IS 436 - Structured System Analysis & Design

Deliverable 1 - Proposal

Team Members:

Adam Afilaka: Developer/Programmer

Ashley Braun: Business Analyst/Legal Compliance/Project Manager (410-991-1496; abraun1@umbc.edu)

Zaid Islam: Cyber Security Engineer (zislam1@umbc.edu)

Rithika Sayini: Researcher/Programmer (rithika1@umbc.edu)

Shanese Scott: Database Administrator (443-760-1459; scsh1@umbc.edu)

Xin Zheng: Quality Assurance(443-931-9403; xinz1@umbc.edu)

October 3, 2019

**Team Bios**

Adam Afilaka: Developer/Programmer

Information systems major also trying to acquire a certificate in decision support. Aim to earn a masters in data science. Enjoys watching HG TV and reading.

Ashley Braun: Business Analyst/Legal Compliance/Project Manager

Current IS major at UMBC with associates in legal studies. I have been a paralegal for 16 years; 2 years as a paralegal specialist in the Army Reserves and 14 years doing defense litigation in areas of medical malpractice and products liability in pharmaceuticals. I have an interest in healthcare informatics.

Zaid Islam: Cyber Security Engineer

Current IS major at UMBC with focus on cyber security. Desire to have a profession in cyber security engineering. Currently interviewing all over US for this position.

Rithika Sayini: Researcher/Marketer

Current undergraduate student at UMBC. I am pursuing a dual degree in B.S Biology and B.S Information Systems. I will be graduating in the Spring Semester of 2020. After graduation, I plan on working in the Health Informatics Field

Shanese Scott: Database Administrator

Current undergraduate student studying at the University of Maryland Baltimore County. In the spring I will be completing a Bachelor of Science in Information Systems. I hope to attend graduate school at the University of Maryland College Park for cyber security.

Xin Zheng: Quality Assurance

Current undergraduate student at UMBC. IS major and MLL minor of Chinese Track. I’ll be graduating in Spring, 2020. After that, I would like to get a job and go to graduate school.

**Objective**:

Integrating the current EMR with a product (perhaps a wrist device of some other key fob, chip or a medical/insurance card) that is consistent amongst all HCP (health care personnel) networks, is reliable, and can provide pertinent medical data in making critical and time-sensitive medical decisions. 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 also in non-emergent situations.

System Request:

Say you were just walking downstairs one day with normal vitals. Heart rate between 50-100 beats per minute, body temperature around 87 degrees Fahrenheit, and a normal blood pressure under 120/80. Suddenly, you trip and fall down the stairs and get a concussion, resulting in a coma. What happened to your vitals between the impact and the coma?

Hospitals can run many expensive tests to determine what treatment you may need, without completely being able to know what homeostatic imbalance your body went through. However, our device has been tracking your vitals in real time and knows exactly what happened when it happened. A quick scan of your carotid artery determines that blood flow to the brain had ceased, and that your body’s natural immune response has caused you to have intracranial pressure. No oxygen to the brain equals comatose state. The device has recorded these changes as well as blood pressure, heart rate, breathing rate, possible atrophy, organ function, etc. down to the very last second.

All this information along with your recent medical records can be quickly accessed by your healthcare provider through our EMR device. Instead of wasting precious time by running an MRI, PET, EEG, blood pressure check, heart rate check, etc. your healthcare provider can just examine your vitals at each time stamp during and after the coma to determine exactly what treatment you may need. This device will eradicate the need for expensive technologies, and allow for efficiency and accuracy in treating medical ailments. We’re focused on bringing this device into the mass markets through potential sponsors that manufacture and distribute biomedical and EMR technologies.

Project Sponsor: Siemens Healthineers, Thermo Fisher Scientific, GE Healthcare.

We focus our sponsor on companies that are known for the manufacture, distribution, and maintenance of common biotech, biomedical technology and products. Siemens Healthineers our primal focus is to purpose enable healthcare providers to increase value by empowering them on their towards expanding precision medicine, transforming care delivery, and improving patient experience, all enabled by digitizing healthcare.

