MedChain: Secure, Decentralized, Interoperable Medication Reconciliation Using the Blockchain

A submission to the "Use of Blockchain in Health IT and Health-related Research" Ideation Challenge

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Abstract
Medication prescribing errors are common and can cause patient harm, including death. An important tool to reduce medication errors is medication reconciliation, which identifies a complete and accurate list of medications the patient is currently taking and updates according to latest treatment plan. However, medication reconciliation has important limitations, including access to all relevant data and the clinician time-burden of accurate reconciliation. As a method of addressing these challenges, we describe "MedChain," a medication-specific private blockchain network that would enable members to share patient medication events through a decentralized blockchain of medication data. Members would include patients, outpatient prescribers, inpatient facilities, pharmacies and benefit managers. We provide an overview of how blockchain is currently used in the context of bitcoin, and how this could be adapted to support MedChain to improve the safety of medication prescription and delivery.

Medication Safety: The Importance of Accurate Medication Lists

Adverse Drug Events (ADEs), which have been previously defined as "an injury resulting from medical intervention related to a drug"[1], are a substantial patient and public health safety problem in the United States. ADEs occur in all care settings, and are often caused by errors in prescribing, for example, the wrong dose of a medication.[1] The prevalence and impact of medication errors and ADEs for hospitalized patients has been well described[2–9], with one study estimating a rate of 8.8 errors per 100 inpatient medication orders.[3] Prescribing errors, a common cause of ADEs, are not unique to hospitalized patients, and occur in ambulatory settings[10,11] as well as emergency departments.[12,13] Transitions of care, for example, a patient being admitted to a hospital, or a patient being discharged to a skilled nursing facility, are particularly ripe for medication errors leading to ADEs.[2,14]

Medication discrepancies—differences between what medications a patient is taking, and what medications are prescribed or given—are an important contributor to medication errors and ADEs. In one study, 14% of patients had at least one medication discrepancy following hospital discharge;[14] another study demonstrated that 41.3% of patients had medication discrepancies at discharge.[15] Medication discrepancies are particularly problematic for patients prescribed many medications. These patients may receive care in a variety of settings, see multiple practitioners, and may have multiple prescribers managing their medications. Each point of contact with clinical care is another opportunity for a medication error.

Medication reconciliation is defined as the process of "identifying the most accurate list of medications a patient is taking — including name, dosage, frequency, and route — and using this list to provide correct medications for patients anywhere within the health care system."[16] Medication reconciliation provides an avenue for minimizing medication discrepancies.[17] Medication reconciliation, however, is time intensive and expensive; a geriatric patient's medication reconciliation, for example, can take on average more than 90 minutes to complete on hospital admission.

Many factors contribute to the challenges of accurate medication reconciliation. Some factors are clinical: a critically ill patient (for example, severe trauma, or cardiac arrest) may only allow time for a targeted review of medications—like anticoagulants. Other factors include physician, nursing, or pharmacy workflow, lack of patient awareness of their medications, or minimal interoperability of patient medications across the electronic health record.[18] Numerous interventions have been studied, including patient counseling, communication with outpatient providers, medication history taking, and medication appropriateness review. These interventions have been studied in multiple settings, including pre-admission, admission, discharge, and post-discharge, instrumented by different roles (physician, pharmacist, and nurse).[6] Yet medication reconciliation discrepancies occur frequently. As a result, in 2005 medication reconciliation was named a Joint Commission National Patient Safety Goal across the entire care continuum.[19–21]

