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PRINCIPAL INVESTIGATOR: Kenneth W. Lucas, MS

CONTRACTING ORGANIZATION:

Visual Telecommunications Network, Inc. (ViTel Net)
8210 Greensboro Drive, Suite 820
McLean, Virginia 22102

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Kenneth W Lucas (deceased)
Allen A. Izadpanah

E-Mail: Allen@vitelnet.com

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14. ABSTRACT
The emerging nature of telemedicine is an environment in which health care providers seek to share a vast array of medical information which is captured, disseminated, and displayed in a variety of modalities ranging from email to high resolution imagery and real-time video teleconferencing. In theory clinicians should be able to select and use the information modalities and electronic medical record systems they prefer, with the technical systems integration issues of information discourse among disparate sources being transparent. The overall research and development goals of the Secure Wireless Military Healthcare Telemedicine Enterprise System research effort is to evaluate the use of ViTel Net's commercial-off-the-shelf (COTS) telemedicine integration tools and platform for rapidly configuring and dynamically integrating disparate medical teleconsultation systems, medical information and image display modalities, and electronic medical records systems. These tools span the continuum of the Defense Health System from the foxhole to the medical center in a secure environment.

15. SUBJECT TERMS
Tele-medicine; Hospital Information System, Medical Informatics, Point of Care, Centric Specific Data Collection, HL7 Interface Engine

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INTRODUCTION:

This Final Report spans the period from 1SEP02 to 30JUN08 and reports results from multiple years of Congressional Special Interest appropriation funding. Details regarding research hypotheses, SOWs, methods, study designs, and outcomes for each period of performance can be found in submitted Annual Reports.

The emerging nature of telemedicine is an environment in which health care providers seek to share a vast array of medical information that is captured, disseminated and displayed in a variety of modalities ranging from email to high resolution imagery and real-time video teleconferencing. In theory clinicians should be able to select and use whatever information modalities and whatever electronic medical record systems they prefer – with the technical systems integration issues of information discourse among disparate sources being transparent. This research was undertaken to explore and test one approach for turning this theory into reality.

The initial concept for the research plan was that each task, although related, would be able to be performed as individual tasks. As the execution of the plan began we quickly realized that several factors, described below, were impacting the planned approach making it difficult to execute and limiting productivity. First, many of the tasks were dependent upon the availability and access to the military' s legacy and emerging health information systems, access to clinical areas within selected military facilities, and access to point-of-care medical personnel at various points across the military's operational health care continuum. Second, it became evident that we needed to continuously adapt to the dynamics of technological changes occurring both in the biomedical and information technology fields. Third, through experience we learned that the most appropriate and productive means of accomplishing the tasks was to identify specific meaningful projects in which there was support either within a military or civilian healthcare facility that would involve the performance application of task objectives and goals and at the same time provide a means for testing and evaluation. These factors led us to the adoption of a research approach that was responsive to project opportunities within the general context of the research design and that insured timely and productive task accomplishments.

This revised approach enabled ViTel Net to apply planned research methodologies – including computer modeling and simulation – followed by prototype development and bench testing. Following successful bench testing, the next step was to attempt to interject the prototype into a "live" environment and integrate it with existing medical informatics systems for data retrieval and input process testing. The final step – where possible and allowable – was the introduction of the integrated device into field and clinical settings for testing and evaluation.

The research and development methodology that served to guide the project was a four-step process, as follows:

- **<u>Step 1: Concept Formulation</u>** - During this period effort was devoted to defining requirements, conducting preliminary analysis, developing the initial problem solution approach, and formulation of the design concept.

- **<u>Step 2: Laboratory Development</u>** - Work during this period was focused on the design and building of prototype models, prototype testing within a "sterile" laboratory environment, and refining the prototype model based upon the results of the laboratory test.
- **<u>Step 3: Field Application</u>** - Prototype models were subjected to field applications where limited tests were conducted. Results of the tests were applied and compared with the design objectives, and necessary engineering and design modifications were applied to the prototype design.
- **<u>Step 4: Clinical Demonstrations</u>** - Targeted clinical demonstrations were conducted within a controlled environment to enable a more robust comparison with stated objectives and actual outcomes as well as user adaptation. These results were intended to enable the final engineering changes in preparation of clinical trials.

The primary goal of this multi-year research effort was to determine whether a commercial-off-the-shelf (COTS) telemedicine integration tool (“solution”) could allow health care providers to share a vast array of medical information across the continuum of the Defense Health System, while enabling them to select and use whatever information modalities and whatever electronic medical record systems they prefer. Critical to the integration process is the maintenance of security requirements while operating across the spectrum of communications systems supporting the Medical Operational Continuum from the front-line Medic to the fixed facility Medical Centers.

The primary objective of the research evolved as milestones were achieved. Initially, the focus was to **integrate** ViTel Net's telemedicine COTS integration solutions to existing DoD legacy and developing healthcare information systems, clinical repositories, and knowledge base systems for application at the point of care. After successfully integrating these tools, the objective was then to **evaluate** ViTel Net's telemedicine COTS integration solutions – spanning the continuum of the Defense Health System from the foxhole to the medical center in a secure environment – for rapidly configuring and dynamically integrating disparate medical teleconsultation systems, medical information and image display modalities, and electronic medical records systems. In the final years of the research effort, the primary objective was to **demonstrate the effectiveness** of the use of ViTel Net's telemedicine COTS integration solutions to integrate COTS medical devices and to configure and deploy applications across platform systems, inclusive of computer based systems, handheld wireless PDA devices, and miniature computers.

While there were technically oriented integration tasks in each year of the research, the nature of the additional tasks changed to support the evolution of the objectives over the course of the research effort. Thus, in the early years there was emphasis on identifying requirements, integrating with general medical systems and point of care devices for both data and images, and demonstration of security capabilities. Later tasks were added that had more specific deliverables such as to perform the research in civilian settings and to plan and demonstrate connectivity among systems located in both in the civilian and federal sectors. The final years of the research effort included tasks for developing and demonstrating laboratory prototypes of an enhanced Centric Specific Data Collection Instrument to connect with COTS medical devices; using ViTel Net's telemedicine COTS integration solution to integrate with specific COTS products and to provide the flexible user interfaces and workflow support for the Centric Specific Instrument and for a prototype wound management kit; and developing clinical protocols, treatment procedures, and decision aid tools for wound care and non-wound care.

This Final Report addresses each of the specific overarching tasks and describes, by task, the concept, research approach, integration and development activities, and results of implementation and evaluation. The list of specific tasks associated with each funding year of the research and the mapping between these 33 tasks and the 15 overarching tasks is shown in the Appendix.

KEYWORDS:

Tele-medicine; Hospital Information System, Medical Informatics, Point of Care, Centric Specific Data Collection, HL7 Interface Engine

BODY:

Task 1: Demonstrate that a COTS medical information system tool (MedVizer™) facilitates rapid integration and implementation of teleconsultation systems within military treatment facilities.

As noted in the introduction, the primary objective throughout this research effort was to integrate and then demonstrate that a telemedicine COTS integration solution would be a major contribution to the development, deployment, and implementation of effective telemedicine systems by providing the ability to rapidly configure and dynamically integrate disparate medical teleconsultation systems, medical information and image display modalities, and electronic medical records systems that span the continuum of the Defense Health System from the foxhole to the Medical Treatment Facilities (MTFs). Use of such a solution made it possible for us to rapidly develop, test, prototype, and enhance telemedicine systems and solutions through an iterative process.

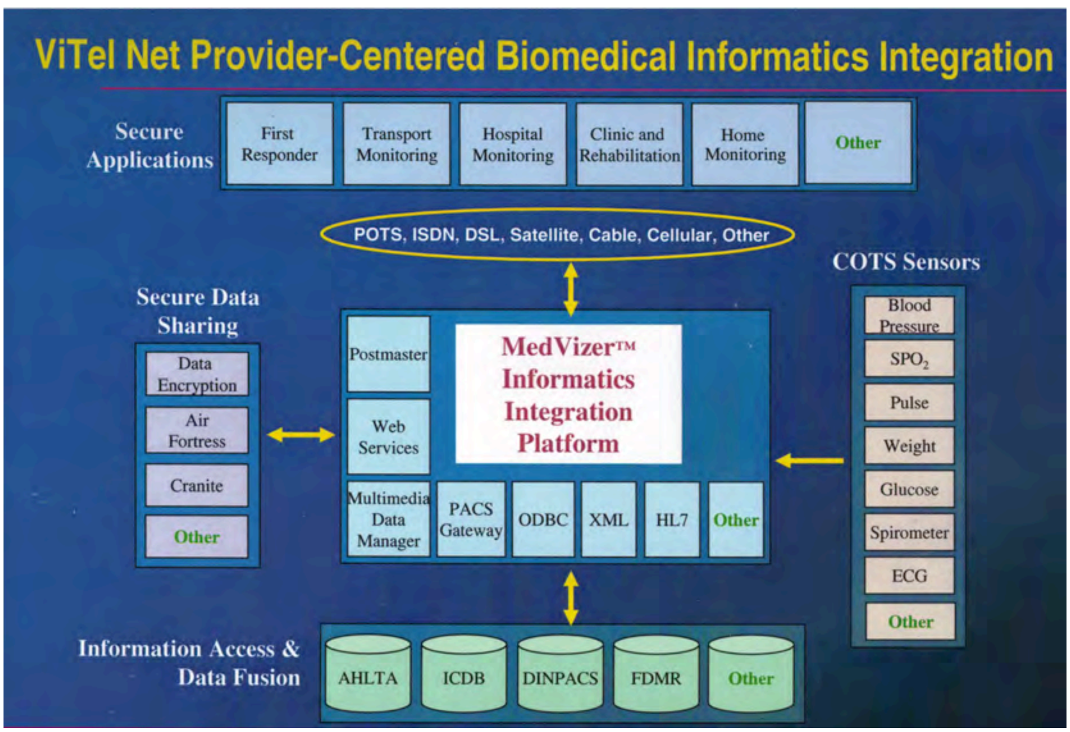
This task provided the technical resources and the underlying informatics architecture for most of the other tasks (described below) undertaken during this research – specifically those tasks involving either integration with other health IT systems or the delivery of software to support the clinical workflow necessary to use a wide range of telemedicine systems across the continuum of care.

ViTel Net began the research effort by using its **MedVizer Dvision Tools** – a COTS telemedicine integration tool that was originally developed for use on the Microsoft DOS – plus some additional MedVizer Tools to perform the device and systems integrations as well as the modeling of user (clinician or patient) interfaces and workflows and of the patient record structure.

By the second year of the research effort, the MedVizer Dvision Tools and additional MedVizer tools were redefined and expanded into the more comprehensive, COTS-based **MedVizer Informatics Integration Platform (MIIP)** consisting of a core set of functionalities that enable the rapid integration of medical information systems, medical sensoring devices, medical imaging devices, and secure data devices that are used across the operationally defined continuum of care. The MIIP provided the tools necessary for the seamless integration of systems that is essential to facilitate rapid response to healthcare needs by optimizing the interaction of patient to physician and physician-to-physician.

Because of the range of technologies that were integrated, there were times over the course of this research that the MedVizer Dvision Tools was used in addition to the MIIP. **For simplicity in this report, we will use the term "MIIP" to describe the COTS solutions used to facilitate integration and rapid configuration of user interfaces and workflows, rather than differentiating between whether the work was done using MedVizer Dvision Tools, other MedVizer tools, or the MIIP itself.**

The following graphic shows the MIIP:



Task #1 was successfully demonstrated on multiple occasions during this research by the ability of the MIIP to provide the functionality required to support the wide variety of tasks described in the rest of this report. The MIIP was successfully used to rapidly configure and dynamically integrate disparate medical teleconsultation systems, medical information and image display modalities, and electronic medical records systems that spanned the continuum of the Defense

Health System from the foxhole to the Medical Treatment Facilities (MTFs). This capability was demonstrated for configuring both wired and wireless teleconsultation systems from both emerging and legacy Department of Defense health informatics systems without investing in additional conventional programming or costly systems integration efforts.

Task 2: Identify, evaluate, and finalize health care provider's patient and clinical information, and data entry requirements originating at the point of care.

It was assumed that the patient information required by the medical professional at the point of care and the type of entries that would be placed into the patient's record would be specific to, and different at, each level of care, therefore three levels of medical care were assessed. The first assessment was of a neurology inpatient ward; the second assessment was within an outpatient continuous care environment where patients were being treated remotely using telemedicine technology; and the third was of an outpatient intake process within a clinical setting. As expected, the clinical information requirements were different at each level, with the most specific and complex requirements being within the inpatient neurology ward application. Although the differences in requirements were significant, it was found that there were some similarities in the acquisition of a patient's condition, specifically in the area of vital signs monitoring. In general, however, it was found that not only were the data entry requirements substantially different but that the method of entry of that data into a patient's record, in terms of responsibility, differed for each of the assessed areas. Within the neurology ward, multiple professional health care providers – primarily attending physicians and ward staff members – executed all data entries. For the outpatient continuous care scenario, both the attending nurse and the patient required the capability to make data entries into the record. And in the patient intake scenario, all data entries were made solely by the patient. In each scenario the participants all desired, where feasible, that entries should be made electronically without need of direct manual data entry, believing such a process would result in a reduction of data entry errors.

