Implementation of Blockchain Standards for Compliance and Trust in Medical Implants Supply Chain

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The aim of this study is to introduce a management system based on Blockchain technology for the creation of a national tracking system throughout the supply chain of medical implants. The system could provide valuable information for various levels of users, such as supervisory bodies, manufacturers, and consumers. The presented model can be implemented internationally and locally for countries with common interests or health policies in the field of medical devices. Moreover, it can be extended to higher supply chain levels, such as those for capital goods in the medical device industry, in health centers across the country and successfully overcome monitoring, safety, and management challenges in the area of healthcare products. The presented model based on blockchain technology by creating a reliable data and a traceable management system, enhances the performance of the supply chain components and encourages them to improve the product quality while maintaining information integrity in the supply chain. This is an open access article which permits unrestricted reuse of the work in any medium, provided the original work is properly cited. [DOI: 10.22034/ASAS.2022.352010.1007] All rights reserved.

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Introduction

Nowadays, medical implants are widely used in treating, monitoring, and restoring limb function. These implants are made of biocompatible artificial materials and are planted in patients' bodies for medical purposes usually for a long time. Applications of these devices include replacement of body parts, such as hip and knee joints; drug delivery to a limb or organ for pain relief or treatment; regulation of a limb or organ, such as heartbeat regulation; and functional support for a limb or tissue, such as orthopedic implants. In many cases, these devices are planted inside the body for some time for the structural support of a member or limb. Examples include artery stents, orthopedic implants, and bladder meshes.

Implants are categorized based on structure, material, and function. Advances in technology, including information technology, have led to the advent of a novel type of implant, named smart implants. These implants are usually attached to the surface of the body and benefit from a wireless connection to other medical devices and software. They include neuromuscular actuators, external defibrillators, and wearable health monitors [1, 2]. Figure 1 demonstrates some applications of medical implants in the body.

The current rapid growth in biomedical engineering and its subfields, such as biomechanics, bioelectrics, and biomaterials, is a major cause of the widespread use of medical implants. Although no comprehensive data bank on the number of implants in use is available, regional and local statistics around the world indicate an exponential growth in their usage. One reason for the boost in the applications of these devices is the increase in the elderly

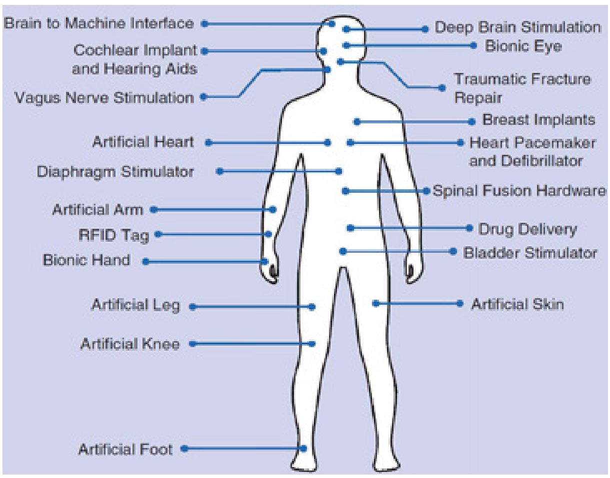

Figure 1- Applications demonstration of Medical Implants

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population given the rise in life expectancy, especially in developed countries. For instance, almost 100000 hip joint replacements were performed in the UK in 2017. About 80% of these replacements belonged to those 60 years or older. Based on commercial reports, the global medical device market is estimated to have an average annual turnover of more than 200 billion dollars, a significant share of which belongs to medical implants, [3,4].

Despite growing concerns over health issues associated with the increasing usage of these devices, supervisory bodies around the world are unable to fully protect millions against damage due to defective or low-quality implants. Numerous patients have endured pain or even lost their lives due to faults in medical devices entering the market as a result of ineffective supervisory regulations, insufficient evaluation, or a lack of transparency. The following occurrences are examples of faults in marketed medical devices, [5-9].

• Replacements of a hip joint and a bladder mesh were performed using tools not having passed clinical evaluations prior to marketing.

• A patient was treated using a cardiac pacemaker with functional issues known to the manufacturer.