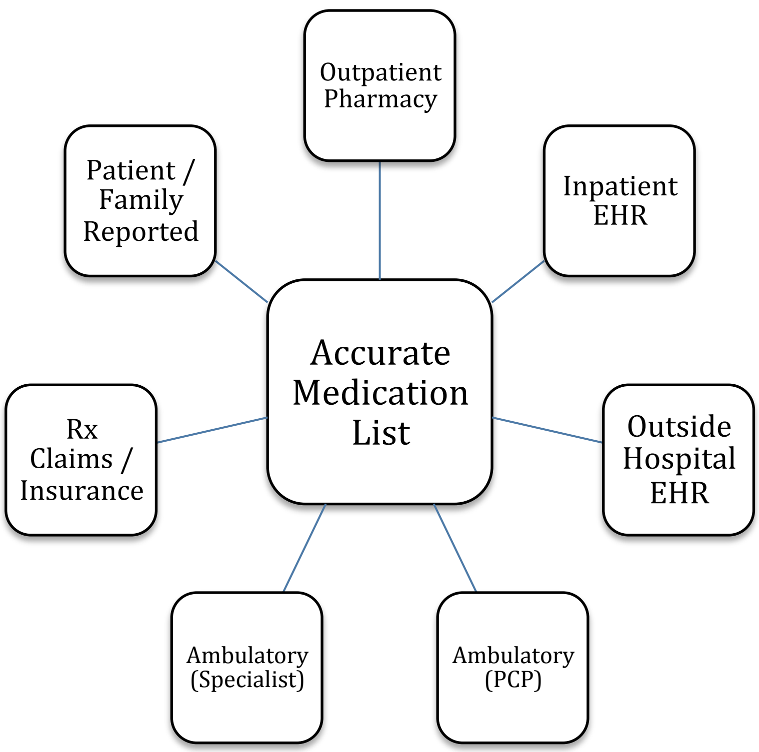


Figure 1: An example of the multiple sources of data that a clinician must parse to generate an "Accurate Medication List"

Medication Reconciliation: A Need for Better Data

In order to generate an "Accurate Medication List," a clinician must synthesize data from numerous sources. (For the purpose of this discussion, "Accurate Medication List" is defined as the list of medications, including dosing and administration information, a patient should be taking, with reasonable consensus from their prescribing providers.) As Figure 1 demonstrates, there is no central “source of truth” for medication reconciliation. In practice, the “Accurate Medication List,” when reconciled, defaults to what a patient reports they are taking—even if this not what the patient’s clinicians suggest, or perceive, that the patient is taking. There are substantial challenges with the current model:

1. **Access to information**: a provider trying to reconcile a patient’s list of medications may not have access to all relevant information due to limitations in patient awareness or data interoperability.
2. **Incomplete data**: different data sources may have different views into a patient’s medications. For example, a pharmacy may know medications prescribed by only one prescriber.
3. **Multiple sources of truth**. Each potential data source attempts to maintain its own “truth” of medications. An outpatient specialist, for example, may gather a slightly different medication list than the patient’s primary care provider (PCP)—each maintains a unique “reconciled” list of medications.
4. **Validation**. Because there are multiple sources of truth, even if a clinician has access to all of them, there is no a priori way of knowing which list is “accurate.”
5. **Inconsistencies.** Even if medication data is fully transparent, there could be changes—for example, a PCP may prescribe a medication not covered by a patient’s insurance, which is switched to a different or generic form by the pharmacist.
6. **Time Intensive**. Each clinician attempting to determine the “Accurate Medication List” must synthesize all of these sources, which may be time-prohibitive in many cases.

These challenges are multiplied as patient complexity increases—more medical problems, medications, and prescribing providers will increase the amount of information that must be coalesced to form an “Accurate Medication List.” Because of these challenges, medication discrepancies exist in all aspects of clinical care, potentially leading to adverse drug events.

The Office of the National Coordinator for Health Information Technology (ONC) has recognized the importance of interoperability and comprehensive medication management in its 2015 Interoperability Roadmap.[22] Medications are one of the “Near-term Priority Data Domains.” Additionally, there are several call-to-actions in the roadmaps that address the challenges with medication reconciliation and the importance of addressing these challenges. For example, providers and individuals should “work together to define a reconciliation process for electronic health information from multiple data sources to ensure accuracy, completeness and a more comprehensive picture of a person.” (p. 73). On the developer side, the ONC calls for “technology platforms that allow providers and other users to perform certain key interoperability functions, such as standardized exchange… using clear instructions provided by the technology developers and made publicly available.” (p. 75). As we will describe, blockchain technology is an exciting opportunity to improve medication reconciliation, minimize medication discrepancies, reduce Adverse Drug Events, and to do so in a manner that supports the Interoperability Roadmap put forth by the ONC.

An Overview of Bitcoin and Blockchain Technology

Blockchain technology was first described in a 2008 pseudo-anonymous paper by Satoshi Nakamoto.[23] Nakamoto described a decentralized, public, cryptographically empowered currency system—a way for financial transactions to go “from one party to another without going through a financial institution.” In the years since this was published, blockchain currency—most famously bitcoin—has emerged as a viable form of financial transaction, without requiring a centralized "trusted" authority like a bank.

