Cloud Technologies in Focus of Redesignig Medical Devices for Patients' Convenience and Data Safety

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Abstract—**Cloud technologies have an immense potential in medicine, because they enable patients to (pro)actively take part in their healthcare management and partner up with their doctors. This partnership can be seen in the usage of various medical apps for monitoring vital signs, tracking diet and exercises, as well as on a more serious note - using medical devices with or without instructions of their doctors. Although this brings benefits, it also has a downside. Not all apps are reliable, not all medical devices are as safe as supposed. In emergency, medical data can be easily obtained by entering visible PIN code. How safe are medical data if someone decides to misuse them? To answer our doubts, we have researched relevant websites and scientific papers and proposed changes in one medical device and completely redesigned the procedure of accessing someone's medical records to ensure their safety.**

Keywords-cloud computing; medical apps; medical devices; data safety

I. INTRODUCTION

Cloud computing refers to on-demand, self-service Internet infrastructure [1, 2], which allows cloud services to become accessible to anyone, anytime, anywhere [1]. Cloud carries a lot of potential, because it is complementary with e.g. mobile computing, wireless networks, sensor technologies, thus enabling creation and delivery of newer type of cloud services as well as important benefits such as fast deployment, lower costs, scalability, rapid provisioning, instant elasticity, greater resiliency, rapid reconstitution of services, low-cost disaster recovery and data storage solutions [1]. Hospitals can choose among different types of cloud service models and deployment models.

A. Types of Cloud Service Models

There are three types of cloud service models: software as a service (SaaS), platform as a service (PaaS) and infrastructure as a service (IaaS).

In a SaaS model applications are located in the cloud and available to customers through the Internet. In PaaS, development tools are in the cloud and are accessed through a browser for building Web apps, without having to install them onto a computer, and then deployed. In an IaaS type, the cloud user outsources the equipment which supports operations, including storage, hardware, servers, and networking components, while the provider owns the equipment and is responsible for housing, running, and maintaining it [2, 3].

This means that users, depending on the model chosen, do not have to invest in software, hardware and IT staff and their upgrades and innovations, which frees up financial resources available for focusing on their primary business. Since these services are based on the "pay per use" pricing model [1], this means that users will pay just the amount of service currently using, giving them a chance to manage their costs according to their needs.

B. Types of Cloud Deployment Models

Customers (medical facilities) can also choose among four deployment models: public, dedicated, private or hybrid. Public cloud deployment is marked as multitenant, because the services provided are run on data centre resources belonging to a cloud service provider and resources are shared amongst many different cloud service customers.

Dedicated cloud deployment is single-tenant, because the services provided are run on data centre resources belonging to a cloud service provider and resources are used by one cloud service customer and are not shared with any other customer.

Private cloud deployment means that the cloud service is run on data centre resources belonging to the cloud service customer, typically on-premises and run and controlled by the customer. Dedicated cloud deployment is often regarded as a form of private cloud deployment due to the isolation provided to the customer's applications and data.

Hybrid cloud deployment represents the use of multiple deployment models together, often in combination with non-cloud resources of the cloud service customer [3].

Each medical facility should make decision about the most suitable model for its business based on: security, data classification, business model, target operating model, application architecture, cost and performance [3].

C. Research plan

General Research Plan has 5 sections. The first presented potentials of cloud computing, their types of service and deployment models. The second explains the difference between software as a medical device and software as a part of medical device and presents Kardia Mobile, Sense4Baby and Tap2Tag key chain. The third points out problems regarding patient and data safety when using these devices. The fourth suggests how to

improve Sense4Baby and completely redesign the emergency key chain. Conclusion is given in the fifth section. The research was based on relevant articles and websites of FDA, IMDRF and manufacturers' documentation available on the Internet.

II. SOFTWARE AS A (PART OF) MEDICAL DEVICE

It is important to distinguish the two categories of medical devices according to the International Medical Device Regulators Forum: software as a medical device (SaMD) and software in a medical device (sometimes referred to as "embedded" or "part of") [4].

SaMD is software which can perform specific medical task on its own, without any specialized machines [4], e.g. an app for diagnostics Johns Hopkins, or ePocrates for medications.

Software in a medical device needs a specialized machine to perform a specific medical task [4], e.g. software for ultrasound needs specialized computer and different types of probes for an examination.

