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Award Number: DAMD17-01-2-0048

TITLE: Secure Wireless Military Healthcare Telemedicine Enterprise System

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REPORT DATE: September 2003

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

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20041214 068

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	September 2003	Final (1 Sep 01 - 31 Aug 03)

4. TITLE AND SUBTITLE
Secure Wireless Military Healthcare Telemedicine Enterprise System

5. FUNDING NUMBERS
DAMD17-01-2-0048

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES
Original contains color plates; All DTIC reproductions will be in black and white

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. Abstract ***(Maximum 200 Words)*** *(abstract should contain no proprietary or confidential information)*

The primary objective of this research effort is to integrate ViTel Net's MedVizer™ software and Dvision Tools with cross platform telemedicine systems, inclusive of computer based systems, handheld wireless PDA devices, and miniature computers, to existing DoD legacy and developing healthcare information systems, clinical repositories, and knowledge base systems for application at the point of care. This annual report reflects a number of projects wherein the tasks defined in the SOW are being accomplished. Specific project reports referenced herein detailing the specific application, work progress, and results will be submitted as supplementary reports.

14. Subject Terms (keywords previously assigned to proposal abstract or terms which apply to this award)
Telemedicine, Patient Distributed Record, Medical Infomratics, Point of Care, Knowledge Acquisition, Wireless Information Technologies

15. NUMBER OF PAGES
41

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

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TITLE: Secure Wireless Military Healthcare Telemedicine Enterprise System

INTRODUCTION:

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 MedVizer Informatics Integration Platform; a commercial-off-the-shelf (COTS) telemedicine integration tool 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.

The objective is to demonstrate the use of the MedVizer Informatics Integration Tools—a telemedicine information integration software product—for the rapid configuration of wireless and wired teleconsultation systems with legacy and emerging Department of Defense health informatics systems without need of additional conventional programming or costly systems integration efforts. 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.

BODY:

Throughout the research process, ViTel Net remains focused upon the following development guiding principles:

- Focus on the full spectrum of the Continuum of Care
- Minimize training and technology challenges and enhance data portability through cross-platform products and services
- Provide complete, up-to-date patient information throughout the Continuum of Care
- Incorporate the most appropriate current technology while remaining flexible to technology changes
- Achieve better outcomes through integrated data fusion

The initial concept for the research plan as described within the Statement of Work was that each task, although related, would be able to be performed as individual tasks. As the execution of the plan began it was quickly realized that several factors, described below, were impacting on the planned approach making it difficult to execute and limiting productivity.

- 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.
- The need to continuously adapt to the dynamics of technological changes occurring both in the biomedical and information technology fields.
- The realization 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 the same time provide a means for test and evaluation.

These factors have led us to the adoption of a research approach that is responsive to project opportunities within the general context of the research design and that will ensure timely and productive task accomplishments.

This revised approach continues to enable ViTel Net to apply the planned research methodology as described in our proposal—including computer modeling and simulation—followed by prototype development and bench testing. Following a successful bench test, the prototype is introduced into a "live" environment where it can be integrated with an existing medical informatics system for data retrieval and input process testing. The final step will be the introduction of the integrated device into field and clinical settings for testing and evaluation.

The research project from conception was projected as a four-year project. The research and development methodology that serves to guide the project is a four-step process, corresponding to the project year, as follows:

- **Step 1: Concept Formulation** – During this period effort was devoted to defining requirements, conducting preliminary analysis, developing the initial problem solution approach, and formulation of the design concept.
- **Step 2: Laboratory Development** – Work during this period is focused to the design and building prototype models, prototype testing within a "sterile" laboratory environment, and refining the prototype model based upon the results of the laboratory test.

- **Step 3: Field Application** – Prototype models will be subjected to field applications where limited test are conducted. Results of the test are applied and compared with the design objectives, and necessary engineering and design modifications are applied to the prototype design.
- **Step 4: Clinical Demonstrations** – Targeted clinical demonstrations will be conducted within a controlled environment to enable a more robust comparison with stated objectives and actual outcomes as well as user adaptation. These results will enable the final engineering changes in preparation for clinical trials.

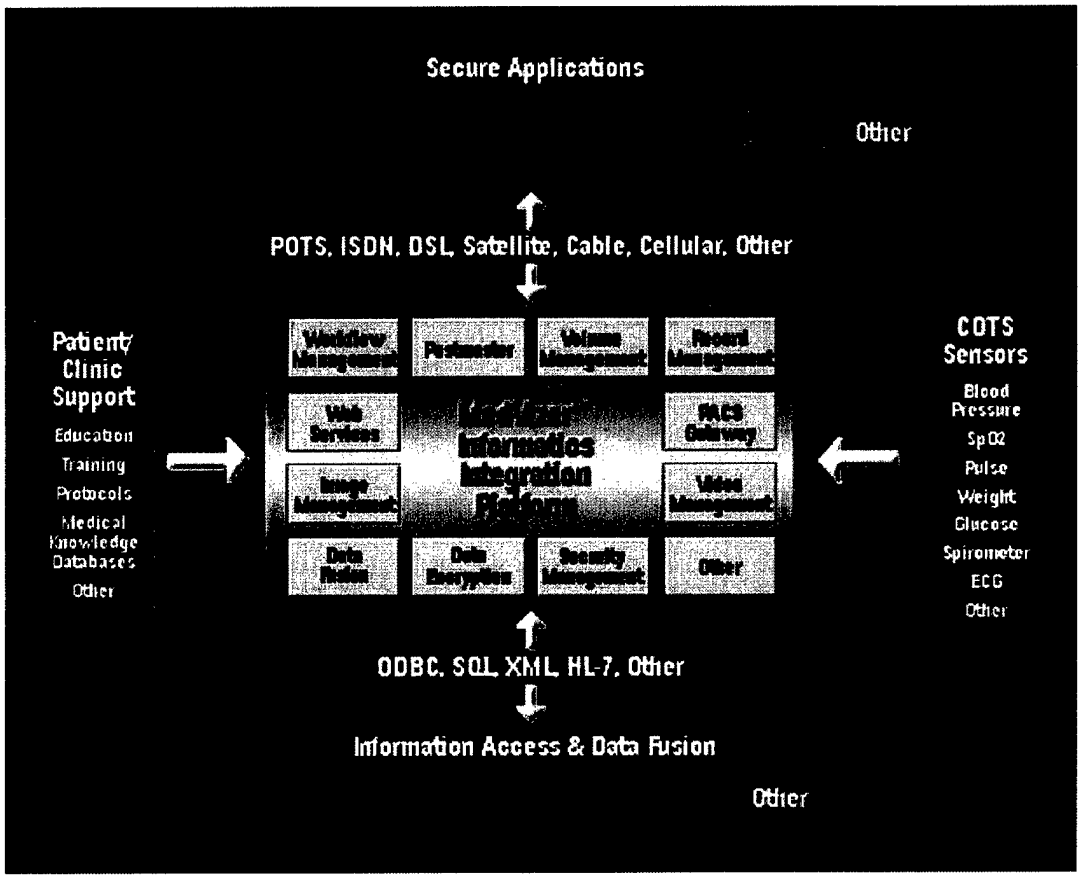
The many variables impacting on the research and development effort, some of which are described above, have precluded our efforts to precisely follow the steps and time sequence as initially planned. In an effort to take advantage of opportunities both within the military and commercial sectors, development of component attributes that would lead to the research objectives were undertaken and moved forward. Others were delayed in an effort to develop the clinical concept necessary to precisely describe requirements that forms the cornerstone of the research methodology.

