

AD _____

Award Number: W81XWH-06-2-0074

TITLE: A Clinician-Centered Evaluation of the Usability of AHLTA and Automated Clinical Practice Guidelines at TAMC

PRINCIPAL INVESTIGATOR: LTC Caterina Lasome
Dr. Nancy Staggers
Dr. Bonnie M. Jennings

CONTRACTING ORGANIZATION: The Geneva Foundation
Lakewood, WA 98496-8687

REPORT DATE: October 2008

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				<i>Form Approved</i> OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE 1 Oct 2008		2. REPORT TYPE Annual		3. DATES COVERED 29 Sep 2007 – 28 Sep 2008	
4. TITLE AND SUBTITLE A Clinician-Centered Evaluation of the Usability of AHLTA and Automated Clinical Practice Guidelines at TAMC				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-06-2-0074	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) LTC Caterina Lasome; Dr. Nancy Staggers; Dr. Bonnie M. Jennings E-Mail: jhulbert@thegenefound				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The Geneva Foundation Lakewood, WA 98496-8687				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The purposes of the study were to examine critical usability issues in AHLTA; redesign problematic features and test the new functions; and, using this knowledge, design and evaluate automated clinical practice guidelines (aCPGs) in AHLTA. Usability issues were examined using naturalistic observations and structured interviews. The naturalistic observations were done in two clinics, Family Practice and Pediatrics, and involved six physicians during nine patient encounters. The 12 clinicians who were interviewed walked the interviewer through their daily routines related to using AHLTA. Their verbal responses were audio-taped. Their use of AHLTA was captured on videotape, with the camera focused solely on the computer screen. These data were analyzed by staff from Pacific Science and Engineering. Over 175 usability issues were identified. The plans to redesign and test AHLTA and design and evaluate aCPGs were thwarted by operational issues. In particular, it was not possible to collect data using future releases of AHLTA that were under development. Despite months of effort to devise a feasible alternative, the only reasonable solution was to modify the original Scope of Work and address new research aims.					
15. SUBJECT TERMS Automated clinical practice guidelines, usability issues in designing electronic health records.					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			USAMRMC
			UU	14	19b. TELEPHONE NUMBER (include area code)

Table of Contents

Page

Introduction.....	1
Body.....	1
Key Research Accomplishments.....	10
Reportable Outcomes.....	10
Conclusion.....	11
References.....	14
Appendices.....	NA

INTRODUCTION:

The intent of this investigation was to automate clinical practice guidelines (aCPGs) in AHLTA, the military health system's (MHS) electronic health record (EHR). The purpose of the study was to examine critical usability issues in AHLTA, redesign functions to improve their usability and test these functions, and then design and evaluate an aCPG for asthma patients by incorporating the improvements in usability. Four aims guided the work: (1) Determine critical AHLTA usability issues and redesign these AHLTA functions based upon user-centered design principles; (2) In a laboratory setting using mock patient scenarios, compare clinicians' human performance in two computerized applications—the current version of AHLTA and the redesigned functions in an AHLTA prototype derived from aim 1; (3) Identify issues with aCPG use and convert the existing Veteran's Administration and Department of Defense (VA/DoD) asthma clinical practice guideline into an aCPG in AHLTA using user-centered design principles; and (4) In a laboratory setting using mock patient scenarios, compare clinicians' performance using the current asthma aCPG alternate input mode (AIM) form in AHLTA with the newly designed aCPG in an AHLTA prototype derived from aims 1 and 3.

Despite the four aims, only aim 1 was accomplished. As delineated in the body of this report, the investigators confronted numerous challenges since receiving funding in October 2006. Many of these challenges related to attempting to conduct a research study that was heavily dependent on the AHLTA development and operational environments. In fact, operational issues were the catalyst for the decision to cease efforts on the original protocol and to begin efforts on a knowledge management repository and clinical decision support protocol under the leadership of a different Principal Investigator.

Numerous conversations were held with key staff members at high organization levels, (e.g., MHS and CITPO). These conversations related to the wide array of creative efforts that were considered in trying to find a feasible solution to keep the project viable. Staff from The Geneva Foundation (TGF), Dr. Stanley Saiki, Director of the Pacific Telehealth & Technology Hui, and the Principal Investigator communicated formally to discuss how to best meet the congressional intent of the award. A letter detailing various courses of action was sent from TGF to Ms. Lisa Wells-Roark at USAMRAA in October 2007. Because of issues associated with AHLTA related to contracting, scheduling, and deployment, it became clear in March 2008 that the only responsible course of action was to cease efforts on the original protocol effective 30 June 2008 and to begin work on a new protocol.