Blockchain technology, in the context of bitcoin, is characterized by several important attributes:

1. **Decentralized.** Traditionally, electronic financial transactions require a 3rd party intermediary or arbiter to keep a history of activity (a "ledger"). The ledger is the source of truth. This puts a large amount of trust in a central authority. Blockchains enable one entity to directly 'transact' with another entity *without an intermediary*.
2. **Public**. All transactions are broadcast to the entire network—all users/nodes are aware of all transactions.
3. **Anonymous**. Though all transactions are announced publicly, cryptography obfuscates the identity of the entities transacting.
4. **Cryptographically Enforced.** By using private/public key cryptography, senders and receivers of transactions can be verified mathematically.

For example, imagine Alice wants to send one bitcoin to Bob. Alice first generates a new transaction record. The transaction record has three main components: first, the "input", which contains a hashed representation of prior transactions that gave Alice that bitcoin to begin with (proof that she actually has a bitcoin to spend). Second, the transaction contains an output—the destination, in this case Bob's public bitcoin address. Third, Alice signs the entire transaction with her private key, and adds that signature to the transaction. The private-key signature proves that Alice initiated the transfer, since only her public key can decrypt the signature. The transaction thus contains proof that Alice owns a bitcoin, a target destination to send it to (Bob), and Alice's authorization of the transaction (her digital signature).

The transaction is then announced and broadcast to the entire bitcoin network. The transaction is combined with other pending transactions into a block, validated and added to the ledger – the "blockchain." The blockchain contains a linked set of blocks of transactions, and is publicly available, duplicated and distributed throughout the bitcoin network. Once Bob sees the new transaction added to the blockchain, he knows that the bitcoin has been transferred to him, since the "block" that represents the bitcoin Alice sent to him is linked to him through his public key. He has successfully received a bitcoin from Alice, and he can now spend this bitcoin if he wants by generating a new transaction with a hash of transaction he just received, a new output address, and his signature.

There are a few important questions that arise from this description. The first is the "double spend" question: *What prevents Alice from "double spending" her bitcoins? Couldn't she just send her 1 coin to Bob, Charlie, and David?* The answer is yes and no. Alice could certainly initiate several transactions for her bitcoin. However, by announcing the transaction publicly, each receiver (Bob, Charlie, David) is essentially asking the bitcoin network to "verify" that Alice indeed owns this coin and hasn't already spent it. Once the network agrees, it will incorporate the transaction into the blockchain—but it will only do this for one recipient. Thus, addition to the blockchain effectively validates a transaction.

The next question that arises is how this is done—specifically, *How does the network verify the transaction?* The answer is through incentivized "proof of work." Each potential block of transactions has a cryptographic puzzle associated with it—a "nonce." This puzzle can only be solved through trial and error. When the nonce for a block is solved, the other nodes verify the solution, and the block is added to the end of the blockchain (similar to public/private key cryptography, the nonce is difficult to calculate, but easy to verify). The user that solves the nonce is rewarded with bitcoins—incentivizing users to validate potential transactions. Finally, nodes will only work on the longest chain, ensuring continuity and "one" blockchain. As blocks are solved and added to the chain, transactions are codified into the blockchain, and since the blockchain is public and distributed, individuals can trust that their transactions are now "live." Importantly, since the solution to the nonce is dependent on the hash in that block, *any attempt to change the data in the block would require re-calculating the nonce*. As the blockchain expands, modifying a block would also require re-calculating the nonce for every block after it as well. This quickly becomes impractical, again ensuring the integrity of the blockchain.

By creating a system of financial transaction that is decentralized (the blockchain is maintained by all nodes, without one central owner), public (all transactions are announced publicly), anonymous (identities are hidden behind public keys), and cryptographically enforced (public/private key ensures identity, proof-of-work/nonce calculation ensures blockchain integrity), bitcoin shows us what is possible with blockchain technology—a group of people or institutions, who do not know each other, can trust a shared history of data and events surrounding that data.

Decentralized, Trust-Based Medication Lists: Creating the "Medication Chain" (MedChain)

Bitcoin uses blockchain technology to facilitate financial transactions. However, there is nothing intrinsic about a blockchain that limits its usage to finance—any piece of information can be transacted, with the same benefits—a public, anonymous, decentralized, cryptographically enforced ledger of information. For example, blockchains can be used to record land ownership—something Honduras and Greece are both currently exploring.[24] Precious metal ownership is another potential use-case. Any scenario that involves numerous individuals or entities that need to agree on a data record, but need a way of establishing trust, could benefit from the blockchain. Therefore, medication reconciliation is an excellent target for blockchain technology. What makes it such a good target is the inherent decentralized nature of medication prescribing, and the fact that for a given patient, their "medication list" will be built from multiple entities, across disparate organizations or provider networks. Blockchain technology would allow all interested parties to share, in a way that builds trust and confidence in the accuracy and fidelity of the data being shared.