This report therefore should be viewed as an interim report which addresses each of the specific task specified in the SOW and provides a brief overview of projects that have been completed or that are in progress related to the respective research tasks. Subsequent reports will be developed for each specific project describing the concept, research approach, integration and development activities, and results of implementation and evaluation.

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

The MedVizer™ Tools were redefined and expanded into a more comprehensive COTS based Informatics Integration Platform 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 need for the seamless integration of systems that would enable the interaction of patient to physician and physician-to-physician to facilitate rapid response to healthcare needs was essential. The MedVizer™ Informatics Integration Platform provides the tools necessary for such integration.

The following graphic shows the MedVizer™ Informatics Integration Platform:



The MedVizer Informatics Integration Platform has been demonstrated to facilitate rapid integration and implementation of teleconsultation systems within military treatment facilities, including Walter Reed Army Medical Center.

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 an opportunity to address data collection and data entry requirements at a different level of care. The desired objective was to automate the patient registration and intake interview process using wired and wireless technology to replace the traditional labor-intensive process currently used. 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 must enable the patient's record to be immediately updated within the legacy hospital information (Composite Health Care System I [CHCSI]) using an ICDB interface, the record that an attending physician will review prior to seeing the patient. Therefore, transfer of data from the intake station to the CHCSI database must occur in real-time. The goal of the process is to eliminate the traditional labor-intensive method of obtaining patient information and of the manual data entry into the hospital information system.

This project accomplishes the following objectives:

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

The project has been undertaken in several phases to accommodate the clinical process and to insure interoperability with the legacy HIS systems. The MedVizer Informatics Integration Platform enables this rapid development, testing, prototyping, and enhancing iterative process.

The initial phase involves:

1) Assessing the vital sign data sets that need to be electronically entered into the patient record
2) Using MedVizer tools to build an XML interface to the ICDB
3) Implementing a transaction bridge from the ICDB interface to CHCSI

The second phase involves the integration of the electronic registration. The third phase requires the integration of the patient intake questionnaire to be developed using the MedVizer tools and the integration of the data to the patient record contained in CHCSI.

Phase I is complete. Patients can scan their military identification card using ViTel Net's integrated card reader technology that will automatically initiate a transaction to retrieve or gain access to their patient record. In the event it is a new patient, a new record must be created using the system. Patients update their record by using the electronic vital signs monitor located in the Kiosk. The acquired data, without further intervention, is transmitted to the patient record residing in the ICDB database. ViTel Net, with this conceptual framework, has completed the model design for the user interface and technology workflow. Using the MedVizer tools, an XML interface to the ICDB is under development to enable the transaction for updating the patient record in the legacy hospital information system. A prototype demonstration model using ICDB database simulation provided by WRAMC has been developed, and is currently in field testing.

Task 2: Integrate ViTel Net's Wireless MedVizer™ 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.

In addition to the ongoing work to interface with the ICDB and CHCSI discussed above, ViTel Net has used the MedVizer integration tool to successfully establish connectivity to the following DoD health care information systems:

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

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

c. Integration with portable DoD record devices:
   (1) USAMRMC multimedia personal information carrier (PIC)
   (2) DOD CAC card
   (3) Standard bar code strips

This integration was demonstrated during a TATRC briefing held at ViTel Net on November 12,2003. The presentation demonstrated integration with ViTel Net's Wireless MedVizer Telemedicine Systems to achieve interoperability with DoDs legacy and emerging Hospital Information Systems and electronic medical record is located in Appendix A.

Task 3 : Demonstrate interoperability of ViTel Net's Wireless MedVizer™ Telemedicine Products with the Air Fortress Technology's Air Fortress 802.11b security system.

The design configuration and work plan for implementation of the OB-GYN Outpatient Clinic, Walter Reed Army Medical Center (WRAMC), continued from Task 1, has been completed and agreed upon by all participating WRAMC agencies/departments. WRAMC is now in the process of obtaining the necessary authorizations required for the system design and implementation plan.

In a parallel process, ViTel Net has 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 CHCSI), uses a simulated patient database.

During the preliminary testing of the prototype it was determined that a wireless (802.11b) security system would need to be integrated prior to implementing within WRAMC. As a result Task 3, year 2 "Demonstrate interoperability of ViTel Net's Wireless MedVizer Telemedicine Products with the Fortress Technology's Air Fortress 802.11b security system" was advanced. Interoperability testing with Air Fortress 802.11b security system in a laboratory environment with a variety of MedVizer Telemedicine Products has been completed.