BODY:

Task 1: Complete preparatory work prior to the grant initiation

- a. Tripler Army Medical Center (TAMC) Scientific Review Committee (SRC): approved the protocol with modifications on 7 November 2006.
- b. Institutional Review Board (IRB) approvals
 - 1) TAMC
 - a) Initial approval was granted on 18 December 2006 with stipulations.
 - b) The start letter was received on 13 March 2007 following completion of second level review.
 - c) The first modification was approved on 29 May 2007. In it, asthma was specified as the aCPG to be studied, naturalistic observation was added as a data collection technique for Aim 1 and a request was made to have all audio-taped qualitative data transcribed. A new onsite PI was also noted.
 - d) The second modification was approved on 23 July 2007. Two changes were listed in this modification: (a) adding in-depth interviews to guide the development of the asthma aCPG and (b) recruiting clinician volunteers from existing administrative meetings to validate the usability findings instead of convening focus groups.
 - e) The third modification was approved on 26 September 2007. It was submitted to allow access to actual patient records in AHLTA during the interviews that would be conducted related to aCPG development.
 - f) The multiple modifications, within the six months following receipt of the start letter, reflect the considerable challenge of attempting to conduct a research study that was so tied to the operational environment. The investigators could not anticipate the continuation or even escalation of these challenges, especially as new versions of AHLTA were released at the centrally managed enterprise level from the Clinical Integration Technology Program Office (CITPO) without consideration for existing issues and/or studies at local (TAMC and other) levels. Evidence supporting this belief was brought to the attention of the study team on 23 August 2007 when the PI arranged a virtual demonstration of an AHLTA release that was in development and scheduled for deployment (AHLTA 3.5). Information gathered in this session raised many questions in the minds of the study team regarding the ultimate scientific and operational contributions of the project because the protocol and proposal were based on the current version of AHLTA. The planned release had already addressed many of the usability issues identified during the initial data collection, rendering that effort more obsolete than insightful.
 - 2) University of Utah—initial approval was granted on 29 Mar 07

- 3) Second level review—the investigators were directed to use Tricare Management Activity (TMA) for the second level review rather than MPMC. TMA approved the study on 15 FEB 07.
- c. A subaward was made to Pacific Science & Engineering (PSE) on 10 December 2006.
- d. TAMC IMD Proprietary Evaluation Group (PEG) approved the Cooperative Research and Development Agreement. Signature was obtained in January 2007.
- e. Space was allocated for the research team in D wing of TAMC. However in mid-December 2007, the Project Manager (PM) found mold growing in both rooms dedicated for project use; she also reacted to it (e.g., watery eyes). Preventive Medicine was notified about the problem. Study files were relocated to Nursing Research Service at TAMC, equipment was moved to clinical informatics, and the PM was given an office in the clinical informatics area. The rooms in D-wing were ultimately cleaned, ruined furniture was removed and the carpeting was replaced with tile. On 30 June 2008 the investigators assessed any remaining items in the rooms. Mr. Dale York of clinical informatics at TAMC is aware that some supplies are still there and these can be moved to clinical informatics for use by the staff.
- f. Source code for AHLTA computer training system (CTS) was obtained from CITPO on 26 January 2007. This source code was requested by Pacific Science and Engineering (PSE) to support and expedite their development of the revised AHLTA prototype interface. However, the CTS could not be used for protocol analysis because the patients in the CTS were not sufficiently complex nor was the CTS maintained at a level currently representative of the production environment. In addition, discussions with CITPO staff and the CTS developers confirmed that the CTS could not be modified and that updates to CTS were only completed with major AHLTA releases.
- g. Morae software was recommended by PSE to capture the keystrokes of AHLTA users during the tests of aims 1 and 3. The software was thoroughly tested by PSE and it was purchased for use in this study. Subsequently, a variety of problems related to Morae surfaced, including that it was not compatible with AHLTA. PSE staff obtained a beta version of Morae that was compatible with AHLTA, but it adversely impacted network performance. Consequently, PSE self-developed data collection software to capture audio, video and observer notes that were time-synchronized to one another.
- h. Statement of Work approved by Clinical Investigation Regulatory Office (CIRO) 7 March 2007.

Task 2: Complete grant start-up

- a. Project director hiring
 - 1) The position was filled on 4 December 2006 and vacated on 13 April 2007 due to an unanticipated family issue.