Business Need :

* Expanding the current myChart/patient portals to medical records to be available to all treating physicians and medical-treating facilities. To include access to pertinent patient information, to include the complete medical chart (Rxs, labs, diagnoses, surgeries, allergies, current meds, patient medical Hx, current and past treating physician list, radiology studies, pathology results, immunizations) under emergent situations (e.g., unconscious patient taken to ER, HCPs have access via a band or some other personal device, which can be scanned, and uploads all critical healthcare data: allergies, medical hx, diagnoses, etc.). This device will automatically populate between hospital and Dr. offices’ systems and the device triggering any potential adverse events/reactions.

Business Requirements :

There are 12 million Americans misdiagnosed each year. The most common reasons for misdiagnosis include problems with ordering diagnostic tests; failure by the patient to provide an accurate medical history; and errors made by a doctor in interpreting test results. The data integrity can directly effect one the performance of this device. It’s important to ensure the info provided to HCP is consistent and reliable. For example, if a patient in coma, the EMRs will need reliable medical record to diagnose patients. Required to have permission to access the information, such as the medical records from the patient portals. The doctor's office and the patient should be both agree to allow this device to collect and store medical records.

* Provide consistent and reliable info from EMRs to all HCP
* Access to the current myChart/patient portal

After the device is designed and ready to move to the next phase, we need to conduct clinical trials to test the efficacy and accuracy of the devices and compose the results into a report for approval from FDA. Designing the clinical trials must follow Good Clinical Practice (GCP) guidelines and divide the trail in to different phases based on different goals. It usually has 3-4 phases and require research site to collect info from the volunteers that guide by the DCFs.

* Conduct clinical trials

Generally, any business entity engaged in medical device manufacturing or trading (distribution and/or sale) must obtain specific licenses in addition to the normal business licenses. Partner with a manufacturer who already has license of producing health devices will shorten the process by eliminating the process of applying license and ensure the legality of the final products.

* Partnership with licensed manufacturers

Business Value Estimate :

Like money value from projected earnings and whatnot sales projections Y axis is the high to low estimates and probability then weighted

The wearable device industry is a 120 million dollar industry by 2023. The healthcare industry will be 3.4 trillion dollars industry. So the projections of our project are quite high.

|  |  |  |
| --- | --- | --- |
|  | Sales Projection |  |
|  | Hospital Purchase | Subscription (over the course of a year) |
| High level Estimate  Probability: 60% | $5000000 | 20,000,000 |
| Medium Level Estimate  Probability: 30% | $2000000 | 10,000,000 |
| Low Level Estimate  Probability: 10% | $1200000 | 7,000,000 |
| Weighted Average Expected Sales | 3180000 | 15700000 |

Total: $ 47500000

Feasibility Analysis

* Technical Feasibility:

All large enterprises need a database system for handling their information. The data collected can be used for local assessments or evaluations within a healthcare system. The EMR device will collect various data about the patient and will be updated in real-time. The database will have to be able to maintain and update millions and millions of rows of patient data. The main objective is to allow his data to be accessible to a healthcare provider in real-time.

In manner of process to the is essential to focus on the process of how data is transferred from a client who to a system for a Doctor to be able to analyze and use with secure, and reliable data. During the System Development Create software and usage of hardware (phones) to follow security guidelines given to app developers for Operating Systems for phones. Scanning of a person’s EMR should be protected, since the collection of data is constant the software should prevent any ways hackers can connect and begin to record to an end system that records the EMR, or change it’s usage if placed on a person.

1. Software Requirements:

* FoundationDB
* InnoDB
* OS (Linux, Windows, and macOS)
* MongoDB

1. Hardware Requirements:

* 16-64 GB of RAM
* JDK 64-bit
* Disk Space 250 GB or higher
* 8-16 core processor
* High speed drive (SAN)

C. Server Requirements:

* 32 GB

D. Database Requirements:

* Backup Compression
* ACID Properties
* Replication
* Ordered key-value store
* Layers

Integration with app: MongoDB will allow us to develop amazing mobile applications that can handle millions, even billions, of users. It will give us the ability to manage any kind of data and make frequent updates to the database without application downtime.

Compliance: We would have access to public health following policy protocol established by legal permissions to access protocol based on the respective database systems.