ViTel Net's MedVizer and MedVizer Informatics Integration Platform interoperability with the Army Medical Material Command accepted system, Air Fortress, was demonstrated. However, WRAMC uses 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. Successful MedVizer and MedVizer Informatics Integration Platform interoperability with Cranite was demonstrated during these tests.

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/Cranite technology but rather that interoperability between these systems and MedVizer products. The test environment validated full compatibility without any degradation in quality of performance of the MedVizer products. The prototype system, currently being tested at ViTel Net, now includes the Air Fortress security technology. This system has demonstrated the capability to achieve the objectives of Phase 1. ViTel Net is now in the process of refining the "User Interface" using the MedVizer Tools.

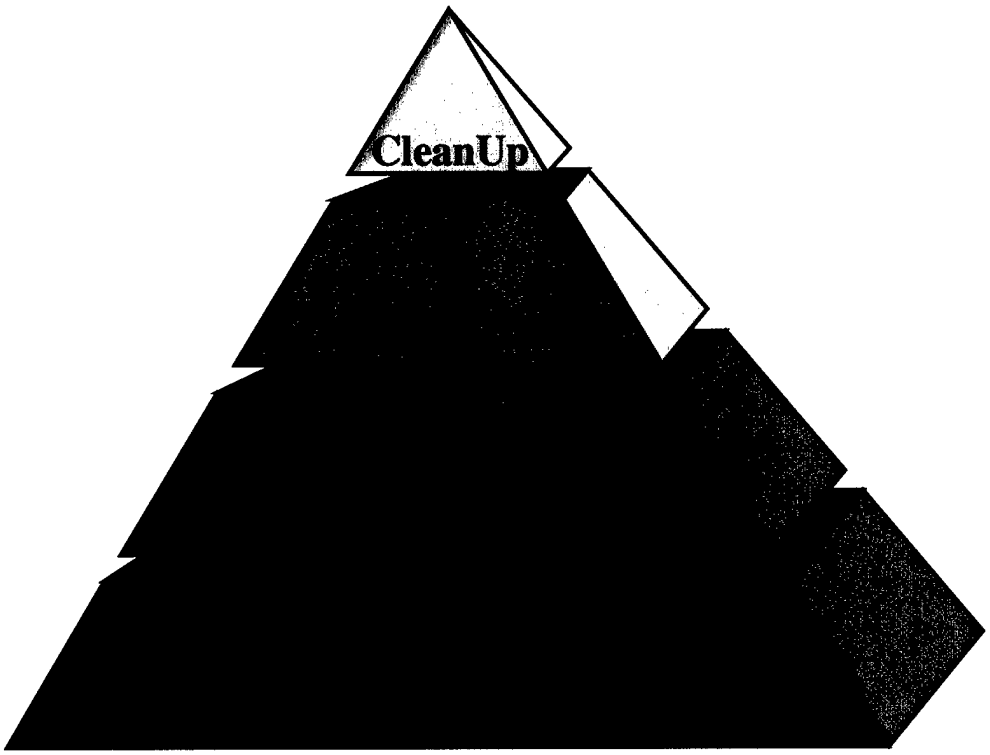
The user interface must enable the patient, with limited instructions, to use bar code technology to access their record simply by swiping their military identification card. Upon accessing and verifying that their record is correct the patient then must be able to electronically gather their vital signs, using the electronic vital signs medical device for blood pressure, pulse and temperature, the results are then automatically updated in the patient's record. The patient then will step on the electronic scale; those results will also be automatically updated in the record. Upon verifying that all fields have been completed the patient will exit their record, which will clear the system of all data. Upon exiting the system it will automatically update that patients record in the ICDB and CHSCI (now a prototype data base). The record is immediately available for review by the attending physician with all data updates.

The user interface and instructions are being 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 are exchanging 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 will be tested in a laboratory environment using a simulated ICDB database provided by WRAMC. It is anticipated that Phase 1 of this project will be ready for clinical trails at WRAMC later this calendar year assuming that all necessary WRAMC approvals are granted in a timely fashion.

Task 4: Integrate ViTel Net's MedVizer Telemedicine systems, to include the Medical Personal Digital Assistant (MPDA), with security protocols (HIPAA, digital certificates, ellipectic curve encryption)

MedVizer™ Informatics Integration Platform provides an effective security architecture combining an authentication / privilege access model, windows application policies, data secure in transmission, data secure at rest, and watch dog tools for auto logoff and data cleanup. During our integration activities, ViTel Net identified the following security tollgates:



ViTel Net's four-tier security model

Identification

Today's systems must be equipped to accept manage and distribute information from a variety of sources. Flexibility and adaptability are the key avenues to success. The MedVizer™ Informatics Integration Platform use authentication to combine

identification with personal knowledge (password /pin) providing a very effective means for securing equipment, application access, and data.

ViTel Net's MedVizer™ Informatics Integration Platform was evaluated and successfully provides 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 MedVizer™ Informatics Integration Platform was evaluated and successfully provides security for the following types of data:

- Audio
- Vital Signs
- NIBP, SPO2, Pulse, Temperature, Blood Glucose, ECG, Weight
- Multimedia
- X-Ray, Ultrasound, Echocardiograph, Etc.

The following methods of secure data transmission of were tested. Applications developed with the MedVizer™ Informatics Integration Platform 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 testing of sensor acquisition methods. These difficulties included the following:

- Device can easily loose their Bluetooth connection
- Bluetooth devices can easily loose their configuration settings
- Bluetooth devices can not 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 MedVizer™ Informatics Integration Platform provided effective security across the following mechanisms:

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

Integration / Fusion
The MedVizer™ Informatics Integration Platform provided effective security when integrating with the following databases:

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

Collaborative Methods
The MedVizer™ Informatics Integration Platform 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

Task 5: Integrate point-of-care data collection, medical order entry, and knowledge base acquisition tools with ViTel Net's MedVizer software.

