Research Plan

A. Specific Aims

The Institute of Medicine concludes that up to 98,000 patients die annually from preventable systematic medical errors. Many of these errors were caused by mis-communication between health care professionals. The exact extent of damage caused by mis-communication is hard to track. Most errors are either dealt with, ignored, or they are never realized. We propose an electronic solution by creating a Wearable Medical Memory Device (MMD) combined with an Electronic Medical Records (EMR) database software suite. Our solution will be designed to compliment existing communication methods in order to bridge current gaps in the broken lines of medical communications. The memory device and software combined will create the Medical Memory System (**MMS**). The memory device will be designed for patients. It will be wearable, easily updatable and durable. The patient will wear the memory device implanted in some type of jewelry. Each time they visit a participating medical facility, the patient's medical information will be read directly off of their personal memory device. At the end of the visit, the memory device will be updated with the latest health information. Participating medical facilities will buy the MMS software suite that will allow them to read and update patients' memory devices. The memory device and the software will allow a free-flow of patient information between facilities. This information sharing will alleviate broken communication lines.

During Phase I, MMS wishes to focus on a specific goal. We will work to design and develop the Medical Memory System software. XML, Extensible Markup Language, will be used to create the data storing software. XML provides a flexible data structure and will allow for data encapsulation. These traits will prove useful in creating software to transfer information back and forth between the medical device and a personal computer. Since XML contains pre-developed data objects, it will also reduce the time and cost necessary to develop our software suite. The development of the software must also focus on ease and speed of the software. The software will be designed to interface with currently used Electronic Medical Records (EMR), such as General Electric's Logican and Medplus' eMaxx system. By interfacing with current EMRs, our software will be simple for medical personnel to learn and use. The database will be created to store important medical information such as allergies, medications, radiology reports, labs, medical history, and physicians' notes.

The MMS software suite must be designed with Health Level 7 (HL7) standards in mind. The software suite will be compliant with these standards govern the "exchange, integration, sharing, and retrieval of electronic health information".

In addition to keeping in mind HL7 standards, MMS will also be mindful of current HIPAA privacy regulations. The HIPAA regulations help to set standards

for the handing and sharing of a patient's protected health information. In order to avoid any legal issues, MMS must be HIPAA compliant. We plan do this by seeking HIPAA certification from a third-party company. We will also encourage security of patient data by designing our software to use encryption. During Phase I software development, HIPAA and security will be a major focus of the software design team.

In addition to the development of the Medical Memory Systems software suite during Phase I, MMS will work to produce a user manual. The user manual will explain the MMS software and memory device in detail. The user manual will be written to be easily read and easily understood. It will contain diagrams and step-by-step instructions. The manual will be broken down into clear sections. There will be a trouble-shooting section and also information about contacting the MMS Company.

B. Significance

The 98,000 patients that the IOM estimates die annually, die from preventable medical errors. Many of these errors are caused by mis-communication between health-care professional. Project MMS wishes to alleviate this problem and develop stronger communications between medical facilities. We wish to create an impact on the medical field and on society.

The MMS will assist medical facilities by saving time, saving money, and reducing patient harm by allowing a smooth flow of information between facilities equipped with the MMS system. MMS will save time by giving medical facilities quick access to a patient's medical information. Money will be saved by decreasing the number of excess tests done as a result of incorrect or absent medical history. And third, and most importantly, MMS will save lives and reduce patient harm by allowing an easier flow of medical information. The quality of medical service will increase as information is made available sooner and in a more complete entity to medical staff.

MMS will make the lives of patients easier. Patients will now be able to transport their own personal medical records with them at all times. This will alleviate the need for patients to remember and recite complex medical information. When told from memory, the information may be inaccurate and incomplete. While using the portable memory device, the patient will be able to give health care professionals reliable and up-to-date information. This information will include allergies, medications, labs, medical history and radiology reports. This quick and reliable exchange of information will decrease the risks of mistakes and decrease the time spent by medical facilities trying to gather and confirm medical information from sources other than the patient.

The Medical Memory System consists of a software suite for medical facilities and a wearable medical memory device for patients. The Project MMS team will develop our own database software using XML. The software will also be easy and quick to use. It will be designed to be HIPAA compliant and use HL7 standards. The MMS software suite will interface with currently used EMR systems. Currently 27% of physicians use some sort of EMR system. This number is expected to rapidly increase over the next 3 years. With the growth of EMR systems, MMS will be able to increase our impact and increase communications between many medical facilities.