A. Patients can perform EKG in 30 seconds

One of the exams which a patient can perform on her/his own is EKG in 30 seconds. Heart diseases and stroke are hidden killers of world population [18]. E.g. stroke is the fourth cause of death [5] and the leading cause of survivors' disability in the USA, but up to 80% of stroke cases could be prevented [6]. It is estimated that the number of strokes will increase for 34% till 2035 in Europe [7]. In Serbia, stroke is the leading cause of death [8, 9]. EKG could help in anticipating these diseases. Kardia Mobile is a small device slightly bigger than a thumb drive. Its measurements are 8.2 x 3.2 cm and it is powered by a CR2016 coin cell battery, which can last for 200 hours. When connected with a smartphone app (for iOS and Android operating systems), it gives EKG readings anytime, anywhere. It has two electrodes on the surface; user puts two fingers on each electrode (Figure 1) and runs a scan which lasts for 30 seconds. Therefore, a patient can find out right away whether her/his heart rhythm is normal or not [10, 11]. When this data is sent to a Cloud, a doctor can download the data and, decide the best course of action.

Figure 1. Using Kardia Mobile
Source: http://www.coolthings.com/kardia-mobile-home-ekg/

B. Patients perform prenatal monitoring

AirStrip OB (Sense4Baby) is a new way of providing prenatal monitoring. The system is designed to collect various patient data such as fetal heartbeat with a Doppler based ultrasound, uterine contractions with a tocodynamometer as well as maternal heart rate. The kit is also equipped with straps, gel and a cell phone/tablet where the data is displayed. The Sense4Baby system can be applied wherever the mother to be is. The patient performs the examination and the collected data is then wirelessly uploaded to a HIPAA compliant cloud based web server from where it can be downloaded where and whenever convenient for a clinician. Therefore, the patient and the clinician do not have to be at the same time in the same place for important medical assessment [12].

Obstetrician-gynaecologists can use their IPhone for monitoring their patients' deliveries with the help of this system (Figure 2), which sends real time data (mother's and baby's heart rate, contractions and oxygen levels) from sensors wrapped around a patient's belly. Before this device, doctors had to interpret the explanations of maternity ward nurses regarding lines of heartbeat. If their description was unclear/ unsatisfactory, doctors would have to return to hospital and see and assess important measurements [13]. Now, this type of monitoring and necessary assessments can be done via smartphone in real time and adequate courses of action can be taken.

Figure 2. Sense4Baby Prenatal Monitoring System
Source: http://www.made4baby.com.au/the-future-of-high-risk-pregnancy-management-is-here/

A research conducted by Harkey et al in 2014 [14] in a prenatal clinic in the USA, compared the two mobile fetal monitoring devices, Phillips and Sense4Baby, in 20 clinical cases, which were examined by 3 doctors. The results have shown that there are no differences between performances of these two devices. Sense4Baby was seen as reliable in monitoring of fetal heartbeat line, its speeding up and slowing down, as well as monitoring contraction patterns. The device has also provided enough information for all 3 obstetrician-gynaecologist to set important diagnosis in all 20 cases.

C. Key chain as a decision making factor in providing critical care

The importance of (red) key chain for a patient's health even life is tremendous. This device is based on Near Field Communication (NFC). If a reaction of an emergency team is necessary, the key chain tells them to send a unique PIN code on 51020 to get that person's medical information (e.g. that person could have a particular form of epilepsy and does not respond well to the most common seizure drugs and certain medications make that person manic) [13]. In this way, patients can tell doctors important medical information, without a

single word, and make an important difference in doctor's decision making.

III. PROBLEMS WITH MEDICAL APPS AND DEVICES

Although the idea of being a patient-doctor seems innovative and is in focus were people, in general, are actively participating in managing their own care, there are certain risks these people face.

Firstly, there are a lot of medical apps (SaMD) for monitoring vital signs, tracking diet, exercises, drug identification and diagnostics available free of charge or with a symbolic year fee paid for its use, but reliability of some of them is questionable. Some medical apps used for diagnostics are not very reliable, so people should always consult with their doctors. E.g. SG and ePocrates always gave good treatment recommendation, while Johns Hopkins Antibiotic Guide (JHABx) was correct in 99% of cases, 5MCC in 97%, 5MID in 95%, but PMID was correct in only 52%, which is not satisfactory [15]. The same rule applies for medication apps (do not take medications without consulting doctors).

