

Review

Improving the Healthcare Effectiveness: The Possible Role of EHR, IoMT and Blockchain

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Abstract: New types of patient health records aim to help physicians shift from a medical practice, often based on their personal experience, towards one of evidence based medicine, thus improving the communication among patients and care providers and increasing the availability of personal medical information. These new records, allowing patients and care providers to share medical data and clinical information, and access them whenever they need, can be considered enabling Ambient Assisted Living technologies. Furthermore, new personal disease monitoring tools support specialists in their tasks, as an example allowing acquisition, transmission and analysis of medical images. The growing interest around these new technologies poses serious questions regarding data integrity and transaction security. The huge amount of sensitive data stored in these new records surely attracts the interest of malicious hackers, therefore it is necessary to guarantee the integrity and the maximum security of servers and transactions. Blockchain technology can be an important turning point in the development of personal health records. This paper discusses some issues regarding the management and protection of health data exchanged through new medical or diagnostic devices.

Keywords: electronic health record; medical devices; blockchain; internet of medical things (IoMT)

1. Introduction

Diagnostic and treatment choices are often driven by physicians' opinions and not always based on scientific evidence. It is a common occurrence to receive different advice from different physicians for identical medical problems. An interesting study of a second opinion program at the Cleveland Clinic reported that a new plan or a significant change in prior treatment occurs in 90% of cases [1]. Finding reports which show the shortcomings of medical practice is rather easy. The United States (US) Institute of Medicine stated that medical errors cause 49,000 to 98,000 deaths in US hospitals every year [2]. A Johns Hopkins study found that as many as 40,500 patients die in intensive care units in the US each year due to misdiagnosis [3].

As stated in the last report edited by the statistical office of the European Union (Eurostat) in 2016 more than a million deaths in persons aged less than 75 could have been avoided in the European Union through effective public health and primary prevention interventions, considered the current medical knowledge and the new technologies [4], while, in the same year, medical errors were the third leading cause of death in the US [5].

Inadequate data collection and low rates of communication lead to errors in clinical reasoning which decrease the quality of care, so it is likely that many of these errors are due to the reduced availability of the information necessary to make the correct decisions in organizing a patient's therapeutic diagnostic path when needed [6,7].

In “Medical Error Prevention” [8] the authors analyze the different causes of medical errors suggesting several ways to prevent them. As suggested by the authors, by a better and broader use of ICT some diagnostic or therapeutic errors could be avoided: as an example, surgical errors depending on “Incomplete or missing pertinent imaging information and relying on memory”, “Incomplete preoperative assessments such as failing to note abnormal pre-op labs or EKGs” or diagnostic errors due to inability to cross-reference easily with colleagues. In light of the above, great support can be given also by the massive introduction of technologies such as Electronic Health Record (EHR) to decrease medical errors and increase patient safety.

Many types of EHRs have been developed, especially since the new millennium; in this work, we will refer to a particular type of EHR, the Patient Health Record (PHR) which considers citizens as personally responsible for their own health and therefore for the collection and storage of all their clinical information. The Personal Health Electronic Record (PHER) is a PHR developed at the Computer Science Department of the University of Bari allowing the physician to see at a glance the patient’s clinical parameters, so as to be able to link any alarming physical status to recent medical history [9,10].

Simultaneously with the development of new EHRs, a lot of portable and wearable medical devices and apps, allowing the detection of numerous clinical parameters at citizens’ homes or wherever the citizens need, have been developed in recent years. Frequency meters, pulse oximeters, devices not greater than a credit card able to record an electrocardiographic trace are some examples, together with the well-known smartwatches; electronic stethoscopes for transmitting lung and heart sounds over the Internet have been added to the common sphygmomanometers or glucometers spread since twenty years ago. To undergo frequent blood tests, it is no longer necessary to go to a laboratory and take a sample, but they can be carried out at pharmacies or at health points distributed throughout the territory. Even more complex investigations, such as spirometry or ultrasound, can be carried out by specialists at the patient’s home, with new portable devices. Many recent studies in the field of computer vision applied to medical and biomedical fields have demonstrated that additional CAD-based tools might support specialists in their tasks effectively [11–22]. Modern technologies and IoMT allow the improvement of the acquisition, transmission and analysis of digital images and clinical parameters. A growing benefit is also provided by the possibility of transferring complex clinical data, useful for the diagnosis of pathologies, thanks to the spread of fast and secure connections also with mobile phone networks that allow the exchange of large amounts of data [16–19].