Continuous care of patients on an outpatient basis (Continued from Task 1). A prototype system integrating the MedVizer tools with commercial off the shelf (COTS) components has been completed. The prototype system uses the ViTel Net Clinical Call Center to remotely access the patient's home monitoring unit using standard plain old telephone circuits (POTS). Using the MedVizer tools a standard (COTS) Welch Allyn vital signs monitor and a Cardionics (COTS) electronic stethoscope has been integrated with a

Motion Media Video Phone (COTS) and MedVizer software to form the home unit. The home unit is totally 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 will be required only to properly place the medical device (e.g., blood pressure cuff) following the guidance given by the clinical call center operator. The clinical call center operator will be 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 will activate the medical sensor device to obtain the output readings. ViTel Net's clinical call center, using the MedVizer rapid integration tools, is configured to receive the data directly from the medical device without further patient intervention. The system is also designed to enable the clinician to review current medication dosages and enter changes to medications.

Appendix B shows sample online knowledge base acquisition tool output protocol content developed by ViTel Net for use with the Clinical Call Center unit.

A patient questionnaire has also been designed that can either be 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 is used to assess the current condition of the patient. The data at the clinical call center is maintained in a longitudinal format to enable viewing of patient conditions over time. The clinical call center has the capability to forward patient data to the attending physician for review and consultation as needed.

The system is currently being field tested with patients from The Home Nursing Agency. To date, most feedback has centered around the following:

- The system is easy to use – ViTel Net and The Home Nursing agency have used an iterative process during user interface development. The most current system is on its fourth iteration, and patients report satisfaction with usability and functionality.
- The system has too many wires – because of this feedback, ViTel Net is incorporating Bluetooth wireless sensor technology into the patient unit.

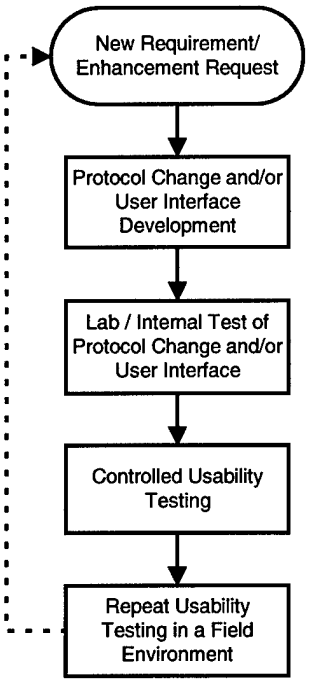
ViTel Net intends to continue the iterative development cycle with The Home Nursing Agency, integrating point-of-care data collection (in the home), medical order entry (at The Call Center), and knowledge base acquisition tools (from the protocols) with ViTel Net's MedVizer software.

ViTel Net's Home Monitoring application requires 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 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 must be very user friendly considering the range of technology awareness that will be exhibited by the potential population.

The initial assessment demonstrated that some patients would be quite capable of performing multiple functions and be quite comfortable with the use of the technology while others will be 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 of the clinician to formulate the information and data entry requirements. The basic need was to have the capability to develop and maintain a longitudinal record of a patient that would reveal vital sign (blood pressure, pulse, oxygenization, and temperature), weight, blood glucose, and heart lung sound (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. Additional information considered beneficial to quality healthcare was the maintenance of a longitudinal accounting of the patient's daily condition, which would need to be acquired by both visual observations and the patient's response to specific health related questions. Ideally the patient would respond to specific questions by responding online electronically; however, an alternative means where the clinician using verbal cues would acquire 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 is presently collected using the traditional daily home visit of a health care provider.

ViTel Net conducted a variety of usability studies using a standard methodology to provide ongoing product improvement:



A recent usability study conducted in the controlled lab environment provided usability feedback for systems created with the Medvizer tools. 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 begins with the patient using medical devices that are integrated with the home unit to collect physiologic data. The process ends when the data is successfully transferred to the central database on the ViTel Net server. The success of the data collection and transfer process is verified by viewing the data on the server using the Care Coordinator application.

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 patient unit, 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.

The primary objective was to enable a health care provider to perform all functions remotely to include 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 methodology. It is believed that using the technological approach for providing home health services will 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 modeled using the MedVizer Tools. The model design and prototype was provided to the same health care providers used in the initial assessment for review and comment. Based upon comments received final revisions were completed. The next step involves the integration of a prototype demonstration model.

Task 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).

The MedVizer integration tools have been used to demonstrate interoperability with:

a. Wireless access to and transmission of medical information via IP/internet
b. 802.11B wireless networks
c. Air Fortress Security Device
d. Cranite Security System
e. 128 Bit Encryption System

The MedVizer integration tools have 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) (ongoing)

The MedVizer integration tools have successfully been 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) Interoral 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

(1) Skin O2
(2) Respirations
(3) Glucose
(4) Spirometer
(5) Temperature

Task 7: Applications for homeland defense

This task will be reported in the 2004 report.

Task 8: 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 have been 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. In recent months many newer knowledge base systems have been identified that use the more common Microsoft Windows Operating System and thus offer the possibility for cross platform implementation. Due to the limited number of such knowledge databases currently, we have deferred further investigation until the availability of such systems develop further which will enable a more comprehensive comparative analysis of potentially usable systems.

Additionally, ViTel Net evaluated a series of commercial off-the-shelf (COTS) medical informatics knowledge based systems. The goal was to identify systems that could be integrated into standard COTS functionality enabled by Medvizer tools. Much of this research is ongoing; one example of a COTS informatics knowledge based system integrated into MedVizer tools is 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 are based on current standards of care and are reviewed by physicians, nurses, and healthcare providers. ViTel Net has integrated the X-Plain.com patient education modules into its MedVizer enabled functionality.

