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Blockchain-Enabled Multisensor Clinical Laboratory Information System

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ABSTRACT— ***The purpose of this paper is to design an information system for clinics to implement multiple sensors for laboratory testing and telemedicine use. IoT is adopted in major hospitals but many smaller healthcare organizations have not benefited from the recent innovation due to lack of access to technology [1]. The paper presents the 'sensor lab' information system architecture for small clinics that includes sensors, a secure blockchain cloud to link the sensors and transmit data, and an electronic health record (EHR) analytics tool to evaluate patients' health conditions. Additionally, costs and benefits for smart clinics are shown to prove the business value of smart clinics. The goal of a smart clinic is to improve outpatient visit efficiency and patient data security, provide telemedicine care management, and reduce clinic expenses.***

Keywords— Blockchain, Sensor, IoT, Information System, EHR, Clinical

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1. INTRODUCTION

One of the biggest hindrances to utilizing novel biosensors in medicine has been that a single sensor is not useful in reaching a comprehensive diagnosis. The prices of biosensors are still considered high to be purchased in multitude by an individual patient [2]. Another obstacle of frequent data exchange in patient data collection and analytics is the heavy penalty of failing to secure private information. This challenge can be amended by using the secure blockchain-based system. The real-time multisensor system seeks to replace or subsidize the traditional practice of clinics that do not have internal

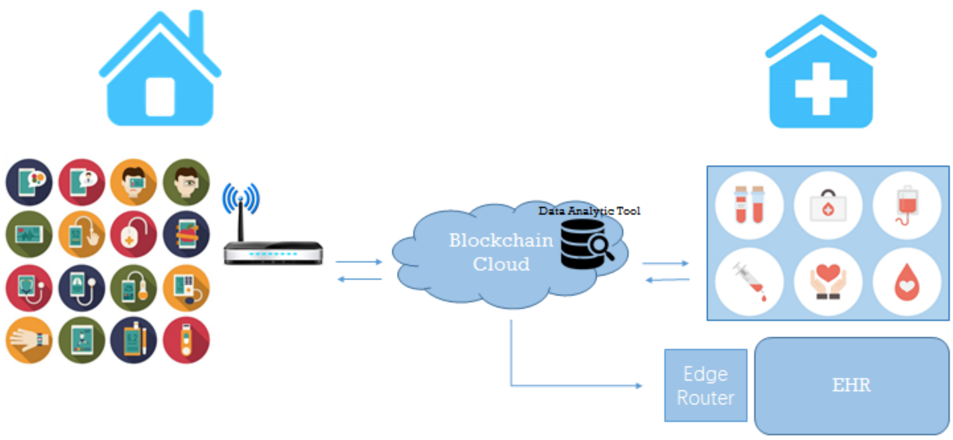

Figure 1: IS Architecture

laboratories and outsource medical tests which can take a few weeks for the results. This system can be expanded to screening that checks vital signs or telemedicine application for patients that demand prolonged monitoring.

2. PARAMETERS USED AND SENSORS

The typical accuracies of the conventional laboratories range from 94% to 95.4% [3]. The sensors found for our study are FDA approved sensors that ensure detection accuracy. The sensors used in IoT lab system have accuracies between 91% and 99% which is the equivalent of traditional laboratories.

The prices of traditional equipments range from $900 to $10,000 whereas the mini biosensors in our study cost mostly around $100 to a maximum of $2,000 [4].

3. IS ARCHITECTURE

Blockchain-based system architecture will serve as the backbone of the IoT Sensor Lab, enabling sensor communication as well as secure data retrieval and transfer while maintaining the privacy of sensitive data [5]. Traditional data security practices rely on robust encryption mechanisms for data-at-rest as well as data-in-flight, typically including a verification mechanism between actions; blockchains remove the need for a trusted third-party and enhance auditing capabilities for organizations to identify threats to the system.

