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CONCEPTUAL BLOCKCHAIN MODEL FOR REINFORCED DATA INTEGRITY ABOUT CONSUMED DRUGS

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Abstract

Data integrity is essential in the distribution of public goods, particularly in healthcare where medicinal drugs must be accurately and reliably tracked from supplier to consumer. Issues such as counterfeiting and data tampering compromise drug safety, prompting a need for effective data integrity solutions. This study explores how blockchain technology can enhance the integrity of data in the distribution of medicinal drugs. It reviews the current status of data integrity in drug distribution, reviews literature on blockchain requirements, and designs a conceptual blockchain model aimed at reinforcing data integrity. This study employs a qualitative research methodology, including a comprehensive literature review and stakeholder interviews to assess the current state of data integrity in the drug distribution process and Primary data was collected, then analyzed thematically. The study presents a clear research question for investigation: How can a blockchain model effectively reinforce data integrity throughout the drug distribution process? Furthermore, we designed a conceptual blockchain model aimed at reinforcing data integrity throughout the drug consumption process. This model offers benefits for various stakeholders including pharmaceutical stores, pharmacists, doctors, nursing heads, procurement managers, accountants, hospital administrators, patients, and healthcare providers by providing a reliable, immutable, secure, and transparent system for recording and tracking drug-related information across all departments.

Keywords: Blockchain, Data Integrity, Consumed Drugs, Traceability, Drug Distribution.

Introduction

Data integrity is a critical concern in public sectors, particularly in healthcare, where it underpins the distribution of medicines and the overall safety of drug consumption (Welsher and Agalloco 2021). Breaches in data integrity stemming from human error to system flaws pose significant threats to the efficacy of medicinal drugs. For example, research indicates that poor data integrity results in significant financial losses for organizations and jeopardizes patient safety (Agalloco 2021). The Governance Advisory team has underscored the necessity for transparency and accountability in data management, particularly within drug distribution networks. For instance, the lack of adequate data integrity measures in drug procurement and supply has significant ramifications, as noted in a locality survey conducted in Homabay County Referral Hospital (UNICEF 2018). Notably, the survey reported an alarming shortage of essential drugs in health facilities, leading to adverse effects on patient care and overall healthcare delivery. Data integrity is often compromised by human errors, bugs, and insufficient hardware, raising concerns about the systems that manage sensitive information,

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including medication safety. This situation necessitates innovative technological solutions to reinforce integrity in data management. Traditional approaches to ensuring integrity are increasingly inadequate. Therefore, technologies such as blockchain offer promising solutions

Efforts have been made to address the menace of data integrity for distribution of goods and services to the final consumer by the use of blockchain and internet of things, as amode of emerging trends of technology (Warren 2021), but in the case of this project, blockchain technology was applied to reinforce the data integrity about consumed drugs which has been witnessed in other research study in the world though under different geographical scope and platform. Several governments across the world have embraced the use of technology for improved governance. Blockchain has emerged as some of the technologies that offer actual means to fight menace and ensure that citizen's interests are protected, given that technology such as blockchain offers transparency, trust, traceability, consensus and immutability. Blockchain is a distributed ledger or a decentralized database that permanently records transactions between users without requiring a third-party. In this ledger, transactions are cryptographically chained such that they cannot be tampered with and are shared with the linked users, verified transactions in the ledger cannot be modified without obtaining a consensus from users. (Gartner2018)

In 2019, Sierra Leone became the first country in the world to use blockchain model in tallying presidential elections alongside the normal process to demonstrate that indeed blockchain model can be used in tallying votes. The Sierra Leone announcement prompted the Independent Electoral and Boundaries Commission of Kenya (IEBC) to announce plans to also utilize blockchain model to offer real-time polling results and thus improve vote data integrity and trust in the voting process. Blockchain technology has been successfully deployed throughout the world, including Kenya, for food supply chain traceability and authenticity (Warren 2021)

According to (World Economic Forum 2021) typical considerations around ensuring that the data used in a blockchain solution is correct, reliable, timely for all participants, and preserved from the point of data creation to the point of usage on the blockchain

With the advent of blockchain technology, a decentralized method of recording transactions and data, there is potential to enhance data integrity in the medicinal drug supply chain. Blockchain's features such as immutability, transparency, and traceability allow for robust tracking of medicines, ensuring that healthcare professionals and patients have access to accurate and reliable information. This study seeks to develop a conceptual model that incorporates blockchain technology in drug distribution processes to enhance their integrity, establishing a clear link among the concepts of data integrity, supply chain management, and technology adoption. And this demonstrate that it cannot be used in those existing systems without modifications in terms of requirement and design, and to initiate this, we examine the current status of integrity of data in medicinal drugs, establish blockchain requirements and design.