First Level of Care

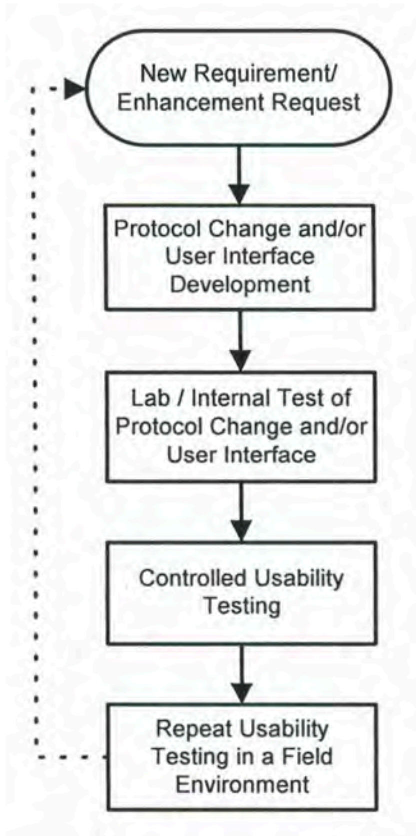
Following initial investigation and planning, the first subtask – assessing the patient information requirements at the level of care on an neurology inpatient ward – was placed on hold due to the need to gain permission to access the legacy information systems and use of wireless technology within the Walter Reed Army Medical Center (WRAMC). Execution of this project required the use of both wired and wireless technology for data entry and the ability to directly access several modules of the hospital information system. The complexity of this effort coupled with the time required to obtain all necessary approvals to proceed resulted in placing the project on hold while seeking appropriate authorizations. Because such authorizations were never received, the functionalities that were to be assessed through this subtask were accomplished through successful demonstration of similar applications on a smaller scale during the other subtasks.

Second Level of Care

The second level of care assessment – continuous care of patients on an outpatient basis – was a rapidly growing need within both the public and private health care sectors, and it fit well in a more controlled environment. This application required the ability to access a patient record from a database, update data entries using remote telemedicine technology, and interaction between the patient and health care clinician using audio and video technology. To be practical and available to a large population, the goal was to integrate ViTel Net's low bandwidth technology, which would enable the objectives to be accomplished using standard plain old telephone (POTS) circuit. The technology used in such an environment had to be very user friendly considering the range of technology awareness exhibited by the patient population. The initial assessment demonstrated that some patients were quite capable of performing multiple functions and were quite comfortable with the use of the technology, while others were incapable of doing much more than following basic instructions and responding verbally to the healthcare provider. Interviews were conducted with healthcare providers attending continuous care patients involving daily face-to-face home visits by the clinician to formulate the information and data entry requirements. The basic requirement was to develop and maintain a longitudinal record of a patient that would reveal vital signs (blood pressure, pulse, oxygenation, and temperature), weight, blood glucose, and heart lung sounds (wave forms) over time. The patient record also needed to have a means whereby a detailed registry of medication and changes in medication including dosage rates and begin and end date for each change order.

We identified additional information considered beneficial to quality healthcare to include the maintenance of a longitudinal accounting of the patient's daily condition, which needed to be acquired by both visual observations and the patient 's response to specific health related questions. Ideally, we wanted the patient to respond to specific questions by responding online electronically; however, an alternative means was used whereby the clinician, using verbal cues, acquired the information needed to complete the daily questionnaire. In essence to meet the requirements the system needed to able to collect the same amount and detail of information remotely that was routinely collected using the traditional daily home visit by a health care provider. The primary objective was to enable a health care provider to perform all functions remotely including the maintenance of a longitudinal multimedia record for each patient. An additional desired objective was to have the capability of distributing the multimedia patient information to the patient's attending physician for review and possible consultation. The overriding objective was to enable the health care provider to provide equal or better delivery of healthcare to the patient compared to the traditional in person methodology. We believed that using the technological approach for providing home health services would result in a reduction of data entry errors occurring during the traditional manual transcription process.

Having completed the requirements assessment, the workflow and prototype patient record was initially modeled using the MIIP. The model design and prototype was provided to the same health care providers who participated in the initial assessment for their review and comment. Based upon comments received, final revisions were completed. ViTel Net conducted a variety of usability studies to provide ongoing product improvement using the standard methodology summarized in the following diagram:



A usability study conducted in a controlled lab environment provided usability feedback for systems created with the MIIP. The purpose of the study was to evaluate point of care patient data collection and transfer process using an in-home health monitoring unit with multiple sensors and an interface unit. The study evaluated the process using errors as an indicator of process performance. The data collection and transfer process began with the patient using medical devices that are integrated with the home unit to collect physiologic data. The process ended when the data was successfully transferred to the central database on the ViTel Net server. The success of the data collection and transfer process was verified by viewing the data on the server using the Care Coordinator application, used by the clinical Care Coordinator responsible to monitor a panel of patients.

Five volunteer patients were recruited to participate in the study. Demographics of this patient population were consistent with those of the types of targeted users of the monitoring unit. Each patient was given instruction and a demonstration on how to use the medical devices and a home monitoring prototype unit (“In Touch”), and then given the opportunity to practice the entire process before the evaluation started.

Patients were told that the focus of the study was to evaluate the technology, not the patient's performance. The evaluator explained that during the process, she would be recording any difficulties or errors that the patient experienced with the technology. Once the volunteer patient said that they understood the tasks they were being asked to perform, the evaluation process began.

During the process the evaluator observed and documented any errors that occurred with the technology in the data collection and transfer process. Once the data was transferred from the In Touch unit, the evaluator verified the successful transfer to the ViTel Net server by accessing and reviewing the patient record using the Care Coordinator software and verifying that all of the data was transferred into the centralized record accurately.

Third Level of Care

The third level of care assessment involved an outpatient intake process within a clinical setting. The OB-GYN Clinic at Walter Reed Army Medical Center (WRAMC), seeking to reduce the time and cost involved in intake interviews for their outpatient service, provided this third opportunity to address data collection and data entry requirements at a different level of care. The goal of the process was to eliminate the traditional labor-intensive method of obtaining patient information and of the manual data entry into the hospital information system. The approach used was to replace the current process with an automated patient registration and intake interview process using wired and wireless technology. It was determined that an integrated system must provide the means whereby a patient can automatically access their record, update the record with their current vital signs (blood pressure, pulse, temperature and weight), and complete an intake questionnaire describing current physical condition without any intervention by hospital personnel. The system had to enable the patient 's record to be immediately updated within the legacy hospital information (Composite Health Care System I [CHCS-I]) using an ICDB interface, since that is the record that an attending physician would review prior to seeing the patient. The transfer of data from the intake station to the CHCS-I database had to occur in real-time.

This work accomplished the following objectives:

- Evaluated the efficacy of patients' participation in the capture and charting of vital signs and health outcomes assessments.
- Automated the check-in and registration functions, freeing up medical staff to provide better medical care.
- Leveraged legacy systems by extending their ability to control vital sign devices, while automatically collecting this information without human intervention.
- Evaluated medical devices and protocols that could be utilized by patients to provide valuable information in the care delivery process.

The work was conducted in two phases to accommodate the clinical process and to insure interoperability with the legacy HIS systems. We used our suite of tools in the MIIP, which enabled us to rapidly develop, test, prototype, and enhance solutions through an iterative process.

The initial phase involved:

1) Assessing the vital sign data sets that needed to be electronically entered into the patient record
2) Using the MIIP to build an XML interface to the ICDB

3) Implementing a transaction bridge from the ICDB interface to CHCS-I

The second phase involved:

1) Integration of the electronic registration.
2) Integration of the patient intake questionnaire to be developed using the MIIP
3) Integration of the data to the patient record contained in CHCS-I.

The work was accomplished through sequential tasks across multiple years. To insure full compliance with existing hospital technology each phase was developed in accordance with the model referenced above and tested within the clinical setting prior to implementation of the next phase.

During Phase 1 patient identification information was manually entered and sent to the ICDB Healthy Forces database to retrieve or gain access to the patient record. In the event it was a new patient, a new record was created using the system. Patients updated their record by using the electronic vital signs monitor. The acquired data, without further intervention, was transmitted to the patient record residing in the ICDB database. ViTel Net, with this conceptual framework, completed the model design for the user interface and technology workflow. Using the MIIP, an XML interface to the ICDB was developed to enable the transaction for updating the patient record in the legacy hospital information system. A demonstration was conducted including the retrieving of a patient record, adding current data and sending it to ICDB through the XML interface to populate and update the data base record.

Phase 2 required that the user interface enable the patient, with limited instructions, to use bar code technology to access their record simply by swiping their military identification card. Upon accessing and verifying that their record was correct the patient was able to electronically gather their vital signs, using the electronic vital signs medical device for blood pressure, pulse and temperature, the results were then automatically updated in the patient's record. The patient then stepped on the electronic scale; those results were automatically updated in the record. Upon verifying that all fields had been completed the patient exited their record, which cleared the system of all data. Upon exiting the system, it automatically updated that patient's record in the ICDB Healthy Forces. The record was immediately available for review by the attending physician with all data updates.

The user interface and instructions were evaluated for ease of use prior to submission to the WRAMC project personnel for comment and approval. Concurrently, ViTel Net's engineers and WRAMC information technology team assigned to the project exchanged necessary data to enable the integration of the XML interface to the ICDB for accessing patient records stored in that legacy hospital information system. This interface was tested in a laboratory environment using a simulated ICDB database provided by WRAMC.

1) The patient swiped their military identification card using ViTel Net's integrated card reader technology that automatically initiates a transaction to retrieve or gain access to their record. In the event it was a new patient, a new record was created using the system.

2) Patient intake questionnaire was developed in coordination with the clinical medical staff. The questionnaire was integrated into the intake process user interface using the MIIP. The questionnaire was developed to provide the user a choice of responses using a response tree format for example, do you drink alcohol? If the answer is yes the system automatically asks the next question concerning number of drinks and type of alcoholic beverage. If the answer was no, the system automatically took the patient to the next question. This approach was tested with the MedVizer database. The question response format was modified based upon medical clinic review and re-tested.
3) Integration of the questionnaire with ICDB Healthy Forces using an XML was developed using the MIIP. At this point it was determined that Healthy Forces did not contain all the fields corresponding to the questionnaire and therefore the transaction could not be completed. The questionnaire was modified to contain only those questions that corresponded to those in Health Forces. With this modification the patient questionnaire data was successfully transferred to ICDB Health Forces using the XML interface.

The design configuration and work plan for implementation of the OB-GYN Outpatient Clinic, Walter Reed Army Medical Center (WRAMC), was completed and agreed upon by all participating WRAMC agencies/departments. However, the plan was never implemented due to the inability to secure the necessary authorizations at WRAMC.

In a parallel process ViTel Net completed the integration of a prototype system following the phase 1 design. The prototype system, due to the ongoing effort by WRAMC to obtain necessary authorization for interface to the legacy hospital information systems (ICDB and CHCS-I), used a simulated patient database. During the preliminary testing of the prototype it was determined that a wireless (802.11 b) security system would need to be integrated prior to implementation at WRAMC. As a result, an additional Task "Demonstrate interoperability of ViTel Net' s Wireless MedVizer Telemedicine Products with the Fortress Technology's Air Fortress 802.11 b security system" was advanced. Interoperability testing was completed with the Air Fortress 802.11b security system in a laboratory environment with a variety of MedVizer telemedicine products.

Although ViTel Net had demonstrated the interoperability of MedVizer products and the MIIP with the Army Medical Material Command accepted system, Air Fortress, it turned out that WRAMC used the Cranite security system. Because ViTel Net was field testing at WRAMC, ViTel Net performed the same security and interoperability tests with the Cranite security system and demonstrated the interoperability of MedVizer products and the MIIP with Cranite as well.

There were no compatibility issues identified in the testing environment. The test did not, however, evaluate the level of security afforded by the Air Fortress technology but rather demonstrated interoperability between that system and MedVizer products. The test environment validated full compatibility without any degradation in quality of performance of the MedVizer products. The prototype system, tested at ViTel Net, included the Air Fortress security technology.

Task 3: Identify and evaluate commercial off-the-shelf (COTS) medical informatics knowledge-based systems pertaining to clinical requirements.

Using the Internet as the search engine, a number of medical knowledge databases were identified for possible application within a clinical setting. Many of the initial knowledge bases reviewed, however, were limited in application to the Palm hand held device using the OS operating system and thus failed to meet the requisite criteria for operating cross platforms that would be found within a clinical setting. Due to the limited number of such knowledge databases extant at the time, we deferred further investigation until the availability of such systems evolved which would enable a more comprehensive comparative analysis of potentially usable systems. We did, however, complete an assessment of a Microsoft Windows knowledge-based system developed by a Norwegian partner for a separate USAMRMC contract. This knowledge base was evaluated and tested as a proof of concept for compatibility with the MedVizer telemedicine products and interoperability across multiple platforms. The database proved compatible and capable of operating on various Microsoft operating systems to include Windows 95, 98, 2000, and NT. However, additional development was required for full cross platform compatibility, specifically with the CE operating system.

