IS 436 - Structured System Analysis & Design

Deliverable 2 - Requirements Definition Document and Use Cases

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**Requirements Definition Document**

**Functional Requirements:**

Process-Oriented

* The system should allow doctors to view a patient’s medical records
* The system must collect recent health data and store it in a database
* The system must be able to track user response time

Information-Oriented

* The System must retain a patient’s full medical history
* The system must include real-time health updates
* The system must include history of authenticated users

*Kafka* is an application that is used for building real-time data pipelines and streaming apps. Since it is horizontally scalable, fault-tolerant, fast, and runs in production in thousands of companies, it can provide us with a constant update to a patient’s current status at all times. Building real-time streaming data pipelines that reliably get data between systems or applications but also it has, Building real-time streaming applications that transform or react to the streams of data.

**Non-Functional Requirements:**

Operational

* The system will run on Android and iOS devices
* The system should be able to easily integrate with existing databases
* The system must be compatible and optimized to work with multiple EMR devices

Like all mobile applications, They client application must run through the code and protocols in the mobile running applications, most notably Android and iOS devices. Since object-oriented code merge very well with each other. The coding of the applications for the Doctor’s end of the software should easily be compatible with the mobile transfer. Requirements include the usage of programming ethics and syntax that connects and work reliably and efficiently with both ends from mobile to Doctor’s Database.

Performance

* Patient information should be available to view 24/7
* The system needs to be able to support millions of user data. Doctors should be able to view patient data in seconds
* Response and refresh times should be shorter when processing queries

Database management is a crucial requirement for the stability of this project. Although the data itself will be reliable and thorough due to the application client-server architecture. It, however, will require Database administrators to update, edit, and maintain the usage of data and ensure the reliable data is being sent and structured. It is required to have DBA and Database Engineers working (in labor) to maintain this. Also, constant surveys and reviews between Doctors and Patients will be conducted to see where and when the system fails or fails to meet customer requirements. Since initial versions will be made, it is required that the system is maintained through a team.

Security

* Only authorized users should be able to access patient data
* Ensuring data encryption for database tables
* Make sure that inactivity timeouts and login requirements are met

In order for this system to work, it follows a step-by-step process from the initiation of information requests from an always running program. This request is then acknowledged by a verified client (in this case the doctor’s end application). Upon verification, a secure connection is then established and data is sent to the doctor’s database. Therefore there is a constant application that is being run by the user, that has no access to extend information elsewhere until the authorized client asks to receive information. Also known as “handshaking” in-network requirements. The application can only deliver data once, the secure network is established.

Cultural and Political

* Patient information should be compliant with the Data Protection Act
* The system needs to be accessible worldwide
* The HITECH Act

According to The HITECH Act established ONC, the law and provides the U.S. Department of Health and Human Services has the authority to establish programs to improve healthcare quality, safety, and efficiency through the promotion of health IT. This also includes electronic health records (EHRs) and private and secure electronic health information exchange.

**Interview**

Interviewee: JHH Employee

Position: Applications Coordinator for Epic Systems

Date: 10/14/19

Interviewer: Rithika Sayini

Questions / Answers

1. Let us say that a person using our EMR device has a career that requires them to be constantly on the move. Every time their heart rate spikes the natural response for the device would be to alert them of their change in homeostasis. This would become redundant after a while. How can we implement the heart rate function to learn from the User’s patterns?

Use artificial intelligence and advanced neural network to analyze the changes in the body. The EMR device would have to learn from the user’s patterns by building a trend report of some type. Take the application Flo for example. This application tracks female cycle changes by building a trend report. Based on this, it can accurately predict the next day of ovulation and begins counting down from that day.

1. Would it be a good idea to implement a function that tests response time for a user that just underwent a major accident, such as a concussion? For example, if the user’s vital levels drastically change due to a concussion, the EMR device displays a screen stating “Are you responsive; Yes or No.” If the user does not respond within 10 seconds the device notifies 911 and their PCP.

