Clinical Advisory Board

for an

Advanced En Route Care System

22 September 2006
1. BACKGROUND

a. Maneuver warfare has resulted in a shift from centrally controlled, linear operations to asynchronous operations that impose significant operational constraints when casualties occur. Operational units currently lack the capability to safely transport and provide continuous care from the point of stabilization to final definitive care. The En Route Care System (ERCS) is envisioned as a Joint system to support the ongoing and seamless care of the ill or injured warfighter during all aspects of care and transport from Level II to Level V and beyond. The ERCS shall provide a level of care that matches or exceeds the current standard of care as established within the U.S. medical system.

b. The ERCS Clinical Advisory Board (CAB) was formed and convened at the request of the Research Area Director for the U.S. Army Combat Casualty Care Research Program (CCCRP) and U.S. Navy Office of Naval Research (ONR). Two meetings were held: 8 November 2005 and 3 March 2006. The CAB was tasked to develop/define the clinical capability requirements needed to support the en route care of combat casualties from post-operative forward resuscitative surgery to definitive care in continental U.S. medical treatment facilities and any intervening level of military medical care.

c. Fielding of the first increment for an advanced ERCS is planned during fiscal year (FY) 2010. Spiral development will address subsequent capabilities and the maturation of technology to accommodate increased capability requirements.

2. CLINICAL ADVISORY BOARD MEMBERSHIP AND ORGANIZATION

a. CAB Membership. Clinical subject matter experts from each Service and from academic institutions were identified by CCCR and ONR personnel. Department of Defense (DoD) personnel were identified based upon their recent and relevant experience in the care and transportation of combat wounded during current operations in Iraq and Afghanistan. Other personnel were identified based upon their clinical and/or research expertise regarding trauma and critical care. These individuals were invited to participate and based upon their desire and area of expertise were assigned to one of five focus groups (see next paragraph). Members of the CAB are identified at Appendix A. This appendix also identifies each member’s focus group and the meetings the member attended; November 2005, March 2006, or both.

b. CAB Organization. The CAB was organized into five clinically relevant focus groups that corresponded to anticipated ERCS subsystems. These five focus groups are the following:
   - Ventilation
   - Therapeutic and Fluids Management
   - Physiologic Monitoring
   - Neurologics and Central Nervous System
   - Hardware/Software Systems

3. PURPOSE. The purpose of the ERCS CAB was to develop a set of clinical capabilities that define the ERCS. The mechanism selected to document these capabilities is the Work Breakdown Structure (WBS) and WBS Dictionary. Appendix B provides definitions for acronyms used in the ERCS WBS Dictionary.
a. **Work Breakdown Structure.** The ERCS WBS utilizes the generic structure and definitions provided in Appendix B (Electronic/Automated Software System) from Military Handbook-881A, DoD Handbook, WBS, dated 30 July 2005. This WBS is meant to be a product-oriented family tree composed of the hardware, software, services, and data required for reaching an operational capability. It does so by displaying and defining the product to be developed/produced and relates the elements of work to be accomplished to each other and the end product. The ERCS WBS is composed of the following four levels:

- System (Level 1)
- Primary Mission Product or PMP (Level 2)
- Subsystem (Level 3)
- Component (Level 4)

b. **Application to ERCS.** Preparation of the WBS and WBS Dictionary is an initial step in the systems engineering process. The WBS will evolve throughout the engineering, design, test, and production phases of the program to reflect the technical and programmatic realities to include cost, schedule, and risk. This evolution will take place through the systems engineering process that includes the development of system and functional specifications leading to an item configuration. It evolves through iterative analysis of the program objective, functional design criteria, program scope, technical performance requirements, proposed methods of performance, and other technical documentation.

1. The focus of this WBS Dictionary is to provide clinical specifications for WBS elements so that advanced development efforts for fielding of an initial capability during FY 2010 can focus on critical path items, such as subsystems and components.

2. The baseline system shall include provisions for an incremental development program that will improve system capabilities in an iterative process. For example, future increments will include product improvements such as closed-loop algorithms for selected clinical subsystems and components.

4. **RESULTS**

a. **WBS.** Element numbers are provided for the prime mission product and each subsystem and component at Appendix C. However, the focus of the CAB was on the clinical portions of the system, represented by WBS element numbers 1100–1900.

b. **WBS Dictionary.** The WBS Dictionary providing detailed capability requirements developed during the meetings is at Appendix D. Where the CAB could, threshold and objective values are provided. Only those WBS elements identified by numbers 1100 – 1900 (inclusive) are addressed. All other WBS elements are left as placeholders and will be defined in the future.

5. **DISCUSSION**

a. During the November 2005 CAB meeting, representatives from each Service provided a briefing of their Service requirements. The greatest concerns from attendees centered on power requirements, interaction with current medical command and control assets (e.g., Theater Medical Information Program), and logistical requirements for consumables (primarily oxygen).

b. LTC Gerhardt noted the importance of including a capability for application of an advanced ERCS at Levels 1 and 2a of the combat health service system. Current operations indicate these far-forward health care levels represent the largest target for significant improvement in casualty survival. It is important, therefore, to build flexibility into the system allowing it the capability to migrate into far-forward tactical settings.
c. LTC Gerhardt also emphasized the training requirement that must accompany the development and fielding of an advanced ERCS. Skilled providers, whether physicians, physician assistants, emergency/critical care nurses, advanced practice medics, or some combination, must be properly trained for this system to succeed in its stated mission to save lives on the battlefield. He volunteered to help define the WBS elements covering training, publications, facilities, etc.

d. The consensus from the CAB was that the next step in the development of an ERCS capability needed to be a Joint effort, possibly led by the U.S. Transportation Command. It was recognized that the CAB was an initial step in the Joint process and that follow-on efforts may take the form of a Capability Development Document (CDD), a “requirements” document that is part of the Joint Capabilities Integration and Development System mandated by Chairman, Joint Chiefs of Staff Instruction 3170.01 E, dated 11 May 2005. In support of this effort, a Defense Technology Objective for an “Advanced Critical Care Life Support System” has been proposed by the U.S. Army Medical Research and Materiel Command, CCRP.

e. Dr. Pearce emphasized that some leaders may have the misperception that there is no need for an advanced ERCS since statistics show there have been no deaths while in transit. This is an artificial statistic because a patient cannot be declared dead while en route. Representatives were asked to collect data regarding morbidity and mortality during patient transit.

f. It was pointed out that the advanced ERCS capability will apply to more than combat casualties. It may also be used by military medical organizations during national and international humanitarian operations.

g. The March 2006 meeting was convened to further refine capabilities developed during November 2005 and propose an initial set of capabilities of the system for fielding in the FY2010 timeframe.

6. SUMMARY. The Advanced ERCS CAB met on 8 November 2005 in McLean, Virginia and on 3 March 2006 in Arlington, Virginia to develop a set of desired capabilities. Subgroups developed threshold and objective values for desired capabilities in five clinical areas: (1) Ventilation, (2) Therapeutic and Fluids Management, (3) Physiologic Monitoring, (4) Neurologics and Central Nervous System, and (5) Hardware/Software Systems. A WBS and WBS Dictionary were developed to provide a starting point for further system engineering leading to an initial operational capability in the FY 2010 timeframe.