Literature Review

Data Integrity Status in Drug Distribution

As articulated by regulatory bodies, data integrity is defined by the principles of ALCOA: Attributable, Legible, Contemporaneous, Original, and Accurate (Draft Guidance to Industry, Data Integrity and Compliance 2016). These principles are essential in ensuring comprehensive data management. The inability of healthcare facilities, especially in low-resource settings, to maintain these standards has been linked to patient safety risks, including medication errors and ineffective treatment protocols.

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Data integrity encompasses the accuracy, consistency, and reliability of data throughout its lifecycle. Critical elements include the Attributable, Legible, Contemporaneous, Original, and Accurate (ALCOA) principles. These elements ensure that drug-related information remains trustworthy and traceable from the point of manufacture to patient administration. Studies suggest that health care data integrity is compromised due to several factors: human errors, inadequate training, and inefficient data management systems. Evidence indicates that improving data integrity directly contributes to enhancing service delivery within the healthcare sector (Global health science 2021). Existing pitfalls in the data integrity ecosystem can, therefore, be addressed effectively through blockchain technology.

Notably, existing healthcare systems often struggle with data integrity issues due to poor documentation practices and insufficient technological infrastructure. This gap increases the risk of counterfeit drugs entering the supply chain and reduces patient's trust in healthcare systems. Critical elements include the Attributable, Legible, Contemporaneous, Original, and Accurate (ALCOA) principles.

Attribution of data

All data needs to be attributable to the individual who generates it and should include a timestamp indicating when an action regarding the data was performed. The concept of "attributable" in data integrity regarding consumed drugs at public hospitals involves ensuring that drug-related information is traceable, accountable, and linked to identifiable sources or individuals (Gartner 2018). He further states that attributes or characters associated with attributabilty in maintaining data integrity about consumed drugs include. Clear Source Identification: Ensuring that all drug-related data is traceable to its originating source, such as the prescribing physician, pharmacist, nurse, or any healthcare professional involved in medication administration; Unique Identifiers: Implementing unique identifiers or codes for medications, prescriptions, and patient records to ensure traceability and accountability in the event of audits, reviews, or investigations. (Global health science 2021).

Legibility of data

Recorded data needs to be permanent and legible. Legibility in data integrity concerning consumed drugs at public hospitals is critical for ensuring that information related to medications is easily readable, understandable, and accessible to healthcare professionals (Global health science 2021). They further states that attributes that contribute to legibility in maintaining data integrity: Clear Documentation: Ensuring that drug-related information, including medication names, dosages, frequencies, and administration instructions, is documented in a clear and easily understandable format. This facilitates accurate interpretation by healthcare providers involved in patient care; Standardized Formats: Following standardized formats and guidelines for documenting drug-related data, such as using universally accepted abbreviations, symbols, or terminology. (Friedman et al., 2018)

Contemporaneousness of data

The principle states that all data must be recorded at the time an action are performed, not retroactively to fit expectations. The attribute of contemporaneousness in data integrity concerning consumed drugs at public hospitals refers to the timely and immediate recording of drug-related information as it occurs (Gartner 2018). He furthers states that attribute ensures data regarding medication administration and usage is captured accurately and promptly. Here are the key attributes related to contemporaneousness in maintaining data integrity: Real-Time Documentation: Recording drug-related information at the time of drug administration or prescription, ensuring that details are documented immediately and accurately without delays ; Electronic Health Records (EHRs): Leveraging

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electronic systems to enable instantaneous recording and updating of drug-related data, facilitating immediate access and retrieval by authorized healthcare providers.

Originality of data

According to (Ivanov 2021), all data should be in its original form and should not be transferred to alternate formats. He further states that, ensuring originality in data integrity regarding consumed drugs at a public hospital involves several key characteristics or aspects. Source Validation: Verifying the authenticity and credibility of the sources providing information about consumed drugs. This includes confirming that data comes from reputable pharmaceutical suppliers, authorized healthcare providers, or reliable electronic health record systems; Unique Identifiers: Implementing unique identifiers for each drug administered or prescribed, ensuring that every medication has a distinct identity within the hospital's records. Unique identifiers help prevent confusion or duplication of drug-related data; These characteristics collectively ensure the reliability and trustworthiness of drug-related information within the hospital's records and systems.