Secondly, when it comes to medical devices, manufacturers have made some of them quite user friendly, that is, patients can use them as well, with or without their doctor's instructions. If used on your own initiative, always check if they are approved for use by a referent medical body (e.g. FDA in the USA) or consult your doctor. A doctor can also give a device to the user/patient and instruct her/him how to use it. This brings benefits for both sides. Instead of going to a hospital for an examination, the patient can simply perform the examination and send the data to the HIPAA/GDPR compliant cloud and a doctor can check the data and take adequate course of action. If the results are normal, doctor would lose time on patients who do not need attention. But now her/his resources can be concentrated to those who are critical. There is a downside to this, because some medical devices can have defects of different class (I, II or III according to FDA) that were not noticed during trials and were approved by regulatory bodies for usage by doctors as well as patients. The problem related to Sense4Baby was exposure of electrical parts due to belt clip detachment (FDA class II) [16], which was noticed after the approval for patient use by the FDA. Besides that, there is a lack of fetal ultrasound imaging and providing videos in monitoring high risk pregnancies.

In an emergency, medical data can be easily obtained by entering visible PIN code from the back of a key chain. How safe are medical data or even a patient, if someone decides to misuse them? The problem regarding Tap2Tag key chain is safety of the patient data, because anyone can see and enter the PIN on the web site to receive medical data which is located on the company's server and which will be displayed on the web site.

IV. IMPROVING THE DEVICES

A. Empowering the Sense4Baby with ultrasound imaging and additional safety feature

Sense4Baby lacks certain safety measures. Firstly, the device has a problem with exposure of electrical parts due to belt clip detachment (FDA class II) [16], so the electrical wires should be better isolated. Secondly, the manufacturer should consider developing and installing software as a mechanism which would check if all cables are in place and whether it is safe for patient use.

This device is developed for monitoring high risk pregnancies and avoiding patients going to the doctor's for routine testing. The monitoring device should be able to provide ultrasound images, but it doesn't, so if an ultrasound image is necessary, patients would have to go to the doctor's. This problem can be overcome.

Today, smartphones are being used as ultrasound devices [17]. This has an important influence in rural areas and developing countries, because patients are far from hospitals and quality ultrasound equipment, which can cost up to few tens of thousands of dollars. This unit is given to patients to do the required tests at home when agreed and send data to the cloud, from which their doctor can download the data, examine it, make a decision and notify the patient.

The change the authors are suggesting is to modify the existing Doppler based ultrasound which monitors fetal heartbeat to an ultrasound device which will, apart from the fetal heartbeat, send real time images and video clip of the baby to the cloud. The modified device will be slightly bigger, because of the new feature, which should give quality 2D images and measurements. In the future, this device will be further developed by empowering it with 3D imaging.

B. Authentication via code for providing medical data safety of the key chain

The new approach is that sensitive patient information is in the cloud of the hospital, that is, the information is not in database of the manufacturer and cannot be seen on the website of the manufacturer after entering a PIN, from the back of a key chain, on the website, like in the case of Tap2Tag Company's key chain.

The newly designed key chain (Figure 3) has a Wi-Fi modem, which can be turned on and off. Inside of the device is a flash drive with software which has stored username and password of the specific user for the cloud and it can receive and send this data and a code wirelessly as well as check if the app accessing the data is genuine through communication with the company.
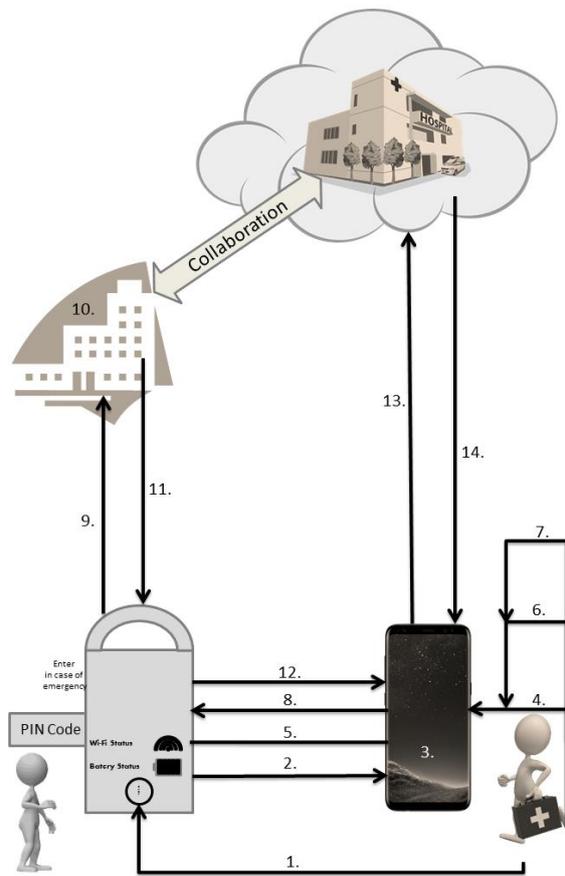
Figure 3. Receiving a patient's medical chart with redesigned emergency key chain