- 2) A second project director was hired on 1 Apr 2006. She submitted a letter of resignation effective 29 June 2007. The job description was re-crafted by the PI and co-PIs based on feedback from the second project director and in consideration of the needs of the study. A project manager rather than a project director was recruited.
 - 3) A project manager (PM) was hired with a start date of 27 August 2007. A co-PI made a site visit 5-8 September 2007 to orient the project manager. Toward the end of 2007 the PIs determined that an alternate approach and timeline for the study would be required. These changes to the project made it unnecessary to have a 50% effort PM. The PM was therefore given the option to remain with the project but with a change in work hours to an as needed basis. This did not suit the PM's needs, so she resigned effective 28 January 2008.
 - 4) Given the need to retool the study or close it, no efforts were made to fill the PM position.
- b. Project plan
- 1) A high-level project plan was developed during the second quarter of the study (Jan-Mar 2007).
 - 2) The project plan was revised to adjust for the protocol modifications as well as the need to de-identify June data prior to proceeding with further data collection
- c. Kick-off meeting held at TAMC 18 June 2007
- 1) Participants included the PI, co-PIs, local PI, project director and staff from PSE
 - 2) Topics covered were:
 - a) Project history
 - b) TAMC culture and complexity
 - c) Relationships among TATRC, the Hui, and The Geneva Foundation
 - d) Discussion of AMEDD Centers of Excellence including the current status of the concept and their implementation
 - e) Impact of Defense Business Transformation policies on the project
 - f) Project priorities for this site visit
 - 3) Additionally, the PI, coPIs and lead staff member from PSE met to review the study methodology and earmark potential dates for future work onsite (e.g., aCPG interviews in September 2007, piloting the AHLTA prototype in December 2007)
- d. Advertise the study
- 1) The physician consultant, in collaboration with the TAMC Deputy Commander for Clinical Services (DCCS), distributed an email explaining the study and encouraging clinician participation
 - 2) A study brochure was designed, printed, and distributed at key meetings attended by TAMC providers

- 3) The physician consultant and project director attended departmental administrative meetings to explain the study
- e. Recruit participants for the usability data collection in June 2007
 - 1) The project director recruited 7 clinicians for the usability interviews
 - 2) The PI recruited an additional 6 clinicians for the usability interviews
 - 3) The PI also recruited 6 clinicians to participate in the naturalistic observations
 - 4) Ultimately, 12 of the 13 clinicians were able to participate in the interviews. One of the clinicians who participated in the naturalistic observations was also interviewed yielding a total of 17 participants in data collection related to study aim 1.

Task 3: Construct initial Functional Decomposition Diagrams (FDDs)

- a. A literature review was completed but no FDDs were located relevant to the study environment.
- b. The FDDs were to be developed by PSE from the June 2007 data. During the analysis of the June 2007 data, PSE determined that the information required to prepare the FDDs was not available in the data. In place of the FDDs, PSE developed rudimentary workflow diagrams which were provided to the PI's in their analysis report.

Task 4: Interview, audiotape, and/or videotape participants about AHLTA usability

- a. A co-PI and the PSE staff completed a site visit to TAMC in May 2007 to ensure site readiness for the June data collection
 - 1) Network connections were installed in the designated office space
 - 2) Power was restored to a wall in one of the offices
 - 3) All equipment was tested and problems were solved (e.g., cameras, computers)
 - 4) Other equipment needed for June data collection was acquired
 - 5) The interview guide was developed in conjunction with PSE
- b. Meet with individual clinicians – completed in June 2007
 - 1) Twelve individual clinician interviews were completed; one provider was ill and could not be rescheduled
 - 2) Six naturalistic observations were completed
 - 3) During June 2007, sufficient data were collected to conduct the analysis to meet Aim 1
- c. Analyze audio and videotapes
 - 1) During June data collection, some clinician participants chose to use AHLTA screens from their panels of patients as they were better able to illustrate usability issues. This was not intended. The plan in the protocol was to have providers use patients in the AHLTA CTS (computer training system) to demonstrate their concerns with AHLTA. Because actual patient records were used during data collection, the investigators knew these data would need to be de-identified. They also brought this unintended

occurrence to the attention of the Human Use Committee (HUC) at TAMC. The HUC was grateful for the investigators' forthrightness and found the plans to de-identify the June data adequate to protect information from actual patients.