• A disc replacement surgery was performed via tools that, although certified by a supervisory body, gradually disintegrated after being implanted and spread throughout the patient's body.

• The inappropriate design and functionality of hip and knee replacements caused metal wear, leading to metal particles from the implant entering the blood flow and resulting in blood toxicity.

• The material of a dental implant destroyed gum tissue and the mandible.

• In some cases, surgeons claim that despite being aware of the risks involved in implants, they are unable to inform the patients or supervisory bodies of these risks since they lack sufficient information and documents for this purpose.

• In some countries, certain equipment is used that is certified based solely on foreign certification (such as EU certificates) without undergoing further tests in the country of use.

Similar to other structures, medical implants suffer from natural wear and various functional failures during their service life. This issue is of greater concern for internal implants due to their higher exposure to erosion and wear from direct contact with body tissue and biological conditions in the body. The long presence of implants inside the body with chemical interactions with their surroundings can deteriorate the physical, mechanical, and functional characteristics of all their mechanical, electronic, and other system components and lead to total functional failure under certain conditions, [9].

The International Consortium of Investigative Journalists (ICIJ) has reported that, between 2007 and 2015, American medical equipment manufacturers spent more than 6.1 million dollars as settlement for violations and fraud related to implants across the US and in other countries. For instance, Johnson & Johnson alone was sentenced to pay 3.4 billion dollars in compensation for complaints about damage from detective performance of implants, such as hip joints, implant meshes, and surgical staplers, across the US. Only in the UK, supervisory bodies recorded 62000 reports of damage from the malfunction of medical equipment between 2015 and 2018. Out of this number, one-third led to serious injuries, and 1004 resulted in death, [10-11].

These data represent merely part of the actual number of violations taking place in the medical device industry. In many cases, manufacturers and physicians deny reports of equipment malfunction or present incomplete or unconfirmed information. To make matters worse, healthcare supervisory organizations in some countries avoid publicly revealing information about various damages to society. According to the report by ICIJ, unlike pharmaceuticals, many surgical and implant innovations have been marketed without sufficient scientific evidence and laboratory testing. This has increased the health risks faced by patients and reduced public trust in these products. The report further states that powerful lobbies have been created and considerable sums of money have been spent by the manufacturers of these products with the aim of pressuring supervisory and regulatory bodies into accelerating the certification process or lowering safety standard levels, [10-13].

Considering the mentioned issues, the creation of a secure data bank for tracking healthcare products, including medical implants, along their manufacture, distribution, and consumption chain with the aim of authenticity control can greatly mitigate the harm caused by fake or low-quality devices to consumers or patients. In addition to controlling quality at the supply level, this data bank can ensure the authenticity of products by preventing fake and smuggled products from entering the supply chain. The blockchain, which is a distributed and decentralized database, is widely used nowadays as a data management solution to improve systematically the trust level among the beneficiaries and relevant parties and the security level of data banks, [14].

The aim of this study is to introduce a management system based on blockchain technology for the creation of a national tracking system throughout the supply chain of medical implants. The system could provide valuable information for various levels of users, such as supervisory bodies, manufacturers, and consumers. The presented model can be implemented internationally and locally for countries with common interests or health policies in the field of medical devices. Moreover, it can be extended to higher supply chain levels, such as those for capital goods in the medical device industry, in health centers across the country and successfully overcome monitoring, safety, and management challenges in the area of healthcare products.

Materials and method

The main objectives, in the design of modern information systems, are transparency, comprehensiveness, and distribution of data storage. The blockchains resolves issues associated with centralized systems, such as the possibility of data manipulation and errors and the lack of integrity in the data storage.

Blockchain technology

Blockchain is a digital ledger of transactions or logs of updates that are distributed across the entire network. The blockchain is an immutable database, which means the manipulation of data in it is nearly infeasible. As the blockchain is a distributed system it can provide a secure data-storage and data-processing foundation for business applications, without requiring complete trust in a central node. This technology by storing all transactions in a decentralized manner increases trust and transparency in a data management system. Everyone in the system can check all the transactions and verify their accuracy. Additionally, cryptographic keys ensure data immutability and consistency, [16, 18].

