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Computerized Patient Record

PRINCIPAL INVESTIGATOR: Azad M. Madni, Ph.D.
Doctor Weiwen Lin
Carla C. Madni

CONTRACTING ORGANIZATION: Intelligent Systems Technology, Incorporated
Santa Monica, California 90405

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1. INTRODUCTION

1.1 Problem Overview

The goal of Military Health System (MHS) is for military physicians to spend no more than 15 minutes with each patient during routine outpatient appointments. However, today administrative and medical data collection for the MHS Military Treatment Facilities (MTFs) tends to be time-consuming and resource-intensive. Specifically, the collection of information for diagnosis and treatment from sources other than the patient tends to be delay-prone. Waiting for such information significantly detracts from the time the physician has to directly interact with the patient during examination, diagnosis, treatment, and consultation. The military has determined that research needs to be performed on *“methodologies and technologies to enable necessary data collection without impacting patient/physician interaction.”* To this end, a program is currently underway to develop a Computerized Patient Record (CPR). MTF healthcare providers currently use a combination of handwritten and computerized data entry techniques to capture and document the clinical encounter. The desktop workstations currently employed to capture this information seem to hinder the productivity as the military strives to deliver effective and efficient healthcare. In light of this finding, the military has determined that a method is needed to reduce the footprint of the computer workstation and to integrate several capabilities into efficient, practical hand-held devices that operate potentially in a wireless environment.

To improve work processes, the military has determined that any new automation/system needs to provide specific capabilities. The military envisions these capabilities to be delivered via handheld, wireless web devices that are intended to support physicians, nurses, pharmacists, and combat medics in the field. These wireless web devices are called Medical Digital Assistants [1] in the military healthcare community.

1.2 The Promise of Medical Digital Assistants

The Medical Digital Assistant (MDA) is envisioned to be a small, portable, unobtrusive computing and/or telecommunications device that assists in collection, retrieval, and communication of data relevant to medical care [2]. At USAMRMC, MDA-related developments are under the purview of the TATRC's Integrated Research Team (IRT) that is tasked with setting research directions and themes for Wireless Medical Applications. Within TATRC, there is a center-wide research program called the Wireless Medical Enterprise (WME). The WME investigates the utilization of wireless medical digital assistants (MDAs) within DoD settings. The WME views MDAs as wireless handheld computing devices that are designed for use in “point-of-care” medical applications [3]. The objectives of WME are to: (1) explore the use of wireless networking in medical settings within Medical Treatment Facilities (MTFs) as well as in the field; and (2) develop systems that make use of MDAs as point-of-care “end agents” in a wireless, distributed, computing environment. The WME, as part of its charter, is engaged in specifying a suite of web-based, spreadsheet style, secure software applications that

offer a congenial user interface for patient record viewing, data entry, data collection [4], [5] remote data access, patient record update, and secure transmission. In light of the foregoing success criteria is to make sure that the MDA applications fit within both the cultural and practical constraints of both the Army Medical Treatment Facilities as well as the operational environment in which combat medics operate.

For a MDA to deliver on its promise, certain important tradeoffs need to be made (Table 1). For example, the thin client solution, based on browser technology is being viewed more favorably than the traditional client-server implementation by the military healthcare community. However, with thin client architectures, issues related to speed of access, security, and privacy need to be carefully addressed.

Table 1. Challenges in MDA-enabled Mobile Computing

- Lack of hospital/field experience with wireless realtime connections; new clinical applications
- Architecture design (e.g., thin client, client-server)
- Speed of access to new information (content pull, push, publish-subscribe)
- Information security and privacy (i.e., confidentiality)
- Extended battery life
- Electromagnetic interface (EMI)

1.3 MDA-enabled CPR management

Since the MDA is expected to support the entire physician-patient encounter starting with examination and concluding with treatment and/or consultation, it is imperative that the “learning curve” to reach proficiency be no more than 30 minutes for a casual computer user. The desired functionalities and features of an MDA-enabled Computerized Patient Record management system are presented in Table 2.

Table 2. Desired Capabilities of a Medical Digital Assistant

- Appointed patient record caching with Patient Encounter Modules
 - patient demographics and immunization
 - patient's active medications, allergies, and drug-drug interactions
 - patient problem list and alerts
 - local registration, appointment-making, and scheduling
 - order entry, status, and results retrieval
- Voice transcription and speech recognition
- Encounter Notes using natural language processing (NLP)
- Coding for billing based on auto-NLP
- Web-based open architecture with XML-based data exchange and application interaction
- Biometric identification and login [6]

The challenges in developing and institutionalizing MDA-based CPR management system revolve around technology choices [7], user acceptance, and privacy policy. Technology issues range from battery life of MDA devices, to network speeds, EMI, and “small footprint” architecture. User acceptance challenges [8] encompass device practicality, and ease-of-use (e.g., system should be more practical than a 3x5 card, or dictating to a tape recorder for transcription), as well as ensuring that the MDA-enabled new process is clearly established and

properly introduced within the medical team [9]. Finally, protection of medical records under HIPAA privacy regulation needs to be assured.

At first blush it might appear that there are a few medical healthcare systems on the market with a suitable PDA interface. However, the U.S. Army has decided to avoid all proprietary solutions that invariably limit what the Army can do in terms of modifying the code base or adding new functionality. In addition, COTS products have some serious technological shortfalls including: (a) *small, moderate quality displays* that limit the size and quality of images that can be viewed; (b) *limited computing power* that precludes the possibility of incorporating an “intelligent assistant” to help physicians with data entry and treatment processes; (c) *lack of connectivity* to enterprise information systems that create problems in authentication and information access; and (d) *immature wireless technology* which, continues to advance rapidly, but still has a ways to go.

It is equally important to understand the operational “drivers” resulting from the force deployment locales, mission operational tempos, increased emphasis on prevention of disease, non-battle injury, and the need to sustain optimal performance in both normal and contingency operations. It is also important to appreciate the guidance for forward treatment only as necessary; and the recurring need for rapid, long-range casualty evacuation. Finally, it is important to discern where and how medical informatics is embedded in the spectrum of healthcare. It is with these considerations in mind that the HealthTrak system is being designed.

1.4 Project Overview

This SBIR project is concerned with the development and deployment of a technology-enhanced CPR that can be accessed through a wireless Medical Digital Assistant (MDA). The recently-concluded Phase I effort consisted of: (a) conducting a front-end analysis of scenarios that encompass patient-care provider interactions both in the clinic (i.e., fixed facilities) and in the field; (b) evaluating promising new technologies in terms of their application and impact in improving patient-care provider interaction; (c) creating a system concept and preliminary technical and operational design for application of promising technologies that can dramatically enhance patient-physician interaction; and (d) creating a concept prototype of a MDA capable of supporting the information requirements of the different classes of users across operating systems including PocketPC and Palm. Phase I has established the feasibility of an operating system agnostic MDA solution and a scalable, extensible system architecture for integrating with legacy systems containing Computerized Patient Records, as well as billing and payment information.

1.5 Report Roadmap

This report presents the accomplishments of Phase I. Section 2 presents the study and front-end analysis conducted on this project. It presents the problem formulation, the methodology pursued to accomplish the stated objectives of Phase I, and the information requirements generated for the various user classes involved in the patient care continuum. Section 3 develops the HealthTrak™ system concept starting with HealthTrak requirements and concluding with the key highlights of the system concept. Section 4 presents the key technology tradeoffs and



decisions leading to the selection of high payoff technical approaches that bring the system concept to life in a cost-effective, high performance package. Section 5 presents the results of the horizontal prototyping effort on both PocketPC and Palm PDAs. The purpose of the user interface prototypes was to communicate the value proposition of a MDA with its viewing area limitations to care providers by showing how the limited available "real estate" can be effectively used. Section 6 presents the HealthTrak technology and operational design as well as a detailed implementation architecture design. Section 7 presents the key research accomplishments of Phase I. Section 8 presents the reportable outcomes. Section 9 presents the results and findings of Phase I as well as other key considerations with a view to planning a successful Phase II implementation, transition, and commercialization effort.

2. STUDY AND ANALYSES

2.1 Phase I Summary

The overall objective of this effort was to create a prototype electronic patient record system that is built on an open, XML-based architecture and that integrates patient data from a variety of distributed, heterogeneous sources (e.g., pharmacy, laboratory, ...). Phase I of this effort was devoted to:

- (a) Understanding the unique requirements of the entire continuum of military patient care.
- (b) Defining requirements for health information integration, patient safety, and security.
- (c) Evaluating promising technology approaches that are complementary and synergistic.
- (d) Developing a system concept and a preliminary technical and operational design for effective application of selected promising technologies to patient/physician interaction.

The **first objective** was concerned with understanding the unique patient care requirements of the U.S. Armed Forces in the field or in the theater of operation. This included developing a thorough understanding of the environmental and communication constraints in the field. The **second objective** was concerned with explicitly defining all pertinent requirements for health information integration, patient safety, and security. This included identifying the various sources of patient data, along with their respective formats. The **third objective** was concerned with evaluating state-of-the-art technologies for HealthTrak™ in terms of their overall usefulness and cost-effectiveness. The **fourth objective** was concerned with formulating the HealthTrak system concept as well as a preliminary technical and operational design that delineated which technologies fit where in the overall system concept.

During the conduct of Phase I we successfully accomplished all these objectives and went beyond in terms of our overall contribution (Table 3). In the following paragraphs we describe these accomplishments in more detail for the various tasks in the approved statement of work.

Table 3. Accomplishments Summary

- Fully satisfied the objectives of Phase I SOW ...and went beyond ("extra credit")
- Created and applied BuildRite™, a user-centric, risk-mitigated methodology for prototyping MDA applications
 - streamlines and accelerates MDA application development
- Addressed not just the physician's information requirements but also those of the nurse, pharmacist, and combat medic
- Developed and delivered two horizontal prototypes to TATRC
 - these run on PocketPC and Palm O.S.
 - the prototypes are intended to demonstrate feasibility of congenial physician-patient interaction to end users and sponsors
 - these prototypes show creative use of viewing area in presenting CPR information from different perspectives and in different formats
- Published refereed paper in the Six Biennial World Conference on Integrated Design and Process Technology (2002)
- Presented the paper in the "Formal Methods in Healthcare" session at this conference
- Secured Northrop Grumman Corporation as Phase III commercialization partner

2.2 Problem Formulation

Medical Digital Assistants with fast information retrieval capabilities from CPR systems are viewed as a promising solution to not only increasing patient throughput but also making the patient-physician interaction more satisfying and complete. However, the basic fear of new technology by a generation that did not grow with computers coupled with security and privacy concerns pose real challenges to achieving widespread acceptance in the care provider community. A further complicating factor is the limited viewing areas of handheld, wireless web devices, that pose a real challenge to the human factors practitioner and cognitive psychologists. Despite these perceptions, Personal Digital Assistants are making fast inroads into the care provider community with nurses being the last to accept the value proposition of MDAs. Against this backdrop, we have identified the critical success factors that are key to MDA acceptance by physicians (Table 4). The other classes of users have similar requirements as well.

Table 4. Critical Success Factors

- **Attract physicians**
 - e.g., voice annotation or handwriting recognition of physician's progress notes
- **Facilitate physician's progress** to more sophisticated functions
 - e.g., complex documentation, medical data review, medical decision support
- **Enable physicians to develop proficiency** in at most 30 minutes with minimal computer skills
- **Assure compatibility** with typical "office" workflow and physician's thought process
- **Streamline other physician-used processes** such as billing and transcription and make them more accurate
- **Provide near-realtime feedback** to physicians and nurses by performing instantaneous analysis of complex data in centralized databases
- **Enable nationwide access** to database through wireless cellular data, packet data, or other secure wide-area networks
- **Achieve satisfying patient-physician interaction** in the "15-minute" encounter

2.3 Key Considerations

Creating a MDA that achieves wide acceptance in the military healthcare community requires an upfront evaluation of a variety of considerations. It requires a systematic methodology that evaluates each consideration from a user-centric perspective where the user is defined by the family of care providers that span the patient care continuum. The key considerations in the development and deployment of a MDA for both fixed facility and field use are presented in Figure 1.

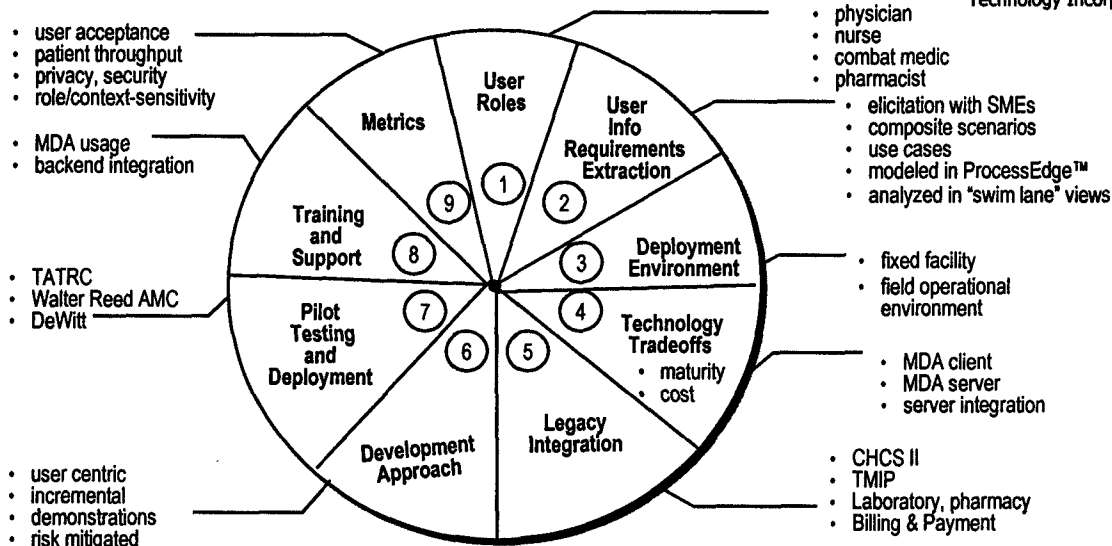


Figure 1. Key Considerations in MDA Development and Deployment

2.4 The BuildRite™ Methodology

At the very outset, we created BuildRite, a user-centric, risk-mitigated methodology for rapid development of MDA applications. This methodology which has its genesis in [10] was successfully applied in Phase I leading to the development of the two horizontal prototypes. The methodology consists of five inter-related stages that collectively achieve the goals of a user-centric design in risk-mitigated fashion. Table 5 presents each stage of the methodology and the associated risk mitigation.

Table 5. Risk Mitigation

Stage	Risk Mitigation
Front-end Analysis and Process Modeling	Overcome risks associated with incomplete requirements; understand deployment issues, care provider roles, technology trends, and care provider-patient interactions with new technologies (e.g., MDA)
Horizontal Prototyping	Maximize user acceptance through early evaluation and critique of usage concept by end users
Server Side Prototyping	Minimize technology and integration risks through appropriate tradeoffs
Spiral Development	Harmonize user and developer views; minimize implementation risks through iterative, incremental prototyping, demonstration, improvement
Transition and Deployment	Minimize deployment problems through pilot testing and evaluation prior to full scale deployment

These stages come together with special attention on the user. In fact, the methodology is designed to assure early and frequent involvement of end users throughout the project life cycle while allowing developers sufficient time to create a scalable, extensible architecture based on sound technology tradeoffs and technology trend projections. Figure 2 shows the overall methodology.

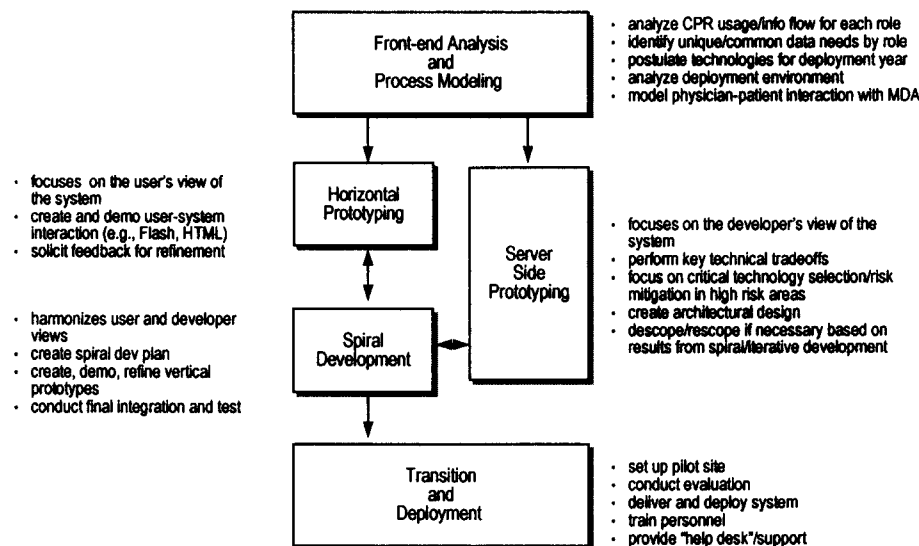


Figure 2. BuildRite™ Methodology Overview

2.5 Metrics

Ultimately, the "litmus test" lies in the identification and application of the right set of metrics. The metrics are associated with both the process (i.e., methodology) and the products (i.e., the resultant MDA applications). Table 6 presents sample metrics for a successful HealthTrak development and deployment.

Table 6. Sample Metrics

- Methodology-related
 - ability to communicate vision
 - ability to mitigate risks
 - opportunities to collaborate and refine design
 - opportunities to involve end users initially and frequently
 - ability to accommodate changes in requirements
- Application-related
 - did it hit the user's "sweet spot"
 - did it satisfy functional requirements
 - was it easy to deploy in the target environment
 - does it offer facilities for continuous improvement
 - does it scale well
 - is it easily extensible
 - does it connect seamlessly to "backend" systems/legacy apps
 - does it have proper documentation, online help
 - is the physician's diagnosis speed and efficiency improved
 - is the physician's prescription writing speed and efficiency improved
 - are more patient-centric activities performed in the "15-minute encounter"

2.6 End-User Analysis

HealthTrak functional requirements were derived from an end-user analysis based on: a) interviews with end-users, i.e., physicians, nurses, pharmacists; b) literature review; c) cognitive

task analysis; d) subject matter expert elicitations; and e) analysis of emergency room procedures as the best proxy for the combat medic operational environment. The results of the foregoing end-user analysis are presented in Table 7.

Table 7. Results of End-User Analysis
(Computerized Patient Record (CPR) Information Requirements Vary with Role)

User data requirements (to be displayed in limited screen environment)	
Physician	• patient data: especially height, weight • allergies (drug) • recent laboratory results • current medications • diagnoses (problem list) • procedures • drug references: dosage calculation, drug interaction alert • access to formulary (organizations list of available drugs to prescribe) • approximately 2,000 characters from recently transcribed reports (radiology, operative, consults, etc.) • vital signs (temperature, pulse, respiration, O2 sat)
Pharmacist	• patient data: especially height, weight • allergies (drug) • current medications • dosage calculation • drug interaction alerts • current lab results (especially therapeutic ranges of high-risk meds: e.g., Coumadin)
Combat Medic (Paramedic/EMT)	• access to past medical history (PMH): diagnoses, medications, allergies • patient demographics: age, height, weight • ability to record patient assessments with menu choices • medical calculation assistance: drug dosage, IV drips, GCS (Glasgow Coma Score), etc. • access to protocols/algorithms • ability to time events (time stamp) during a code (CPR), procedures, drug administration • track total dosages of a drug; based on patient height and weight • prompt (beep) for next drug dosage administration time (e.g., epinephrine) • transfusion bag scan against patient identification scan to ensure safe match
Nurse*	• vital signs – ability to view as well as record • pending physician orders (in essence a to-do: meds to administer, procedures to perform such as finger stick, etc.) • allergies (drug) • diagnoses • current medications • other types of 'nursing flowsheet' data: Intake and output, neuro-sign checks, ABGs, etc. • nursing plan of care – review and select from menu

* Hard to find information. One article indicated that the barriers to PDA use by nurses may be social rather than technological. Perhaps this is another area of gender differences. Nursing is very documentation-intensive.

2.7 Common Data Requirements

The foregoing end-user analyses reveal that there are certain information requirements that are common to the four classes of users. These are shown in Figure 3.