- 2) The analysis of the June data was put on hold until the patient data were de-identified or redacted by PSE. This proved to be a rather lengthy and complex process. Documents had to be staffed through numerous individuals for approval, including USAMRAA. The data were finally redacted and analyzed during the first quarter of 2008 (Oct-Dec 2007).
 - 3) PSE delivered their analysis in a report dated January 2008. The PIs had a number of concerns about the report. Among these was the request to provide the FDDs which had been promised as a part of the analysis. It was at this point the investigators learned the information required to prepare the FDDs was not available in the June data. A particular disappointment to the investigators was the absence of high resolution screen shots as they are important to complete manuscripts. The investigators learned that the poor quality of the screen shots was due to having the June data de-identified.
 - 4) Although there were plans to submit a manuscript to a high tier research journal, this is not possible the PI's plan to prepare a paper to submit for publication based on the usability analysis that was done. Because of the nature of the analysis, the manuscript will focus on methods to remedy usability issues in AHLTA.
 - 5) As an alternative, the investigators are working on a manuscript to be submitted to *Military Medicine*.
 - 6) The work has not progressed beyond this point.
- d. Collate usability issues with the current version of AHLTA: this work was not done because of issues related to the inability to get access to future releases of AHLTA while they were in development. As stated in the introduction, AHLTA development, deployment, and operational issues were a serious interference in conducting this study. The operational stumbling blocks were viewed as insurmountable by a number of individuals, leading to the decision to close the study and return unused funds.
- e. Expand FDDs: this work was not done.

Task 5: Develop the new AHLTA prototypes with user-centered design principles—work was not done on task 5.

Task 6: Complete pilot testing—work was not done on task 6.

Task 7: Complete the human performance study Aim 2 comparing the current version of AHLTA and the new AHLTA prototype—work was not done on task 7.

Task 8: Data analysis and manuscript writing

- a. The only analysis that was completed pertained to the interviews and naturalistic observations conducted for aim 1.
- b. There are two manuscripts in progress: one related to the usability data as noted in Task 4 and one to delineate issues related to establishing Centers of Excellence at the Army Regional Medical Commands

Task 9: Identify issues and requirements for aCPGs

- a. The research team realized that the actual aCPG work could begin sooner than reflected in the linear task list.
 - b. On 21 July 2007, the PI and co-PIs discussed general areas and ideas to be purposed during the aCPG interviews.
 - c. On 5 August 2007 a draft interview guide for collecting data related to aCPG issues and requirements was shared with PSE.
 - d. During various team calls lively discussions took place regarding the best focus of the aCPG interviews.
 - e. On 31 August 2007, PSE developed a separate draft interview guide.
 - f. Due to the insights gained during a virtual demonstration of functionality in future releases of AHLTA, the investigators did not do additional work on Task 9.
- The PI explored numerous alternatives for addressing the remaining study objectives in collaboration with Dr. Saki and The Geneva Foundation. After exploring options to keep the original protocol active, it was determined that the best course of action to mitigate any continued expenditure of resources was to work towards a new set of deliverables. As such, The Geneva Foundation formally closed out the research activities at Tripler Army Medical Center at the University of Utah. No further scientific efforts were made on the award during this reporting period.
 - This decision was communicated to TAMC personnel such as the onsite PI and Department of Clinical Investigations. Appropriate paperwork to close the study at TAMC has been completed.
 - The three Principal Investigators closed the Tripler Army Medical Center research site during the last week of June 2008. The PI's met with command leadership, submitted the Institutional Review Board Final Report, cleared out the research office and worked on an article for publication. The three original investigators are no longer supporting current grant activities.

Work was not accomplished on Tasks 10 – 14.

Task 10: Develop the new aCPGs in AHLTA with user-centered design principles

Task 11: Complete pilot testing of the aCPG prototype

Task 12: Complete the human performance study Aim 4 comparing the current aCPG AIM forms with the new aCPG prototype in AHLTA

Task 13: Data analysis

Task 14: Completing the final report and writing manuscripts

KEY RESEARCH ACCOMPLISHMENTS:

- Completed 4 required IRB approvals
- Completed data collection about usability issues
- Two manuscripts are in progress: one on usability issues based upon the grant data collection and the other on Centers of Excellence

REPORTABLE OUTCOMES:

- The investigators developed a strong appreciation for conducting a research study using an electronic health record that is still undergoing significant changes, especially because the oversight, configuration management, and development are managed at a central MHS program office rather than locally
- Due to the decision to close the study, PSE was given a 30-day notice and their contract was terminated on 20 February 2008. On 29 April 2008 The Geneva Foundation notified The University of Utah that no further administrative or scientific activity towards the Scope of Work was to occur past 30 June 2008. It was requested that The University take all reasonable steps to reduce financial obligation to the award. The University of Utah research site closed effective 30 June 2008.
- Data files remain onsite at TAMC and are ready to be inspected as required by Army and other Federal regulations.