One of the largest (and most costly) threats to hospital systems involve infiltration and deletion of security and auditing logs - blockchain's Digital Ledger Technology (DLT) addresses this weakness by requiring system agreement in order to modify any records. Additionally, the systematic record-keeping system enhances analysis and threat detection tools such as anomaly detection because established 'norms' in system behavior are more consistent. Therefore, they are more able to spot deviations [6].

3.1 Data Transfer to EHR

The IoT Sensor Lab will feature a private blockchain cloud which will integrate with existing EHR systems. Several EHRs offer their system as SaaS model with IoT capabilities which can be implemented by small clinics. Some of the advantages of blockchain for EHR includes: security of files and data, integration of secured accounts, and monitoring including accuracy of healthcare information with increased efficiency and security.

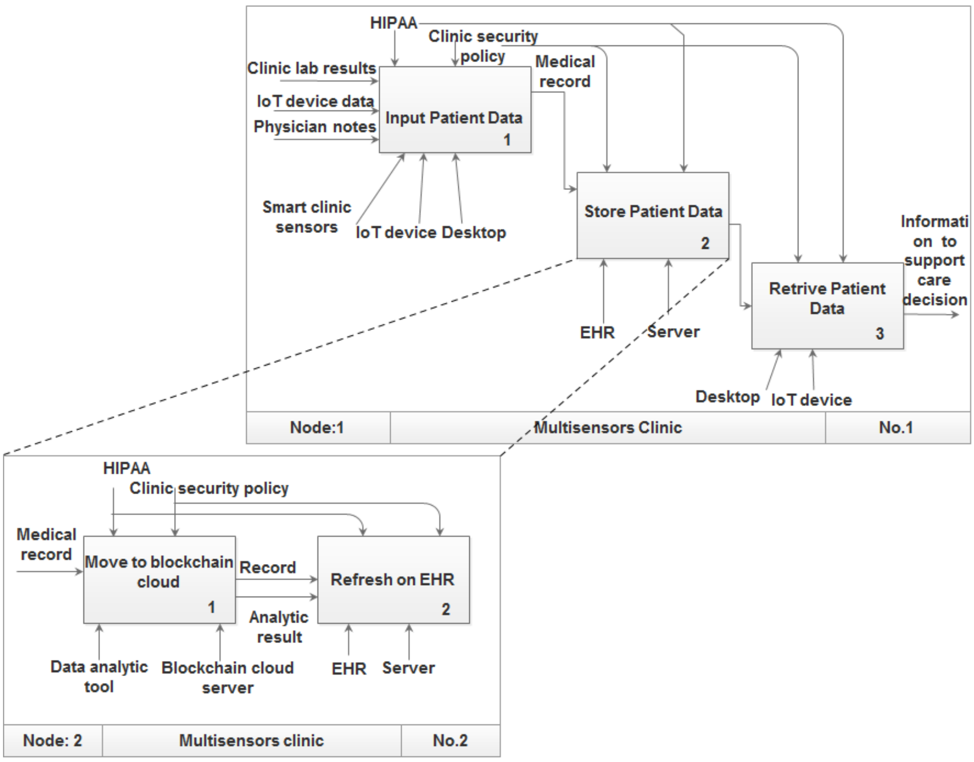

Figure 2. Process Flow IDEF

Medical records do not have to be placed on blockchain cloud, as information committed to blockchain is globally visible and may require extra storage. The blockchain cloud may still be temporarily used to store sensor data awaiting transfer, however its primary purpose will be to connect the IoT devices together and transmit that data back to the existing EHR system. The Enigma Protocol describes a privacy respecting programmable substrate that uses secret sharing and secure multiparty computation to achieve Turing complete computation over private data. The Enigma protocol uses an open blockchain to perform identity management, access control, and auditing. This identity management can be maintained via private keys or standard hospital check-in procedures.

Ethereum 'Smart Contracts' can be used to integrate the sensors within the Cloud and back to the EHR [7]. As existing medical records are stored on location, cryptographic instructions will be needed to read and write data within the existing system.

Three contracts are needed to integrate the Sensor Lab into the local system:

3.1.1 Registrar Contract

This provides identification string to a patient's EHR address identity which allows for the use of existing IDs.