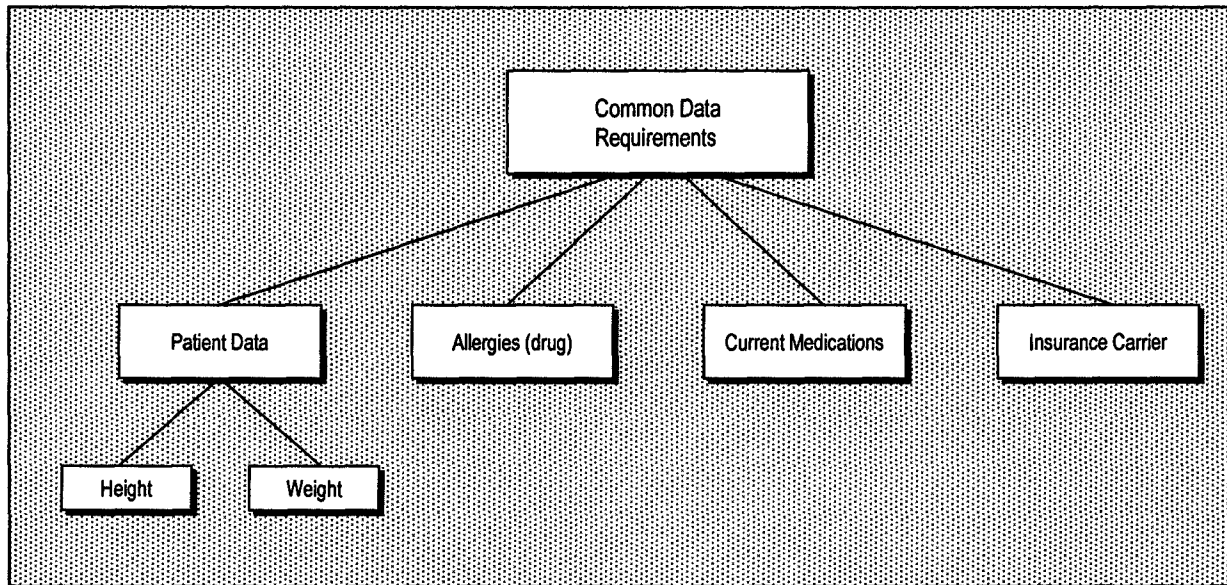


Figure 3. Common End-User Data Viewing Requirements

The implication of these common requirements is that the user interface and user-system interaction for these portions of the CPR should be consistent and standardized.

2.8 Unique Data Requirements

The majority of the data requirements for each role are unique (i.e., role-specific). The unique data requirements for each user role are presented in Figures 4 through 7. As can be seen in these figures, the pharmacist's data requirements are the least intensive, the nurse's data requirements are the most intensive, the physician's data requirements are most complex, while the combat medic's data requirements are the most time-stressed and varied.

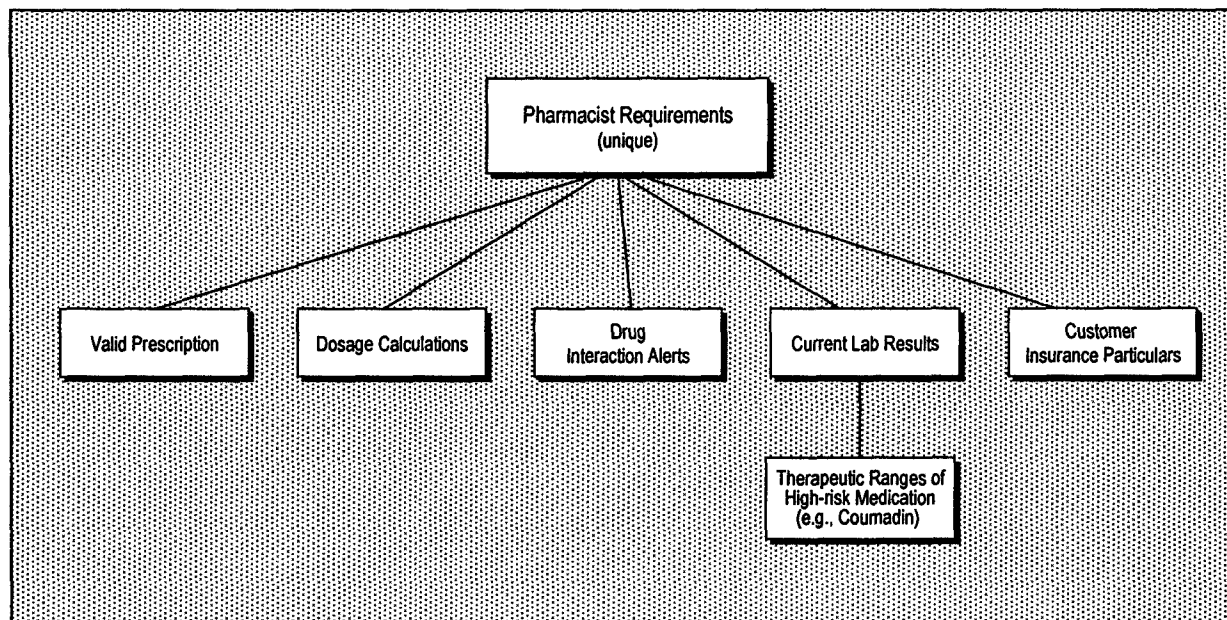


Figure 4. Pharmacist-specific Data Requirements

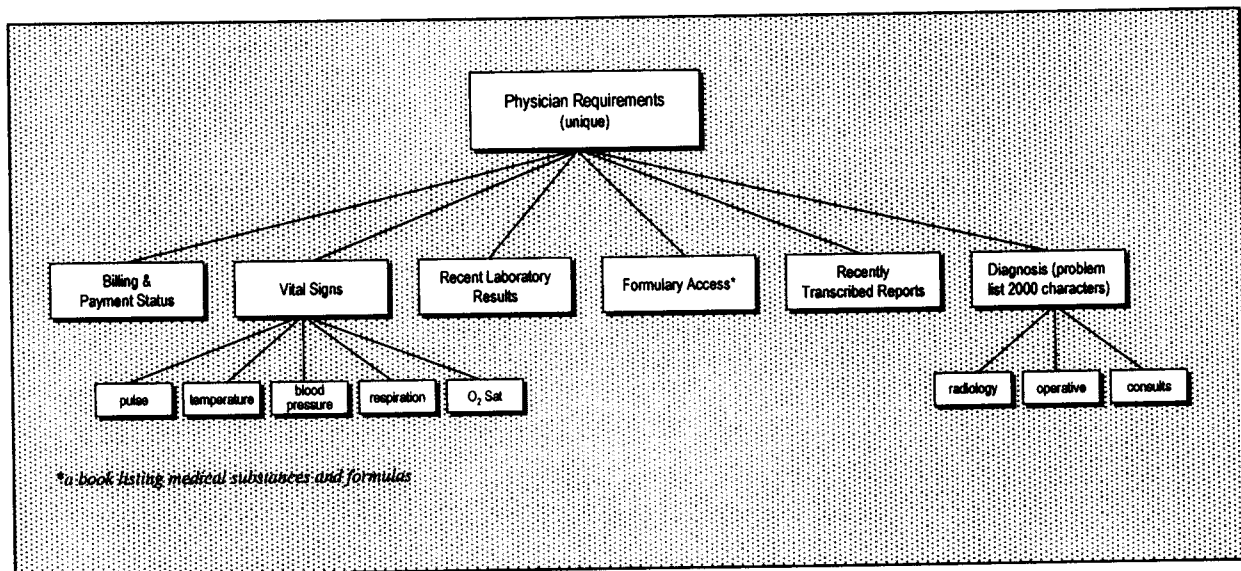


Figure 5. Physician-specific Data Requirements

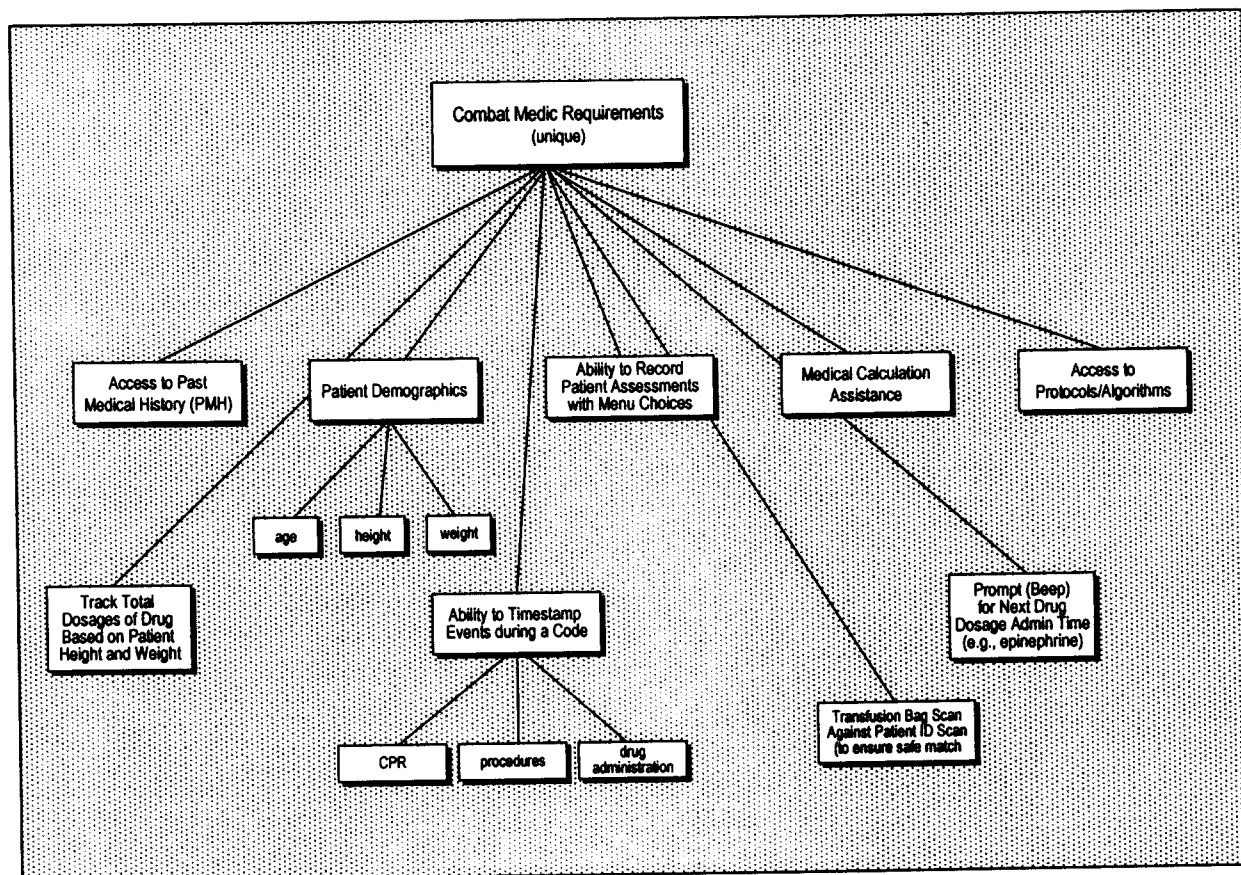


Figure 6. Combat Medic-specific Data Requirements

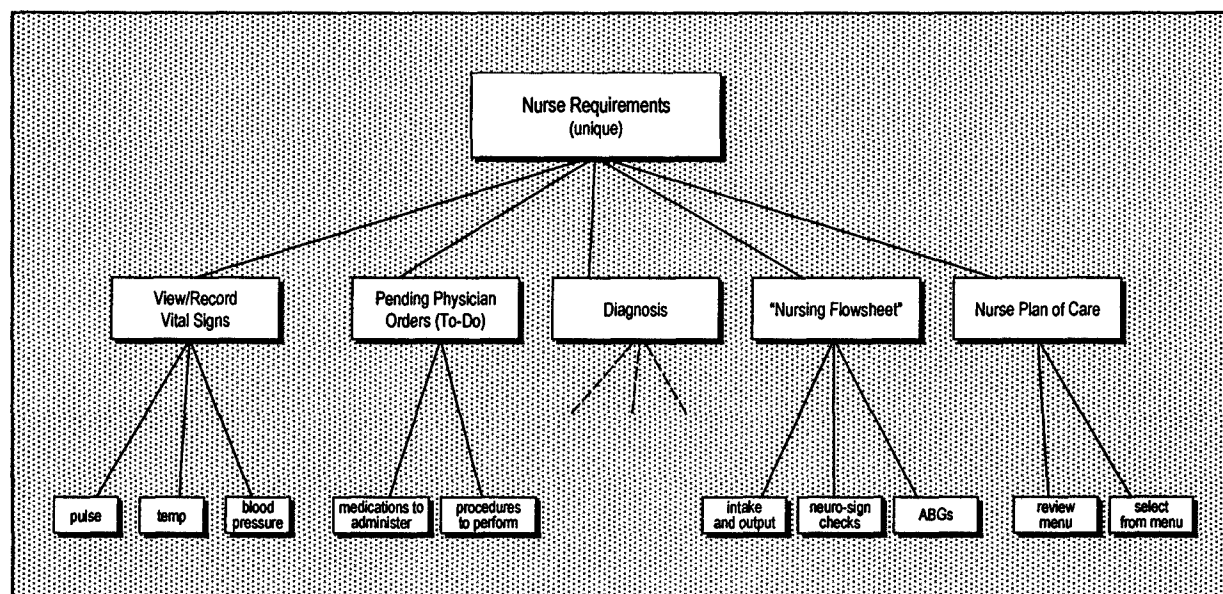


Figure 7. Nurse-specific Data Requirements

The foregoing results and findings were used along with the results of scenario modeling to create "horizontal" prototypes (i.e., concept prototypes featuring fully functioning user interfaces) that run on both PocketPC and Palm operating systems.

2.9 Scenario Modeling

To complement the end-user analysis, we synthesized and modeled a multi-role HealthTrak scenario in ProcessEdge™, our commercial software product for modeling and analysis of complex processes. The purpose of this modeling effort was to make explicit and visualize the interactions of the various roles in order to develop a better understanding of the information requirements, especially for the combat medic.

The HealthTrak scenario consists of four contiguous stages: emergent care and transport; acute care hospital; rehabilitation hospital; and ambulatory care. Each stage is described next.

Emergent Care and Transport. Soldier sustains burn injury on the battlefield. Combat medic arrives at scene and performs initial assessment of the patient. Combat medic estimates the patient's total body surface area (TBSA) burned and enters the soldier's identification number into HealthTrak.

Baseline patient data (name, rank, SSN, military occupational specialty, religion, sex) from the Theater Medical Information Program appear on screen in template of DD Form 1380, Field Medical Card. Height, weight, current medication and any drug allergies also appear. Combat medic enters initial vital sign information. Date/time of recording automatically inserted by HealthTrak. Using HealthTrak protocol feature, combat medic accesses the fluid resuscitation formula used for fluid replacement of burn patients. Using MDA, medic determines the amount

of Ringer's lactate to be administered based on patient weight and TBSA burned. IV is started. Combat medic monitors soldier's vital signs. As vital signs are entered, date and time automatically recorded.

Patient is transported to aid station and ultimately to acute care hospital. Throughout transit, seamless data capture of patient vital signs and treatments rendered (dosage and time of medications such as morphine and antibiotics) are entered into HealthTrak. HealthTrak performs quality checks such as monitoring cumulative dosage of drugs against maximum safe levels for patient's weight and audio prompting of combat medic when next dosage of a medication is due. Redundant data entry of baseline information, patient history, drug allergies, etc. is eliminated. Entries are legible, chronological and maintained in one location. Need for DA Form 4006 (Medical Record Field Jacket) and supplemental DD Form 1380s is eliminated.

Acute Care Hospital. Physician examines patient upon arrival to ICU unit of burn center. Via HealthTrak, physician has access to patient's most recent vital signs and response to treatment and medications administered in the field. Patient demographics and past medical diagnoses and surgical procedures are displayed. Summary findings of previously transcribed radiology, operative, consult or discharge summary reports are available. Physician accesses standing admission orders for burn patients (labs, EKG, tetanus, vital signs every 15 minutes, etc.). Revisions made to standing orders based on individual patient's needs and entered via HealthTrak.

Nurse accesses physician orders for patient via MDA. Nurse performs vital sign checks every 15 minutes and monitors patient intake and output. Data entered into patient medical record via HealthTrak. 24-hour intake and output totals calculated and displayed on HealthTrak. Nurse accesses drop down menu to select nursing diagnoses (e.g., satisfactory pain control; and absence of wound infection) to be entered.

On daily rounds, physician is able to view the new laboratory results and other test outcomes for patient; enter new orders and record progress (SOAP) notes.

Pharmacist is made aware of new patients admitted to facility via HealthTrak. Patients height, weight, drug allergies, recent laboratory results and current medication orders displayed on MDA. HealthTrak provides information regarding potential drug interactions and dosage calculations.

Rehabilitation Hospital. Patient transferred to rehabilitation level of care. Pertinent transfer data, such as, diagnoses, procedures performed during hospitalization, rehabilitation goals, current medications, patient behavioral status, ambulatory status and nutritional status displayed on MDA.

Ambulatory Care. Patient discharged to home. Primary care physician receives notice of patient discharge through HealthTrak. Final diagnoses, discharge instructions and current medications displayed. Summary findings of transcribed reports from hospitalizations available in

HealthTrak. Contact information of acute care and rehabilitation providers available on HealthTrak.

2.10 Usage Scenarios

Tables 8 and 9 present representative HealthTrak usage scenario segments for the physician and the combat medic. The latter scenario is used to convey the subsequent analysis done using ProcessEdge™.

Table 8. Physician Usage Scenario

- Physician downloads schedule with relevant patient data into HealthTrak
- Takes HealthTrak to exam room to see patients
- Taps on "appointment" -- HealthTrak displays patient chart (the patient's complete medical history is also available) Reviews previously prescribed treatment
- Asks patient questions to assess progress and enters the notes into HealthTrak
- Performs some physical exams and enters the notes into HealthTrak
- Receives message on HealthTrak that latest lab report result is now available
- Shows lab reports to the patient and explains it
- Orders new prescription and puts that information into HealthTrak
- HealthTrak sends latest treatment notes and prescription to hospital's enterprise medical information system via wireless network
- New prescription is forwarded to the pharmacy where it is filled and ready for pickup 15 minutes later

Table 9. Combat Medic Usage

- Soldier sustains injury
- Combat medic arrives/does initial assessment
- Combat medic estimates TBSA and enters soldier ID into HealthTrak™
- Baseline patient data from TMIP appears on screen (DD 1380 template)
- Height, weight, current medication, and drug allergies appear
- Combat medic enters initial vital sign information
- Date/time stamp auto-recorded by HealthTrak
- Using HealthTrak's protocol feature, combat medic accesses fluid resuscitation formula used for fluid replacement of burn patient
- Using HealthTrak, medic determines amount of Ringer's lactate to be administered based on patient weight and TBSA
- Intra-venous (IV) feeding is started
- Combat medic monitors vital signs
- As vital signs are entered into HealthTrak, date and time are auto-recorded

2.11 Process Models for HealthTrak Scenario

Processes associated with each of the four contiguous scenario stages were modeled using ProcessEdge™. Figures 8 through 14 show representative ProcessEdge screen shots for scenario process modeling and scenario-related data entry. Figure 15 shows the swim lane views (outputs) of ProcessEdge. This view shows the interactions between the various care providers and their respective MDA-related tasks. These models provided the basis for the horizontal prototyping that was done on both PocketPC and Palm wireless, handheld devices.

Process Definition: Emergent Care and Transport

Activity Name: Enter Initial Vitals
Duration: 1.0

Parent Process Step Name:
Cost \$: 0.0
Calculate Cost

Description:
The combat medic with the support of his PDA will enter the patient's vital signs and burn information.

Resources:
☐ Rates
☐ Personnel
☐ Tools
☐ References

Entry Criteria:
☐ Inputs
☐ Pre-Conditions
☐ Exit Criteria
☐ Outputs
☐ Post-Conditions

Other Data:
☐ Organizations
☐ Locations
☒ Products

Products (If Qty. Produced):
Master List **Delete Item** **Change Quantity**
 No Products of Qty. Produced Assigned.