Accuracy of data

Data should be accurate, truthful, complete, and free of errors. Data isn't altered or aggregated in any way that affects data analytics. For example, test results aren't rounded up or down, and any test criteria or conditions are well-documented and understood. Repeating tests should return the same results Accuracy in data integrity concerning consumed drugs at a public hospital involves specific characteristics that ensure the reliability, safety, and effectiveness of medication administration (Weng, 2013). He further states that there are key characters like: Dosage Accuracy: Ensuring the precise measurement and administration of medication dosages according to the prescribed amount for each patient. Accurate dosing is critical to avoid under or overdosing, which can lead to adverse reactions or ineffective treatment; errors due to confusion

Complete data

Data is maintained in its full form and no data elements are filtered, truncated or lost. For example, if 100 tests are performed, complete data reflects the results of all 100 tests. Tests that failed or yielded undesirable results aren't omitted from data requests (Dolgui, 2021). He further states that completeness in data integrity concerning consumed drugs at public hospitals refers to the presence of comprehensive and all-encompassing drug-related information. Completeness in data integrity about consumed drugs at public hospitals involves several key attributes that ensure comprehensive and thorough information regarding medication usage. These attributes include: Full Patient Profile: Recording complete patient information, including demographics, medical history, current medications, allergies, and any relevant conditions or diagnoses that could impact drug administration;

Consistent of data

Data remains unchanged regardless of how, or how often, it's accessed and no matter how long it's stored. For example, data accessed a year from now will be the same data that's generated or accessed today (Weiskopf 2013). He further states that consistency in data integrity concerning consumed drugs at public hospitals refers to the uniformity, coherence, and reliability of drug-related information across various records and systems. Here are the characters or attributes associated with consistency in maintaining data integrity: Uniform Data Entry Practices: Implementing standardized procedures for entering drug-related information, ensuring consistency in terminology, abbreviations, and formatting across all records and systems; Interdepartmental Consistency: Ensuring consistency in drug-related data among different hospital departments, such as pharmacy, nursing, and medical records, to avoid discrepancies or conflicting information.

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Gap on the Status

Having reviewed the status of data integrity based on: Attributable, legibility, completeness, contemporaneous, accuracy and consistency, little is known on integrity status.

Blockchain Requirements in Drug Distribution

A robust blockchain model should serve critical functions like securing data transmission, authenticating drug delivery, and enabling real-time tracking of medicinal drug transactions. The essential requirements for the proposed blockchain model include several key components: The Blockchain Platform itself, Distributed Ledger maintenance, The Consensus Process or protocols, Access Control cryptographic requirements of the blocks, the role of nodes and nodes, discover the transactions that make up a block and the underlying network.

Blockchain Platform itself as a requirement (Ethereum)

According to survey done by Price Water Coopers (PWC 2018) a blockchain platform is a shared digital ledger that allows users to record transactions and share information securely, tamper-resistant and a distributed network of computers maintains the register, and each transaction is verified by consensus among the network participants

Ethereum is a decentralized blockchain platform that establishes a peer-to-peer network that securely executes and verifies application code, called smart contracts. Smart contracts allow participants to transact with each other without a trusted central authority (Nowinski & Kozma , 2017). Transaction records are immutable, verifiable, and securely distributed across the network, giving participants full ownership and visibility into transaction data. Transactions are sent from and received by user-created Ethereum accounts. A sender must sign transactions and spend Ether, Ethereum's native cryptocurrency, as a cost of processing transactions on the network (Buterin, 2014).