It would be effective to implement a function like that. However, from experience, a response within 10 second is effective only if the user knows that they have to acknowledge the device. Therefore, consider implementing an alarm system during situations like these so that the user cannot ignore the alert.

1. How do you feel about tracking oxytocin levels with pregnant women, so when the woman is about to give birth, the EMR device is aware of the sudden spike in hormone levels? Would you say this is an efficient method for detecting hormone changes or is there a method that is easier to measure?

The two main reasons for oxytocin release would be due to childbirth and lactation. Of course the device would need to be able to distinguish these different processes. Tracking would be an effective method for determining large spikes to differentiate between the two. Implementing loops into the code for your device would alert the user that they will have contractions if their hormone levels have spiked. This logic can be used to various other parts of the endocrine system.

1. That leads me to my next question about which alert system you would find to be the most reliable for emergency services and for medical centers. What about when cell phone services are down like in a natural disaster?

Implement some type of technology that works the same as LifeAlert emergency response device. A way to communicate through radio or even using the bluetooth all around us for peer to peer communication.

1. What do you believe would be the best way to encrypt user medical records on this device so that only the user and their PCP will have access to it?

To properly encrypt PHI, identify where the PHI enters your device to determine where to start encrypting. I suggest researching how hospitals encrypt their patient information and what companies they’ve hired to do so.

Summary:

It was a fairly simple process for contacting someone who works at Johns Hopkins Hospital as an applications coordinator for Epic Systems. We chose to interview a JHH employee because they can provide thorough knowledge about how they store, encrypt, and access their user medical information. The interview itself went very smoothly, and it provided us with the knowledge we need to create our device.

Interviewee: Senior Physician

Date: 10/15/19

Interviewer: Adam Afilaka

Questions / Answers

1. Let us say that a person using our EMR device has a career that requires them to be constantly on the move. Every time their heart rate spikes the natural response for the device would be to alert them of their change in homeostasis. This would become redundant after a while. How can we implement the heart rate function to learn from the User’s patterns?

If possible I would like to be aware of the patient’s schedule. So if its a redundant process it should be included in the schedule but even if it is on schedule a spike should be followed by a notification from the device just to make sure or a check from the device to make sure the patient is ok. If unresponsive, call emergency services.

1. Would it be a good idea to implement a function that tests response time for a user that just underwent a major accident, such as a concussion? For example, if the user’s vital levels drastically change due to a concussion, the EMR device displays a screen stating “Are you responsive; Yes or No.” If the user does not respond within 10 seconds the device notifies 911 and their PCP.

That’s exactly what I would recommend, could not say it better myself.

1. How do you feel about tracking oxytocin levels with pregnant women, so when the woman is about to give birth, the EMR device is aware of the sudden spike in hormone levels? Would you say this is an efficient method for detecting hormone changes or is there a method that is easier to measure?

The oxytocin level is evasive since it goes up and down a lot and could lead to a lot of false positives. The most reliable thing to measure is contractions since 1 in every 5 minutes is the tell tell sign to go the hospital if a belt around the belly for pregnant women only than I would recommend that instead.

1. That leads me to my next question about which alert system you would find to be the most reliable for emergency services and for medical centers. What about when cell phone services are down like in a natural disaster.

Tricky, so for emergency services like police, firefighters, and EMTs they have a radio band systems in order to communicate when cell phone services are down. I believe channel 9 is reserved for emergencies. So if your device is able to use that channel that would be useful in a natural disaster.

1. What do you believe would be the best way to encrypt user medical records on this device so that only the user and their PCP will have access to it?

I’m not well versed on the topic of encryption but I would recommend passwords be kept very confidential since real time data is very valuable, corporations like Google and Amazon would benefit from that sort of patient data.

Summary:

Interviewing the physician gave the team ideas about having back up plans since the daily life of the individual will require 2 step verification since these are human beings lives. We were on the right track with concussion responses . The pregnancy scencerio if possible would be better with a belt application that would allow the device to track contractions. During an emergency where cell phone towers are down, a method of communicating an emergency would be using citizen bands that allow for radio communications. Also our data is quite important that could is definitely sought after.