Challenges: The data collected from the user must be refreshed in real-time. The data must also be stored in a database and accessible by the user’s doctor. Another challenge is getting access to other healthcare data warehouses. The following are the technical challenges identified for the system below:

* The database will need to be able to secure and have user authentication
* The system will need to be able to track vitals
* The system needs a responsive UI
* The database will need to be able to handle increased data volumes
* The system will need to be accessible to doctors, nurses, or receptionists
* The system will need to be updated
* Precautions to avoid data loss or artificial threats
* Access to patient portals
* Connecting Back-end database with app framework

Maintenance: Freshly loaded databases usually have good sequential behavior, but it becomes harder to maintain as the database grows. The biggest challenge is constantly maintaining and updating our database. The first approach would be to enable InnoDB table compression since this database requires a lot of inserts. Overall this helps improves performance and scalability. It is recommended that all files are backed up in case of data loss or threat. It is also important that the facility have an uninterruptible power supply to reduce the rate for hard disk failure. The biggest aspect of maintenance is testing the database thoroughly. Schemas, triggers, procedures, constraints, and acid properties should be tested regularly. Another proposal is to take advantage of SSD since this database performs a lot of reads.

* Economic Feasibility :

<https://investor.fitbit.com/press/press-releases/press-release-details/2019/Fitbit-Reports-571-Million-Q418-Revenue-and-151-Billion-FY18-Revenue/>

Identify costs and benefits

|  |  |
| --- | --- |
| **Development Costs**   * Salary * Software Development * Hardware Development * Data Conversion * Hardware and Software Architecture * Clinical Trials | **Operational Costs**   * Maintenance * Salary * Hardware Manufacturing * Customer Service and Support * Outreach |
| **Tangible Benefits**   * Cuts Doctor’s Offices Cost * Free Advertising | **Intangible Benefits**   * Customer Ease of Mind * Faster Patient Care * More Efficient Healthcare * Faster doctor’s office visits |

* Organizational Feasibility :

<https://www.businessinsider.com/wearable-technology-healthcare-medical-devices>

* US consumer use of wearables jumped from 9% in 2014 to 33% in 2018, [according to](https://newsroom.accenture.com/news/accenture-study-finds-growing-demand-for-digital-health-services-revolutionizing-delivery-models-patients-doctors-machines.htm) Accenture.
* more than 80% of consumers are willing to wear fitness technology.
* According to [Business Insider Intelligence research](https://www.businessinsider.com/intelligence/digital-health?IR=T&itm_source=businessinsider&itm_medium=content_marketing&itm_campaign=report_teaser&itm_content=top_text&itm_term=bundle_subscription_text_link-wearable-technology-healthcare-medical-devices), the total installed base of fitness tracker and health-based wearables in the US will grow at an annualized rate of 10% to surpass 120 million by 2023.
* 15 hours a week could be saved by doctors whose patients use wearable technology
* Special Issues or Constraints (Xin - Olivia and Ashley (legalities)):
* Privacy issue
* HIPAA, HITECH
* Availability to all HCPs
* Device compatibility
* Restricting access to only licensed HCPs (this is already done with patient portals, but needs to be addressed with a device/product)
* Patient data cannot be altered by patient.
* Another device that transfers medical record data to device (this is only available to HCPs) -- blockchain concept
* Not all individuals will carry the product/device
* Medical record retention periods (data will have to be phased in and may only go back so many years. This resolves in the future, maybe decades later.)

Methodology

We are proposing the parallel methodology considering the complexity of the system and the need to be compatible with other systems. Therefore, the development can be tested in phases alongside all the components.

Project Cost Estimation:

* <https://www.beckershospitalreview.com/telehealth/typical-mhealth-app-costs-425k-to-develop-report-finds.html>
  + Healthcare app development is appx. $425,000.

Project dates/estimation dates:

* Team Meetings-
  + Two initial meetings were held on:

Monday, Sept. 23, 2019 (Adam, Rithika, Shanese, Zaid)

Wednesday, Sept. 25, 2019 (Ashley & Xin)

* Deliverables -
  + One - Oct. 2, 2019
  + Two - TBD
  + Three - TBD
  + Four - TBD
  + Five - TBD
  + Six - Dec. 2019
* Presentations -
  + One - Oct. 3, 2019
  + Two - TBD
  + Three - TBD
  + Four - TBD
  + Five - TBD
  + Six - Dec. 2019