ViTel Net has also integrated disease management protocol information into the Clinical Call Center functionality for the following clinical conditions:

- CHF
- COPD
- Diabetes
- Hypertension
- Major Depression

This knowledge-based system is constructed from a disease management model. Components of the initiative are consistent with the definition of disease management by the Disease Management Association of America. These components include:

- Population identification
- Evidence-based practice guidelines
- Collaborative practice models to include physician and support-service providers
- Patient self-management education
- Process and outcomes measurement, evaluation and management
- Routine reporting/feedback loop

This information is available to clinicians from ViTel Net's applications and is intended as a guideline for the nurse clinician and should not supersede the clinical judgment of the healthcare provider. Guidance is given on areas to assess and teach in an effort to better monitor the patient, improve self-monitoring and reporting by the patient, and to improve clinical outcomes. Appendix B shows sample online knowledge base acquisition tool output protocol content developed by ViTel Net for use with the Clinical Call Center unit.

KEY RESEARCH ACCOMPLISHMENTS:

The MedVizer Information Informatics Platform, a commercial-off-the-shelf (COTS) telemedicine integration tool has proven, within a laboratory environment, to be a rapid integration and configuration telemedicine tool. It has 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 will be published describing research outcomes. These reports will be distributed as Projects are completed.

CONCLUSIONS:

Execution of the research plan should be applied to specific worthy projects wherein proof of concept applications can be tested and evaluated in military and commercial healthcare systems, which will demonstrate task accomplishments. Each of these projects will have an associated report.

REFERENCES:

References will be provided in project reports.

APPENDIX A: ViTel Net Government Briefing

Slide 1

Slide 2

Slide 3

Purpose of This Meeting

- Review the goals and objectives of ViTel Net's Congressionally funded research and development
- Review overall status in relation to those goals and objectives
- Demonstrate selected outcomes of our efforts to date
- Review future planned activities and next steps

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Research and Development Goals

- Develop methods to securely collect and disseminate health information across the Continuum of Care
- Demonstrate ViTel Net's COTS MedVizer™ Informatics Integration Platform (MIIP) to integrate:
  - –COTS sensors
  - –COTS data collection instruments
  - –Legacy health systems

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ViTel Net's Guiding Principles

- Focus on the full spectrum of the Continuum of Care
- Minimize training and technology challenges and enhance data portability through cross-platform products and services
- Provide complete, up-to-date patient information throughout the Continuum of Care
- Incorporate the most appropriate current technology while remaining flexible to technology changes
- Achieve better outcomes through integrated data fusion

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Technology Objectives

Leverage ViTel Net's MIIP tools to:

- –Securely interface with standard, approved COTS medical devices
- –Provide a common architecture acros COTS products
- –Enable secure retrieval and entry of data into the patient medical record directly from COTS sensors
- –Support live interaction with medical consultants worldwide

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Technology Objectives (continued)

Leverage ViTel Net's MIIP tools to:

- Support cross-platform operation (PDA, tablet, laptop, workstation, Internet)
- Securely integrate with legacy patient record systems (FDR, GEMS, PTS, CHCS-II / ICDB, DINPACS, Etc.)
- Enable secure patient data sharing
- Integrate COTS applications across the full continuum of the military healthcare enterprise
- Link and extend existing telemedicine capabilities

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Research and Development Methodology

Step 1
Concept

- Define Requirements
- Preliminary Analysis
- Initial Approach
- Design Prototype System

Step 2
Lab

- Build Prototype
- Test Prototype in Lab Environment
- Update Prototype Based on Test Results

Step 3
Field

- Deploy Prototype in Limited Field Environment
- Compare Outcomes to Design Objectives
- Update Prototype Based on Test Environment

Step 4
Clinical

- Conduct Targeted Clinical Trials
- Compare Outcomes to Design Objectives
- Update Product Based on Clinical Trials

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Design Considerations

- Designs must incorporate comprehensive security and privacy measures
- Telemedicine must be integrated into day-to-day operations to be effective in a disaster or combat situation
- Telemedicine must provide rapid dissemination of critical information in a timely manner through an integrated medical system
- Systems must adapt to a variety of communication methods and bandwidths including POTS, LAN, WAN, 802.11b, and Cellular
- Systems must adapt to changes in technology and medical care delivery protocols

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Design Considerations (continued)

- Interoperability is the key, with MedVizer™ providing the common architecture integrating discrete systems across the Continuum of Care
- Systems must be appropriate to the constraints of the environment (for example field systems must be rugged, light, and mobile)
- Interface and operation must be unambiguous and support rapid data entry, retrieval, and dissemination
- System must support the response to the full spectrum of mass casualty situations including terrorist attacks, natural disasters, and battlefield
- Mass casualty environments have a long evacuation time, enhancing the importance of telemedicine

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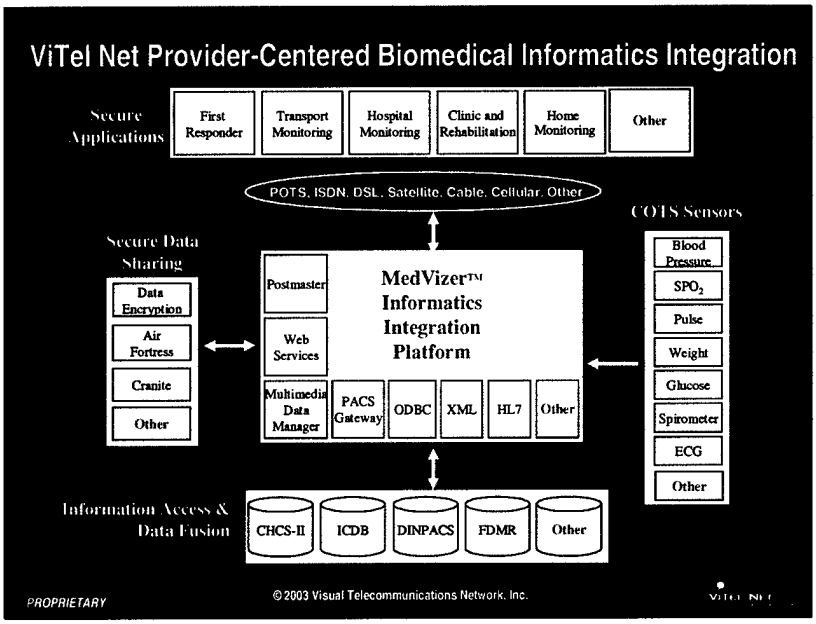

