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INTRODUCTION:

The subject of this investigation pertains to usability and automated clinical practice guidelines (aCPGs) in AHLTA, the military health system's (MHS) electronic health record (EHR). The purpose of the study is to examine critical usability issues in AHLTA, redesign and test these functions, and design and evaluate aCPGs by incorporating the improvements in usability. Four aims guide the work: (1) Determine critical AHLTA usability issues and develop a new AHLTA prototype by redesigning these AHLTA functions based upon user-centered design principles; (2) In a laboratory setting, compare clinicians' performance using the current version of AHLTA and the redesigned functions in an AHLTA prototype derived from aim 1; (3) Using the existing Veteran's Administration and Department of Defense (VA/DoD) asthma clinical practice guideline as a foundation, convert it to an aCPG in AHLTA using user-centered design principles; and (4) In a laboratory setting, 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.

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) Approval of the first modification specifying asthma as the aCPG to be studied, naturalistic observation, transcribing all qualitative data, and a new onsite PI was granted on 29 May 2007
 - d) Approval of a second modification to conduct in-depth interviews to guide the development of the asthma aCPG and recruit clinician volunteers from existing administrative meetings to validate the usability findings instead of convening focus groups was approved on 23 July 2007.
 - e) Approval of a third modification to allow access to actual patient records in AHLTA during the interviews related to aCPG development was granted on 26 September 2007.
 - 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 is so operationally focused. These challenges will continue, especially as new versions of AHLTA are 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. For example, the PI was

able to arrange a virtual demonstration of a release that is in development and scheduled for deployment (AHLTA 3.5). Information gathered in this session on 23 August 2007 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 are based on the current AHLTA.

- 2) University of Utah—initial approval was granted on 29 Mar 07
 - 3) Second level review—rather than MRMC, the investigators were directed to use TriCare Management Activity (TMA) for the second level review. TMA approved the study on 15 FEB 07.
- c. Pacific Science & Engineering (PSE) was awarded a subcontract on 10 December 2006. A discussion of the initial work plan was held involving the PI, coPIs, and PSE staff.
 - d. TAMC IMD Proprietary Evaluation Group (PEG) approved the CRADA. Signature was obtained in January 2007.
 - e. Space was allocated for the research team in D wing of TAMC.
 - 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), a subcontractor, to support and expedite the 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 can not be modified and that updates to CTS are only completed with major AHLTA releases.
 - g. Morae software (used to capture keystrokes) was thoroughly tested by PSE. Many issues were identified including that Morae software is not compatible with AHLTA and therefore cannot be used as planned in this study. PSE staff obtained a beta version of Morae that was compatible with AHLTA, but it adversely impacted network performance. Consequently, PSE developed data collection software to capture audio, video and observer notes that were time-locked to one another.
 - h. Statement of Work approved by Clinical Investigation Regulatory Office 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 recrafted by the PI and co-PIs based on feedback from the second project director and in consideration of the needs of the study. Rather than a project director, a project manager was recruited.

- 3) A project manager was hired with a start date of 27 August 2007. A co-PI made a site visit 5-8 SEP 07 to orient the project manager.
- b. Project plan
 - 1) A high-level project plan was developed during the second quarter
 - 2) The project plan is under revision to adjust for the various modifications to the protocol 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, piloting the AHLTA prototype in December)
- 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
 - 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

Task 3: Construct initial Functional Decomposition Diagrams (FDDs)

- a. A literature review was completed but no FDDs were located
- b. The FDDs are being developed by PSE from the June data

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
- b. Meet with individual clinicians – completed in June 2007
 - 1) Twelve individual clinician interviews were completed
 - 2) One provider was ill and could not be rescheduled
 - 3) Six naturalistic observations were completed
 - 4) 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 test patients to demonstrate their concerns with AHLTA. 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 due until the patient data can be de-identified.
 - 3) As soon as documents are staffed through all necessary parties and USAMRAA gives the approval, PSE will de-identify the data and proceed with the analysis
 - 4) The work has not progressed beyond this point. There are no publications, to date, resulting from this work. However, once the June data are analyzed, a manuscript will be prepared to reflect the findings.
- d. Collate usability issues with the current version of AHLTA
- e. Expand FDDs

Task 5: Develop the new AHLTA prototypes with user-centered design principles—work has not progressed to task 5.

Task 6: Complete pilot testing—work has not progressed to task 6.

Task 7: Complete the human performance study Aim 2 comparing the current version of AHLTA and the new AHLTA prototype—work has not progressed to task 7.

Task 8: Data analysis and manuscript writing—work has not progressed to task 8.

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.

Work has not progressed yet to the remaining tasks.

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

REPORTABLE OUTCOMES:

- Developing a strong appreciation for conducting a research study using an electronic health record that is still undergoing significant changes

CONCLUSION:

- A real challenge with this work, as noted, is conducting a site-specific research study based on the current version of AHLTA when future releases, managed, developed, and deployed centrally by the MHS, contain functionality that is relevant to usability and aCPGs. This issue has been the source of considerable contemplation by the PI and coPIs. Without attending to this in a very thoughtful way, the entire project could be completed successfully from a research standpoint but make very little contribution to science or operations because of failing to answer the ‘so what?’ question.
- A second significant challenge directly affects the ability to execute any/all Center of Excellence objectives. When the proposal was conceived, there was an intention by the Army Medical Department to work with CITPO to establish local service development environments to support the ongoing development of AHLTA. 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 impacts 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.

REFERENCES:

NA

APPENDICES:

NA