We evaluated a series of commercial off-the-shelf (COTS) medical informatics knowledge-based systems. One such COTS informatics knowledge-based system integrated into the MIIP was the X-Plain.com patient education modules from The Patient Education Institute. ViTel Net evaluated these tutorials, with primary criteria of the modules being easy-to-follow, and that they would "chunk" information into pages covering single concepts and include text, graphics, animations, full narration, and questions with immediate positive feedback. These integrated modules developed by The Patient Education Institute were based on current standards of care and were reviewed by physicians, nurses, and healthcare providers. ViTel Net integrated the X-Plain.com patient education modules into its MedVizer enabled functionality.

Task 4: Integrate point-of-care data collection, medical order entry, and knowledge base acquisition tools with ViTel Net's MedVizer software.

A prototype system integrating the MIIP with commercial off the shelf (COTS) components was completed. The prototype system used the ViTel Net Clinical Call Center to remotely access the patient's home monitoring unit using standard plain old telephone circuits (POTS). Using the MIIP a standard (COTS) Welch Allyn vital signs monitor and a Cardionics (COTS) electronic stethoscope was integrated with a Motion Media Video Phone (COTS) and MedVizer software to form the home unit. The home unit was controlled through ViTel Net's Clinical Call Center unit. This configuration was specifically designed to limit the amount of interaction required by the patient. The patient was required only to properly place the medical device (i.e., blood pressure cuff) following the guidance given by the clinical call center operator. The clinical call center operator was able to observe the patient's placement of the medical sensor device and direct necessary adjustments to insure accurate readings. Once properly placed the clinical call center operator activated the medical sensor device to obtain the output readings. ViTel Net' s clinical call center, using the MIIP, was configured to receive the data directly from the medical device without further patient intervention. The system was also designed to enable the clinician to review current medication dosages and enter changes to medications.

A patient questionnaire was also designed that was completed directly by the patient and automatically transmitted to the clinical call center or completed by the clinician based on questions asked of the patient. The questionnaire was used to assess the current condition of the patient. The data at the clinical call center was maintained in a longitudinal format to enable viewing of patient conditions over time. The clinical call center had the capability to forward patient data to the attending physician for review and consultation as needed. The system underwent a prototype evaluation in a beta test environment at the Medical University of South Carolina.

Task 5: Identify interoperability requirements and demonstrate integration with DoD's legacy and emerging heath care information systems and electronic medical records (Composite Health Care System II [CHCS-II], Field Deployable Medical Record [FDMR], Personal Information Carrier [PIC], and other informatics systems).

In addition to the ongoing work to interface with the ICDB and CHCS-I discussed above ViTel Net, using the MIIP, successfully established connectivity to the following DoD and VA health care information systems:

a. Integration with legacy hospital information systems HIS and electronic medical records systems:
   (1) CHCS-II
   (2) CHCS-II Theater
   (3) FDMR (field version)

b. Integration with medical imaging systems & standards:
   (1) DINPACS
   (2) DIS
   (3) DICOM
   (4) JPEG
   (5) MPEG
   (6) H.323 VIC

c. Integration with portable DoD/VA/Commercial record devices:
   (1) USAMRMC multimedia personal information carrier (PIC)
   (2) DOD CAC card
   (3) Standard bar code strips
   (4) Integration with the Veterans Administration (VA) VISTA HIS system was completed. The VA "home monitoring" program is designed to enable home bound patient, using the ViTel Net Turtle Product to acquire vital sign information and to respond to a series of questions concerning the status of

their health condition. The data was transmitted using standard telephone lines to the MedVizer PostMaster Database Server located at the VA National Center. The data was received, processed and the patient record updated with the current information. The respective VISN clinical team accesses the MedVizer central database using a web browser interface. ViTel Net developed the HL7 interface to enable the data received by the MedVizer PostMaster database to be forwarded to the VA VISTA database.

(5) Integration with Commercial Hospital Information Systems: HL7 interface was developed using the MIIP with two commercial HIS systems, Cerner Beyond Now, Nemours EPIC. Both interfaces were completed.

(6) Integration with the Centric Specific Data Collection Instrument as an example of a telemedicine system that could be used by First Responders.

The integration was demonstrated during a briefing to staff from TATRC held at ViTel Net's Virginia office. The presentation demonstrated integration with ViTel Net's Wireless MedVizer Telemedicine Systems to achieve interoperability with DoD's legacy and emerging Hospital Information Systems and electronic medical records. ViTel Net also demonstrated the capability to acquire patient data from DOD HIS system and transfer data to VA for access and merging with the VISTA patient record, where the record was viewable on the MedVizer screen of the VistA workstation.

Task 6: Identify scalability requirements for cross platform interoperability inclusive of hand-held PC (CE) based PDA through Windows NT operating systems.

In support of the execution of this task, a laboratory was established at both WRAMC Telemedicine Directorate and ViTel Net for use in demonstrating and testing the MIIP used in cross platform applications running on hand-held PC (CE) based PDA devices using the Microsoft Windows operating systems in both a wired and wireless environment.

The applications developed through this research were tested in both laboratories with all platforms, and the scalability function of the MIIP was successfully demonstrated.

Task 7: Integrate point-of-care data collection, medical order entry, and knowledge acquisition tools with ViTel Net' s MedVizer Physician Personal Assistant in a wireless distributed computing environment for military and commercial applications.

The MIIP was used to demonstrate interoperability with:

a. Wireless access to and transmission of medical information via IP/internet
b. 802.1lB wireless networks
c. Air Fortress Security Device
d. 128 Bit Encryption System

The MIIP also enabled the successful integration with related USAMRMC research and Congressionally directed projects:

a. Heads up Laser Retina Display (Microvision)
b. Voice capable PDA (PLI)

The MIIP was successfully used to demonstrate automatic input and integration of physiological data from the following medical instruments and sensors:

a. Standard medical scopes & instrumentation devices

    (1) Vital Signs Monitor
    (2) Electronic Stethoscopes
    (3) Electronic Weight Scale
    (4) Micro camera and Endoscopic Devices
    (5) Inter-oral camera device
    (6) Fundus camera device
    (7) ECG - 12 lead interpretive and 3 lead
    (8) Microscopes
    (9) X-Ray Film Digitizers

b. PCMIA card-based input devices

    (10) Skin 02
    (11) Respirations
    (12) Glucose
    (13) Spirometer
    (14) Temperature

A task to integrate the Sustained Unit Monitoring System (SUMS) Sensor Device with the Navy's Mobile Integrated Diagnostic and Data Analysis System (MIDDAS) Data Acquisition Glove (DAG) – a point of care device used to obtain vital signs during initial triage – was unsuccessful. Not only did the relationship with L-3 Communications Holdings not materialize in time to enable integration work but also the SUMS prototype device failed initial stand-alone testing. Additional work on the SUMS device was recommended for future funding if the L-3 Com relationship can be established.

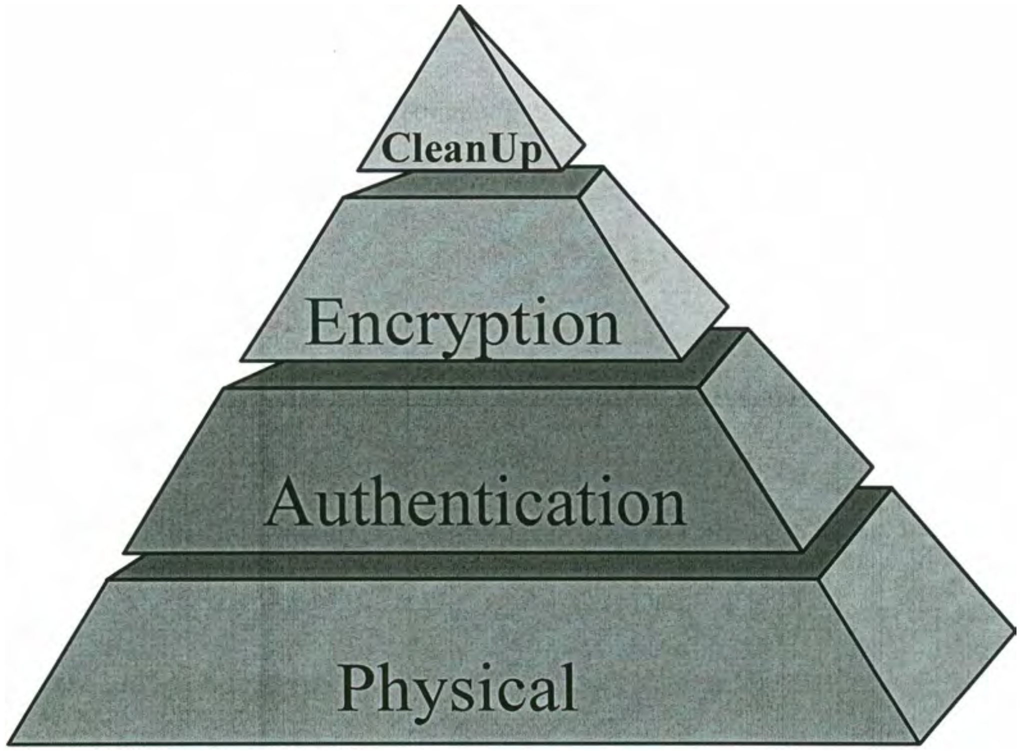
Task 8: Proof of concept: (a) limited fielding prototype system in military and commercial hospital and (b) testing and evaluation.

A proof of concept demonstration was conducted at the Telemedicine and Advanced Technology Research Center (TATRC). This demonstration was conducted during a review of the Combat Support Hospital (CSH) by the Commanding General, USAMRMC and TATRC officials. The demonstration involved using the MedVizer products and tools to enable following the flow of the patient through the field hospital. The MedVizer hand held PDA (CE) was used to create a search capability of the existing database for the patient's record and or to create a new record. The PDA was integrated to access patient identification from either the PIC or military medical card using a card scanner. A query was sent wirelessly to the MedVizer Postmaster. Upon receipt the MedVizer Postmaster automatically queried the CHCS-II hospital information system to search and present the patient record. If no record was found a new record was created using the PDA in a format compatible with CHCS-II. Then, as the simulated patient was processed through the CSH, additional data was continuously added to the record by acquiring information from multiple sources to include DINPACS, TOPCON fundus camera, and CHSCII. Healthcare providers at various stages within the CSH, used similar MedVizer wireless hand-held PDAs to access the continuously updated patient record and for additional data entry.

Task 9: Integrate ViTel Net's MedVizer Telemedicine Systems, to include the Medical Personal Digital Assistant (MPDA), with security protocols (HIPAA, digital certificates, elliptic curve encryption)

The MIIP provided an effective security architecture combining an authentication/ privilege access model, windows application policies, data secure in transmission, data secure at rest, and WatchDog tools for auto logoff and data cleanup. The diagram on the next page shows ViTel Net's four-tier security model.

ViTel Net's four-tier security model



ViTel Net identified the following security tollgates:

Identification

The MIIP used authentication to combine identification with personal knowledge (password/pin) providing a very effective means for securing equipment, application access, and data.

ViTel Net's MIIP was evaluated and successfully provided the following methods of identification:

- Military ID Personal Information Carrier.
- PIC with access policies - ViTel Net investigated a wide variety of flash disks, USB memory keys of varying capacity to be used as transport devices for the PIC. We successfully placed our encrypted medical record on each PIC device tested.
- Unique PIN/ Password Linked to access controls.

Acquisition

ViTel Net' s MIIP was evaluated and successfully provided security for the following types of data:

- Audio
- Vital Signs
- NIBP, SP0 2, Pulse, Temperature, Blood Glucose, ECG, Weight
- Multimedia
- X-Ray, Ultrasound, Echocardiograph, Etc.

The following methods of secure data transmission were tested. Applications developed with the MIIP provided effective security across the following methods:

- Wireless (Bluetooth, 802.11b)
- Wired
- Continuous data streams
- Timed / event driven data transmission

During our integration activities, we identified some difficulties resulting from the testing of sensor acquisition methods. These difficulties included the following:

- Devices can easily lose their Bluetooth connection
- Bluetooth devices can easily lose their configuration settings
- Bluetooth devices cannot be easily transferred from one processor to another
- Wired sensors can create a cable management problem

Some best practices learned from our integration activities include the following:

- Data acquisition and distribution frequency must remain flexible
- Integration of sensor data with video data is the best method of ensuring patient data integration
- Abnormality Alerting is required in a data rich health monitoring environment

Medical Record Distribution

The following mechanisms of secure data transmission of were tested. Applications developed with the MIIP provided effective security across the following mechanisms:

- Personal Information Carrier - PIC
- Secure Message Basket
- Secure XML

Integration/Fusion

The MIIP provided effective security when integrating with the following databases:

- CHCS-II / ICDB (Oracle)
- DINPACS -DICOM 3.0
- ODBC

Collaborative Methods

The MIIP provided effective security when used with the following collaborative methods:

- -Interactive Multimedia Conferencing
- -Store and Forward Multimedia Conferencing
- -Continuous Monitoring with Real-Time Data Overlay

Physical security for ViTel Net applications (to include the Medical Personal Digital Assistant) was accomplished using policies and cyberkeys. Authentication combined identification with personal knowledge (password/pin) providing a very effective means for securing equipment, application, and data.