3.1.2 Patient-provider Relationship Contract

This contract is issued between two nodes in the system when one node stores and manages identification records for the other. Additionally, this contract explains different data pointers and access permissions that identify the records held by care providers. Each pointer contains a query string, which is attached to a hash, which returns a subset of patients' data when executed on the provider's database - our individual sensors will each have their own 'pointer.' This guarantees that patients' data have not been altered from the source without permission.

3.1.3 Summary Contract

Summary contract functions as a trial for patients to locate their sensor data and summary analytics. A list of references to Patient-provider Relationship Contract and user notifications are provided [8].

3.2 Security and Cloud

Cryptographic hashing of the sensor data can prevent tampering of data since the data viewership permission is required. Information sharing between providers is authorized by patients. Cryptographic hashing ensures system security and data integrity via cryptographic proof- of-work while sensor communicates with local EHR; providing a distributed trustless consensus among nodes in the system.[9]

The private cloud does not store patient data, but acts as a medium between the IoT sensor lab and the central EHR system. The cloud not only communicates sensor data to the EHR, but also runs analytics and feeds those summary statistics directly to the patient. Data stream is saved temporarily but the analytical result can be stored long-term in the patient's existing record [10]. Patients will verify their identity on the Cloud via public-key encryption, which will enable their sessions when they enter the Sensor Lab and automatically terminate them when they leave the lab.

3.3 Patient Interface

Most small-sized medical biosensors are mobile-based and therefore each mount to a smartphone. Those that are PC-based can be all connected to one PC. Data feeds from all sensors in the Sensor Lab and will be directed to the local EHR, where it will be analyzed in conjunction with existing patient data. Machine-Learning based analytic methodologies will feed valuable health information back to the blockchain cloud, where patients will be able to access summary statistics from their mobile devices.

3.4 Data Analytics

The optimal combination of sensors for each patient will produce different datasets. Different sources of data in each leading principal condition are depicted in Appendix A. The results will prove useful since when only one parameter is out of range, the reasons are often benign or simply the sensor has budged, Dr. Kott notes. Notification of dangerous combinations of events to the physician will add value to random data [11]. However, analytics need to be conducted for correlated diseases as well as at disease-specific level; 96% of high- utilizing patients have three or more chronic conditions and 20% of U.S. adults have two or more chronic conditions [12]. EHRs can be used to identify and risk-stratify patients with multiple chronic conditions. EHR includes ICD-10 diagnosis codes, administrative data, chart, medication and clinical notes. Analytics is performed on limited dataset that excludes the following contents of protected health information: Names; Postal address information, other than town or city, State, and zip code; Telephone numbers; Fax numbers; Electronic mail addresses; Social security numbers; Medical record numbers; Health plan beneficiary numbers; Account numbers; Certificate/license numbers; Vehicle identifiers and serial numbers, including license plate numbers; Device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; Biometric identifiers, including finger and voice prints; and Full face photographic images and any comparable images. [13]

A platform is necessary for streaming data acquisition and ingestion that has the bandwidth to handle multiple waveforms at different fidelities. Enriching the data by analytics makes the system more robust, and balances the sensitivity and specificity of the predictive analytics. There are several options for platforms including those below.

