Remote Access to Medical Specialists (RAMS) – Maui Test

Investigators

Dr. (COL) James Breitweser, MC
Dr. (MAJ) Greg Pettermen , MC
Maj (USAF) Mary Nilges, MSC

BACKGROUND

The Remote Access to Medical Specialists (RAMS) program will be used to demonstrate the applicability of advanced digital medicine techniques to military medicine. The term "military medicine" is seen as encompassing the urgent, combat casualty care associated with military operations in hostile environments, as well as the often more costly peace-time military readiness and family member care.

RAMS will focus on three main areas which have direct applications both to combat casualty care and to peace-time military medicine:

1. Digital Radiographic Image Transfer and Remote Diagnosis – Digital radiography, a diagnostic modality which replaces x-ray film with digital x-ray image sensors, is rapidly emerging due to development of digital x-ray image sensors, digital transmission, and image display technologies. RAMS will develop and install digital radiography equipment for modalities including digital mammography and digital general radiography, and develop techniques for remote medical diagnosis. Clearly, the technological developments, which flow from this effort has profound implications for the provision of medical care in remote military locations on land or at sea.

2. Critical Care Monitoring Project – This effort will focus on the digital acquisition and analysis of real-time ICU patient monitoring data. Computer algorithms will be developed to analyze this data and to present the data set in meaningful ways to a health practitioner. Techniques for reducing the data sets and transmitting the data through the Internet will be developed and implemented for use in remote monitoring of both military and civilian critical care patients.

RAMS is designed to provide a tightly focused demonstration of the near-term benefits of digital medicine. RAMS will evolve to include emerging developments in diagnostic medical devices, digital image processing, image display and archive, and internet-based telecommunications technologies. The long-term goal is to develop models for integration of digital medicine systems into the computer-based patient record, to include system configurations, image management and techniques, algorithms and clinical databases.

Research Question and Hypothesis

The Remote Access to Medical Specialists project will utilize integrated digital communication links to establish a digital medical testbed. The proposed techniques encompass digital radiography, digital mammography, and remote monitoring of critical care patients. It is our thesis that improved systems of digital medicine, including digital communication data links, algorithm development; remote diagnostic capabilities will greatly benefit DOD beneficiaries.

Specifically RAMS will address:

- Uses of digital x-ray image sensor technology and determination of diagnostic standard for mammography digital images
- Acceptability of acquired digital images by comparing images to identified diagnostic standards
- Acceptable imaging hardware standards to determine the minimum mammography imaging capability
- Advanced teleconsultation system for critical care can enhance the quality of patient care information exchanged between remote provider and a critical care specialist and improve the overall management of the critically ill patient

Project Description

Digital Image Transfer and Remote Diagnosis –Focus of this effort is two-fold:

-Digital radiography, a diagnostic modality that replaces x-ray film with digital x-ray image sensors, is rapidly emerging due to development of digital x-ray image sensors, digital transmission, and image display technologies. RAMS will develop and install digital radiographic equipment for digital mammography and develop techniques for remote medical diagnosis. Digital medicine applications would provide remote medical care and monitoring to individuals during "care in the air" transit and enable treatment for acute battlefield injuries in rapidly deployed surgical facilities in support of force health protection.

-Explore prototype system architecture design alternatives to accommodate image acquisition, manipulation, retrieval and migration into DOD enterprise systems. Digital networks are particularly relevant to military medical needs and are currently not part of CHCSII or the Government Computer-based Patient Record (G-CPR). The highly mobile nature of military life illustrates the need for digital medicine and digitally archived data to be an intrinsic part of the computer-based patient record. Exploration of an architecture migration strategy positions the Akamai image prototypes to converge into DOD enterprise systems.

DIGITAL RADIOGRAPHIC IMAGE TRANSFER AND REMOTE DIAGNOSIS

Digital radiography with internet-based image transfer capability certainly forms a cornerstone of the remote access to medical specialist concept. Our intent is to explore emerging technologies, which enable direct digital captures of x-ray radiographs as well as the transmission, storage, display of these radiographs. Unlike computed radiography, this modality does not require the separate CR plates and bulky laser scanner. In the ultimate digital radiographic device, the entire imaging chain, from image acquisition to

image display, are digital. This device could produce quality x-ray radiographs without the necessity of chemical film processing. The digital image data could be efficiently stored, and transmitted rapidly via Internet for remote diagnosis. The display of the digital radiographs on a computer display would enable a physician to electronically magnify and interactively adjust the local contrast of the image. In addition, the computer-aided diagnosis techniques could be utilized to analyze the digital image data, and provide the physician with a second opinion, thus helping to standardize the quality of the diagnosis.