Precedence Graph **Process Decomposition** **Close**

Figure 8. Defining the Emergent Care and Transport Scenario Fragment

Locations Master List: Emergent Care and Transport

New **Delete** **Cut** **Copy** **Paste** **Find** **Find Again** **Indent** **Outdent**

Battlefield
 Army Medical Facilities
 Walter Reed
 De Witt
 Army Testing Facilities
 TATRC
 Walter Reed
 De Witt

Location Name: Battlefield
Location Category:

Description:

Address:

Contact:
Phone:

Geocode:
Area Code: **Zip Code:**

Time Zone:
Local Currency:

Mode of Deliveries:
Preferred Carrier:

Assign Location(s) **Location Hierarchy** **Close**

Figure 9. Entering Scenario-related Location Data

Organizations Master List - Assign Organization(s) to Process

New
Delete
Cut
Copy
Paste
Find
Find Again
Indent
Outdent

Medical Service Corps
AMEDD
TATRC

Organization Name
Medical Service Corps

Organization Category

Description
The Medical Service Corps is an integral part of the Army Health Care Team. They work together with other members to provide health care services for soldiers, their families and retirees.

Organization Hierarchy

Assign Organization(s)

Close

Figure 10. Entering Organization Information

Define Precedence: Emergent Care and Transport

View Precedence Graph **Define Precedence**

Select Predecessor(s):

- ☐ 1 Sustain Burn Injury
- ☐ 2 Perform Initial Assessment
- ☐ 3 Estimates Patient's TBSA Burned
- ☐ 4 Enter Soldier's ID Number
- ☐ 5 MDA retrieve CPR from TMIP
- ☐ 6 Review Baseline Patient Record
- ☐ 7 Enter Initial Vitals
- ☐ 8 MDA AutoRecords

Assign

Select a Process Step:

- ☐ 10 MDA Supplies Formula
- ☐ 11 Determine Amount of Ringer's Lactate
- ☐ 12 MDA Calculates Amount Based on Pattern
- ☐ 13 Start IV
- ☐ 14 Monitor & Enter Vitals
- ☒ 15 MDA AutoRecords

Entry Logic
☒ AND
☐ OR

Edit Logic
☒ Concurrent
☐ Conditional

Select Successor(s):

- ☐ 1 Sustain Burn Injury
- ☐ 2 Perform Initial Assessment
- ☐ 3 Estimates Patient's TBSA Burned
- ☐ 4 Enter Soldier's ID Number
- ☐ 5 MDA retrieve CPR from TMIP
- ☐ 6 Review Baseline Patient Record
- ☐ 7 Enter Initial Vitals
- ☐ 8 MDA AutoRecords

Assign

Assigned Predecessor(s):

- ☐ 14 Monitor & Enter Vitals

Assigned Successor(s):

Probability:

Update

Delete Predecessor **Find Predecessor** **Find Predecessor Again**

View
☒ By Name ☐ By Number

Process Decomposition **Close**

Figure 11. Defining Precedence Relationships

Roles Master List: Emergent Care and Transport

Left Panel (Buttons): New, Delete, Cut, Copy, Paste, Find, Find Again, Indent, Outdent, Assign Role(s)

Left Panel (List): Patient, Combat Medic, Nurse, Pharmacist, MDA, CPR Database, CHCS II, TMIP

Right Panel (Form):

Role Name: Combat Medic

Role Category:

Description: Medical Service Corps. member assigned to assist or support battlefield injuries.

Qualifications:

Average Cost \$: 0.0

No. in Organization(s): 0.0

Role Hierarchy

Close

Figure 12. Defining the Various Role Categories

Tools Master List: Emergent Care and Transport

Left Panel (Buttons): New, Delete, Cut, Copy, Paste, Find, Find Again, Indent, Outdent, Assign Tool(s)

Left Panel (List): MDA, 802.11x Wireless Card, ProcessEdge, MS Project, MS Visio, MS Office

Right Panel (Form):

Tool Name: MDA

Tool Category:

Description/Functionality: A Handheld device with wireless connection, which allows data synchronization between the end user and hospital server.

Vendor: Compaq iPaq

Costs:

Fixed Cost \$: 600.0 Time-based Cost \$: 0.0

Training Required: 7.0 days

Qty. in Organization(s): 0.0

Tool Hierarchy

Close

Figure 13. Defining the Various Tools/Applications Used by or in the MDA

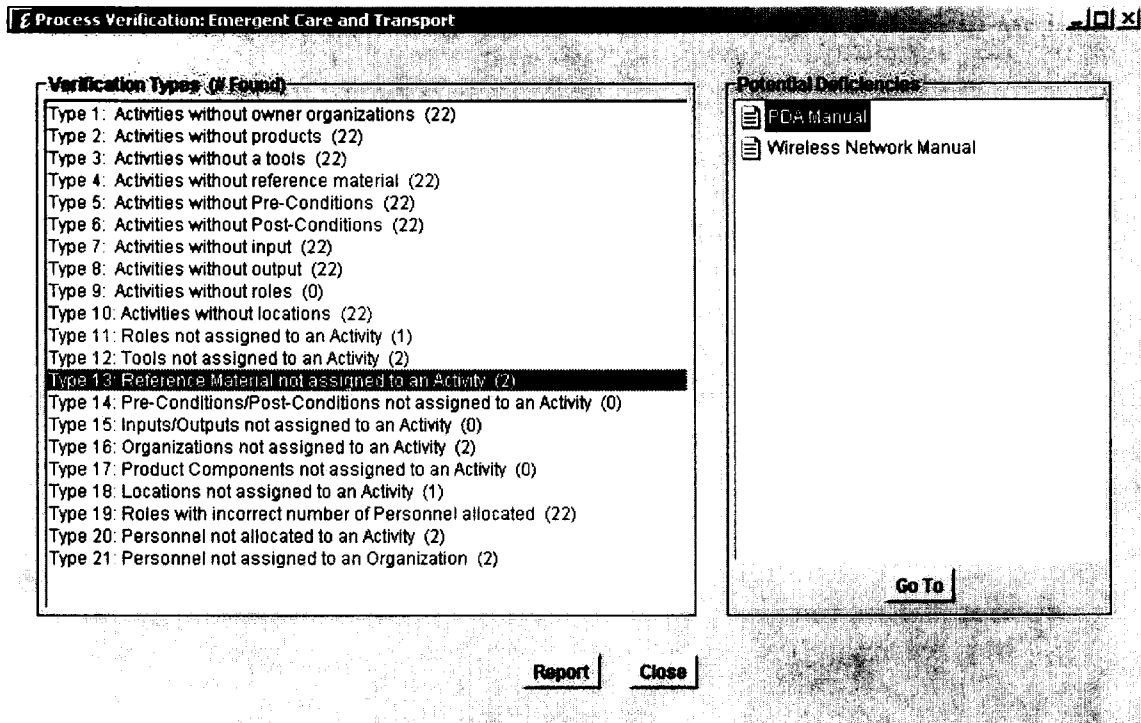


Figure 14. Correcting Deficiencies in the Model by Verifying Model Correctness

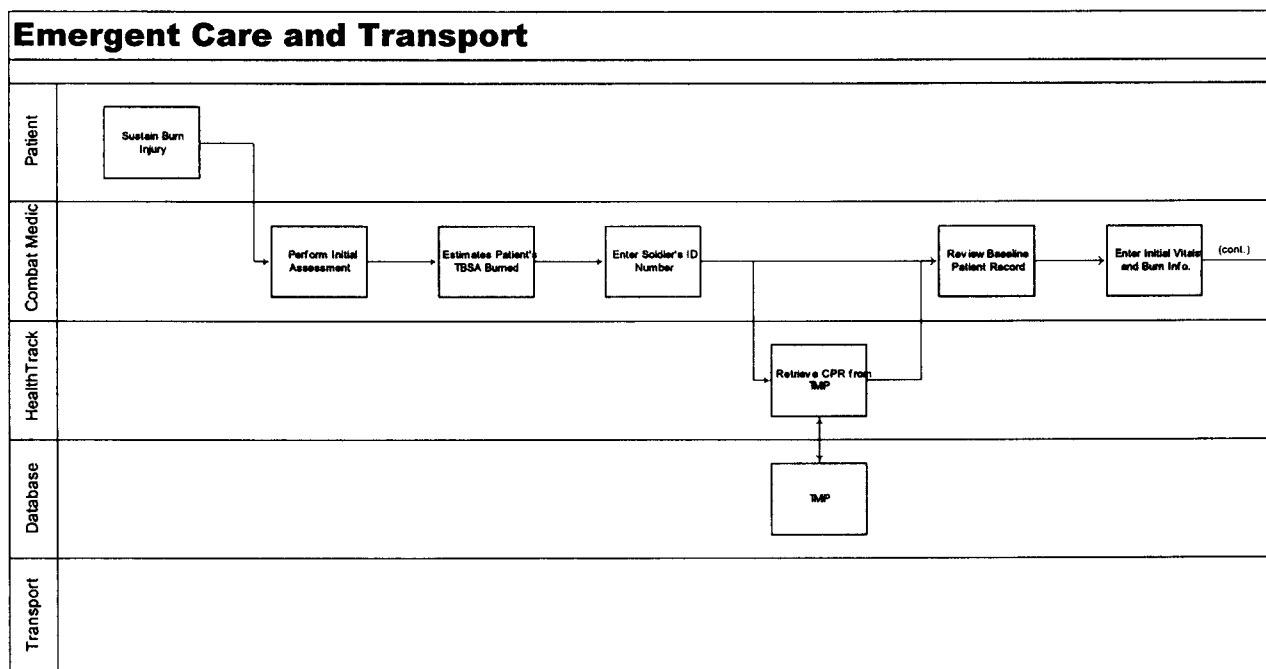


Figure 15. Swim Lane View of Emergent Care and Transport Process Fragment Showing "Multi-agent" Interactions and Activity Dependencies

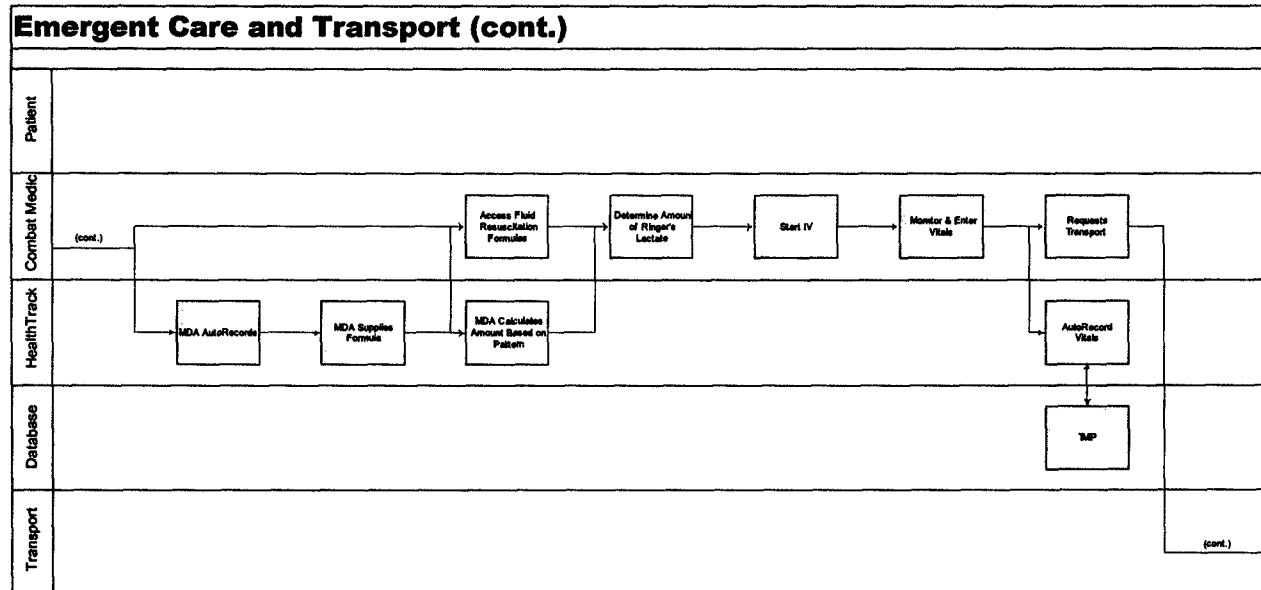


Figure 15. Swim Lane View of Emergent Care and Transport Process Fragment ...(cont'd)

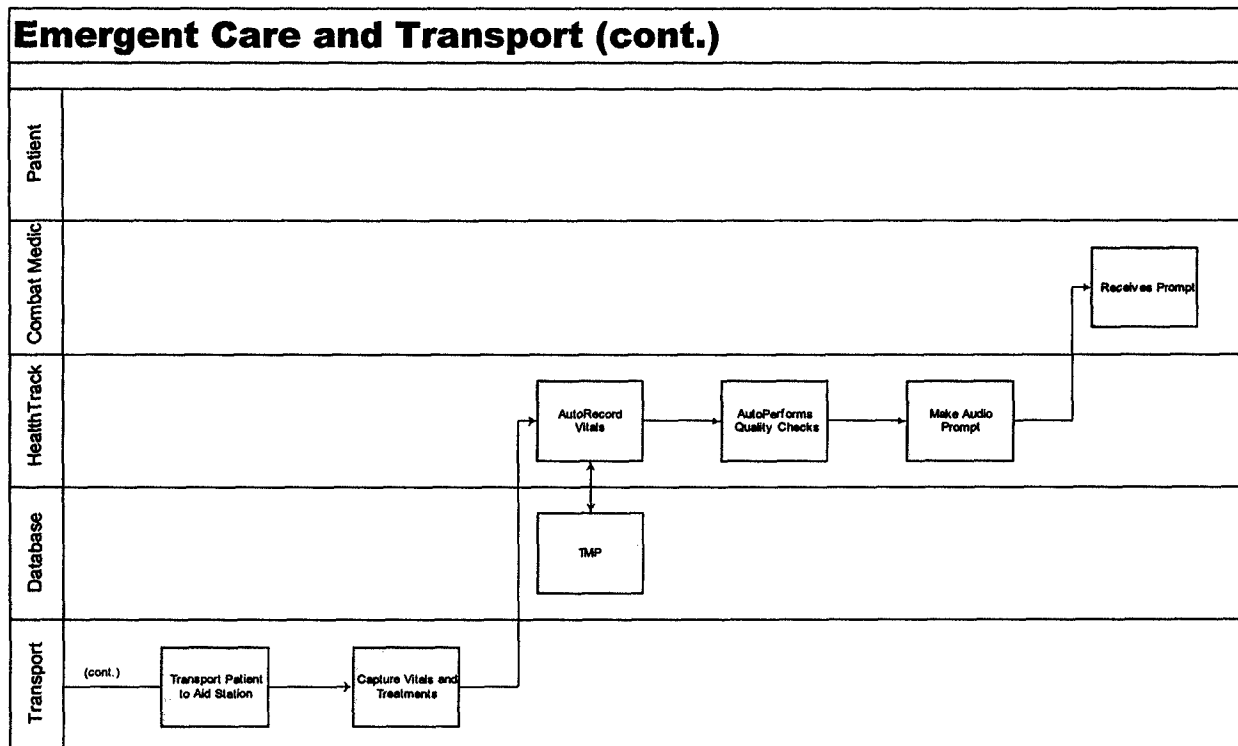


Figure 15. Swim Lane View of Emergent Care and Transport Process Fragment ...(cont'd)

3. HEALTHTRAK™ SYSTEM CONCEPT

3.1 HealthTrak Requirements

In light of the foregoing indepth front-end analysis, we can specify the HealthTrak vision and major requirements that drive the creation of the system concept. Table 10 presents these requirements at a suitable level of detail for developing the overarching system concept.

Table 10. HealthTrak Vision and Key Requirements

- Build on top of non-proprietary technology (e.g., Linux and Java)
- Standards-compliant (e.g., HL7 or any emerging medical standards)
- Ensure compliance with Health Insurance Portability and Accountability Act (HIPAA) and future legislation
- Incorporate a terminology database and an intelligent assistant to speed up data entry
 - Periodic database update from master database on server
 - After users types/taps the first few characters of a term, the system can pop-up a list for users to select
 - Terminology database designed with domain-specific ontology (no long irrelevant lists)
- Incorporate process/task-based user interface
 - Link patient records with the physician's appointment/schedule so physician doesn't have to search for patient record
- Offer color-coded information display (e.g., out of normal range lab result)
- Incorporate ability to download and display high quality image information (e.g., X-ray images)
- Provide an easy-to-use user interface (e.g., pull-down/pop-up lists, check boxes for data entry)
- Synchronize with enterprise medical information system (e.g., CHCS II, TMIP, billing and payment)
- Access medical information systems on multiple servers
- Access medical information across enterprise boundary via information gateway servers
- Incorporate ability to receive event notification (e.g., new lab report available)
- Encryption for data transmitted over the wireless network
- Prescription writing facilities
- Faster data entry with user-defined templates
- Medical history tracking
- Links to family medical history
- Keeping track of progress notes
- Fast information search

3.2 Medical Digital Assistant

The term Medical Digital Assistant [11] implies any small portable and unobtrusive computing and/or telecommunications device that assists in the collection, retrieval or communication of data relevant to medical care. In other words, an MDA is a PDA specialized for medical care.

There is compelling evidence of the value of MDAs in medical applications. For example, research indicates that 50% of physicians using a hand-held drug reference guide avoided one or more serious adverse drug events per week. Current uses for MDAs in health care include: (a) providing medical decision support; (b) providing point of care interaction with the CPR; (c) niche clinical applications such as expert systems; and (d) re-engineering of medical business processes.

Today, there are many existing thin client applications for patient data entry and retrieval using PDAs. While these applications have had limited success, there are several interesting challenges that remain on the road to transforming a PDA into an effective system for Computerized Patient Record access, viewing, analysis, and update. In this regard, new developments in PDA

technology such as voice recognition, natural language processing, increased screen resolution, longer battery life, wireless networking (including remote wireless sensors), and open/scalable architectures hold the potential of overcoming many of these technical challenges. By far the most important challenge is finding a solution that hits the caregiver's "sweet spot." In fact, the biggest challenge is to overcome the resistance of physicians and other caregivers who expect a MDA to be faster and more practical than a 3 x 5 card, or dictating to a tape recorder with the tape being passed to an assistant for transcription. Such challenges cannot be overcome with technology alone. They require that care providers perceive high value at acceptable complexity [12] to embrace the technology-enabled solution. To achieve this result, requires a careful study of cognitive and human factors. Beyond these challenges are regulatory constraints imposed on the medical care profession. For example, recent regulations enacted by the Federal Government, mandated by the Health Insurance Portability and Accountability Act, require that health plans and health-care providers protect all medical records and individually identifiable information.

3.3 HealthTrak System Concept

Based on the analyses of care provider information requirements and the potential capabilities that can be created with state-of-the-art technologies, we developed a comprehensive HealthTrak system concept. The major elements of this system concept are presented in Table 11.

Table 11. System Concept Highlights

1. **Device-dependent Presentations.** This involves designing different GUIs for showing a Computerized Patient Record according to the device characteristics of PDA, tablet, or desktop.
2. **Operating System Agnostic Solution.** The software will run on both the Palm Operating System as well as the PocketPC.
3. **Role-based CPR Display.** The different users of HealthTrak are: (a) physician; (b) nurse; (c) pharmacy; and (d) combat medic. Based on the role assigned to the user, HealthTrak will display the appropriate CPR elements of interest.
4. **Voice Recognition System Capability.** Voice recognition technology is being used in the public domain when the vocabulary set is small (e.g., radiology). The vocabulary set of emergency room environments is more extensive because emergency room (ER) records are scrutinized for billing and risk issues. Nevertheless, voice recognition is beginning to make its way into ER settings. The emergency room setting provides a suitable parallel for combat medics. We need to be able to construct a scenario with a set of limited "effective" vocabulary to show voice recognition.
5. **Process-aware Zero Latency Retrieval [12]** "Process-awareness" provides a context for retrieval of pertinent records (e.g., patient record, billing). More specifically, process-awareness allows prefetching of these records thereby eliminating delays in information retrieval. The result, of course, is superior patient-physician interaction made possible by elimination of delays arising from the physician having to wait for information.
6. **Smart Data Replication and Synchronization Algorithm.** Limited wireless network bandwidth demand prefetching and data replication to minimize latency; limited storage space on the handheld device prohibit pre-loading of all data that might be used; data synchronization is needed to ensure the accuracy of the pre-fetched data. We have developed a smart algorithm that provides a balanced solution to these important technical issues.
7. **Interfaces to CHCS II and TMIP.** Military medical records reside in CHCS II for fixed facilities, and in TMIP for combat medic use. These records will be automatically updated (without the need for a human intermediary)

4. HEALTHTRAK™ TECHNOLOGY TRADEOFFS

At the very outset, it is worth noting that technology is a moving target with innovations occurring routinely. Thus, any comparisons that we make today can get outdated very quickly. For example, the emergence and increasing acceptance of 802.11a makes it a real contender today but six months ago it would not have been so. With this caveat, we present the enabling technologies and a comparison of major wireless technologies in Tables 12 and 13.