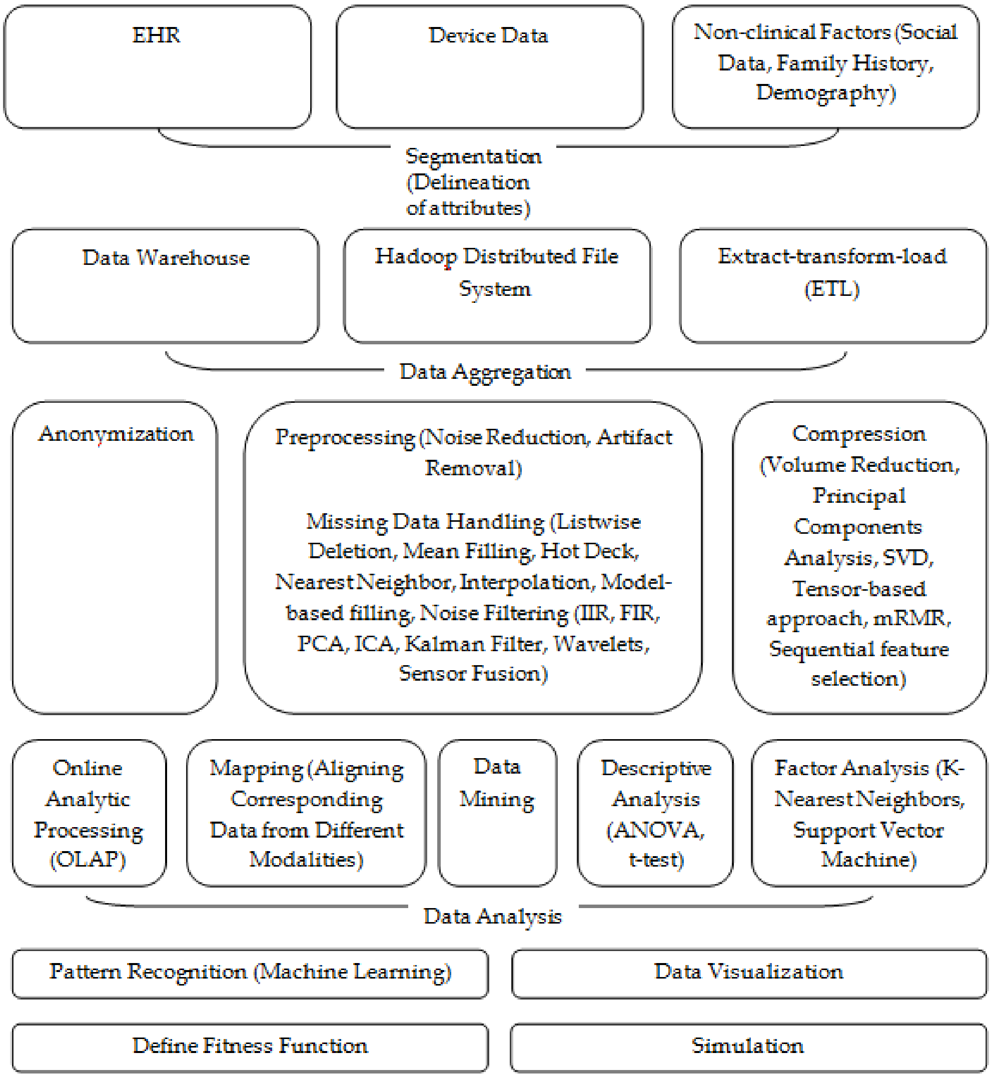

Figure 3. Analytical Workflow

Apache Spark can integrate with Hadoop stack and is applicable for analytics on continuous telemetry waveforms, because it allows ingesting and computing on streams of data and using machine learning and graphing tools. It requires one code base for both batch-mode and online analysis but needs large RAM. MongoDB is a free cross-platform document-oriented database and is independent of the traditional table-based relational database. [4]

Fault-tolerant exhaustive, fault-tolerant, and or consensus-based strategies can be implemented for data crowd-sourcing. Inconsistent data can be cleaned through outlier detection, data repairs or combination with other data integration operators. [16] Several tensor models are available for unsupervised phenotyping. Unsupervised methods have limits in that 1) integration of physician's existing knowledge still need to be manually leveraged, 2) phenotypes can overlap with each other, and 3) phenotypes can be large in size and dimensions and require good scalability. [14] Combining dynamic waveform data with static EHR data can be another challenge but will provide situational and contextual insight. As one patient's symptoms evolve over time, so may the dimensions of the data, and the semantic overlap will occur.