In order to create the wearable memory device for the patient, MMS will use a memory button technology developed by MacSema Incorporated. The memory button is about the size of a quarter and contains up to 8 megabytes of non-volatile memory. The memory button is designed for durability. It will operate at temperatures of up to 185 degrees Fahrenheit. The button is encapsulated allowing it to withstand elements such as water, oil, dust, grease, radiation, weather extremes, electromagnetic fields, and mechanical stresses.

The transfer of data between the software suite and the memory button will be facilitated by the use of a handheld interface also designed by the MacSema Company. In order for the data to be transferred, the medical personnel will place the handheld device next to the memory button and data transfer will occur. Transfer will happen at a rate of up to 300 Kilobytes per second.

C. Relevant Experience

Primary Investigator
Jeff McCreary has had 4 years experience in the field of computer science, and 10 years working in the medical field. He has been a student at Old Dominion University since 2001. Through his studies, he has gained knowledge in the fields of research and software development. He also has an A.A.S in Radiology Health Sciences.

Co-Investigator
Daniel Anderson has had serveral years experience in project management. Currently an Old Dominion University student, he has gained both technical knowledge and addition project management experience.

Co-Investigator
Megan Babb has had 4 years experience in the field of computer science. She has been a student at Old Dominion University since 1999. Through her studies, she has gained knowledge in the fields of research and software development.

Co-Investigator

      Christopher Fronda has had 4 years experience in the field of computer science. He has been a student at Old Dominion University since 2000. Through his studies, he has gained knowledge in the fields of research and software development.

Co-Investigator

      Rabia Haq has had 6 years of experience in the Computer Science field. She has been a transfer student at Old Dominion University since 2002

Co-Investigator

      Richard Strosahl has had 6 years experience in the field of computer science. He has been a student at Old Dominion University since 2001. Through his studies, he has gained knowledge in the fields of research and software development.

D. Experimental Designs and Methods

      The goal of MMS is to decrease patient harm by opening lines of communication between medical facilities. MMS has designed a system that is based on current technology.
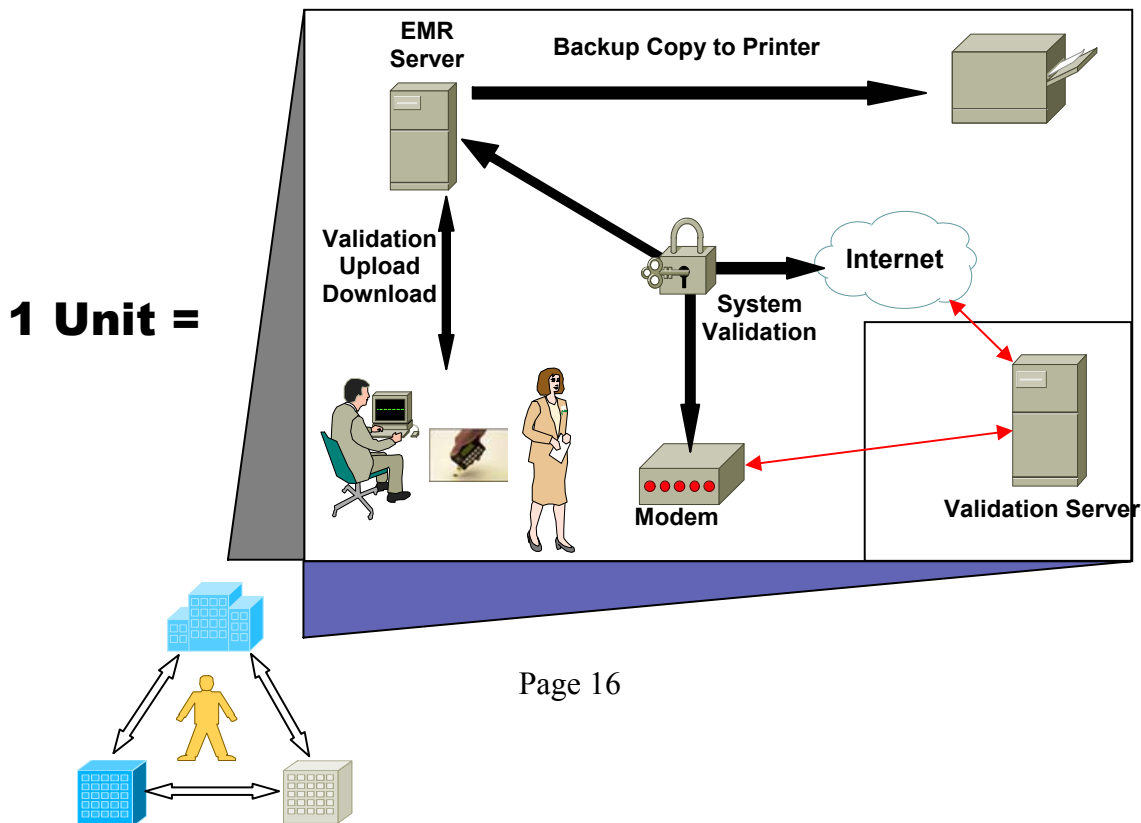
The Major Functional Component Diagram displays the different components necessary use the Medical Memory System. In order to have a working version of the MMS it will be necessary to have the following components.