Task 10: Applications for Homeland Defense (Needs Analysis)

ViTel Net – in coordination with Walker Baptist Hospital (Jasper, AL) and the Jasper, AL emergency response team – developed a concept plan for implementing a telemedicine program that would contribute to the delivery of healthcare on a daily basis for Jasper residents. The design had to have the capability to be rapidly re-configured and be integrated with the Jasper emergency response team in the event of a mass casualty event, resulting from either natural or man-made events. The design also had to have an interface with the DoD legacy HIS, CHCS-II or ICDB - Healthy Forces. Several phases were involved in this work.

Phase 1: A series of meetings were conducted with representatives of the hospital and the community emergency response team to gain understanding of current workflow and relationships, communication infrastructure and compatibility among agencies, and the type of telemedicine systems that were needed by each agency.

Within the community emergency response team and hospital there was no common communications infrastructure other than the standard telephone. Several alternatives were considered to address this issue. It was determined that the by establishing a central database using the MedVizer PostMaster Database configuration, all data from each agency, in reference to a person or location, could be collected using various data gathering instruments. The data would be available to each agency by accessing the database through DSL connection.

It was also agreed that four telemedicine applications were needed. First a small compact unit for use by the first responder was needed to gather patient/location information and to obtain vital sign information at the point of casualty and to transmit that data wirelessly to the MedVizer PostMaster Database. Emergency medical and fire department personnel would use this First Responder system (MedVizer First Responder System).

The second requirement was for a capability that would enable continued transmission of data during the evacuation process. This device would be designed for mounting in an ambulance and in air evacuation vehicles. The system would enable the medical team to continue to monitor the patient and transmit data to the central database. The addition of voice annotation and still image capture was to be included in this configuration (MedVizer Mobile Transport System).

Since patients would be evacuated to the nearest medical facility, local hospitals and medical centers, a third system was needed that would enable connectivity to the larger regional hospital and other tertiary hospitals within the Baptist Hospital Group. This system would be used primarily in the emergency room of these facilities with connectivity to trauma specialist at other locations. The system would be specifically designed for Trauma applications and would have access to the central database, provide means for continuous monitoring of vital signs and integrated live video connectivity. It was also believed that, in a mass casualty event, schools, churches, recreation centers and other public facilities might be used as patient collection points (MedVizer Trauma System).

A fourth system for use in patient collection centers was needed. The system had to be small compact and enable the collection of vital sign data, still image transfer, voice and graphic annotation on images, and interactive video conferencing. This system had to be adaptable to available communication circuits to include standard telephone circuits (POTS), DSL, and cable (ViTelCare™ Monitoring System).

Phase 2: ViTel Net and SINTEF (a collaborator on a related TATRC-managed award) developed the First Responder and the Evacuation Telemedicine products. These two products were not developed as a part of the DAMD 17-01-2-0048 award but were, however, used to demonstrate capabilities and products to Walker Baptist Hospital and the community emergency response team and are thus included in this report.

ViTel Net leveraged previous work and the integration capabilities of the MIIP to develop and integrate the other two products, the Community Emergency Collection Center and the Trauma Specialist in local and regional hospitals. ViTel Net's suite of products was employed to enable trauma specialist to immediately become involved in monitoring the patient's condition and directing treatment from the point of incident or casualty through the evacuation process to the trauma center and beyond. These products were developed for use to provide early intervention by trauma specialist from the point of recovery through the evacuation process. Specialized intervention beginning at the time the medic encounters the casualty enhanced stabilization of the patient and enabled the trauma team to be prepared to appropriately treat the patient upon arrival at the trauma center. Trauma specialists at tertiary level facilities had the capability to continuously monitor the patient's condition and to provide guidance as the forward trauma team administered emergency care.

MedVizer First Responder System

ViTel Net' s MedVizer First Responder, developed under separate award (as part of the US/Norway award) was designed to allow the medic at the scene to immediately collect, transmit, and disseminate vital patient data and wound images for review by the forward/area trauma team for assessment. The trauma team through a wireless connection with the First Responder guides the procedures necessary to stabilize the patient for evacuation. The First responder system was wirelessly connected to a variety of medical health care sensors for collecting vital information, automatically transmitting the collected data leaving the medic to focus attention to the patient. The two-way wireless communications enabled the trauma center to immediately and directly begin treating the patient and to prepare for treatment upon arrival at the trauma center.

MedVizer Mobile Transport System

The Mobile Transport System, developed under separate award (as part of the US/Norway award) continued the direct involvement of the trauma team through the evacuation process by providing a continuous monitoring capability. Real time video with embedded vital signs monitoring data was continuously wirelessly transmitted to the trauma center. Two-way wireless communications were maintained between the evacuation team and the trauma team throughout the transport process insuring that the trauma team was directly and continuously monitoring and directing the treatment and care of the patient. When high-speed wireless digital communication is available two-way interactive videoconference is used during the period of transport providing the trauma center specialist the ability to view the patient and guide the functions of the emergency evacuation team.

The need for a capability to monitor patients during evacuation set the basic requirement for the development of the Mobile Transport Telemedicine System. When it was learned that the Jasper County Alabama Emergency Response Teams would not be able to participate in the research effort ViTel Net begin to look for other interested partners. ViTel Net having a long established relationship with Driscoll Children's Medical Center located in Texas sought their participation in the development and testing of a mobile transport system. Driscoll services a large geographic area in southern Texas frequently air transporting patients from the remote locations to the main Medical Center for treatment. These transports although typically not conducted under emergency situations require continuous monitoring of the patient during the evacuation period. Initially the requirements for the system was to provide the capability to collect patient vital signs during evacuation, transmit the data to the Medical Center's Emergency Room for evaluation, and audio communication between the ER Specialist and the Evacuation Team. The Driscoll Staff in addition to the capability to transmit vital sign data required a system that would enable the transport team to maintain an assessment record of the patient, record of material used during the transport, and other features unique to their application and organizational work flow.

The transport system was 'beta' tested, using simulated vital sign data using an RF communications link. As a result of the beta test, several needed modifications to the application were identified. Those modifications were completed and the system was evaluated in a simulated environment.

MedVizer Trauma System

The MedVizer Trauma System was designed to enhance the trauma team's capability of forward/regional emergency intervention by providing direct access to tertiary level trauma specialist. The system wirelessly collected patient vital signs data and embedded the data into a live continuous video stream enabling the specialist to monitor the patient's condition as he/she guided the treatment procedures. The trauma specialist had full control of the remote video sources enabling them to obtain the view of the patient and the attending physician and guide the treatment application.

When it became apparent that Walker Baptist Hospital was not in a position to continue to participate by providing clinical advice in the development of the Trauma System, ViTel Net initiated a research effort with the University of Arizona to provide that capability. The University of Arizona provided medical services with a focus on remote rural areas including border communities. Local hospitals within this area had limited staff and virtually no specialization, resulting in the need to transport patients to the University for treatment at an extreme cost to the state. Implementing a remote healthcare delivery system designed specifically for use in the emergency room and enabling local hospitals' ERs to connect directly with a trauma specialist at the University would reduce the number of patient transports. The intervention by the trauma specialist would enable the direction of procedures to better stabilize the patient in preparation for transport of those patients that could not be treated remotely.

The University's Director of Trauma provided general requirements for the design of a Trauma System. Most importantly the system had to be user friendly requiring minimal intervention, provide high quality video and audio, integrate continuous vital sign monitoring, and support far end camera control. With these basic requirements ViTel Net developed a Trauma System that provided continuous video and vital signs monitoring. The design of the system was verified in a demonstration project at the University and a remote hospital in southern Arizona. Although not designed specifically for use in a mass casualty the system could easily be adapted for that application.

ViTelCare Monitoring System

This product was designed and developed for use at a mass casualty collection center. It was a compact system that could be easily moved within the collection center and that enabled the collection of vital sign data, provided text data entry, still image capture, and live interactive video. It allowed for communication across a number of different media. Based on this needs analysis, subsequent work was performed on the development and integration of a Centric Specific Data Collection Instrument, described below in Task 13.

The initial plan to implement a telemedicine program utilizing the systems identified in the needs analysis and developed as a result of that assessment was not fully implemented due internal issues and restrictions that limited their full participation. Walker Baptist Hospital did, however, obtain permission to commit personnel and limited resources for a proof of concept project that was limited to 90 days. The proof of concept project was designed by ViTel Net in coordination with the Hospital staff to engage two aspects of the types of systems envisioned to be needed in support of a Home Land Defense event.

A plan was developed to install a trauma system at a small clinic type hospital within the county that was aligned with Walker Baptist. The intent of this project was to enable Trauma Surgeons and ER Specialist at Walker Baptist Hospital to interact with the medical personnel at the remote clinic in emergency situations. In doing so the specialist would provide appropriate guidance and direction to the remote clinical staff to stabilize the patient in preparation for evacuation. In the event of a mass casualty situation the systems would be used by the specialist to guide the clinical staff in treating and triaging the anticipated large numbers of patients that would be arriving at the clinic for treatment. It was anticipated that the data; vital signs, images, video, textual, and audio, transmitted to the trauma center would be used to identify the cause of the mass casualty event. The information could also be sent to state and local agencies as an alert for the type of symptoms that would indicate possible spreading of the mass casualty causal agent.

The final element of the plan included a three-day demonstration to be conducted during the last week of the pilot project. The purpose of the demonstration was to demonstrate the other products ViTel Net developed in response to those identified during the assessment phase as needed to meet the demands of a mass casualty event. The local emergency response groups and local elected officials, in addition to the hospital staff, were invited to visit at least one day of the demonstration. In addition to the demonstration of the equipment a briefing of the results of the pilot project and conceptual planning in the event of a mass casualty event was to be provided.

Walker Baptist Hospital an affiliate of Baptist Health System was not able to conduct the demonstration project, although all planning and development was completed, as a result of legal issues involving the parent organization, Baptist Health System. The demonstration was however conducted at the Walker Baptist facility.

The plan also included installing a monitoring system at a local elder care facility connected to a care coordination unit within the hospital for use to supplement the on-site staff in caring for the elder patients. In the event of a mass casualty situation it was envisioned that the elder care facility could possibly be a collection center/assembly area expanding the reach of the Walker Baptist staff in treating large numbers of ill personnel. The system would also be used to collect data in an effort to identify and isolate the cause of the mass casualties.

Walker Baptist appointed clinical representatives to work with ViTel Net's clinical staff to develop the workflow, clinical application, and assessment protocols that would be used in the senior resident home pilot project. A prototype system integrating the MIIP with commercial off the shelf (COTS) components, computer technology and medical vital sign sensor dev ices, was completed. It was planned that each patient involved in the pilot program would be issued an identification card; by swiping the card with the integrated card swipe function patient would gain access to their medical record, which was stored at a central site. Patients once gaining access to their record would update their vital sign information and provide response to series of questions related to their health condition. The patient was provided an option, when sending their updated information to the central clinical site, to request a video conference with the clinical staff member or just to send the data. If a video conference was requested the Clinical Call Center would be alerted and would establish the call to the patient. The communications between the two sites was to be standard plain old telephone circuits (POTS).

Using the MIIP, a standard (COTS) Critcare vital signs monitor and a Cardionics (COTS) electronic stethoscope was integrated with the ViTelCare Monitoring System with an integrated video conferencing software package. Once a patient registered into the system (card swipe) the system automatically instructed that patient on how to use the medical devices available. It was noted that the stethoscope would not be used unless a videoconference was established by the Clinical Staff.

A patient questionnaire was designed for completion by the patient (who was automatically transmitted to the clinical call center) or the clinician (based on questions asked of the patient). The questionnaire was used to assess the current condition of the patient. The data at the clinical call center was maintained in a longitudinal format to enable viewing of patient conditions over time. The clinical call center had the capability to forward patient data, as an e-mail attachment, to the attending physician for review and consultation as needed.

To meet the requirements for use in a mass casualty situation the system software allowed an override function that would enable the local (patient) site to create a " new" patient record, which was automatically assigned a unique identifier that, when sent, would notify the clinical staff of a "new" patient. The "new" patient record, with its unique identifier, would be stored in a temporary database to maintain the purity of the original database. The clinician would access the temporary database and view the patient information. The data could be compiled at the clinical call center to show trends over time for a patient and group of patients. This capability was essential in order to capture useful information in a mass casualty situation, such as progression of certain symptoms across a large group of patients. It was envisioned that within a region there would be several casualty collection sites each equipped with one or more monitoring systems connected to the central clinical site for data transfer and video conferencing.