Table 12. Enabling Technologies

•For MDA communication with enterprise medical information systems in LAN behind enterprise firewall
– Bluetooth, Wi-Fi, 802.11b wireless LAN, 802.11a
•New PDA formats (e.g., tablets, color PDA)
– Hitachi ePlate, Microsoft tablet
– color PDAs such as Palm m505, Sony CLIE, Compaq's iPAQ, HP Jornada Color PocketPC
– Linux-based VR3 PDA from Agenda Computing
– Linux-based PDAs from Compaq, HP, Japanese PDA vendors
•Java 2 Micro Edition
– an effective compromise between a traditional client and browser-based, multi-platform thin client
– a lightweight, powerful engine that supports software development for any platform
•Biometric Device-based Authentication
•capability expected for PDA devices

Table 13. Comparison of Major Wireless Technologies

Comparison Factors	802.11a	802.11b	Bluetooth
Range	1640 feet	1640 feet	100 feet
Data Transfer Rate	54 Mbs	11 Mbs	0.5 to 1.5 Mbs
Security Encryption	64-bit and 128-bit WEP	64-bit and 128-bit WEP	138-bit Data Encryption
Frequency	5GHz	2.4 GHz	2.4 GHz
OS Support	Palm & Windows CE	Palm & Windows CE	Palm & Windows CE
Availability	Just Released	Widely Available	Just Released
Purpose	Wireless Local Area Network	Wireless Local Area Network	To develop connectionless short-distance radio devices
Cost	\$399	\$200	\$200

With technological advances continuing at a fast and furious pace, it is prudent to defer technology decisions until one is ready to implement. This strategy ensures that we have the benefit of leveraging the latest breakthroughs in technologies such as wireless, handheld devices, and voice recognition systems. Therefore, the principles and guidelines for selecting appropriate technologies are to: (a) continue to look ahead to emerging technologies; (b) design a system such that it can be used years from now; (c) avoid proprietary formats and technologies whenever possible; and (d) always strive for cost-effectiveness.

For HealthTrak, technology choices have to be made for: MDA client technologies; MDA server technologies; client-server communication technologies; server integration technologies; and input equipment and modality. Since HealthTrak is expected to be a web-based client-server system, the technology choices that have to be made are for the MDA client, the MDA server, and the communications between client and server. In addition, there is the larger integration

problem pertaining to the technologies that will be used to integrate HealthTrak with existing server-side systems (e.g., computerized medical records, hospital billing system).

Certain technology choices are straightforward. For example, HealthTrak needs to support:

- all wireless communication protocols (802.11a, 802.11b, Bluetooth)
- popular PDA operating systems (Palm OS, PocketPC, EPOC)
- non-PDA client operating systems (MS Windows, Mac OS, Linux)

It is also prudent to avoid choices that limit the server operating system to either MS Windows, Unix, or Linux. In the following paragraphs, we present the technology tradeoffs for MDA client, MDA server, client-server communication, server integration, and client input-output capabilities.

MDA Client Technologies. MDA client technologies can be based on “thick” client, “thin” client, or “medium” client. The tradeoffs between these three options are presented in Table 14.

Table 14. MDA Client Technologies

Technology Options	Pros	Cons
OS-specific “thick” clients (e.g. a native program on PalmOS)	• Computationally efficient, faster • Best use of PDA graphical capabilities given its limitations • Low bandwidth needs	• One interface per OS (longer, more expensive development time) • Code can become obsolete with OS • Requires installation and setup (complicates maintenance) • Requires special development tools
“Thin” clients (Web browser with HTML interface)	• Usable across a variety of PDAs, PCs • No installation process necessary (lower maintenance costs) • Widely available development tools	• Inherent limitations in graphical and layout capabilities (can be increased with XSL or JavaScript, but this erodes compatibility benefits) • “Heavy” for this specific use (e.g., memory-intensive) • Not all PDAs have good browsers (yet) • Consumes significant network bandwidth
“Medium” clients based on Java 2 Micro Edition (J2ME) Standard Edition (J2SE)	• Usable across PDAs, PCs • Partially automated installation possible (lower maintenance) • Low bandwidth needs • Widely available development tools	• Not available for all platforms (yet) • Computationally heavy (potentially slow on current PDAs)

MDA Server Technologies. MDA Server technologies can be Microsoft-based, Java-based, proprietary, or open source. The pros and cons of each option are presented in Table 15.

Table 15. MDA Server Technologies

Technology Options	Pros	Cons
Microsoft-based (ASP, C++/Visual Basic, SQL Server)	• Moderate acquisition price • Reasonably efficient	• Limited scalability • Proprietary technology • OS-specific (MS Windows) • Prone to security problems (Microsoft)
Java-based (Java 2 Enterprise Edition - Java, JSP, JMS, JDBC - plus Relational Database)	• Moderate acquisition cost • Standards-based • Available from multiple vendors • OS-independent • High scalability	• Higher acquisition costs (but: open source alternatives, e.g., JBoss) • May be less computationally efficient (require more powerful machines)
Other proprietary server technology (e.g., Cold Fusion, Oracle Wireless)	• Some geared to wireless applications • Potentially cost-effective	• Highly proprietary • Uncertain future • Requires specific hardware and OS • High learning curve/maintenance costs
Other open source server technology (e.g., PHP, Perl, CGI)	• Widely available • Extremely low acquisition costs	• Uncertain future • Usually OS-specific • High learning curve/maintenance costs

Client-server Communication Technologies. Client-server communication technologies need to be examined at both the low level and high level. Tables 16 and 17 present the choices at the low level and high level along with their pros and cons.

Table 16. Client-server Communication Technologies (low level)

Technology Options	Pros	Cons
HTTP (TCP/IP)	• Widely adopted standard • Highly efficient implementation (e.g., Apache) • Low implementation and maintenance costs • Standard encryption protocols (e.g., SSL)	• Limited capabilities (GET/POST) • Limited security
Custom communication protocol (on top of HTTP)	• Potentially more efficient • Can be made as secure as desirable	• Higher development costs • Higher maintenance costs • Lower interoperability

Table 17. Client-server Communication Technologies (high level)

Technology Options	Pros	Cons
XML-based (XML, XPath, DOM, etc.)	• Widely adopted, continually improving standard • Low implementation and maintenance costs through widely available software libraries	• High use of bandwidth (verbose protocol)
Custom communication protocol (on top of HTTP)	• Low use of bandwidth • Tailored to application needs	• Higher development costs • Higher maintenance costs • Lower interoperability

Server Integration Technologies. The solutions required here involve “wrapping” or encapsulating legacy systems. The technologies in this space tend to be dictated by the specific system in use. In some cases, Enterprise Application Integration software may be available to perform this function depending on the platform. Regardless, no solution is completely interoperable, and no end-to-end standards currently exist. The trend today, however, is to

design wrappers based on XML. A more recent trend is to use Web Services, and to use technologies such as SOAP and UDDI.

MDA Client Input-Output Capabilities. It is important to realize that the different client equipment provide different input and viewing capabilities. The different screen sizes, resolutions, and colors coupled with a variety of input mechanisms (e.g., mouse, pen on screen, keyboard, voice) make for an interesting set of Graphical User Interface (GUI) requirements. What this means is that we need to design a family of Graphical User Interfaces (GUIs) that accommodate all these inputs. This requirement can be satisfied by using the Model-View-Controller (MVC) Design pattern. With this pattern, the GUIs would reflect the different views that communicate with the same underlying information model. Then, the server side code could be made to adapt to the different types of client devices.

High Payoff Technical Approaches

The technical approaches considered for HealthTrak need to facilitate or achieve HealthTrak objectives of standardized IT infrastructure, multi-device capable architecture and implementation, elimination of delays in accessing patient records and administrative information, and effective management of knowledge bases and patient records. Table 18 presents the highlights of the technical approach to that achieve these objectives.

Table 18. Technical Approach Highlights

- Device-compliant GUI specification
 - based on handheld device display resolution, number of colors, and viewable area
- Ontology-guided CPR management
 - use domain-specific ontology to manage medical knowledge bases and CPR
 - ontology for patient records based on combination and modification of the SOAP (subjective, objective, assessment and treatment plan) concept and established medical information standards (e.g., HL7)
- Process/workflow based approach
 - link patient records to the physician's schedule/task
 - visualization of the complete treatment plan
 - alert the physician when certain task/information is overdue
- Intelligent information synchronization
 - update only the changed data instead of complete record
 - when limited wireless bandwidth is available, update only the information needed in the next few hours/tasks
- Legacy integration
 - Use XML as communication data format
 - Use XSLT for data transformation
 - Use style sheets for presentation format

5. HEALTHTRAK™ HORIZONTAL PROTOTYPE

In accord with our BuildRite™ methodology, horizontal prototyping was performed on both PocketPC and Palm. Both the PocketPC and the Palm versions of the resultant software were delivered to TATRC for viewing on their respective PDAs. The demonstrations on PocketPC and Palm showed: (a) effective use of viewing area; (b) intuitive user-system interaction; (c) effective presentations of forms, graphs, charts; (d) aspect ratio-sensitive graph presentation; (e) synchronization with backend legacy systems (e.g., CHCS II); (f) use of controlled, domain-specific vocabulary to minimize learning curve; and (g) effective use of color code to establish context, alert, notify.

Sample user-system interactions for the physician using PocketPC as the exemplar platform are presented in Figures 16 through 35.

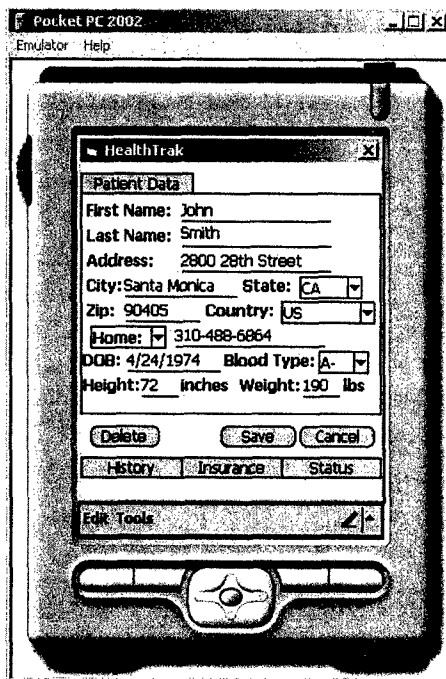


Figure 16. Patient Personal and Demographic Data

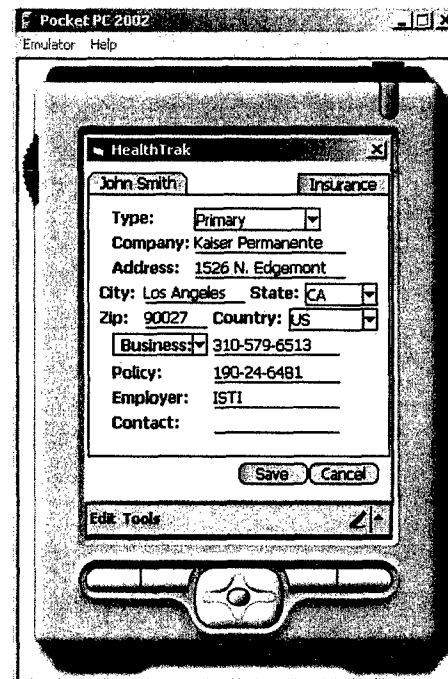


Figure 17. Insurance Information

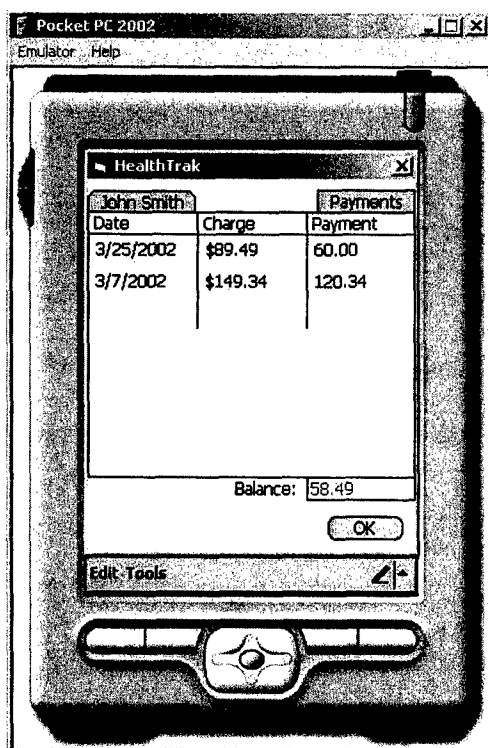


Figure 18. Billing Status

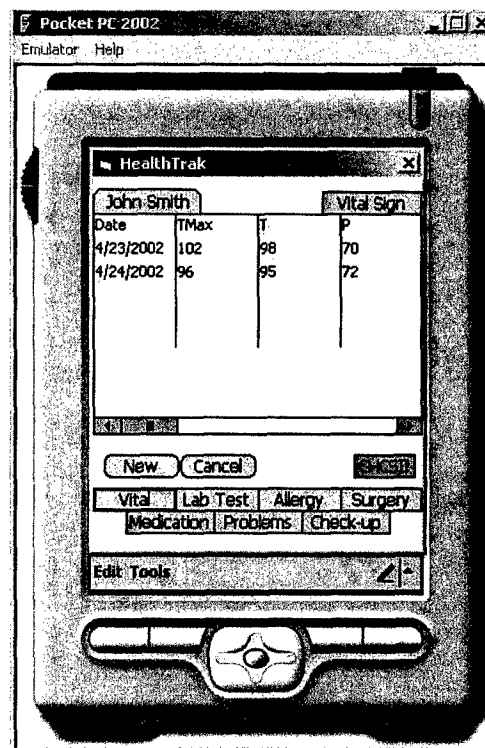


Figure 19. Vital Signs

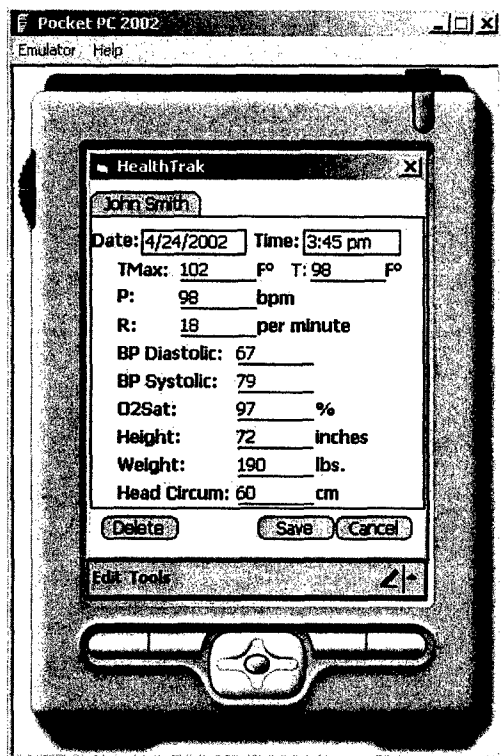


Figure 20. Vital Signs Edit Form

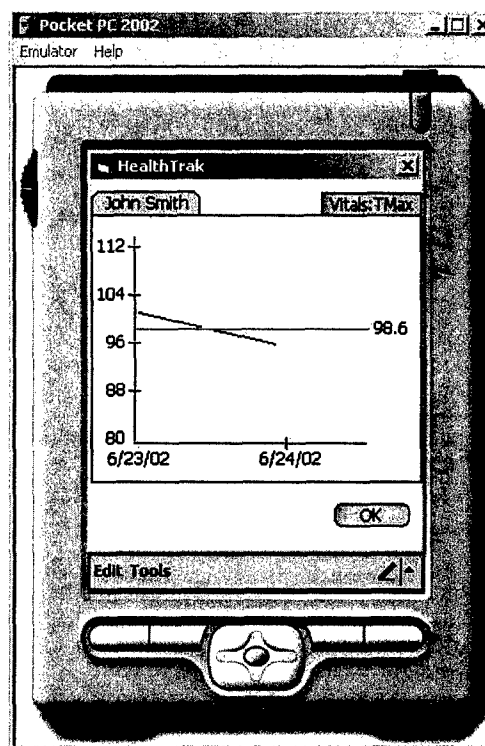
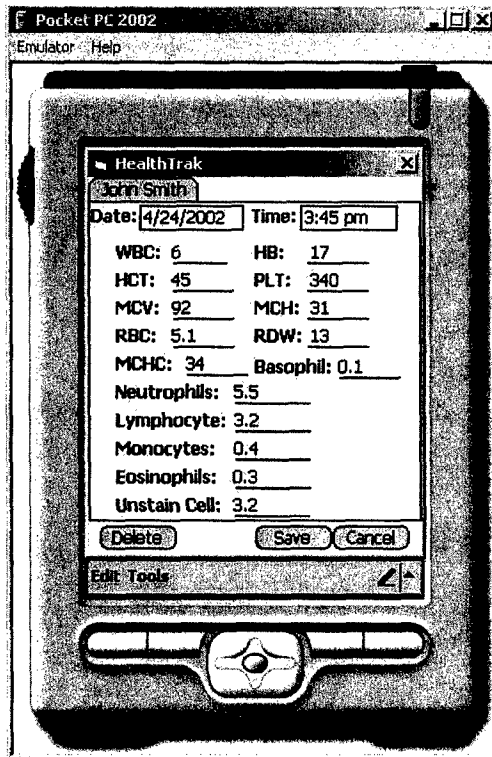


Figure 21. Vital Sign Chart



Pocket PC 2002
Emulator Help

HealthTrak

John Smith

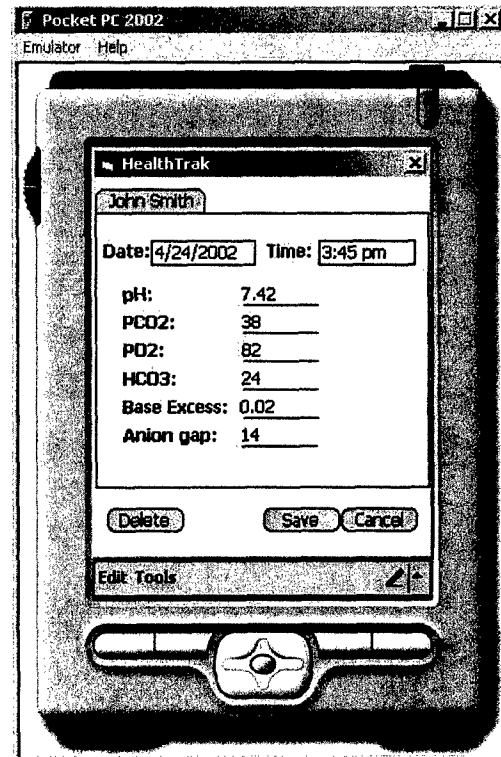
Date: 4/24/2002 Time: 3:45 pm

WBC: 6 HB: 17
HCT: 45 PLT: 340
MCV: 92 MCH: 31
RBC: 5.1 RDW: 13
MCHC: 34 Basophil: 0.1
Neutrophils: 5.5
Lymphocyte: 3.2
Monocytes: 0.4
Eosinophils: 0.3
Unstain Cell: 3.2