The social interest in a system that can support the continuous availability of personal clinical information for everybody, so that it is readily usable whenever and wherever somebody needs it, especially in an emergency case, is clear. Furthermore, it is equally important that it becomes possible to make personal health decisions freely and personally; in fact, at the basis of each free choice there must be correct and complete information, and one of the greatest current paradoxes is that the choices regarding one’s own health are taken or relying on the decisions of the doctor to whom patients turned, often without even knowing them [23]. In this way, complete information is rarely obtained; then, in more and more frequent cases, anxiety gives rise to the habit of looking independently for information among friends and more and more often on the web (in this last case information will be not often correct [23,24]). In addition to supporting the choices of each citizen, an EHR should allow health professionals to have immediately available not only the report of a previous radiography, but also the radiography itself, even on its portable device, as required; a cardiologist will be able to view previous reports but also directly view previous electrocardiograms, echocardiograms and coronary angiography of the patient they are visiting, certainly obtaining a more complete view of the patient’s condition without necessarily having to trust the reports of other colleagues, who can be very good, but can be wrong, as we said at the beginning of this paper.

The photographic documentation of pathological changes may constitute an objective tool for evaluating the effectiveness or otherwise of the therapies implemented.

Listening to lung and heart sounds has become an important practice during a medical exam since Laennec invented the stethoscope, two centuries ago; however, it has been, for doctors, very difficult, if not impossible, to exactly describe the listened sounds for comparing what two different doctors had heard in two different moments. Thanks to electronic phonendoscope use and the possibility of recording auscultation, a doctor who has not previously visited the patient will be able to compare the objectivity found with the initial one. An EHR should support a request of a second opinion without the need to move the patient, simply granting the access to the EHR to a second specialist.

Normally, EHR data safety and privacy are preserved by the use of specifically designed procedures [25]. The identity of care providers who are allowed access to the patient data is guaranteed, patients can activate their accounts through a secure online registration and can choose whether to share them with their care providers or to use this system only as a personal repository of their own history and clinical documentation.

The huge amount of sensitive data that is stored in the EHR certainly attracts the interest of numerous criminals, therefore the security of patient access is not sufficient: it is necessary to guarantee as much as possible the integrity and impenetrability of servers and transactions protection for obeying at laws and regulations as the European “General Data Protection Regulation” and the “Health Insurance Portability and Accountability Act” of the United States [26,27]. In this context, blockchain technology can be an important turning point in the development of personal health registers [28,29].

However, as other authors note, Blockchain is necessary to have a secured system to increase privacy and security to ensure accountability and monitoring of medical usage data. Blockchain is considered secure and transparent, and as the catalyst for a revolution in existing healthcare systems [30]. In addition, most existing studies about Distributed Ledger Technologies and IoT in health care are focused on the conceptual design of health data sharing systems, in order to make possible data sharing with hospitals and researchers that will be able to gather relevant data for their studies [31].

2. The Importance of IoMT in the ‘Time of the Coronavirus’

Due to the actual epidemiologic moment caused by the COVID-19, the whole society has the responsibility of finding solutions against the pandemic. While knowing that the scope of this paper does not allow us to be exhaustive in listing and describing all the real lifesaving or very useful medical devices currently on the market, we will briefly describe some of them which would have been particularly useful in this COVID-19 pandemic period: we hope to make evident how much important they will be in the future for the organization of modern health systems. It is believed that they will become fundamental for the acquisition of clinical information in an economic and efficient way at the patient’s home. Thanks to their use, especially chronic patients can be monitored continuously without having to go to hospital centers, where they will only go when a specialist reassessment is necessary. The changes to the treatments will be more timely and the time of the doctors will be used only for patients who actually need them.

The pulse oximeter is a biosensor that allows you to measure both the amount of oxygen present in the blood and the frequency of the heartbeat and indicates the ability of the lungs to oxygenate the blood by displaying the saturation of the hemoglobin. The low-cost latest models allow the recording of measurements and transmission of data via standard connections. During the current pandemic it would have proved extremely useful in monitoring pauci-symptomatic patients at home, in order to be able to intervene promptly in case of worsening of saturation. But more importantly, it would have allowed mass screening of the oxygenation level of thousands of citizens equipped with the device and connected to an EHR. A widespread use would be desirable for all patients affected by Chronic Obstructive Pulmonary Disease in oxygen therapy to more accurately assess the need for oxygen throughout the day. Smart thermometers, by detecting body temperature every time a person believes they have a fever, together with smartphone applications that allow the collection of these

measurements, have shown that they can predict the trend of flu and flu-like epidemics on a regional and national basis and by age groups [32,33].