In describing this system (the "Medication Chain" or "MedChain"), there would be a few import changes from Nakamoto's original paper:

(1) **A Private Blockchain**. The bitcoin blockchain is distributed publicly for all to see. The MedChain would instead be built within a "private blockchain," which means the nodes would be invite-only, and restricted to members—hospitals, ambulatory practices, pharmacies, benefit managers—any organization that prescribes or processes medications. Communication could leverage the ONC Direct Project,[25] e-prescribing protocols, or statewide Health Information Exchanges (HIEs). Private blockchains have garnered significant interest recently—particularly for highly sensitive data, and some companies (for example, MindChain), are built around this idea. While blockchains are *anonymous*, they are not *private*, which is problematic for highly sensitive data, like health data.

(2) **Proof of Work / Validation**. There are two ways a new block can be validated (each block contains one medication event):

   a. Additions to the MedChain could be signed by a patient's private key. For example, when an outpatient specialist prescribes a new medication for a patient, this transaction will be offered for approval by the rest of the nodes—and added to the MedChain—provided the patient or patient representative digitally signed the transaction. This allows a patient to "acknowledge" and "accept" the prescription.

b. Alternatively, a new block can be offered for MedChain addition if two members of the private chain agree on the addition. For example, if an outpatient prescriber and an inpatient hospital both sign the transaction, then the block could be offered as a new block.

Having two signatories ensures that either the patient, or another provider/hospital acknowledges the medication event. Additionally, two signatures removes the need for a nonce calculation, because the 2^{nd} signature effectively validates the transaction, deeming it "valid" for MedChain addition.

(3) **Contents of MedChain**. Each "block" in the MedChain represents a single medication-patient pair. The data would be represented using a standardized format, such as the Health Level 7 MedicationStatement Fast Healthcare Interoperability Resources (FHIR) Resource.[26] The MedicationStatement FHIR Resource includes references for the "source" of the record (pharmacy, hospital, etc.), dosing information, indication ('reasonForUse'), and quantity. MedicationStatement.patient would contain that patient's public key, ensuring anonymity. MedicationStatement.status would indicate if the medication were active or not—so a prescriber could also discontinue a medication and have that be recorded in the MedChain. The FHIR standard allows for improved interoperability, so that the different entities can easily communicate the medication information in a standards-compatible format.