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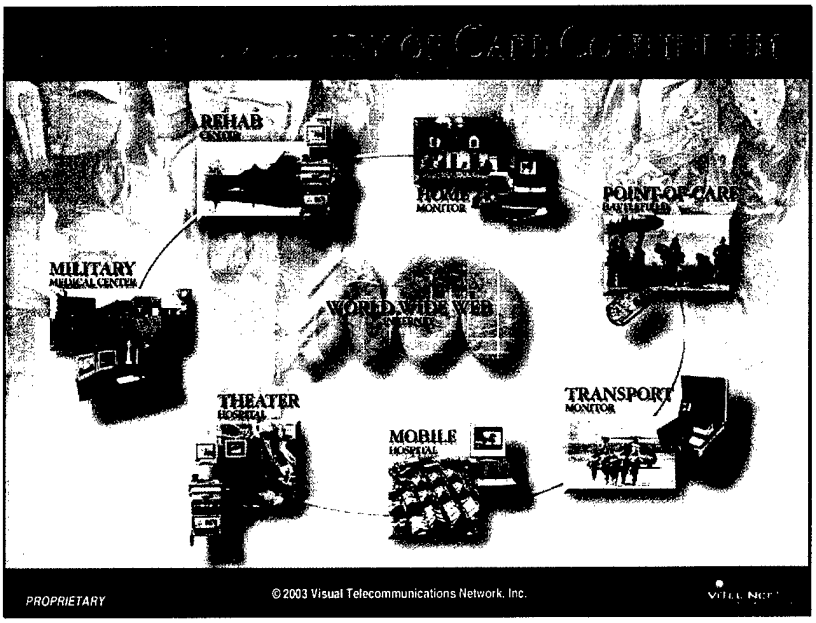

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Year 1 Tasks

- Test interoperability of handheld digital devices
- Evaluate the usage of the PIC as a Medical Record Transport
- Define data requirements at point of care
- Use MIIP tools to integrate data collection sensors with Continuum of Care applications
- Test AirFortress 802.11b
- Demonstrate ViTel Net's thin client to retrieve data in a web-based environment
- Document wireless networks architecture concepts

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Year 1 Tasks (continued)

- Develop a Wireless RS 232 adapter
- Develop a concept for integrating wireless sensors into point of care solutions
- Develop a PCMCIA Card for Medical Sensors (PDA and Laptop)
- Establish Wireless Lab Model to test Point of Care PDA applications
- Use MIIP tools to establish data fusion / information integration with Legacy HIS Systems

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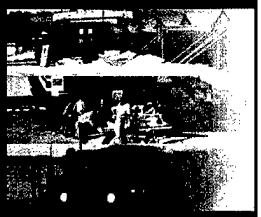
Year 2 Tasks

- Demonstrate use of MIIP tools to facilitate rapid integration and implementation medical applications
- Evaluate feasibility of anytime, anywhere delivery of radiographic images across platforms
- Expanded integration of point-of-care data collection, entry, and distribution across the Continuum of Care
- Expand the development of a single PCMCIA card with four sensor devices
- Continue to test and evaluate COTS sensors
- Integrate graphics and video for continuous monitoring applications



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Year 2 Tasks (continued)

- Continuing to demonstrate MIIP tools facilitate rapid integration of telemedicine systems
- Integrated MIIP to achieve interoperability with DOD legacy and emerging HIS and electronic medical record systems
- Demonstrated interoperability of MIIP with Cranite 802.11b
- Integrated MIIP with security protocols such as HIPAA
- Demonstrate MIIP integration with other military systems and applications
- Integrate and develop applications applicable to homeland defense, disaster relief, peacekeeping operations, and casualty care

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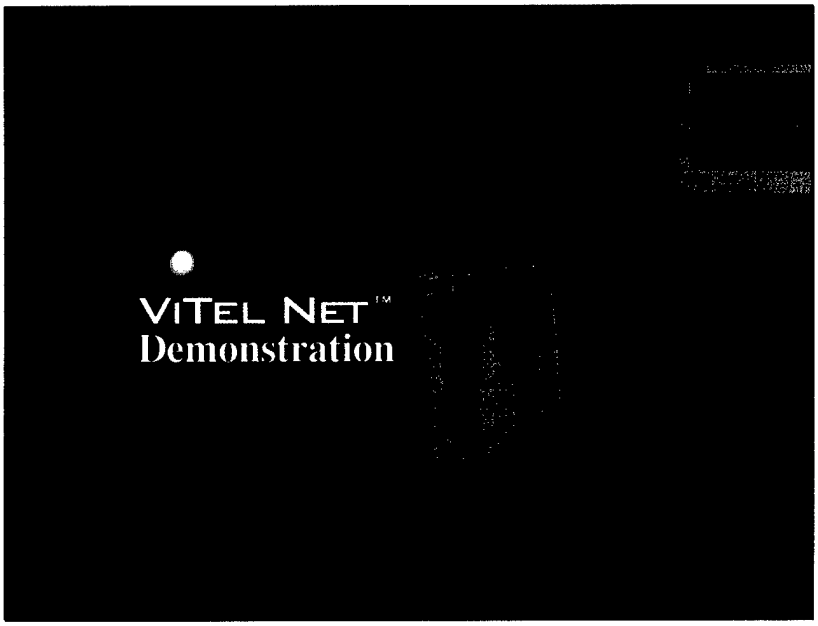