**Correspondence with Siemens and GE Healthcare**: Initiated but not answered.

“Good morning. I am emailing regarding prospective technology I am currently working on with a team at UMBC. Being a leading technology and engineering school, we have a well-rounded group collaborating to present an application for wearable medical devices that will integrate a patient's current EMR that is consistent amongst all health care provider networks, is reliable, and can provide pertinent medical data in making critical and time-sensitive medical decisions. Perhaps a wrist device, some other key fob, chip or a medical/insurance card can use the application. It, also, provides a reliable source of medical information that is consistently up-to-date, providing stakeholders, the patient and treaters, with needed medical data to make informative decisions in emergency situations. Suppose an individual is brought to the ER, unconscious. Medical staff springs into action to start treating the patient. However, nothing is known about this patient's medical history, to include: allergies, pre-existing conditions, health issues/concerns, medications, etc. With this device, which is only accessible to restricted applications by approved healthcare providers. We have considered and are working the development of this product in consideration of HIPAA and HITECH and will continue the development with security measure being a top issue. Our team has researched some potential sponsors and we found that this technology would benefit your company and would be a great investment. We are hoping you could provide us some feedback as to the feasibility of this product for your company and if there are any other concerns or issues your company has, which would help us to better develop the product. As mentioned, this is all in connection with a semester project at the University of Maryland Baltimore County, UMBC. Respectfully, Ashley Braun”

**Use case analysis**

UC-1

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| **Use Case Field** | Description |
| **Use Case Name:** | Record Patient’s Current Vital Sign |
| **Use Case ID:** | UC-1 |
| **Created By:** | Xin Zheng |
| **Created Date:** | Oct 13, 2019 |
| **Last Update By:** | Xin Zheng |
| **Last Update Date:** | Oct 16, 2019 |
| **Actor:** | Patient |
| **Trigger:** | External: The patient allows the device to collect the data of their vital signs. |
| **Description:** | The patient’s vital signs are constantly being collected by this device, and when anything abnormal happens, it will alter the patient’s data. For example, when there is an abnormal heartbeat is record, it will send warning to patient for potential heart attack . |
| **Precondition:** | 1. Patient has to wear the device. 2. Patient gives the device and database permission to collect and store vital data. 3. The database is up-to-data and on-line. 4. Patient’s medical history is stored in the database. |
| **Post Condition:** | 1. Patient’s vital sign data is stored. 2. The sent warning is also recorded. 3. The collected data will be sent to the doctor to help treat the patient. |
| **Priority:** | High |
| **Frequency of Usage:** | Daily |
| **Normal Course of Event:** | 1.0 Recording patient’s vital sign   1. The patient’s medical history is uploaded to the system. 2. The patient’s vital signs will be recorded in to a pattern.   2.0 Predict the potential adverse event   1. The device will compare collected data to previous pattern of patient’s vital signs.    1. If the abnormality is recorded, it will send out the alert to the patient.    2. The alert specifies the potential illness by referencing the patient’s medical history.   2. The alert will be stored in the alert history.   1. The patient’s doctor will also receive the notification of abnormality. |
| **Alternative Course:** | 1. The doctor’s office will perform manual data entry of vital signs after the patient’s visit. 2. The data manager will reconcile the entered data. |
| **Exception:** | E1. The data collected by the device is inconsistent.   1. The system notified the patient and data manager to valid the highlighted data. 2. It will record into the query list.    1. If both patient and data manager approval for the highlighted data, it will stored without any change.    2. If they found the inconsistency of highlighted data, it will be deleted. 3. The corresponding query will be marked as solved. 4. The patient will be notified the inconsistent data was deleted. |
| **Special requirement:** | The usage of data must follow by the related privacy regulation and other laws. |
| **Assumption:** | The patient is willing to wear and use the devices. Also, the patient gives permission for device to collect his personal health data. |
| **Notes and Issues:** | Additional details and changes will be added to a revised version of UC-1 and name as UC-1.1 if the change is approved. . |