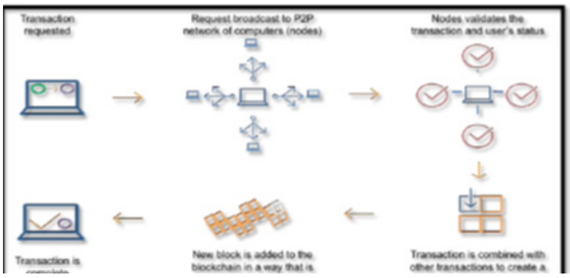

Figure 2- The basic description and schematic diagrams of a blockchain system.

Blockchain technology in the supply chain

A supply chain consists of processes such as manufacturing, storage, transportation, marketing and sales, and consumption. Customer trust, transparency, product quality, transportation issues, environmental impact, product safety, fraud, and the accuracy of the information provided by the beneficiaries are among the factors that determine the reliability of a supply chain.

Consumers and customers desire better transparency, comprehensiveness, and distribution of data storage; however, this cannot be achieved through the traditional system approach in centralized databases. Disadvantages of these systems include high cost, the possibility of data manipulation and error, lack of integrity in the data stored in data banks, or fraudulent certificates, and the difficulty faced by the beneficiaries in authenticating the processes or products. The use of blockchains today has resolved the mentioned issues to a great extent and has improved transparency and beneficiaries' trust in supply chains. As a result, this technology is witnessing growth in various applications. As a distributed technology, blockchain is widely used to build trust and improve security and transparency in data management systems. Specifically, an event or process registered by a beneficiary in the system will be unmodifiable once it is evaluated and confirmed. All records related to raw materials, production, and supply chain cycles belonging to medical implants can be stored and tracked in the blockchain, [19, 20].

Numerous studies have demonstrated that blockchain technology is not restricted to cryptocurrency transactions and could be also used in data management systems. For example, Li et al. presented a blockchain in the energy sector. Their work consisted of a secure energy trade system that used a blockchain consortium to address security and privacy issues associated with unreliable energy markets. Kraft et al. studied the application of blockchain technology related to the Fourth Industrial Revolution, [21, 22].

Numerous studies have been published on the use of blockchains in supply chains. In a study, Tian et al. employed radio-frequency identification (RFID) and blockchain technology to develop a traceability system for an agricultural supply chain. In another work, Ahmed et al. investigated the use of blockchain technology to manage foodstuff safety. Lu et al. proposed blockchain technology for tracking products throughout a supply chain. A case study was conducted by Tonnissen et al. on the impact of blockchain technology on supply chain management. In the area of food supply chains, Behnke et al. studied the boundary conditions and used blockchain technology for traceability in a food supply chain, [23-27].

Saberi et al. analyzed blockchain-technology-based applications and smart contracts for supply chain management with the aim of reducing opportunistic behavior. In the area of data management, Pan et al. examined the use of blockchain technology in production management in a company. They showed that a blockchain can effectively establish trust among the supply chain members. Nevertheless, they did not present any execution method, [28, 29].

These studies demonstrate that blockchain technology is a promising innovation for data management in product supply chains with a focus on implementing traceability and administrative functions. Therefore, blockchain technology can be readily applied to the monitoring of supply chains in order to address the safety issues associated with medical implants.

Design of a medical implant blockchain

Traditional medical implant traceability and monitoring methods are based on numerical labeling and suffer from various issues. For example, these labels are susceptible to fraud, and the information on them can be easily manipulated or erased. On the other hand, blockchains can provide reliable information for the traceability of medical implants in supply chains. In modern systems, an RFID label is assigned to every implant during the design of the blockchain. As such, information about the implant is readily attached to it without any labor involved. RFID is a secure and complete technology widely used in public transportation and membership card systems. This technology can be utilized to overcome the first two issues mentioned for the numerical labeling method. The third problem, involving the falsification and manipulation of information, may easily occur in a centralized database or server. In contrast, manipulating or erasing data stored in a blockchain or distributed system is nearly impossible, [29, 30].

Specifically, a blockchain system for medical implants is focused on the four main institutions in a supply chain: manufacturers or importers of medical implants, supervisory bodies, distribution companies, and medical centers. The data recorded, by these four institutions, are continuously stored in the blockchain system, with manipulation or elimination of records being almost impossible. To manipulate a datum, more than half of the nodes in the system must be simultaneously manipulated, a task that is practically unfeasible. The records in the blockchain are public and accessible to consumers and other beneficiaries, such as insurance companies, for confirmation and tracking of the used implants.