Distributed Ledger Technology as a requirement (DLT)

Distributed ledger technology is a platform that uses ledgers stored on separate, connected devices in a network to ensure data accuracy and security (Nowinski & Kozma , 2017). Blockchains evolved from distributed ledgers to address growing concerns that too many third parties are involved in too many transactions. Distributed ledger technology has the potential to effectively improve these traditional methods of bookkeeping by updating and modifying fundamental methods of how data is collected, shared, and managed in the ledger. DLT allows real-time sharing of data with transparency which gives trust that data in the ledger is up to date and legitimate. Also Distributed Ledger Technology eliminates the single point of failure which prevents data in the ledger from being manipulations and errors. In DLT, there is no need for a central authority to validate transactions here different consensus mechanisms are used to validate transactions which eventually makes this process very fast and real time

The Consensus Process/protocols as a requirement

According to (Tasatanattakool and Techapanupreeda, 2018), consensus mechanism is a program used in blockchain systems to achieve distributed agreement about the ledger's state. Generally, it is implemented in a network with many processes and users. Cryptocurrencies, blockchains, and distributed ledgers benefit from their use because the consensus mechanism replaces much slower human verifiers and auditing.

Nakamoto Consensus (proof of work). The mother of all blockchain consensus, the Nakamoto consensus protocol was devised as a new means of verifying the authenticity of a blockchain network and preventing double-spending. (Satoshi Nakamoto 2009)

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Classical consensus, on the other hand, reaches consensus through voting. These protocols confirm transactions faster than the types of Nakamoto consensus discussed above as the consensus network size is fixed and progress can be made as soon as the required votes are seen

Access Control cryptographic requirements of the blocks as a requirement

Access control cryptographic requirements in blockchain ensure that only authorized entities can perform specific actions, such as reading, writing, or modifying data within the blockchain (Zhao, Fan , & Yan , 2016). To meet these requirements, several cryptographic techniques and mechanisms are commonly employed, each serving a specific purpose in maintaining the security and integrity of the blockchain. As part of the mandatory nature of NDAC, consensus mechanisms of permissioned blockchains are mostly required so that only permitted AC administrators or security officials are allowed to create and modify AC rules through the restricted publishing of AC nodes, such that the consensus mechanism is restricted to general subjects. Note that the coordination of the permitted AC nodes can be centrally managed by a designed AC node, an out-of-the-chain process, or smart contracts published by authorized administrators.

The role of nodes and nodes discover as a requirement

Any device connected to the blockchain can be classed as a node and examples include: servers, computers, laptops, online or desktop wallets and mobile phones. All of the nodes are connected to the blockchain in some way and are constantly updating each other with the latest information being added to the blockchain. Nodes are a critical component to the infrastructure of a blockchain. They act as further validation for the ledger and allow anyone to transparently view transactions or data conducted or held on the network. Node discovery is a crucial component of network communication in a blockchain. It refers to the process by which nodes in the network locate and connect. The core benefits of nodes are to ensure the data being held on the blockchain is valid, secure and accessible to authorized parties (SEBA 2018)

The transactions that make up a block and the underlying network as a requirement .

According to Price water Cooper's (PwC 2018), the operation of blockchain technology can be expressed in five major processes: transaction definition involving sending transaction request sent to the network, transaction authentication which involve all nodes in the network receiving the information about the transaction request on the distributed ledger and validation of the authentication of the requested transaction. After the authentication the block is created and validated by other nodes and finally the block is attached to the chain. (PwC 2018) recommends private or consortium deployment model. When a chain of transactions is transmitted across the network, they don't always arrive in the same order. Sometimes, the child might arrive before the parent. In that case, the nodes that see a child first can see that it references a parent transaction that is not yet known. Rather than reject the child, they put it in a temporary pool to await the arrival of its parent and propagate it to every other node.

Gap on the Requirements

Having reviewed the requirements based on; The Blockchain Platform itself, Distributed Ledger maintenance, The Consensus Process or protocols, Access Control cryptographic requirements of the blocks, the role of nodes and nodes, discover the transactions that make up a block and the underlying network, little is known on the blockchain requirements.

Conceptual Blockchain Model Design

The conceptual model integrates various blockchain elements to create a reliable framework for drug distribution. Summary of integrity status and requirements status in order of priority have

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been used to model conceptual blockchain design. In conjunction with the summary on the blockchain model, diagram below illustrates the software architecture involved in the blockchain system. The diagram enabled stakeholders to visualize how various entities interacted with the blockchain platform for the secure tracking of medicinal drugs. The diagram components typically include:

Entities Involved: Such as healthcare providers, pharmacists, and regulatory authorities that interact with the blockchain for transactions.

Blockchain Nodes: Representing the network of connected devices that validate and record transactions.

Transaction Flow: There might be arrows or lines denoting how transactions move through the system and how they are recorded on the ledger.