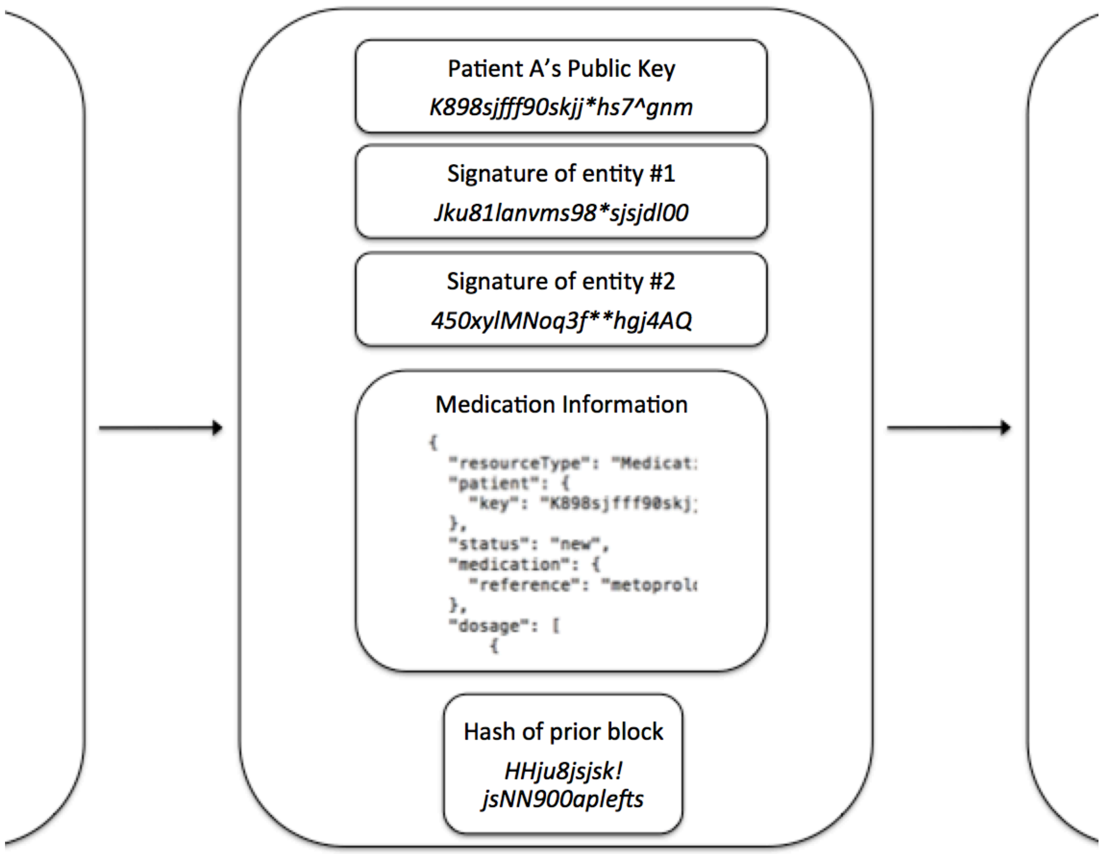


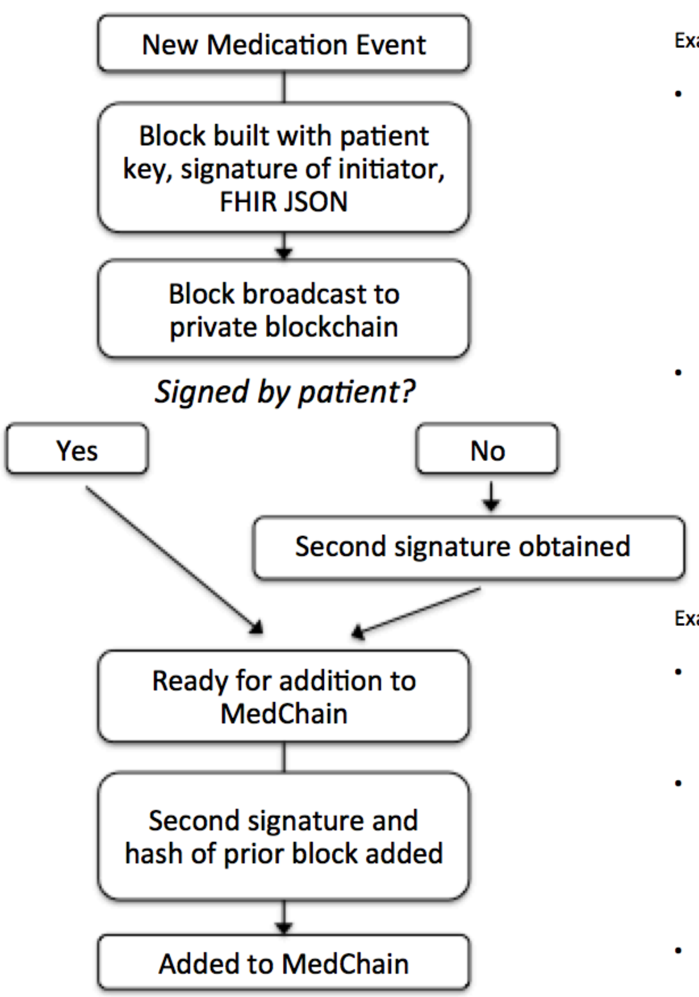
Figure 2: Example of a block in the MedChain. Each block contains a patient's public key, two signatures, a hash of the prior block, and the MedicationStatement FHIR JSON with information about the medication event.

(4) **Electronic Access to Private Blockchain**. Interested parties (patients, prescribers, insurance) would need access to a common interface to allow for peer-to-peer sharing of new transactions, validation, as well as block retrieval. This could could be through an EHR (for prescribers) or patient portal (for patients), using a secure messaging platform (like ONC Direct).

MedChain: **How it Works**

Figure 3 provides an overview of how the MedChain works. Specifically:

(1) A "Medication Event" is generated by one of the entities. Examples include a new prescription from an outpatient provider, a provider discontinuing a medication, or a patient self-reporting an over-the-counter medication. The "Medication Event" is signed by the originator and broadcast to the entire private network as a block candidate.
(2) Servers in the network wait for a second signature on the block candidate. The block candidate must contain a second signature—for example, the patient, or another party in the network—to be validated and added to the MedChain.
(3) Providers looking to obtain an accurate medication list would need credentials to view the MedChain (perhaps tied to their National Provider Index (NPI) number), and would need a patient's public key. This would ensure clinicians have access to only the data they need.