To be practical and available to a large population, the goal was to integrate ViTel Net's low bandwidth technology that would enable the accomplishment of the objectives using the standard plain old telephone (POTS) circuit. The technology to be used in such an environment had to be very user friendly considering the range of technology awareness that will be exhibited by the potential population.

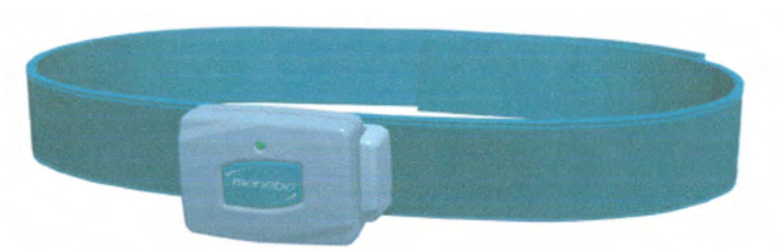
Beyond mass casualty events, the successful development and integration of ViTel Net capabilities and systems was applied to conditions of interest to the DoD for general health (Cardio-vascular disease) and injury (wound management).

Task 11: Development and integration of a Cardiology Monitoring Device

Cardiovascular disease is the leading cause of incapacitation among middle-aged DoD retirees and beneficiaries. With careful management of this disease many of those afflicted should be able to return to the work place and live a normal productivity life. Part of the recovery process and continued well-being involves continuous monitoring of the cardiovascular system. Most monitoring systems are restrictive requiring the patient to collect cardiovascular data using a single lead ECG, blood pressure monitor and oximeter at a single point in time while resting. A more beneficial cardiovascular monitoring system would be one that is capable of monitoring heart functions of patients while he/she performs their daily activities, not just a point in time. The "holter monitor" systems frequently used for continuous patient monitoring was limited in that they had no means of warning a patient or a healthcare provider of an impending problem. Integrating an ECG device that enabled the continuous monitoring of a patient during periods of activity with ViTel Net's Centric Specific Data Collection Instrument (reported below) supported automatic sending of abnormal data to a central clinical monitoring station where it could be read and/or analyzed to initiate alarms if the data is out of norms.

Monebo Technologies had developed a device for monitoring patients during periods of activity in a controlled exercise type environment. The cardio monitoring system consisted of three components:

- **Acquisition:**
  The CardioBelt™ is the data acquisition subsystem in the Monebo ECG system.



The CardioBelt™ consisted of a simple sensor unit with three embedded electrodes, which were wirelessly connected via Blue Tooth to a nearby processor such as a PC or PDA/PocketPC. It used one lead with three electrodes inserted in a flexible material and connected to an embedded processor unit. This configuration provided for the capture of a modified Standard Lead 1 ECG signal.

- **Electronics Embedded in the CardioBelt Package:**
  Embedded electronic package captured, filtered, amplified, and digitized body surface potentials and transmitted the digitized signal using Bluetooth technology to the PC for further ECG display and system analysis.

- **Operating and User Software:**
    - The Automatic Arrhythmia Detection Software that analyzes ECG signals captured from the surface of the human body.
    - The ECG analysis, interpretation, risk stratification, and alarm software analyzes body surface ECG signals .

This device was integrated with using the Blue Tooth short-range communications embedded in the Centric Computer System (details below). The automatic arrhythmia detection software filtered out unnecessary information and data allowing for the continuous flow of data to the data collector. The collected data was then transmitted using secure internet mode to the ViTel Net PostMaster Server where it was decrypted and placed in the respective individual's medical record. A separate computer, acting as the Clinical Call Center system, was used to access the stored patient data and, using the Monebo ECG analysis software, the data was analyzed. There was no effort to evaluate the accuracy of the data transmitted and analyzed; the sole purpose of this effort was to demonstrate the capability to integrate the product using the MIIP tools.

The integration from a technological perspective, within a controlled environment, posed no problems using the MIIP integration tools. At the time that this work was completed the Monebo Software was in preliminary development and did not include many of the analytical software tools being developed by Monebo. The additional analytical software, when fully developed, would have required excessive processing power and would not be supported by the use of the small Centric Computer System used in this research.

Task 12: Development and integration of a Wound Management System-Wound Field Kit

The recovery period for wounded military personnel is lengthy and costly, often with the final several months of recovery completed as an outpatient with periodic visits to a medical facility. Patients recovering from surgical procedures likewise often require frequent wound healing evaluations as outpatients. The cost to the government in providing quality care to personnel recovering from wounds and surgical procedures was unknown but assumed to be extensive. Within the civilian population, it has been estimated that the cost was more than $10 billion each year. This estimate included both those recovering from wounds as result of surgery and as a result of injuries resulting from an accident. Of this expenditure by providers, the majority was driven by nursing hours and costs related to extended stays in facilities for wounds that are difficult to heal.

Recovery from such wounds often required a multidisciplinary approach to include nutritional, dermatology, infectious issues, and general healthcare. A means of monitoring the patient's health status, to include blood pressure, temperature, heart rate, and, in some cases, respiration on a daily basis as well as the healing process of the wound was needed.

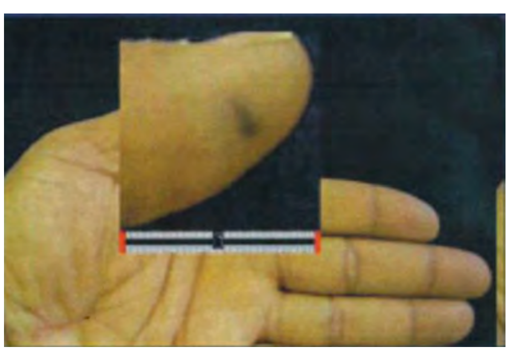
The design considerations for the Wound Management Kit were that it must be simple enough to be used by a patient with minimal training, have a simple user interface, use standard off the shelf products, and be fully integrated with other healthcare products developed by ViTel Net during the course of this research.

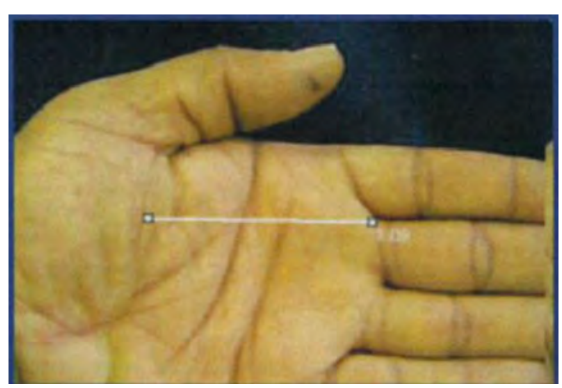
ViTelCare Wound Care Kit

Required Key Features of the Wound Care Kit

- Wound dimension measuring
- Image annotation
- Image enhancement tools
- User-friendly touch-screen/stylus interface
- Digital camera with auto focus and auto flash
- POTS, wireless, and cellular communications

A wound care management tool was developed for use by the caregiver as a means of acquiring, documenting and annotating wound images in the field and sending these images with annotations back to a wound care nurse (WOCN), physician or other healthcare practitioner for immediate review and response for a corrective treatment plan. The wound care application was configured to communicate via standard telephone line, broadband, or cellular without interfering with existing telephone service.





Operational Workflow

The Wound Care Kit contained two hardware components as well as the ViTelCare software developed previously:

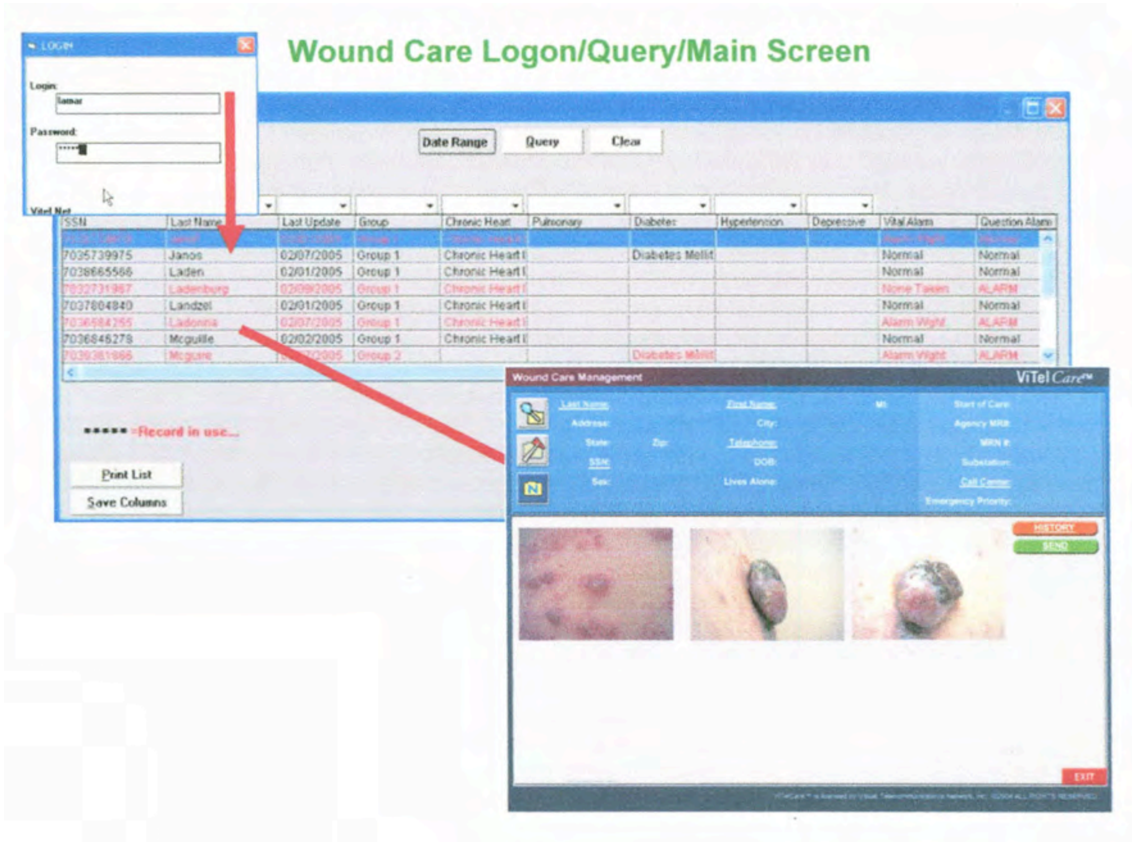
1. Wireless Ricoh digital camera with 80211 b/g card
2. Wireless handheld Fujitsu PC (Lifebook)

The kits were to be used for the purpose of transmitting wound images from the patient's home to the call center at the client's office where a wound specialist reviewed the wound and could call the nurse in the patient's home if needed for treatment recommendations or for later follow up.

Periodically the handheld laptop was synchronized with the call center. A patient list containing only the patient name and ID was transmitted to the handheld PC. This allowed one to select a patient from the roster, take an image, wirelessly transmit the image to the handheld PC, and from the handheld, transmit the image to the call center, via wireless cellular or phone line. Should a patient be newly admitted who was not previously synched, manual entry of the patient's name created an ID number and a new record. The Wound Care Kit software is a mini version of the VuLink wound care application displaying only patient names and patient ID's.

Selecting the patient

1. Once the handheld is turned on, the ViTel Net Wound Care icon appears. Clicking on the icon launches the application program.
2. A list of patients appears, listed alphabetically with a scroll bar on the side to scroll up or down to view patients not currently displayed on the screen. A query function allows the user to enter a letter, indicating the first letter of the patient's last name, which advances to that section of the patient list.
3. Doubling clicking on the patient brings up that patient's medical record that is storing images. Previously captured and transmitted image are identified as sent.
4. A thumbnail of images is displayed horizontally or vertically to allow a number of images to be shown on one screen. The images are sorted to display the most current image first. When a new image is received from the camera, that image becomes the first image shown for that patient.