UC-2

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| **Use Case Field** | **Description** |
| **Use Case Name:** | Request medical records and vital signs data |
| **Use Case ID:** | UC-2 |
| **Created By:** | Xin Zheng |
| **Created Date:** | Oct 13, 2019 |
| **Last Update By:** | Xin Zheng |
| **Last Update Date:** | Oct 16, 2019 |
| **Actor:** | An ER doctor (Speciality Doctor) |
| **Trigger:** | The request of medical records and vital signs by the doctor |
| **Description:** | If the patient is having an adverse health event and in a loss conscious state, the data of medical history and vital signs can be exported into ER’s system by the request of doctor. It will help the doctor to diagnose the patient more accurately. |
| **Precondition:** | 1. The patient allows the device to collect personal medical data. 2. The patient wears the device when an emergency happens. 3. The data of patient’s medical history and vital signs is stored in the database. 4. The credential of ER doctors and other staff is stored in the system. 5. The hospital has access to the system. 6. The device is compatible to hospital’s system. |
| **Post Condition:** | 1. The request made by doctor will be stored in the system 2. The patient history will be stored into database as new medical record. |
| **Priority:** | High |
| **Frequency of Usage:** | As it needed. |
| **Normal Course of Event:** | 1.0 request medical record and vital sign data   1. The ER doctor request the needed medical record and vital sign data from the device. 2. The device will verify the credential of the user.    1. If the credential is confirmed, the system will general list of needed medical record and vital signs.    2. If the confirmation is failed, the system will deny the data export. |
| **Alternative Course:** | 1. The patient can give the ER doctor permission if they are not in the pre-existing credential list. 2. Or the hospital can use a universal reading device to read the data in the wearable device. |
| **Exception:** | E1. The patient not allow the ER doctor and staffs to access his data.   1. The ER doctor request the needed medical record and vital sign data from the device. 2. The request will be denied, and the message will be sent to the doctor. |
| **Special requirement:** | Any transfer of the medical data should made by professionals and follow the privacy regulation and laws. |
| **Assumption:** | The patient is wearing the device when emergency happens and also when the patient is in the emergency room. The hospital is allow the device sending data to their system. |
| **Notes and Issues:** | Additional details and changes will be added to a revised version of UC-2, and name as UC-2.1 if the change is approved. |

UC-3

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| **Use Case Field** | **Description** |
| **Use Case Name:** | Oxytocin Hormone Changes in Patient |
| **Use Case ID:** | UC-3 |
| **Created By:** | Xin Zheng |
| **Created Date:** | Oct 13, 2019 |
| **Last Update By:** | Xin Zheng |
| **Last Update Date:** | Oct 16, 2019 |
| **Actor:** | Patient |
| **Description:** | If the patient is having spikes in oxytocin hormone levels during certain processes such as childbirth or lactation, the device should be able to record this change and alert the user. This will also alert the user if they are about to undergo early childbirth. |
| **Precondition:** | 1. The user has inputted the delivery due date for their pregnancy. 2. The user has given the device access to previous and present medical records regarding the pregnancy. 3. The user has inputted the credentials for the hospital and doctors. 4. The user is wearing the device during the time of hormone changes. |
| **Post Condition:** | 1. Oxytocin hormone trend is recorded and displayed 2. User is alerted that they will undergo contractions soon 3. The device alerts the user’s doctor about the upcoming delivery. |
| **Priority:** | High |
| **Frequency of Usage:** | As it needed. |
| **Normal Course of Event:** | 1.0 Device detects spike in oxytocin hormone levels   1. Device compares current oxytocin hormone levels to previous levels. 2. Determines whether there is a drastic change. 3. Alerts the patient of this change and alerts. |
| **Alternative Course:** | 1. If the patient has a sudden spike in oxytocin hormone levels, but the device does not record further increases.    1. This means that the patient is undergoing false contractions    2. Device should alert the user that the spikes were not followed up with consistent increases in oxytocin levels, therefore, the contractions are false. |
| **Exception:** | E1. The patient not allow the ER doctor and staffs to access his data because the user has decided to undergo childbirth outside of hospitals. |
| **Special requirement:** | Any transfer of the medical data should made by professionals and follow the privacy regulation and laws. |
| **Assumption:** | The patient is wearing the device when spike in oxytocin hormone levels occurs. |
| **Notes and Issues:** | Additional details and changes will be added to a revised version of UC-3, and name as UC-3.1 if the change is approved. |