Registering and monitoring medical implants in an integrated system plays a key role in improving consumer safety. For instance, in case of an issue with a specific type of implant, it is possible to access the whole supply chain and issue the necessary warnings and perform corrective actions, such as informing consumers and recalling products, in the shortest possible time.

The first step to the high-quality production of medical implants is to adapt the production processes to the GMP standards. Hence, the designed medical implant blockchain provides access to the implant production records. A minimum of three data types including: batch packaging, batch production, and inspection, must be recorded.

Implant inspection and sampling by inspectors (third parties) during the production process occur in the form of point sampling from the production line and, then, after which the sealed samples are sent to specialized laboratories for validation tests. The laboratory can directly upload the test results to the system. A permit to market a product will depend on its ability to pass the test and the confirmation of the relevant expert. Throughout this process, the production records of manufacturers or authorized importers are registered on the GMP chain, and the inspection records are registered by the specialized laboratory or the supervisory body. During each of the distribution steps, each loop in the chain is responsible for registering the information pertaining to the subsequent loop. The health center is tasked with registering basic information about the receivers of the implants, the health center, the specialist, the implanting time, etc. Personal information from the implant receivers will not be publicly available to protect their privacy. Figure 3 shows the authentication model and traceability concept in our proposed medical Implants blockchain.

Block structure information

A blockchain system is used to store all the information regarding medical implants. The overall blocks structure information in proposed model is demonstrated in Fig. 4. In this system, each block mainly includes information uploaded by the manufacturer, authorized importer, distributor, supervisory body, and medical center. The data are organized and recorded in a hash table structure. At each supply chain step, each beneficiary or relevant party can register any issue with respect to

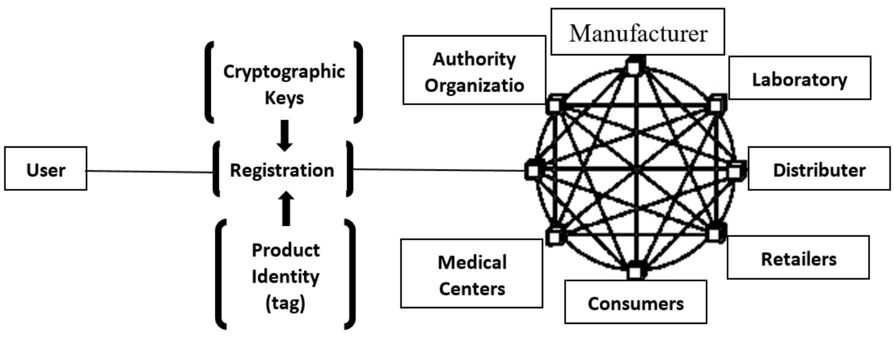

Figure 3- Authentication model and traceability concept in the proposed medical Implants blockchain.

Medical Implants Blockchain System								
block n			**block n+1**			**block n+2**		
HEADER			**HEADER**			**HEADER**		
block version	timestamp	hash of block n-1	block version	timestamp	hash of block n	block version	timestamp	hash of block n+1
BODY Transaction 1 Transaction 2 . . . Transaction n			**BODY** Transaction 1 Transaction 2 . . . Transaction n			**BODY** Transaction 1 Transaction 2 . . . Transaction n		

Transaction 0	timestamp	sender	recipient	amount	Data = {P: production, packing}
Transaction …	timestamp	sender	recipient	amount	Data = {I: inspection}
Transaction n	timestamp	sender	recipient	amount	Data = {M: Medical center, Patient}

Legal & Authority Organization	Enterprise	Batch Production Records Batch Packing Records	…
	Third Party Inspection	Inspection Records	…
	Distributer	Market & Trade Information	…
	Medical Center	Implantation Records Patient Information	…

Figure 4-The overall blocks structure information in a medical Implants blockchain system

quality or expiration time. In this case, no other action can be performed on that particular product until allowed by the supervisory body.