Taking an image

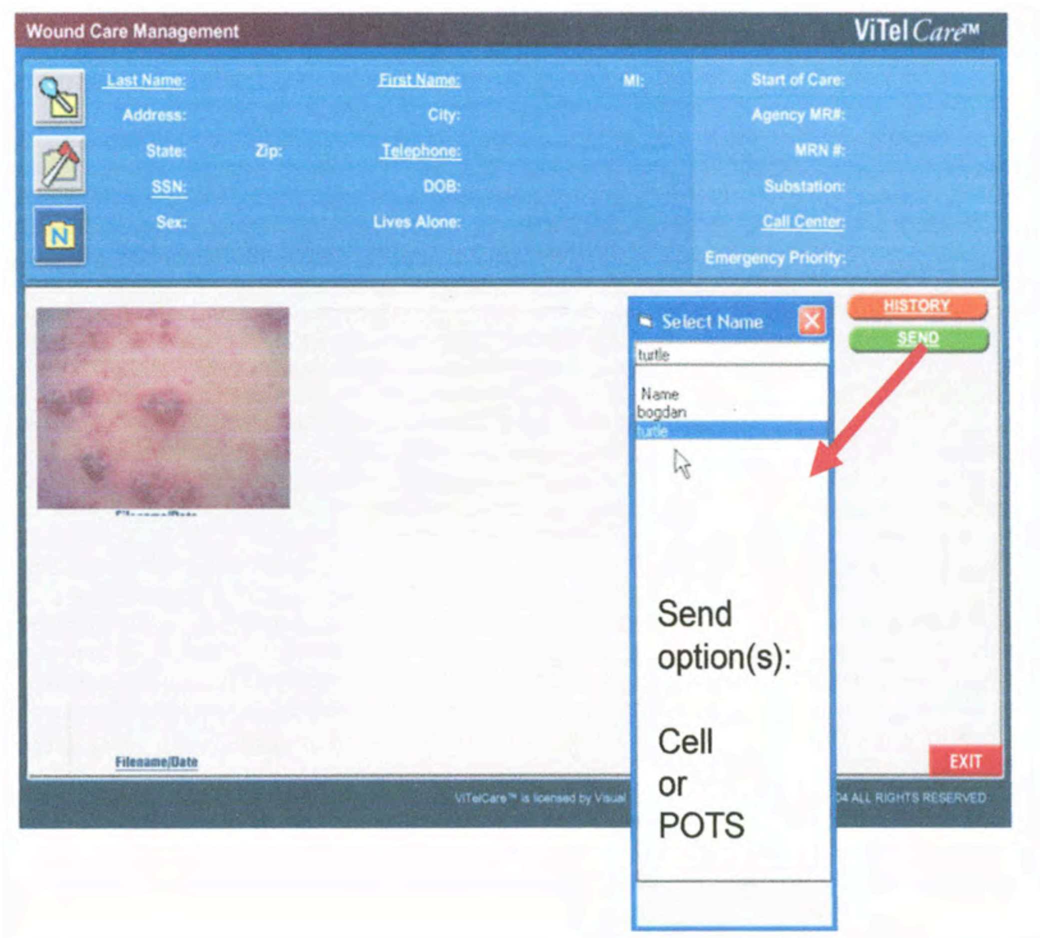
1. Each time prior to use the camera should be checked for stored images prior to use. The camera's memory should be empty of images.
2. Once the patient record is open, the camera can be activated and begin taking images of the patient's wound.
3. Using the camera option button, the user can preview the image, select ok, and wirelessly transmits the image to the handheld device.
4. Once it is confirmed that the image has been received at the handheld, the image on the camera MUST be deleted. Deleting the image minimizes the risk of an image being transmitted to an incorrect patient record.

Wound Care - Take Photos and Upload Images to Tablet

Wound Care Main Screen – Preview Images, Thumbnails & Image Tools – (Notes)

Transmitting the image

1. Once the image has been transmitted to the patient record on the hand-held device, the user can imbed a text box in the image before sending. This text entry can include any questions concerning immediate treatment, color or odor of discharge, size or depth of wound, etc.
2. The mode of transmission (cellular or phone line) is then selected and the call launched
3. Only images from the current episode are transmitted. This helps limit the file size and transmission time.

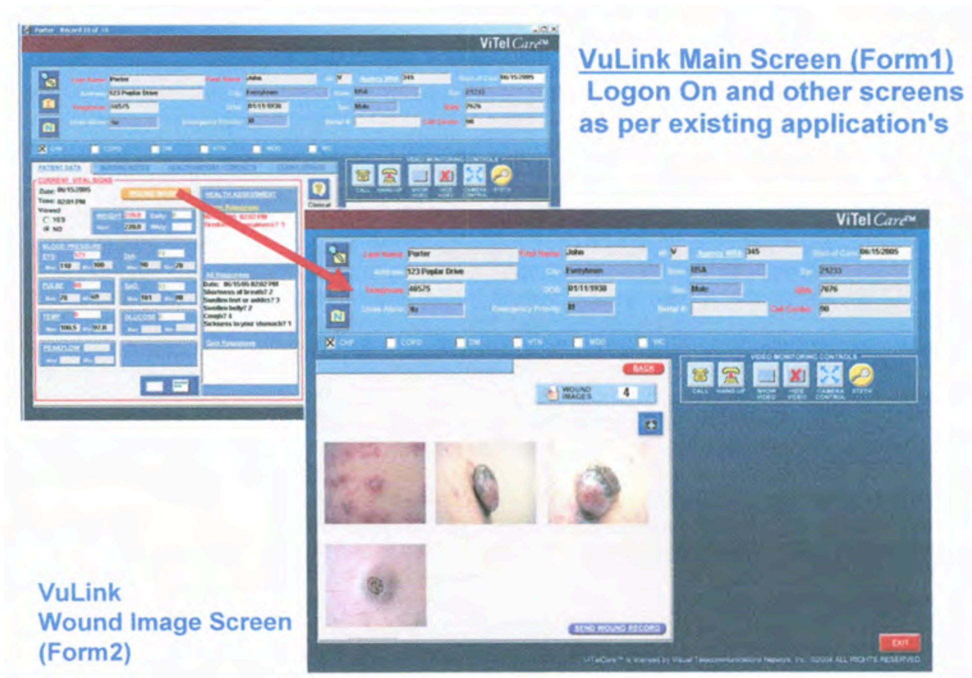


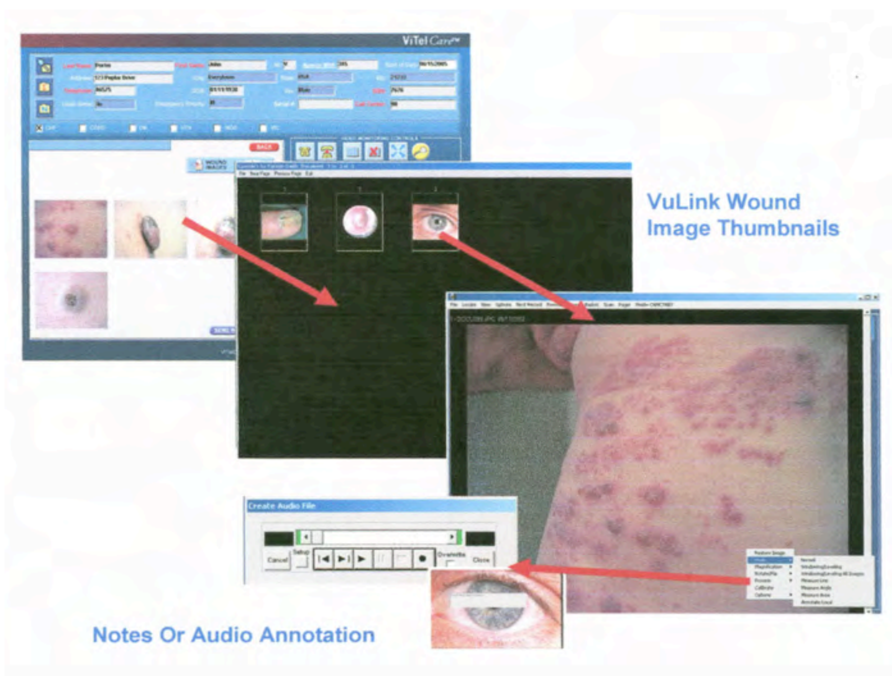
Wound Care Tablet Send Options – Episode sent

Receiving the image

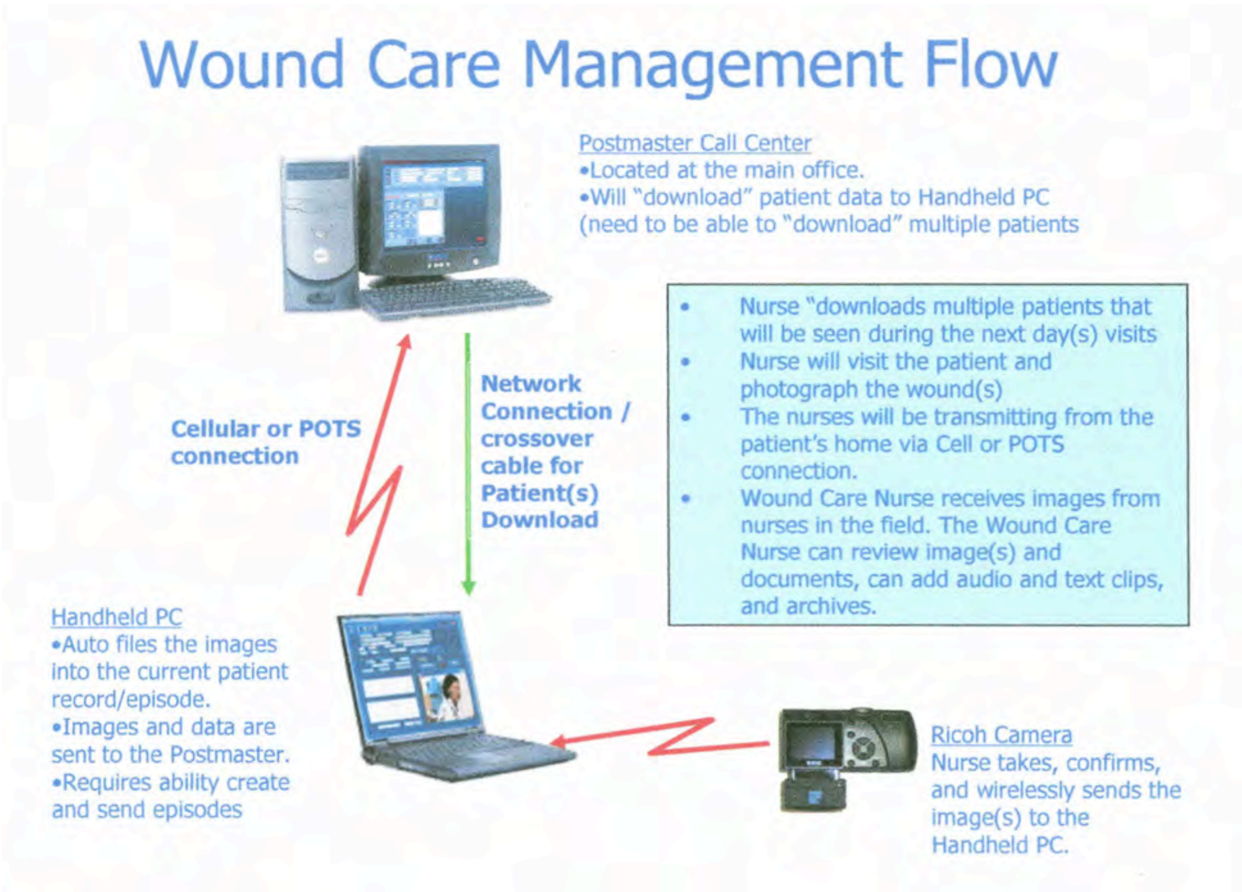
1. The call center receives the images where they are automatically added to the patient's record. If there was no previous record for the patient, a new record is automatically created.

2. In the wound care section of the VuLink workstation screen, the care coordinator (wound specialist) can view a thumbnail summary of images received, with the most recent image being shown first.
3. Double clicking an image enlarges the image and shows any imbedded icons for text that was added by the field nurse.
4. The wound specialist can view the imbedded text, add new text, or record an audio file that is imbedded into the image.