Delete Save Cancel

Edit Tools

Figure 22. CBC Edit Form



Pocket PC 2002
Emulator Help

HealthTrak

John Smith

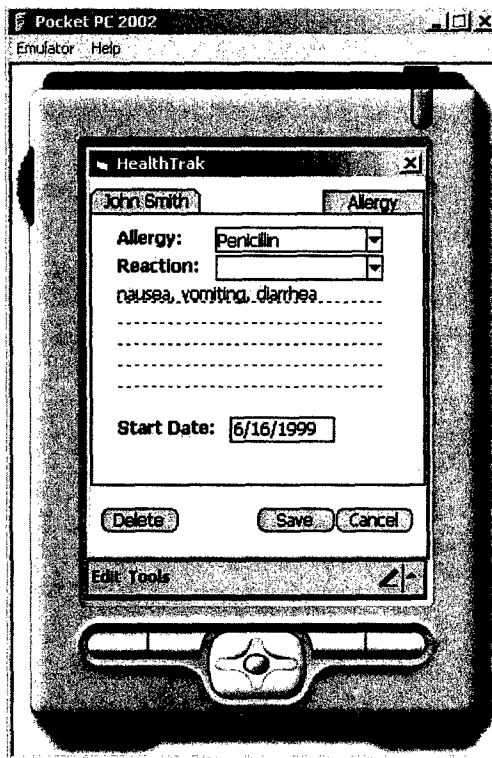
Date: 4/24/2002 Time: 3:45 pm

pH: 7.42
PCO2: 38
PO2: 82
HCO3: 24
Base Excess: 0.02
Anion gap: 14

Delete Save Cancel

Edit Tools

Figure 23. ABG Edit Form



Pocket PC 2002
Emulator Help

HealthTrak

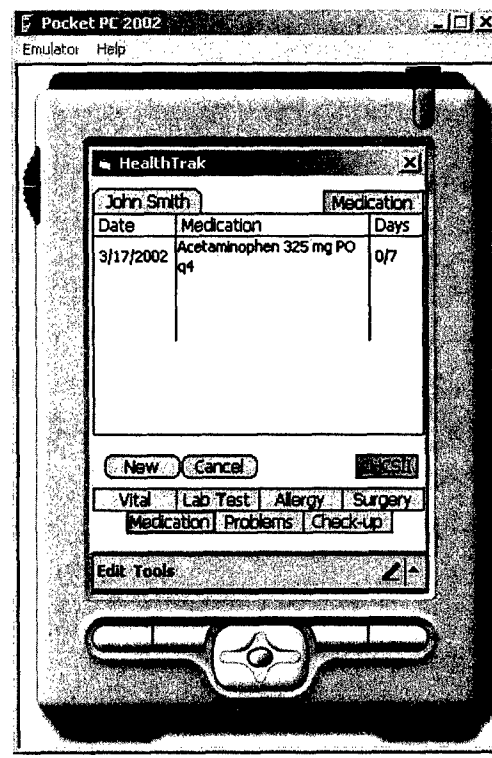
John Smith Allergy

Allergy: Penicillin
Reaction: nausea, vomiting, diarrhea
Start Date: 6/16/1999

Delete Save Cancel

Edit Tools

Figure 24. Allergy Edit Form



Pocket PC 2002
Emulator Help

HealthTrak

John Smith Medication

Date	Medication	Days
3/17/2002	Acetaminophen 325 mg PO q4	0/7

New Cancel Prescription

Vital Lab Test Allergy Surgery
Medication Problems Check-up

Edit Tools

Figure 25. Medication History and Prescription History

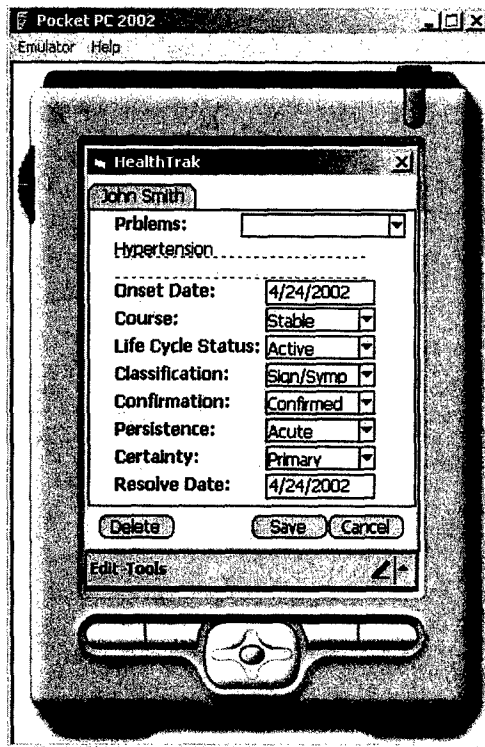


Figure 26. Problem Edit Form

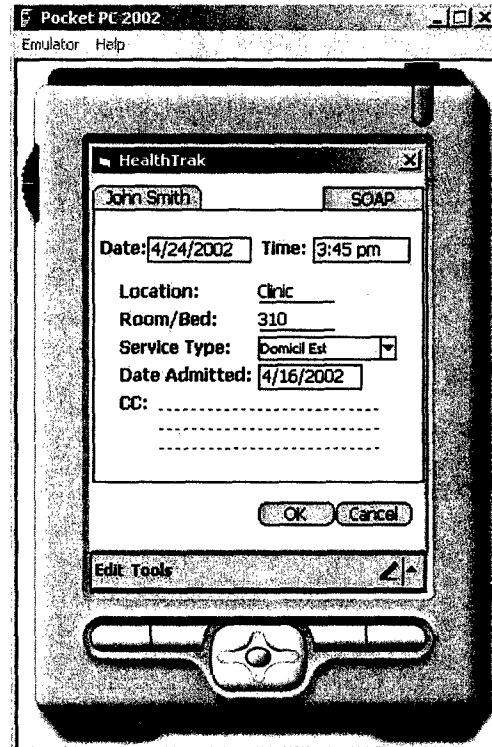


Figure 27. SOAP Edit Form

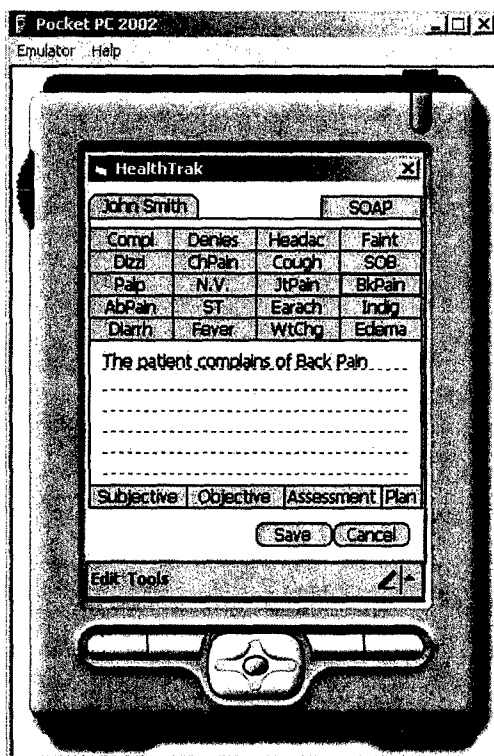


Figure 28. Subjective Edit Form

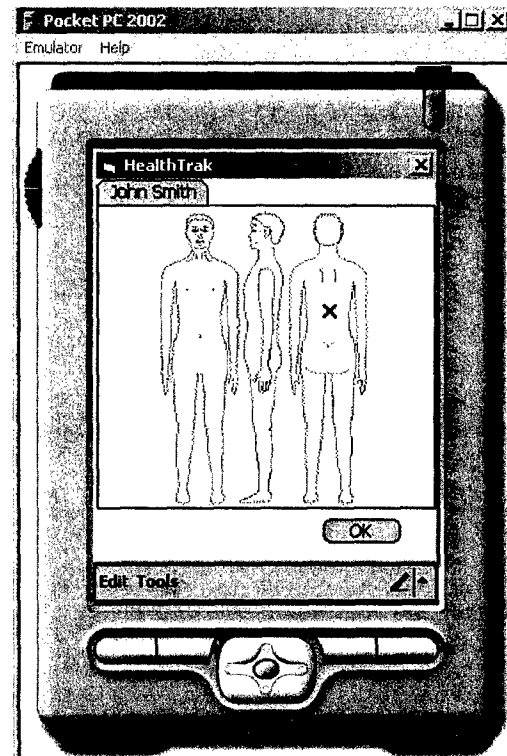


Figure 29. Problem Image Supplement

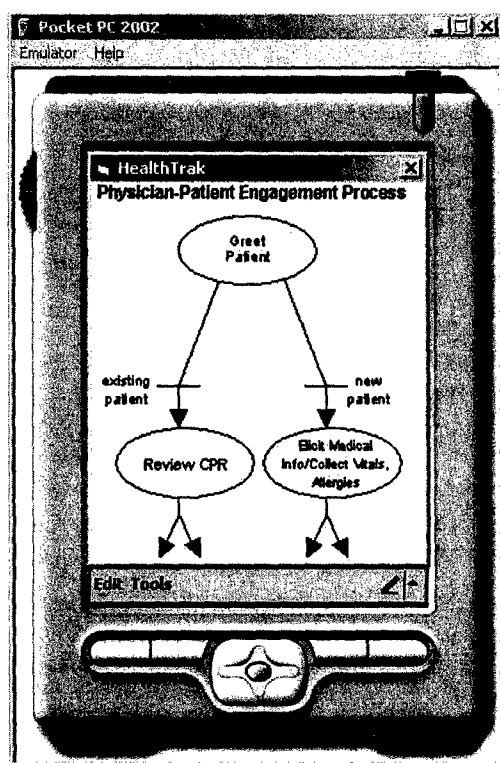


Figure 30. Physician-Patient Engagement Process (PPEP): Greet Patient

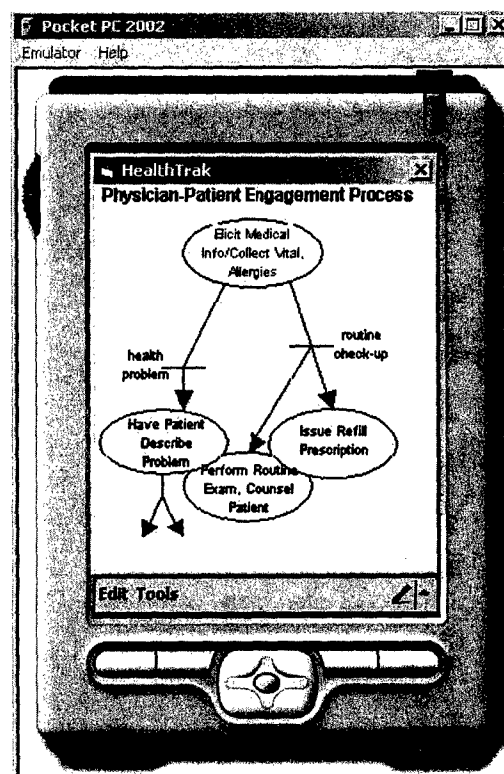


Figure 31. PPEP: Elicit Medical Info/Collect Vital, Allergies

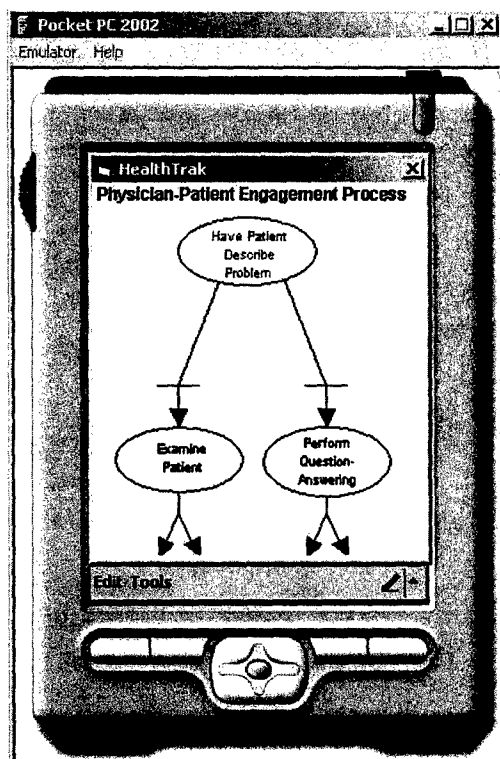


Figure 32. PPEP: Have Patient Describe Problem

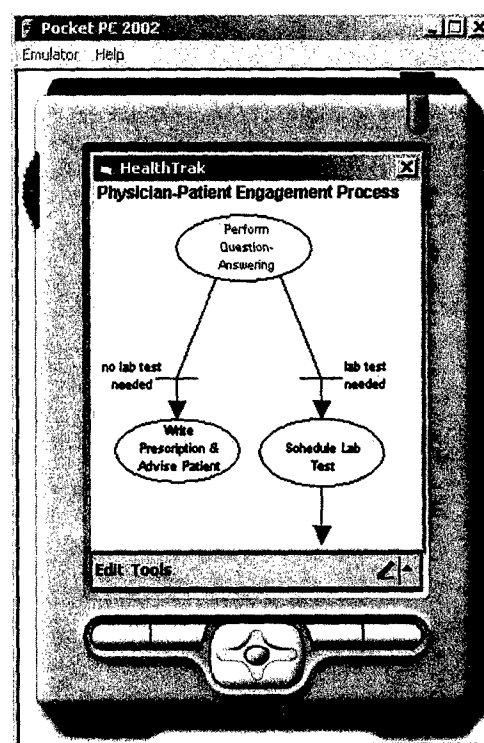


Figure 33. PPEP: Perform Question-Answering

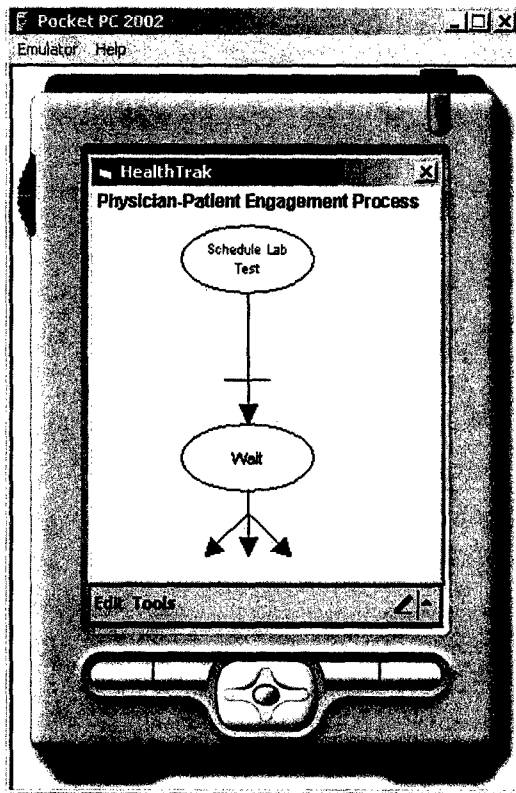


Figure 34. Schedule Lab Test

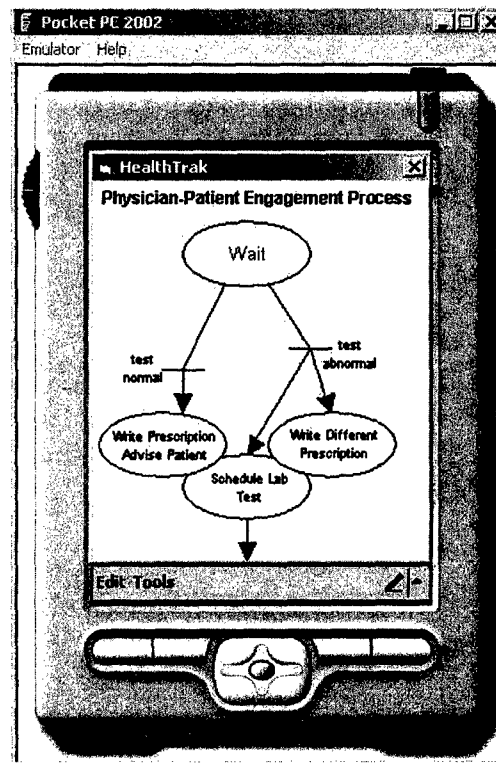


Figure 35. Wait for Lab Test Results

6. HEALTHTRAK™ ARCHITECTURE

6.1 Technology and Operational Design

The HealthTrak architecture is driven by the technology and operational design shown in Figure 36.

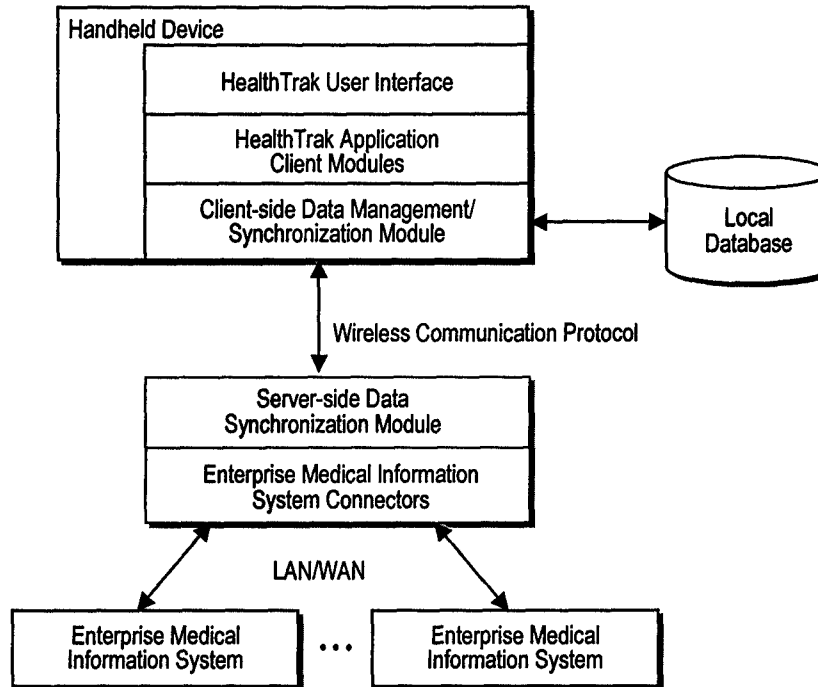


Figure 36. Technology and Operational Design

In this design, our client system, which resides on the wireless hand-held device will have a three-layered architecture. The HealthTrak User Interface is intended to allow a user to conveniently access and view patient record information needed during a patient encounter. The HealthTrak Application Client Modules implement specific utility functions that help a user in activities such as data entry, data retrieving, diagnosis, and scheduling. The Client-side Data Management/Synchronization Module is responsible for managing all data that the user needs. To this end, it will maintain a local database on the hand-held device, and synchronize the data with enterprise medical information systems whenever a reliable communication connection is available. On the server side, will be a Data Synchronization Module that maintains awareness of what data is needed by which hand-held device, and is then able to push only the updated data information to the requestor hand-held device via the wireless communication protocol. In addition, there will be Medical Information System Connectors to integrate with specific enterprise information systems.

6.2 Implementation Architecture Design

Figure 37 presents the draft implementation architecture for HealthTrak.

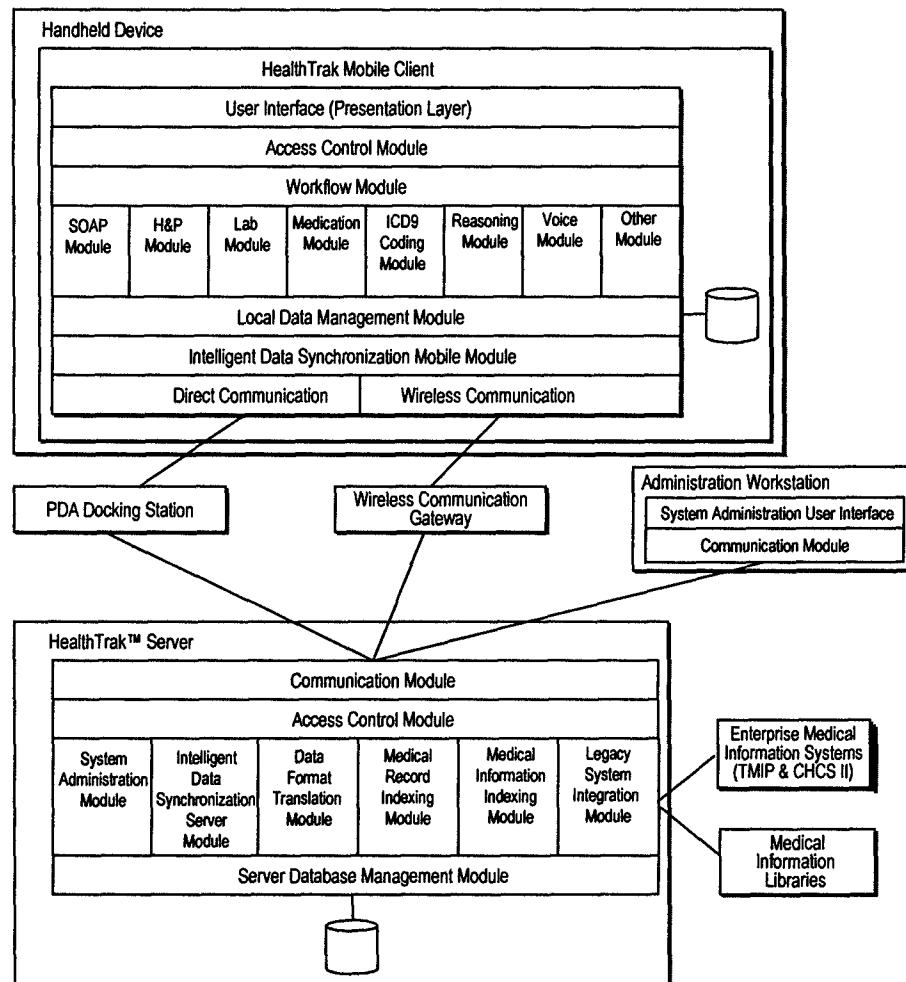


Figure 37. Draft HealthTrak Implementation Architecture Design

At the highest-level in this architecture, the HealthTrak system will have the HealthTrak Server. This server will serve multiple HealthTrak Mobile Clients through communication gateways.