- Windows Computer – The medical facilities will be equipped with at least a basic computer running the Windows operating system. The computer will run the MMR software and contain the database of patient information.
- Button Memory – The button memory will be a small, durable, and portable memory device. It will be implanted on a piece of jewelry allowing the user to wear it at all times. The memory will hold the user's important medical information including: personal information, medical conditions, prescriptions and allergies.
- Button Memory Reader – The reader will be a device that plugs into a standard USB port. It scans the button memory to transfer data. Data will be transferred from the memory to the software. The reader will also allow for software data to be written onto the button memory.
- EMR Server – The electronic medical records (EMR) server will store the medical facility's patient information. Our completed software package will interface with a medical facility's pre-existing EMR database. If the facility does not have EMR, we may provide them a database as an addition to the MMS software.
- Validation Server and Modem – The medical facility's computers should be equipped with modems. The modem will allow the facility to access the MMS's validation server through the Internet. The validation server will be a computer that will verify the software and hardware used by the facility. This will aid in security and prevent the use of the MMS equipment in the case that it is stolen or lost.
- Printer – The medical facilities that are equipped with a printer will be able to print out a hard copy of a patient's records if they wish. This is not a vital part of the MMS.

During Phase I of the Medical Memory System (MMS) project; it will be necessary to build a lab prototype. The purpose of this prototype will be to prove feasibility and workability of our product based on our Major Functional Component Diagram. In Phase I, we will make a lab prototype that will prove the feasibility of our product. It will be a scaled-down version of MMS. While some of the major functional components will differ from those in the final product, the prototype will give an overall view of how our system will function. The following will be our major components for the lab prototype.

- Windows Computer – The prototype will rely on a basic computer running the Windows operating system. This computer will run the prototype MMS software and contain the database of sample patient information. It will also be networked to the validation server. It will simulate a facility's computer.

- Validation Server – The prototype will need a basic computer that can serve as a validation server for the "facility computer". It will be networked to the facility computer and verify that computer's software and hardware are valid. There is no need to validate over the Internet or use a modem for the lab prototype.
- USB Memory Device – For our prototype, we will replace the memory button and reader with a small, portable, USB storage drive. This will be an easy way to simulate the data transfer and data storage of the USB reader and memory button.
- Patient Database – The prototype will simulate an EMR patient database by using a simple Microsoft Access database. This database will contain sample patient data that can be used to show successful data transfer and storage. It will be contained on the facility computer.
- Printer – A basic printer can be hooked to the simulated facility machine in order to print out sample patient data.

The Phase I design goal of MMS is to test our software as it is developed. By the end of Phase I, our system should be able to effectively share information between the MMS software suite on a personal computer and the portable memory device. The user should find the software easy and quick to use.

E. Human Subjects

No human subjects are involved in this project.

F. Vertebrate Animals:

No vertebrate animals are involved in this project.

G. Consultants

We have had preliminary discussions with Dr. Irwin Levinstein concerning the development of the MMS database.

Lori Prowant, Director of Radiology at Maryview Medical Center, and Dr. Bennett, Medical Center Radiologist, have been consulted in Phase 0 to determine problem scope in terms of size, frequency and patient impact.

H. Contractual Arrangements

None