The Wound Care Management Work Flow is Shown in the Diagram Below:



Task 13: Development and integration of the Centric Specific Data Collection Instrument

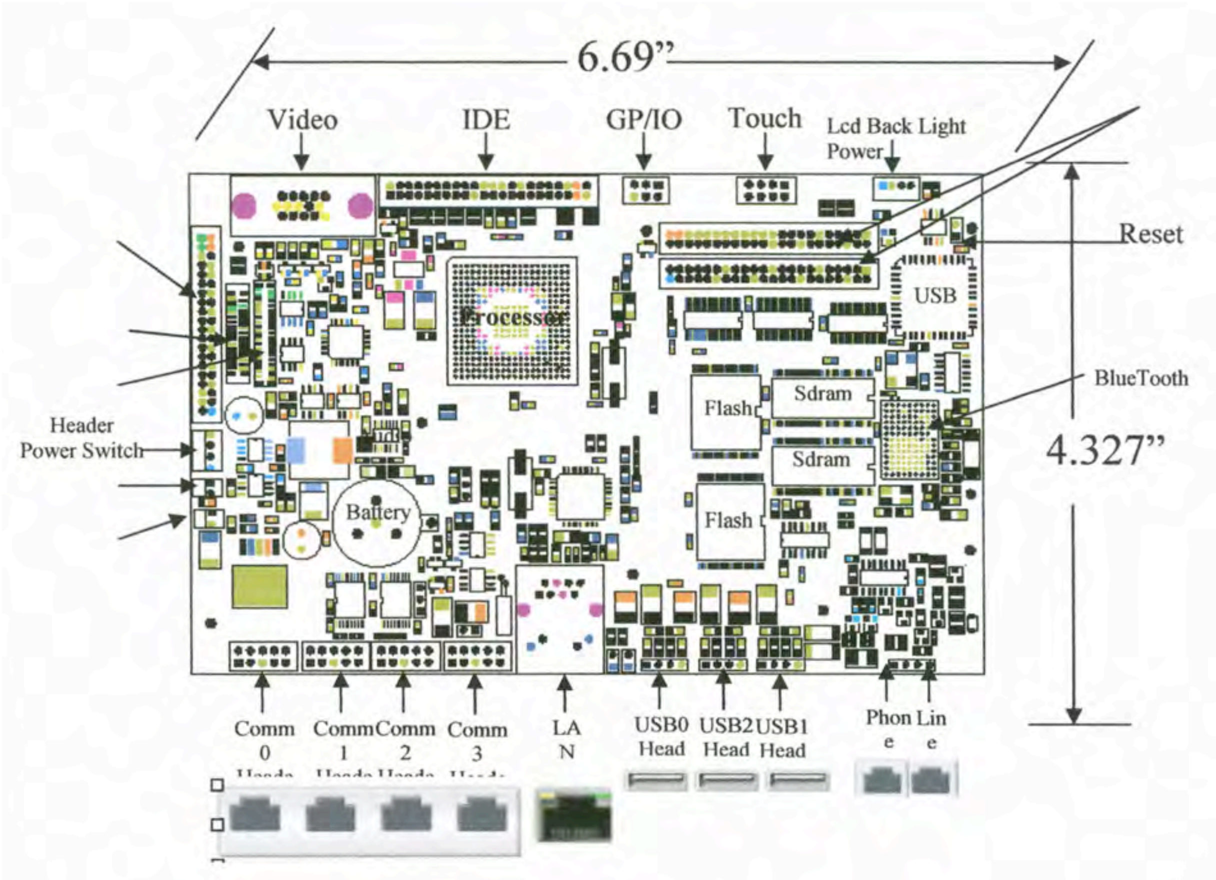
The objective of this task was to develop an integrated data collection device capable of connecting to medical devices using either direct connect or wireless and transmitting collected data via wireless and wired communication circuits. The device had to be a fully integrated computer system weighing less than two pounds and be able to connect directly to multiple COTs medical devices using either short-range wireless communications technology or directly through a serial or USB connection. The data collected by the device had to be automatically transmitted to a central site were the data was integrated with the patient's medical record and presented to the caregiver for review.

Currently available small computer systems, such as PDA's, were evaluated and did prove satisfactory as a data collection device. Commercially available PDA's and similar computer devices could not connect directly to COTs medical devices and were limited in capacity to connect wirelessly to such devices. Wireless connections required the installation of a wireless PCMCIA card for short-range communications to connect to a single medical device, often multiple PCMCIA cards had to be used to connect to very specific medical devices. Once data was collected, an additional wireless communications PCMCIA card had to be inserted in the device to establish the communications link. These systems were far too cumbersome for use by first responders or point of care healthcare providers. As a result, ViTel Net, in support of the capability, accomplished the following objectives:

- A prototype miniature computer device with embedded short-range wireless communications and long-range wireless communications was developed.
- The capability to demonstrate interoperability with COTs devices was established.
- Embedded short range (Blue Tooth) was used to connect to Blue Tooth capable COTS medical sensors; a wired serial/USB connection was used to connect to non-Blue Tooth enabled sensors.

To accomplish these objectives, it was necessary to design a complete system including the computer board, viewing screen, and housing for the computer. The concept was to have a self-contained device that could only be used as a data collecting instrument and that was entirely controlled using touch screen icons, eliminating need for keyboard or mouse. The system was also designed to operate using either standard AC or DC electrical power. The system had a built-in speaker and microphone, blue tooth, cellular modem, and flash memory.

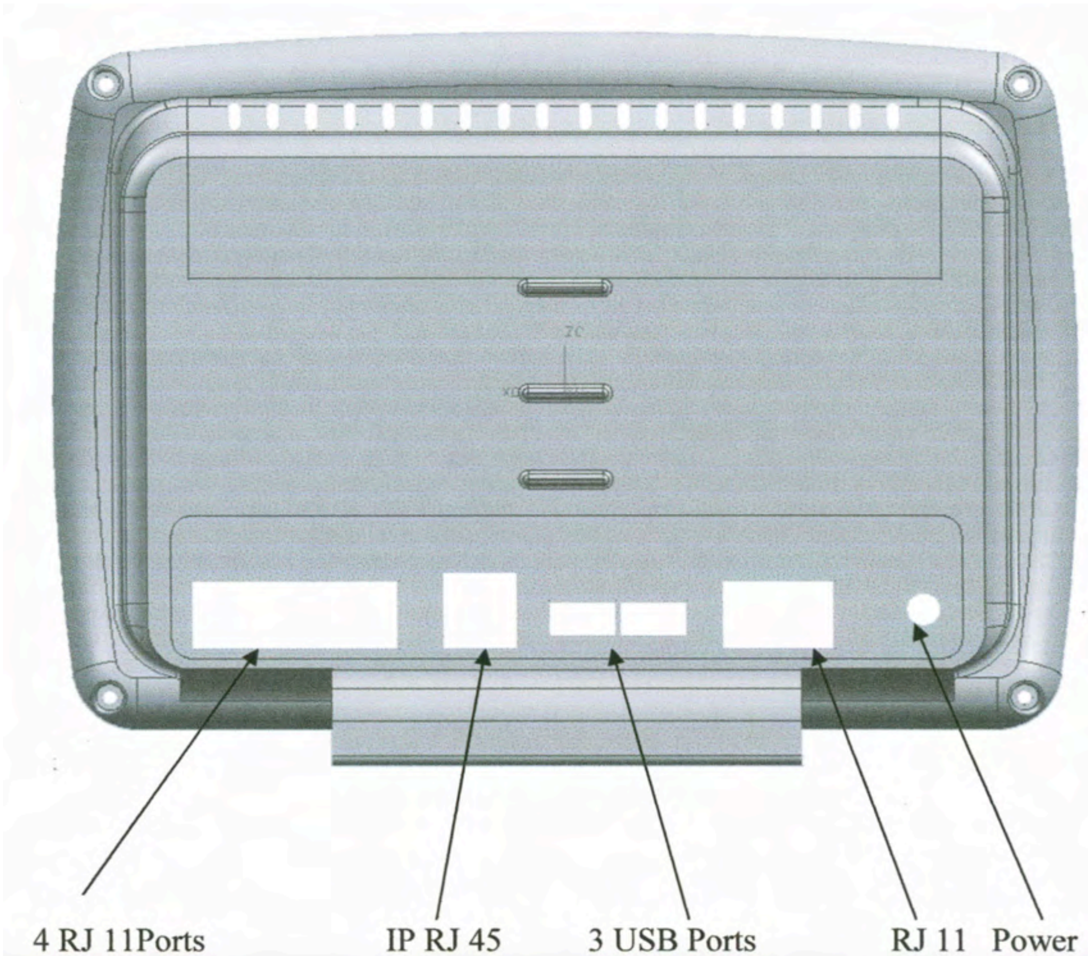
Key to developing the system was the design and development of the PC board. Our goal was to make the board as small as possible with all required functionality, with exception of the COTS medical sensors to be embedded on the board. Developing a PC board that was sufficiently small and that would support all necessary functionality was a significant accomplishment. The final design of the Data Centric PC Board is shown on the next page:



Once the PC Board was developed and tested in the laboratory it was possible to proceed with the design of the system housing. The initial design was changed to conform to the design of the board. The final design is shown below and on the next page:

FRONT VIEW

REAR VIEW

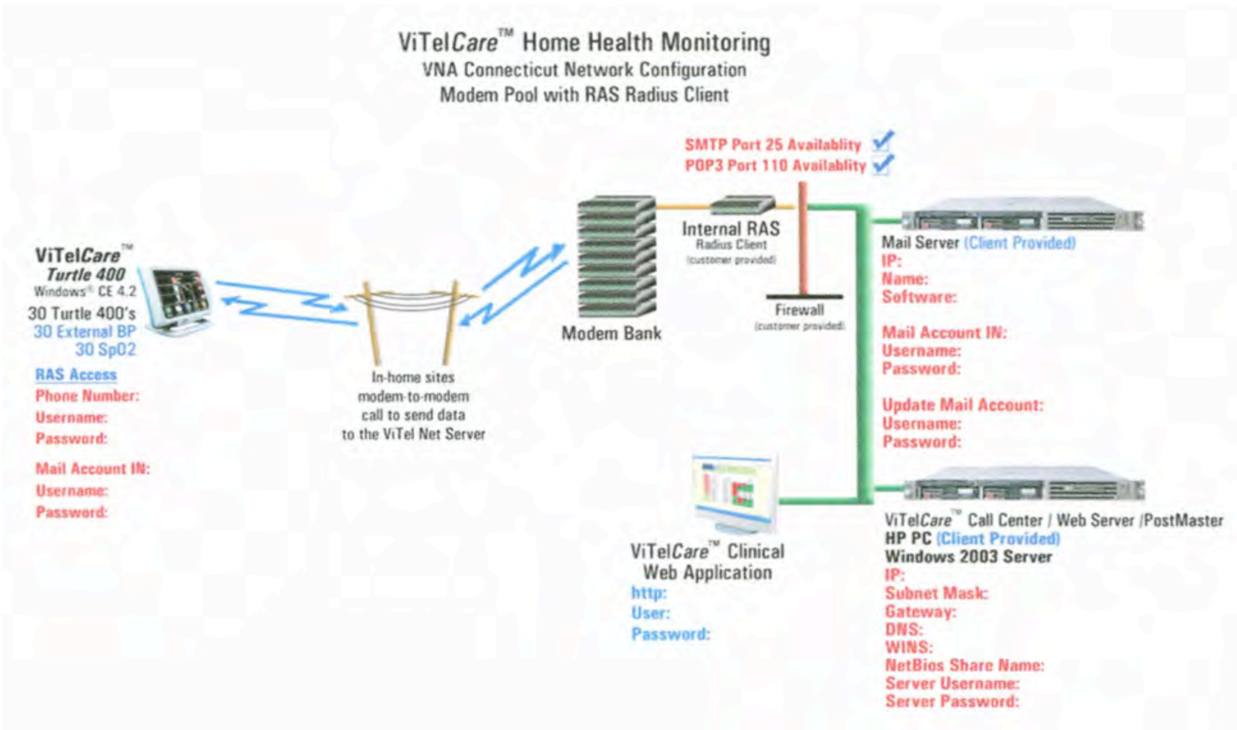


The Centric Specific Data Collection Instrument was successfully interfaced with the following medical devices:

- A&D Life Source Blood Pressure and Pulse Device
- Welch Allyn Blood Pressure and Pulse Device
- LifeScan Glucometer
- Roush Glucometer
- AccuCheck Aviva Glucometer
- Nonin Sp02 Blood Oxygen and Pulse
- Welch Allyn Temperature
- Piko Electronic Peak Flow Meter
- R&K Electronic Stethoscope
- Zoe Fluid Status Monitor
- ProTime PT/NR
- Life Source Weight Scale

Collected data was automatically encrypted and sent using standard telephone or broad band connection to the ViTel Net Postmaster. The Postmaster received the in-coming message, decrypted the data and filed it to the respective individual' s medical record.

A typical network using the Centric Specific Data Collection is shown below.



In a follow-on task, an enhanced Centric Specific Data Collection Instrument was developed that provided video conferencing capability via POTS or via the Internet. The device has embedded Blue Tooth connectivity that can support multiple sensors and its integrated camera can be used for image capture and enhancement

The enhanced Centric Specific Data Collection Instrument was used – as an example of the small compact unit that could be used by a First Responder – to collect, analyze, and transmit physiological data, images, and video into a patient's medical record.

Task 14: Development of an HL7 Interface

A key objective throughout the course of this research program was the ability to achieve interoperability between hospital information systems. ViTel Net developed an XML interface which was successfully used to transmit collected patient data to a legacy DoD Hospital Information System. A second interface was developed, using ODBC to link with another legacy DoD Hospital Information System. However, these two systems could not share clinical information or data. Neither of these systems could directly exchange data with commercial hospital information systems. In theory, with the evolving Health Level Seven (HL7) messaging standards becoming the "accepted" standard for the exchange of key sets of information, interoperability with and between various Hospital Information Systems should be achievable in the future. To achieve such interoperability an HL7 interface engine is needed to serve as a gateway for the translation of data to legacy hospital information systems both government and non-government.