A promising technology for digital radiographic image sensors is the thin-film transistor (TFT) array technology. The TFT technology involves coating large glass sheets with amorphous silicon, and then fabricating electronic circuits on these sheets. The TFT technology has matured over the last twenty years for the application of flat panel displays commonly incorporated in laptop computers. In addition, this technology has been developed for the application of digital x-ray image sensor. The large electronic circuit arrays are coated with materials which convert incident x-rays to electronic charge; this pixelated charge distribution is then digitized to provide a digital image. The TFT technology enables the fabrication of digital x-ray image sensors which are the size of x-ray film (14" x 17") and with sufficient spatial resolution and image performance to compete with x-ray film. A number of companies are developing TFT technology for digital radiography applications, including Xerox/dpiX, General Electric/EG&G, Trixxel, Canon, and others.

Digital Mammography

Conventional film-screen x-ray mammography provides an image on film of the attenuation of x-rays passing through the breast is currently the only reliable method for early detection and diagnosis of breast cancer. Although x-ray mammography is considered as a sub-specialty of x-ray radiography, the image performance required for x-ray mammography are considerably more stringent than the image performance required for general radiography. The detection of subtle lesions and microcalcification clusters indicative of early breast cancer requires very high spatial resolution and very high sensitivity to slight differences in image contrast (grayscales).

Digital mammography, an emerging diagnostic modality which replaces the film-screen combination with a digital x-ray image sensor, has shown potential for greatly improved image quality over conventional x-ray mammography and has great potential for saving the lives of women by earlier detection and more accurate diagnosis of breast cancer. The radiology community as the next inevitable revolution in breast cancer screening and diagnosis generally accepts digital x-ray mammography. However, to date, the lack of maturity of digital x-ray image sensors and digital transmission, archival, and display technologies has precluded widespread clinical deployment of digital mammography.

This effort will demonstrate and validate a prototype that has been under development for the past six years by Trex Enterprises, prototype is a digital x-ray image sensor technology, which is commercially viable for digital mammography applications. This image sensor must have sufficient image format, spatial resolution, range of contrast, and

detective quantum efficiency to effectively image the full breast. In addition, the sensor must be compact, reliable, easy to manufacture, and fairly inexpensive.

Trex Enterprises has fabricated two clinical test units for digital mammography, which utilize this sensor technology. The clinical test units feature a 1664 x 2048 pixel digital x-ray image sensor with 66 micron pixels (11 cm x 13 cm image format). The image sensor is incorporated inside the breast tray of a conventional Lorad M-IV mammography unit. The prototype unit is a mid-field digital mammography unit; the image sensor is not of sufficiently size to effectively image the full breast for screening purposes. The unit is designed to be used for diagnosis of suspicious abnormalities present on the screening x-ray mammogram. The digital mid-field mammogram offers a high performance magnified image of the abnormality in order to accurately determine the benign or malignant nature of the abnormality thus enabling the radiologist to more accurately determine if a surgical biopsy is required. The digital mid-field mammography unit is presently undergoing initial clinical testing at the University of California, San Diego Center for Women's Health.

Critical Care Monitoring Project

Critical Care Monitoring, this effort will focus on the digital acquisition and analysis of real-time ICU patient monitoring data. Computer algorithms will be developed to analyze this data and to present the data set in meaningful ways to a health practitioner. Techniques for reducing the data sets and transmitting the data through the Internet will be developed and implemented for use in remote monitoring of both military and civilian critical care patients.