The spirometer is an instrument used to measure the volume and speed of the air that is inhaled and exhaled, composed of a sensor connected to a mouthpiece and a part that measures the movements (volumes) of air caused by the patient who inhales and exhales through the sensor in a specified period of time. This is one piece of fundamental equipment for respiratory function tests and therefore it is particularly useful both for an assessment of acute asthma attacks and for monitoring the effectiveness of therapies in chronic respiratory diseases. As in the case of pulse oximeter, also these data can be recorded, stored in the EHR and made available online.

In recent months, many national governments have introduced confinement measures for the population trying to reduce the speed of propagation of the virus. Furthermore, in this period, in which the lockdown, in many countries, is going to end, an immediate implementation of solutions is needed to avoid the number of infected people all over the world beginning to rise again. The core objective of these measures is to keep the proper operation of the national health services, allowing clinical professionals to give attention to the population. Clinicians who need to examine the respiratory evolution of a patient could use eKuore's [34] low-cost wireless stethoscope to perform lung auscultation maybe also without using their personal protective equipment. Wireless stethoscopes allow doctors to auscultate without direct contact with the patient, transmitting lung sounds without any wire to the doctor's headphones. But since clinicians and sanitary personnel are limited key resources for the national health services, a device like eKuore could be used directly at home by the patient or by unskilled, easily trained people who live at home with the sick person. Again, these data can be recorded on an EHR and made available promptly, a project like this, described in [10] is now in an advanced phase of experimentation.

3. The Challenges in Healthcare

Until the last century, those who turned to doctors or health systems were generally healthy subjects, suffering from a single pathology which was the reason why they resorted to the doctor. Their clinical history was silent or relatively short, they were relatively young or otherwise maintained a good degree of autonomy, usually the level of education was low and they had no possibility of inquiring about their pathology. A single doctor had been caring for them throughout all their life and, if they were hospitalized, a single team had the entire responsibility of the care path. Before the great development of image diagnostics in the second half of the 1900s, the diagnosis was almost exclusively or mainly clinical. Medical advances of the 20th century have profoundly changed the characteristics of patients and their needs. Fortunately, diseases that previously led to death in a high percentage of cases can be treated or treated effectively for many years or even for decades. This resulted in an increase in the lengthening of life expectancy which was accompanied by a strong increase in the elderly population with varying degrees of disability and a high prevalence of patients with multiple pathologies. The diagnostic pathways have been enriched with new investigations and more and more often the correct definition of the therapeutic diagnostic process involves a plurality of specialists.

The rapid digitization of the world of healthcare has led to the creation of huge quantities of medical data; it has been recently estimated by the World Economic Forum that the near totality of the 50 petabytes of data per year produced by hospitals goes unused; "This mass of information comprises clinical notes, lab tests, medical images, sensor readings, genomics, and operational and financial data" [35]. As much as information technology has been able to keep up with the development of more and more large physical supports, it must now face an increasing demand for technologies for their management. In the overall vision, the first challenges to emerge relate to economics and confidentiality: the phenomenon of rising costs of a medical infrastructure that can provide satisfactory care is increasingly common [36], especially for countries with a high index of aging. The idea of a highly centralized system may be surpassed by a more decentralized architecture, which can preventively solve scalability problems and which can safely delegate the services. The issue of privacy proceeds as

much; in critical contexts such as healthcare, it is no longer enough to guarantee protection only from external attacks, but also from attackers inside the organizations themselves intent on abusing their power [37]. Constraints of transparency and verifiability should therefore be incorporated into the foundations of any healthcare infrastructure, to allow end users greater control over their information.

Equally important is the increasing number of connected medical devices, typically grouped under the name of the internet of medical things (IoMT): as we have said above, they are playing a fundamental role in increasing the accuracy and reliability of clinical and non-clinical data and can play an important role in critical situations; it would therefore be important to prepare the ground for an increasingly massive use of these technologies [38–40]. Furthermore, the logistical aspect of the health reality must be considered, namely the supply chains of medicines, medical equipment and their relative management; it is futile to adopt the newest technologies if there is no way to communicate the data they generate. Managing this data requires inter-operational skills, or the ability to exchange information in a precise, efficient and concise manner [41].

Interoperability, in addition to being a key factor in the ease and speed of data distribution between two interested parties [42], allows providers to securely share a patient's sensitive information regardless of where they are, thus maximizing effective action times [43]. This characteristic assumes even more importance when considering that the data are heterogeneous in nature since they come from a myriad of electronic and non-electronic sources, sometimes dated and not very compatible with modern systems.

In the face of all these challenges, blockchain can provide valid support to manage data and secure the internet of medical things devices.