ViTel Net developed a data transmission communication interface that supports multiple modalities to include HL7, XML and ODBC. Using HL7 messaging format data and simulated hospital information system data collected using the Centric Specific Data Collector was successfully transmitted using both XML and ODBC interface engines. Using the developed interface engine ViTel Net successfully transmitted medical data collected using the Centric Specific Data Collector to the following Hospital Information Systems, all of which were operational:

- AHLTA "Armed Forces Health Longitudinal Technology Application" Test Data Base
- Veterans Administration Hospital Information System
- Nemours Epic Hospital Information System
- McKesson Hospital Information System
- Cerner Beyond Now Hospital Information System

Task 15: Develop Clinical Protocols, treatment procedures, and decision aide tools for wound care and non-wound care

Clinical Protocols were developed for multiple disease states including the following:

• Wound Care	• Heart Failure (HF)
• Weight Loss (MOVE)	• Hypertension (HTN)
• Stroke	• Major Depressive Disorder (MDD)
• Anxiety	• COPD
• PTSD	• Diabetes Mellitus (DM)
• Traumatic Brain	• Expanded co-morbidities:
• Spinal Cord Injury	• HF-HTN-MDD
• Injury Stress Management	o COPD-HTN-MDD
• Substance Abuse	o HF-DM-MDD
• Bipolar Disorder	o HF-MDD
• Asthma	

KEY RESEARCH ACCOMPLISHMENTS:

- Within a laboratory environment, the MedVizer Dvision Tool – a commercial-off-the-shelf (COTS) telemedicine integration tool – more comprehensive, COTS-based MedVizer Informatics Integration Platform (MIIP)
    - have proven to be a rapid integration and configuration telemedicine tool.
    - have been demonstrated within this environment to be capable of dynamically integrating disparate
        - medical teleconsultation systems,
        - medical information and image display modalities, and
        - electronic legacy hospital information systems within a wired and wireless environment

REPORTABLE OUTCOMES:

- Project Reports describing research outcomes were submitted and distributed as Projects were completed.
- The series of demonstration projects have proven the capability of the MedVizer tools for rapid prototyping of systems for specific applications.
- All of the products were set up in the ViTel Net demonstration site with connectivity to DoD Hospital Information Systems (ICDB and CHCSII).
- Patient intake questionnaire data were successfully transferred to ICDB Health Forces using the XML interface.
- Interoperability testing with Air Fortress 802.11b security system in a laboratory environment with a variety of MedVizer Telemedicine Products was successfully completed.
- MedVizer and MIIP interoperability with Cranite was successfully demonstrated.
- A Centric Specific Data Collector instrument was developed.
- The Centric Specific Data Collector instrument was able to securely communicate the collected data to a central site, which was then transferred to the patient's medical record retained in the hospital information system (using 5 different electronic medical record systems) using an HL7 interface engine.
- Publications:
    - ***eVitals Kiosk for Vital Signs and Health Questionnaire Capture***
      Carl Clifford DD[1], Jay Carlson, MD[1], COL Ronald Poropatich, MC[1], MAJ Mike Smythe, MD[1], Robert Harbick, MS, BS[2] [1]*Walter Reed Army Medical Center, Washington, DC;* [2]*Visual Communications Network, Inc., Tyson's Corner, VA*
    - ***Automated Vital Signs Capture and Clinical Database Acquisition***
      Carl Clifford DD[1], Robert Harbick, MS, BS[2], Jay Carlson, MD[1], COL Ronald Poropatich, MC[1], [1]*Walter Reed Army Medical Center, Washington, DC;* [2]*Visual Communications Network, Inc., Tyson's Corner, VA*
    - ***Wireless Teleradiology in Acute Brain and Cervical Spine Injury***
      MAJ John Y. Choi, MD[1], LTC James M. Ecklund, MD[1], CDR Ross R. Moquin, MD[1], Carl Clifford DD[1], Robert Harbick, MS, BS[2], Lisa M. Koenman, MA[1],

MD[1], COL Ronald Poropatich, MC[1], Bagriele Feolo, RN, MSN[1] [1]*Walter Reed Army Medical Center, Washington, DC;* [2]*Visual Communications Network, Inc., Tyson's Corner, VA*

- ***Tailoring a Telehome Care Solution for Improved Business Processes***
  Kim Lee, MSN, RN, BC, Audrey Kensella, MA, MS, Brenda Ecken, Med, BSN, RN, Robert Harbick, MS, BS *Visual Communications Network, Inc., Tyson's Corner, VA*

CONCLUSIONS:

As noted at the beginning of this report, this work was accomplished over many years with individual year-to-year Congressional Special Interest Appropriations. The nature of these appropriations required that there be both a civilian and military relevant aspect to the research and development. In cases where there was no direct military relevance (a device or system that was not going to be used by the military, for example) military relevance was established by knowledge gained through the research and development and the application of that knowledge and the lessons learned in future development of military systems. Thus, while the work reported regarding the Walker Baptist facility and the elder care facility was not directly relevant to military processes or mission, the knowledge gained in designing and developing the capability did inform military disaster response considerations. Throughout the execution of the tasks we encountered significant obstacles, which delayed (or in the case of the WRAMC Neurology Clinic task, precluded) the planned tasks. As the execution of the plan began, we quickly realized that several factors were impacting the planned approach making it difficult to execute and limiting productivity:

- Availability of, and access to, the military' s legacy and emerging health information systems
- Access to clinical areas within selected military facilities
- Access to point-of-care medical personnel at various points across the military's operational health care continuum
- The need to continuously adapt to the dynamics of technological changes occurring both in the biomedical and information technology fields.

As a result, our revised execution approach enabled us to apply planned research methodologies including computer modeling and simulation, followed by prototype development and bench testing. Following successful bench testing, interjection of the prototype into a "live" environment where it was integrated with existing medical informatics systems for data retrieval and input process testing was attempted. The final step – where possible and allowable – was the introduction of the integrated device into field and clinical settings for testing and evaluation.

Throughout these efforts, several individual capabilities were developed each one tied to a larger telemedicine system. The modularity inherent in our design plan demonstrated the value of a system of systems approach to telemedicine, setting the stage for future development of cost-effective, efficient, need-focused telemedicine systems that would apply equally well to Federal (VA/DoD) and civilian health care.

Although ViTel Net's suite of technologies and software was successfully demonstrated and iteratively improved through this research and development, it was through the identification of processes, requirements, workflows, and use cases, that this research program evinced primary value. Our success in working with civilian and DoD (and VA) clinicians, program managers, hospital staff, first responders, patients, and others, to identify needs and requirements, has laid the foundation for future development and refinement of telemedicine systems based on a logical and efficient development path for identifying requirements and workflows. Future telemedicine systems will benefit from the knowledge gained, and the lessons learned, from this Secure Wireless Military Healthcare Telemedicine Enterprise program.

REFERENCES:

None

APPENDIX

OVERARCHING TASKS

Task 1: **MIIP**
Demonstrate that a COTS medical information system tool (MedVizer™) facilitates rapid integration and implementation of teleconsultation systems within military treatment facilities.

Task 2: **POC Requirements**
Identify, evaluate, and finalize health care provider's patient and clinical information, and data entry requirements originating at the point of care.

Task 3: **COTS KB**
Identify and evaluate commercial off-the-shelf (COTS) medical informatics knowledge-based systems pertaining to clinical requirements.

Task 4: **Integrate POC w/KB**
Integrate point-of-care data collection, medical order entry, and knowledge base acquisition tools with ViTel Net's MedVizer software.

Task 5: **Interop Requirements & Demo**
Identify interoperability requirements and demonstrate integration with DoD's legacy and emerging heath care information systems and electronic medical records (Composite Health Care System II [CHCS-II], Field Deployable Medical Record [FDMR], Personal Information Carrier [PIC], and other informatics systems).

Task 6: **Scalability Requirements**
Identify scalability requirements for cross platform interoperability inclusive of hand-held PC (CE) based PDA through Windows NT operating systems.

Task 7: **Integrate w/PPA**
Integrate point-of-care data collection, medical order entry, and knowledge acquisition tools with ViTel Net's MedVizer Physician Personal Assistant in a wireless distributed computing environment for military and commercial applications.

Task 8: **PoC in hospitals**
Proof of concept: (a) limited fielding prototype system in military and commercial hospital and (b) testing and evaluation.

Task 9: **Integrate w/MPDA**
Integrate ViTel Net's MedVizer Telemedicine Systems, to include the Medical Personal

Digital Assistant (MPDA), with security protocols (HIPAA, digital certificates, elliptic curve encryption)

Task 10: **Homeland Defense**
Applications for Homeland Defense {Needs Analysis)

Task 11: **Cardiology**
Development and integration of a Cardiology Monitoring Device

Task 12: **Wound Management**
Development and integration of a Wound Management System-Wound Field Kit

Task 13: **Centric Specific DCI**
Development and integration of the Centric Specific Data Collection Instrument

Task 14: **HL7**
Development of an HL 7 Interface

Task 15: **Clinical Protocols**
Develop Clinical Protocols, treatment procedures, and decision aide tools for wound care and non-wound care.

SPECIFIC TASKS BY FUNDING YEAR

1st Year Funding

1. Identify, evaluate, and finalize health care provider's patient and clinical information, and data entry requirements originating at the point of care.
2. Identify and evaluate commercial off-the-shelf (COTS) medical informatics knowledge based systems pertaining to clinical requirements.
3. Integrate point-of-care data collection, medical order entry, and knowledge base acquisition tools with ViTel Net's MedVizer software.
4. Identify interoperability requirements to establish seamless connectivity to the existing DoD heath care information systems (Composite Health Care System II [CHCSII], Field Deployable Medical Record [FDMR], Personal Information Carrier [PIC], and other informatics systems.
5. Identify scalability requirements for cross platform interoperability inclusive of hand held PC (CE) based PDA through Windows NT operating systems.
6. Integrate point-of-care data collection, medical order entry, and knowledge acquisition tools with ViTel Net's MedVizer Physician Personal Assistant in a wireless distributed computing environment for military and commercial applications.
7. Proof of concept: (a) limited fielding prototype system in military and commercial hospital and (b) test and evaluate.

2nd Year Funding

1. Continue to demonstrate that a COTS medical information system tool (MedVizer™) facilitates rapid integration and implementation of teleconsultation systems within military treatment facilities.
2. Integrate ViTel Net's Wireless MedVizerTM Telemedicine Systems, to include the Medical Personal Digital Assistant MPDA, to achieve interoperability with DoDs legacy and emerging Hospital Information Systems and electronic medical record.
3. Demonstrate interoperability of ViTel Net's Wireless MedVizerTM Telemedicine Products with the Air Fortress Technology's Air Fortress 802.11b security system.
4. Integrate ViTel Net's MedVizer Telemedicine systems, to include the Medical Personal Digital Assistant (MPDA), with security protocols (HIP AA, digital certificates, ellipectic curve encryption)
5. Integrate point-of-care data collection, medical order entry, and knowledge base acquisition tools with ViTel Net's MedVizer software.
6. Expand the integration of point-of-care data collection, medical order entry, and knowledge acquisition tools with ViTel Net's MedVizerTM Telemedicine systems to include the Medical Personal Digital (MPDA)
7. Applications for homeland defense [to be reported in 2004 report]
8. Identify and evaluate commercial off-the-shelf (COTS) medical informatics knowledge based systems pertaining to clinical requirements.

3rd Year Funding

1. Continue to demonstrate that a COTS medical information system tool (MedVizer™) facilitates rapid integration and implementation of teleconsultation systems within military treatment facilities.
2. Integrate ViTel Net's Wireless MedVizerTM Telemedicine Systems, to include the Medical Personal Digital Assistant MPDA, to achieve interoperability with DoDs legacy and emerging Hospital Information Systems and electronic medical record.
3. Demonstrate interoperability of ViTel Net's Wireless MedVizerTM Telemedicine Products with the Air Fortress Technology's Air Fortress 802.11b security system.
4. Integrate ViTel Net's MedVizer Telemedicine systems, to include the Medical Personal Digital Assistant (MPDA), with security protocols (HIP AA, digital certificates, elliptic curve encryption)
5. Applications for Homeland Defense (Needs Analysis)
6. Home Land Defense Telemedicine Application Demonstration
7. Monitoring System for Elder Home Application
8. Mobile Transport System
9. MedVizer Trauma System

4th Year Funding

1. Cardiology Monitoring Device
2. Wound Management
3. Centric Specific Data Collection Instrument
4. HL 7 Interface

5th Year funding

1. Demonstrate capability to collect, analyze, and transmit physiological data, images, and video by first responder and integrate collected data into patient medical record.
2. Medical record transfer from DOD HIS system to the VA VISTA patient record system.
3. Develop laboratory prototype enhanced Centric Specific Data Collection Instrument by capturing still images, adding voice and graphic annotation, and interactive video using standard telephone communications.
4. Develop Clinical Protocols, treatment procedures, and decision aide tools for wound care and non-wound care. Develop database structure, search techniques, and applications for first responder.
5. Integrate MIDDAS DAG unit and the SUMS Sensor Device.

Overarching Tasks

Funding Year	Speciific Task #		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
			MIIP	POC Requirements	COTS KB	Integrate POC w/KB	Interop Requirements & Demo	Scalability Requirements	Integrate w/PPA	PoC in Hospitals	Integrate w/MPDA w/security	Homeland Defense	Cardiology	Wound Management	Centric Specific DCI	HL7 Interface	Clinical Protocols
1st YEAR																	
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