Smart Contracts: Visual representations of automated contracts that execute predefined actions when certain conditions are met.

Data Storage: Indicating where and how dispensation records are securely stored and accessed.

Figure 1

Diagram Components of Conceptual blockchain Model.

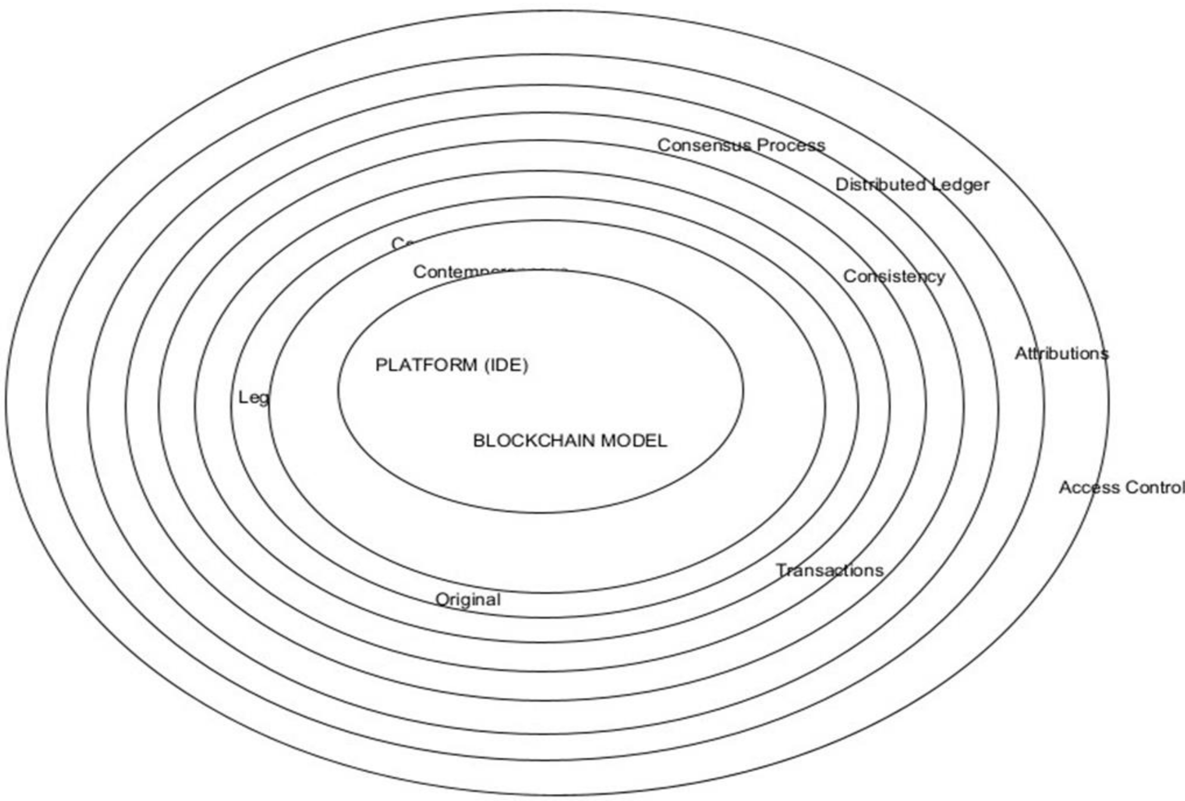

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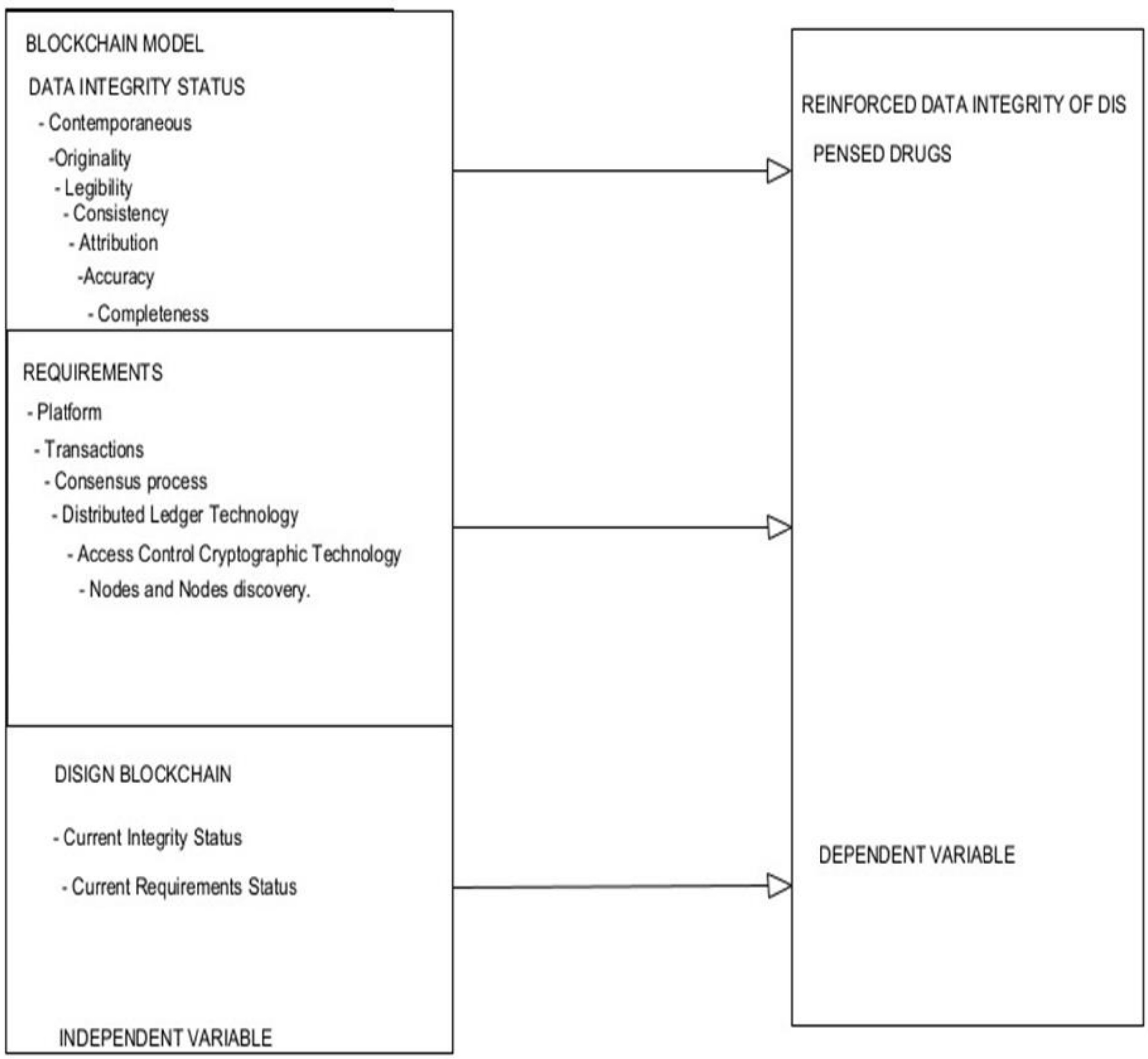
Figure 2

Conceptual Framework for Reinforced Data Integrity



Summary of Knowledge Gaps

Current literature reveals significant gaps in understanding the status of data integrity in drug distribution, specific blockchain requirements pertinent to this application, and best practices for designing an effective blockchain model

Methodological Framework

This study employs a qualitative research methodology, including a comprehensive literature review and stakeholder interviews to assess the current state of data integrity in the drug distribution process. Primary data collection involved interviews with healthcare professionals, pharmacists, and representatives from regulatory bodies. The data collected was then analyzed thematically to draw connections and develop insights into the application of blockchain technology in drug distribution.

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Results and Discussion

Preliminary findings indicate that stakeholders perceive blockchain as a viable solution for enhancing data integrity in drug distribution. The study discusses the current status of integrity and the current requirements status at Homabay County Referral Hospital to enabled design of conceptual blockchain model. The argument emphasizes a need for comprehensive stakeholder education and targeted strategies to address these barriers and gaps by employing conceptual blockchain model.

Conclusion

This conceptual blockchain model for reinforced data integrity highlights the transformative potential of blockchain technology in healthcare. The design of this conceptual blockchain model was a response to the identified gaps in data integrity and the requirements for tracking medicinal drugs. The model aims to enhance the security, transparency, and efficiency of the system at Homa Bay County Referral Hospital, thereby addressing the critical issues identified in the analysis.

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