4. Blockchain in Short

Blockchain is the name originally given to the structural design of the Bitcoin cryptocurrency [44], first proposed in 2008 and subsequently implemented in 2009 [45,46]. The original technology takes the form of a public and digital register, controlled by multiple entities called nodes, among which a reliability constraint is not guaranteed. Each transaction carried out is saved in a list of blocks linked together; this chain grows over time as more blocks are filled and added. Each block contains a timestamp, a list of transactions and a cryptographic hash of the previous block, which guarantees an innate and accurate representation of the chain's history, see Figure 1.

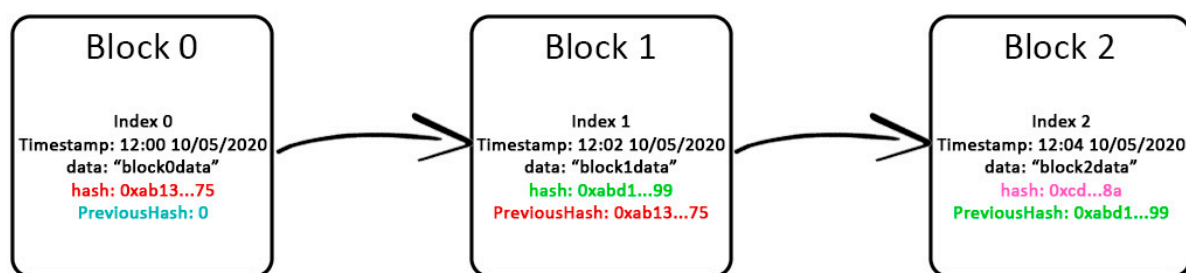


Figure 1. The blockchain flow.

One of the most significant advantages of this technology is the simplicity with which it solves two of the most feared problems in the world of transactions, known as the problem of the "Byzantine generals" (to be sure that a message has been received and understood) and the "double spending" (A sends money digitally to B, but you can't be sure that A can't reuse the same file to send the same money to C).

The original paradigm then changed, adapting to the various zones in which the nodes are more or less reliable and the data transmitted in the transactions are no longer just of a financial nature [47,48]. In Reference [49] the authors examine concrete cases in which new types of networks are most useful, coming to lay the foundations for the definition of a consortium blockchain: a type

of semi-public chain applicable in cases where multiple organizations have the same goal and are willing to share the data, thus eliminating the need for a third party entity to conduct transactions for members. There must therefore be an internal mechanism within the network itself that guarantees the reliability of each transaction and the data contained therein. This reliability is called consensus, i.e., when each member of the network agrees on the authenticity of the incoming data. The way in which the network implements the management of consent, directly and indirectly, determines its resilience to tampering and attacks as much as to the insertion of incorrect or accidental data. Much of the work therefore focuses on the study and implementation of algorithms and protocols that are stable, minimally invasive, and above all safe [50]. In Reference [51] the authors state that “blockchain technology has emerged as a key technology recently in the digital revolution of the healthcare sector and several research studies have identified blockchain potential for the healthcare ecosystem”.

5. Data Management

Making data and transactions secure and managing their correct integration are valuable functions for any data-driven organization. Khezr identifies some points for the management of this data with blockchain technology [52]. Blockchain applications in this area include data sharing, management and EHR functions. First of all, the primary data are generated by the interactions between the patient and his doctors/specialists. These data contain the anamnesis, current problems and other physiological information. An electronic health record is created for each patient using the data collected in the first step. Other medical information, including that generated during the treatments, imaging and medicines taken are attached to the register; an example is shown in Figure 2.

Then, full access control and data sharing are given to the patient concerned. Other entities desiring access to this information will have to request it through the electronic file. From there, the owner will decide whether or not to accept it. Now the central point of the whole process can be identified, which includes a database, blockchain and cloud storage. Database and cloud store data in a distributed way, while the blockchain allows a guarantee of the privacy functions. Finally, we find the providers, such as ad-hoc clinics and hospitals. The providers represent the end users, who can be authorized by the owner of the data to access the medical file: wherever the treatment takes place, their information will be available and accessible on their phone, validated through a blockchain that is gradually updated. This application is therefore considered the most crucial possible use of blockchain in the health sector [53].

The contributions to the topic range from studies on the state of the art to real complete implementations. In Reference [54] the authors propose, for example, a logging system to facilitate and improve the exchange of medical data across multiple countries in a secure way. In Reference [55], on the other hand, it is presented a framework for cross-domain sharing of images using blockchain technology as distributed storage. In this work, the authors evaluate any applications in the radiology and imaging field through customized user permissions. Similarly, in Reference [56] a blockchain-based framework to solve data management and data sharing problems in electronic medical records is presented. Patients can access the record files of different hospitals through this framework, thus preventing previous medical data from being segmented into various databases. They also note how this framework can help hospitals get an idea of a patient’s medical history before any consultation. Among the most influential implementations of such a framework is the approach demonstrated by Yue et al. [57], which consists of a data sharing application based on blockchain: this implementation provides a means to control and share user data without compromising privacy and an excellent way to improve the intelligence of health systems while keeping patient data private.

