A biometric system is fundamentally a pattern recognition system that sets up the validity of an explicit physiological or behavioral feature possessed by the user. Any biometric system is divisible into two modules rationally; these are the enrollment module and the identification module. In the enrollment segment, firstly a biometric sensor scans the biometric characteristic of a human to obtain a digital depiction of the human's characteristic. In the identification module, the biometric machine saves human's unique features and translates this to a digital format. Next it is processed again by the characteristic extractor to come up with the same depiction as the template. The final illustration is sent to the characteristic checker which equates it with the template to prove the identity of the individual [34].

In our framework we are proposing a one-step more secure set up of the biometric system. Here the biometric information is stored in a permissioned Blockchain which is highly secure and tamper proof. Hence, it is not easy for an imposter to get access to the injections or medicines. The medicine vending machine or the injection valve would only open the authentication is met and the person is authorized as per the authentication mechanism based on the biometric history of the HCP and based on the rule written in the smart contract (Fig. 1).

3.6 Overall Flow

A patient suffering from some chronic illness is admitted to a hospital. The patient and his/her next of kin, in most cases are unaware what kind of medications and medicinal treatments are being given to the patient. Whether the healthcare professional (HCP) is authorized to give the medication or injection is the first important question. Blockchain would first validate the identity of the person. For this the biometric record of the HCP would be taken and then the biometric machine would be linked to the Blockchain platform where the smart contract would authorize the person based on the biometric identity. Based on the patient's health situation, the HCP would select a particular medication which is again based on the smart contract rule of the Blockchain. Smart contract includes if that medication is a valid one for that type of disease for such kind of a severity. The medicines would be available only through vending machines controlled by IoT and linked with Blockchain. If the condition is met, then only the vending machine will dispense of the medicine. If the consensus is achieved the medicine will come out of the vending machine, otherwise it will decline the person. Similarly, IoT controlled injection's valve would only operate if the condition is fulfilled as per smart contract, otherwise the fail-safe lock would not be opened.

For some critical scenarios a jury of doctors would give the final verdict if this drug should be administered or not. Even that transaction would be recorded in Blockchain which would be available for future audit. The regulator gives special permission in such cases and separate rule or smart contract would be written for such transactions.

Again, all the medicines and vaccines would be controlled using coldchain mechanism and IoT devices which measure temperature will check if the temperature in any time is crossing the threshold. Blockchain network will be notified in such a situation. This track and trace and provenance mechanism would ensure safety for patients from all angles. Below figure (Fig. 1) gives the details of the overflow flow of the Blockchain and IoT based framework.

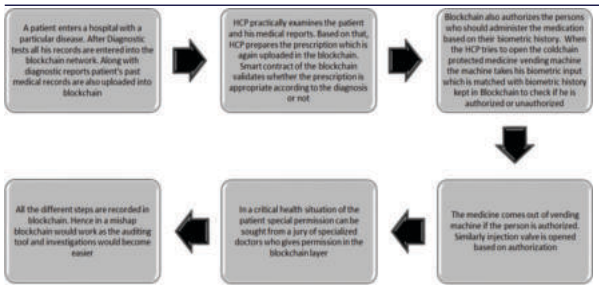

Fig. 1: Blockchain & IoT based Medical Compliance Framework

4. DISCUSSION

Many patients die due to wrong administration of drugs and intravenous injections. Unauthorized people administer medicines leading to severe damage to patient health. There is proposed or already existing IoT equipment which helps in designing full-proof safety locks or indicators that avert the unplanned or unauthorized use of medication, medical devices, or medical supplies. The existing system corroborates patient, the care provider, the medical device, and the way it is to be used and authorizes the action to be undertaken through an interface on a personal digital assistant (PDA) over a wireless communication channel. However, this process is not tamper-proof as although it is communication between machine to machine it is not above hacking. The proposed framework addresses the loopholes exist in current process and suggests a comprehensive and robust framework which can substantially reduce the risk of fatality of ADRs. The process also helps with future audit as every transaction is saved in Blockchain and hence is immutable. The immutability feature helps in investigation to find out the cause of fatality and people responsible for that. The medical history of the patient is saved in Blockchain which helps in the continuity of medication and deciding what could be the next line of steps doctors can take. The diagnosis to treatment mapping route through smart contract helps in automated decisions and whenever there is a need to override the automated decision, a group of experts can take the decision and that is possible because all the historical records of the patient is stored in Blockchain. Then whether the medicines were put under a certain temperature is also getting tracked and as when the coldchain is broken it is notified and stored in Blockchain as failures often resulting in the delivery of ineffective and sub-therapeutic doses. Then it is also ensured that authorized persons are administering drugs or injections as medicines are kept in biometric controlled vending machines and injection valves are also controlled by authorized biometric information.

5. CONCLUSION

The proposed framework is to ensure that medicinal treatment and associated steps are tracked continuously and with the immutability feature giving the patients and the care providers greater transparency in the whole process. The framework digitizes the existing healthcare system and medical treatment information on Blockchain creating a single historical record. The hospital and medical institutions create new levels of trust between the care receivers and care providers through information sharing. The framework also controls the authorized administration of medicines and injections thereby reducing the case of ADRs. If implemented this framework would bring much more transparency and control in the overall healthcare system.

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