The manufacturer is responsible for providing the necessary processes and infrastructure for controlling and guaranteeing the quality of the ID production processes, ID labeling, and validation and activation of IDs prior to delivering products to the distributor. Moreover, the distributor, supplier, and consumer are responsible for ensuring the validity of the IDs, matching them to the information registered in the system, and refusing to accept and use any product lacking a valid and active ID.

Supervisory control

The manufacturers, importers, laboratories, inspection companies, distributors, and health or medical centers must use a public key and a private key to enter any information. The private key is provided to them by the supervisory body. The supervisory body monitors all data entry processes. The beneficiaries upload the records using their private key signature, which is then confirmed by the blockchain system to ensure that the records have been correctly sent and stored by the relevant beneficiaries. Continuous monitoring by supervisory bodies of the data uploaded by the beneficiaries and institutions guarantees their authenticity. In the case of an issue with these records, the relevant institution will be investigated and prosecuted if necessary. When a fault in an implant is reported, the medical implant blockchain reviews the whole product cycle to track the implant and determine the responsible party.

Evaluation unit

In general, the credit information has high value in a system and could determine the quality of the supply chain links. Accordingly, it is possible to create a supervision and evaluation mechanism based on the records and information of an implant in the blockchain. Normally, the users could comment online on the quality of medical implants and the distribution chain services, and the evaluation history is recorded in the system. Using a combination of machine learning models and the present database, one is able to analyze the quality of each beneficiary and create a smart system for the evaluation of companies and supply chain links.

Discussion

Appropriate modeling is a major factor affecting the performance of a supply chain. There are still insufficient studies in this field, especially in the area of medical devices. The present work designed a system, based on blockchain learning technology, to manage medical implant data on a national level. In this study, the

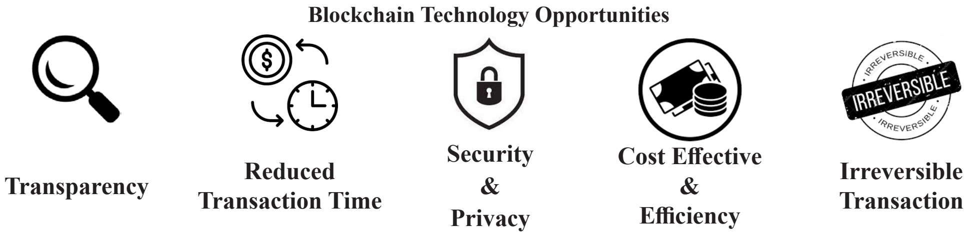

Figure 5- Opportunities of a blockchain system in healthcare sectors.

supervisory body, manufacturers, importers, major and minor suppliers, and health centers were considered as the main institutions in the supply chain of medical implants. The proposed medical implant blockchain removes the need for centralized control and provides reliable records for the traceability of medical implants, leading to a more secure and transparent supply chain for these products. Designing the medical implant supply chain, as a blockchain, provides consumers with a trust mechanism in which records are nearly impossible to manipulate after being registered while being also easily traceable. The stored records, in the blockchain, could be employed automatically to train machine learning models for smart suggestion systems. This process equips the system with smart suggestion functions. Our proposed blockchain system as an emerging technology has many opportunities, some of these benefits are listed in Fig. 5.

Conclusion

The Blockchains are a novel technology with a promising outlook. They are widely used to create trust-building mechanisms in the area of data management. This structure is useful to supply chains by creating a reliable data and traceability management system, enhancing the performance of the supply chain components and encourage them to improve the product quality while maintaining information integrity in the supply chain. Therefore, companies producing low-quality products gradually lose the market.

The implementation of a supervisory system, in the medical implant supply chain, is a useful tool to encourage effective and flexible responsibility, traceability, and suggestion functionality. The combination of machine learning and blockchains could lead to a smart and reliable system. The present paper investigated the authentication issue of medical implants and the use of a blockchain to supervise the associated supply chain. Moreover, a smart system based on blockchain technology, for supervising the medical implant supply chain, was introduced. Implementing smart contracts provide beneficiaries with the ability to detect expired medical implants automatically in the supply chain. The experimental results indicated that the blockchain technology could identify manipulation in medical implant records, while machine learning can pick up the common rules from actual records and provide valuable suggestions to customers.

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Conflicts of interest None declared

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