Actually, the developed EHR uses FHIR HL7 standard which regulates common rules for EHRs interoperability, including access levels. So, the patient establishes an access level for each file upload on the blockchain through the EHR, and only authorized care providers will be able to access patients’ files [58].

The image shows two overlapping screenshots of an Electronic Health Record (EHR) system. The top screenshot displays the 'Patient Summary' for a patient named Janitor Jan. The interface includes a navigation menu on the left with options like 'Visite', 'Anamnesi', 'Vaccinazioni', 'Diagnosi', 'Terapie farmacologiche', 'IoMT', 'Files', 'Taccuino Paziente', and 'Calcolatrice Medica'. The main content area shows patient details such as name, date of birth (23/01/87), gender (male), and residence (ABBATESSE). It also features sections for 'Contatti di emergenza' (Emergency contacts) and 'Altri Contatti' (Other contacts), both with add and delete buttons. On the right, there are sections for 'Terapie farmacologiche in corso' (Ongoing pharmacological therapies) and 'Farmaci da non somministrare' (Drugs not to be administered). The bottom screenshot shows a 'Pain representation' tool with a human figure and a list of pain levels: 'Nessun dolore', 'Dolore lieve', 'Dolore moderato', 'Dolore intenso', 'Dolore forte', and 'Dolore molto forte'. It also includes a date selector set to 04/2020 and a text input field for notes.

Figure 2. An example of electronic health record (EHR) (<https://www.resp.cloud>)—detailed in Figure A1a–c (see Appendix A).

However, in the EHR shown in Figure 2 the solution adopted is similar to the one described in Reference [59]; a solution based on the use of smart contracts within blockchain Ethereum is proposed. The Smart Contract consists of three sub-contracts: a Contract Registrar containing their user ID and identity on Ethereum and aims to link the user’s identity to their Summary Contract. The Summary Contract is used by patients to trace their medical records and the Patient–Provider Relationship Contract (PPR). Finally, the PPR manages the relationship between patient and health care provider, defines pointers consisting of a query that is executed in the provider’s database and returns patient data.

In order to share the data with third parties, the patient node retrieves the PPR with the query of the data it wants to share and updates the PPR of the third party with this query and the hash code of the requested data. The third party node will access the DB of the provider that had stored this information, and through a gatekeeper that analyzes the hash code originally generated by the starting provider, recognizing the signature of its provider, it will allow access for data recovery.

In Reference [60] a possible use of blockchain technology as a system that has the role of controlling access to medical records and health data contained within it as an index. The transactions within the blocks would contain an identifier of the user plus an encrypted link to this data, all enriched with metadata to improve efficiency.

All medical data would be stored outside the chain, in a Data Lake. Any information must be digitally encrypted and signed to ensure the privacy and authenticity of the information before it is

stored within the Data Lake. Once saved in a Data Lake, the indicator of this information is recorded within the blockchain along with the user’s unique identifier.

The data structure within the Blockchain, combined with Data Lake, can support a wide variety of health data such as EMR, documents, images. Of significant importance is the issue of data from sensors, smartphone applications and wearable devices that can be managed in real-time by Data Lakes, making a significant contribution to research for improvement in the management of medical emergencies and the continuous monitoring of behaviors that can affect public health.

The strengths and weaknesses of the works mentioned in this section are summarized in Table 1.

Table 1. Summary of strengths and weaknesses of the solution proposed in Section 5.