When connected, healthcare professional launches the app (Fig3: 6) he/she has received from the hospital on the smartphone, enters his/her access code (Fig 3: 7) and sends the request – the app is programmed to send code and its serial number – (Fig3: 8). The software in the key chain receives the code and the app's serial number and sends them to the company (Fig3: 9), whose software checks the validity of the received data (Fig3: 10). If the code and the serial number are correct, it sends a confirmation message to the key chain (Fig3: 11) which then sends the username and the password of that patient's cloud account to the healthcare professional's smartphone (Fig3: 12), but showing these data as stars (*). The healthcare professional then sends request to the cloud (Fig3: 13) and receives medical chart of that patient (Fig3: 14) which represents a source of decision making.

The medical chart allows the doctor on sight to sees if the patient is allergic to penicillin, what types of drugs make the patient's condition worse, or if a patient has a peacemaker, joint replacement. E.g. if a patient was having a stroke and a doctor sees the existence of peacemaker, this means that this patient will not undergo MRI scan. Or in the case of the girl from Section II C, she will not be given medications that worsen her condition or make her manic.
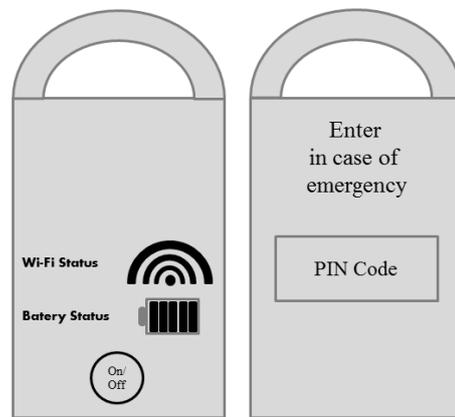

Figure 4. Key Chain with Wi-Fi modem, battery and flash drive (front) and PIN for connecting with other devices (back)

Medical data of a patient are not stored on the key chain for safety reasons. The partnership among hospitals and the company is necessary for this to work, because the sensitive data (username and password for cloud account of a patient) is received from a hospital, then stored during fabrication onto flash drive and after that sealed so that it can no longer be accessed by anyone.

The only way to access the data stored on the device is to have a specialized app installed on a smartphone. The app will not be available online for free download. In fact, the only way to download the app is through the mother hospital of a doctor. That is, each doctor will receive execution file from the hospital' IT sector. Each app has its unique serial number which is correlated with a two part compound primary key consisting of healthcare professional's full name and number of her/his medical licence and an access code. These data (app's serial number, healthcare professional's full name and number of her/his medical licence and access code) would be located on the company's server.

This will function in the following way: In case of an emergency, healthcare professional will locate the key chain and turn on the Wi-Fi (Fig3: 1). The key chains sends the signal (Fig3: 2) Her/his smartphone will register the device in the Wi-Fi Settings (Fig3: 3) and a PIN code, visible on the back of the key chain surface, should be entered (Fig3: 4) to connect the two devices (Fig3: 5).

By having medical chart of a patient on sight, doctors can make life saving decisions, improve care and with the authentication step, patient data is safe.

V. CONCLUSION

Patients are much more informed about diseases thanks to the Internet and availability of medical textbooks. Medical devices manufacturers have taken a step forward in designing devices and apps which enable patients to monitor their diet, exercises, vital signs, perform the EKG in 30 seconds, identify and learn about medications they are taking, perform prenatal monitoring.

All these possibilities decrease the number of visits to the doctor's, because routine tests are done by the patients who get the devices from their hospitals. After performing a test, a patient sends the results in the HIPAA/GDPR compliant cloud from where their doctor can download them, interpret and take proper course of action.

However, these procedures raise question regarding the safety of the patients during testing, as well as the safety of data sent to the cloud.

In this paper we have discussed how to improve safety of the Sense4Baby and suggested adding the feature of ultrasound imaging of the fetus/baby, so that an obstetrician-gynaecologist can examine the images and video clip to see if additional examination with traditional ultrasound is needed. We have also redesigned the emergency key chain. Previously, anyone could go to the website, enter the PIN and get certain medical information about certain person. This could be a major safety issue. Our key chain is equipped with security code before accessing the delicate patient information in order to ensure data safety.

Cloud computing will continue to play an important role in modern, patient-oriented medicine, with focus on data safety. The development of sophisticated medical devices, tailored for both patients and healthcare professionals connected via cloud puts the patient in the centre of decision making regarding their health, preventive diagnostics and treatment.

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