CONCLUSION:

- Based on the naturalistic observation of 6 providers and interviews with 12 clinicians, significant usability issues were identified in the AHLTA software. The PSE analysis identified 175 usability issues, with more than 20 of these being highly critical to user performance and efficiency. PSE concluded that a majority of the issues are related to the design and layout of the data views that are presented to the providers
- Conducting a site-specific research study based on the current version of AHLTA ultimately was determined to be not reasonable because it would not answer the 'so what?' question; this is because future releases of

AHLTA—which are managed, developed, and deployed centrally by the MHS—are scheduled to contain functionality that is relevant to usability and aCPGs

- Executing any/all Center of Excellence objectives was not possible. When the proposal was conceived, there was an intention by the Army Medical Department to work with CITPO to establish local service development environments at the Regional Medical Command levels to support the ongoing development of AHLTA. TAMC was designated by The Army Surgeon General to serve as the Center of Excellence for the automation of DoD/VA CPGs for the AMEDD. Due to changes in leadership, acquisition rules and regulations, and new guidance resulting from the Defense Business Transformation initiative, there have been no MTFs approved for establishing a local service development environment. This negatively impacted the ability of TAMC to serve as a Center of Excellence for automating DoD/VA approved CPGs as well as for accomplishing the study objectives.

SCOPE OF WORK MODIFICATION AND CHANGE IN RESEARCH TEAM:

- On 8 April 2008 representatives of The Geneva Foundation met with Dr. Stan Saiki and a TATRC representative in Seattle, WA to discuss the closeout of LTC Lasome's SOW and the process for submitting a protocol modification to extensively revise the existing SOW and to identify a new Principal Investigator.
- On 16 July 2008, The Geneva Foundation submitted a request to USAMRAA to modify the SOW, budget, program end date and appoint LTC Nahn Do as the new Principal Investigator. The Foundation responded to USAMRAA's 29 July 2008 budget verification request on 13 August 2008. Modification three (3) was issued on 20 August 2008 approving the Foundation's 16 July request.
- Between 20 August 2008 and 31 September 2008 the new research team met extensively by teleconference to discuss the study start-up activities. Below is an accounting of the work being done in support of the revised protocol:
 - a. Update/revise work plan. A project plan previously developed is in the process of being updated, based on recognition that technical work group priorities will need to be driven by content work group requirements. Thus, the team has been working on defining use cases for tasks involving content submission, review/editing, addition to the knowledge repository (KR), successive modifications of representation based on analysis of content, standardization, and subsequent retrieval and use development.

- b. Identifying Clinical Decision Support materials. Progress has been made to assemble contributed content on primary diabetes management and definitions related to diabetes for alerts, reminders, and recommendation logic rules and additional definitions and rules about management of diabetes-related conditions. The team is in the process of recasting the previously submitted content into the format of a prototype submission template, in order to elucidate its appropriateness and need for any modification. Subsequent tasks will look at requirements for methods for comparing different rules, abstracting and generalizing them, and identifying axes on which similar rules differ. Order sets continue to be deferred for the current period.
- c. Refining processes for distributed research and coordination with technical work group. The project plan is aimed at continuing to identify technical issues in supporting the visualization, tagging, representation, retrieval, and secondary adaptation of rules in the knowledge base, as driven by the work of the content work group. These issues involve coordination with the Technical WG. This process is occurring through continued participation of a liaison between the content and technical work groups

2. Technical WG

- a. Reviewing various applications and software for Clinical Decision Support. This includes the JBoss platform, JBoss Rules Engine and the jBPM engine. Various technical requirements and subscriptions have been identified and ordered for.
- b. Conducted a methodical interview process for candidates for the Java Developer position. The Technical WG has interviewed 7-8 candidates and they have been ranked in the order of fit and expertise based on the development requirements of the project. These candidates will be further tested for their knowledge of Glass Fish, an Application Server, which is one of the candidate tools being planned for use in the project. The technical work group is awaiting instructions from the administrative team to determine the next steps to move this forward.
- c. The technical work group will work on the use cases developed by the content team and perform analysis from a systems perspective, propose a technical architecture and design and a roadmap for implementation and release of functionalities related to the Knowledge Management Repository and clinical guideline execution.

REFERENCES:

NA

APPENDICES:

NA

BIBLIOGRAPHY:

Publications and meeting abstracts—NA

LIST OF PERSONNEL RECEIVING PAY FROM THE RESEARCH EFFORT:

Original team:

coPI: Dr. Nancy Staggers

coPI: Dr. Bonnie Jennings

PD: Mr. Lonnie Wheeler

PD: Ms. Renee Latimer

PM: Ms. Patricia Price

Subcontract: PSE staff

Revised team:

PM: Ms. Angela Silva