	Strengths	Shortcomings
MedRec [59]	The blockchain contains only data related to smart-contracts that enable access to the clinical data ensuring that only registered healthcare providers are permitted to append blocks to the MedRec blockchain.	Blackout times on a provider’s database does not allow access to raw data but only to smart contracts that have registered data access consent. This could create problems in case of emergencies.
	The raw medical record content is never stored on the blockchain, but rather kept in providers’ existing data storage infrastructure.	The use of a centralized arbiter of a ‘provider whitelist’ to determine the validity of each potential sealer contradicts the decentralized spirit of blockchain technology.
	Facilitates reviewing, sharing and posting of new records via a flexible user interface.	Privacy: direct disclosure of a patient name could be drawn from metadata of one Ethereum address with multiple others. Even with a private blockchain, it is necessary to consider the mining nodes, who process this sensitive metadata.
	Focus on usability for the medical record use case, hiding the complexity of blockchain-based technology.	Security: clinical data security is entrusted to the providers.
	The interface includes a notifications system to alert users when a new record has been posted on their behalf or shared with them.	-
	Security: security on clinical data access consent metadata is guaranteed.	-
Blockchain and Data Lake [60]	Hight level of scalability due to the information contained in the blockchain that represents an index, a list of all the user’s health records and health data.	Data Lakes must be implemented in a national technology infrastructure for health IT based on open standards.
	The security of clinical data is guaranteed thanks to the centralized and secure management of data lake.	Centralized data lake architectures could open realistic ways for cyber-attacks. It is necessary to verify the security levels relates to this kind of data containers.
	Biometric identity systems would be utilized as they offer enhanced security.	The solution inherits the limits of data lakes: large amounts of data that in most cases are not useful. Potentially high latency. Geographically distributed data lakes feeding could lead to regulatory violations. Inefficient and ineffective “store everything” model.
	Complete control by patients of the management of access permissions to their sensitive data.	It is unclear what entity would be responsible for hosting such a large data store and for what motivation.
	-	The encryption of such amount of data in the lakes requires large computational effort.
	-	Improvable security policies.
Medical imaging data sharing via blockchain consensus [61]	Good efficiency level, there are no medical images stored on the blockchain.	Compliance with regulations and privacy laws.
	The proposed solution satisfies many of the requirements of an interoperable health system.	Complex user experience.
	Patient-controlled image sharing without the need for a central clearinghouse.	Cyber security is not absolute, as in many similar solutions.
	User authentication is activated only when required.	Correlation between data in the blocks and external sources could lead to the owner of the imaging data being traced back to the owner of the data.
	Handles most standard formats for medical imaging.	-
Medblock [62]	Good security level: private blockchain and fingerprint technology. The system can resist identity disguise, reply attack, binding attack.	
	Authentication and access control based on public-private key pair—used to associate activity on the network with a specific participant i.e., patient, entity or device.	While latency is slightly better than other approaches, it remains a weak point when the number of users grows.
	Peer-to-peer network that ensures a highly protective trust-less based system between patient and practitioner removing the need for third party intermediaries.	

6. Securing the IoMT

As has already been stated, IoMT systems play an increasingly important role in the development of medical information systems [61]. With this technology, tools such as heart rate monitors, body scanners and wearable devices can collect, process and share information in real time through the internet. As technology advances, providers can perform data analysis at the same time they are produced and share the results with those who have access rights to this information.

The implementation of the blockchain within the IoMT allows the patient to act as a source of all data, with the additional instrumentation that is normally in constant operation and therefore generates huge amounts of data. The generated data will then be mediated by intelligent systems that will filter the key information and add it to the blockchain when necessary. The result is, as desirable, a vertically integrated system that is secure and available at any time.

Griggs et al. [62] introduce the integration of Wireless Body Area Network (WBAN) with blockchain technology for a secure real-time patient monitoring system. Their study proposes the use of this technology to evaluate the information collected by the patient's IoMT instruments based on personalized threshold values, see Figure 3. This is done to overcome the limitations of temporarily storing data transfers in a medical system.

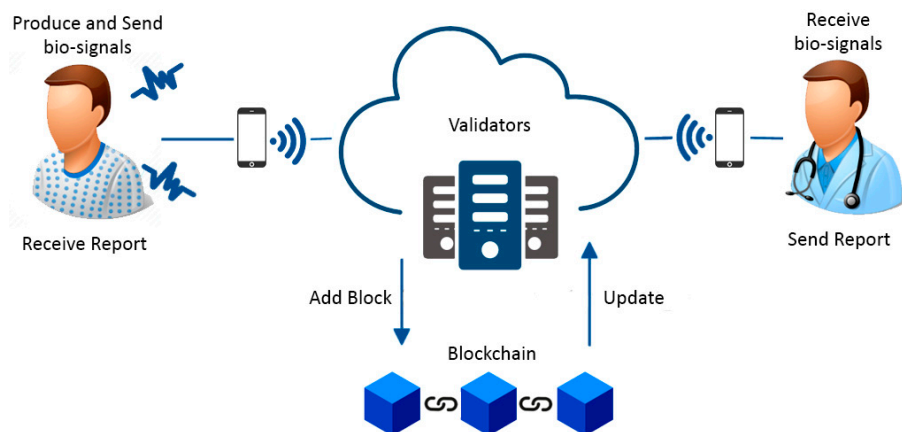


Figure 3. Wireless Body Area Network (WBAN) Pipeline.