Example Patient #1: Jane Smith

- Jane Smith is discharged from the hospital on a new medication, lisinopril 40mg oral daily. The hospital broadcasts Jane's "Medication Event" to the MedChain Network.
    - Jane signs the transaction,
      -OR-
    - Jane's PCP, in follow up, sees the pending medication event, and confirms the new medication by signing the transaction.
- Lisinopril 40mg oral daily as a 'new' medication is added to the MedChain with the appropriate digital signatures.

Example Patient #2: John Smith

- John Smith goes to see an out-of-network specialist who prescribes a new medication. The specialist broadcasts a new "Medication Event" to the MedChain network.
- John Smith goes to the pharmacy to pick up the medication. The pharmacy, seeing the pending Medication Event under John's public key (which John reveals), fills the prescription and signs the pending transaction, adding it to the MedChain.
- All of John's other providers who know his public key can see the confirmed Medication Event in the MedChain.

Figure 3: Overview of adding to the MedChain with two examples.

MedChain: Limitations and Potential Pitfalls

Though the blockchain is an exciting technology that could be used to improve interoperability, there are several potential limitations:

(1) **Private vs. Public Blockchains**. Bitcoin is a public blockchain—all transactions are announced publicly with an electronic paper trail all the way back to the original block. MedChain would be a private blockchain—the contents of the blockchain would not be publicly available, except for "members" of the network—hospitals, provider organizations, pharmacies, etc. Critics of private blockchains would point out that a private blockchain forces traditional governance around a model designed to exist without central governance. However, we feel that the advantages of a private blockchain outweigh the disadvantages of a public blockchain.

(2) **Public Key Identity**. If a patient's public key is revealed, that individual's entire medication history can be known and traced back to them (provided a user has access to the MedChain). Some of this risk is mitigated by the private nature of the MedChain network. Other ways to mitigate this include frequent public-key changes (a strategy many bitcoin users use).

(3) Information Security Regulations (Health Insurance Portability and Accountability Act). Exploring the extent to which the encryption underneath the public/private key system is aligned with HIPAA and other regulations would be an important component of vetting feasibility.

(4) User Interface Software. A core component of the MedChain is the software that allows entities to announce medication events and sign existing blocks. This software should be part of the existing workflows, so ideally could be integrated into EHRs (for providers) and patient portals (for patients). A service layer for MedChain would allow integration of MedChain functionality into these products.

(5) Access to the MedChain. Controlling which non-entities have access to view the MedChain (for example, individual provides, or clinicians within a hospital) would also need to be addressed. There are several possibilities—member organizations can grant access to their employees, for example—however this issue would need attention, especially because of the amount of data that the MedChain offers.

(6) Patient Engagement. The MedChain works best when patients or their caretakers are engaged and able to validate new medication events. The electronic software would facilitate this, however there would still need to be patient engagement and education for this to be successful.

(7) Patient Identification. For MedChain to work, each patient would need their own public key / private key pairs. While hospital systems may have a Master Patient Index (MPI) to identify patients, this may not translate outside of that context, therefore we would need a mechanism for generating public / private keys that uniquely identify patients—one idea would be to have patient portals tackle this through a MedChain services layer.

MedChain: Conclusion

We have described the clinical implications of inaccurate medication lists, and the importance of medication reconciliation in minimizing Adverse Drug Events. A major challenge is the numerous entities involved in medication prescribing and the lack of a "source of truth" medication list, since each entity may only have visibility into its own set. Blockchains are a decentralized, public, anonymous method of facilitating data transfer between parties. Used primarily in the context of financial transactions currently (bitcoin), these blockchains hold promise for healthcare. We have described “MedChain,” which takes the concept of a blockchain and extends it to allow for medication reconciliation to be represented in a decentralized chain of information. As a private blockchain network, MedChain would have improved access controls; dual-signature requirements ensure that medication events are validated. Access to a patient’s MedChain would be limited to clinicians and relevant entities, and would require a patient’s public key. Finally, we described some of the limitations, including security, implementation, and patient education. Nevertheless, we feel that medication reconciliation could be improved using blockchain technology. If successful, the MedChain would allow reconstruction of an accurate medication list instantly, at any time. This would eliminate a large amount of healthcare provider time spent reconciling medications and reduce medication errors.

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