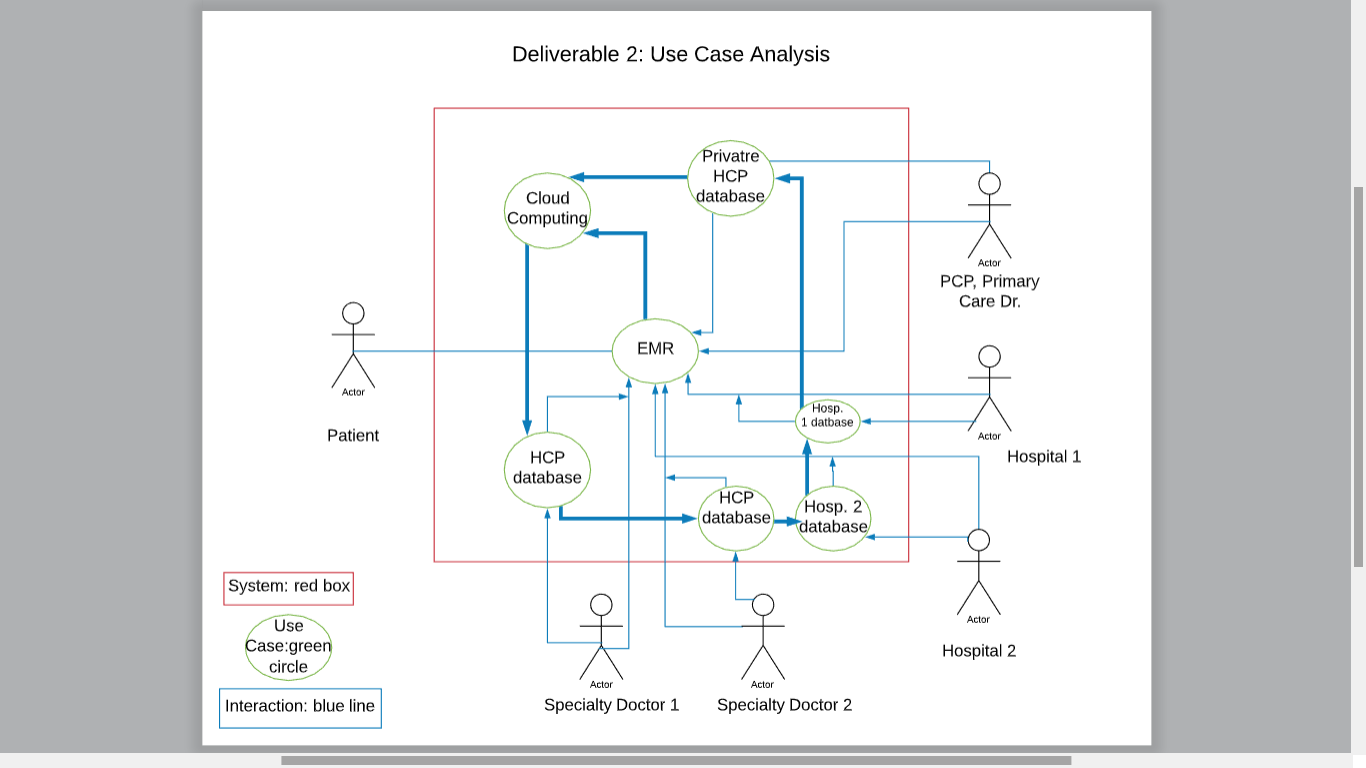
UC-4

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| **Use Case Field** | **Description** |
| **Use Case Name:** | Upload Medical History to database |
| **Use Case ID:** | UC-4 |
| **Created By:** | Xin Zheng |
| **Created Date:** | Oct 26, 2019 |
| **Last Update By:** | Xin Zheng |
| **Last Update Date:** | Nov 6, 2019 |
| **Actor:** | Primary Care Doctor |
| **Trigger:** | External. Patient request Primary Care to upload data to the device.. |
| **Description:** | If the patient is given permission of the device to collect their personal medical data, Primary Care doctor or Office staff will upload patient information that is stored in patient portal to the devices, then the information will be automatically recorded in the database. |
| **Precondition:** | 1. Patient allow the device to collect his personal medical data. 2. Primary Care Doctor willing to share and transfer data to the device and the database |
| **Post Condition:** | 1. The medical records will be uploaded to the database and stored in the devices. 2. Speciality and hospital can extract data from the device in an emergency situation. 3. The devices use medical records to find the pattern and based on the pattern, alert patient when an abnormality is detected. |
| **Priority:** | High |
| **Frequency of Usage:** | As patient requested. |
| **Normal Course of Event:** | 1.0 Primary care upload medical history to the device.   1. Primary care verifies their credentials and login to patient portal. 2. Primary care push the medical record from the patient portal to device. 3. The device stores the uploaded data. 4. Send all data to the database. |
| **Alternative Course:** | 1. If the Primary Care Office record medical records in papers. 2. Patient can request a login account for Doctor's office staff to enter medical history manually. 3. After the data is entered, database admins will reconcile the data to make sure there is not errors.    1. Then, the medical history will send to patient’s device. |
| **Exception:** | E1. Primary Care not willing to transfer medical history to database.  E2. The system or software that used by primary care is in compatible to the devices. |
| **Special requirement:** | Any transfer of the medical data should made by professionals and follow the privacy regulation and laws. |
| **Assumption:** | The patient notify the Primary Care doctor to transfer data with proper request form. |
| **Notes and Issues:** | Additional details and changes will be added to a revised version of UC-3, and name as UC-3.1 if the change is approved. |