Zhang et al. [63] introduce a model for safely using a Pervasive Social Network (PSN) based medical system, where they address the issue of ensuring secure sharing across multiple PSN nodes. To do this, they created two protocols: the first, based on an already existing IEEE protocol, deals with establishing secure links with the small computational capacity of mobile devices; the second uses blockchain technology for the actual sharing of data. Other authors [64] offer an interesting health monitoring technology where centralized and decentralized data distribution systems are activated based on an internal division between edge networks and core networks. This model shows signs of greater efficiency and scalability for a blockchain system, especially when related to the dynamism of the data involved.

In the solution proposed by [65], the prototype system consists of three entities: mobile phone users who download applications, application providers who require data processing, and nodes that store data on the blockchain in exchange for rewards. Users remain anonymous, while the identities of the providers are recorded on the blockchain. The system is designed as follows: blockchain accepts two types of transactions: T-access, for access control management; T-data, for data storage and retrieval.

When the user registers for the first time, a new shared identity is generated and sent to the blockchain, along with associated permissions, via a T-access transaction. The data collected (from devices) is encrypted and sent to the blockchain in a T-data transaction, which then routes the data to a key-value repository, a distributed hashtable (DHT) located outside the blockchain, maintaining a

pointer to the distributed registry data. Both the provider and the user can now query the data using a T-data transaction with the pointer (key) associated with it. The blockchain then verifies that the digital signature belongs to the user or the service (for the service, its data access permissions are also checked). Finally, the user can change the permissions granted to a service at any time by issuing a T-access transaction with a new set of permissions, including the revocation of access to previously stored data. Table 2 summarizes the strengths and shortcomings of the different models presented here.

Table 2. Summary of the strengths and weaknesses of the solution proposed in Section 6.

	Strengths	Shortcomings
Distributed Hash Table (DHT) [65]	Combine blockchain and off-blockchain storage to construct a personal data management platform focused on privacy.	Suitable for storage and random queries, it is not very efficient for processing data (big data analytics).
	Users own and control their personal data.	
	The user may alter the set of permissions and revoke access to previously collected data.	
Blockchain, Smart Contracts for Automated Remote Patient Monitoring [62]	The measured data are safely embedded in the smart contracts entrusted to the blockchain.	Traceability of large amounts of measured data could increase latency and reduce performance if demand comes from real time applications.
	Privacy: no associations can be made between patients and their data.	Large scale key management mechanism with large numbers is required.
	Transparency: Patients are able to link remote monitoring actions directly to their medical records while maintaining privacy and control.	A minimum number of nodes is required to ensure the necessary level of validation signature.
	Exact replicas of the blockchain on all nodes allow high levels of fault tolerance.	-
Hybrid Blockchain and Internet-of-Things Network [64]	Fully decentralized architecture.	The system does not consider the standardization of smart contracts.
	Good efficiency: near real-time.	Efficiency in case of public blockchain network.
	Interoperability.	A minimum number of online nodes is required for verification of the blocks generation and new transactions.
	Immutability.	Vulnerability due to hacker attacks on smart contract.
	Transferability with little effort to other application domains.	-

7. Conclusions

Blockchain technology is receiving a lot of attention from individuals and organizations of all types and sizes. It has the ability to transform the industry with its important qualities of decentralization, anonymity and collective vigilance: this is why it is expected to create a revolution in the healthcare sector, where it can increase the quality of processes by lowering costs. There is consensus among the various researchers that, with the blockchain, patient data will be fully checked by their owner: the patient. Patients will have the right to decide who or what can access it. The goal is to help make sure that the different interests involved in complex organizations such as Healthcare Systems are subordinated to the patient's interest, avoiding what is increasingly happening: that the patient is the instrument of the interests of the different operators.

There are still certain challenges to be solved, for example the exchange of data across countries. Privacy laws are varied and legislative times are notoriously long, so standardization and regulation issues should be resolved as soon as possible.

Another potential problem is the blockchain's ability to process the huge amount of parallel access that is expected in contexts such as the medical one. As the volume of transactions increases, the various algorithms that guarantee the reliability of the network gradually slow down. Therefore, there is a need to research innovative mechanisms that develop almost perfectly together with the increase in data load.

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Conflicts of Interest: The authors declare no conflict of interest.