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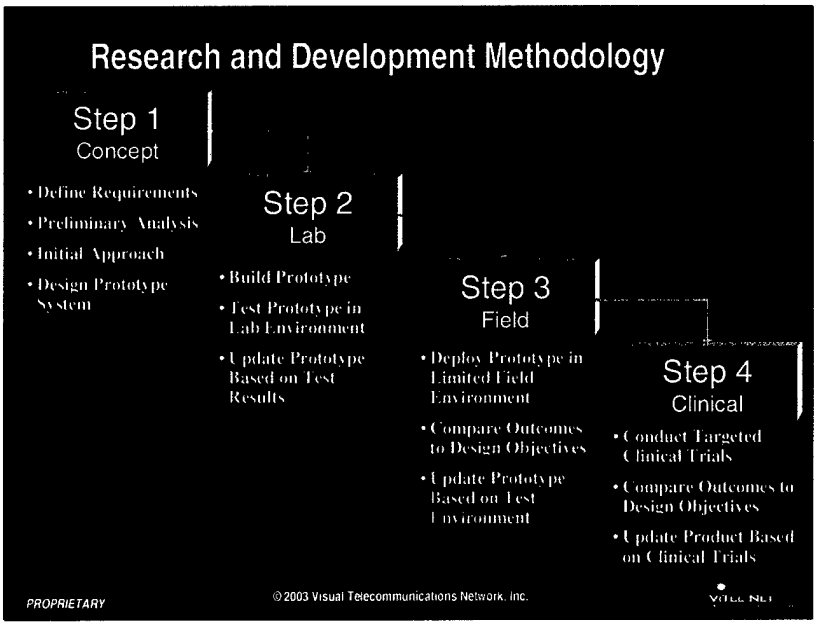

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Year 3 Tasks

- Connect multiple sensors using a single PCMCIA card
- Conduct engineering feasibility study for a miniaturized wireless patient monitoring system for military and homeland defense
- Interface to WRAMC's ICDB patient record database and the University of Minnesota HIS
- Conduct clinical evaluations of a patient Kiosk system at WRAMC and the University of Minnesota
- Integrate and test ViTel Net's Transport System at University of Minnesota
- Design, develop, and enhance a H.323 compliant videoconference system
- Conduct clinical evaluations of monitoring technology

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Year 3 Tasks (continued)

- Continue to develop clinical procedures, protocols, and content-driven decision trees
- Establish a wireless medical informatics network to conduct limited field testing of a MPDA in a clinical setting
- Explore the feasibility of implementing other operating system technology
- Integrate miniaturized wireless acquisition devices
- Conduct a telemedicine business process evaluation and an equipment needs assessment
- Implement a telemedicine solution at a selected regional hospital system within the state of Alabama
- Investigate COTS stethoscope and ECG technology for integration with Continuum of Care medical applications

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Year 3 and 4 Tasks

- Establish connectivity between selected local hospitals and hospitals within the DOD medical system, local emergency response teams, and public health authorities
- Demonstrate the capability to rapidly disseminate essential information concerning a disaster situation caused by a natural disaster or terrorist activity
- Demonstrate the capability to interface with DOD and civilian HIS systems at WRAMC and USAMRMC TATRC Forward Deployable Digital Medical Treatment Facility

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Year 4

- Use MIIP tools to integrate medical information management tools into military and civilian telemedicine systems
- Conduct clinical evaluations of continuous patient monitoring technology during transport and in an emergency room environment
- Use MIIP tools to integrate COTS stethoscope and ECG technology into Continuum of Care medical applications
- Evaluate the capability of ViTel Net's MedVizer™ technology to integrate military medical response teams, local civilian medical institutions, and emergency personnel to respond to terrorist incidents and / or natural disasters
- Demonstrate how ViTel Net's secure telemedicine infrastructure can reduce medical staff deployments
- Demonstrate the capability of MedVizer™ to support clinical vaccine trials conducted by DoD

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Points to Remember Moving Forward

MedVizer™ Informatics Integration Platform enables:

- Rapid integration of COTS sensors and medical data collection devices
- Secure interface with any standards-based database
- Communication across virtually any telecommunications infrastructure
- Accelerated development of secure custom applications without coding

Open architecture adapts to changes in technology

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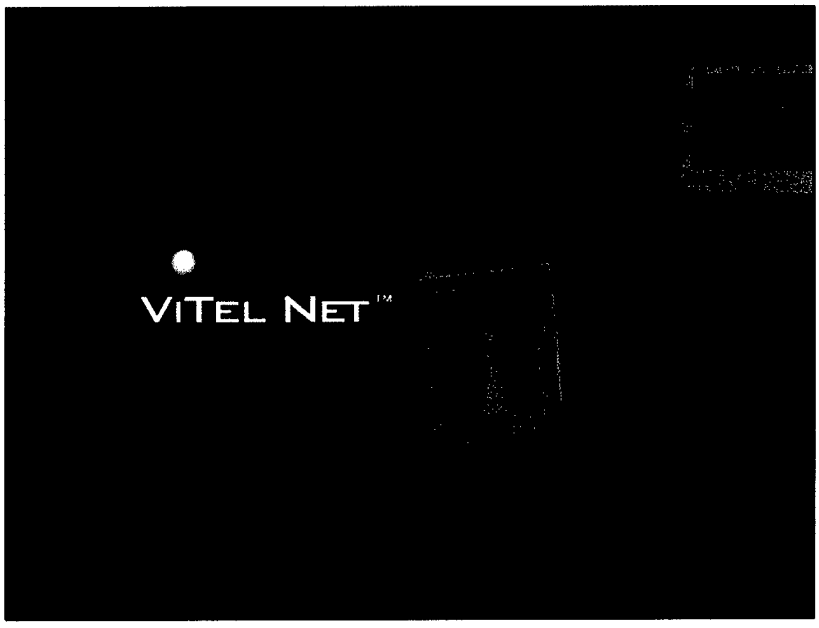

APPENDIX B: Protocol Knowledge Base Tools

FOR HIGH WEIGHT READINGS:

- Verify results.
- If immediate distress, take appropriate action.
- Reweigh if results are in question.
- Patient should weigh at the same time each day.
- Patient should wear same amount of clothes when weighing.
- Observe for S/S fluid retention.
- Review dietary intake from previous day.
- Is the patient taking medications as prescribed?
- Use professional judgment, exploring other possible causes as needed.