UC-5

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| **Use Case Field** | **Description** |
| **Use Case Name:** | Transfer Medical History to database |
| **Use Case ID:** | UC-5 |
| **Created By:** | Xin Zheng |
| **Created Date:** | Oct 26, 2019 |
| **Last Update By:** | Xin Zheng |
| **Last Update Date:** | Nov 6, 2019 |
| **Actor:** | Hospital |
| **Trigger:** | External. Patient request the hospital to share their medical record to the device. |
| **Description:** | If the patient is given permission of the device to collect their personal medical data, hospitals will transfer patient information from the hospital system to their devices, then the information will be automatically recorded in the database. |
| **Precondition:** | 1. Patient allow the device to collect his personal medical data. 2. Hospital willing to share and transfer data to the device and the database. 3. Patient’s medical record is stored in their system. |
| **Post Condition:** | 1. The medical records will be uploaded to the database and stored in the devices. 2. Speciality and other PHP can extract data from the device in an emergency situation. 3. The devices use medical records to find the pattern and based on the pattern, alert patient when an abnormality is detected. |
| **Priority:** | High |
| **Frequency of Usage:** | As patient requested. |
| **Normal Course of Event:** | 1.0 Hospital Transfer medical history to the device.   1. Hospital verifies their credentials and login to patient portal. 2. Hospital transfer the medical record from their system to device. 3. The device stores the transferred data. 4. Send all data to the database. |
| **Alternative Course:** | 1. If hospital system is not compatible to the devices.    1. Patient can request a login account for hospital staff to enter medical history manually.    2. After the data is entered, database admins will reconcile the data to make sure there is not errors.    3. Then, the medical history will send to patient’s device. |
| **Exception:** | E1. The hospital is shorted of staff to transfer medical history to database. |
| **Special requirement:** | Any transfer of the medical data should made by professionals and follow the privacy regulation and laws. |
| **Assumption:** | The patient notify the hospital to transfer data with proper request form. |
| **Notes and Issues:** | Additional details and changes will be added to a revised version of UC-3, and name as UC-3.1 if the change is approved. |

**Use Case Diagram**

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