Appendix A

The screenshot displays a patient's medical record interface. On the left is a vertical navigation menu with the following items: Visite, Patient Summary esteso, Anamnesi, Vaccinazioni, Indagini diagnostiche, Diagnosi, Terapie farmacologiche, IoMT, Files, Taccuino Paziente, Calcolatrice Medica, and Utility. The main content area is divided into several sections:

- Personal Data:** Name: Janitor Jan; C.F.: XASWEG51T61AS522; Data di nascita: 23/01/87; Et : 33; Telefono: 389485698.
- Physical Data:** Altezza: ALTEZZA-VAL m (DATA INSERIMENTO ALTEZZA); Peso: PESO-VAL kg (DATA INSERIMENTO PESO); BMI: BMI-VAL; P.A.: PA-VAL (DATA-PA>); F.C.: FC-VAL bpm (DATA INSERIMENTO FC).
- Terapie farmacologiche in corso:** A table with columns Farmaco, Data inizio, and Data fine. It lists Tachipirina starting on 20/03/2020 and ending on 20/03/2020.
- Farmaci da non somministrare:** A table with columns Farmaco, Principio Attivo, and Motivo. It lists Aspirina with the active principle Aspirina and the reason Allergia grave.
- Anamnesi Patologica (prossima e remota):** A table with columns Patologia, Data Principio, Data Guarigione, and Stato.

(a)

Figure A1. Cont.

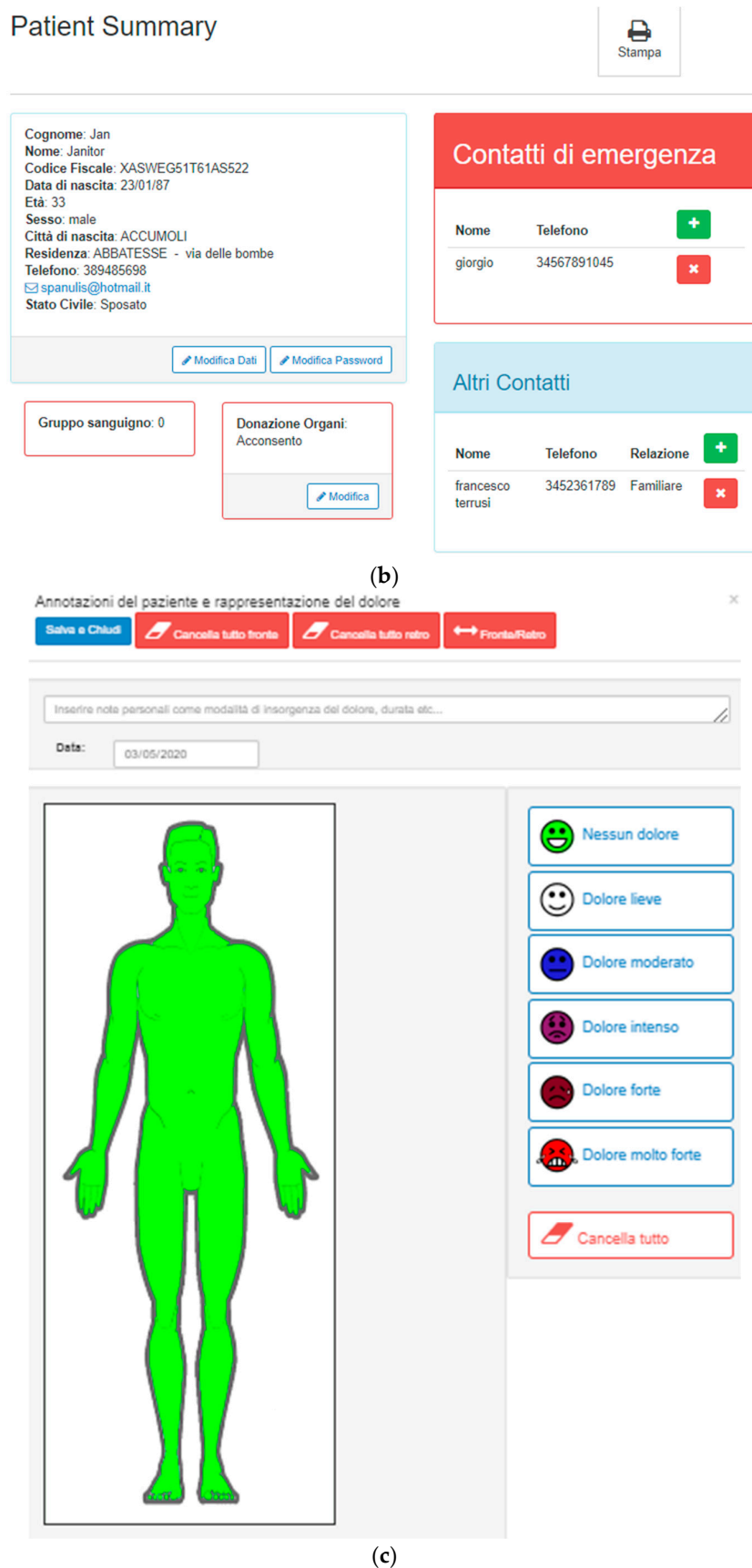


Figure A1. (a) Left menu and right bar. (b) Patient summary. (c) Patient’s notebook.

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