The HealthTrak Mobile Client has a layered architecture, with the user interface (i.e., presentation layer) at the top and the communication modules at the bottom. The user interface layer provides an easy-to-use, graphical interface for the mobile user to access HealthTrak functions. The next layer is the access control module which is responsible for ensuring that only authorized users can use the functions appropriate for their role and the data they are authorized to access. The layer below that is the workflow module that utilizes the patient encounter process information to: integrate the various functional modules; guide the user; and orchestrate the data management modules. Below the workflow module are various functional modules that implement the business logic for the HealthTrak application. These modules include, SOAP, H&P, lab, medication, ICD9 coding, reasoning, voice, and other functional modules that will implement the “business logic” of the system. These modules will be supported by the local data management module that implements the data layer on the mobile device. This data layer will manage persistent storage on the mobile device and may also cache

other information received from the server. This module relies on an intelligent data synchronization mobile module that ensures that it has all the latest data it needs, and all updates on the mobile device are safely uploaded to the server. At the bottom of this layered architecture are two communication modules: one for data synchronization when the mobile device is connected physically to a docking station; and the other one for data communication using a wireless communication protocol when cable connection is not available.

Similarly, the HealthTrak Server also has a layered architecture. At the top is the communication layer that is responsible for managing communications with multiple mobile devices indirectly through either the PDA docking station (either a special hardware or a regular workstation with special software installed) or the wireless communication gateway (e.g., router for wireless LAN). The number of communication gateways needed depends on the physical characteristics of the facilities as well as the technology used for wireless communication. The next layer is the server-side access control module that will provide additional security for the system. Below this, will be a layer of server-side functional modules that implement various business logic for system management and for providing various utilities for accessing enterprise medical systems. These modules will include, system administration module, intelligent data synchronization server module, data format translation module, medical record indexing module, medical information indexing module, and legacy system integration module. They will be supported by the server database management module that is responsible for persistent storage of the server data.

It is important to note that the HealthTrak Server is not an enterprise medical data management system itself. Instead, it serves as a portal for mobile devices to access any enterprise medical information systems (e.g., the CSCH II and the TMIP). To see how this works, let us examine the circumstance in which a physician is interested in using his mobile device to review the medical records of a particular patient. In this circumstance, the HealthTrak system will first use its medical record indexing module to search for relevant medical records for that patient. These medical records may reside on multiple heterogeneous enterprise medical record systems. HealthTrak will then use the appropriate legacy system integration module(s) to retrieve the records from the distributed system using the index information from the Indexing Module. Once the medical records have been retrieved from the legacy systems, they will be converted into suitable format for the physician's mobile device through the data format translation module. Thereafter the patient data is sent to the requesting mobile device by the data synchronization modules.

6.3 Data Synchronization Design

There are several considerations that go into integration design. First, the bandwidth of current wireless technology for mobile device (MDA) is quite limited. Second, the connection between client and server may be sufficiently unreliable so as to make the implementation of a mobile, thin client capable of instantly retrieving all the data from the server impractical. On the other hand, the computation power and the storage space on a mobile device is also limited so that it is

not practical to store all the data on the mobile device. Consequently, what is needed is an intelligent data synchronization design that provides a balanced solution between the two extremes. This smart synchronization design is presented in Table 19.

Table 19. Smart Synchronization Design

- An Intelligent Synchronization Agent (ISA) that will manage the following data synchronization activities and decisions:
 - What data to be downloaded (pre-fetched) to the MDA before it is needed. When to download the data.
 - What data to be uploaded to the server to make it available to other users.
 - What data to be deleted from the MDA to improve the effective usage of the limited memory space on MDA.
 - Monitor the server database and update the MDA whenever new relevant data is available.
- There will be a client-side component (Intelligent Data Synchronization Server Module) as well as a server-side component (Intelligent Data Synchronization Mobile Module) in the ISA.
- Pre-fetch strategy
 - The system will pre-fetch and download data to the MDA whenever appropriate:
 - Periodically, the ISA will download the patient data according to the scheduled appointments for the day.
 - Why pre-fetch?
 - Wireless connection is much slower than traditional wired connection.
 - Whenever possible, we should pre-download the data when the MDA is connected through the cable and the docking station.
 - Since it will take longer to download data to MDA through wireless (as opposed to wired) connection, pre-fetch will enable us to do the data transfer while the MDA is "idle". This will reduce user wait time.
 - Question: do we need to download all data for each patient?
 - Potentially, the amount of data can be quite large if we want to pre-fetch all data on the mobile device. Therefore, this approach is inadequate.
 - So, we will identify and pre-fetch the essential data (e.g., summary of medical history, most recent detail information, etc.) and just those data predicted by the process. The remaining information will be downloaded as needed.
- Data update strategy
 - If the data needed is not on the MDA, the system will download it dynamically from the server using the wireless connection.
 - The server-side component of the ISA knows what information each MDA needs (by maintaining a list of patients that each MDA is interested in). Whenever new relevant information for the patients is available (e.g., the lab report is available), it will notify the client-side component of ISA which will then notify the user and/or download it to the MDA.
 - Whenever the user updates any data on the MDA, the system will update it on the server whenever it is possible (i.e., whenever the wireless connection is available or whenever the MDA is connected through a cable).
 - When no network connection is available, the system will save the modified data and transfer it to the server whenever the connection is re-established.
- Other information management strategy
 - To make efficient usage of the limited available memory space on MDA, the data will be deleted from the MDA when it is no longer needed. This data cleanup, which will be performed periodically, can be part of the daily synchronization activity. So, how do we decide what data is to be deleted?
 - The user can specify the number of days the data should be stored on MDA.
 - The system can delete all expired data.
 - The user can "mark" specific patients to keep their data available for a longer time period.
 - The system will regularly monitor the memory usage and warn the user when it foresees any potential storage problem.
 - Whenever there is a potential memory problem on the MDA, the system will guide the user in deleting older data to free up memory for new data. The system will not delete the data without authorization by the user.

6.4 Legacy Integration Design

Another important consideration is the design for integration with enterprise medical record systems (such as TMIP and CHCS II) as well as other medical information systems. The

Theater Medical Information Program (TMIP) is a major information system initiative designed to create an effective medical tracking system and health record before, during, and after deployments.

The DoD's Composite Health Care System (CHCS) supports the electronic capture of laboratory, radiology, pharmacy, and patient administration data within a medical treatment facility. A near-term upgrade is expected to include a medical records disposition and archiving function, as noted previously. DoD's next generation health information system, CHCS II, will move toward a common database that links data between facilities. It is also expected to add new areas such as surgical services and ambulatory care; facilitate data exchange on the tracking of patients and location of medical information with other DoD functions (for example, military personnel); and generally support development of the computer-based patient record (CPR). Increments of CHCS II are projected to be fielded through fiscal year 2006. We have identified the TMIP as our initial integration target for supporting combat medics and the CHCS II as another initial integration target for supporting the fixed facilities.

In general, there is no "one-size-fits-all" solution for all legacy system integration. This is because each existing system may have its own unique interfaces and data formats. Nevertheless, we have identified specific strategies for attacking this issue in Table 20.

Table 20. Legacy System Integration Strategies

- Adopt industrial standard such as HL-7.
- Use XML as the communication data format.
- Use XSLT for data transformation and translation.
- Use style sheets for presentation formatting

7. KEY RESEARCH ACCOMPLISHMENTS OF PHASE I WORK

The Phase I effort was concerned with: (a) understanding the continuum of military patient care; (b) defining requirements for health information integration, (c) patient safety and security; (d) analyzing technology approaches; and (e) developing a system concept and preliminary technical and operational design for the application of candidate technologies to patient/physician interaction. We accomplished these objectives, and, in the process, created an innovative, user-centric concept and design for HealthTrak™ that satisfy key metrics while being sensitive to the constraints of the operational environment. Table 21 presents our Phase I accomplishments.

Table 21. Phase I Accomplishments

- Developed a user-centric methodology for prototyping MDA applications [13]
- Developed an indepth understanding of the continuum of patient care for fixed facilities as well as field medicine
 - episode to recovery
 - e.g., hip injury requiring hip replacement has the following care continuum: outpatient visit to doctor, inpatient orthopedic surgery, acute care stay, transfer to rehab, outpatient physical therapy
 - involves movement from outpatient to inpatient to outpatient
- Conducted indepth analysis of user information requirements for various user roles (i.e., physician, nurse, combat medic, pharmacist)
- Evaluated major wireless technologies, handheld web devices, integration strategies with backend systems such as CHCS II and TMIP
- Developed a smart data replication and synchronization design to ensure the availability of latest information with minimum delay and limited storage requirement on the handheld device
- Harnessed process-aware zero latency strategies [12] to assure just-in-time information delivery (e.g., the relevant web pages) based on where the care provider was in the overall care process
- Developed a system concept and technical architecture for HealthTrak
 - support for multiple handheld web devices (e.g., Palm, PocketPC)
 - operating system agnostic
 - interface for automatic update of CHCS II, TMIP
 - interface for rapid access to patient records from CHCS II, TMIP
 - process-driven information (e.g., medical history) prefetching
- Developed and delivered two horizontal prototypes to TATRC
 - these run on PocketPC and Palm O.S.
 - the prototypes are intended to demonstrate feasibility of congenial physician-patient interaction to end-users and sponsors
 - these prototypes show creative use of viewing area in presenting CPR information from different perspectives and in different formats
- Published refereed paper [14] in the Six Biennial World Conference on Integrated Design and Process Technology 2002
- Presented the paper in the "Formal Methods in Healthcare" session at this conference
- Secured Northrop Grumman Corporation as Phase III commercialization partner

8. REPORTABLE OUTCOMES

The reportable outcomes that resulted from this Phase I work are:

- International Conference paper (refereed)
 - Madni, A.M. Healthtrak™: A Process-Aware Medical Digital Assistant (MDA) for Web-Based Management of Computerized Patient Records, *Proceedings of the Integrated Design and Process Technology Conference, (IDPT-2002)*, Pasadena, CA, June 23-28, 2002
- Methodology paper
 - Madni, A.M. BuildRite™: A User-centric Methodology for Developing Web-based Applications, Intelligent Systems Technology, Inc. White Paper, ISTI-WP-6/02-4, June 13, 2002
 - this paper will be submitted to the INCOSE Transactions for publication.
- Horizontal prototype of HealthTrak on PocketPC (iPAC)
 - this prototype shows physician-patient interaction on a PocketPC, including the interface to synchronize with medical information system such as CHCS II, TMIP
 - this prototype was delivered to TATRC (Mr. Daimen Michaels) and is operational there
- Horizontal prototype of HealthTrak on Palm
 - this prototype shows physician-patient interaction on a Palm PDA
 - the purpose of this prototype is to show the scalability and adaptability of an approach to different PDAs (i.e., Palm, PocketPC)
 - this prototype was delivered to TATRC (Mr. Daimen Michaels) and is operational there
- Phase I Project Kickoff briefing presented to TATRC personnel
- Phase I Final Presentation briefing presented to TATRC personnel
- Acquired Phase III Commercialization Partner in the form of Northrop Grumman Corporation

9. CONCLUSIONS

9.1 Results and Implications

Phase I of this SBIR project concluded with specific results and findings. These results have implications for downstream development as well as for prototyping MDA/PDA applications in general. The results and their implications are presented next.

- **Scenario-enabled Front-end Analysis.** We created a composite Army scenario spanning the patient care continuum. This scenario involved the four classes of users (i.e., physician, combat medic, nurse, pharmacist). This scenario served as the basis for identifying interactions between the various classes of users and their MDAs. This approach paid significant dividends. First, this scenario served as a contextual backdrop for specifying the information requirements and required HealthTrak capabilities. Second, the user-MDA interactions points and the surrounding context were invaluable in creating a horizontal prototype of the MDA.
- **Process-aware Role-driven Just-in-Time Information Delivery.** The process-aware, role-driven information retrieval is key to eliminating the latencies in accessing “back-end” medical information systems (e.g., CHCS II, TMIP, lab tests), as well as administrative systems (e.g., billing, payment). Explicitly representing processes has several benefits. First, the system has ongoing awareness of context (i.e., task audit trail, upcoming tasks). This knowledge can be used to prefetch information for upcoming tasks (e.g., retrieve computerized patient record from CHCS II or TMIP) thereby eliminating waiting time for information. Second, by making information delivery role-driven, we assure that no user would see extraneous or irrelevant information. This technology has wide applicability beyond MDA/PDA applications and into the desktop world.
- **Innovative Approach for Wireless-Connected PDA Hardware Issue.** The limited, unreliable network connection and the limited memory storage are two key technical issues for wireless-connected PDA hardware. To resolve these issues, we have developed an innovative data management and synchronization scheme. This scheme will enable users to view the data they need as if the data were stored locally (i.e., overcome the network connection problem) without the requirement for a large storage capability and/or tedious manual data management effort (i.e., overcome the storage problem).
- **Device-adaptive Presentation.** One of the key requirements for HealthTrak is for the software to run on a variety of handheld web devices to assure solution generality. This includes PDAs, tablets, and desktops but not cell phones. (The available display area on cell phones is patently inadequate for presenting medical information.) We prototyped HealthTrak on both PocketPC and Palm devices, which run under different operating systems and which have different viewing areas. We prototyped a series of user-system interaction screens in support of our scenarios and found that we could accommodate the full range of

visuals needed for congenial presentation of specific segments of patient records to care providers.

- **Aspect Ratio-driven Presentation.** The aspect ratios of PDAs, for example, do not lend themselves to presentation of most graphs (e.g., process maps) and charts (e.g., Gantt charts). We found that by redirecting the time axis to be vertical as opposed to horizontal, we were able to expand the effective “real estate” of the MDAs.
- **User-centric, Risk-mitigated MDA Application Prototyping.** As part of the Phase I effort, we developed BuildRite™, a risk-mitigated approach to user-centric prototyping of MDA applications. This approach, which builds on the original work of Madni [10], consists of: front-end analysis and process modeling; horizontal prototyping, server side prototyping; spiral development; and transition and deployment. We successfully applied the first three stages of the approach in the conduct of Phase I. The front-end analysis and process modeling stage produced a composite scenario spanning the health care continuum. The horizontal prototyping produced two user interface prototypes; one that runs on the PocketPC and the other that runs on the Palm OS. The server side prototyping allowed us to select specific technologies that satisfy the tradeoffs. The remaining stages will be exercised during Phase II to create a fully functional HealthTrak prototype.
- **Horizontal Prototypes.** We created and delivered two horizontal (i.e., user interface) prototypes to TATRC. The first runs on PocketPC, the second on Palm. These user interface prototypes enable us to: a) communicate human-system interactions to the end users; b) establish the strategy of supporting both PocketPC and Palm handheld wireless web devices; and c) establish the feasibility of supporting the four classes of users, i.e., physician, combat medic, nurse and pharmacist. These prototypes were intended to show: operating system agnostic solutions; viewing area-sensitive presentation; creative presentation of graphs and charts to maximally exploit the available viewing area of the different devices; and a variety of graphical views to, for example, convey context (through color-coded process maps) and provide help with scheduling (through modified Gantt charts).

9.2 Phase II Considerations

There are additional key considerations that will be addressed during the conduct of Phase II. These include:

Unified Medical Language System (UMLS). UMLS is a translator between multiple controlled vocabularies (e.g., SNOMED, CPT) that exist today. UMLS will assist in rapid data entry as well as generating reports on quality of care issues. For example, if a medical term is associated with different cases, UMLS can help in the search for all related terms (e.g., abdominal pain, nausea, and gastroenteritis). Similarly, UMLS can help nurses with a list of acceptable diagnoses (e.g., altered skin integrity, pain management, patient knowledge deficit) to select from.

Natural Language Processing (NLP). The use of NLP for coding/charge capture is “hot” these days. Dictaphone, a major vendor (in some financial trouble these days) in the medical dictation/transcription arena, has been developing products to apply coding based on NLP (www.dictaphone.com/products). NLP can expedite coding for billing purposes, and assignment of ICD-9-CM and CPT codes.

Private Practice Requirements. Capabilities such as billing, coding, insurance verification, and routine health maintenance are of great interest to the private sector. Auto-assignment of ICD-9-CM codes for diagnosis, and CPT (E&M – a type of code within CPT) is a feature of great interest to many physicians in private practice.

Routine Health Maintenance. Primarily under the purview of the physician and nurse. Includes annual exams (e.g., medical, dental, vision). Routine Health Maintenance is a major focus of the national Committee on Quality Assurance (NCQA), an accrediting body for managed care companies. Some examples of routine health maintenance areas for which evidence must be provided for accreditation are: immunizations (flu shots for high risk groups), cancer screening (mammograms, PAPs, colonoscopy, advice to quit smoking, beta blockers after an AMI, and prenatal care in the first trimester.

Prompts for Overdue Activities. This scheduling aid is primarily oriented to physicians, nurses, and pharmacists. We will incorporate this capability in Phase II after a detailed use case analysis for each role.

Prevention of Medical Errors. A hot issue these days in healthcare, encompasses features such as drug-drug interaction and allergies to specific medications. Decision support systems typically address these issues.

HIPAA. The Health Insurance Portability and Accountability Act (HIPAA) of 1996. Administrative simplification provisions address three separate areas: (1) code and transaction sets; (2) privacy; and (3) security. To date, there is little available on security requirements other than acknowledgement of the fact that patient data has to be secure.

AIR Interface. The AIR project, which deals with Clinical Needs Assessment, can be expected to produce results that will be useful to us in Phase II. In the same vein, our results and findings should be useful to AIR.

CPR Viewed as a “Cognitive Artifact”. CPRs can be considered “cognitive artifacts” that shape the way in which physicians acquire, organize and reason with knowledge. Patel et.al [4] found that the way a physician organized clinical information in CPRs was correlated with the physician’s information gathering and reasoning strategies. Differences were also found in the content and organization of information, with paper records having a narrative structure, and computer-based records organized into discrete information items. The differences in how knowledge was organized had an effect on data gathering strategies, whereas the nature of the physician-patient dialogue was influenced by the structure of the CPR. From these findings we

can conclude that technology has a profound influence in shaping cognitive behavior, so with an effective design of the physician-MDA interaction model, we could potentially improve the speed and efficiency of the physician's diagnosis and treatment.

9.3 Understanding and Leveraging Related Initiatives

There are several related initiatives that will be evaluated in terms of mutual leverage during the conduct of Phase II. The more significant ones are:

BMIST. Of particular relevance to this project are the results of the Battlefield Medical Information System (BMIST) project. BMIST is a specific program designed to provide a first responder digital assistant to forward deployed field medics. It has a small limited objective inside a much larger picture, according to Dr. Sessions. Its goal is to develop a point-of-care wireless hand-held MDA device and support architecture to improve military health care by improving medical decision making and reducing errors. The system is expected to consist of a handheld wireless point of care patient data entry and telemedicine palm device, receiving station, and web-enabled database. Continued research and development of the BMIST is expected to carry to the pre-production prototype stage. BMIST could potentially feed higher echelon medical information systems. In contrast, our SBIR is focused on innovative research addressing the entire issue of the man-machine interface ("medical informatics within DoD").