The approach will resemble crowd-sourced entity resolution in that various patient data will be contributed to certain diseases the conditions of which can be monitored more closely after diagnoses. A set or subset or record is sorted according to a priority metric and added to a priority queue. The queue can be iteratively ordered according to their pertinence to a disease, and a clustering algorithm determines the entity resolution solution. [15]

Once a pre-trained machine learning model is generated, diagnostic or predictive conclusions can be drawn, to be further interpreted by physicians and be conveyed to prescription. This will also enable interpretation of the parameters for primary care that originally belongs to specialties. For example, more precise diagnosis and reference in specialty areas is possible through understanding the analytical results of EKG, EMG, brain waves, etc. [16]

4. BUSINESS MODEL

4.1 Value-based Primary Care Practices

Primary care providers are the single largest purchasers of laboratory tests. About half of the 800 million visits to office-based physicians are to primary care practices: general and family practice (24%), internal medicine (15%), and pediatrics (13%) [17, 18].

Clinics providing value-based care can benefit from the improvement in diagnostic precision from expansive and fast sensor data analytics that even span some specialty areas. Since the use of a Sensor Lab will incur close to no marginal cost, the cost-saving factor in value-based payment modifier will be notable. Medicare's value-based payment modifier is imposed on physicians in groups of 10 or more as of 2016, and it will be for physicians in groups of 2 or more starting in the year 2017 [19]. The incentives or penalties can be ±4% of reimbursement for provider groups of 10 or more eligible professionals (EPs) and ±2% for smaller provider groups. Medicare beneficiaries' and physician's office visits account for about half of the total visits. The sensor lab can replace existing testing equipment in clinics such as EKG, glucose meter, rapid strep, INR, and urinalysis. The total expenses of a typical clinic with the traditional sensors are much higher than those without. This applies to a total of 30,122 primary care clinics as of 2013 [18] and 9,300 urgent care centers in the U.S. that IoT sensor lab systems can serve. [19, 20]

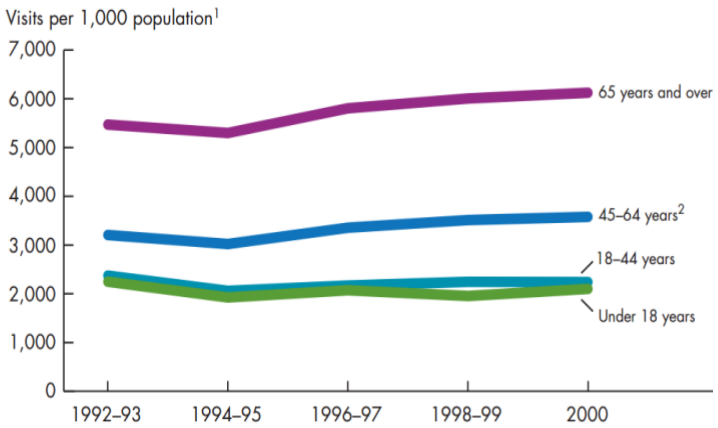

Figure 2. Physician office visits by age: United States, 1992–2000 [18]

Cumbersome conventional method of checking yeast infection or vaginitis under the microscope in the clinic can be substituted with sensors that take mere seconds. Delayed diagnosis can increase medical costs by thousands of dollars per patient and increase chances for malpractice claims [21]. Insurers have an incentive to reimburse such system as payers of medical costs.

4.2 Critical Access Hospitals (CAH) and Field Hospitals

The system has a potential to be applied in remote regions with inadequately equipped hospitals and 1,332 CAHs as of 2016; CAHs are those with less laboratories. There were 1,912 rural hospitals with 26 beds that are at least 35 miles away from another hospital [22]. The IoT Sensor Lab can also serve military battalion aid stations, field hospitals, and combat support hospitals in the wilderness or on foreign lands. A limited employment of the Sensor Lab system is possible in civilian medical emergency cases as well.

4.3 Partnership

Although real-time data streaming is simple, cooperation with sensor companies may be necessary in cases where further insight into patients' historical records is required. In such case, a general partnership may be sought to transfer the patient data from the sensor's cloud to private data store. A general partnership will be preferred over a joint venture because this arrangement will allow for proportional sharing of business profits, no need for income taxes utilizing personal income tax returns, and have more valuable feasible advantages [23].