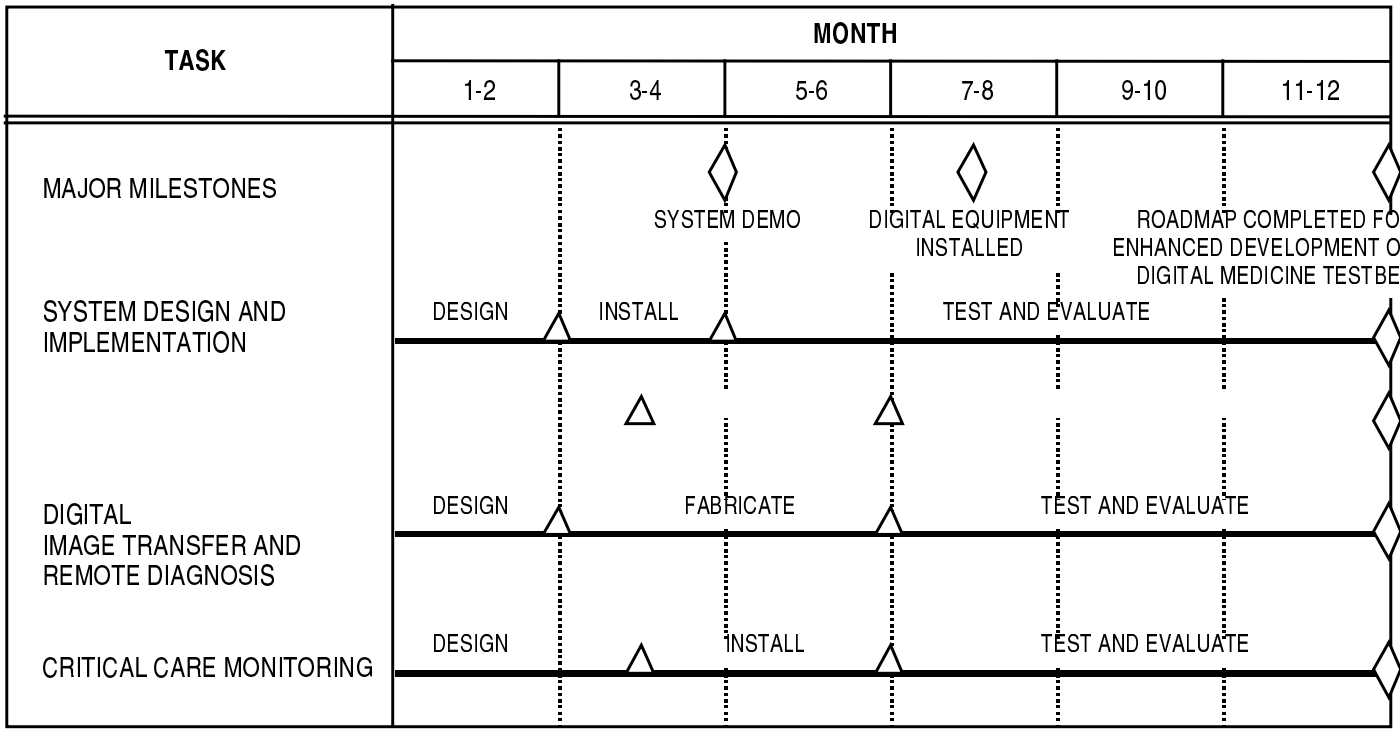
The program will concentrate on critical care patients in ICUs. According to a recent Hewlett-Packard study, 60-70 percent of healthcare corporation costs transpires in acute care settings. Perishable data currently obtained from medical monitors and devices will be analyzed for the purpose of developing associations, patterns, and "states" that can lead to new algorithms capable of predicting trending and analyzing patient outcomes, response to therapy, efficacy of therapy and other to be determined end points. These data will be acquired from standard interface ports. These data will include but not be limited to EKG waveforms, pulse oximetry, end tidal CO2, arterial pressure wave forms, blood pressure, temperature, wedge pressures and cardiac output measurements.

The proposed system of integrated data analysis with high-speed networks will improve the outcome and care of critically ill and or injured individuals in a variety of intensive care settings. Not only will this data supply a detailed record of patient care for accountability and billing purposes; it will provide a profiled assessment of the patient's condition and recovery, enabling practitioners to predict future responses to similar conditions. Over time, comprehensive data analysis will provide trending outcomes, R&D statistics and help to establish more effective treatment protocols. Comprehensive data ensures accurate data analysis and provides effective risk management support. The traditional patient chart is often incomplete and untimely and does not provide for trend analysis or comparison with previous cases. Real time data monitoring reduces variation in treatment. Additionally, access to real time patient data allows physicians to be

directly involved in patient care, regardless of their current location. For difficult cases, computerized data allows instantaneous consultation with specialists. These applications have direct bearing on U.S. military requirements and could lead to improve patient outcomes and reduced costs.

PROPOSED PROJECT TIMELINE (Program Plan and Schedule)

The Remote Access to Medical Specialists program is a one year effort as outlined below: 1) development of the RAMS network system, 2) demonstration and validation of a digital radiography/mammography prototype device, and 3) development of critical care monitoring project.



PERFORMANCE OBJECTIVES AND DELIVERABLES

1. Refine, demonstrate and validate a prototypical radiographic system that is portable and deployable and has capability for transmission of digital images for remote diagnosis.
2. Refine, demonstrate and validate a prototypical digital mid-field mammography unit that is currently undergoing clinical testing at the University of California, San Diego Center for Women's Health.
3. Document diagnostic standard for mammography digital images; acceptability of acquired digital images compared to identified diagnostic standards; acceptable imaging hardware standards to determine the minimum mammography imaging capability
4. Prototype interoperability tool for data transmission in support of remote provider and a critical care specialist.

5. Document a system architecture design that addresses image acquisition, manipulation and retrieval and migration into DOD enterprise systems, (e.g., CHCSII, G-CPR, CEIS, TMIP).