IMED. While emergency medicine is not necessarily a primary goal of our project, there is another likely association with the project on Informatics-based Medical Emergency Decision Tools (IMED Tools), led by IITRI/DSCC (<http://www.iitri.org>).

Composite Health Care System (CHCS) II. The DoD's current Composite Health Care System (CHCS) supports the electronic capture of laboratory, radiology, pharmacy, and patient administration data within a medical treatment facility. CHCS is a somewhat dated text retrieval system, physicians and nurses use it on a daily basis to access a variety of healthcare facilities. CHCS supports the electronic capture of laboratory, radiology, pharmacy, and patient administration data within a Medical Treatment Facility. Recent upgrades include medical records disposition and archiving function. CHCS is moving toward a common database that links data between facilities. It is also expected to add new areas such as surgical services and ambulatory care, facilitate data exchange on the tracking of patients and location of medical information with other DoD functions (e.g., military personnel), and generally support the development of CPRs. Therefore, our intent is to conceptualize how CPR fits with CHCS and where and how HealthTrak fits into the overall process between the caregivers and patients in the presence of CHCS and CPR. A near-term CHCS upgrade is expected to include a medical records disposition and archiving function. DoD's next generation health information system, CHCS II, will move toward a common database that links data between facilities. It is also expected to add new areas such as surgical services and ambulatory care; facilitate data exchange on the tracking of patients and location of medical information with other DoD functions (for

example, military personnel); and generally support development of the computer-based patient record (CPR). Increments of CHCS II are projected to be fielded through fiscal year 2006.

Ongoing Army and Related Initiatives. There are several initiatives (Table 22) within the Army that need to be carefully tracked to create a complete mental picture of related work within the Army.

Table 22. Ongoing Army Initiatives

- The TATRC has initiatives in the following areas:
 - Clinical Needs Assessment and Human Factors, Wireless Point-of-Care Medical Technologies
 - Battlefield Medical Information System-Telemedicine (BMIST)
 - Telemedicine Infrastructure: goals, capabilities, and partnerships
- MC4, First Responder (PEO STAMIS, ASA-ALT)
- Walter-Reed AMC Initiatives
 - Diabetes Home Monitoring
 - ObGyn, Neurosurgery, Pulmonary
- Madigan AMC Initiatives

In addition to Army initiatives, there are several related congressionally funded initiatives including: (a) DREAMS- Disaster Relief and Emergency Medical Services; (b) Informatics Based Medical Emergency Decision Tools (IMED Tools); (c) Secure Telemedicine; and (d) US-Norway Telemedicine.

9.4 Phase II Objectives and Payoffs

The overall goal of Phase II is to further develop and implement a fully working HealthTrak™ prototype and transition it to TATRC and TATRC-designated end users for evaluation and feedback. The specific objectives of Phase II are to:

- 1) finalize HealthTrak functional specification by conducting use case analysis for the various classes of users in operational deployment contexts;
- 2) further develop and implement a working prototype of HealthTrak;
- 3) transition HealthTrak prototype to TATRC and TATRC-designated sites; and
- 4) create a commercialization plan.

The **first objective** is concerned with finalizing the functional specification of HealthTrak by studying operationally meaningful usage scenarios for the various classes of users: (a) physician; (b) nurse; (c) pharmacist; and (d) combat medic. The **second objective** is concerned with refining the design of HealthTrak in the light of the usage scenarios and implementing the resultant design using a spiral development approach consisting of two builds. The **third objective** is concerned with setting up transition sites at TATRC and TATRC-designated locations for pilot testing and evaluation. The **fourth objective** is concerned with preparing a commercialization plan containing product positioning, SWOTT analysis, and investment strategy.

A key strategy that is being pursued on this project is to defer final implementation architecture decision as late as possible. A key assumption that we are making is that computing power and

more powerful search capabilities will inevitably come along with advances in technology. These advances will provide us with a larger repertoire of technology options to choose from.

Successful accomplishment of Phase II will result in an unprecedented capability for the various care provider roles associated with the patient care continuum. At the conclusion of Phase II, pilot sites will be set up at TATRC, Walter Reed AMC, and DeWitt Army Medical Facility. Evaluation results from these evaluation sites will be used to refine HealthTrak as a prelude to wider deployment within the military. At the time of completing this report, the Phase II proposal, which was invited by DoD, had already been submitted.

9.5 The Proliferation of PDA Applications in the Medical Community

PDA applications are continuing to proliferate in the medical community. All one has to do is to go to pdaMD.com's web site (www.pdamd.com) and see a number of PDA applications ranging in price from \$15.00 (for the DDH Thesaurus and Spelling Checker 1.11) to \$65.00 (for the 5-Minute Emergency Medicine Consult). Today, aspiring pediatricians are all given the handheld version of The Harriet Lane Handbook, Johns Hopkins Hospital, 15th Edition (price: \$49.95). Companies such as Skyscape are offering the most extensive collection of medical reference software for the Palm, PocketPC, or Windows CE-based handhelds.

In light of the foregoing, the question is not whether a MDA would find acceptance in the medical community, but how much more effective and satisfying it can make the physician-patient interaction. We have set our sights on achieving these goals in Phase II of the HealthTrak™ project.

9.6 Achieving a "Win-Win"

The history of DoD patient records is quite illuminating. The DoD has been constrained by being in a relationship with an existing vendor that provides their Patient Record product. Specifically, as a result of having limited rights, the DoD has been severely limited by what it could do with the actual code that the vendor claims to be proprietary. In recognition of this problem, ISTI is committed to providing the DoD with an open system architecture without proprietary claims for Government medical use. ISTI intends to make this endeavor into a profitable venture for itself by maintaining full and complete rights with respect to the commercial sector, and by maintaining and upgrading the functionality for the military based on a source-code license coupled with a time and material contract.

10. REFERENCES

- [1] Sessions, G. R. Wireless device applications in health care. Paper presentation at the 2001 Meeting of the American Telemedicine Association, June 2001, Orlando, FL.
- [2] Sessions, G.R. Wireless Medical Enterprise, Third Annual Strategic Business Opportunities for Telemedicine: 2001 Series, American Telemedicine Association Advisory Board, Dec 2001.
- [3] Freiherr G. Wireless technologies find niche in patient care. *MEDICAL DEVICES, DIAGNOSTICS & INSTRUMENTATION REPORTS*. August 1998. <http://www.devicelink.com/mddi/archive/98/08/011.html>
- [4] Patel, V. L., Kushniruk, A. W., Yang, S., and Yale, J., Impact of a Computer-based Patient Record System on Data collection, Knowledge Organization, and Reasoning, 2000.
- [5] McBride J.S., Anderson R.T., Bahnson J.L. Using a hand-held computer to collect data in an orthopedic outpatient clinic - A randomized trial of two survey methods *MED CARE* 37: (7) 647-651 JUL 1999.
- [6] Woodward, John D. "Biometrics: Privacy's Foe or Privacy's Friend?" *IEEE* 85.9, 1997, 1480-91.
- [7] Bottitta L. Wilson J. No strings attached--mobile computing and healthcare productivity. [6 refs] In: *HIMSS '99. Discover the synergy: proceedings of the 1999 Annual HIMSS Conference*, February 21-25, 1999, Atlanta, Georgia, Volume 4. Chicago, IL: HIMSS, 1999. p 127-38.
- [8] Blackman J. Gorman P. Lohensohn R. Kraemer D. Svingen S. The usefulness of handheld computers in a surgical group practice. *Proc/AMIA Annual Symposium*. 686-90, 1999.
- [9] Madni, A.M. "Thriving on Change through Process Support: The Evolution of the ProcessEdge™ Enterprise Suite and TeamEdge™," in *International Journal on Information • Knowledge • Systems Management*, Special Issue Vol. 2, No. 1, Spring 2000.
- [10] Madni, A.M. The Role of Human Factors in Expert Systems Design and Acceptance. *Human Factors Journal*, August 1988, 30(4), 395-414.
- [11] Sessions, G. R. U.S. Army R&D initiatives in wireless Medical Digital Assistants. Presentation at the Health-Online 2001 International Conference, March, 6-10, 2001, Thessaloniki, Greece.
- [12] Madni, A.M., Madni, C.C., Salasin, J. ProACT™: Process-aware Zero Latency System for Distributed, Collaborative Enterprises, *Proceedings of Twelfth Annual International Symposium of the International Council On Systems Engineering (INCOSE)*, Las Vegas, Nevada, 28 July – 1 August 2002.
- [13] Madni, A.M. BuildRite™: A User-centric Methodology for Developing Web-based Applications, Intelligent Systems Technology, Inc. White Paper, ISTI-WP-6/02-4, June 13, 2002.
- [14] Madni, A.M. Healthtrak™: A Process-Aware Medical Digital Assistant (MDA) for Web-Based Management of Computerized Patient Records, *Proceedings of the Integrated Design and Process Technology Conference, (IDPT-2002)*, Pasadena, CA, June 23-28, 2002.



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APPENDIX A SWIM LANE VIEWS

These views show the interactions between the various care providers and their respective HealthTraks. These models provided the basis for the horizontal prototyping on the PDAs (both PocketPC and Palm).

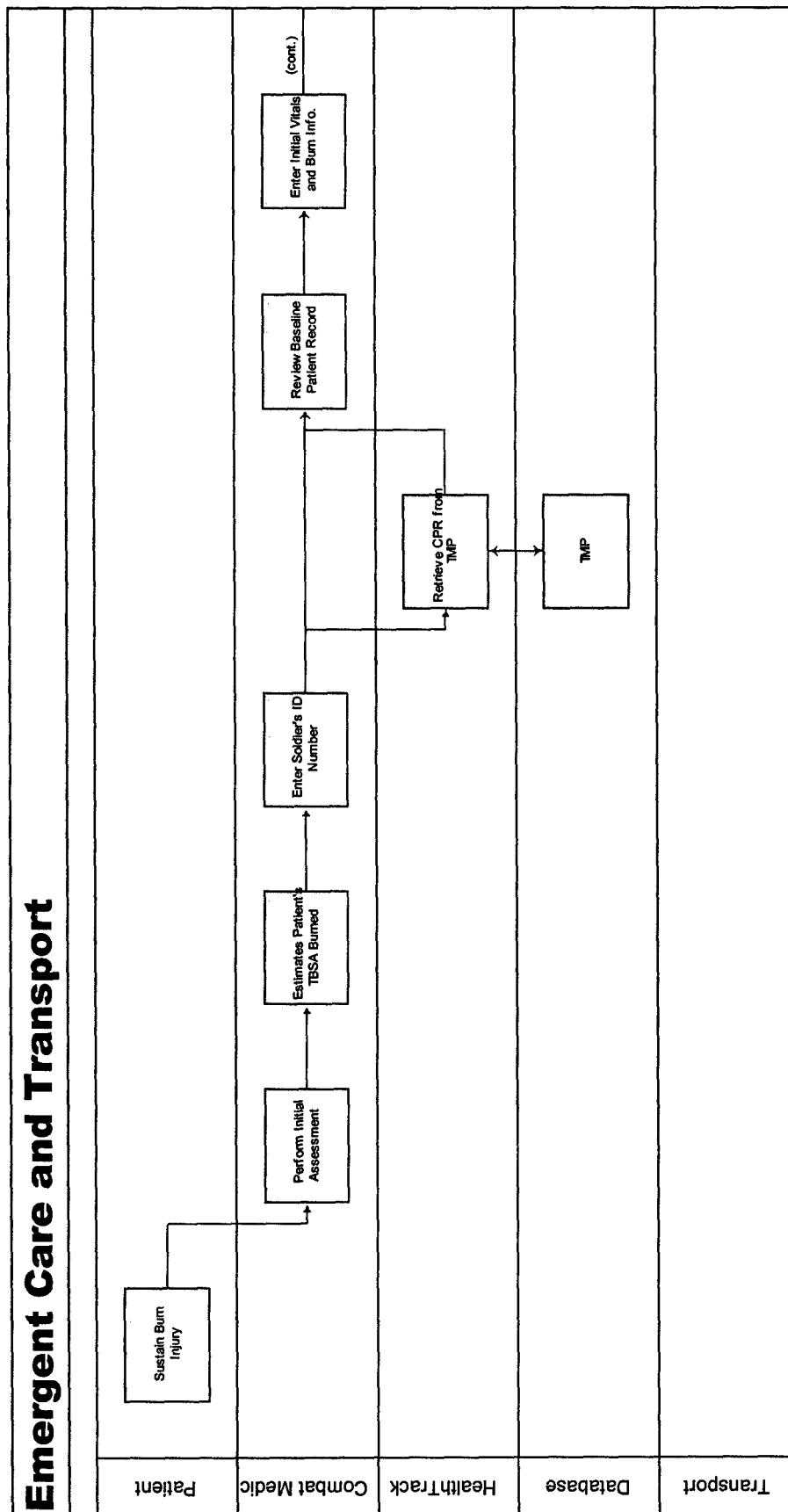


Figure A-1. Emergent Care and Transport

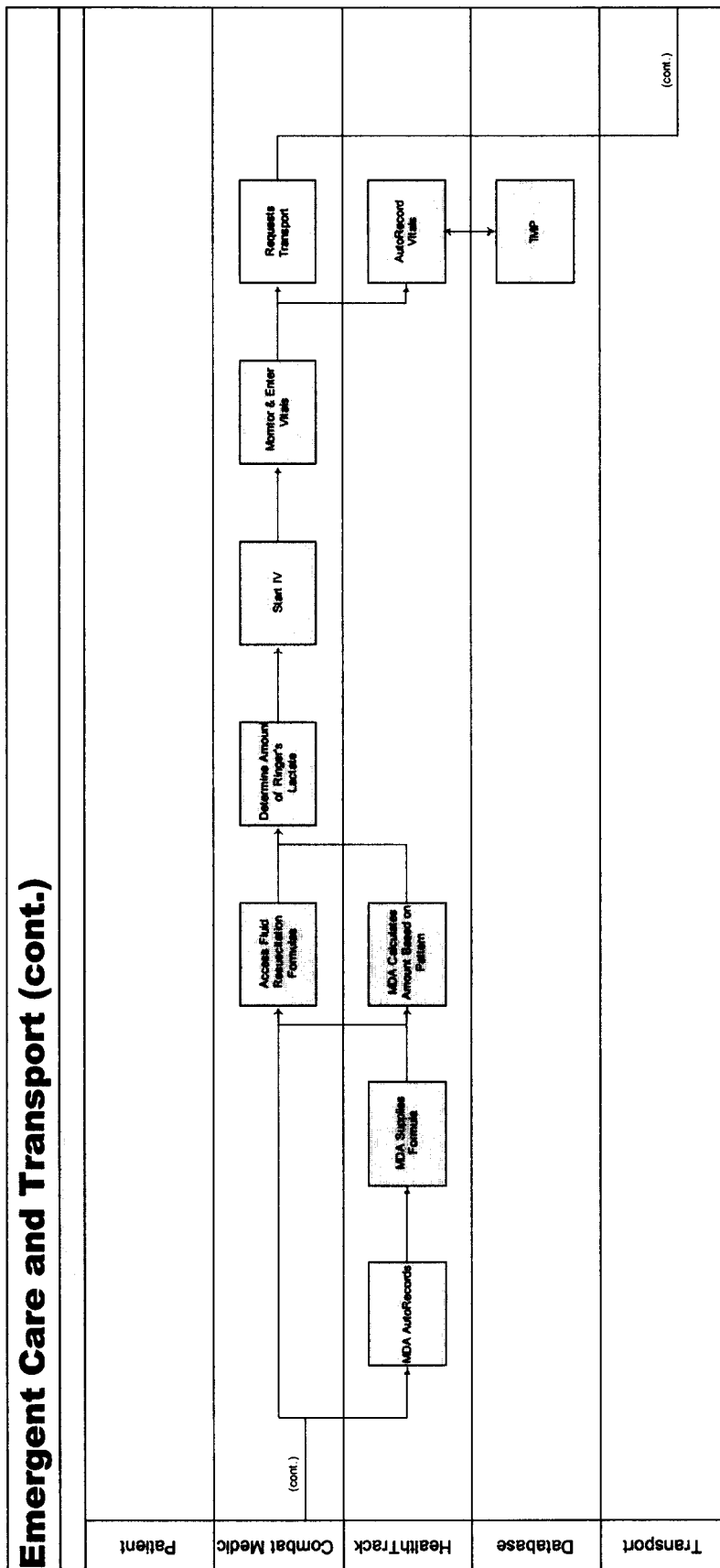


Figure A-1. Emergent Care and Transport (cont'd)

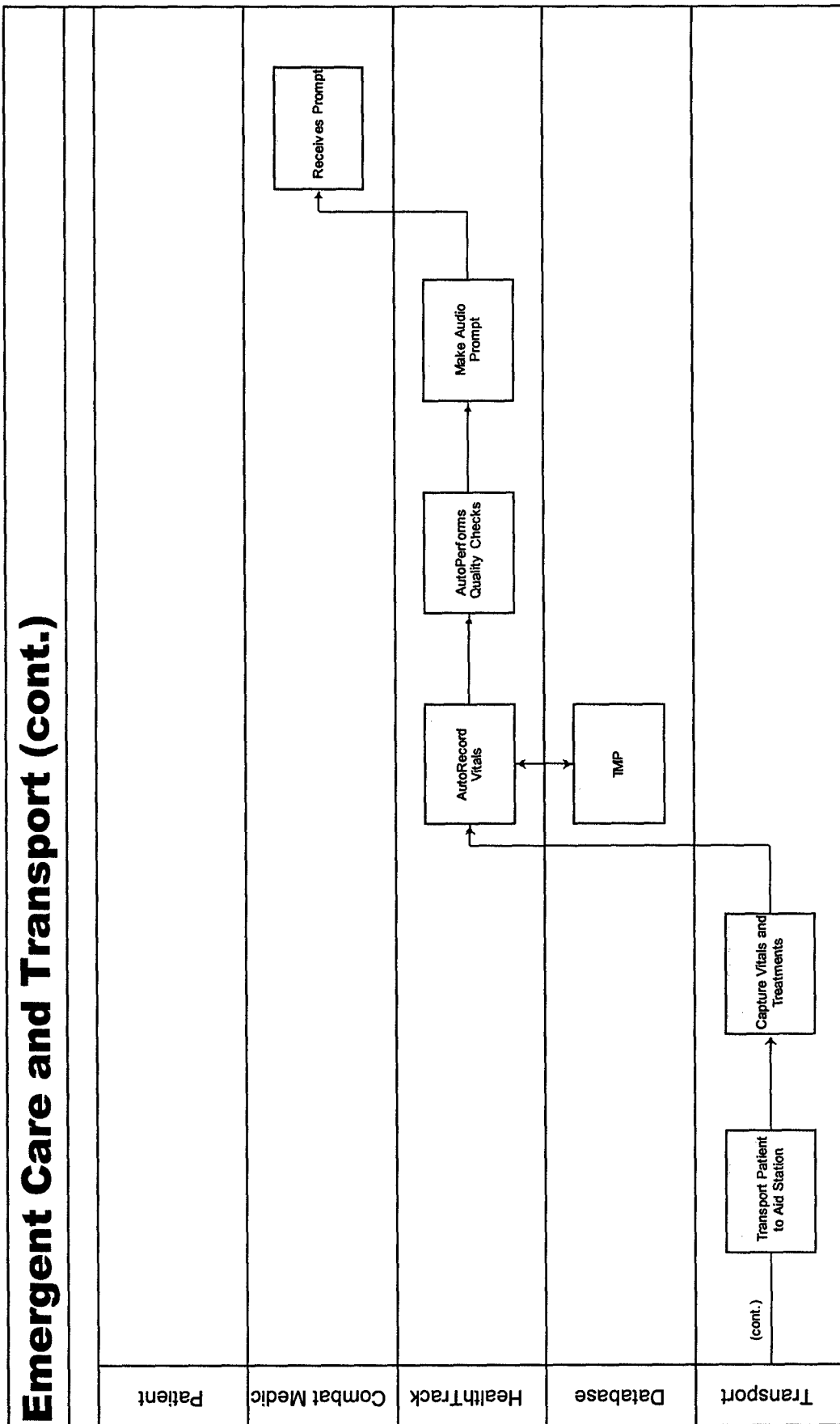


Figure A-1. Emergent Care and Transport (cont'd)