However, in case of EHR integration, commercialization of such venture has limits since the use of limited dataset is confined by covered entities for the purposes of research, public health, or health care operations. [13]

5 CONCLUSION

IoT multisensor clinical information system will provide a more efficient and comprehensive diagnosis. The information system enables real-time monitoring of a patient's health condition by using biosensors and data analytics tools. Each patient will have an optimal combination of sensors for his condition. Machine-learning-based analytics is necessary to interpret the parameters. The Sensor Lab can reduce patients' waiting time, and recovery time in clinics due to the fact the lab results are immediate.

Patient's information will be securely transmitted by the blockchain cloud and saved in the clinic's EHR system using three contracts: registrar contract, patient-provider relationship contract, and summary contract. Patients will verify their identity on the cloud via public-key encryption.

By implementing the IoT multisensor clinical information system, the primary care clinics providing value-based care can receive at minimum incentives on their care. The Sensor Lab can reduce costs by replacing the testing equipments and lessen the chance of malpractice claims from delayed diagnoses. The comprehensive flow of data from the Sensor Lab can also provide the basis for better population health surveillance by public health authorities or planners.

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Appendix A: Leading principal reasons for outpatient visits and relevant devices [24]

%	Reason for Visit	Cause	Necessary Tests/ Parameters	Company 1	Criteria 1	Company 2	Criteria 2
6.2	General medical exam		CBC, Chemistry panel, EMP, BMP, CMP, Urinalysis, Pap smear, Cholesterol, Glucose, A1C, Stool	A Time to result: <10 mins	ALP, Glucose, LDL/HDL, Cholesterol, Triglycerides, ALT, Lithium, (Hepatitis C), BNP, Hemoglobin, Lymphocytes, Monocytes HbA1c, , Creatinine, Stool	B MARD 11.8%	Glucose
2.1	Cough	Flu, Pertussis, Pneumonia, Asthma, Acid reflux, Allergy, Tuberculosis		A	Allergy testing, Granulocytes, Lymphocytes, Monocytes	C Accuracy: +/- 0.2°C	Heart/lung sounds
1.9	Diabetes mellitus		Glucose, A1c, Urinalysis(Ketone, Microalbumin) , Cholesterol	B	Glucose	A	HbA1c, Total Cholesterol, HDL/LDL Cholesterol, Triglycerides
1.7	Symptoms referable to throat	Strep, Acid reflux, Allergy, Mononucleosis		D	Airway inflammation Accuracy: +/- 5 ppb	A	Allergy testing
1.5	Well-baby Exam		Bilirubin, Iron, CBC	A	Lead, Hemoglobin, Lymphocytes, Monocytes		
1.2	Stomach and abdominal pain, cramps and spasms			E Accuracy: 91.3%	Culture	A	Liver function test, Stool, Celiac disease, Colon cancer
1.2	Gynecological Exam (Not including male exams)			A	UTI, Yeast infections, Syphilis, HSV, HIV-1/-2	E	Culture

1.1	Skin rash			A	Allergy testing		
1.1	Hypertension			A	Total Cholesterol, HDL/LDL Cholesterol, Triglycerides	F	Blood pressure

Others

Reason for Visit	Cause	Company 1	Criteria 1	Company 2	Criteria 2
Vital signs		F	Blood pressure, Oxygen level	G Accuracy: 92%	Blood pressure, Heart rate
Heart disease	Heart failure, Atrial fibrillation	H Accuracy: 94.4%	EKG	A	Homocysteine
Psychiatry		I	Alzheimer's, Autism, Cancer, Epilepsy, Depression, Schizophrenia	J	Depression, Traumatic brain injury, Concussion, Cognitive impairment, Parkinson’s Disease
Neurology	Weakness, Loss of sensation	K	EMG		
Rheumatology	Systemic inflammation	A	CRP		
Medication	Coumadin use	A	INR		
	Asthma	D			

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