FOR LOW WEIGHT READINGS:

- Verify results.
- If immediate distress, take appropriate action.
- Reweigh if results are in question.
- Patient should weigh at the same time each day.
- Patient should wear same amount of clothes when weighing.
- Observe for S/S dehydration.
- Observe for vomiting, diarrhea, and fever.
- Review dietary intake from previous day.
- Is the patient taking medications as prescribed?
- Use professional judgment, exploring other possible causes as needed.

FOR HIGH BLOOD PRESSURE READINGS:

- Verify results.
- If immediate distress, take appropriate action.
- Retake blood pressure if results are in question.
- Patient should take blood pressure at the same time each day.

- Are there other signs of symptomatic hypertension?
- What was patient's activity level just prior to taking blood pressure?
- Review dietary intake from previous day.
- Has patient increased caffeine intake?
- Is the patient taking medications as prescribed?
- Review medications for possible side effects.
- Use professional judgment, exploring other possible causes as needed.

FOR LOW BLOOD PRESSURE READINGS:

- Verify results.
- If immediate distress, take appropriate action.
- Retake blood pressure if results are in question.
- Patient should take blood pressure at the same time each day.
- Are there other signs of symptomatic hypotension.
- Observe for S/S dehydration.
- Review dietary intake from previous day.
- Is the patient taking medications as prescribed?
- Review medications for possible side effects.
- Use professional judgment, exploring other possible causes as needed.

FOR HIGH PULSE READINGS:

- Verify results.
- If immediate distress, take appropriate action.
- Retake pulse if results are in question.
- Are there other signs of tachycardia?
- Does the patient have a fever?

- What was patient's activity level just prior to taking pulse?
- Review dietary intake from previous day.
- Has patient increased caffeine intake?
- Is the patient taking medications as prescribed?
- Review medications for possible side effects.
- Use professional judgment, exploring other possible causes as needed.

FOR LOW PULSE READINGS:

- Verify results.
- If immediate distress, take appropriate action.
- Retake pulse if results are in question.
- Are there other signs of bradycardia?
- Is the patient taking medications as prescribed?
- Review medications for possible side effects.
- Use professional judgment, exploring other possible causes as needed.

FOR HIGH TEMPERATURE READINGS:

- Verify results.
- If immediate distress, take appropriate action.
- Retake temperature if results are in question.
- Are there other febrile reactions?
- What was patient's activity level just prior to taking temperature?
- Did patient eat, drink, or smoke just prior to taking temperature?
- Review fluid intake.
- Observe for S/S dehydration.
- Observe for S/S of infection.
- Use professional judgment, exploring other possible causes as needed.

FOR LOW SpO2 READINGS:

- Verify results.
- If immediate distress, take appropriate action.
- Retake SpO2 if results are in question.
- Are there other signs of decreased oxygenation?
- Is patient short of breath?
- Is the patient using oxygen as prescribed, if applicable?
- Assess for ineffective breathing.
- Assess for increased nervousness or anxiety.
- Assess for fluid retention and ascites.
- Is the patient taking medications as prescribed?
- Use professional judgment, exploring other possible causes as needed.

FOR LOW SPIROMETER READINGS:

- Verify results.
- If immediate distress, take appropriate action.
- Retake Spirometer results if they are in question.
- Are there other signs of decreased lung volume or capacity?
- Is patient short of breath?
- Assess for ineffective breathing.
- Assess for increased nervousness or anxiety.
- Assess for fluid retention and ascites.
- Assess for congestion.
- Is the patient taking medications as prescribed?
- Use professional judgment, exploring other possible causes as needed.

FOR LOW GLUCOSE READINGS:

- Verify results.
- If immediate distress, take appropriate action.
- Recheck blood glucose if results are in question.
- Are there other signs of hypoglycemia?
- Did the patient exhibit symptoms of hypoglycemia?
- Did the patient alter their exercise routine?
- Did the patient alter their diet?
- Is the patient taking medications as prescribed?
- Use professional judgment, exploring other possible causes as needed.

FOR HIGH GLUCOSE READINGS:

- Verify results.
- If immediate distress, take appropriate action.
- Recheck blood glucose if results are in question.
- Are there other signs of hyperglycemia?
- Does the patient have ketones in the urine?
- Does the patient have an elevated temperature or infection?
- Has the person been ill?
- Did the patient alter their exercise routine?
- Did the patient alter their diet?
- Is the patient taking medications as prescribed?
- Use professional judgment, exploring other possible causes as needed.

CHANGE IN HEALTH STATUS:

- Verify results.
- If immediate distress, take appropriate action.
- Assess for severity and frequency of symptoms.

- Evaluate what may have triggered the decline.
- Assess for environmental factors that may have contributed to the decline.
- Assess for patient behaviors that may have contributed to the decline.
- Assess for changes in other health status areas not indicated by monitoring questions.
- Is the patient following the medication regime?
- Could the change in health status be a result of medication side effects?
- Use professional judgment, exploring other possible causes as needed.
- Instruct on appropriate topics as needed.

MEDICATION SIDE EFFECTS:

- Verify results.
- If immediate distress, take appropriate action.
- Does the patient have all of the prescribed medications, if not, take appropriate action.
- Review the patient's understanding of medication regime (name, dose, frequency, delivery method, purpose).
- Has the patient altered the prescribed dose?
- Assess for additional medication side effects that were not covered by the questions.
- Explore the possibility that the answers to the questions may be disease related and not medication side effects.
- Use professional judgment, exploring other possible causes as needed.
- Instruct on appropriate topics as needed.

NOT FOLLOWING MEDICATION REGIME:

- Verify results.
- If immediate distress, take appropriate action.
- Does the patient have all of the prescribed medications, if not, take appropriate action.

- Review the patient's understanding of medication regime (name, dose, frequency, delivery method, purpose)
- Assess for mental status changes, i.e. forgetfulness, confusion.
- If the patient stopped taking a medication or decreased the frequency prescribed, inquire about the reason.
- Is the patient presenting symptoms because of the missed medications?
- Review medications for possible side effects.
- Use professional judgment, exploring other possible causes as needed.
- Instruct on appropriate topics as needed.