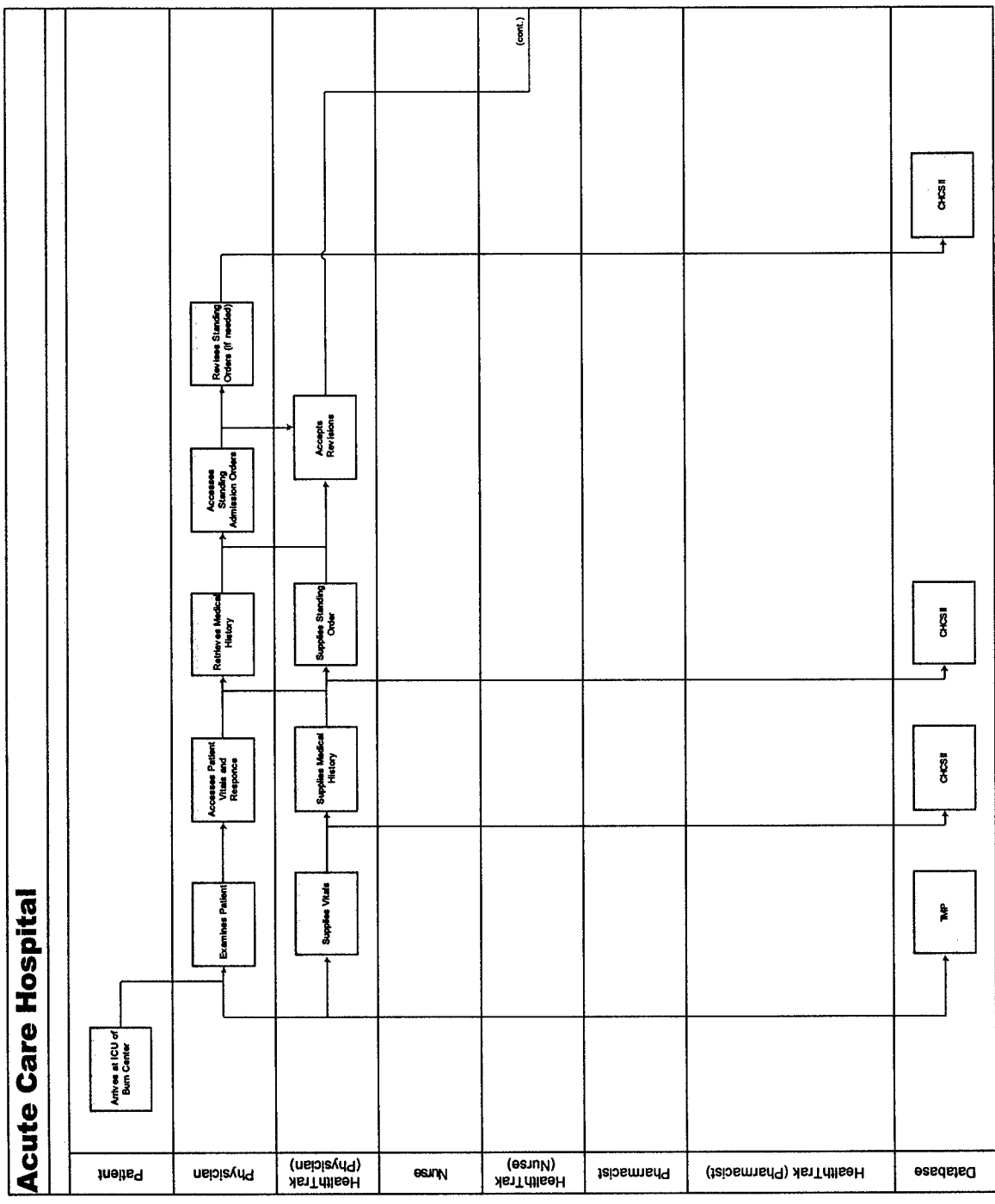
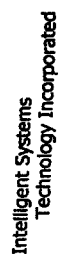


Figure A-2. Acute Care Hospital



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Figure A-2. Acute Care Hospital (cont'd)

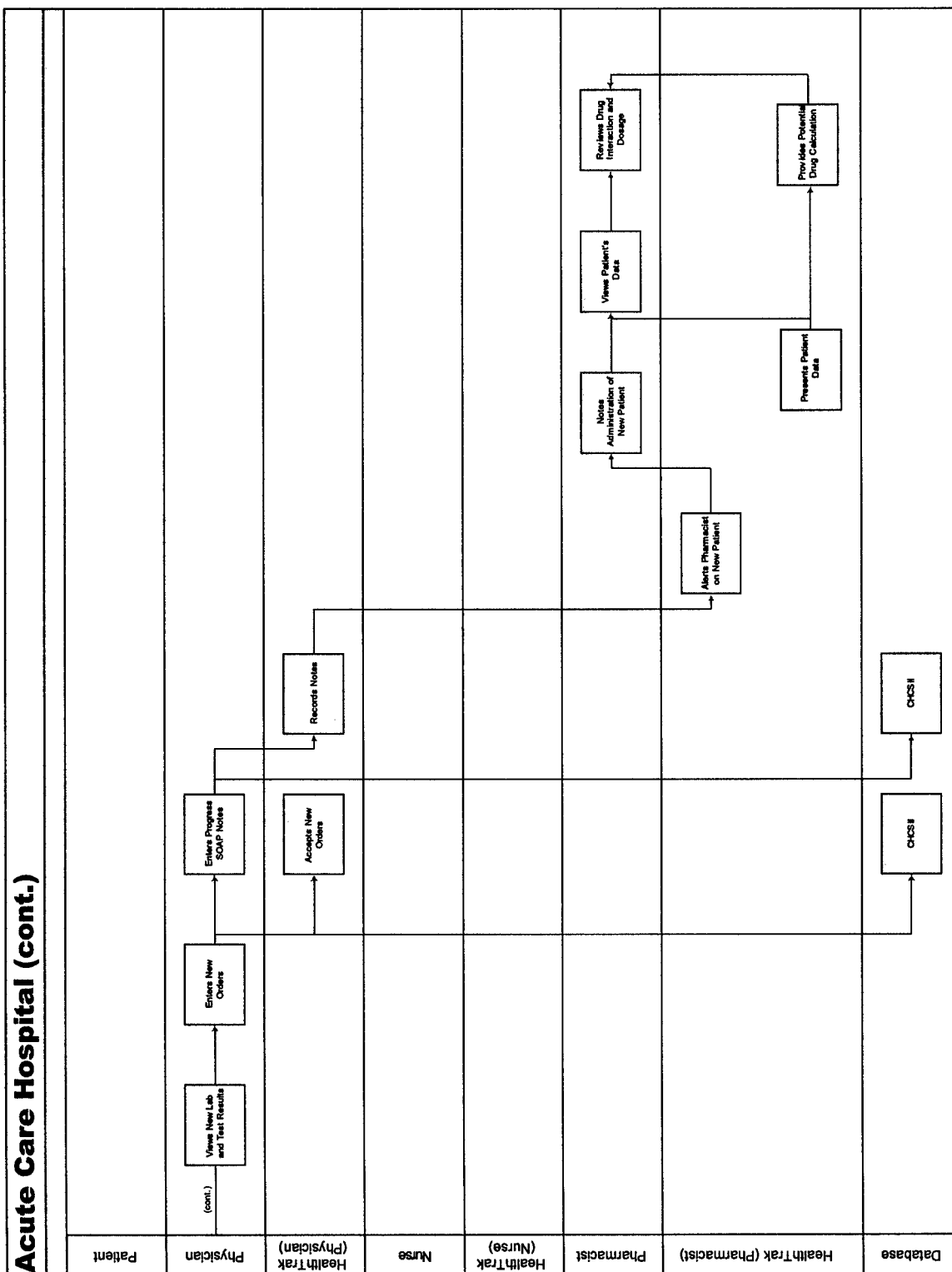


Figure A-2. Acute Care Hospital (cont'd)

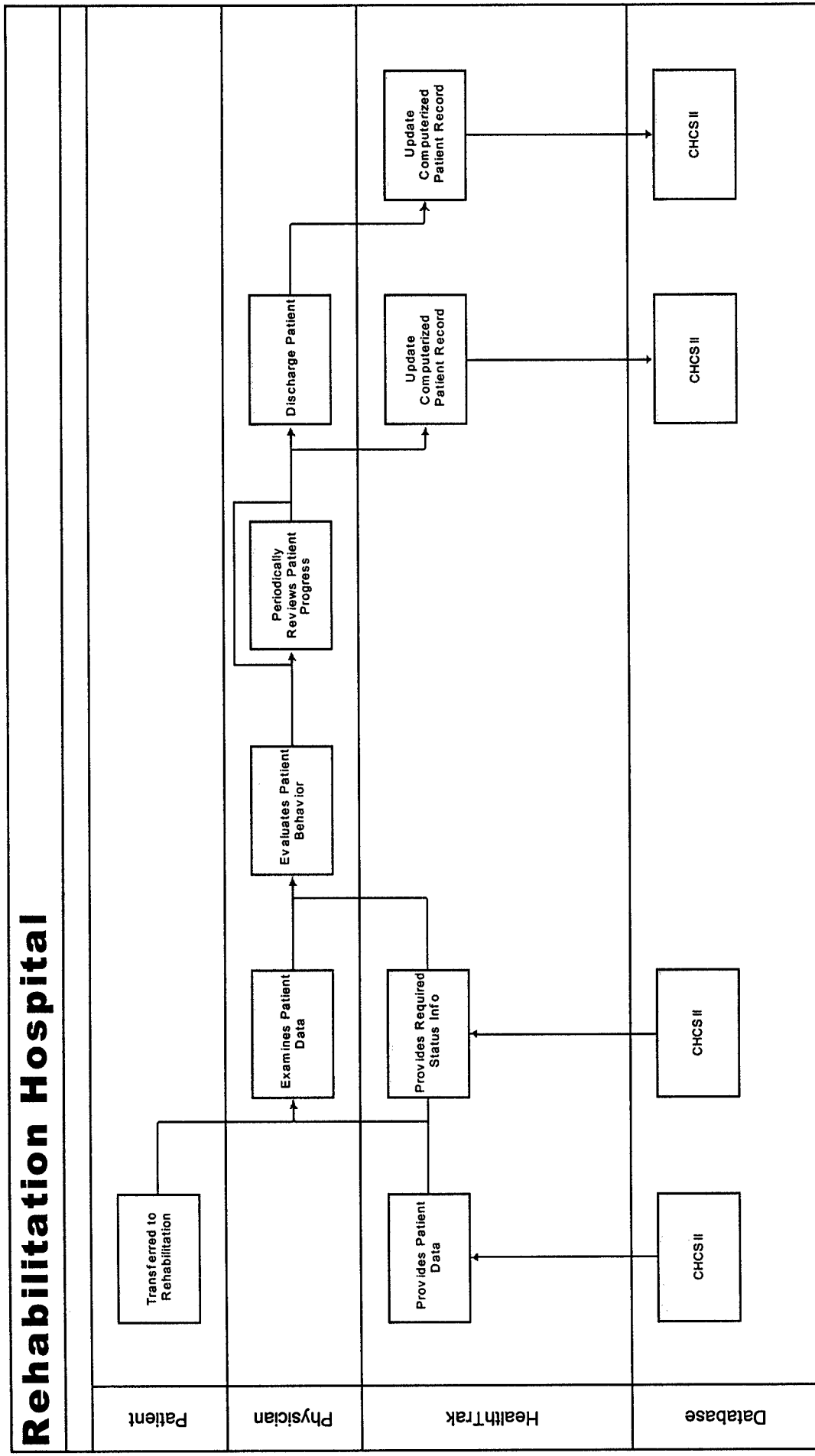


Figure A-3. Rehabilitation Hospital

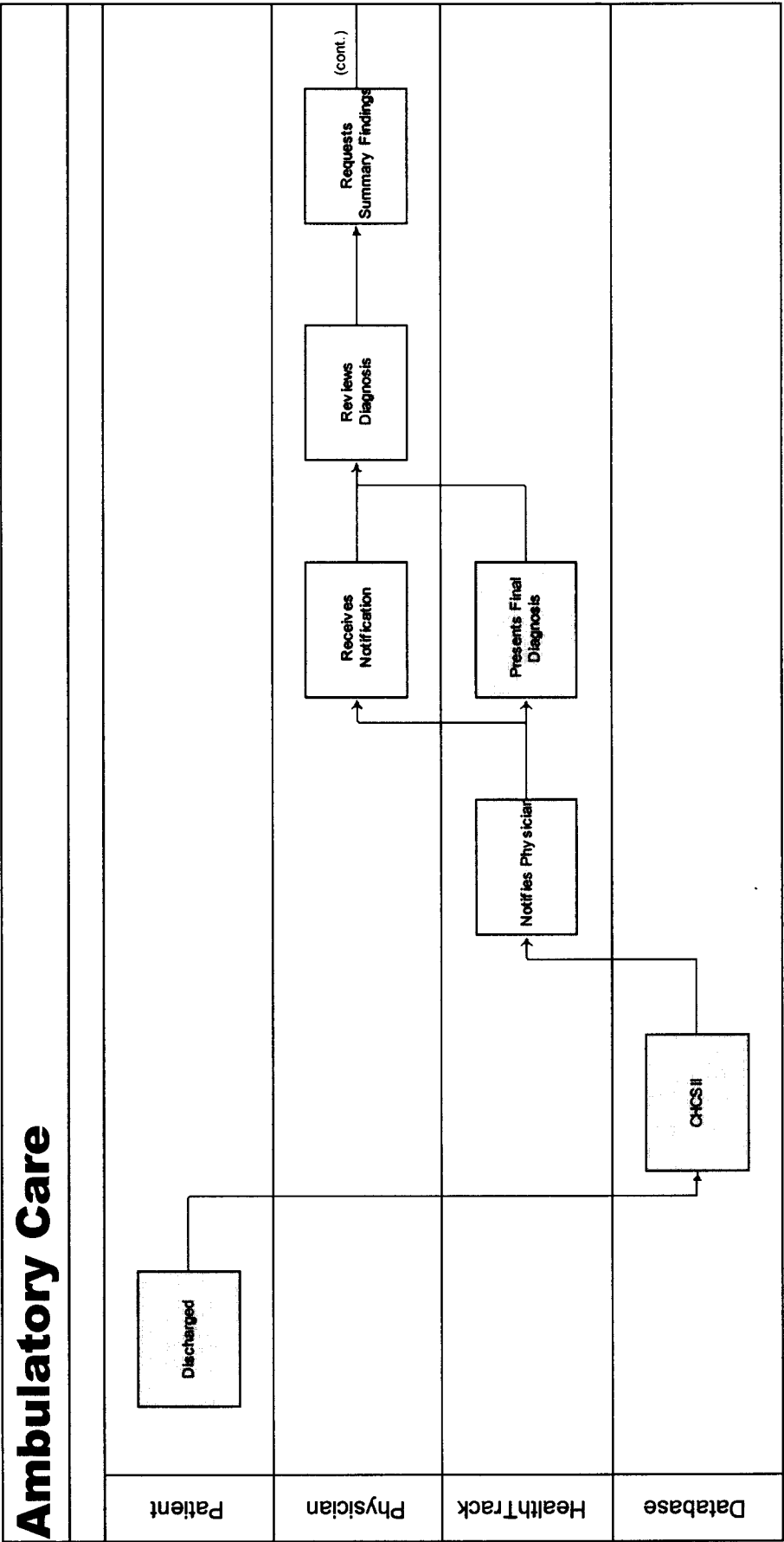


Figure A-4. Ambulatory Care

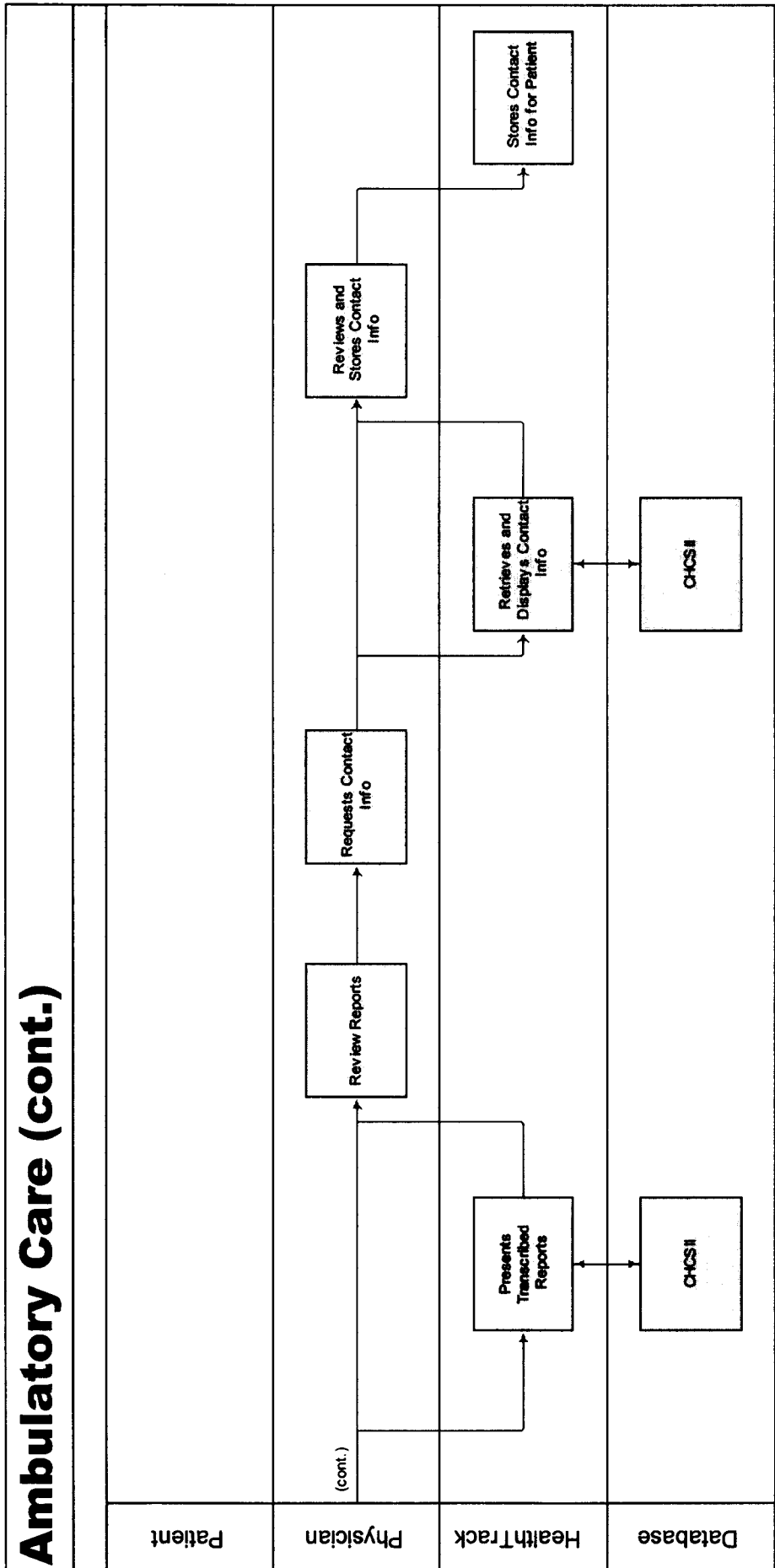


Figure A-4. Ambulatory Care (cont'd)



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
304 SCOTT STREET
FORT DETRICK, MARYLAND 21703-4111

REPLY TO
ATTENTION OF:

MCMR-RMI-S (70-1y)

17 Jan 03

MEMORANDUM FOR Administrator, Defense Technical Information
Center (DTIC-OCA), 8725 John J. Kingman Road, Fort Belvoir,
VA 22060-6218

SUBJECT: Request Change in Distribution Statement

1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for this Command. Request the limited distribution statement for accession numbers [REDACTED], ADB227335, ADB236551, and ADB283653 be changed to "Approved for public release; distribution unlimited." These reports should be released to the National Technical Information Service.

2. Point of contact for this request is Ms. Kristin Morrow at DSN 343-7327 or by e-mail at Kristin.Morrow@det.amedd.army.mil.

FOR THE COMMANDER:

Phyllis M. Rinehart
PHYLLIS M. RINEHART
Deputy Chief of Staff for
Information Management